Internet-Based Cognitive Behavioural Therapy to Treat Adolescent Anxiety: An Exploration of Intervention Designs and the User Experience

by

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Abstract

Background: Internet-based cognitive behavioural therapy (iCBT) is a complex, 'persuasive system' as its design combines therapeutic content, technological features, and interactions between the user and the program. The design and delivery of iCBT differs across programs. While iCBT is considered an effective approach for treating child and adolescent anxiety, how outcomes are produced remains unclear. This lack of clarity is, in part, due to paradoxical findings such as low program usage despite high satisfaction ratings. This dissertation aimed to understand how, why and for whom iCBT works, and how iCBT is experienced by adolescent users.

Methods: Three studies comprise this thesis. In studies 1 and 2, a realist synthesis approach was used to explore the design and delivery features of iCBT for children and adolescents with anxiety and to examine their relationship to program use (study 1) and anxiety-based outcomes (study 2). The syntheses were conducted according to recommended steps and reporting guidelines, incorporated published and grey literature, and critically appraised this literature for relevance and rigor prior to analyses. Data extraction, coding, and analyses were guided by the Persuasive Systems Design (PSD) model, a framework for designing and evaluating persuasive systems. Using realist and meta-ethnographic methods, iCBT design (PSD mechanisms) and delivery features (contexts of use) were linked to outcomes. These linkages were expressed as Context-Mechanism-Outcome configurations—hypotheses for how, why and for whom iCBT programs are effective. Study 3 was a multiple method study embedded within a randomized controlled trial (RCT) comparing the effectiveness of a 6-session iCBT program for adolescents with anxiety ('*Breathe*') to anxiety-based resource webpages. A combination of automatically captured data (intervention use) and user-reported data (anxiety symptoms, user experience using

the User Experience Questionnaire for Internet-based Interventions [UEQII], global rating of change scale) were collected pre- and/or post-intervention to: describe *Breathe* and webpage usage; describe and compare *Breathe* and webpage user experiences; calculate a user-defined small, but meaningful change in *Breathe* users' anxiety (minimal clinically important difference [MCID] using global rating of change scores); and explore relationships between the multiple outcomes among *Breathe* users. Descriptive statistics summarized usage and experience outcomes, an anchor-based method was used to calculate the MCID, and independent sample t-tests and parametric and non-parametric correlations tested the relationships between usage, experience, and MCID data.

Results: *Realist syntheses:* Forty-five documents detailing 10 iCBT programs and 63 documents detailing 15 iCBT programs were included in studies 1 and 2, respectively. In both studies, I generated hypotheses using moderate-to-high quality found across multiple iCBT programs. I developed 5 (study 1) and 11 (study 2) hypotheses that identified key PSD features and delivery contexts (adjunct program support; level of prevention or treatment that programs were designed to target) that may lead to moderate-to-high program use (study 1) and anxiety reductions (study 2). I suggested that incorporating multiple PSD features may have additive or synergistic effects on outcomes. *Multiple method study:* In this study, intervention use was low for adolescents allocated to either *Breathe* (mean=2.2 sessions, standard deviation [SD]=2.3; n=258) or webpages (mean=2.1 visits, SD=2.7; n=278), but use was higher among the adolescents who reported on their user experience post-intervention (*Breathe*: median=6.0, range=1-6, n=81/258; webpages: median=2.0, range=1-9, n=148/278). The user experience was more positive for *Breathe* than webpage users (P<.001); for *Breathe* users, most user experience scores were correlated with their use of the program (P's<.05). Adolescents who used *Breathe* reported

barriers (time constraints, avoiding uncomfortable activities) and facilitators (liked learning about anxiety, use of videos) to their use and experience of the program. A user-reported MCID was calculated and, based on the estimate, 43% (n=35/81) of *Breathe* users were considered 'treatment responders'. This response did not correlate with user experience scores or *Breathe* use (P's>0.05).

Conclusions: This dissertation generated hypotheses about the key PSD features of iCBT thought to support desired program use, anxiety reductions, and a positive user experience. Adjunct program support may have an important role in complementing or replacing the usefulness and function of PSD features across programs. The relationships between program use, program experiences, and perceived program impacts require further clarification. Future studies can validate and incorporate the more novel self-report assessment tools (UEQII, MCID) and analytic approaches that I used (realist syntheses, triangulating objective and subjective data) to formally test my hypotheses and identify new avenues of research. Findings from this dissertation can be applied to comparisons of user experiences between Internet-based interventions, interpretations of iCBT treatment outcomes, optimization of iCBT program design and delivery, and improvement of treatment decision-making tools for adolescents with anxiety.

Preface

This doctoral dissertation is original work by Ashley D. Radomski and consists of 3 research studies—each study is associated with its own chapter.

The first study is a realist synthesis of the literature on Internet-based cognitive behavioural therapy for children and adolescents with anxiety. The purpose of the synthesis was to identify key contextual delivery and technological design features hypothesized to increase users' use of iCBT programs. Chapter 3 of this dissertation has been published as: "©Radomski AD, Wozney L, McGrath P, Huguet A, Hartling L, Dyson MP, Bennett K, Newton AS. Design and delivery features that may improve the use of internet-based cognitive behavioral therapy for children and adolescents with anxiety: a realist literature synthesis with a persuasive systems design perspective. J Med Internet Res 2019;21(2)e11128. The manuscript is available at https://www.jmir.org/ 2019/2/e11128/." Under the mentorship of ASN, ADR designed and conducted all aspects of the study, including data collection, analysis and interpretation, and drafted the manuscript. LW participated in the study design and conduct. PM, AH, LH, MPD and KB conceived of the study and participated in its design and conduct. ASN conceived of, designed and coordinated all aspects of the study, and participated in interpretation of the results. All authors provided feedback and approved the final manuscript. This is an open-access article distributed under the terms of the Creative Commons Attribution License 2.0 (or 4.0 as of June 2017), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited.

The second study is another realist synthesis of the literature on Internet-based cognitive behavioural therapy for children and adolescents with anxiety. The purpose of this synthesis was to identify key contextual delivery and technological design features hypothesized to reduce the anxiety of iCBT users. Chapter 4 of this dissertation has been accepted for publication in the Journal of Medical Internet Research Mental Health as: "Radomski AD, Wozney L, McGrath PJ,

Huguet A, Hartling L, Dyson MP, Bennett KJ, Newton AS. Potential reduction of symptoms with the use of persuasive systems design features in internet-based cognitive behavioral therapy programs for children and adolescents with anxiety: a realist synthesis". A preprint of the manuscript is available at http://preprints.jmir.org/preprint/13807. Under the mentorship of ASN, ADR designed and conducted all aspects of the study, including data collection, analysis and interpretation, and drafted the manuscript. LW participated in the study design and conduct. PM, AH, LH, MPD and KB conceived of the study and participated in its design and conduct. ASN conceived of, designed and coordinated all aspects of the study, and participated in interpretation of the results. All authors provided feedback and approved the final manuscript.

The third study involved using multiple methods to study the relationships between program use, self-reported user experience and perceived changes in anxiety following participation in an Internet-based cognitive behavioural therapy program for adolescents with anxiety as compared to resource webpages. Chapter 5 of this dissertation is being revised and resubmitted for publication to the Journal of Medical Internet Research as: "Radomski AD, Bagnell A, Curtis S, Hartling L, Newton AS. Examining the usage, perceived impact and user experience of an Internet-based cognitive behavioural therapy program for adolescents with anxiety: results from a randomized controlled trial". A preprint of the manuscript is available at http://preprints. jmir.org/preprint/ 15795. Under the mentorship of ASN, ADR conducted all aspects of the study, including data collection, analysis and interpretation, and drafted the manuscript. AB, SC, LH and ASN conceived of the study. AB and SC participated in the conduct of the study. ASN designed and coordinated all aspects of the study and participated in interpretation of the results. All authors provided feedback and approved the manuscript. This research study received ethics approval from the University of Alberta Health Research Ethics Board (Pro00066393).

Dedication

I dedicate this dissertation to my grandparents, my mother, my father, Jonathan, Mackenzie, my kindred spirits, and all my loved ones who offered friendship, compassion, encouragement and inspiration over the years.

Thank you for reminding me that I am a *match for my mountain.*

Acknowledgements

I wish to thank my supervisor, Dr. Mandi Newton, for kindly providing me with the opportunity to pursue this degree. Dr. Newton, you have been a strong and steady force in helping me reach for, and constantly extend, my academic potential. Your patience and support of my 'process' has been much appreciated. You have been an excellent role model of what focus, clarity and deliberate and deep thinking can yield. A sincere thank you to Dr. Newton and my committee members, Drs. Alexa Bagnell, Sarah Curtis and Lisa Hartling, for your mentorship, time, and expertise over the course of my degree. Each of you has uniquely encouraged my growth and provided me with opportunities to develop as a professional. Thank you to the chairs and external examiners who participated in my doctoral program evaluations.

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lunches with you), introductions to like-minded colleagues (locally and internationally; Dr. Newton), and demonstration of your tireless commitment to students and research.

This dissertation would not have been possible without the generous financial support provided by my graduate studentships and awards from Alberta Innovates, the Women and Children's Health Research Institute (WCHRI), the Government of Alberta, the Medical Sciences Graduate Program (MSGP), the Faculty of Graduate Studies and Research, and various travel awards. I was also able to benefit from Dr. Newton's funding sources, such as the Canadian Institutes of Health Research (CIHR), the Stollery Children's Hospital Foundation and Royal Bank of Canada (RBC) Foundation, that supported the research projects I was a part of.

Chapters 3 and 4: I wish to thank all co-authors, Drs. Wozney, McGrath, Huguet, Hartling, Dyson, Bennett, and Newton, for their constructive input throughout the project. Thank you, Robin Featherstone, for developing and running the initial search strategy for these studies. Thank you to authors of previously published studies who responded to requests for additional information about study details relevant to documents included in these reviews. Special thanks to Drs. Kristin Silfvernagel and Sarah Vigerland who were in contact with me during my training and who warmly welcomed me into their research labs and homes to discuss science and life.

Chapter 5: I wish to thank all co-authors, Drs. Bagnell, Curtis, Hartling, and Newton, for their valuable feedback during the project. Nicole Gehring, Melody Cesar and Hilary Fast, thank you for being enthusiastic, devoted and helpful *Breathe* research study teammates. Thank you to the research and mental health teams in Pediatric Emergency Medicine and the Stollery Children's Hospital Emergency Department, the primary and specialized mental health clinics who participated in *Breathe* recruitment efforts. Thank you to the youth who participated in our studies—I hope you (and future youth) found value in the program. Our communications were so valuable and served as a strong reminder of why I chose this career path.

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List of Abbreviations

AACAP	American Academy of Child and Adolescent Psychiatry
ACM	Association for Computing Machinery digital library
Apps	mobile applications
ASQ	Ask Suicide-Screening Questionnaire
AUDIT-C	Alcohol Use Disorders Identification Test Consumption subscale
Breathe	Being Real, Easing Anxiety: Tools Helping Electronically
CBT	cognitive behavioural therapy
CIHR	Canadian Institutes of Health Research
CINAHL	Cumulative Index to Nursing and Allied Health Literature database
C-M-O configuration	Context-Mechanism-Outcome configuration
CONSORT-EHEALTH	Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and online TeleHealth
df	degrees of freedom
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th edition
EMBASE	Excerpta Medica database
ERIC	Education Resources Information Center database
GAD	generalized anxiety disorder
GRCS	global rating of change scale
iCBT	Internet-based cognitive behavioural therapy
IEEE	Institute of Electrical and Electronics Engineers database
IOM	Institute of Medicine
IRIS	Intelligent Research Intervention Software

MASC-2	Multidimensional Anxiety Scale for Children-2nd edition
MCID	minimal clinically important difference
MeSH	Medical subject headings
MHS	Multi-Health Systems
MMAT	Mixed Methods Appraisal Tool
MOST	multiphase optimization strategy
MRC	Medical Research Council
N/A	not applicable
PSD	Persuasive Systems Design
RAMESES II	Realist And Meta-narrative Evidence Syntheses: Evolving Standards
RCT	randomized controlled trial
REDCap	Research Electronic Data Capture
SAD	separation anxiety disorder
SCARED	Screen for Child Anxiety Related Disorders
SD	standard deviation
SMART	sequential multiple assignment randomized trials
SR	systematic review
STEPI	Schizophrenia Test and Early Psychosis Indicator
UEQII	User Experience Questionnaire for Internet-based Interventions

Chapter 1

Introduction

For my doctoral thesis, I conducted three research studies that focused on exploring the designs and delivery of Internet-based cognitive behavioural therapy (iCBT) programs for anxiety and experiences of adolescents who use iCBT. iCBT is a technology-based approach to cognitive behavioural therapy, a recommended first line treatment for adolescents with anxiety disorders. iCBT is considered a novel and accessible treatment approach for those with barriers to receiving in-person treatment or prefer an online format. To date, iCBT programs have been tested for their impact in helping adolescents with anxiety self-manage their symptoms. A consistent evidence base has shown that such programs are effective in reducing anxiety as compared to waitlist, with moderate-to-large effect sizes. However, studies have yet to comprehensively explore *how* the components of iCBT work together (eg, context of delivery + therapeutic content + technological features) to produce treatment effects. This new perspective acknowledges iCBT as a complex, social innovation inherently influenced by individual users and the contexts within which it is delivered. Under this perspective, disparate findings reported in the literature—low rates of adherence and program usage, and high rates of program satisfaction, acceptability, usability and interest among adolescent users—may be clarified.

All 3 of the doctoral research studies I conducted yielded hypotheses for how the design and delivery of iCBT could be improved to optimize treatment outcomes. For studies 1 and 2, I conducted realist syntheses to examine patterns across iCBT programs to identify plausible explanations for what iCBT delivery conditions ('Context') and key technology-based iCBT program components ('Mechanisms') are the most influential for generating iCBT effects ('Outcomes'). The syntheses relied on published and grey literature of iCBT programs and

multiple analytic methods. Studies 1 and 2 used the same methodology and methods, but differed in the iCBT outcomes that I examined. In study 1, I was interested in understanding how certain contexts and mechanisms resulted in iCBT program use. In study 2, I was interested in understanding how certain contexts and mechanisms resulted in anxiety symptom reduction. Study 3 of my doctoral research occurred within a national randomized controlled trial (RCT) comparing the effectiveness of an iCBT program ('*Breathe*') in reducing anxiety symptoms among adolescent users as compared to standard anxiety-based resource webpages. My study involved examining adolescents' use of and experiences with both interventions, and among those adolescents who completed the *Breathe* program, their perceptions of change in anxiety (minimal clinically important difference; MCID) after program participation. In this study, I conceptualized the user experience as a multi-faceted one that includes satisfaction, acceptability, credibility, impact, adherence, and program use.

This paper-based dissertation includes one peer-reviewed publication (Chapter 3), one manuscript that has been accepted for publication (Chapter 4), and another manuscript that is undergoing the review and revision process with a peer-review journal (Chapter 5). Chapter 1 represents an introduction to my doctoral dissertation and includes: (i) a brief overview of the literature on adolescents with anxiety, CBT as a recommended treatment, iCBT as a new treatment option, and common outcomes of iCBT for adolescents with anxiety; (ii) knowledge gaps related to how iCBT for adolescent anxiety can be designed and delivered to improve program use, effectiveness, and the user experience; and (iii) the objectives of my three studies. Chapter 2 provides a concise introduction to the main methods used to meet my study objectives.

1.1 Background

1.1.1 Adolescent anxiety

Anxiety is the most common mental health issue among children and adolescents (Bennett et al., 2016; Merikangas, 2005), affecting up to 30% of individuals between 10 and 24 years of age (Beesdo, Knappe, & Pine, 2009; Costello, Egger, & Angold, 2005; Merikangas, Nakamura, & Kessler, 2009; Merikangas & Swanson, 2010; Pine & Klein, 2008; Rapee, Schniering, & Hudson, 2009). Anxiety is characterized by excessive and persistent worry about the future (Connolly & Bernstein, 2007) and avoidance of activities, people or situations that are feared (Beesdo et al., 2009). Commonly, adolescents with anxiety have somatic complaints, such as headaches or stomachaches, which may be caused by a heightened physiological state associated with a readiness for 'fight or flight' (Barlow, 1991). Behavioural indications of anxiety may be school refusal, difficult relationships with family and friends and decreased participation in activities once considered enjoyable (Connolly & Bernstein, 2007).

When anxiety symptoms become maladaptive and inconsistent with typical development (eg, distress when separated from a parent) or contextual behaviours (eg, adjustment problems when changing schools) a diagnosis of an anxiety disorder may be made (Beesdo et al., 2009). The Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (DSM-5) (American Psychiatric Association, 2013) is a diagnostic system used to diagnose an anxiety disorder(s) (American Psychiatric Association, 2013), of which there are several types: separation anxiety disorder (SAD), selective mutism, generalized anxiety disorder (GAD), social phobia, specific phobia, panic disorder, and agoraphobia.

Anxiety disorders often co-occur among themselves and with many other psychiatric disorders (Essau, 2003; Essau, Conradt, & Petermann, 2000; Feehan, McGee, & Williams, 1993;

Lewinsohn, Zinbarg, Seeley, Lewinsohn, & Sack, 1997; Wittchen, Nelson, & Lachner, 1998), most commonly with depression (Essau et al., 2000; Essau, Lewinsohn, Olaya, & Seeley, 2014; Lewinsohn et al., 1997). Most anxiety disorders have an early onset—generally in childhood or early adolescence (Kessler et al., 1994; Mathew, Pettit, Lewinsohn, Seeley, & Roberts, 2011). Separation anxiety disorder and some types of specific phobias (animals, needles) are the first to emerge, typically in children <12 years of age; social phobia, panic disorder and GAD appear in late childhood to adolescence, and incidences of these anxiety subtypes tend to increase into adulthood (Beesdo et al., 2009; Beesdo, Pine, Lieb, & Wittchen, 2010; Ronald C Kessler et al., 2005). Sub-clinical anxiety conditions have been reported in up to 70% of adolescents (Muris, Meesters, Merckelbach, Sermon, & Zwakhalen, 1998), causing distress and impairment, and can eventually lead to a clinical need (Cartwright-Hatton, McNicol, & Doubleday, 2006; Van Oort, Greaves-Lord, Verhulst, Ormel, & Huizink, 2009).

Anxiety in adolescents can lead to poor total adjustment, academic performance, coping skills, family relationships, employment, life satisfaction, and enduring (mental) health-related issues (Essau et al., 2014; Kessler et al., 1994; Pine, Cohen, Gurley, Brook, & Ma, 1998). If left untreated, disorders or sub-clinical conditions that begin early in life can become chronic (Feehan et al., 1993; Ferdinand & Verhulst, 1995; Keller et al., 1992; Letcher, Sanson, Smart, & Toumbourou, 2012; Pine et al., 1998), are more likely to recur (Bruce et al., 2005), and increase the risk for anxiety in adulthood by two-to-three times (Essau et al., 2000; Pine et al., 1998). Given the significant negative effects and persistent nature associated with anxiety, it is important to intervene as early as possible.

1.1.2 Cognitive behavioural therapy (CBT) as a first-line treatment

Cognitive behavioural therapy (CBT) is the first-line psychotherapy treatment for anxiety that is mild-to-moderate in severity (eg, Compton et al., 2004; Connolly and Bernstein, 2007; Walkup et al., 2008; Higa-McMillan et al., 2016), and may be paired with medication for those who are severely impaired (Connolly & Bernstein, 2007). CBT is based on learning theory principles and is designed to bring about changes in an adolescents' thoughts, feelings and behaviours that allow them to feel a sense of mastery over their anxiety symptoms and the situations that trigger their distress and impairment (Connolly & Bernstein, 2007; Silverman, Pina, & Viswesvaran, 2008). The American Academy of Child & Adolescent Psychiatry (AACAP) clinical practice parameter for the assessment and treatment of children and adolescents with anxiety disorders describes 5 major components of CBT (Albano & Kendall, 2002; Connolly & Bernstein, 2007): (1) psychoeducation about anxiety and CBT; (2) somatic skills management training (eg, relaxation skills, self-monitoring); (3) cognitive restructuring (eg, challenging negative expectations, positive self-talk); (4) exposure methods (eg, gradual desensitization to feared stimuli); (5) relapse prevention plans (eg, referral to follow-up services, booster sessions). Self-assessment of mood and symptoms, goal setting, reinforcement of skill application, interpersonal strategies and problem solving, and homework assignments are often included in CBT as well (Rapee et al., 2009). Depending on the type and severity of anxiety, treatment protocols vary in the number of sessions provided and the extent to which they focus on the different therapeutic components (Albano & Kendall, 2002; Rapee et al., 2009). Typically, adolescents with an anxiety disorder receive 9-20 sessions of in-person psychotherapy, delivered by a trained professional, over the course of several weeks or months (James Anthony et al., 2013). CBT for anxiety problems in children and adolescents has been

found to be effective at reducing symptoms and improving daily functioning (Bennett et al., 2016; Cartwright-Hatton, Roberts, Chitsabesan, Fothergill, & Harrington, 2004; Edmunds, O'Neil, & Kendall, 2011; Kendall, Safford, Flannery-Schroeder, & Webb, 2004; Silverman et al., 2008), with generally large effect sizes as compared to no therapy (Silverman et al., 2008).

Despite CBT being an effective treatment for adolescents, many do not receive this treatment due to the multiple barriers to receiving CBT in-person (Essau, 2005; Essau, Conradt, & Petermann, 2002). Common barriers include direct and incidental costs to families, lack of trained deliverers, inconvenient service times and locations, adolescent concerns around stigma and privacy, and/or adolescents' preference for self-help options (Clarke, Kuosmanen, & Barry, 2014; Gulliver, Griffiths, & Christensen, 2010). Internet-based interventions are proposed as treatment options that circumvent access and availability barriers.

1.1.3 Internet-based CBT (iCBT)

Technology and Internet use is nearly ubiquitous in adolescents from industrialized countries (Shaw Rocket Fund, 2014; Steeves, 2014), with over 90% accessing the web daily (Madden, Lenhart, Duggan, Cortesi, & Gasser, 2013; Steeves, 2014). The increased use of technology has facilitated the provision and use of Internet-based resources and interventions to help people manage their health. Adolescents confirm using the Internet as a major source of health information (Stallard, Velleman, & Richardson, 2010; Steeves, 2014), and rates of use increase in times of psychological distress (Rickwood, Webb, Kennedy, & Telford, 2016; Steeves, 2014). Adolescents seek Internet-based resources that are useful, credible, confidential, and convenient (Bradley, Robinson, & Brannen, 2012); however, finding personally- and developmentally-relevant, high-quality information can be challenging as many resources target adults and the trustworthiness of the resource content can be difficult to determine, especially

when sources are not cited (Gray, Klein, Noyce, Sesselberg, & Cantrill, 2005; Skinner, Biscope, Poland, & Goldberg, 2003).

Internet-based interventions offer several advantages over traditional in-person intervention: (1) increased accessibility, (2) greater anonymity, (3) flexibility, (4) reduced expenses, (5) eliminated travel time, and (6) interactivity (Christensen, Batterham, & Calear, 2014; Lenhard et al., 2016; Nielsen et al., 2018). Some Internet-based interventions are considered to be 'self-help' tools ('unguided') in that their use is initiated and led primarily by the user—increasing adolescents' participation, sense of control and empowerment in their treatment (Eysenbach, 2008). Other Internet-based interventions are delivered with the guidance and/or supervision of a clinician ('guided') or may be used to extend aspects of treatment outside of individual sessions (eg, clinician-adolescent communication, supports the practice of skills acquired during the session) (Andersson, 2014).

The structured and sequential nature of CBT lends itself well to being translated to an online delivery platform, making it available to users anytime or anywhere there is Internet connectivity (Andersson, 2009; Proudfoot et al., 2004). Internet-based CBT (iCBT) is a product of cross-disciplinary collaborations between experts in psychology, computing science, human-computer interactions, medicine and more. iCBT is comprised of 3 major components (Andersson & Titov, 2014; Barak, Klein, & Proudfoot, 2009; Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012):

(1) *Therapeutic content:* evidence-based CBT techniques, strategies and information presented in structured modules in a progressive format;

(2) *Technological features:* multimedia (eg, video, audio, email) and other technological features (eg, drop-down response menus, animated demonstrations, quizzes) that deliver therapeutic content;

(3) *Interactions between the user and the program:* reciprocal activities that offer users the opportunity to participate in the program (eg, self-assessment, self-monitoring), apply their knowledge and skills, and receive feedback or communicate with others.

iCBT programs differ from one another in the specific components that are combined and used in the design of the program. For example, some programs have a greater emphasis on exposure activities (Newton et al., 2016; Spence, Holmes, March, & Lipp, 2006; Vigerland et al., 2013; Vigerland, Ljótsson, et al., 2016), whereas others may focus on psychoeducation, self-monitoring and cognitive strategies (Calear, Christensen, Brewer, Mackinnon, & Griffiths, 2016; Calear, Christensen, Mackinnon, Griffiths, & O'Kearney, 2009; Wong, Kady, Mewton, Sunderland, & Andrews, 2014). More recently developed iCBT programs use a variety of technological components to personalize and increase users' interactivity with the content (Parmanto, Silk, & Pramana, 2013; Patwardhan, 2016; Spence et al., 2006), whereas programs developed earlier on were minimally-dynamic and adopted a workbook-style format (Calear et al., 2009; Keller, 2009). iCBT also varies in the extent that it is unguided or guided (ie, automated or human support provided). Reminder emails, telephone calls or notifications are often incorporated to promote use, resolve issues or provide performance feedback to the user throughout the program (Radomski et al., 2019).

iCBT for adolescents requires special developmental and age-appropriate design considerations (Sauter, Heyne, & Michiel Westenberg, 2009; Spence et al., 2008). The language (eg, reading level), degree of personalization (eg, use of user's name), tailoring (eg, content is

related to gender or type of anxiety), aesthetics and layout (eg, fashionable colour scheme, pop-culture references) should meet adolescents' unique abilities, needs and preferences. Since iCBT is typically accessed at home, without a clinician present to deliver the session, it may be especially important for younger child-focused programs (eg, programs intended for children and younger adolescents) to include parents as a source of support during treatment (Adelman, Panza, Bartley, Bontempo, & Bloch, 2014). Parent involvement may include the development of their own knowledge and skills that they can model to their child (Keller, 2009; Pramana, Parmanto, Kendall, & Silk, 2014; Shahnavaz, 2016; Spence et al., 2006; Vigerland et al., 2013) or by reinforcing treatment content and progress and helping with exposure-based tasks (Silfvernagel, Gren-Landell, Emanuelsson, Carlbring, & Andersson, 2015). Finding a balance between preserving the child's or adolescent's autonomy in anxiety self-management and incorporating parental support to ensure an appropriate understanding and use of program skills is important for children and adolescents who participate in iCBT. For some iCBT programs parental involvement is mandatory (Keller, 2009; Pramana et al., 2014; Spence et al., 2006; Vigerland, 2015; Vigerland et al., 2013), for others it is voluntary/based on the child's decision (Newton et al., 2016; Silfvernagel et al., 2015). The majority of parents have reported positive attitudes toward their child accessing an Internet-based self-help program for their anxiety (eg, felt program could help their child learn how to cope better with anxiety; would be in favour of their child using a self-help program) (Stallard et al., 2010). Parental involvement in iCBT, however, has not been shown to improve symptom-based outcomes (Ebert et al., 2015; Richardson, Stallard, & Velleman, 2010), but may increase a child's use of the program, confidence in the program's credibility/quality, or parents' awareness of their child's safety and symptom changes during treatment (Stallard et al., 2010). iCBT for adolescent anxiety can be

designed to recognize crises of its users, like thoughts of self-harm or suicide or a significant worsening of symptoms, that warrant further attention (Ander et al., 2017; Newton et al., 2016). Tools to assess or follow-up on health or safety risks by an expert can ascertain the nature, severity and level of risk, and to provide suggestions for appropriate local services.

At present, I am aware of at least 17 different iCBT programs (2 of which are mobile applications [apps]) for children or adolescents with anxiety that have been developed and empirically tested for at least one outcome: participant usage (adherence), user (or parent) satisfaction, efficacy, or effectiveness. Most iCBT programs have first undergone feasibility, acceptability and/or usability testing followed by evaluation for effectiveness in clinical trials. Recent systematic reviews and meta-analyses have found iCBT to be more effective at reducing anxiety symptoms in children and adolescents as compared to wait-list for service, with moderate to large treatment effect sizes reported for iCBT (Ebert et al., 2015; Hollis et al., 2017; Pennant et al., 2015; Podina, Mogoase, David, Szentagotai, & Dobrean, 2016; Vigerland, Lenhard, et al., 2016). When compared to face-to-face CBT, iCBT has demonstrated slightly inferior or comparable impacts on symptom reduction (Ebert et al., 2015; Podina et al., 2016; Rooksby, Elouafkaoui, Humphris, Clarkson, & Freeman, 2015). Although iCBT has been shown to be effective in reducing anxiety symptoms, the heterogeneity in program format and delivery (Lehto & Oinas-Kukkonen, 2011; Vigerland, Lenhard, et al., 2016) makes it less clear as to what specific program components and combinations lead to more favourable outcomes.

In contrast to face-to-face CBT (Cartwright-Hatton et al., 2004; Spielmans, Pasek, & McFall, 2007; Weisz, Weiss, Han, Granger, & Morton, 1995), relatively little research has been conducted on the 'active ingredients' contributing to iCBT outcomes. Several meta-analyses have indicated a trend for greater iCBT effects among adolescents (as compared to children) and

those with elevated baseline symptoms (as compared to mild) (Ebert et al., 2015; Hollis et al., 2017; Pennant et al., 2015; Podina et al., 2016). However, inconsistent results between iCBT studies and small study sample sizes limit the reliability of these findings (Ebert et al., 2015; Hollis et al., 2017; Pennant et al., 2015; Podina et al., 2016). Further, what also remains unclear, and an important area of study, is the relationship between iCBT outcomes and unique design and delivery characteristics of iCBT—such as which embedded technologies (eg, videos, online quizzes), user contexts (eg, home, desktop computer), and program support methods (eg, therapist emails, program modules for parents)—lead to the most optimal outcomes for program users. Based on recommendations from experts in the field, including my doctoral supervisory committee members and study collaborators, I set out to explore these relationships under the theoretical perspectives of iCBT as a: (1) complex intervention, and (2) persuasive system.

1.1.3.1 iCBT as a complex intervention

A complex intervention is an intervention with several interacting components (Campbell et al., 2000). Complexity can refer to more than just the number of intervention components; complexity can be attributed to the range of an intervention's possible outcomes or the variability of its effect in the target population (Craig et al., 2019). Complex interventions can be especially difficult to evaluate from a practical (eg, feasibility of identifying and operationalizing components) and methodological (eg, heterogeneity in outcomes to be tested and compared) perspective (Craig et al., 2019). The Medical Research Council (MRC) originally published a framework for development and evaluation of RCTs for complex interventions to improve health in 2000 (Campbell et al., 2000); the framework was revised and extended in 2008 (Craig, Dieppe, Macintyre, Michie, Nazareth, Petticrew, Health, et al., 2008) and again in 2019 (Craig et al., 2019). Along with establishing practical (real world) effectiveness and an understanding of

whether an intervention works, the MRC recommends evaluating *how* the intervention works—what are the active ingredients of the intervention and how do they generate their effect? The MRC framework suggests that intervention designs should be based on a theoretical understanding of how an intervention produces change so the 'strong and weak links in the causal chain' can be identified and strengthened (Craig et al., 2019). Advantages of addressing the 'how' of intervention effects is that it can provide evidence of the contributing mechanisms of an intervention, suggestions of design strategies that may improve effectiveness, and considerations that support the implementation of interventions across different users and use settings (Craig, Dieppe, Macintyre, Michie, Nazareth, Petticrew, Health, et al., 2008).

iCBT can be thought of as a complex intervention due to the multiple contextual, behavioural, and technological components involved in its delivery and use (Craig, Dieppe, Macintyre, Michie, Nazareth, Petticrew, & Medical Research Council Guidance, 2008). Evidence of *how* iCBT works in reducing anxiety symptoms among adolescent users has been slower to accumulate than evidence of whether it reduces anxiety symptoms (studies of efficacy and effectiveness). Numerous methods can be used to evaluate complex interventions (for a brief overview see Craig et al., 2019), but the MRC recommends using a mixed-methods or multiple method approach. Relevant to my dissertation projects, I used multiple methods to develop hypotheses of: (1) how iCBT programs and their components lead to intended outcomes for children and adolescents with anxiety, and (2) what program features and activities of an iCBT program may explain or influence the use, experience, and perceived impact of the program for adolescents with anxiety. These approaches will be described in Chapter 2 Methods.

1.1.3.2 iCBT as a persuasive system

iCBT can also be considered a 'persuasive system'. A persuasive system is a technology-based intervention designed to reinforce, change or shape people's attitudes and behaviour towards to their desired health outcome (Chatterjee & Price, 2009; Fogg, 2002; Oinas-Kukkonen & Harjumaa, 2009). iCBT 'persuades' users by leveraging the characteristics and possibilities of technology to deliver therapeutic content that creates interactions between the user and the program (Barak et al., 2009; Kelders et al., 2012). Approaching the evaluation of iCBT as a persuasive system is useful given that:

(1) iCBT is a technology-based treatment and the online platform and delivery features are inseparable aspects of the intervention (van Gemert-Pijnen et al., 2011), and

(2) there is emerging evidence that certain technological features can enhance the 'persuasiveness' of an Internet-based intervention, and lead to increased program adherence and effectiveness (Kelders et al., 2012; Lehto & Oinas-Kukkonen, 2011, 2015; Wildeboer, Kelders, & van Gemert-Pijnen, 2016).

1.1.3.2.1 The Persuasive Systems Design (PSD) Model

The Persuasive Systems Design (PSD) model was developed by Oinas-Kukkonen and Harjumaa (2008) to provide systematic design methods to develop and evaluate persuasive systems (Oinas-Kukkonen & Harjumaa, 2008). Based on the work of BJ Fogg (2002), the first researcher to study the persuasive potential of technology, the PSD model is described by its developers as 'conceptual-theoretical' and practical framework (Oinas-Kukkonen & Harjumaa, 2008). The model includes 28 persuasive, technological features (design principles) and examples of how they can be implemented by an intervention to guide users toward their desired

health outcome (bring about behaviour change). The 28 features are organized into 4 categories based on their key benefits:

(1) *Primary task supports* assist the user in completing their target behaviour. Features include reduction, tunneling, tailoring, personalization, self-monitoring, simulation, and rehearsal.

(2) *Dialogue supports* provide computer-human communication to guide user toward target behaviour. Features include praise, rewards, reminders, suggestion, similarity, liking, and social role.

(3) *System credibility supports* increase user's perceptions of the credibility of the intervention and its content. Features include trustworthiness, expertise, surface credibility, real-world feel, authority, third-party endorsements, and verifiability.

(4) *Social supports* leverage the interactions and influence of others to motivate users. Features include social facilitation, social comparison, normative influence, social learning, cooperation, competition, and recognition.

The PSD model can be utilized to understand the underlying principles behind persuasive systems, such as information technology is never neutral, persuasion is often incremental and persuasive systems should aim at being both useful and easy to use. The model also provides a framework from which to analyze the persuasion context by recognizing the influence of the users' existing beliefs or attitudes on their desired behaviour change, and defining the technological feature(s) in use (Oinas-Kukkonen & Harjumaa, 2008, 2009). Thus, the PSD model provides a valuable approach to examining how iCBT works because it can be used to anticipate and describe users' behaviour (Langrial, 2012) based on the program features or conditions of use and how they are applied (Oinas-Kukkonen & Harjumaa, 2008; Yardley et al., 2015).

Recently, it has been suggested that some PSD features (eg, reminders) may be more strongly associated with Internet-based intervention outcomes (eg, adherence) (Kelders et al., 2012; Lehto & Oinas-Kukkonen, 2011; Webb, Joseph, Yardley, & Michie, 2010; Wozney et al., 2017). Although some reviews have described the designs of Internet-based interventions from a persuasive systems perspective (Kelders et al., 2012; Lehto & Oinas-Kukkonen, 2011; Lentferink et al., 2017; Matthews, Win, Oinas-Kukkonen, & Freeman, 2016; Radomski et al., 2019; Wildeboer et al., 2016; Wozney et al., 2017), the authors of relatively few studies have identified or explained what program components (design and delivery features) can be used to optimize therapeutic gains or meet the needs and preferences of users. Similar to other studies in other fields (Drozd, Lehto, & Oinas-Kukkonen, 2012; Kuonanoja, Langrial, Lappalainen, Lappalainen, & Oinas-Kukkonen, 2015; Lehto & Oinas-Kukkonen, 2011; Räisänen, Lehto, & Oinas-Kukkonen, 2010; Stibe, Oinas-Kukkonen, & Lehto, 2013), but novel to the field of iCBT, I used the PSD model to understand the specific persuasive elements (software or technology features) that can increase desired health outcomes (or behaviour change) in existing iCBT programs for children and adolescents with anxiety (Fogg, 2009; Fogg, 1999; Parada, Martínez, Daniel Espinosa, Bauer, & Moessner, 2019).

1.1.3.3 The user experience of iCBT

A person-based approach to iCBT use gives attention to the adolescent's subjective experience with this intervention type (Morrison, Muller, Yardley, & Bradbury, 2018; Yardley et al., 2015) and aims to empower users and improve the quality and safety of healthcare systems (Lutz & Bowers, 2000; Viksveen et al., 2017). The approach emphasizes understanding the adolescent's views on the helpfulness or likability of the intervention's techniques to support their desired health outcomes (Yardley, Spring, & Riper, 2016; Yardley et al., 2015), as well as

their context (social and developmental) (Morrison et al., 2018; Viksveen et al., 2017), when selecting or continuing with an intervention. Discourse around the applicability of the person-based approach to Internet-based interventions design and delivery is increasing (Lievens, Livingstone, Mclaughlin, O'neill, & Verdoodt, 2018; Rickwood, Deane, Wilson, & Ciarrochi, 2005; The Mental Health Commission of Canada Youth Council, 2015; Viksveen et al., 2017; Yardley et al., 2015). When adopted, the approach promotes an iterative data collection process to understand users' views, context and experiences of an intervention and using this understanding to optimize the intervention's design to ensure users find it to be feasible, engaging and meaningful (Yardley et al., 2016; Yardley et al., 2015). At this time, most evaluations of iCBT programs are limited in their assessment of how a program was experienced and what the adolescent user expected and gained from using the program (Black et al., 2011). Rather, most evaluations have tended to focus on measuring treatment effectiveness or intervention usability from a program design standpoint (Feather et al., 2016). In my dissertation research, I developed a tool for adolescents to describe their 'user experience' with an iCBT program, '*Breathe'*, and felt that this individual reporting was an essential part of the evaluation of the *Breathe* iCBT program.

Based on my review of the literature, I consider user experience to be a multifaceted concept that goes beyond assessing symptoms alone to understanding adolescents' perceptions of iCBT and what program features, activities or psychosocial contexts adolescents deem important to their use, experience and perceived impact of an iCBT program. Evaluations of users' experience can be used to: (1) ensure that iCBT programs are usable and engaging, (2) anticipate and interpret program usage and effectiveness outcomes across different users and contexts, (3) enable iCBT program developers and researchers to optimize and successfully implement

programs, and (4) support the treatment decision-making process of adolescents, parents and/or clinicians (Baker, Gustafson, & Shah, 2014; Kaltenthaler et al., 2008; Pagliari, 2007; van Gemert-Pijnen et al., 2011; Yardley et al., 2015). For these reasons, study of the user experience is important for ethical (user safety), methodological (preserving internal and external validity by maintaining study participation) and practical reasons (the influence it has on program usage and treatment effects) (Feather et al., 2016; Kaltenthaler et al., 2008).

Previous studies of the adolescent user experience with iCBT have primarily focused on assessing iCBT program:

(1) *Usability:* The extent to which the design and functionality elements of an intervention are easy to use and free of errors (Yardley et al., 2015)—assessed using, for example, self-report surveys, log data, and semi-structured interviews (Currie, Mcgrath, & Day, 2010; Patwardhan, 2016; Stoll, Pina, Gary, & Amresh, 2017; Wozney, Baxter, & Newton, 2015),

(2) *Acceptability:* The extent to which users view the intervention as reasonable, justified, and fair (Kazdin, 2000)—assessed using, for example, self-report surveys (Calear et al., 2016; Pramana et al., 2014; Shahnavaz et al., 2018),

(3) *Satisfaction:* users' rating of important attributes to the process and outcomes of his or her treatment experience (Revicki, 2004)—assessed using, for example, self-report surveys (March, Spence, & Donovan, 2009; Nordh et al., 2017; Spence, Donovan, Kenardy, & Hearn, 2017; Spence et al., 2006; Vigerland, Ljótsson, et al., 2016),

(4) *Adherence:* program use and the extent to which users experience the content of the intervention (Christensen, Griffiths, & Farrer, 2009)—assessed using, for example, log data (Calear, Christensen, Mackinnon, & Griffiths, 2013; Neil, Batterham, Christensen, Bennett, & Griffiths, 2009).

Many of the user experience terms and concepts overlap in their meaning and how they are evaluated (Feather et al., 2016). Generating a more comprehensive, and inclusive, definition of user experience, and a complementary tool to assess it, could help us begin to explore how adolescents' experience of iCBT may influence other commonly evaluated outcomes (ie, program use, effectiveness) and provide us with suggestions for how to improve program design and delivery to better meet their expectations, needs or preferences.

One important missing component of the user experience evaluation is the adolescents' perception of a health improvement (ie, anxiety symptoms) as a result of participating in an iCBT program. Most clinical trials rely on statistical evaluation (p-values, effect sizes) to indicate whether an intervention was more/less effective than another intervention. Statistical significance, however, is void of indications of an intervention's clinical significance from the perspective of a user (relevance or benefit to the user in their daily life) (Guyatt, et al. 1995; Jaeschke, Singer, & Guyatt, 1989). Generating a 'critical threshold' that indicates whether a small, but meaningful change in an adolescent's self-reported anxiety has been achieved with an iCBT program could add value to determining whether an intervention should be implemented and offered to the adolescents outside of a research study (eg, will its use matter to adolescents?; is it worth the costs or risks?) (Leopold & Porcher, 2017). In the literature, this threshold is referred to as the patient-derived minimal clinically important difference (MCID) (Jaeschke et al., 1989) and it has yet to be defined for iCBT for adolescents with anxiety. In my dissertation research, I set out to define a MCID for change in anxiety symptoms, the main outcome for the *Breathe* trial.

1.1.4 Research Questions and Objectives

As a complex intervention, iCBT involves multiple components in its design and delivery. Though research has demonstrated that iCBT can be effective in reducing anxiety in adolescent users, questions remain about how, why, and for whom these effects occur. This includes gaps in knowledge about the active ingredients of iCBT programs and indicators of what the user experience of iCBT is like for adolescent users with anxiety. My doctoral research objectives addressed these key gaps and were to: explore the designs of iCBT for children and adolescents with anxiety, and examine adolescent treatment experiences with Internet-based interventions for mild-to-moderate anxiety. To achieve my objectives, I conducted 3 research studies within the context of two, large-scale, collaborative projects: (1) a realist synthesis of iCBT for child and adolescent anxiety, and (2) a national RCT evaluating the effectiveness of an iCBT program (*Breathe*) as compared to anxiety-based resource webpages for adolescents with anxiety.

My research questions for my realist syntheses, studies 1 and 2 of my dissertation research, were:

1. What therapeutic principles (content), interactions and delivery features (technologies) have been evaluated in iCBT for adolescents with anxiety?
2. Which content, interaction and technologies produce which outcomes and for whom?

These questions represent a novel direction in the iCBT field. To understand the active ingredients of iCBT, alternative evaluation methods are required to begin answering the questions that have not been clarified with RCTs and traditional objectives (eg, is X intervention more effective than Y intervention at reducing anxiety in adolescents?). My first synthesis involved a focus on which iCBT program content, interaction and technologies leads to increased program use (Chapter 3). My second synthesis involved examining which iCBT program

content, interaction and technologies resulted in improved anxiety-based outcomes among adolescent users (Chapter 4).

My research questions for study 3 of my dissertation research, were:

1. What is adolescents' usage of the *Breathe* program and resource-based webpages?
2. What is adolescents' user experience with the *Breathe* program and resource-based webpages? Is there a difference in experiences between users of the *Breathe* program and resource-based webpages?
3. What do adolescent users of the *Breathe* program consider to be a small but important change (the minimal clinically important difference [MCID]) in their anxiety following program use?
4. What is the relationship between adolescents who used the *Breathe* program and their program use, user experience and the MCID?

These questions reflect my interest in examining the comparative experiences of Internet-based interventions. I wanted to explore how adolescents with anxiety experienced iCBT and how their experience compared to users of another Internet-based intervention. I was also interested in defining the minimal change that adolescents would want to see following their iCBT use. This concept, the MCID, has been examined in other fields, namely, rehabilitation medicine (Bohannon & Glenney, 2014; Keurentjes, Van Tol, Fiocco, Schoones, & Nelissen, 2012; Wu et al., 2015), but not in the iCBT field. The results could yield insights that can be used to interpret clinical trial findings and inform the planning of future iCBT studies.

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Chapter 2

Methods

1.2 Realist Synthesis

The realist synthesis is an explanatory evidence synthesis designed to understand complex interventions (Pawson, Greenhalgh, Harvey, & Walshe, 2005). The purpose of a realist synthesis is to test and build theories on the relationships between the multiple components to explain 'how an intervention works, for whom, and under what circumstances' (Pawson et al., 2005; Pawson & Tilley, 1997). This approach focuses on defining the **contexts** ([C] circumstances that surround the implementation of a given intervention or phenomena), that activate underlying **mechanisms** ([M] underlying processes that are sensitive to context and influence outcomes), that lead to intervention **outcomes** ([O] effects that occur over time) (Astbury & Leeuw, 2010; Pawson et al., 2005; Pawson & Tilley, 1997; Wong et al., 2013). See Table 1 for an overview of realist synthesis terms, adapted from Pawson et al. (1997) and others (Jagosh et al., 2015). For my dissertation research studies 1 and 2, analyzing Context-Mechanism-Outcome (C-M-O) configurations across several iCBT interventions allowed me to identify overarching, semi-predictable patterns ('middle-range theories'; Merton, 1967) of how iCBT for adolescents with anxiety works at the aggregate (group) level (Pawson et al., 2005). My realist syntheses were conducted according to the process recommended by Pawson and Tilley, the originators of the realist approach (Pawson et al., 2005; Pawson & Tilley, 1997) (Table 1). All stages of the syntheses (Table 2) were presented and discussed at regular team meetings with a wide range of experts in the development, evaluation and knowledge translation of Internet-based treatments from across Canada. I also used specific guidelines, the Realist And

Meta-narrative Evidence Synthesis: Evolving Standards (RAMESES II) (Wong et al., 2016), to support the conduct and reporting of my work.

Table 2.1. An overview of realist synthesis terms.

Term	Definition	Examples
Context	The environment or "backdrop" of an intervention is called Context. Context can change over time, which could reflect aspects of change while an intervention is implemented. The context may limit or allow the mechanisms.	• Delivery setting (eg, home, school, clinic) • Adjunct support (eg, weekly emails from a therapist, teacher administration, parent-directed program sessions) • Program delivery platform/medium (eg, computer with Internet, smartphone app)
Mechanism	This refers to aspects ("resources") that are a part of the intervention and the users' response to those resources, for example, cognitive, motivational, and emotional changes.	• Technological (PSD; Oinas-Kukkonen and Harjumaa, 2008) features (eg, reminder emails, electronic quizzes, video demonstrations) • Therapeutic (CBT) content (eg, cognitive restructuring, exposure activities)
Outcome	Outcomes may be intended or unintended and refer to what may happen because of an intervention.	• Program usage (eg, number of activities completed, proportion of participants who completed the program) • Anxiety symptoms (eg, self- or parent-reported questionnaires, diagnostic interviews)
Middle-range theory	A proposed theory of how an intervention works that finds a 'middle-range'—a description that is between a universal claim with relatively little detail and one that can only apply to a single intervention delivered under a specific set of conditions. The middle-range theory is specific enough to generate propositions that can be applied or	• A description that describes how iCBT programs may work that has consistency when applied to multiple programs (eg, presence of an adjunct support person), yet can still distinguish programs from one another based on important differences (eg, parental support).

	tested across slight variations in interventions, its users or context.	
Context-Mechanism-Outcome (C-M-O) configuration	A proposition of the presence and relationships between key Context, Mechanism and Outcome variables that have emerged across multiple interventions or studies as useful for explaining how an intervention works and for whom. Configurations describe what the working components are and how they are proposed to work.	• Provision of adjunct support (Context), that complement the use of iCBT's technological features (Mechanisms), may lead to greater iCBT use (Outcomes)
Evidence	Includes primary outcome data, but also program and setting descriptions that portray contextual elements as well as interpretation of outcomes by study authors.	• Proportion of adolescents who completed an iCBT program • The average number of iCBT sessions completed by adolescents
Testing	C-M-O configurations are compared, contrasted or refined based on available evidence to determine the usefulness of the configurations. Testing is used to support, refute or improve our current understanding of how an intervention works.	• The technological features of iCBT programs with adjunct parental support and high program usage are compared to those with low program use

The realist approach is based on the realist philosophy—social reality cannot be measured directly, but can be understood through investigating the underlying causal mechanisms, the contexts in which interventions occur, and the outcomes produced (Bhaskar, 1978). Realist syntheses are different from systematic reviews in that they require a high degree of iteration (eg, recursive analysis based on a deeper understanding of the evidence), transformation and translation of primary studies (eg, linking related evidence across studies to find meaning behind the data), and abstraction (eg, articulating a common pattern relevant across multiple interventions) to generate findings (Pawson, Greenhalgh, Harvey, & Walshe, 2004; Petticrew et al., 2013). Advantages of a realist synthesis include the flexibility and inclusivity of evidence (literature, primary studies) and the explanatory nature of the process and findings (Rycroft-

Malone et al., 2012). Challenges of a realist synthesis include the significant commitment of the reviewer's time and resources, its inherent non-reproducibility due to the iterative and interpretive process, and its reliance on published or identified literature which may be subject to publication or availability bias (Cooper, Lhussier, Shucksmith, & Carr, 2017; Petticrew et al., 2013).

Table 2.2. The five main phases of a realist synthesis.

Phase of the realist synthesis	**Description**
Clarify the scope of the review	• Identify the review question • Refine the purpose of the review • Articulate candidate Context-Mechanism-Outcome configurations based on presuppositions, theories or current understandings of how interventions work
Search for relevant evidence	• Define a purposive sampling strategy including search sources, terms, methods to be used • Refine inclusion and exclusion criteria during the iterative search process
Appraise the quality of evidence	• Assess the methodological rigor of studies • Assess the relevance (or fit) of the evidence for review purposes
Extract data and synthesize findings	• Develop a data extraction template and code book and populate it using existing evidence from primary studies • Compare and contrast findings from different studies • Combine, exclude or refine Context-Mechanism-Outcome configurations based on evidence
Make recommendations based on findings	• Involve relevant stakeholders in the development of recommendations or summary of findings • Disseminate findings to relevant stakeholders or audiences

1.2.1 Measurement of adolescent user experiences

User experience describes an individual's perception and overall experience of their use of an Internet-based intervention for their targeted health condition. Previous studies have explored the user experience of iCBT using various concepts, like satisfaction or usability, and instruments, such as self-report questionnaires or in-depth interviews (Bradley, Robinson, & Brannen, 2012; March et al., 2018; Patwardhan et al., 2015; Shahnavaz et al., 2018; Spence et al., 2008; Wozney, Baxter, & Newton, 2015). However, most previously developed user experience questionnaires are based on traditional face-to-face treatments (Feather et al., 2016) and contain items that may not be relevant to Internet-based interventions. A new approach to assessing the user experience that maintains adolescents' perspectives, would be specific to Internet-based interventions, could measure facets beyond just that of satisfaction and usability, and would be required to gain a deeper understanding of how adolescents experience iCBT programs. A new approach could shed light on some of the paradoxical findings (ie, low iCBT usage but high satisfaction) reported in the literature, may help explain treatment effects and may be used to optimize the design and delivery of iCBT.

1.2.2 UEQII Development

My third dissertation study involved my developing the User Experience Questionnaire for Internet-based Interventions (UEQII) to provide an expedited, yet wide-ranging, assessment of the adolescent user experience of Internet-based interventions. It is becoming increasingly common for comparative effectiveness studies to compare iCBT to another Internet-based intervention (Danaher & Seeley, 2009; Orbach, Lindsay, & Grey, 2007). Therefore, another motivating factor for my development of the UEQII was to have an instrument that could be used in such studies. To ensure content validity of the UEQII, I pooled and adapted frequently asked

questions, concepts and questionnaires from published studies (Ritterband et al., 2005, 2008; Thorndike et al., 2008) to inform the development of the UEQII. The resulting tool was an electronically administered, self-report instrument that allowed me to assess the following aspects of user experience:

- *Satisfaction and Acceptability:* including global satisfaction, helpfulness, expectations met, convenience, engagement, privacy, preference for mode of delivery;
- *Credibility and Impact:* including confidence in treatment, skill development, perceived treatment effectiveness; and
- *Adherence and Usage:* ease of use, including technical, psychosocial and general barriers and facilitators to use of an intervention.

The UEQII consists of 21 items that can be administered to both adolescents using a type of Internet-based intervention ('Core' questions). In the *Breathe* RCT, I administered these items to both *Breathe* participants and those who were using resource-based webpages (the comparison group). An additional 14 questions of the UEQII were administered to *Breathe* users only as these items are specific to iCBT ('Treatment' items). In the *Breathe* RCT, treatment participants were also provided the opportunity to provide open-text feedback on the aspects of the program they found to be most challenging and enjoyable (2 additional UEQII questions). I designed the UEQII to collect such experiences and perceptions as I thought it may help explain adolescents' experience ratings and provide indications of important aspects of the program or intervention experience that may have influenced iCBT program use, enjoyment, and treatment effects.

1.2.3 Minimal clinically important difference (MCID)

In the context of the *Breathe* RCT, I calculated a MCID for anxiety symptoms using the primary outcome measure of the trial. The MCID was generated based on the changes in anxiety

that *Breathe* users perceived to have occurred as a result of participating in the program (Jaeschke, Singer, & Guyatt, 1989). The MCID was part of the adolescent-centered approach to the *Breathe* evaluation as it was used to indicate whether the program's impact on users' anxiety was meaningful to them. At present, there is no standard for how to define or calculate a MCID (Copay, Subach, Glassman, Polly, & Schuler, 2007; Crosby, Kolotkin, & Williams, 2003), and at least 9 methodological approaches have been described (for a review see Wright, Hannon, Hegedus, & Kavchak, 2012). A global rating of change scale (GRCS) is one method widely used to calculate the MCID because of the simplicity of its administration and scoring, adaptability to suit the needs of the researcher, and its clinical utility (Crosby et al., 2003; Kamper, Maher, & Mackay, 2009; Long & Dixon, 1996). Although the GRCS is a subjective measure, and recall bias and the accuracy of adolescent reports can limit the reliability and validity of the estimate (Cook, 2008; King, 2011; Norman, Stratford, & Regehr, 1997), I chose to use it in my research because it accounts for adolescents' perspectives (Crosby et al., 2003), which is of critical importance when adolescents themselves become the initiators of an online treatment program (iCBT), and when adolescents themselves experience an internalizing disorder, for which not all symptoms can be observed (anxiety). The GRCS asks respondents to rate the extent to which their anxiety has improved or deteriorated, or whether it remained unchanged, after participation in iCBT ('much better', 'somewhat better', 'the same/ no change', 'somewhat worse' and 'much worse'). The GRCS ratings are compared to a standardized symptom questionnaire that respondents completed pre- and post-intervention. The average pre- to post-intervention change on the symptom questionnaire is calculated (along with the standard deviation) for the group of adolescents who provided the same rating (either 0, or +1, or +2, etc.) on the GRCS. Respondents who reported that their anxiety was 'somewhat better' (+2) were considered to have

experienced a minimal but important difference in their anxiety; therefore, the mean symptom change score of these respondents became the MCID estimate. I used the MCID estimate to identify adolescents who responded positively to the *Breathe* program and those who did not based on whether their symptom change score was above ('treatment responder') or below ('non-responder') the MCID estimate. Treatment response provides a crude indication of the overall effectiveness of a program that does not rely on the complete absence or remission of symptoms, but rather a change that is meaningful for program users (Macher & Crocq, 2004).

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Chapter 3

Design and delivery features that may improve the use of Internet-based cognitive behavioural therapy for children and adolescents with anxiety: a realist synthesis with a persuasive systems design perspective

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Abstract

Background: Internet-based cognitive behavioural therapy (iCBT) is a 'persuasive system' as its design combines therapeutic content, technological features and interactions between the user and the program to reduce anxiety for children and adolescents. How iCBT is designed and delivered differs across programs. While iCBT is considered an effective approach for treating child and adolescent anxiety, program use (eg, module completion rates) is highly variable for reasons that are not clear. Since the extent to which users complete a program can impact anxiety outcomes, understanding which iCBT design and delivery features improve program use is critical for optimizing treatment effects.

Objective: A realist synthesis approach was used to explore the design and delivery features of iCBT for children and adolescents with anxiety as described in the literature and to examine their relationship to program use Outcomes.

Methods: A search of published and grey literature was conducted up to November 2017. Pre-specified inclusion criteria identified documents from research studies, study protocols and program websites on iCBT for child and adolescent anxiety. Literature was critically appraised for relevance and methodological rigor. The Persuasive Systems Design (PSD) model, a framework for designing and evaluating persuasive systems, was used to guide data extraction. iCBT program features were grouped under four PSD categories—Primary task support, Dialogue support, System credibility support, and Social support. iCBT design (PSD Mechanisms) and delivery features (Context of use) were linked to program use (Outcomes) using meta-ethnographic methods and described as Context-Mechanism-Outcome configurations. We identified key PSD features and delivery Contexts that generated moderate-

to-high program use based on evidence that was of moderate-to-high quality and found across multiple iCBT programs.

Results: Forty-five documents detailing 10 iCBT programs were included. Seven iCBT programs had at least one document that scored 'High' for relevance and most studies were of moderate-to-high methodological rigor. We developed 5 configurations that highlighted 8 PSD features (Tailoring, Personalization [Primary task supports]; Rewards, Reminders, Social Role [Dialogue supports]; and Trustworthiness, Expertise, Authority [System credibility supports]) associated with moderate-to-high program use. Important features of delivery Context were adjunct support (a face-to-face or online communications component) and whether programs targeted the prevention or treatment of anxiety. Incorporating multiple PSD features may have additive or synergistic effects on outcomes.

Conclusions: The Context-Mechanism-Outcome configurations we developed suggest that, when delivered with adjunct support, certain PSD features contribute to moderate-to-high use of iCBT prevention and treatment programs for children and adolescents with anxiety. Standardization of the definition and measurement of program use, formal testing of individual and combined features, and use of 'real world' design and testing methods are important next steps to improving how we develop and deliver increasingly useful treatments to target users.

3.1 Introduction

Cognitive behavioural therapy (CBT) is recommended as a first line treatment for children and adolescents with anxiety (Arnberg, Linton, Hultcrantz, Heintz, & Jonsson, 2014; Compton et al., 2004; Connolly & Bernstein, 2007; Seligman & Ollendick, 2011). Trained mental health professionals have traditionally delivered CBT, but there is an increasing interest in the Internet as a delivery platform to circumvent the multiple barriers to receiving in-person treatment. These barriers can include direct and incidental costs to families, lack of trained deliverers, and inconvenient service times and locations (Clarke, Kuosmanen, & Barry, 2014). Internet-based CBT (iCBT) is also proposed to preserve adolescent autonomy, appeal to user preferences, reduce health care system costs, and improve time to receipt of treatment (Calear & Christensen, 2010; Richardson, Stallard, & Velleman, 2010; Skinner, Biscope, Poland, & Goldberg, 2003). iCBT is recognized as an important treatment option (Podina, Mogoase, David, Szentagotai, & Dobrean, 2016; Spence, March, Vigerland, & Serlachius, 2016; Vigerland, Lenhard, et al., 2016) to meet the increasing demands of a population where anxiety is often undetected and untreated, and where early access to care can improve long-term outcomes (Connolly & Bernstein, 2007; Donovan & Spence, 2000; Essau, Lewinsohn, Olaya, & Seeley, 2014; Neil & Christensen, 2009).

iCBT uses technological features (ie, multimedia, email) to deliver treatment content through online interactions between the user and the program (Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012). In this way iCBT aims to reinforce, change or shape attitudinal or behavioural health outcomes and aligns with the concept of a ‘persuasive system’ (Chatterjee & Price, 2009; Fogg, 2002; Oinas-Kukkonen & Harjumaa, 2008). Although recent efforts have been made to provide guidance on the design and delivery features of iCBT (Hill et al., 2018),

considerable differences exist across programs in terms of their features and the health outcomes they produce. Recent systematic reviews and meta-analyses have found a range of iCBT programs to be effective at reducing anxiety in children and adolescents (Pennant et al., 2015; Podina et al., 2016; Rooksby, Elouafkaoui, Humphris, Clarkson, & Freeman, 2015; Vigerland, Lenhard, et al., 2016); however, 'poor' and highly variable rates of completion can be found across programs (up to 50% of participants not reaching the end of a program) (Christensen, Griffiths, & Farrer, 2009; Clarke et al., 2014; Richardson et al., 2010; Rooksby et al., 2015; Vigerland, Lenhard, et al., 2016). The term 'program use' captures the various, typically objective, outcomes used across studies (ie, adherence, compliance, number of program activities/homework completed) to describe the extent to which users interact with a program.

Understanding the factors that influence program use is important since there have been indications that greater program use is associated with better outcomes (Calear, Batterham, Poyser, et al., 2016; Spence, Donovan, S, Kenardy, & Hearn, 2017). Studies of iCBT in children and adolescents with anxiety (Calear, Christensen, Mackinnon, & Griffiths, 2013; Neil, Batterham, Christensen, Bennett, & Griffiths, 2009) have found that certain participant demographics (eg, gender, age, location, anxiety severity) and delivery features (eg, parental or therapist support) relate to or predict program use. However, the relationship between technological features of a program designed to enhance its 'persuasiveness' and actual iCBT program use by children and adolescents with anxiety has received minimal attention in the literature.

Recognizing iCBT as a persuasive system, we conducted a realist synthesis to examine the technological and program delivery features of iCBT for children and adolescents with anxiety, and to document their potential relation to persuading program use. The realist synthesis

approach provided a framework to answer two main questions: (1) What design and delivery components (technological features, treatment content, interactions) are described for iCBT programs for children and adolescents with anxiety? and (2) What components may explain reported program use outcomes?

3.2 Methods

3.2.1 Study Design

This realist synthesis was conducted using steps recommended by Pawson and Tilley (Pawson, Greenhalgh, Harvey, & Walshe, 2005; Pawson & Tilley, 1997) and is reported in accordance with the Realist And Meta-narrative Evidence Synthesis: Evolving Standards (RAMESES II) (Wong et al., 2016). Realist synthesis is theory-driven in that the synthesis searches for and refines explanations of intervention effectiveness by asking: "What works, for whom, and in what circumstances?" (Pawson et al., 2005). In this synthesis, we examined and tested the relationships between iCBT program format, treatment content, interactions (Context) and program use (Outcomes), and the underlying technological or persuasive system design features of iCBT (Mechanisms) that connect them. We expressed these relationships as Context-Mechanism-Outcome configurations, which are hypotheses that iCBT works because of the action of an underlying Mechanism, which is produced under certain circumstances.

3.2.2 Context-Mechanism-Outcome Configuration Development

We began the synthesis by developing 'candidate' Context-Mechanism-Outcome configurations. The development process consisted of brainstorming activities with the research team and reviewing literature on human-technology interaction and studies of iCBT programs for anxiety to identify relevant, preexisting theories, models or frameworks to work from. The Persuasive Systems Design (PSD) model (Oinas-Kukkonen & Harjumaa, 2008) emerged as a

key framework for understanding how iCBT as a persuasive system was intended to work, and we used this model to develop the initial list of Context-Mechanism-Outcome configurations. The model describes persuasive system design features across four categories that can be implemented by programs to guide the user toward their health-related goal: (1) Primary task support, (2) Dialogue support, (3) System credibility support, and (4) Social support.

Using the PSD model, we identified what PSD features (Mechanisms) might be associated with iCBT program use (Outcomes) to formulate Mechanism-Outcome dyads. We then hypothesized what program formats, delivery features and conditions for use (Context) might promote the occurrence of the Mechanism-Outcome interactions. Together these steps led to the generation of 5 candidate Context-Mechanism-Outcome configurations (Multimedia Appendix 1). The configurations were as comprehensive and justifiable as possible, referencing literature that supported their development and inclusion in the list. These configurations would undergo refinement and 'testing' during the analysis stage of the synthesis, whereby we used evidence from the literature to validate their explanatory usefulness and applicability for answering our research questions.

3.2.3 Literature Search

We used three main strategies to identify literature for iCBT programs. The first search strategy involved an information specialist conducting a systematic and comprehensive search of 8 electronic databases: Medline, Embase, ERIC, PsycINFO, CINAHL, Cochrane Library, ProQuest Dissertations & Theses Global, and PubMed for the period 1990-2017. The second strategy involved a manual search using Google, an online search engine, and grey literature repositories (ACM Digital Library, Open Grey, IEEE Digital Library, Canadian Agency for Drugs and Technologies in Health) to identify conference proceedings, program evaluations, and

government or technical reports. For both search strategies, MeSH terms and text words were based on mental health condition (anxiety, phobias), intervention modality (online, Internet-based, mobile application ['app']), intervention type (prevention, treatment) and therapeutic approach (CBT) (Multimedia Appendix 2). The third strategy involved manually searching the table of contents in the Journal of Medical Internet Research, Internet Interventions, Journal of CyberTherapy & Rehabilitation, and Journal of Telemedicine and Telecare, and a review of reference lists of included documents and reviews (eg, systematic reviews).

We employed the search strategies on an iterative and recurrent basis until November 2017 to ensure the review was up to date and inclusive. Prior to discontinuing the literature search, a 'test of saturation' was applied to the search strategies, which involved verifying that further searching would not yield any new results (Walker, 2012).

3.2.4 Literature Selection

Two independent, trained reviewers (authors ADR, LW) screened the search strategy results for eligibility using a two-stage approach. During this process, reviewer discrepancies were resolved by consensus or third-party arbitration (author ASN). At stage 1, all documents were screened for eligibility using title and abstract. During this stage we randomly selected 100 citations to assess inter-rater agreement for inclusion/exclusion decisions; Cohen's kappa was =0.74) between raters, reflecting substantial agreement (McHugh, 2012). All documents that were screened 'yes, include' or 'unsure to include' moved to stage 2. At stage 2, the full-text of documents were reviewed by one reviewer (ADR), in consultation with another (ASN), with a resulting decision to either include or exclude from the synthesis.

For an iCBT program to be included in this synthesis supporting documents needed to be published in English and provide information on treatment Context, PSD features, and program

use Outcomes. Each document did not need to provide details on all three, but all three needed to be represented in the total documents for an iCBT program. Additionally, at least one published study on the iCBT program needed to be available for inclusion so that we could assess the methodological quality of the study providing program use outcome data.

Intervention studies (eg, clinical trials) were eligible for inclusion if they evaluated iCBT anxiety programs with children (<14 years) and/or adolescents (12-19 years). As some iCBT programs were designed for and evaluated with participants from a broader age range (eg, programs also geared towards 'young adults'), only those studies that provided separate data for participants aged ≤ 19 years were included. We also required that the type of iCBT program under evaluation be designed for an anxiety disorder(s) or anxiety symptoms associated with a disorder as classified according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013): social phobia (social anxiety disorder), generalized anxiety disorder, panic disorder, separation anxiety disorder, or specific phobia. Transdiagnostic programs (ie, programs designed for anxiety plus another diagnosis such as depression) were also eligible for inclusion. We also required that the iCBT program consist of modules designed for use by the child or adolescent (and not solely delivered to or facilitated by a parent or therapist) since child or adolescent program use was our outcome of interest. Theoretical papers, mixed-methods and qualitative studies, and policy/implementation documents were also eligible if they included a focus on how an iCBT program was proposed to work.

3.2.5 Literature Appraisal

Documents were assessed for relevance and rigor based on consensus between two reviewers (authors ADR, LW). Relevance was assessed based on the level of contribution a

document provided for an iCBT program in 3 domains: (1) underpinning theory and/or the Context and sequence for delivery (Context), (2) PSD features (Mechanism), and (3) program use outcomes (Outcomes). The level of contribution for each domain was rated 'low' if little or no information was provided, 'medium' if some information was provided, and 'high' if information was well described. Exemplar documents with a 'high' level of contribution across the 3 domains informed decision rules for the rating of all other documents.

The methodological quality (rigor) of research studies was assessed using the Mixed Methods Appraisal Tool (MMAT) (Pluye, Robert, Cargo, & Bartlett, 2011; Pluye, Gagnon, Griffiths, & Johnson-Lafleur, 2009). The MMAT is a reliable, efficient, and valid tool that provides different sections for assessing studies of qualitative, randomized, non-randomized studies, descriptive studies, and mixed method design (Pace et al., 2012; Pluye et al., 2011; Pluye et al., 2009). Multiple publications of the same study (thesis + journal publication) received the same MMAT score. MMAT scores can range from 0-100%, with a greater score indicating more quality criteria were met.

3.2.6 Data Extraction and Coding

Documents for each iCBT program were grouped together during data extraction and coding. Two reviewers (ADR, LW) cross-referenced extraction and coding decisions with a random subset of 10 documents; the remaining documents were coded by one reviewer (ADR). In addition to document characteristics (type, year of publication), iCBT program data were extracted for the following:

- Participants: eligibility criteria, participant demographics.

- iCBT program Context: number of modules, module workflow and sequence, delivery setting, adjunct support and program type according to the Institute of Medicine model (Institute of Medicine, 1994).
- Theory and/or proposed Mechanisms: program features and components, including PSD features, and information on why the iCBT program was designed a certain way and/or how the program was proposed to work.
- Program use Outcomes: information related to how many online sessions, exercises or activities were completed by users, or how many users completed certain aspects of the program, measured at post-treatment.

3.2.6.1 Context and Mechanism Data

Adjunct support details were coded when human-derived technological and/or therapeutic communication was provided to users to complement iCBT program delivery.

Therapeutic content in programs was coded according to the 5 main CBT components found in the American Academy of Child and Adolescent Psychiatry (AACAP) practice parameter (Albano & Kendall, 2002): psychoeducation, somatic management skills, cognitive restructuring, exposure methods, and relapse prevention.

As most authors did not use PSD terminology or concepts, program descriptions were coded as PSD features using a code book and glossary (Oinas-Kukkonen & Harjumaa, 2008) (Multimedia Appendix 3). PSD features were coded when they were executed by the technology (intrinsic to the design and delivery of the Internet-based program) and not by human action (eg, congratulatory comments provided in person by a parent or teacher), which is in line with the use of the PSD model by others (Kelders et al., 2012). When available, suggested mediators and

moderators of program use were extracted, as was information on partial or full Context-Mechanism-Outcome configurations, as discussed by original authors of the included documents.

3.2.6.2 Outcome Data

We found inconsistent and heterogeneous measurement and reporting of program use Outcomes—program adherence, compliance and completion. These limitations have been noted by others (eg, Christensen, Griffiths and Farrer, 2009).

For each study, program use Outcomes are reported as published by original authors and are collectively referred to in this review using the umbrella term 'program use'. When possible, Outcomes were also converted into percentages (based on quartiles) to assist with interpreting program use. Since no applicable cutoff scores have yet been established, we used the following to define program use: 'High' use (≥75%), 'Moderate' use (50-74%), 'Low' use (25-49%), or 'Very Low' use (≤24%). Study dropout or attrition data were not included in the analysis because these data may not directly reflect program use, but rather rates of study participants who did not fulfill the research protocol (eg, filling out questionnaires) (Kelders et al., 2012), and not necessarily those who did not complete the program itself. Corresponding authors were contacted to provide clarity and completeness of unclear or unreported information and to ensure accurate application of the PSD model for coding iCBT program features. An author for each of the included programs responded to the requests (n= 10).

3.2.7 Data Analysis and Synthesis Process

We used a multi-step approach to data analysis that was structured according to Pawson's techniques (Pawson et al., 2005; Pawson & Tilley, 1997) and meta-ethnography (Atkins et al., 2008; Noblit & Hare, 1988). The first step involved determining recurrent patterns or themes ('demi-regularities') across documents for each iCBT program for delivery Context, PSD

features and program Mechanisms, and Outcomes related to program use. The purpose was to use evidence from the literature to: 1) identify PSD Mechanisms in each program most frequently associated with the program use Outcomes to refine the candidate Mechanism-Outcome dyads, and 2) incorporate delivery Context of each iCBT program into the dyads to refine the overall Context-Mechanism-Outcome configurations. Context-Mechanism-Outcome configurations that were supported by evidence from at least 2 different iCBT programs progressed to the next step of analysis.

The second step in analysis involved reciprocal translation analysis, a meta-ethnographic technique that involved reviewing the Context-Mechanism-Outcome configurations between iCBT programs (Byng, 2005). Configurations that were found to have mixed (ie, more heterogenous support with no larger trend) or confounding evidence across programs or could not be refined by better describing or recombining the Context, Mechanism or Outcome factors, did not progress to the next stage of analysis. What remained were configurations that provided the best support, across multiple programs, to explain the relationship of design and delivery components of iCBT with program use.

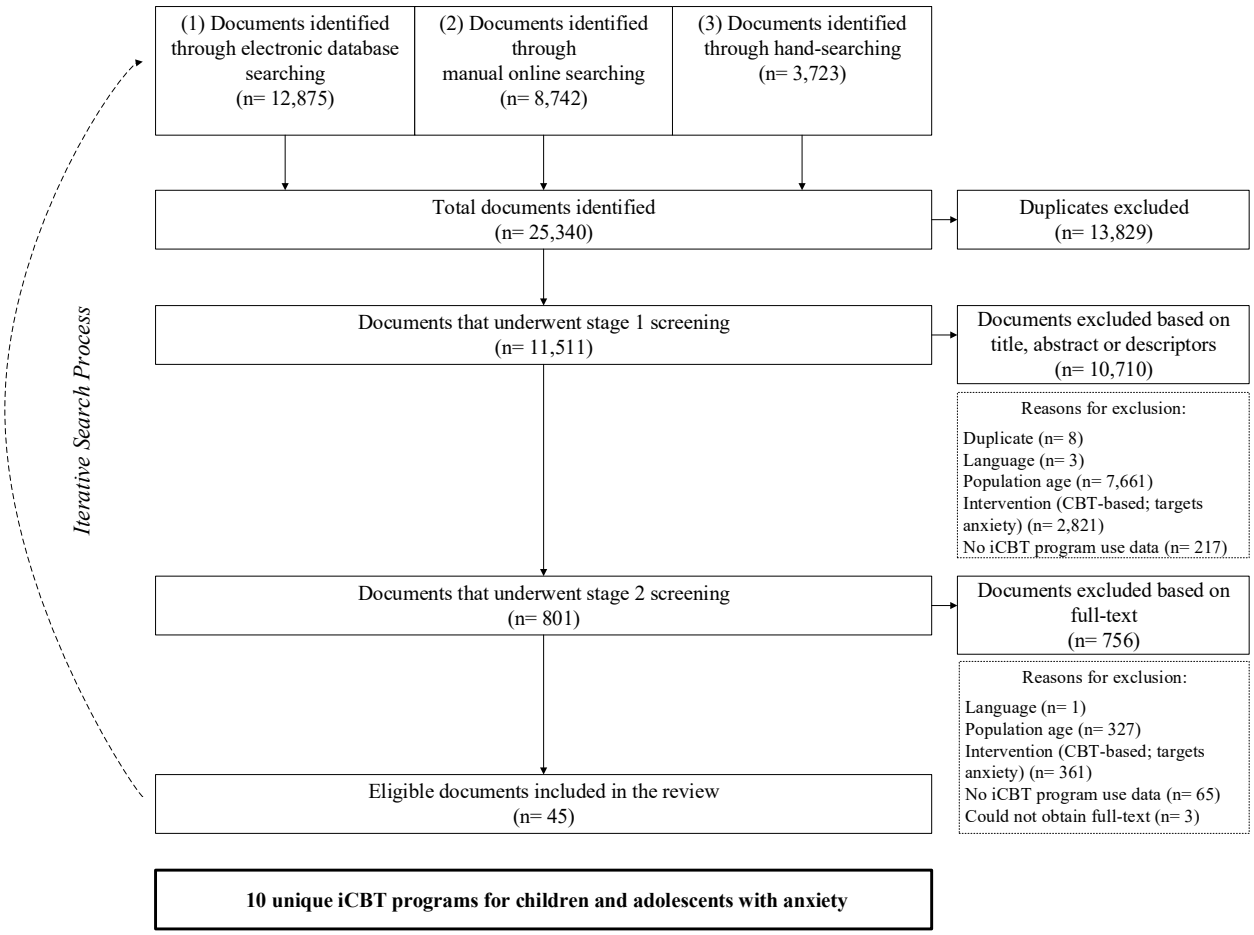
In the final step, we used lines-of-argument synthesis, a theorizing technique (Noblit & Hare, 1988) that involved assessing how well each Context-Mechanism-Outcome configuration could explain why the same PSD Mechanism(s), operating in different iCBT program Contexts, might result in particular program use Outcomes. We took into consideration the quality and quantity of evidence supporting the configuration, and held a meeting to discuss, amend and finalize configurations with individuals from across Canada with expertise in e-Health interventions. Configuration refinement continued until we felt that it reflected a pattern that

would remain consistent despite differences in small- or large-scale details across iCBT programs. At that point in time we considered the configuration to be adequately developed.

3.3 Results

Figure 1 presents the literature search and selection progress. The search strategy yielded 11,511 unique documents for stage 1 screening, after duplicates were removed. Of these, 801 documents underwent stage 2 screening. In total, 45 documents detailing 10 iCBT programs were included in the realist synthesis. Documents were published studies (n= 20), theses (n= 5), published or registered protocols for trials (n= 13), study or program websites (n= 6), and a study flyer (n= 1).

Figure 3.1. Flow diagram of the literature search and selection process.



3.3.1 Characteristics of iCBT for Anxiety in Children and Adolescents

3.3.1.1 Program and Participant Characteristics

Table 1 presents an overview of iCBT program and participant characteristics. The majority of child and adolescent users were Caucasian, English speakers, of middle-to-high socioeconomic status, who lived in urban centers with both biological parents. Programs designed to treat an anxiety disorder tended to be longer in duration than prevention-based programs. Treatment-based programs were delivered in the community (some included occasional health care clinic visits) and involved weekly online therapist interaction and parent-dedicated modules. Prevention-based programs were provided in schools with a teacher facilitating program administration. Most programs were adaptations of previously developed mental health prevention or treatment resources (Calear, Christensen, Griffiths, et al., 2013; Calear, Christensen, Mackinnon, Griffiths, & O'Kearney, 2009; Keller, 2009; Patwardhan, 2016; Pramana, Parmanto, Kendall, & Silk, 2014; Shahnavaz, 2016; Silfvernagel, Gren-Landell, Emanuelsson, Carlbring, & Andersson, 2015; Spence, Holmes, March, & Lipp, 2006; Vigerland, 2015; Vigerland et al., 2013).

Table 3.1. Overview of the iCBT user, program and delivery characteristics.

Numbered List of Programs[a]		User Details	Program Details					
			Delivery		Therapist Support			Other adjunct support
			Setting	Number of sessions and duration	Online	Phone	In-person	
Treatment Programs								
1.	BRAVE-Online	Children and/or adolescents with anxiety	Clinic or Community	10 weekly sessions + 2 booster sessions 60 minutes each	✓	✓		Parent
2.	iCBT for children and adolescents with dental anxiety	Children and/or adolescents with anxiety	Community plus Clinic	12 weekly modules	✓			Parent Dental professional[b]
3.	Internet-delivered CBT for children with anxiety disorders	Children with anxiety	Community	11 modules over a 10-week period[c]	✓	✓		Parent
4.	Internet-delivered CBT for children with specific phobia	Children with anxiety	Community	11 modules over a 6-week period 15-45 minutes each	✓	✓		Parent
5.	SmartCAT App	Children with anxiety	Community	Daily entries completed over 8 in-person sessions 3-4 minutes each	✓		✓	Parent
Indicated Prevention Programs								
6.	Internet cognitive-behavioral skills-based program	Children with anxiety	Community	3 modules over a 12-week period[d]		✓[e]		Parent
7.	REACH for Success App[f]	Children with anxiety	School	5 activities 20-30 minutes for each activity			✓	Research Assistant[g]

Numbered List of Programs[a]		User Details	Program Details					
			Delivery		Therapist Support			Other adjunct support
			Setting	Number of sessions and duration	Online	Phone	In-person	
8.	Individually tailored iCBT for adolescents[f]	Adolescents with anxiety and/or depression	Clinic	6-9 prescribed modules over a 6-18-week period[h]	✓	✓	✓	Therapist (Optional)
Universal Prevention Programs								
9.	The e-couch Anxiety and Worry Program	Adolescents with anxiety	School	6 weekly sessions 30-40 minutes each				Teacher[i] Mental health service provider[j]
10.	MoodGYM	Adolescents with anxiety and/or depression	School or Community	5 weekly modules 30-60 minutes each				Teacher[i]

[a]Categorized according to the Level of Prevention Model (Institute of Medicine, 1994): Universal Prevention: target participants are not been identified on the basis of individual risk (ie, no symptoms required); Selective Prevention: target participants have a higher risk of developing an anxiety disorder than others; Indicated Prevention: target participants are 'high risk' who have anxiety signs or symptoms, but do not currently meet diagnostic levels; and Treatment: target participants are diagnosed with an anxiety disorder.
[b]A dental professional (a dentist, dental hygienist, or dental assistant) provided exposure at a dental clinic.
[c]Five versions depending on diagnosis.
[d]Two blocks of modules (containing multiple sections) dedicated to mothers, 1 module block (containing multiple sections) dedicated to child + mother.
[e]Therapist completed a brief (15 minute), non-therapeutic, check-in telephone call with the mother (not the child).
[f]Program was designed for indicated prevention and/or treatment (early intervention).
[g]Research assistant and/or graduate student was present to facilitate aspects of the study, such as assessment and troubleshoot technical issues.
[h]Out of a possible 17 modules, based on symptoms.
[i]Teacher facilitated program administration and was available for general guidance or if questions arose but did not provide an active therapeutic role.
[j]Mental health service provider was present in one study of the program to facilitate program administration and/or address student questions (Calear, Batterham, Griffiths, & Christensen, 2016).

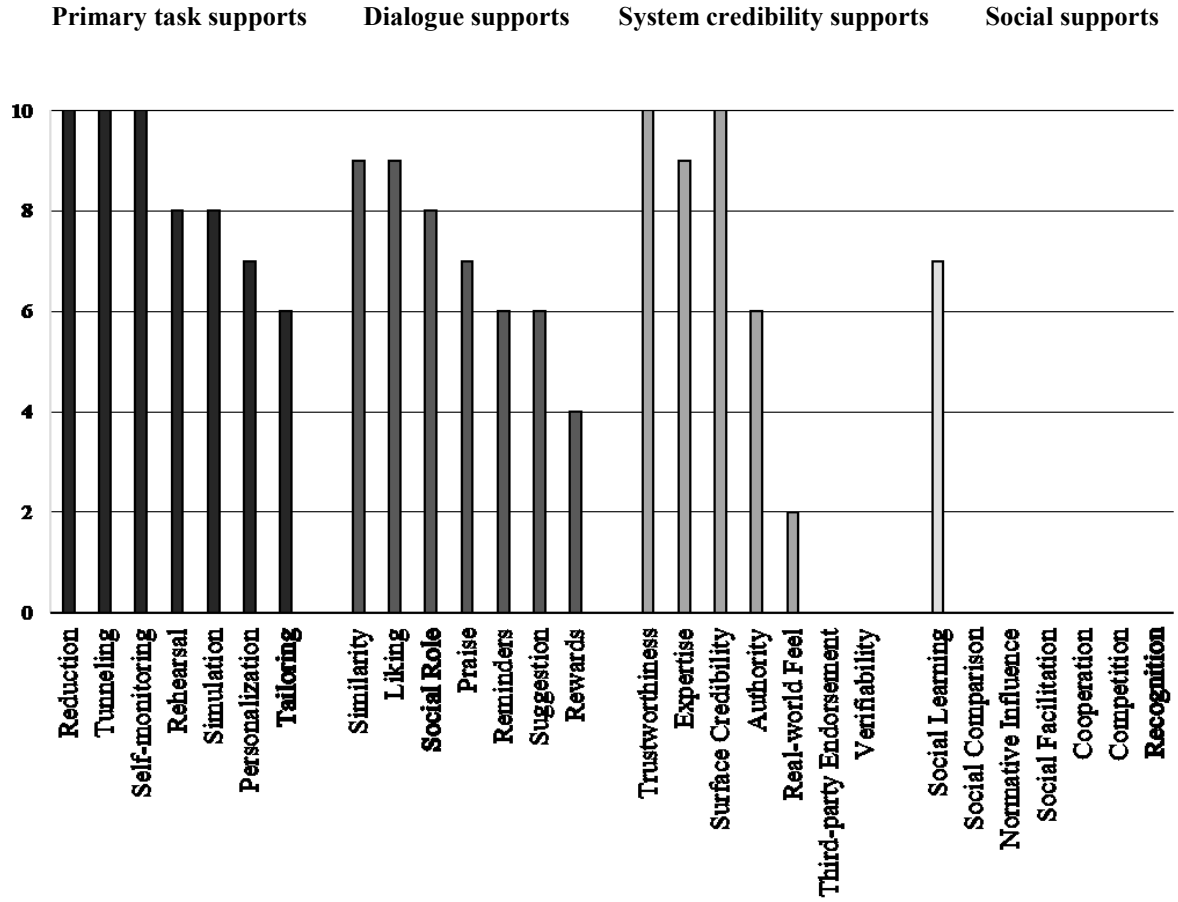
3.3.1.2 CBT Components and Persuasive Systems Design Features

All programs described themselves as CBT-based and contained at least 3 of the 5 AACAP recommended CBT components (most commonly psychoeducation, somatic management skills and cognitive restructuring). The workflow of the programs presented the

more foundational and easier treatment components (eg, psychoeducation, symptom identification) before more challenging skills (eg, desensitization/exposure). Many programs also integrated interpersonal skills (Lipsitz & Markowitz, 2013), such as assertiveness training and problem-solving, to reduce environmental stressors and enhance social support.

The frequency of the PSD features used in the iCBT programs is shown in Figure 2. All programs incorporated Reduction and Tunneling (Primary task supports) to regulate the pace and sequence by which users moved through the program. Self-monitoring, a Primary task support, to track progress or mood/state over time was another feature used in all programs. Eight programs used Rehearsal (Primary task support) via recommended or required online homework or practice activities. Seven programs provided a personalized review (eg, progress report, feedback) of homework or session content before the next module. Most programs utilized Tailoring (n= 6) and/or Personalization (n= 7) (Primary task supports) to adapt the content to user's characteristics, such as their primary anxiety concern, age or name. Incorporating a Social Role, such as an online therapist or cartoon 'guide', was one of the most commonly used Dialogue supports (n= 8). Nine of the ten programs had program content, technology and interaction features that were relatable and appealing to target users (Similarity and Liking features). Since all programs were part of a research study, Trustworthiness and Surface credibility (System credibility supports) were considered inherent to their design (ie, programs were ad-free, not marketed for commercial use, accessed through a secure platform), although few documents explicitly reported this. Authority (System credibility support) was most often observed when online therapist support was provided. Social support features were seldom used amongst programs.

Figure 3.2. Overview of the PSD features across the 10 iCBT programs included in the synthesis.



3.3.1.3 Level of Contribution and Methodological Quality

Details of the quality appraisal are provided in Multimedia Appendix 4. Documents tended to provide the greatest level of contribution to understanding program Context and Outcomes with relatively few details available for program Mechanisms. Seven iCBT programs had at least one document that scored 'High' for level of contribution to understanding program Context, Mechanisms and Outcomes. We evaluated 29 research studies (found in 25 documents) for methodological rigor. Nineteen studies met all 4 MMAT criteria (100%), 7 met 3 criteria (75%), and 3 met 2 criteria (50%). Lower ratings reflected an unclear description of processes for recruitment, selection, randomization or allocation; how group differences (if any) were

controlled for; the percentage of outcome data obtained; or withdrawal/dropout rates were not within acceptable limits.

3.3.2 Summary of Key iCBT Contexts, Mechanisms, and Outcomes

Tables 2 and 3 present an overview of the delivery Context and PSD features that were most frequently or consistently associated with moderate-to-high program use Outcomes across iCBT programs. Contexts most indicative of program use were the adjunct support person and the communication approach with the user—both of which typically varied based on the level of prevention the program was designed for. The type of adjunct support also depended on the age of program users. Children generally received the most extensive adjunct support (ie, therapist and parent), and program use was often greater among this age group than among adolescents. PSD features identified as having a high value to encouraging program use were Tailoring and Personalization (Primary task supports), Social Role, Reminders and Rewards (Dialogue support), and Authority, Expertise and Trustworthiness (System credibility supports). Program use Outcomes most commonly reported either the total proportion or average proportion of program sessions, homework or activities completed by users. More than half of the Outcomes indicated ‘High’ or ‘Moderate’ program use.

When finalizing our proposed configurations, we considered both what program Contexts and Mechanisms were combined (using Tables 2 and 3) and in what way and for what purpose they may have been combined (using excerpts from individual documents; see Table 4) to explain how moderate-to-high program use Outcomes were generated.

Table 3.2. An overview of the delivery Context and PSD features that may explain program use Outcomes across iCBT treatment programs.

Document	Context	Mechanism	Outcomes	
	Target user and adjunct support	PSD feature	Post-treatment findings	Summary[a]
Program 1: BRAVE-Online for children and adolescents with anxiety disorders				
(Spence et al., 2006)	Children Therapist: in-person, online, phone Parent: in-person, modules	<u>Primary task support</u>: Tailoring Personalization <u>Dialogue support</u>: Social Role Reminders <u>System credibility support</u>: Authority Expertise Trustworthiness	91% of homework completed	High use
(Spence et al., 2008)	Children Therapist: online, phone Parent: modules		95% of session activities completed	High use
(March, 2008); (March, Spence, & Donovan, 2009)			Average of 7.5/10 sessions completed	High use
			33.3% of users completed all 10 sessions	Low use
(Stasiak, Merry, Frampton, & Moor, 2016)			Average of 4.88/10 sessions completed	Low use
(Spence et al., 2008)	Adolescents Therapist: online, phone Parent: modules		85% of session activities completed	High use
(Spence et al., 2011)			Average of 7.5/10 sessions completed	High use
			39% of users completed all 10 sessions	Low use
(Spence et al., 2011)	Children, Adolescents Therapist: online, phone Parent: modules		Average of 7.9/10 sessions completed	High use
			42.6% of users completed all 10 sessions	Low use
			73.5% of session tasks completed	Moderate use
			Treatment expectancy predicted compliance	
(Anderson et al., 2012)			Average of 85% session tasks completed	High use

Document	Context	Mechanism	Outcomes	
	Target user and adjunct support	PSD feature	Post-treatment findings	Summary[a]
			Average of 8.9/10 sessions completed	High use
(Conaughton, Donovan, & March, 2017)[b]			Average of 6.7 /10 sessions completed	Moderate use
			19% of users completed all 10 sessions	Very low use
(Spence et al., 2017)[c]			Average of 4.8/10 sessions completed by children	Low use
			Average of 4.0/10 sessions completed by adolescents	Low use
			There was no significant difference in the average number of sessions completed between the CBT-generic and CBT-social anxiety groups	
Program 2: iCBT for children and adolescents with dental anxiety				
(Shahnavaz, 2016)	Children, Adolescents Therapist: online Parent: in-person Dental Professional: in-person	<u>Primary task support</u>: Personalization <u>Dialogue support</u>: Social Role <u>System credibility support</u>: Authority Expertise Trustworthiness	Average of 9.2/12 sessions completed	High use
Program 3: Internet-delivered CBT for children with anxiety disorders				
(Vigerland, Ljótsson, et al., 2016); (Vigerland, 2015)	Children Therapist: online, phone Parent: modules	<u>Primary task support</u>: Tailoring Personalization	Average of 9.7/11 sessions completed	High use

Document	Context	Mechanism	Outcomes	
	Target user and adjunct support	PSD feature	Post-treatment findings	Summary[a]
(Vigerland et al., 2017); (Vigerland, 2015)		Dialogue support: Social Role Reminders System credibility support: Authority Expertise Trustworthiness	83% of users completed ≥ 9 of 11 sessions	High use
(Jolstedt et al., 2017)			Average of 6.0/12 sessions completed[d]	Moderate use
			53% of users reached at least module 4 (first exposure exercise)	Moderate use
Program 4: Internet-delivered CBT for children with specific phobia				
(Vigerland et al., 2013)	Children Therapist: online, phone Parent: modules	Primary task support: Personalization Dialogue support: Social Role Reminders System credibility support: Authority Expertise Trustworthiness	80% of users completed ≥ 9 of 11 sessions	High use
Program 5: SmartCAT App for children with anxiety disorders				
(Pramana et al., 2014)	Children Therapist: in-person, online Parent: in-person	Primary task support: Tailoring Personalization Dialogue support: Social Role Reminders Rewards System credibility support: Authority Expertise	Average of 82.8% of practice entries completed	High use

Document	Context	Mechanism	Outcomes	
	Target user and adjunct support	PSD feature	Post-treatment findings	Summary[a]
		Trustworthiness		

[a]Calculated by dividing the reported value by 100 and/or converting it to a percentage. High' (≥75%), 'Moderate' (50-74%), 'Low' (25-49%), or 'Very Low' (≤24%) program use.
[b]All participants were diagnosed with a High Functioning Autism Spectrum Disorder and anxiety disorder.
[c]This study compared participants who were randomized to one of two iCBT conditions: CBT-generic (CBT relevant to multiple types of anxiety, ie, social, separation and generalized anxiety) or CBT-social anxiety (CBT specific to social anxiety).
[d]Data available for 15 out of 17 participants.

Table 3.3. An overview of the delivery Context and PSD features that may explain program use Outcomes across iCBT indicated prevention and universal prevention programs.

Document	Context	Mechanism	Outcomes	
	Target user and adjunct support	PSD feature	Post-treatment findings	Summary[a]
Indicated Prevention Programs				
Program 6: Internet cognitive-behavioral skills-based program				
(Keller, 2009)	Children Therapist: phone Parent: modules	Primary task support: Tailoring Dialogue support: Rewards System credibility support: Trustworthiness	Average of 82.6% sessions completed	High use
			Users who immediately accessed the program completed more sections (average= 17.35) than those who had delayed access (average= 8.0)	
			Immediate access users spent more time in the program (average= 183.3 minutes) than those who had delayed access (average= 77.6 minutes)	
			Use time was positively correlated with number of sections completed	
Program 7: REACH for Success App				
(Patwardhan, 2016)	Children	Primary task support: Tailoring	93.2% of users completed relaxation practice	High use

Document	Context	Mechanism	Outcomes	
	Target user and adjunct support	PSD feature	Post-treatment findings	Summary[a]
	Therapist: in-person	Personalization Dialogue support: Social Role Reminders Rewards	91.7% of users completed hypothetical cognitive self-control practice	High use
			15.2% of users completed applied cognitive self-control practice	Very low use
			45.5% of users completed self-monitoring	Low use
			The proportion of users who attempted an activity was higher than those who completed	
(Patwardhan, 2016)			Users completed more activities prior to an evaluation session	
			App use was highest in week 1 and decreased over 6 weeks	
			100% of users completed relaxation practice	High use
			100% of users completed hypothetical cognitive self-control practice	High use
			60.0% of users completed self-monitoring	Moderate use
			0% of users completed exposure practice	Very low use
Program 8: Individually tailored iCBT for adolescents				
(Silfvernagel et al., 2015); (Silfvernagel, 2017)	Adolescents Therapist: in-person, online, phone	Primary task support: Tailoring Personalization Dialogue support: Social Role Reminders	Average of 6.5/9 sessions completed	Moderate use

Document	Context	Mechanism	Outcomes	
	Target user and adjunct support	PSD feature	Post-treatment findings	Summary[a]
		System credibility support: Authority Expertise Trustworthiness		
Universal Prevention Programs				
Program 9: The e-couch Anxiety and Worry Program				
(Calear, Christensen, Brewer, Mackinnon, & Griffiths, 2016)	Adolescents Teacher: in-person	Dialogue support: Social Role	45% of users completed all sessions	Low use
(Calear, Batterham, Poyser, et al., 2016)	Adolescents Teacher: in-person		50% of users completed all sessions	Moderate use
	Adolescents Teacher: in-person Mental health provider: in-person		36% of users completed all sessions	Low use
Program 10: MoodGYM				
(Calear et al., 2009)	Adolescents Teacher: in-person	Dialogue support: Social Role	Average of 3.2/5 sessions completed	Moderate use
			32.7% of users completed all sessions	Low use
(Neil et al., 2009)	Adolescents Teacher: in-person		Average of 9.4/28 exercises completed	Low use
			>25% of users completed all sessions	Low use
	Adolescents		Average of 3.1/28 activities completed	Very low use
			<5% of users completed all sessions	Very low use
(Calear, Christensen	Adolescents		<1% of users completed all activities	Very low use

Document	Context	Mechanism	Outcomes	
	Target user and adjunct support	PSD feature	Post-treatment findings	Summary[a]
, Mackinnon, et al., 2013)	Teacher: in-person			

[a]Calculated by dividing the reported value by 100 and/or converting it to a percentage. High' (≥75%), 'Moderate' (50-74%), 'Low' (25-49%), or 'Very Low' (≤24%) program use.

3.3.3 Proposed iCBT Contexts and Mechanisms for Moderate to High Program Use

Key Contexts and PSD Mechanisms that may lead to moderate-to-high iCBT program use Outcomes are described in Table 4 alongside examples from contributing programs.

3.3.3.1 Context-Mechanism-Outcome Configuration 1: Tailoring and Personalization

Evidence from 8 iCBT programs suggested that indicated prevention and treatment programs that provided adjunct support along with Tailoring and Personalization (Primary task support) resulted in greater program use. Studies supporting this configuration had a mean MMAT score of 90.2%.

Tailoring and Personalization were used to provide users with more information, to increase the 'individualized feel' of the program and portray that the program 'knew' and could meet his/her needs. Programs most commonly tailored content (ie, therapeutic elements, examples) based on the user's age or mental health condition (eg, specific phobic, social anxiety). User information was often collected by the adjunct support person during study enrolment (ie, part of eligibility screening). Personalization was a feature that could be initiated through program automation (ie, user's name appeared on the home screen; his/her pronouns) or via program communications (ie, individualized weekly emails, secure messages). The adjunct support person acted as an extension of the Tailored or Personalized program experience through their contact with users within (eg, by providing personalized feedback on online homework

(Spence et al., 2008; Vigerland et al., 2013; Vigerland, Ljótsson, et al., 2016) or outside of the iCBT program (eg, by tailoring in-person session objectives [Silfvernagel *et al.*, 2015]). Programs with a combination of Tailoring and Personalization reported some of the highest program use Outcomes.

3.3.3.2 Context-Mechanism-Outcome Configuration 2: Reminders

Evidence from 6 iCBT programs suggested that indicated prevention and treatment programs that provided adjunct therapist support along with Reminders also resulted in greater program use. Studies supporting this configuration had a mean MMAT score of 92.1%.

The programs contributing to this Context-Mechanism-Outcome configuration involved multiple sessions (number of sessions ranged from 6-11 or daily-weekly app use), therefore, users were required to log into the program over numerous instances. Reminders were used to encourage the user to take program action, either by promoting skills practice (Pramana et al., 2014) or by "prompt[ing] participants who are late in completing a session" (p. 479; March, Spence and Donovan, 2009). Programs provided generic and automatized Reminders through email or the online platform, or were embedded in the regular, electronic, personalized communications (eg, feedback, progress check-ins) sent by the adjunct therapist to the child or adolescent. If users remained absent from the program beyond the recommended treatment schedule (eg, longer than one week) despite receiving electronic Reminders, often the adjunct therapist provided additional in-person or telephone follow-up, encouraging users to access the next available module.

3.3.3.3 Context-Mechanism-Outcome Configuration 3: Rewards

Evidence from 4 iCBT programs suggested that programs and smartphone applications that provided adjunct support along with Rewards resulted in greater program use. Studies supporting this configuration had a mean MMAT score of 85.0%.

Three iCBT programs regularly incorporated Rewards into sessions to encourage ongoing program use and promote the completion of essential treatment exercises (Keller, 2009; Patwardhan, 2016; Pramana et al., 2014). The fourth program opted for a final Reward and presented users with a virtual diploma at the end of treatment (Shahnavaz, 2016). Rewards were also used as a proxy to track program progress including completion of exposure activities (Keller, 2009; Patwardhan, 2016; Pramana et al., 2014). Unlike computer-based programs, the open and flexible design approach to mobile apps gave users with the option to select what treatment content and tasks they wanted to access and when. 'Progressive reward incentives' were used to persuade users to complete more of the program and its critical components. In the REACH app, a cartoon character provided regular guidance and feedback to users, and entertained them with animations following task completion (Reward) (Patwardhan, 2016). In the SmartCAT app, a point system tied to external prizes was used as a Reward feature managed by the adjunct therapist (Pramana et al., 2014). In-person sessions with the adjunct therapist and/or parent also provided positive reinforcement of program use (ie, Praise, Rewards) and were used to instruct users on how to incorporate Rewards into their anxiety management activities outside of the program support (Keller, 2009; Shahnavaz, 2016).

3.3.3.4 Context-Mechanism-Outcome Configuration 4: Therapist, Social role, Authority, Expertise and Trustworthiness

Evidence from 6 iCBT programs suggested that indicated prevention and treatment programs with adjunct online therapist support that also provided a Social Role component, and conveyed Authority, Expertise, Trustworthiness, resulted in greater program use. Studies supporting this configuration had a mean MMAT score of 91.3%.

The Social Role component of iCBT programs was often fulfilled by an online therapist (or 'coach'), who received specialized training with the program but may not have been a licensed psychologist. Online therapists engaged in regular, online communication (via the program platform, email) with the user and served two roles by: (1) facilitating program delivery by providing technical support and answering users' questions, and (2) promoting program completion by providing reminders and encouragement, reinforcing program concepts, and ensuring accurate comprehension and application of CBT skills. Together the Social Role feature and online therapist exchanges complemented other PSD features such as Reminders, Praise, and Suggestion. Therapists had secure access to users' written responses or logged data so that they could send informed communications to users, demonstrating therapists' credibility and competence with both the therapeutic process and individual responsiveness (Authority, Expertise and Trustworthiness). Three studies measured child-reported therapeutic alliance with their online therapist and found it to be strong and program use to be high (Anderson et al., 2012; Spence et al., 2008). One of these studies correlated therapeutic alliance with program use and found a significant, positive relationship (Anderson et al., 2012).

3.3.3.5 Context-Mechanism-Outcome Configuration 5: Therapist + Parent, Social role, Authority, Expertise and Trustworthiness

Evidence from 5 treatment programs suggested that iCBT programs with adjunct therapist and parent support that also included a Social Role component and conveyed Authority, Expertise, Trustworthiness had greater program use. Studies supporting this configuration had a mean MMAT score of 90.8%.

Treatment-based iCBT programs were designed to be child-parent combined or parent-supported child-based interventions. Combined interventions required parents to complete parent-specific modules (eg, psychoeducation, relaxation training, problem solving, modeling adaptive behaviours) either prior to or alongside their child independently completing their own child-directed modules. In parent-supported interventions parents may have also been responsible for explaining program instructions and assisting their children with their modules (Spence et al., 2008; Vigerland, 2015; Vigerland et al., 2013), 'coaching' or supporting their child with in-vivo exposure or practice activities (Pramana et al., 2014; Shahnavaz, 2016; Vigerland et al., 2013), and overseeing their child's treatment schedule (Vigerland, 2015). The adjunct therapist support, and associated Social Role and credibility supports of programs, provided to children were also extended to parents. Parents had the opportunity to ask clarifying questions, receive expert advice and troubleshoot difficulties with their child's iCBT progress with the online therapist. Studies found that both parent and child ratings of therapeutic alliance and program use were high (Anderson et al., 2012; Spence et al., 2008). One study correlated therapeutic alliance and program use and found significant, positive relationships for both parents and children (Anderson et al., 2012). Anderson et al. (2012) hypothesized that therapist emails may have contributed to fostering a strong therapeutic alliance.

Table 3.4. Configuration summaries of the key Contexts and PSD Mechanisms that may lead to Moderate-to-High program use Outcomes.

Context	Mechanism		Program number
	PSD feature(s) and proposed purpose	Example	
	Configuration 1		
Indicated prevention & treatment programs with adjunct support	Tailoring +/or Personalization to increase relevance of program content	Through email the therapist provided "written feedback on worksheets" and was available to "answer questions and clarify treatment content, increase motivation and to help solve problems" (p. 50; Vigerland, Lenhard, et al., 2016). A participant's name was populated in sessions and feedback messages (Spence et al., 2008).	1, 2, 3, 4, 5, 6, 7, 8
	Configuration 2		
	Reminders to increase awareness of program availability and progress	"Participants receive automated, computer-generated, standardized, weekly e-mails both before each session (as a reminder to complete their sessions) and after each session (to congratulate them on finishing their session)" (p. 479; March, Spence and Donovan, 2009). "Each skills coach entry ends with a customized motivational message from the therapist (entered weekly via the portal) that includes encouragement as well as a reminder to complete any assigned home-based exposure or skills practice" (p. 421; Pramana et al., 2014).	1, 3, 4, 5, 7, 8
	Configuration 3		
	Rewards to recognize and encourage achievement	Following task completion, the user received a reward in the form of Bob's abilities/tricks, with more complicated tricks being unlocked as users completed more of the treatment protocol (Patwardhan, 2016). Program progress was presented and tracked with an online sticker chart. A cartoon figure would jump to the next rung of the ladder indicating successful completion of an exposure hierarchy activity (Keller, 2009).	2, 5, 6, 7
	Configuration 4		

Context	Mechanism		Program number
	PSD feature(s) and proposed purpose	Example	
Indicated prevention & treatment programs with adjunct therapist support	Social Role to increase program interaction Authority + Expertise + Trustworthiness to improve perceived value of information or support	Participants received "comments and feedback from their therapist on all exercises, and the technical platform also allowed participants to comment on worksheets" (p. 306; Vigerland et al., 2013). The therapist portal and secure messaging features in the app allowed the participants and therapist to securely exchange information, such as messages, documents or audio/video files related to treatment (Pramana et al., 2014).	1, 2, 3, 4, 5, 8
	Configuration 5		
Treatment programs with adjunct therapist support plus parent support	Social Role to increase program interaction Authority + Expertise + Trustworthiness to improve perceived sense of reliance and cooperation toward program progress	Parents were provided with their own sessions during treatment. "In this way, the parent was empowered to help their child acquire and use the skills presented in the program, and to handle situations in which their child became anxious" (p. 109; March, 2008). Check-in telephone calls from the therapist consisted of 4 elements: (1) progress updates, (2) symptom assessments, (3) encouragement to use the program, and (4) troubleshooting (Keller, 2009).	1, 2, 3, 4, 5

3.4 Discussion

3.4.1 Principal Results

The role of technological, persuasive components in iCBT programs is an understudied aspect of program design and evaluation. The extent of iCBT program use may be a fundamental indication of its 'persuasiveness' and its potential to assist the user with their goals of the program (Baumel & Yom-Tov, 2018; Kelders et al., 2012; Lentferink et al., 2017; Wildeboer, Kelders, & van Gemert-Pijnen, 2016; Wozney et al., 2017). This realist synthesis identified 5 possible relationships as to how the use of specific PSD features (technological Mechanisms)

supported by some key user and delivery features (Context) may generate moderate-to-high program use (Outcomes) in iCBT for children and adolescents with anxiety.

The 5 Context-Mechanism-Outcome configurations provide support for multiple persuasive strategies to improve iCBT program use: Tailoring and Personalization as Primary task supports; Rewards, Reminders and Social Role features in programs serving as Dialogue supports; and Trustworthiness, Expertise and Authority features serving as System credibility supports for a program. Traditionally, PSD features that stimulate human-computer communication, such as Dialogue supports, have been the most widely used and studied features for improving program use (eg, Calear & Christensen, 2010; Lehto & Oinas-Kukkonen, 2011; Kelders et al., 2012; Langrial & Al Araimi, 2017; Wozney et al., 2017). However, this synthesis demonstrated that having credibility (System credibility supports) and supporting users in completing their target behaviour (Primary task supports) may also promote moderate-to-high program use. We hypothesize that utilizing multiple PSD features, both within and across the different support categories, may produce additive or synergistic effects on program use; however, there was insufficient evidence available for our analysis to explain the impact of PSD feature combinations. This is because the authors of the original studies included in our review typically discussed or formally tested the relationship of only one or two PSD features and program use at a time. Therefore, our configurations present the fewest possible PSD features that could be linked to higher program use (ie, we uncoupled features as much as possible)—an approach that may make testing of their effects more efficient in future studies.

Moreover, not all PSD features may have equal influence on program use. Depending on the program, some PSD features may be *necessary* for program use (part of the basic requirements or foundational design framework of iCBT) or *complementary* to program use

(have an impact by enhancing the design framework of iCBT), although both types of features may work together to influence program use. In this realist synthesis, all 10 iCBT programs described a purposeful design that incorporated Reduction and Tunneling (Primary task supports) and Similarity and Liking (Dialogue supports) to create a logical, incremental, relevant and aesthetically-pleasing experience for users—these may be the *necessary* PSD features for iCBT for children and adolescents with anxiety. The PSD features described in our configurations are hypothesized to be *complementary*—building on the persuasiveness of necessary PSD features to further improve iCBT program use.

A meta-analysis of PSD features used in Internet-based interventions for mental health demonstrated that determining the amount and type of persuasive principles to include may be a delicate balance as some principles seem to work together, whereas when other principles occur together, they may have an unapparent or diminishing effect (Wildeboer et al., 2016). As was found for this synthesis, it is not necessarily the number of PSD features used in Internet-based interventions, but it is their proposed function or implementation, that is particularly critical for optimizing program use outcomes (Wildeboer et al., 2016). For example, when comparing two indicated prevention programs, we observed that the Internet cognitive-behavioral skills-based program (Keller, 2009) had fewer PSD features than the Individually tailored iCBT program (Silfvernagel et al., 2015), although the former had greater program use. At this time, our understanding of how to best design and deliver PSD features in iCBT for child and adolescent anxiety, such as personalized Reminders (Langrial & Al Araimi, 2017), is limited. Therefore, further research on the theory, function, quality and effectiveness of individual PSD features is needed to deliberately use and combine them for idealized treatment outcomes. Moreover, involving target users in the (co)design and testing of treatments is recommended to improve the

acceptability, feasibility and effectiveness of iCBT with children and adolescents (eg, Anderson, 2008; Orlowski et al., 2015; Hill, Creswell, et al., 2018). These participatory research efforts may provide important guidance on the usefulness and functionality of select (PSD) features of iCBT programs in the 'real world' and from the user's perspective (Rooksby, Rouncefield, & Sommerville, 2009), therefore facilitating greater program use (Howe, Batchelor, Coates, & Cashman, 2014).

In this synthesis, three important potential relationships were identified: (1) adjunct support seemed to improve program use even when input or support was minimal (eg, in-person, classroom-based program administration with no treatment advice given) and/or was provided by a non-expert (eg, teacher) (Calear, Batterham, Poyser, et al., 2016; Neil et al., 2009); (2) users of treatment programs demonstrated higher program use than users of universal prevention programs; and (3) a trend for increased program use among programs for children was identified. Within these relationships, multiple contextual aspects or user characteristics may have also had an additive or synergistic effect on program use. For example, the level of expertise the adjunct support person had (eg, teacher versus therapist) and the degree of their guidance or therapeutic involvement (eg, in-person program administration versus personalized feedback emails) increased from prevention-based to treatment programs. In the literature, little is known about how much, when and what type of support is necessary for enhancing program use and efficacy (Andersson, Carlbring, Berger, Almlöv, & Cuijpers, 2009; Schueller, Tomasino, & Mohr, 2017). Although some evidence suggests that lay person support is as effective as clinician support (Titov et al., 2010), this synthesis suggests that the person providing support as well as the intensity of their support activities may have a noteworthy effect on program use. The nature of the role adjunct support plays in iCBT program use is also unclear. It has been suggested that

adjunct support leverages the advantages of therapeutic alliance (Howgego, Yellowlees, Owen, Meldrum, & Dark, 2003; Martin, Garske, & Katherine Davis, 2000), which might include principles of persuasion (eg, users feel the need to respond to social cues; see Fogg, 2002), establishing process expectations and social accountability (Mohr, Cuijpers, & Lehman, 2011) (for further suggestions see Santarossa et al., 2018), and developing a sense of legitimacy or credibility (Mohr et al., 2011). Programs that had both therapist and parent involvement may have: (1) reinforced child's understanding of and confidence in treatment content, and (2) increased the child's interaction with the program with a perceived sense of cooperation (shared goals) and accountability toward treatment progress. In this realist synthesis, adjunct support may have been used to complement or replace the use of some PSD features, particularly Dialogue supports, in iCBT. For example, in-person therapist sessions or telephone calls provided opportunities for Reminders, Personalized feedback, or Praise to be conveyed to users (Silfvernagel et al., 2015; Spence et al., 2006; Vigerland, 2015; Vigerland et al., 2013). Consideration of how and when to provide adjunct support is critical when preparing for the implementation and integration of iCBT within routine practice, such as allotting for therapist time, changes in clinical workflow, conducting economic analyses, to improve anxiety for children and adolescents.

3.4.2 Future Directions

This realist synthesis provides support for incorporating some of the well-studied and highly used PSD features into iCBT (ie, Reminders; Fry & Neff, 2009; O'Leary et al., 2016; Langrial & Al Araimi, 2017), but also draws attention to underutilized features that can be incorporated in designs of new treatments. For example, Rewards were occasionally used by iCBT programs included in this synthesis (4 out of 10 programs), but are a technique for

increasing program use in other Internet-based interventions, like those targeting physical activity or dietary behaviours (Lewis, Swartz, & Lyons, 2016). Inconsistent employment of Rewards may be a shortcoming that is being addressed by recent efforts into the 'gamification' of technology-based CBT for pediatric mental health (see for example SPARX; Merry et al., 2012), where incorporating game-design elements, such as Praise and Rewards, are regularly used to enhance program use and engagement (Brown et al., 2016).

Although this synthesis and other recent reviews have been helpful for identifying PSD features of interest for improving program use of Internet-based interventions (eg, Kelders et al., 2012; Wildeboer, Kelders & van Gemert-Pijnen, 2016; Wozney et al., 2017), the next step is to formally isolate and evaluate the effectiveness of these PSD Mechanisms in producing optimal program use. This synthesis suggests 8 features that may be priority for further examination. To evaluate the best set (individual or combination) of program features to use under different conditions (eg, delivery setting, start or end of treatment), modelling, factorial designs or the multiphase optimization strategy (MOST) are potential approaches to evaluation (Collins et al., 2011; Collins, Dziak, Kugler, & Trail, 2014; Collins, Murphy, & Strecher, 2007) (for other suggestions see Baker, Gustafson and Shah, 2014). Studies with multiple, active treatment arms would also allow the examination of the comparative effects of select program features (see for example Alfonsson, Olsson & Hursti, 2015) and/or in different delivery Contexts (ie, type of adjunct support). From this synthesis, only 3 studies of 3 different interventions conducted these comparisons. These studies provided important insights into the impact of delivery medium (Spence et al., 2006), type of adjunct support (Calear, Batterham, Poyser, et al., 2016), and delivery location (Neil et al., 2009) on iCBT program use. Qualitative studies or self-report data would also provide meaningful information on the factors affecting program use from child and

adolescent or healthcare provider standpoints. Another important line of inquiry relates to defining and measuring program use to ensure its validity and reliability for future studies. Designing studies that incorporate in-vivo, objective measurements or automatic data capture of program use (Moller et al., 2017; Rocha, Camacho, Ruwaard, & Riper, 2018) could improve our awareness of program use predictors beyond user demographics (ie, age), for example, to actual usage behaviours (ie, number of webpages viewed). This method would allow for iCBT program use to not only be measured at end of the intervention, but also throughout the program access period to assess usage patterns over time (Kelders et al., 2012), when certain design or delivery features may be more or less 'activated'.

3.4.3 Strengths and Challenges of Realist Synthesis

This is the first study to examine PSD features as they relate to program use in iCBT for children and adolescents with anxiety. Strengths of this synthesis are the inclusion of diverse and high quality evidence (ie, MMAT scores > 75%; Pluye et al., 2009) from both the published and grey literature. Approaching our research questions using a single theoretical framework (ie, the PSD model) allowed for systematic and incremental accumulation of knowledge about how iCBT may work from a trackable, technological perspective.

The lack of operationalization of how PSD features, and aspects of Context and program use Outcomes were defined, described and measured by authors, affected our data extraction and coding strategies. As adherence to recent recommendations (Hill et al., 2018) and reporting guidelines, such as CONSORT-EHEALTH (Eysenbach, 2013), become mandatory for publication, the opportunity to identify the active ingredients of iCBT will improve. Clarifying PSD features with original authors was an attempt to mitigate the potential bias that lies in coding technological program features and interpreting the articles using the PSD model (Lehto

& Oinas-Kukkonen, 2011). However, few details about the time or the 'quality' of communication by the adjunct support person(s) were available, limiting our understanding of the important role this contextual feature played in program use. For reasons of inclusivity, we described the heterogeneous outcomes using the umbrella term 'program use'. Adoption of a recent standardized definition and calculation of "adherence" (Sieverink, Kelders, & van Gemert-Pijnen, 2017) can clarify what is meant by specific program use terms and allow for comparisons of outcomes across programs. iCBT programs' widespread implementation and ability to meet the health goals of users will involve an understanding of the expectations and actuality of program use in the 'real world' (ie, using true effectiveness studies or formative program evaluation), setting benchmarks for an 'effective dose' in different delivery settings. Finally, like others (Halko & Kientz, 2010; Karanam et al., 2014; Xu et al., 2012), we recognized the outcomes of persuasive systems depended on multiple factors, many of which were not examined in this synthesis. However, it was rare to have information on treatment or technology preferences of users (eg, early completers; Christensen & Mackinnon, 2006; Christensen, Griffiths & Farrer, 2009), their psychological characteristics or cognitions (eg, motivation, personality, expectations, treatment perceptions (Melville, Casey, & Kavanagh, 2010) or personal circumstances (eg, program access; Waller & Gilbody, 2009)—factors that are also considered critical to program use and could be used to construct and validate more intricate Context-Mechanism-Outcome configurations.

3.5 Conclusions

The Context-Mechanism-Outcome configurations identified by this realist synthesis provide an initial understanding of how, why and for whom iCBT programs for children and adolescents with anxiety work from a persuasive systems' perspective. Appreciating that the

effectiveness of iCBT programs may hinge on whether and to what extent programs are used, this research is an important step towards successfully implementing and integrating iCBT into routine clinical care. Recognizing that multiple PSD features are incorporated in iCBT program designs, and that individual features may affect each other differently, further knowledge and testing of the purpose and function of these features will help determine the number and combination to use in certain delivery Contexts (eg, adjunct support; level of prevention for target users). As PSD features are modifiable, iCBT program designers and developers can look to create more persuasive programs that promote greater use and improved treatment outcomes.

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Conflicts of Interest

None declared.

Abbreviations

AACAP: American Academy of Child and Adolescent Psychiatry

CBT: cognitive behavioural therapy

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, fifth edition

iCBT: Internet-based cognitive behavioural therapy

MMAT: mixed method appraisal tool

MOST: multiphase optimization strategy

N/A: not applicable

PSD: persuasive system design

RAMESES II: Realist And Meta-narrative Evidence Synthesis: Evolving Standards II

Appendix 3.1. Candidate Context-Mechanism-Outcome configurations.

Context	PSD Mechanism	Program use Outcome	Examples of literature used to develop the configuration
iCBT programs with adjunct therapist, parent and/or professional support	Primary task support features that simplify tasks or streamline the program content for users; ie, Reduction, Tunneling	High	(Fogg, 2002; Silk 2014)
iCBT programs with adjunct therapist, parent and/or professional support	Primary task support features that adapt program content to the users' needs or preferences; ie, Tailoring, Personalization	High	(Parmanto et al., 2013; Keller 2009)
iCBT programs with adjunct therapist, parent and/or professional support	Dialogue support features that provide program progress, feedback or cues to users; ie, Reminders, Suggestions, Social role	High	(O'Leary et al., 2016; Keller & Craske, 2009)
iCBT programs with adjunct therapist, parent and/or professional support	Dialogue support features that provide incentives or positive reinforcement to users; ie, Praise, Rewards	High	(Christensen et al., 2009; Lentferink et al., 2017)
iCBT programs with adjunct therapist, parent and/or professional support	Social support features that motivate users by leveraging social influence; ie, Social learning	High	(Wildeboer et al., 2016; Kelders et al., 2012)

PSD: persuasive systems design

Appendix 3.2. Document electronic search strategy.

1. Cellular Phone/
2. Computers/
3. Electronic Mail/
4. Internet/
5. Text Messaging/
6. Therapy, Computer-Assisted/
7. (android* or apps or cell* phone* or cellphone* or computer* or digital* or e health* or ehealth* or e mail* or email* or electronic mail* or internet* or iPad* or iPhone* or iPod* or m health* or mhealth* or mobile* or online* or personal digital assistant* or short messag* or smart phone* or smartphone* or technolog* or text messag* or virtual* or web*).tw.
8. or/1-7 [Combined MeSH and keywords for internet based technologies]
9. Behavior Therapy/
10. exp Cognitive Therapy/
11. Disease Management/
12. exp Directive Counseling/
13. Persuasive Communication/
14. Problem Solving/
15. Psychotherapy/
16. Self Care/
17. acceptance adj commitment therap*.tw.
18. (behavio* adj (activation or condition* or modif* or therap*)).tw.
19. CBT.tw.
20. cognitive therap*.tw.
21. directive counsel*.tw.
22. interpersonal therap*.tw.
23. mental health program*.tw.
24. mindfulness.tw.
25. motivational interview*.tw.
26. problem solving*.tw.
27. psychotherap*.tw.
28. (selfcar* or self car* or selfhelp* or self help* or selfmanage* or self manage* or selfmonitor* or self monitor*).tw.
29. telemental health*.tw.
30. or/9-29 [Combined MeSH and keywords for CBT]
31. Anxiety/
32. Anxiety Disorders/
33. Depression/
34. Depressive Disorder/
35. Mental Disorders/
36. Mood Disorders/
37. (anxi* or behavio?r* disorder* or behavio?r* problem* or depress* or mental disorder* or mental health* or psychiatric illness* or psychiatric disease* or psychiatric disorder*).tw.
38. or/31-37 [Combined MeSH and keywords for anxiety]
39. and/8,30,38 [Combined results for internet based technologies, CBT and anxiety searches]

Appendix 3.3. The persuasive systems design (PSD) model.

PSD feature	Description	iCBT program example
Primary task supports		
Reduction	Reduces complex behaviour into simple tasks	Development and use of graded exposure activities over the course of the program
Tunneling	Guides a user through a process or experience	Allows users to access program sessions in a specific, predetermined sequence
Tailoring	Tailors the experience to the potential needs, interests, personality or use context	Information entered in at program start (eg, primary anxiety concern) determines program content stream
Personalization	Personalizes content	Displays user's name in a welcome message at the start of every program session
Self-monitoring	Keeps track of the user's performance or status towards goal achievement	Graphs user's self-reported symptom changes over the course of the program
Simulation	Provides simulations to enable the user to observe link between cause and effect	Interactive diagram of the relationship between anxiety symptoms and anxious behaviour
Rehearsal	Provides a way for the user to rehearse a skill or task	Post-session online homework activities
Dialogue supports		
Praise	Offers praise as a form of feedback	Congratulatory pop-up message appears after session completion
Rewards	Rewards target behaviour	User collects points that can be applied to 'reward bank' items following program achievements
Reminders	Reminds the user of their target behaviour	Weekly email prompts user to login and access next available session
Suggestion	Offers fitting suggestions	Information for local mental health supports is provided if user reports a deterioration in mood
Similarity	Reminds the user of themselves in some meaningful way	Age appropriate phrases, metaphors and imagery are used
Liking	Is visually attractive for the user	Multimedia features are incorporated into the program
Social role	Adopts a social role	An internal messaging system for user-therapist communication

System credibility supports		
Trustworthiness	Provides information that is truthful, fair and unbiased	Program provides links to reliable resources and references of evidence-based treatment content
Expertise	Provides information showing knowledge, experience, and competence	Online therapist establishes rapport with user and provides specialized feedback
Surface credibility	Has a competent look and feel	Program is ad-free and appealing with a well-organized layout
Real-world feel	Provides information of the actual people behind its content and services	A Contact page with a description of research and/or clinical team
Authority	Refers to people in the role of authority	Introduces therapist with education and credentials
3rd party endorsement	Provides endorsements from other sources	Includes logos from funders and/or other affiliations
Verifiability	Provides means to verify the accuracy of the program via outside sources	Provides scientific references from which program content is based on
Social supports		
Social learning	Can use the system to observe others performing tasks or behaviour	Video demonstration of a teen practicing relaxation strategies
Social comparison	Can use the system to compare their performance to performance of others	Provides results of standardized questionnaires using normed data
Normative influence	Leverages normative influence or peer pressure	Testimonials from teens who report improvements after using the program
Social facilitation	User discerns via the system that others are performing the behaviour along with them	Virtual counter displaying the number of current online users
Cooperation	Leverages drive to cooperate to complete a task or behaviour	Peer forum allows the user to post helpful tips or strategies to share with others
Competition	Leverages drive to compete against others in completing a task or action	User can contest an artificial character for a higher score during an online quiz
Recognition	Offers public recognition for a user or group	User can share their program status with friends, family or other users

PSD: persuasive systems design

Appendix 3.4. The level of contribution and methodological quality of documents for the included internet-based cognitive behavioural therapy programs.

Document	Document type and study design[a]	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
Program 1: BRAVE-Online for children and adolescents					
(Spence et al., 2006)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Spence et al., 2008)	Published study; Quantitative descriptive	High	High	Medium	100%
	Published study; Quantitative descriptive	High	High	Medium	100%
(March, 2008)	Thesis; Quantitative randomized	High	Medium	Medium	100%
	Thesis; Quantitative randomized	High	High	High	100%
(March et al., 2009)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Spence et al., 2011)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Spence, 2011a)	Registered protocol; Quantitative non-randomized	Medium	Low	N/A	N/A
(Spence, 2011b)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Spence, 2011c)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Anderson et al., 2012)	Published study; Quantitative non-randomized	Medium	Medium	High	100%
(Spence et al., 2017)	Published study; Quantitative randomized	High	High	High	50%
(Conaughton et al., 2017)	Published study; Quantitative randomized	High	High	High	75%
(Stasiak, 2012)	Registered protocol; Quantitative randomized	Low	Low	N/A	N/A
(Stasiak et al., 2016)	Published study; Quantitative non-randomized	High	High	High	75%
(Spence, 2017)	Program website; N/A	Low	Low	N/A	N/A

Document	Document type and study design[a]	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
Program 2: iCBT for children and adolescents with dental anxiety					
(Shahnavaz, 2015)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Shahnavaz, 2016)	Thesis; Quantitative non-randomized	Medium	High	High	75%
Program 3: Internet-delivered CBT for children with anxiety disorders					
(Serlachius, 2012)	Registered protocol; Quantitative non-randomized	Low	Low	N/A	N/A
(Serlachius, 2014)	Registered protocol; Quantitative non-randomized	Low	Low	N/A	N/A
(Serlachius, 2015)	Registered protocol; Quantitative randomized	Low	Low	N/A	N/A
(Vigerland et al., 2015)	Thesis; Quantitative randomized	High	Medium	Medium	75%
	Thesis; Quantitative non-randomized	High	Medium	High	100%
(Vigerland, 2016)	Registered protocol; Quantitative non-randomized	Low	None	N/A	N/A
(Vigerland et al., 2016)	Published study; Quantitative randomized	High	Medium	Medium	75%
(Vigerland et al., 2017)	Published study; Quantitative non-randomized	High	High	High	100%
(Jolstedt et al., 2018)	Published study; Quantitative non-randomized	High	High	High	100%
(Stockholm's Child and Adolescent Psychiatry (BUP), 2013)	Program website; N/A	Low	Low	N/A	N/A
Program 4: Internet-delivered CBT for children with specific phobia					
(Vigerland et al., 2013)	Published study; Quantitative non-randomized	High	Medium	Medium	100%
Program 5: SmartCAT App for children with anxiety disorders					
(Silk, 2014)	Registered protocol; Quantitative non-randomized	Low	Low	N/A	N/A

Document	Document type and study design[a]	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
(Pramana et al., 2014)	Published study; Quantitative non-randomized	High	Medium	Medium	100%
(Parmanto et al., 2013)	Program website; N/A	Low	Low	N/A	N/A
Program 6: Internet cognitive-behavioral skills-based program					
(Keller, 2009a)	Thesis; Quantitative randomized	High	High	High	100%
(Keller, 2009b)	Program website; N/A	Low	Low	N/A	N/A
(Keller & Craske, 2009)	Study flyer; N/A	Low	Low	N/A	N/A
Program 7: REACH for Success App					
(Patwardhan, 2016)	Thesis; Quantitative descriptive	High	High	High	75%
	Thesis; Quantitative descriptive	High	High	High	75%
Program 8: Individually tailored iCBT for adolescents					
(Silfvernagel et al., 2015)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Silfvernagel, 2017)	Thesis; Quantitative randomized	High	Medium	Low	100%
Program 9: The e-couch Anxiety and Worry Program					
(Calear, 2010)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Calear, Christensen, Griffiths et al., 2013)	Published protocol; Quantitative randomized	High	High	N/A	N/A
(Calear, Christensen et al. 2016)	Published study; Quantitative randomized	High	High	High	50%
(Calear, Batterham et al., 2016)	Published study; Quantitative randomized	High	High	Medium	50%
(Griffiths, Tayler, & Christensen, n.d.)	Program website; N/A	Low	Low	N/A	N/A
Program 10: MoodGYM					
(Calear et al., 2009)	Published study; Quantitative randomized	High	Medium	Medium	100%

Document	Document type and study design[a]	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
(Neil et al., 2009)	Published study; Quantitative non-randomized	High	Medium	High	100%
(Calear, Christensen, Mackinnon, & Griffiths, 2013)	Published study; Quantitative randomized	Medium	High	High	100%
(Christensen & Griffiths, n.d.)	Program website; N/A	None	None	N/A	N/A

iCBT: internet-based cognitive behavioral therapy
MMAT: Mixed Methods Appraisal Tool
N/A: Not applicable
[a]Study designs according to MMAT classifications

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Chapter 4

Potential reduction of symptoms with the use of persuasive systems design features in internet-based cognitive behavioral therapy programs for children and adolescents with anxiety: a realist synthesis

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Abstract

Background: Internet-based cognitive behavioral therapy (iCBT) for children and adolescents is a *persuasive system* that combines 3 major components to therapy—therapeutic content, technological features, and interactions between the user and program—intended to reduce users' anxiety symptoms. Several reviews report the effectiveness of iCBT; however, iCBT design and delivery components differ widely across programs, which raises important questions about how iCBT effects are produced and can be optimized.

Objective: The objective of this study was to review and synthesize the iCBT literature using a realist approach with a persuasive systems perspective to (1) document the design and delivery components of iCBT and (2) generate hypotheses as to how these components may explain changes in anxiety symptoms after completing iCBT.

Methods: A multi-strategy search identified published and gray literature on iCBT for child and adolescent anxiety up until June 2019. Documents that met our prespecified inclusion criteria were appraised for relevance and methodological rigor. Data extraction was guided by the persuasive systems design (PSD) model. The model describes 28 technological design features, organized into 4 categories, that help users meet their health goals: primary task support, dialogue support, system credibility support, and social support. We generated initial hypotheses for how PSD (mechanisms) and program delivery (context of use) features were linked to symptom changes (outcomes) across iCBT programs using realist and meta-ethnographic techniques. These hypothesized context-mechanism-outcome configurations were refined during analysis using evidence from the literature to improve their explanatory value.

Results: A total of 63 documents detailing 15 iCBT programs were included. A total of 6 iCBT programs were rated *high* for relevance, and most studies were of moderate-to-high

methodological rigor. A total of 11 context-mechanism-outcome configurations (final hypotheses) were generated. Configurations primarily comprised PSD features from the primary task and dialogue support categories. Several key PSD features (eg, self-monitoring, simulation, social role, similarity, social learning, and rehearsal) were consistently reported in programs shown to reduce anxiety; many features were employed simultaneously, suggesting synergy when grouped. We also hypothesized the function of PSD features in generating iCBT impacts. Adjunct support was identified as an important aspect of context that may have complemented certain PSD features in reducing users' anxiety.

Conclusions: This synthesis generated context-mechanism-outcome configurations (hypotheses) about the potential function, combination, and impact of iCBT program components thought to support desired program effects. We suggest that, when delivered with adjunct support, PSD features may contribute to reduced anxiety for child and adolescent users. Formal testing of the 11 configurations is required to confirm their impact on anxiety-based outcomes. From this we encourage a systematic and deliberate approach to iCBT design and evaluation to increase the pool of evidence-based interventions available to prevent and treat children and adolescents with anxiety.

4.1 Introduction

Anxiety is one of the most common and early-emerging mental health concerns for children and adolescents (Beesdo, Knappe, & Pine, 2009), 20% of whom will experience an anxiety disorder in their lifetime (Beesdo et al., 2009). Often presenting with a chronic and recurring course that extends into adulthood (Costello, Egger, & Angold, 2004), anxiety disorders are associated with considerable developmental, psychosocial, and psychopathological impairments (Beesdo et al., 2009; Creswell, Waite, & Cooper, 2014). The effectiveness of cognitive behavioural therapy (CBT), an adaptive, skills-based psychotherapeutic approach, has been documented in numerous randomized control trials, and is recommended as first line treatment for children and adolescents with mild to moderate anxiety symptom severity (Arnberg, Linton, Hultcrantz, Heintz, & Jonsson, 2014; Compton et al., 2004; Connolly & Bernstein, 2007; Seligman & Ollendick, 2011). Internet-based CBT (iCBT), aims to increase access and availability of this beneficial first line treatment (Grist, Croker, Denne, Stallard, & Stallard, 2018; Orlowski et al., 2016), as the delivery of CBT content no longer hinges on face-to-face appointments with specialized therapists. Recent systematic reviews and meta-analyses have found iCBT to be comparably effective at reducing anxiety symptoms in children and adolescents, relative to face-to-face CBT (Grist et al., 2018; Pennant et al., 2015; Rooksby, Elouafkaoui, Humphris, Clarkson, & Freeman, 2015; Ye et al., 2014), and more effective in reducing symptoms than wait-list conditions (Ebert et al., 2015; Grist et al., 2018; Hollis et al., 2017; Pennant et al., 2015; Podina, Mogoase, David, Szentagotai, & Dobrean, 2016; Vigerland, Lenhard, et al., 2016). Overall, these findings indicate that iCBT is an effective treatment option that can increase access to care.

iCBT is a complex intervention (Craig, Dieppe, Macintyre, Michie, Nazareth, Petticrew, & Medical Research Council Guidance, 2008), and is not merely the upload of therapeutic material onto a Web page. iCBT programs incorporate 3 major components: (1) structured and standardized therapeutic content (ie, CBT), (2) technological features (ie, multimedia, email) used to deliver the content, and (3) interactions between the user as he/she engages with iCBT content and features. These components are characteristic of a 'persuasive system'—an intervention designed to change user's attitudes and behaviour towards to their desired health goal (Chatterjee & Price, 2009; Fogg, 2002; Oinas-Kukkonen & Harjumaa, 2009). To date, considerable variety exists in terms of how these three iCBT components have been incorporated into iCBT program design. Only two studies of iCBT effectiveness have attempted to identify or explain what program components can be used to optimize the therapeutic gains of users and for what reasons. Calear et al. (2016) explored whether the expertise of the adjunct support person had an effect on intervention outcomes (teacher only support versus teacher plus mental health education officer support; Calear, Batterham, Poyser, et al., 2016) and Spence et al. (2017) tested for a difference in adolescents' anxiety reductions because of the specificity of program content (a program with social anxiety disorder-specific content compared to generic anxiety disorder content; Spence, Donovan, S, Kenardy, & Hearn, 2017), but neither study reported a significant difference in outcomes. Therefore, an essential question that remains for the field is, "What components of iCBT work, for whom, and why?" Using realist synthesis methodology, we used a persuasive systems perspective to examine: (1) What design and delivery components are described in studies of iCBT programs for children and adolescents with anxiety?; and (2) What are the components reported in studies that appear to explain the change in anxiety symptoms after completing iCBT?

4.2 Methods

4.2.1 Study Design

The realist synthesis provided us with a mixed-methods approach to generate proposed explanations (hypotheses) of how and why iCBT works despite variations in its design and delivery (Dickson, Riddell, Gilmour, & McCormack, 2017; Pawson, Greenhalgh, Harvey, & Walshe, 2004; Pawson, Greenhalgh, Harvey, & Walshe, 2005). The synthesis was conducted using the steps recommended by Pawson and Tilley (1997, 2005), and reported in accordance with the Realist And Meta-narrative Evidence Synthesis: Evolving Standards II (Wong et al., 2016). We set out to examine the technological features of iCBT (mechanisms), embedded within delivery and conditions or settings for use (program context), that produced changes in anxiety symptoms for children and adolescents (outcomes). Pawson and Tilley refer to these relationships as context-mechanism-outcome configurations. Thus, the overall purpose of the synthesis was to produce context-mechanism-outcome configurations that hypothesized when and how iCBT programs might be effective in reducing anxiety symptoms among children and adolescents with anxiety.

4.2.2 Candidate Context-Mechanism-Outcome Configuration Development

We started the synthesis with the generation of a list of 'candidate' context-mechanism-outcome configurations. We decided a priori to use an established, valid framework to guide the generation of candidate configurations. This also helped us maintain a consistent and streamlined approach to the synthesis (ie, extract and code data according to framework). We conducted an informal literature scan and held research team discussions to identify preexisting frameworks from the fields of psychology, pediatrics, human-computer interaction, and electronic health (eHealth). The persuasive systems design (PSD) model (Oinas-Kukkonen & Harjumaa, 2008)

was selected as the most appropriate framework to direct the candidate configurations and answer our research questions. It is a recent, well-studied model (Lehto & Oinas-Kukkonen, 2011) that describes 28 technological design features that can be incorporated into a persuasive system to help the user meet his or her health goals (Appendix 4.1). The model organizes the design features under 4 categories based on their main purpose: primary task support (assists the user in completing their target behaviour), dialogue support (provides computer-human communication to guide user toward target behavior), system credibility support (increases user's perceptions of system credibility), and social support (leverages the interactions and influence of others).

We used the PSD model to identify PSD features (mechanisms) hypothesized to produce anxiety symptom changes (outcomes) in iCBT programs and recorded these as mechanism-outcome dyads. We then considered the program design and delivery features (context) that might support the operation of the mechanism-outcome dyads and combined them in unified but distinct configurations. The result was 8 candidate context-mechanism-outcome configurations (Appendix 4.2), initial hypotheses, that formed the basis of our analysis. We refined these configurations during the realist synthesis so that they reflected the iCBT literature. Following analysis, we considered our configurations to be fully developed hypotheses ready for future testing.

4.2.3 Literature Search

We required diverse literature to inform this synthesis. We sought to include primary or secondary studies of iCBT interventions, conference proceedings, websites, program evaluations and government or technical reports. We used 3 search strategies to identify this literature: (1) A systematic, comprehensive search of 8 electronic databases from disciplines relevant to the topic

(ie, medicine, psychology): Medline, Embase, ERIC, PsycINFO, CINAHL, Cochrane Library, ProQuest Dissertations & Theses Global, and PubMed for the period 1990-2017, conducted by an information specialist; (2) a manual search using an internet search engine (Google) and gray literature repositories (eg, Association for Computing Machinery Digital Library, Open Gray, Institute of Electrical and Electronics Engineers Digital Library, and Canadian Agency for Drugs and Technologies in Health); and (3) a hand search of medical informatics journals (Journal of Medical Internet Research, Internet Interventions, Journal of Cybertherapy and Rehabilitation, and Journal of Telemedicine and Telecare) and the reference lists of included documents and reviews (eg, systematic reviews). Medical Subject Headings terms and text words for the search were based on mental health condition (ie, anxiety and phobias), intervention modality (ie, internet-based and mobile apps), intervention type (ie, prevention and treatment), and therapeutic approach (ie, CBT; Multimedia Appendix 3). We applied the search strategies in an initial search (conducted up until February 2015) and then in 2 updated searches (conducted in November 2017 and in June 2019) to ensure the realist synthesis was current and inclusive.

4.2.4 Document and iCBT Program Selection

We were interested in including documents relevant to iCBT programs that were designed for use by children or adolescents aged ≤19 years diagnosed with an anxiety disorder(s) or with anxiety symptoms associated with a disorder as classified according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 2013). Documents needed to reflect information for an iCBT program designed for treating child or adolescent anxiety and be available in English. Documents that detailed information for a transdiagnostic program (eg, treating an anxiety disorder plus depression) were eligible for inclusion but documents of programs designed solely for parent use were not. All eligible

documents were grouped according to the iCBT program it represented (ie, program name). We included in the realist synthesis, documents of programs that detailed its delivery context (ie, the conditions for program use), PSD mechanisms (ie, information on the technological features for how the program was proposed to work), and impact on anxiety outcomes after program delivery (ie, at least one published study of postintervention effects). These details could be described within 1 document, or across multiple documents, but needed to be available so that at least one context-mechanism-outcome configuration could potentially be generated for each iCBT program.

During the document selection progress, 2 reviewers (authors ADR and LW) independently applied the inclusion criteria using a 2-stage approach. In stage 1, titles and abstracts of documents were screened for potential eligibility (yes, no, or unsure). The reviewers randomly selected 100 documents to assess inter-rater agreement and found substantial agreement (Cohen kappa=0.74) (McHugh, 2012). At stage 2, the full text of 'yes' or 'unsure' documents were reviewed by the 2 reviewers for inclusion or exclusion in the synthesis. In both stages, they resolved discrepancies through discussion (with author ASN) until consensus was reached.

4.2.5 Literature Appraisal

Quality appraisal of included documents involved assessing relevance to the synthesis objectives and, in the case of research studies, assessing methodological rigor. A total of 2 reviewers (authors ADR and LW) conducted the quality appraisal. Relevance was assessed by reviewing a document's level of contribution, the extent to which information was provided on (1) theory and/or the context and sequences for iCBT delivery (context), (2) PSD features, required interactions by the deliverer/user and the program, and/or other proposed program

mechanisms (mechanism), and (3) the impact of iCBT on anxiety symptoms outcomes and explanations for the findings (outcome). The level of contribution was rated low if little or no information was provided, medium if some information was provided, and high if information was well-described, relative to other documents for other programs.

To understand the quality of the research studies that provided outcome data for the synthesis, the methodological rigor of studies was assessed using the Mixed Methods Appraisal Tool (MMAT) (Pluye, Robert, Cargo, & Bartlett, 2011; Pluye, Gagnon, Griffiths, & Johnson-Lafleur, 2009). The MMAT is a reliable, efficient, and validated tool that provides different sections for assessing studies of qualitative, randomized, non-randomized descriptive, and mixed-methods design (Pace et al., 2012; Pluye et al., 2011; Pluye et al., 2009). Multiple documents using the same, full dataset (ie, thesis plus published paper of the thesis) received the same MMAT score but was only counted once. MMAT scores could range from 0% to 100%, with a greater score signifying more criteria were met.

4.2.6 Data Extraction and Coding

To identify context-mechanism-outcome configurations, we extracted and coded iCBT program data using a data matrix with 6 major domains: (1) document characteristics (eg, study design), (2) participant characteristics (eg, demographics) and study procedures (ie, eligibility criteria), (3) context of iCBT delivery including a program's targeted level of prevention according to the Institute of Medicine (IOM) model [49] and adjunct support details (human-derived technological or therapeutic communication complementary to program delivery), (4) program theory and principles behind iCBT program design, (5) program components or proposed mechanisms (ie, CBT content and PSD features and interactions between the user and program), and (6) pre- to postintervention change in anxiety symptoms. For outcome data, not all

studies reported within-group analyses; therefore, absolute changes in anxiety symptoms among children or adolescents who received iCBT were recorded. If original authors referred to previous publications of an iCBT program, we included the document and extracted relevant data. We also extracted partial or full context-mechanism-outcome configurations, if provided by the original authors.

We used the PSD model (Oinas-Kukkonen & Harjumaa, 2009) and a customized codebook to guide the coding process (Appendix 4.1). PSD features of iCBT programs were coded: (1) when a program feature was executed by technology (eg, video demonstration of an adolescent performing deep breathing) rather than by human action (eg, a parent demonstrating deep breathing in person) (a similar coding approach was used by Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012), and (2) when the feature was part of the iCBT program, not supporting research study materials, such as an informational website. We coded therapeutic content according to the 5 main CBT components found in the American Academy of Child and Adolescent Psychiatry (AACAP) practice parameter for anxiety disorders (Connolly & Bernstein, 2007): psychoeducation, somatic management skills, cognitive restructuring, exposure methods, and relapse prevention. We also extracted other therapeutic content, such as behavioural activation details and interpersonal therapy techniques (Markowitz & Weissman, 2004; Mufson, Dorta, Moreau, & Weissman, 2011). We also extracted other therapeutic content, such as behavioral activation details and interpersonal therapy techniques [51,52]. We contacted corresponding authors associated with each iCBT program to support accurate and complete extraction and coding of the data. Eighty percent (12/15) of original authors associated with the included iCBT programs responded to the request for more information. The interpretation of data extraction and coding between 2 reviewers (authors ADR and LW) was checked with a

random sample of 10 documents and achieved consensus before the remaining documents were coded by a reviewer (author ADR).

4.2.7 Analysis and Synthesis Process

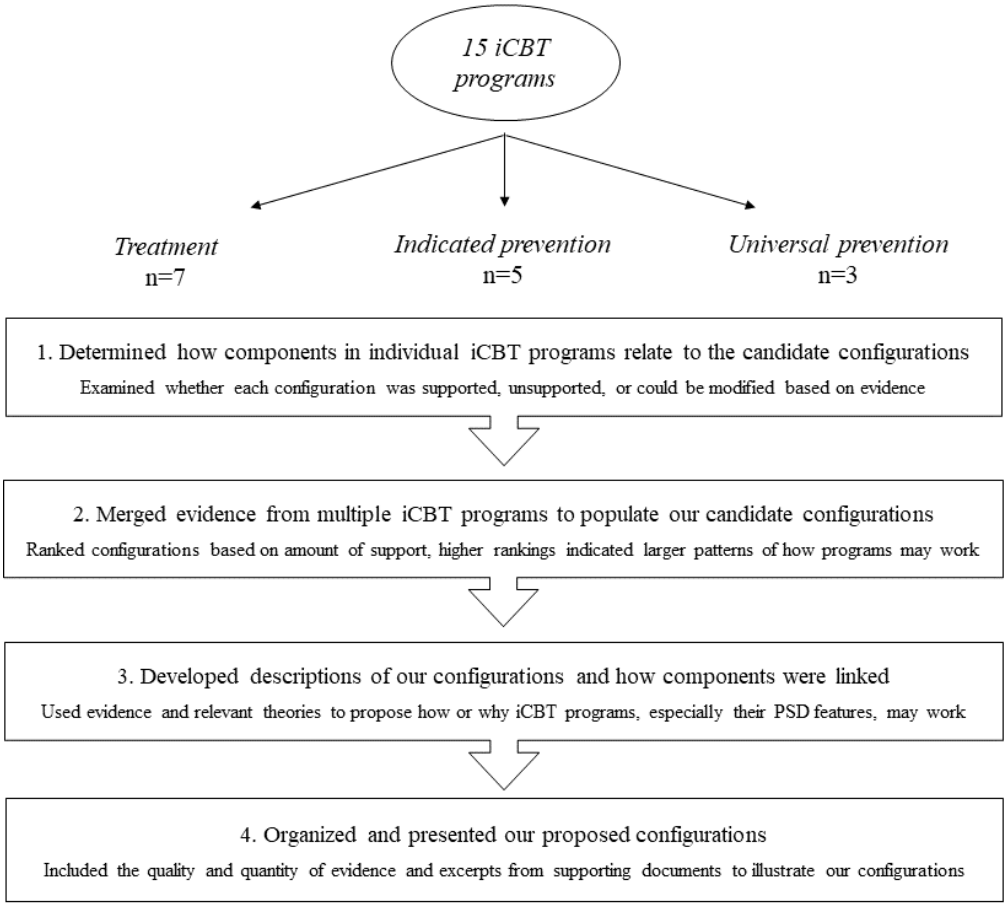
Analysis was conducted at the program level (Pawson et al., 2005) which meant that multiple documents or studies relating to each unique iCBT program were grouped together for analysis of the iCBT program as a whole. Programs were grouped according to their level of prevention using the IOM model (Institute of Medicine, 1994)—whether they were a universal prevention, indicated prevention, or treatment program ('program type'). The IOM model recognizes that the target population (ie, children or adolescents with baseline anxiety symptoms, level of risk for a disorder) differs according to program type, and so does the conceptual focus of the intervention, and together, these differences may influence the fundamental design and delivery of a program (ie, context, clinical techniques), and the expected degree of change users may experience (ie, outcomes) (Springer & Phillips, 2007).

We analyzed the candidate context-mechanism-outcome configurations in 4 stages using meta-ethnographic (Atkins et al., 2008; Noblit & Hare, 1988) and realist techniques (Pawson et al., 2004; Pawson et al., 2005; Pawson & Tilley, 1997) (Figure 4.1). During this process, information from included documents was synthesized to refine each configuration. In stage 1, we recorded the individual components (contexts, mechanisms, outcomes) and the relationships between components (eg, mechanism-outcome dyads) reported in the documents for each iCBT program. We compared the information for each iCBT program with the candidate configurations (initial hypotheses) and documented whether a candidate configuration was supported, unsupported, modified, or newly generated based on the evidence. In stage 2, reciprocal translation analysis was used to determine if common contexts and mechanisms were

being described across programs. The candidate configurations were ranked from the most to least supported, based on the number of iCBT programs supporting each configuration. A configuration was required to be supported by at least 2 iCBT programs to proceed with the next stage of analysis. We considered configurations with the highest rankings to depict the larger patterns or trends (demi-regularities) of iCBT program components. These candidate configurations became our final hypotheses for how iCBT programs were hypothesized to work. In stage 3, we developed descriptions of how the iCBT program components were linked in our configurations. The descriptions focused on the proposed functions (role) of key PSD features in explaining how iCBT programs may reduce anxiety for children and adolescents. To do this, we nested the configurations within our broader understanding of the theoretical underpinnings of the PSD model and CBT, along with original authors' descriptions of the design or delivery of program features. This process allowed us to explore not only *what* iCBT program components might be working together but *why* they might be doing so. We maintained a level of abstraction that allowed us to express the larger similarities across multiple programs while acknowledging the details that made each configuration unique (using lines-of-argument synthesis). This meant that we did not delve deeper into specific details of contexts, mechanisms, or outcomes. For example, we identified whether adjunct support was provided in programs rather than the specific amount of support provided, and we identified the direction of treatment effect rather than specific effect sizes. This approach was not only necessary because of the data available to us, but it also ensured that our configurations remained usable and applicable across the programs. During this stage, we also incorporated into the descriptions other factors that could help explain our understanding of the configurations (eg, multiple PSD features working together; differences in user characteristics). In stage 4, we identified the quantity (ie, number of

programs) and quality (ie, relevance, methodological rigor) of support associated with each configuration. Research team meetings were used to discuss and improve the final detailed descriptions of our proposed configurations.

Figure 4.1. The 4 stages of the realist analysis and synthesis process of internet-based cognitive behavioral therapy (iCBT) programs for children and adolescents with anxiety.



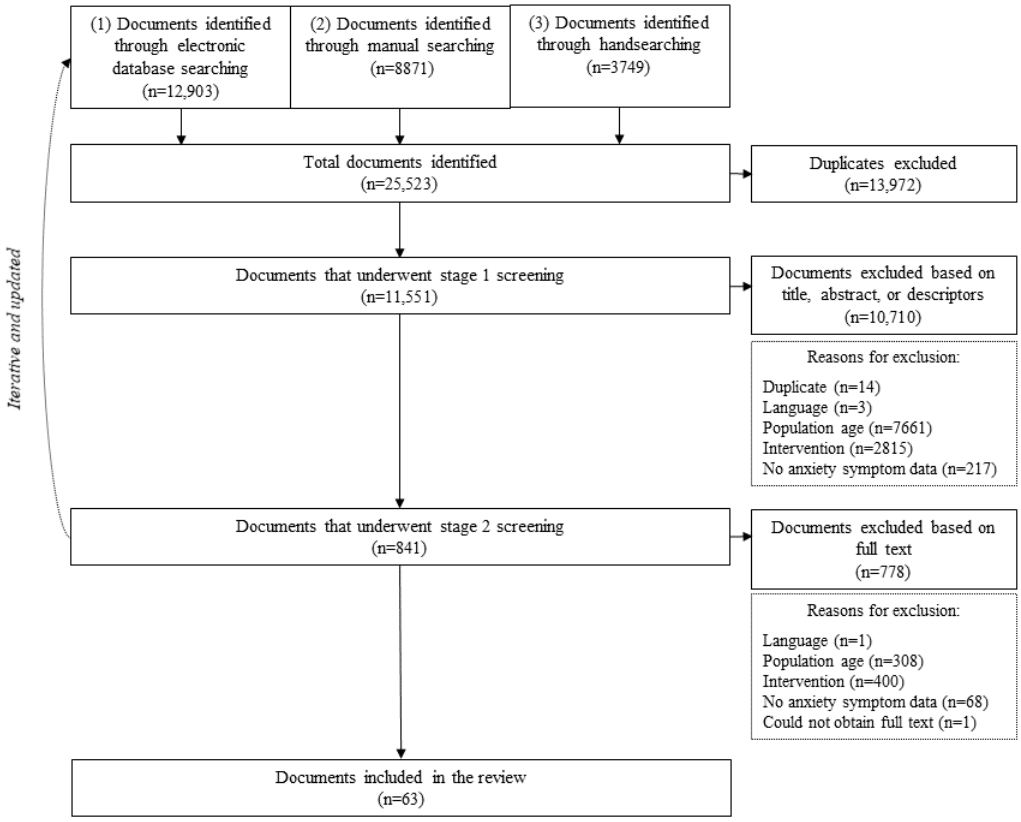
4.3 Results

4.3.1 Included Documents

Figure 4.2 is a flow diagram outlining the results of the two-stage literature search and selection process. A total of 63 documents (30 from the initial search, 15 from the updated search conducted in November 2017, and 18 from the updated search conducted in June 2019) describing 15 iCBT programs were eligible and included in the review. The included documents

were published studies (n=29), theses (n=5), registered protocols for trials (n=15), study or program websites (n=9), study flyers (n=2), and conference abstracts or posters (n=3).

Figure 4.2. Flow diagram of the literature search and selection process.



4.3.2 Level of Contribution and Methodological Quality

Details of the quality appraisal are provided in Appendix 4.4. Across documents, the most details were provided for iCBT program contexts and outcomes. Program mechanisms were not so well described in terms of what the mechanisms were (ie, technological and therapeutic features) and how they were proposed to work. A total of 8 documents were rated as having a "high" level of contribution to understanding contexts, mechanisms, and outcomes (Baker, 2010; Calear, Christensen, Brewer, Mackinnon, & Griffiths, 2016; Conaughton, Donovan, & March, 2017; Keller, 2009; March, 2008; Spence et al., 2017; Stasiak, Merry,

Frampton, & Moor, 2016; Vigerland et al., 2017). These documents were for 6 iCBT programs that provided the greatest contributions to the context-mechanism-outcome configurations we developed: BRAVE-ONLINE, Internet-delivered CBT for children with anxiety disorders, Internet-delivered CBT for children with specific phobia, Internet cognitive-behavioural skills-based program, STAY COOL system for test anxiety, and the e-couch Anxiety and Worry program.

MMAT scores were calculated for 35 research studies: 20 randomized controlled trials, 5 non-randomized studies, 7 quantitative descriptive, 1 qualitative study and 2 mixed methods studies. Twenty-two documents met all 4 MMAT criteria (100%), 7 documents met 3 criteria (75%), 5 documents met 2 criteria (50%), and 1 document met 1 criterion (25%). Lower MMAT ratings were a result of factors like incomplete outcome data or unacceptable response rates, high withdrawal rates, or no mention of whether groups were comparable.

4.3.3 Overview of the Contexts, Mechanisms and Outcomes of iCBT programs for Children and Adolescents with Anxiety

4.3.3.1 Contexts: User and Program Delivery Characteristics

Table 4.1 presents an overview of the user and program delivery characteristics of iCBT programs, organized according to program type. All programs were computer-based and included some form of adjunct support or program facilitation. Most programs (10/15 programs) were designed to solely target users with reported anxiety symptoms. There were similarities in the delivery setting, workflow, and adjunct support of iCBT programs of the same program type. Treatment programs were most often accessed at home, included 7 or more modules, and incorporated weekly Web-based therapist interaction and parent-dedicated modules. Indicated prevention programs demonstrated more variety in their use setting (eg, home, school, or clinic)

and the adjunct support provided (eg, not all programs required parent participation), and the workflow tended to involve fewer modules (ie, typically 6 modules or less). Universal prevention programs were delivered with teacher facilitation in a classroom setting and incorporated the least number of modules relative to other program types. iCBT programs were based on relevant theoretical, anxiety, or CBT literature or published treatment recommendations (Baker, 2010; Bradley, Robinson, & Brannen, 2012; Calear, Christensen, Griffiths, et al., 2013; Calear, Christensen, Mackinnon, Griffiths, & O'Kearney, 2009; Karbasi & Haratian, 2018), established clinic-based programs, manuals or workbooks (Keller, 2009; Ramdhani, Widjaja, & Rahmawati, 2015; Shahnavaz, 2016; Spence, Holmes, March, & Lipp, 2006; Vigerland et al., 2013), a school syllabus (Wong, Kady, Mewton, Sunderland, & Andrews, 2014), or were adaptations of a developed iCBT program designed to target a different population or mental health condition (Nielsen et al., 2018; Nordh et al., 2017; Silfvernagel, Gren-Landell, Emanuelsson, Carlbring, & Andersson, 2015; Vigerland, 2015).

Table 4.1. Overview of internet-based cognitive behavioral therapy user, program, and delivery characteristics.

Numbered list of programs[a]	Target users' age group and symptom severity[b]	Program delivery		Therapist support in program			Adjunct program support
		Use setting	Number of sessions, frequency and/or duration of program	Web or email	Phone	In-person	
Treatment programs: 1, 2, 3, 4, 5, 6, 7							
1. BRAVE-Online	Children and adolescents with an anxiety disorder	Home	10 weekly sessions + 2 booster sessions; 60 minutes each	✓	✓		Parent

Numbered list of programs[a]	Target users' age group and symptom severity[b]	Program delivery		Therapist support in program			Adjunct program support
		Use setting	Number of sessions, frequency and/or duration of program	Web or email	Phone	In-person	
2. iCBT for dental anxiety	Children and adolescents with an anxiety disorder	Home plus Clinic	12 weekly modules	✓			Parent, Dental professional[c]
3. Internet-delivered CBT for children with anxiety disorders	Children with an anxiety disorder	Home	11 modules over a 10-week period	✓	✓		Parent
4. Internet-delivered CBT for children with specific phobia	Children with an anxiety disorder	Home	11 modules over a 6-week period; 15-45 minutes each	✓	✓		Parent
5. Chilled Out	Adolescents with an anxiety disorder	Home	8 modules over a 12- or 14-week period; 30 min each		✓		Parent (optional)
6. Group therapy supported iCBT for adolescents with social anxiety disorder	Adolescents with an anxiety disorder	Home plus Clinic	12 weekly modules	✓	✓	✓	Parent
7. iCBT for anxiety disorders among adolescent girls	Adolescents with an anxiety disorder	Home	7 modules over a 3-month period; 1 hour daily	✓			
Indicated prevention programs: 8, 9, 10, 11, 12							
8. Internet cognitive-behavioural skills-based program	Children with moderate-to-severe anxiety symptoms	Home	3 modules[d] with 20 sections over a 12-week period		✓		Parent
9. Internet-supported brief CBT for shy-socially isolated problem	Adolescents with moderate-to-severe anxiety symptoms	School	6 modules	✓	✓		

Numbered list of programs[a]	Target users' age group and symptom severity[b]	Program delivery		Therapist support in program			Adjunct program support
		Use setting	Number of sessions, frequency and/or duration of program	Web or email	Phone	In-person	
10. STAY COOL system for test anxiety	Adolescents with mild-to-moderate anxiety symptoms	School or Home	6 modules over 8 weeks; 20-30 minutes for each activity			✓	Researcher[e]
11. Feeling Better	Adolescents with mild-to-moderate anxiety and/or depressive symptoms	Home	4 modules[f]	✓	✓		
12. Individually tailored iCBT for adolescents	Adolescents with mild-to-severe anxiety and/or depressive symptoms	Clinic	6-9 prescribed modules over a 6-18 week period	✓	✓	✓	
Universal prevention programs: 13, 14, 15							
13. The e-couch Anxiety and Worry Program	Adolescents with no symptoms required	School	6 weekly sessions; 30-40 minutes each				Teacher[g], Mental health service provider[h]
14. MoodGYM	Adolescents with no symptoms required	School	5 weekly modules; 30-60 minutes each				Teacher[g]
15. Thiswayup Schools for Anxiety and Depression prevention courses	Adolescents with no symptoms required	School	6 (anxiety) or 7 (depression) weekly modules; 40 minutes each				Teacher[g]

[a]Categorized according to the Level of Prevention Model [37]: universal prevention—target participants have not been identified on the basis of individual risk (ie, no symptoms required); selective prevention—target participants have a higher risk of developing an anxiety disorder than others; indicated prevention—target participants are at high risk, those who have anxiety signs or symptoms but do not currently meet diagnostic levels; and treatment—target participants are diagnosed with an anxiety disorder.

[b] Children: mean study age of users ≤12 years; adolescents: mean study age of users ≥13 years. The anxiety severity reported was the severity required for study inclusion; anxiety severity was not necessarily the baseline level of symptoms participants had.
[c]A dental professional (a dentist, dental hygienist, or dental assistant) provided exposure at a dental clinic.
[d]2 blocks of modules (containing 9 major sections) are dedicated to mothers, and 1 module block (containing 12 major sections) is dedicated to the child plus mother.
[e]Research assistant or graduate student was present to facilitate aspects of the study, such as assessment and troubleshoot technical issues.
[fi]The first 4 out of a possible 12 modules were delivered for the purpose of this study: Introduction, Activity and Motivation, Thoughts and Feelings, and Stress Management (Bradley et al., 2012).
[g]Program administration was facilitated by a classroom teacher. The teacher was available for general guidance or but did not provide an active therapeutic role in the program.
[h]A mental health service provider was present in 1 study of the program to facilitate program administration and address student questions (Calear, Batterham, Griffiths, & Christensen, 2016).

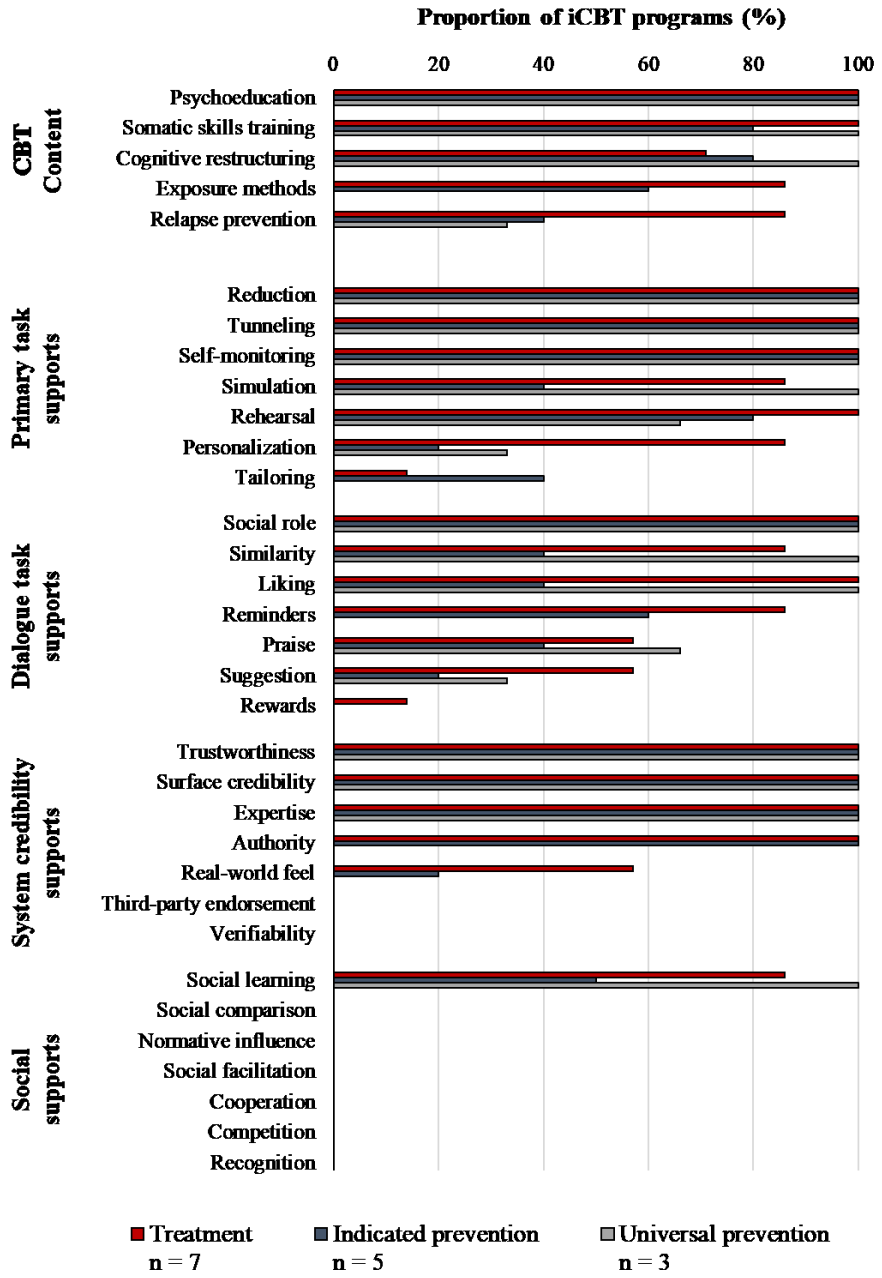
4.3.3.2 Mechanisms: Therapeutic Content and Persuasive Systems Design Features

Figure 4.3 provides an overview of the proportion of iCBT programs that incorporated specific CBT content and PSD features, organized according to program type. All programs described themselves as "CBT-based" and contained AACAP recommended CBT components, although considerable variability in the type and quantity of components was found based on program type and the age of target users. Many programs also integrated techniques with an interpersonal focus, such as assertiveness training and problem-solving skills, to reduce environmental stressors and enhance social support (Lipsitz & Markowitz, 2013). Psychoeducation and somatic skills training were found in all iCBT programs. Cognitive restructuring was reported in more than half of the treatment programs and in nearly all the indicated and universal prevention programs. Relapse prevention was incorporated in a minority of prevention-based programs. Exposure methods were not delivered to users of universal prevention preventions.

Treatment programs incorporated the most PSD features, followed by indicated prevention and then universal prevention programs. Out of the 4 PSD support categories, features from the primary task support and dialogue support categories were most widely used. In terms of primary task supports, iCBT programs of all IOM program types incorporated

reduction and tunneling to regulate the logical and incremental presentation of module content to users, mimicking the progressive delivery format of face-to-face CBT. Self-monitoring of users' iCBT progress was also a primary task support feature common to all programs. Social role, a dialogue support feature, created a virtual presence of others in the program through Web- or email-based messaging between the user and therapist or recurring graphics or videos of real or animated peers. System credibility support features, trustworthiness, and surface credibility, although not explicitly reported, were inherent in all iCBT programs, as they were designed and delivered (tested) within a research study (ie, use of confidentiality and consent processes and declared academic affiliations). Authority features were associated with program content that was presented by a reliable source (ie, therapist) and was, therefore, only incorporated in treatment and universal prevention programs with adjunct therapist involvement. Social learning was the only social support feature included in iCBT programs, but not all indicated prevention programs utilized it. iCBT from different program types varied to the greatest extent on their use of personalization, tailoring, reminders, liking, and similarity features. Appendix 4.1 provides additional examples of how PSD features were reported in the documents included in this synthesis.

Figure 4.3. Frequency of the cognitive behavioral therapy (CBT) content and persuasive systems design features across 15 internet-based cognitive behavioral therapy (iCBT) programs, organized according to program type.



4.3.3.3 Outcomes: Changes in Anxiety Post-intervention

Across program types, there was an overall trend for reduced anxiety symptoms among children and adolescents who received iCBT. An overview of the outcomes is provided in Appendix 4.5. Among treatment programs, anxiety diagnoses, clinical severity, and parent-and

user-reported symptoms were reduced post intervention in 98.5% of studies. Among indicated prevention programs, anxiety diagnoses, parent- and user-reported symptoms were reduced post intervention in 100% of studies. Among universal prevention programs, user-reported anxiety symptoms were reduced post intervention in 83.3% of studies.

4.3.4 Key Relationships Between iCBT Program Contexts, PSD Mechanisms and Outcomes

We found that reductions in anxiety outcomes were reported across iCBT programs with many shared mechanisms and delivery contexts. Self-monitoring, simulation, social role, similarity, social learning, and rehearsal were common PSD features across all program types; however, mechanisms for customizing program content (ie, personalization and tailoring) distinguished treatment, indicated prevention, and universal prevention programs from one another. The key aspect of iCBT context that supported the mechanism-outcome interactions was adjunct support. The adjunct support person (eg, therapist, parent, and teacher), their expertise, and the intensity and frequency of their communication (eg, weekly personalized feedback and technical troubleshooting as needed) was associated with the program type, and, therefore, also the characteristics of users, such as age and symptom severity. In this way, treatment programs received the greatest amount of adjunct support relative to indicated and universal prevention programs.

4.3.5 Context-Mechanism-Outcome Configurations

The refined set of context-mechanism-outcome configurations is summarized in Table 4.2, according to program type. Configurations, organized by PSD mechanism, are based on included information from documents that ranged in level of contribution (low to high).

Table 4.2. Summary of the 11 context-mechanism-outcome configurations for internet-based cognitive behavioral therapy programs for children and adolescents with anxiety.

Context: User characteristics and adjunct support	Mechanisms: PSD features and proposed function	Outcomes: Trend in anxiety changes, pre- to post intervention[a]	Contributing programs, mean MMAT score, and percentage of supporting studies[b]
Treatment programs: 1, 2, 3, 4, 5, 6, 7			
Users were children diagnosed with an anxiety disorder(s) Adjunct support provided by a therapist, parent and/or professional	**Configuration 1**		
	Self-monitoring: To increase users' attention to and comprehension of anxiety-related feelings or behaviours; to track and present users' program progress towards anxiety management or symptom reduction; to assess users' accumulation of program-related knowledge.	• Reductions in user-reported symptoms • Reductions in parent-reported symptoms • Reductions in diagnoses • Reductions in clinical severity	• Programs 1, 2, 3, 4, 5, 6, 7 • Mean MMAT= 88% • Reductions in anxiety were found in 98.5% of studies
	Configuration 2		
	Simulation + Social role + Similarity + Social learning: To normalize users' experience of anxiety, increase motivation or willingness to improve their mood; to model the application of new anxiety management skills.	• Reductions in user-reported symptoms • Reductions in parent-reported symptoms • Reductions in diagnoses • Reductions in clinical severity	• Programs 1, 2, 3, 4, 5, 6 • Mean MMAT= 91% • Reductions in anxiety were found in 97.4% of studies
	Configuration 3		
	Rehearsal: To provide opportunities for developing fear tolerance, reduction and/or extinction; to reinforce the application of program concepts, behavioural anxiety management strategies and problem-solving skills.	• Reductions in user-reported symptoms • Reductions in parent-reported symptoms • Reductions in diagnoses • Reductions in clinical severity	• Programs 1, 2, 3, 4, 5, 6, 7 • Mean MMAT= 88% • Reductions in anxiety were found in 98.5% of studies
	Configuration 4		
	Personalization + Social role + Trustworthiness + Expertise + Authority: To provide customized feedback on user's	• Reductions in user-reported symptoms	• Programs 1, 2, 3, 4, 5, 6 • Mean MMAT= 91%

	program activity to increase accurate comprehension and application of anxiety management concepts and skills.	• Reductions in parent-reported symptoms • Reductions in diagnoses • Reductions in clinical severity	• Reductions in anxiety were found in 98.5% of studies
Indicated prevention programs: 8, 9, 10, 11, 12			
Users were children or adolescents with mild-to-severe anxiety symptoms Adjunct support was provided by a therapist, parent and/or researcher	**Configuration 5**		
	Self-monitoring: To increase users' attention to and comprehension of anxiety-related feelings or behaviours; to track program progress towards anxiety management/symptom reduction; to assess users' accumulation of program-related knowledge.	• Reductions in user-reported symptoms • Reductions in parent-reported symptoms • Reductions in diagnoses	• Programs 8, 9, 10, 11, 12 • Mean MMAT= 89% • Reductions in anxiety were found in 100% of studies
	Configuration 6		
	Simulation + Social role + Similarity + Social learning: To normalize users' experience of anxiety, increase motivation or willingness to improve their mood; to model the application of new anxiety management skills.	• Reductions in user-reported symptoms • Reductions in parent-reported symptoms • Reductions in diagnoses	• Programs 8, 11 • Mean MMAT= 100% • Reductions in anxiety were found in 100% of studies
	Configuration 7		
	Rehearsal: To provide opportunities for developing fear tolerance, reduction and/or extinction; to reinforce the application of program concepts, cognitive and behavioural anxiety management strategies and problem-solving skills.	• Reductions in user-reported symptoms • Reductions in parent-reported symptoms • Reductions in diagnoses	• Programs 8, 9, 10, 11, 12 • Mean MMAT= 89% • Reductions in anxiety were found in 100% of studies
	Configuration 8		
	Tailoring: To adapt program content based on user's demographic or mental health condition to improve the relevance for each user.	• Reductions in user-reported symptoms • Reductions in diagnoses	• Programs 11, 12 • MMAT= 100% • Reductions in anxiety were found in 100% of studies
Universal prevention programs: 13, 14, 15			
Users were adolescents who are not required to have any anxiety symptoms	**Configuration 9**		
	Self-monitoring: To increase users' attention to and comprehension of anxiety-related feelings or behaviours;	• Reductions in user-reported symptoms	• Programs 13, 14, 15

Adjunct support was teacher-facilitated program administration	to track and present users' program progress towards anxiety management or symptom reduction; to assess users' accumulation of program-related knowledge.		• Mean MMAT= 70% • Reductions in anxiety were found in 83.3% of studies
	Configuration 10		
	Simulation + Social role + Similarity + Social learning: To normalize users' experience of anxiety, increase motivation or willingness to improve their mood; to model the application of new anxiety management skills.	• Reductions in user-reported symptoms	• Programs 13, 14, 15 • Mean MMAT= 70% • Reductions in anxiety were found in 83.3% of studies
	Configuration 11		
	Rehearsal: To provide opportunities for developing fear tolerance; to reinforce the application of program concepts, cognitive and behavioural anxiety management strategies and problem-solving skills.	• Reductions in user-reported symptoms	• Programs 13, 14 • Mean MMAT= 75% • Reductions in anxiety were found in 80% of studies

iCBT= internet-based cognitive behavioural therapy.
MMAT= Mixed methods appraisal tool (Pluye et al., 2011).
[a]Categorized according to type of anxiety measure used, although specific instruments varied among studies.
[b]Percentage of studies reporting a reduction in anxiety for iCBT participants from pre- to -post-intervention.

4.3.5.1 Treatment programs, Configurations 1-4

Configuration 1: Self-monitoring

Treatment programs for children with an anxiety disorder, delivered with adjunct therapist, parent or professional support, and include self-monitoring, may produce postintervention reductions in user's anxiety (diagnoses, clinical severity, self-reported and parent-reported symptoms). Self-monitoring was part of the workflow for each module of the BRAVE-Online program and included regular tracking of symptoms and interactive activities and end-of-module quizzes to "facilitate attention and comprehension of material" (p. 414, Spence et al., 2008). Chilled Out program participants were presented with a weekly progress chart based on their reports of anxiety interference in their daily lives (Nielsen et al., 2018).

During program tasks, self-monitoring was employed using automated 'pop-ups' stating the accuracy of users' entries (ie, corrective comments) to ensure understanding of important concepts (Spence et al., 2008). The adjunct support therapist encouraged users to self-monitor and record details of their in-vivo (real world, offline) practice activities (Vigerland et al., 2013; Vigerland, Ljótsson, et al., 2016), including changes in anxiety following exposure exercises (Shahnavaz, 2016).

Configuration 2: Simulation, Social role, Similarity and Social learning

Treatment programs for children with an anxiety disorder, delivered with adjunct therapist, parent or professional support, and simulation with social role, similarity and social learning features, may produce postintervention reductions in user's anxiety (diagnoses, clinical severity, self-reported and parent-reported symptoms). These features were evident in videos and/or animations of peers, cartoon and real-life characters to illustrate the 'experience of different emotions' and the application of therapeutic skills, such as goal setting, developing fear hierarchies, and completing exposure activities (Nielsen et al., 2018; Shahnavaz, 2016; Spence et al., 2008; Vigerland, Ljótsson, et al., 2016). Age-appropriate characters "provided 'models' for the use of coping strategies to overcome anxiety problems" (p. 415, Spence et al., 2008). Role models were designed to be appealing and relatable to users and their anxiety-related challenges; they represented someone with whom "the child can identify, and will be more likely to learn from" (p. 87, March, 2008) (similarity). In another treatment program (Shahnavaz, 2016), the development of exposure-based film scenes used for fear extinction (Golkar, Selbing, Flygare, Öhman, & Olsson, 2013; Melamed, Yurcheson, Fleece, Hutcherson, & Hawes, 1978) of dental procedures were based on principles of observational learning and the development of self-efficacy (Bandura, 1977). Email communication between the user and adjunct therapist (social

role) could mimic or complement Simulations as therapists provided additional anxiety management instructions/tutorials, or helped users problem-solve and plan exposure activities related to their specific situation or fears (Vigerland, 2015).

Configuration 3: Rehearsal

Treatment programs for children with an anxiety disorder, delivered with adjunct therapist, parent or professional support, and including rehearsal features may produce postintervention reductions in user's anxiety (diagnoses, clinical severity, self-reported and parent-reported symptoms). Rehearsal was incorporated in brief, interactive tasks to be completed during the module (eg, drag this sentence to the correct term and drop it there) (Vigerland, Ljótsson, et al., 2016), quizzes for comprehension (eg, recap or summary quizzes) (March, 2008) or more in-depth, application-based "worksheets" at the end of the module (Karbasi & Haratian, 2018; Shahnavaz, 2016). For example, in BRAVE-Online, "Participants consolidate[d] learning of these [anxiety management] strategies through completion of weekly [Web-based] homework tasks, known as 'extreme challenges'" (p. 414, Spence et al., 2008). Post-module rehearsal activities recommended users apply their "target skill" in real life anxiety-provoking situations outside of the program (ie, exposure exercises) (March, 2008). An adjunct therapist was available to help structure and monitor some of these rehearsal activities. For example, in preparation for exposure activities, a supportive telephone call or message from the therapist assisted the user in developing a suitable exposure hierarchy (Nordh et al., 2017; Spence et al., 2008).

Configuration 4: Personalization, Social role, Trustworthiness, Expertise and Authority

Treatment programs for children with an anxiety disorder, delivered with adjunct therapist, parent or professional support, and include personalization, a social role, trustworthiness, expertise and authority may produce postintervention reductions in user's anxiety (diagnoses, clinical severity, self-reported and parent-reported symptoms). Personalization provided a sense of program relatedness or 'knowing' of the user through automated or manual features based on demographic details or program activity of the user. For example, the user's name and that of his or her adjunct therapist could be populated throughout the modules (Spence et al., 2006). Personalized "pop-ups" with immediate and specific feedback (eg, explanations for correct and incorrect answers; Spence et al., 2008) on quizzes and tasks were also provided. Additionally, the adjunct therapist (social role) monitored users' responses to tasks and homework assignments and provided personalized, written feedback by email. Personalized feedback was used to "reinforce effort and success and provide corrective information if required" (p. 417, Spence et al., 2008), to "answer questions and clarify treatment content, increase motivation and to help solve problems" (p. 50, Vigerland, Ljótsson, et al., 2016), or to "[ensure] adolescents' understanding of the program elements" (p. 11, Nielsen et al., 2018). Since the therapist could access user-specific information stored within the program, a response could be crafted with objective and supportive input through the therapist's 'professional lens' (authority); therefore, trustworthiness and expertise were features considered to be inherent to this personalized feedback process.

4.3.5.2 Indicated prevention programs, Configurations 5-8

Configuration 5: Self-monitoring

Indicated prevention programs for children or adolescents with mild-to-severe anxiety symptoms, delivered with adjunct therapist, parent or researcher support, and include self-

monitoring, may produce postintervention reductions in user's anxiety (diagnoses, self-reported and parent-reported symptoms). Self-monitoring was incorporated in the Feeling Better program using standardized symptom assessments at the beginning of modules as a way "to monitor symptom change" over the course of the program (p. 1421, Currie et al., 2010). For some programs, symptom tracking was an essential part of the ongoing risk management of users (Currie et al., 2010; Silfvernagel et al., 2015). The program or the adjunct support therapist would respond (automatically or manually) to safety concerns that arose from these assessments by providing additional mental health/coping resources. In addition to mood, the program tracked the user's progress towards goal achievement via homework completion. Module quizzes in some programs (Baker, 2010; Keller, 2009) were a means for users to review his or her understanding of new program concepts or skills (Keller, 2009).

Configuration 6: Simulation, Social role, Similarity and Social learning

Indicated prevention programs for children or adolescents with mild-to-severe anxiety symptoms, delivered with adjunct therapist, parent or researcher support, and include simulation with a social role, similarity and social learning, may produce postintervention reductions in user's anxiety (diagnoses, self-reported and parent-reported symptoms). Simulation was incorporated in examples or demonstration videos of individuals (social role) "illustrat[ing] certain concepts in the program" (p. 51, Keller, 2009), providing 'suggested solutions', or working through their problems (social learning) (Currie et al., 2010). The examples and activities provided in the Feeling Better program were specific to target users and their reported 'stressors' (similarity) and were employed to "encourage practice and enhance learning of material" (p. 1421, Currie et al., 2010).

Configuration 7: Rehearsal

Indicated prevention programs for children or adolescents with mild-to-severe anxiety symptoms, delivered with adjunct therapist, parent or researcher support, and including rehearsal may produce postintervention reductions in user's anxiety (diagnoses, self-reported and parent-reported symptoms). The STAY COOL program described including evidence-based practice activities (rehearsal) for reducing 'physical and cognitive test anxiety symptoms', and pairing these coping activities with desensitizing exposure tasks to improve the program's effectiveness (Baker, 2010). In the same program, post-module quizzes presented users with "a less-threatening, relatively low stakes exposure by testing them on recently obtained information in an untimed scenario." (p. 62, Baker, 2010). In the Internet-based cognitive-behavioural skills program, 'Talk Time' was used to prompt the mother (adjunct parental support) and child to discuss a therapy topic or work together on a task (Keller, 2009). Additionally, exposure hierarchies were used to guide users' practice (rehearsal) outside of the program as well. Adjunct therapists could provide rehearsal support (eg, encouragement, suggestions), if necessary, through their communications with the user.

Configuration 8: Tailoring

Indicated prevention programs for children or adolescents with mild-to-severe anxiety symptoms, delivered with adjunct therapist, parent or researcher support, and include tailoring, may produce post-intervention reductions in user's anxiety (diagnoses, self-reported and parent-reported symptoms). iCBT content was tailored according to user's symptom profile. In the Feeling Better program, "A standardized assessment of symptoms of distress… [was] built into the start and end of core program modules to monitor symptom change and to help the user choose customized streams of program content specific to their emotional distress [such as anxiety, depression or stress]" (p. 1421, Currie et al., 2010). Another program had gender-

specific versions (male and female) so that therapeutic examples matched the sex of the user (Currie et al., 2010). For the individually tailored iCBT program for adolescents, the adjunct therapist used results from a baseline diagnostic interview to select module content (ie, psychoeducation and case examples) that corresponded to the user's primary anxiety concern (Silfvernagel et al., 2015). According to Silfvernagel (2017), a tailored iCBT program was "designed to identify a participant's unique symptom profile and to provide information and skills that are likely to be helpful based on said profile" (p. 11), aiming to improve the usefulness of the intervention.

4.3.5.3 Universal prevention programs, Configurations 9-11

Configuration 9: Self-monitoring

Universal prevention programs for adolescents with minimal to no symptoms, delivered with teacher facilitation, and include self-monitoring may produce postintervention reductions in user's self-reported anxiety symptoms. The MoodGYM program provided 'anxiety and depression quizzes' (self-monitoring) before and after each module. Adolescents' answers to quizzes and other program tasks were saved in a 'personal web-based workbook' that could be accessed by them at any time (Calear et al., 2009), serving as a benchmark for which they could compare changes over the course of iCBT. Electronic questionnaires were administered to adolescent users of Thiswayup Schools who also received notification if their scores were above average (Andrews & St. Vincent's Hospital, n.d.). In the case of all 3 universal prevention programs, a teacher was present for iCBT administration and could provide referral advice if an adolescent's symptoms required professional follow-up (eg, Neil, Batterham, Christensen, Bennett, & Griffiths, 2009).

Configuration 10: Simulation, Social role, Similarity and Social learning

Universal prevention programs for adolescents with minimal or no symptoms, delivered with teacher facilitation, and include simulation with a social role, similarity and social learning, may produce postintervention reductions in user's self-reported anxiety symptoms. Cartoon vignettes (similarity, social role) provided examples of anxiety management behaviours and responses as a regular part of the modules (simulation, social learning). For example, at the beginning of the MoodGYM program, adolescent users were "introduced to six distinct characters that form the basis of examples and discussion. Each character has a specific way of dealing with stressful situations, which [were] explored in the program." (p. 1025, Calear et al., 2009). Similarly, Thiswayup Schools used a storyline of cartoon teenagers with anxiety or depression to demonstrate ways to solve "real life problems" (Wong et al., 2014).

Configuration 11: Rehearsal

Universal prevention programs for adolescents with minimal or no symptoms, delivered with teacher facilitation, and include rehearsal may produce postintervention reductions in user's self-reported anxiety symptoms. The e-couch Anxiety and Worry program included rehearsal exercises 'to help users understand themselves and others better' (Griffiths, Tayler, & Christensen, n.d.). The MoodGYM program also provided opportunities for users to apply therapeutic strategies to their own situation. Both quizzes and "homework" exercises were incorporated for users to 'practice their skills'. User's answers were recorded in their web-based workbook and could be accessed at any time (Calear et al., 2009). Rehearsal activities appeared to focus on cognitive restructuring, problem-solving and interpersonal skills.

4.4 Discussion

Our study systematically documented important similarities and differences in the design and delivery of iCBT components across 15 existing programs, which to our knowledge, is the

first study of its kind for children or adolescents with anxiety. Anxiety reductions were reported in more than 98% of studies we reviewed. Our use of realist synthesis methods enabled the development of 11 context-mechanism-outcomes configurations that hypothesize the PSD features (technology-based mechanisms) that may contribute to the observed reductions in anxiety symptoms (outcomes), as they relate to key user and delivery features (context). Our results point to the need for increased emphasis on PSD in the development, evaluation, and reporting of iCBT programs for children and adolescents with anxiety concerns, and further research designed to establish their relationship with improved anxiety symptomatology.

4.4.1 Design and Delivery Components of iCBT for Children and Adolescents with Anxiety

The 11 configurations included PSD features from all 4 support categories. However, some category features were more often linked to iCBT program effects than others. Our findings highlight the central role of primary task supports in iCBT interventions for children and adolescents with anxiety; followed by dialogue support and system credibility support categories. Only 1 social support feature was supported by our analysis. These findings are in line with others (Lehto & Oinas-Kukkonen, 2010, 2011) who also found primary task supports to be the most frequently reported persuasive features in technology-based health interventions. As primary task support features are considered to "aid users in completing their tasks and tracking and achieving their goals" (p. 179, Lehto & Oinas-Kukkonen, 2015), they have a similar aim to the goal-directed nature of iCBT programs. Dialogue support features keep "the user active and motivated in using the system" (p. 2, Wildeboer, Kelders, & van Gemert-Pijnen, 2016) so the user has more time and opportunities to complete their intended behaviour(s) in the program. Both primary task support and dialogue support features have been linked to intervention effectiveness in previous studies in other fields (Drozd, Lehto, & Oinas-Kukkonen, 2012; Sitwat

Langrial, Lehto, Oinas-Kukkonen, Harjumaa, & Karppinen, 2012; Lehto, Oinas-Kukkonen, & Drozd, 2012).

4.4.2 Toward Explanatory PSD-Informed Models of iCBT Effects with Children and Adolescents with Anxiety

All iCBT programs in this study contained multiple PSD features. Although detailing the frequency of PSD features in iCBT provides some insight into what a user does within a program (activity), this information does not describe the important patterns or combinations of PSD features or explain why a program may or may not be effective. However, our findings suggest that (1) no one PSD feature is applied in isolation and will likely not 'work' as such (ie, some synergy is expected and essential) and (2) different PSD features have different functions, so we cannot assume that more features are better. We identified features from within and across different PSD support categories that were employed simultaneously, suggesting some synergistic or additive effect in their grouping (eg, simulation [a primary task support] + social role [a dialogue support] + similarity [a dialogue support] + social learning [a social support]). There have been attempts to examine the quantity and combination of PSD features in relation to the effectiveness of other health-based programs (Lehto & Oinas-Kukkonen, 2010, 2011; Lentferink et al., 2017; Räisänen, Lehto, & Oinas-Kukkonen, 2010; Wahle, Bollhalder, Kowatsch, & Fleisch, 2017; Wildeboer et al., 2016) but the literature is largely inconsistent and inconclusive. Wildeboer et al. (2016) indicated a positive relationship between effect sizes and the number of PSD features used in an intervention. Additive or synergistic effects between multiple features, such as simulation and rehearsal, have been reported (Räisänen et al., 2010). In contrast, other features together may negate or interfere with their persuasive potential (Räisänen et al., 2010), depending on the features and what persuasive support category they are from

(Wildeboer et al., 2016). Future studies are needed to systematically assess the use and combination of multiple features as they relate to program effects to optimize the design of programs.

Overlap with the proposed context-mechanism-outcome configurations we generated and the literature on Internet-based interventions indicate larger patterns for how these features operate. For example, others have hypothesized that self-monitoring may be used to increase user's knowledge, self-awareness and ability to monitor and manage their health (Watkins et al., 2018; Burke, Wang, & Sevick, 2011). Simulation allows users to cognitively or physically play out hypothetical situations (Fogg, 1999), such as health-related decision-making (Lieberman, 2001), to observe their effects before applying strategies to the real world (Beard, Wilson, Morra, & Keelan, 2009). In face-to-face CBT studies, rehearsal promotes skill acquisition (Luxton, McCann, Bush, Mishkind, & Reger, 2011), self-efficacy and confidence with health management techniques (Kuonanoja, Langrial, Lappalainen, Lappalainen, & Oinas-Kukkonen, 2015; Peng et al., 2009); rehearsal has been critical to the cognitive improvements found during treatment (S Langrial, Oinas-Kukkonen, Lappalainen, & Lappalainen, 2014; Morgenstern & Longabaugh, 2000; Thorpe, Hecker, Cavallaro, & Kulberg, 1987). We propose that rehearsal may have a similar function in iCBT to that in face-to-face CBT, justifying its use in iCBT programs.

The consistent incorporation of specific key PSD features (rehearsal, self-monitoring, simulation) in configurations across all program types indicates that these may be 'signature features' that appeared to be particularly effective at producing the desired effects of iCBT regardless of the program type—perhaps due to the mental (psychological) activity and the interactions (effortful, suggestive, engaging) between the user, the program content and its features they incite. Our proposed key PSD features may produce symptom reductions in iCBT

because they initiate higher-order cognitive processes, such as information recall, mental reflexivity, and future planning, much like the CBT content in these programs as well (ie, cognitive restructuring) (Dobson, 2013), that may lead to longer lasting changes in learning and behaviour. This observation supports a foundational conceptualization of persuasive systems as being a medium or tool for behaviour change (Fogg, 2002).

Differences in key PSD features may distinguish iCBT programs of one program type from another (ie, indicated prevention programs used tailoring; treatment programs used personalization). It has been recognized that user characteristics (eg, symptom severity, motivation), the focus of a program (eg, technological or therapeutic elements incorporated, the 'at risk' behaviours targeted), and expected benefits (eg, degree of reduction in anxiety) differ depending on program type (eg, universal prevention, indicated prevention, treatment) (Springer & Phillips, 2007). It may be that as the risk level and severity of symptoms of users increases from universal prevention (general population), to indicated prevention (low to high risk) to treatment programs (a diagnosed disorder), so does the program's ability to adapt to user characteristics to improve its applicability and potential effectiveness (eg, providing relevant content based on user's age; providing individual feedback on user's practice activities). We believe maintaining the program type categorization is important in future testing of the PSD-based hypotheses since this categorization may help account for the distinct design and delivery components and the measures of effectiveness used (eg, primary outcomes, instruments, significance level) across program types. Taking the unique contexts, mechanisms and outcomes across program types into consideration will also help prepare the evidence base for implementation efforts of iCBT for anxious children and adolescents, for example, identifying important aspects of delivery setting, program support, or intervention features that may

influence program effects (Hadjistavropoulos, Nugent, Dirkse, & Pugh, 2017; Mol et al., 2016; Vigerland, 2015).

4.4.3 The Context-Mechanism Relationship

Realist synthesis methods focus on uncovering both the mechanisms of a complex intervention and their relationship to context (Berwick, 2008; Craig, Dieppe, Macintyre, Michie, Nazareth, Petticrew, Health, et al., 2008; Dalkin, Greenhalgh, Jones, Cunningham, & Lhussier, 2015; Greenhalgh et al., 2009). We observed the important effect that the delivery context had on the PSD mechanisms that were included in iCBT programs, further confirming the importance of examining iCBT programs of a similar 'program type' together. For example, we found that the context of all universal prevention programs involved widespread delivery in schools, during regular class periods, to all students in attendance, by a teacher with no specialized mental health training. This aspect of context differed considerably from indicated prevention and treatment programs that had a primarily 'self-led' delivery format (ie, users could log into the program from any location at any time) where minimal, but some, Web- or email-based interaction with an adjunct support person was provided. PSD features could be affected by program contexts in a way that determined their presence or absence and the quality or how they were delivered. One example of this is that personalized feedback was provided to users only if an adjunct therapist was available to craft and deliver the message—a feature provided to users of treatment and indicated prevention programs. Another example is, in terms of iCBT practice, at-home or clinic-based delivery of programs required users to complete Web-based homework (rehearsal); whereas with some school-based, universal prevention programs, paper-based homework (non–Web-based) was assigned to users during class.

School-based universal prevention programs have aspects of context (ie, setting of program use) that are different from indicated prevention and treatment programs, making their design and delivery unique (for important considerations of school-based interventions see Langley, Nadeem, Kataoka, Stein, & Jaycox, 2010). In this study, we did not include the setting (home, clinic or school delivery) in the proposed configurations since an understanding of how this context relates to specific PSD features to affect users' anxiety did not emerge in our analyses. Yet, indications of a relationship between use setting, adjunct support and program type (eg, the self-led delivery format of treatment and indicated prevention programs) was evident, indicating that the consideration of the impact of setting in future studies is warranted.

4.4.4 Strengths and Limitations

We took a high-level perspective to develop hypotheses that may explain the effects of iCBT as a complex intervention. To our knowledge, this is the first study to systematically describe what and how PSD features may relate to symptom reductions in iCBT across programs for children and adolescents with anxiety. Although our findings may be similar to those of adult-based studies of Internet-based interventions (eg, rehearsal, Räisänen et al., 2010); self-monitoring, Watkins et al., 2018) or intuitive to researchers and developers in the iCBT field, no formal exploration of the effects of the PSD features on iCBT program outcomes for children and adolescents has previously been conducted. Our study acknowledged that there may be PSD features unique to programs designed for users within our age range (eg, social learning and peer demonstrations [simulation] seemed especially important for children and adolescents using iCBT). Previous research suggests that the age and developmental stage of program users (eg, cognitive development: autonomous thinking; socioemotional: theory of mind) can affect the acceptability of an intervention (Beidas et al., 2014; Hollis et al., 2017; Sauter, Heyne, & Michiel

Westenberg, 2009) as well as intervention features (eg, tailoring, interactivity, reinforcement) (Goh, Ang, & Tan, 2008; Orlowski et al., 2015; Radomski et al., 2019; Wozney et al., 2017), indicating there are unique iCBT design and delivery considerations to account for with children and adolescents that cannot be presupposed based on the adult literature (Cavanagh, 2010; Yardley, Spring, & Riper, 2016).

This review has several strengths. We followed established and rigorous methods for conducting and reporting realist syntheses (Pawson et al., 2004; Pawson & Tilley, 1997; Wong et al., 2016). We included diverse, high-quality evidence from published and gray literature, and used mixed-methods for our analysis. Our approach to program evaluation was *inward-looking* in that it used data from iCBT programs and its users only. This allowed us to focus our analytic efforts to uncovering the within-iCBT relationships between design and delivery feature (program contexts and mechanisms) that may produce the outcomes observed. With increasing emphasis being placed on the need for theory to guide Internet-based intervention development (Kok, Gottlieb, Bartholomew, & Parcel, 2013; Lippke & Ziegelmann, 2008; Michie & Johnston, 2012), especially theories that consider intervention content, technology and context together (Kelders, Oinas-Kukkonen, Oörni, & van Gemert-Pijnen, 2016), our findings may inform theoretical developments in the field by providing new ideas around intervention processes and elements to test in future clinical trials of program effectiveness. We took some important first steps in the theory-building process (laying a foundation of evidence) by bringing together the fragmented and diverse data of iCBT programs; attempting to clearly define and report iCBT design and delivery features; highlighting important relationships between variables (Byrne, 2013; Pawson et al., 2004); and creating generalizable hypotheses. Another strength of this study is our use of the PSD and IOM models to organize the collection, analysis, interpretation, and

presentation of data (Abbott, Foster, Marin, & Dykes, 2014). Although not applied by the original authors of the included documents, the models helped us to identify and link contexts, mechanisms and outcomes in a systematic way within and across programs.

Several challenges placed limitations on our findings. The 11 context-mechanism-outcome configurations we developed were dependent on the level of detail provided in the documents included in this synthesis. iCBT program descriptions were brief and details around therapeutic or technological features used (and associated theory or justification) were limited. Thus, the specifications of each technological (PSD) feature are not accounted for with our approach (which required a high level of abstraction) and that readers should consider that the differences within features of the same type may be just as large as the differences across feature types (eg, rehearsal activities may differ among iCBT programs but these differences are not included in our configurations). We hope the hypotheses that we have generated can be applied to more detailed studies in the future that explore this important issue. Additionally, few ineffective interventions (those that did not generate anxiety reductions) were identified for our review; therefore, we were unable to explore aspects of the delivery context or PSD features that may contribute to undesirable treatment effects with iCBT. As the dissemination and use of reporting standards (eg, Consolidated Standards of Reporting Trials–eHealth, Eysenbach, 2011) and requirements to document the design and delivery components for Internet-based interventions become more common, we may not need to rely on additional models to operationalize data for comparisons across studies. We also acknowledge that information on other factors (ie, mediators or moderators) that may affect how iCBT programs work, such as user's psychological characteristics (eg, cognitive processing style, beliefs or attitudes, skills and literacy; Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009), user engagement

(eg, adherence, satisfaction, motivation; Barello et al., 2016) or environmental and cultural influences (eg, healthcare policies, user's location, societal perceptions of health), were not included in the configurations due to the lack of or inconsistent reporting. Thus, our proposed hypotheses for how iCBT programs for children and adolescents with anxiety work provide a constructive start to understanding their function but may not be complete. For example, once we better understand user characteristics, we may be able to identify subgroups of users who respond to iCBT, or some features of it, more than others. Although organizing our findings by program types lead to a redundancy in the PSD Mechanisms in configurations across program types, this redundancy also demonstrated the similarities that are found in iCBT programs more universally. In the future, we recommend a more 'formal' consideration of program type (ie, explicitly identifying the program's targeted level of prevention) prior to designing and evaluating a program since there are important differences in the target users, program design and delivery, and outcome measures used that may have a significant impact on program effects that should not be overlooked.

4.4.5 Future Directions

As more complex and sophisticated technological mediums or delivery methods (ie, mobile phones, wearables) and features (ie, gamification, virtual reality, virtual agents) are being developed and incorporated into new technology-based treatments, we need to understand the 'first principles' for how the individual and most basic applications of PSD features in iCBT programs work so we can 'scale up' our understanding of their effects in parallel with advancing technology and the complexity of program design. This review highlights 2 recommendations for future directions in the iCBT field.

First, studies designed to assess the impact and functions of identified program components and to identify other components that are relevant for the design of new iCBT programs for children and adolescents with anxiety are needed. Evaluating *individual* program features to understand their theoretical level of action (what the feature intends to do; eg, based on CBT or the PSD model), instantiation (how the feature was executed; eg, timing, volume), quality (a distinguishing aspect of the feature; eg, degree of personalization, size or color) and their effect (the result or consequence of a feature; eg, initiating, reinforcing behaviour) (Anderson & Wallace, 2015; Klasnja, Consolvo, & Pratt, 2011; Mohr, Schueller, Montague, Burns, & Rashidi, 2014; Mohr et al., 2015), may provide insights into what the most persuasive features are and how they can be deliberately combined to support users' desired behaviour change.

Evaluation of individual features require the use of certain methodological frameworks (eg, see Mohr, Cheung, Schueller, Brown, & Duan, 2013; van Gemert-Pijnen et al., 2011) and study designs that allow for more timely feedback, iteration, and fewer resources for testing (ie, participants, multiple healthcare centres, funds). For example, modelling and predictor analyses (Greenland & Brumback, 2002; Kline, 2011), multi-factorial designs (Collins, Dziak, & Li, 2009; Collins, Dziak, Kugler, & Trail, 2014; Dziak, Nahum-Shani, & Collins, 2012), trials with multiple treatment arms (Freidlin, Korn, Gray, & Martin, 2008), adaptive evaluation strategies (ie, the multiphase optimization strategy; Almirall, Nahum-Shani, Sherwood, & Murphy, 2014; Collins, Murphy, & Strecher, 2007), or the use of mixed methods and the triangulation of data (Creswell, 2014; Fielding, 2012) may be attractive alternatives to standard clinical trials (for more suggestions see Chow & Chang, 2008).

Second, to advance our understanding of the causal mechanisms that underpin effective iCBT programs we will need to address what and how therapeutic content (ie, CBT skills) is delivered using PSD (technology-based) features to produce the intended and actual attitude and/or behaviour changes. This will involve developing a framework that integrates the PSD model with the CBT framework and a theory of behaviour change (for a review of theories see Davis, Campbell, Hildon, Hobbs, & Michie, 2015) to identify specific combinations of therapeutic content and technological features designed to help users meet their health goals. A holistic framework by Wang et al. (2018) combines behavioural theories and the PSD model to provide a starting point for more theoretical and comprehensive designing, reporting and evaluation of persuasive systems.

4.5 Conclusions

Although iCBT effectiveness for children and adolescents with anxiety has been demonstrated, not all programs benefit users in the same way. This leaves room for programs to be further optimized. PSD (technological) features can be intentionally selected and incorporated into the design and delivery of iCBT programs, making it an aspect of treatment that is under the control of developers. The hypotheses that we generated suggest that multiple key PSD features may work together to help users actively engage with therapeutic content, and practice newly acquired skills. The type and degree of adjunct support will vary based on the level of prevention and user characteristics (ie, symptom severity) the program was designed to target, and can influence what and how certain features operate in the program. The key PSD features and aspects of context identified require formal testing to understand whether and to what extent they are effective and how they function. These next steps may involve new conceptualizations of effectiveness and evaluation methods. As we improve our understanding of how the components

of iCBT work (their proposed purpose), and what users prefer and need, we can create programs with better objective and subjective effectiveness. This systematic and deliberate approach to iCBT design and evaluation will increase the pool of evidence-based interventions available to prevent and treat children and adolescents with anxiety.

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Conflicts of Interest

None declared.

Abbreviations

AACAP: American Academy of Child and Adolescent Psychiatry

CBT: cognitive behavioral therapy

iCBT: Internet-based cognitive behavioural therapy

IOM: Institute of Medicine

MMAT: mixed-method appraisal tool

PSD: persuasive systems design

Appendix 4.1. The persuasive systems design (PSD) model.

PSD feature	Description	iCBT program example
Primary Task Supports: Assists the user in completing their target behaviour		
Reduction	Reduces complex behaviour into simple tasks	Individual sections of the program will be made available to participants each week to prevent participants completing the program prematurely (Calear, Christensen, Griffiths, et al., 2013)
Tunneling	Guides a user through a process or experience	Modules follow the same general format: instructional presentation, followed by new skill practice, then a final quiz (Baker, 2010)
Tailoring	Tailors the experience to the potential needs, interests, personality or use context	Five versions of the treatment program were created and each one was adapted, through psychoeducation and examples, to fit a specific anxiety disorder (Silfvernagel et al., 2015)
Personalization	Personalizes content	Therapist constructs a brief feedback e-mail to the user after each session (Spence et al., 2011)
Self-monitoring	Keeps track of the user's performance or status towards goal achievement	Mood quizzes are completed at the beginning of each module and at the end of the program (Calear et al., 2009)
Simulation	Provides simulations to enable the user to observe link between cause and effect	Users follow a cartoon based storyline of teenagers with anxiety or depression solve real life problems (Wong et al., 2014)
Rehearsal	Provides a way for the user to rehearse a skill or task	The program provides opportunities to apply strategies to own example; it also includes quizzes and homework exercises (Calear et al., 2009)
Dialogue Supports: Provides computer-human communication to guide user toward target behaviour		
Praise	Offers praise as a form of feedback	Upon completion of a session, users are sent an automatic email from their therapist congratulating them on finishing their session (Spence et al., 2008)
Rewards	Rewards target behaviour	Participants received a diploma at the end of the treatment (Shahnavaz, 2016)
Reminders	Reminds the user of their target behaviour	Automatic email reminders were sent when participants had not completed the next session within one week (March, Spence, & Donovan, 2009)

Suggestion	Offers fitting suggestions	If the user reports high symptoms, specific services are recommended by the program (Calear et al., 2009)
Similarity	Reminds the user of themselves in some meaningful way	The language was adapted to suit the age group (Silfvernagel et al., 2015)
Liking	Is visually attractive for the user	Eye-catching graphics, sounds, games, and quizzes are used to maintain the adolescents' level of interest (Spence et al., 2011)
Social role	Adopts a social role	Users could send written messages to their therapist at any time during treatment (Vigerland et al., 2013)
System Credibility Supports: System design features increase user's perceptions of credibility		
Trustworthiness	Provides information that is truthful, fair and unbiased	Evidence-based information and strategies provided (Calear, Christensen, et al., 2016)
Expertise	Provides information showing knowledge, experience, and competence	The role of the psychologist was to answer questions and clarify treatment content, increase motivation and to help solve problems if necessary (Vigerland, Ljótsson, et al., 2016)
Surface credibility	Has a competent look and feel	The program was visually appealing and interesting with minimal amount of text per page (Spence et al., 2008)
Real-world feel	Provides information of the actual people behind its content and services	A brief biography of the program therapist was provided to users (Spence et al., 2006)
Authority	Refers to people in the role of authority	Each module asks the user to practice the strategies presented and review progress with their coach (Currie et al., 2010)
3rd party endorsement	Provides endorsements from other sources	Logos of academic affiliations were located on the website (Calear et al., 2009)
Verifiability	Provides means to verify the accuracy of the program via outside sources	A dental professional offered training and exposure at the clinic alongside the therapist's web-based guidance (Shahnavaz, 2016)
Social Supports: Leverages the interactions and influence of others		
Social learning	Can use the system to observe others performing tasks or behaviour	"Brave Buddy" is a cartoon character that provides a "model" in the use of anxiety coping strategies (Spence et al., 2008)
Social comparison	Can use the system to compare their performance to performance of others	Users can see the average score of their peers on a mood questionnaire

Normative influence	Leverages normative influence or peer pressure	User testimonials provided on the program website
Social facilitation	User discerns via the system that others are performing the behaviour along with them	Avatars indicate users currently active in the program
Cooperation	Leverages drive to cooperate to complete a task or behaviour	Peer forum allows users to share coping strategies
Competition	Leverages drive to compete against others in completing a task or action	Users challenge an animated character in a quiz
Recognition	Offers public recognition for a user or group	Program completion ‘status’ is shared to social media

Appendix 4.2. The candidate context-mechanism-outcome configurations.

User characteristics	iCBT delivery context	PSD mechanism	Anxiety outcome
Children and/or adolescents with mild-to-moderate anxiety symptoms or an anxiety disorder(s)	Adjunct therapist, parent and/or professional support	Tailoring	Reduction in symptoms
Children and/or adolescents with mild-to-moderate anxiety symptoms or an anxiety disorder(s)	Adjunct therapist, parent and/or professional support	Personalization	Reduction in symptoms
Children and/or adolescents with mild-to-moderate anxiety symptoms or an anxiety disorder(s)	Adjunct therapist, parent and/or professional support	Self-monitoring	Reduction in symptoms
Children and/or adolescents with mild-to-moderate anxiety symptoms or an anxiety disorder(s)	Adjunct therapist, parent and/or professional support	Simulation + Social learning	Reduction in symptoms
Children and/or adolescents with mild-to-moderate anxiety symptoms or an anxiety disorder(s)	Adjunct therapist, parent and/or professional support	Rehearsal	Reduction in symptoms
Children and/or adolescents with mild-to-moderate anxiety symptoms or an anxiety disorder(s)	Adjunct therapist, parent and/or professional support	Suggestions	Reduction in symptoms
Children and/or adolescents with mild-to-moderate anxiety symptoms or an anxiety disorder(s)	Adjunct therapist, parent and/or professional support	Similarity + Liking	Reduction in symptoms
Children and/or adolescents with mild-to-moderate anxiety symptoms or an anxiety disorder(s)	Adjunct therapist, parent and/or professional support	Social role + Expertise	Reduction in symptoms

Appendix 4.3. Electronic database search strategy.

1. Cellular Phone/
2. Computers/
3. Electronic Mail/
4. Internet/
5. Text Messaging/
6. Therapy, Computer-Assisted/
7. (android* or apps or cell* phone* or cellphone* or computer* or digital* or e health* or ehealth* or e mail* or email* or electronic mail* or internet* or iPad* or iPhone* or iPod* or m health* or mhealth* or mobile* or online* or personal digital assistant* or short messag* or smart phone* or smartphone* or technolog* or text messag* or virtual* or web*).tw.
8. or/1-7 [Combined MeSH and keywords for internet based technologies]
9. Behavior Therapy/
10. exp Cognitive Therapy/
11. Disease Management/
12. exp Directive Counseling/
13. Persuasive Communication/
14. Problem Solving/
15. Psychotherapy/
16. Self Care/
17. acceptance adj commitment therap*.tw.
18. (behavio* adj (activation or condition* or modif* or therap*)).tw.
19. CBT.tw.
20. cognitive therap*.tw.
21. directive counsel*.tw.
22. interpersonal therap*.tw.
23. mental health program*.tw.
24. mindfulness.tw.
25. motivational interview*.tw.
26. problem solving*.tw.
27. psychotherap*.tw.
28. (selfcar* or self car* or selfhelp* or self help* or selfmanage* or self manage* or selfmonitor* or self monitor*).tw.
29. telemental health*.tw.
30. or/9-29 [Combined MeSH and keywords for CBT]
31. Anxiety/
32. Anxiety Disorders/
33. Depression/
34. Depressive Disorder/
35. Mental Disorders/
36. Mood Disorders/
37. (anxi* or behavio?r* disorder* or behavio?r* problem* or depress* or mental disorder* or mental health* or psychiatric illness* or psychiatric disease* or psychiatric disorder*).tw.
38. or/31-37 [Combined MeSH and keywords for anxiety]
39. and/8,30,38 [Combined results for internet based technologies, CBT and anxiety searches]

Appendix 4.4. The level of contribution and methodological quality of documents included in the synthesis.

Document	Document type and study design	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
Program 1: BRAVE-Online for children and adolescents					
(Spence et al., 2006)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Spence et al., 2008)	Published study; Quantitative descriptive	High	High	Medium	100%
	Published study; Quantitative descriptive	High	High	Medium	100%
(March, 2008)	Thesis; Quantitative randomized	High	Medium	Medium	100%
	Thesis; Quantitative randomized	High	High	High	100%
(March et al., 2009)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Spence et al., 2011)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Spence, 2011a)	Registered protocol; Quantitative non-randomized	Medium	Low	N/A	N/A
(Spence, 2011b)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Spence, 2011c)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Anderson et al., 2012)	Published study; Quantitative non-randomized	Medium	Medium	N/A	N/A
(Stasiak, 2012)	Registered protocol; Quantitative randomized	Low	Low	N/A	N/A
(Moor, 2012)	Registered protocol; Quantitative descriptive	Low	Low	N/A	N/A
(Stasiak et al., 2016)	Published study; Quantitative non-randomized	High	High	N/A	N/A
(Spence et al., 2017)	Published study; Quantitative randomized	High	High	High	50%

Document	Document type and study design	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
(Conaughton et al., 2017)	Published study; Quantitative randomized	High	High	High	75%
(March et al., 2018)	Published study; Quantitative descriptive	High	High	High	75%
(Moor et al., 2019)	Published study; Quantitative descriptive	Low	Medium	Medium	75%
(Spence, 2017)	Program website; N/A	Low	Low	N/A	N/A
Program 2: iCBT for children with anxiety disorders for children and adolescents with dental anxiety					
(Shahnavaz, 2015)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Shahnavaz, 2016)	Thesis; Quantitative non-randomized	Medium	High	High	75%
(Shahnavaz et al., 2018)	Published study; Quantitative descriptive	Medium	High	Medium	100%
Program 3: Internet-delivered CBT for children with anxiety disorders					
(Serlachius, 2012)	Registered protocol; Quantitative non-randomized	Low	Low	N/A	N/A
(Stockholm's child and adolescent psychiatry research group [BUP], 2013)	Program website; N/A	Low	Low	N/A	N/A
(Serlachius, 2014)	Registered protocol; Quantitative non-randomized	Low	Low	N/A	N/A
(Serlachius, 2015b)	Registered protocol; Quantitative randomized	Low	Low	N/A	N/A
(Vigerland, 2015)	Thesis; Quantitative randomized	High	Medium	Medium	75%
	Thesis; Quantitative non-randomized	High	Medium	High	100%
(Vigerland, 2016)	Registered protocol; Quantitative non-randomized	Low	None	N/A	N/A
(Vigerland et al., 2016)	Published study; Quantitative randomized	High	Medium	Medium	75%

Document	Document type and study design	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
(Vigerland et al., 2017)	Published study; Quantitative non-randomized	High	High	High	100%
(Jolstedt et al., 2018)	Published study; Quantitative randomized	Medium	Medium	High	100%
Program 4: Internet-delivered CBT for children with specific phobia					
(Vigerland et al., 2013)	Published study; Quantitative non-randomized	High	Medium	Medium	100%
Program 5: The Chilled Out program					
(Stjerneklar et al., 2014)	Conference poster; N/A	Low	Low	N/A	N/A
(University of Aarhus, 2015)	Registered protocol; Quantitative descriptive	Low	Low	N/A	N/A
(Nielsen et al., 2016)	Conference abstract; Quantitative descriptive	Low	Low	N/A	N/A
(Stjerneklar et al., 2017)	Conference poster; Quantitative descriptive	Low	Low	Low	100%
(Stjerneklar et al., 2018)	Published study; Mixed methods	Medium	Medium	High	100%
(Stjerneklar et al., 2019)	Published study; Quantitative descriptive	Low	Medium	N/A	N/A
(Centre for Emotional Health, 2014)	Study flyer; N/A	Low	Low	N/A	N/A
(Macquarie University, n.d.)	Program website; N/A	Low	Low	N/A	N/A
Program 6: Group therapy supported iCBT for adolescents with social anxiety disorder					
(Serlachius, 2015a)	Registered protocol; Quantitative descriptive	Low	Low	N/A	N/A
(Nordh et al., 2017)	Published study; Quantitative descriptive	Medium	High	Medium	100%
(Stockholm's child and adolescent psychiatry research group [BUP], 2015)	Program website; N/A	Low	Low	N/A	N/A

Document	Document type and study design	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
Program 7: iCBT for anxiety disorders among adolescent girls					
(Karbasi & Haratian, 2018)	Published study; Quantitative randomized	Low	Low	Medium	25%
(Vivyan, 2015)	Program website; N/A	Low	Low	N/A	N/A
Program 8: Internet cognitive-behavioural skills-based program					
(Keller, 2009)	Published study; Quantitative randomized	High	High	High	100%
(Keller, 2009)	Program website; N/A	Low	Low	N/A	N/A
(Keller & Craske 2009)	Study flyer; N/A	Low	Low	N/A	N/A
Program 9: Internet-supported brief CBT for shy-socially isolated problem					
(Ramdhani et al., 2015)	Published study; Quantitative non-randomized	Low	Low	Medium	50%
Program 10: STAY COOL system for test anxiety					
(Baker, 2010)	Thesis; Quantitative randomized	High	High	High	75%
Program 11: Feeling Better					
(Currie et al., 2010)	Published study; Qualitative	High	High	N/A	100%
(Bradley et al., 2012)	Published study; Mixed methods	Medium	Low	Low	100%
Program 12: Individually tailored iCBT for adolescents					
(Silfvernagel et al., 2015)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Silfvernagel, 2017)	Thesis; Quantitative randomized	High	Medium	Low	100%
Program 13: The e-couch Anxiety and Worry Program					
(Calear, 2010)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Calear, Christensen, Griffiths et al., 2013)	Registered protocol; Quantitative randomized	High	High	N/A	N/A

Document	Document type and study design	Relevance			Rigor
		Level of Contribution			MMAT Score
		Context	Mechanism	Outcome	
(Calear, Christensen et al., 2016)	Published study; Quantitative randomized	High	High	High	50%
(Calear, Batterham et al., 2016)	Published study; Quantitative randomized	High	High	Medium	50%
(Griffiths, Tayler, & Christensen, n.d.)	Program website; N/A	Low	Low	N/A	N/A
Program 14: MoodGYM					
(Calear et al., 2009)	Published study; Quantitative randomized	High	Medium	Medium	100%
(Calear, Christensen, Mackinnon, & Griffiths, 2013)	Published study; Quantitative randomized	Medium	High	High	100%
(Christensen & Griffiths, n.d.)	Program website; N/A	None	None	N/A	N/A
Program 15: Thiswayup Schools for Anxiety and Depression prevention courses					
(Andrews, 2012)	Registered protocol; Quantitative randomized	Medium	Low	N/A	N/A
(Wong et al., 2014)	Published study: Quantitative randomized	Low	Low	Medium	50%
(Andrews & St. Vincent's Hospital, n.d.)	Program website; N/A	None	Low	N/A	N/A

Appendix 4.5. Overview of the pre-intervention to post-intervention changes in anxiety (Outcomes) based on the total number of measures, studies, and iCBT programs across program types.

Change in anxiety, pre- to post-intervention	Anxiety measures			
	User-reported symptoms	**Parent-reported symptoms**	**Diagnosis**	**Clinical severity**
Treatment programs 1, 2, 3, 4, 5, 6, 7				
Reductions in anxiety for iCBT participants	22 measures used across 19 studies of programs 1, 2, 3, 4, 5, 6, 7 (Conaughton et al., 2017; Jolstedt et al., 2018; Karbasi & Haratian, 2018; March, 2008; March et al., 2018, 2009; Moor et al., 2019; Nordh et al., 2017; Shahnavaz, 2016; Shahnavaz et al., 2018; Spence et al., 2017; Spence et al., 2011, 2006, 2008; Stjerneklar et al., 2019; Vigerland, 2015; Vigerland et al., 2013, 2017; Vigerland, Ljótsson, et al., 2016)	17 measures used across 17 studies of programs 1, 2, 3, 4, 5, 6 (Conaughton et al., 2017; Jolstedt et al., 2018; March, 2008; March et al., 2009; Moor et al., 2019; Shahnavaz, 2016; Shahnavaz et al., 2018; Spence et al., 2017; Spence et al., 2011, 2006, 2008; Nordh et al., 2017; Stjerneklar et al., 2017, 2019; Vigerland, 2015; Vigerland et al., 2013, 2017; Vigerland, Ljótsson, et al., 2016)	20 measures used across 18 studies of programs 1, 2, 3, 4, 5, 6 (Conaughton et al., 2017; Jolstedt et al., 2018; March, 2008; March et al., 2009; Shahnavaz, 2016; Shahnavaz et al., 2018; Nordh et al., 2017; Spence et al., 2017; Spence et al., 2011, 2006, 2008; Stjerneklar et al., 2017; Vigerland, 2015; Vigerland et al., 2013, 2017; Vigerland, Ljótsson, et al., 2016)	16 measures used across 15 studies of programs 1, 3, 4, 6 (Conaughton et al., 2017; Jolstedt et al., 2018; March, 2008; March et al., 2009; Nielsen et al., 2018; Nordh et al., 2017; Spence et al., 2017; Spence et al., 2008, 2011, 2006; Stjerneklar et al., 2017; Vigerland et al., 2013; Vigerland, 2015; Vigerland, Ljótsson, et al., 2016; Vigerland et al., 2017)
Increases in anxiety for iCBT participants	1 measure used in 1 study of program 1 (Spence et al., 2008)	—	—	—
Indicated prevention programs 8, 9, 10, 11, 12				
Reductions in anxiety for iCBT participants	4 measures used across 4 studies of programs 9, 10, 11, 12 (Baker, 2010; Bradley et al., 2012;	1 measure used in 1 study of program 8 (Keller, 2009)	2 measures used in 2 studies of programs 8, 12 (Keller, 2009; Silfvernagel, 2017;	—

	Ramdhani et al., 2015; Silfvernagel, 2017; Silfvernagel et al., 2015)		Silfvernagel et al., 2015)	
Universal prevention programs 13, 14, 15				
Reductions in anxiety for iCBT participants	9 measures used across 5 studies of programs 13, 14, 15 (Calear, Batterham, Poyser, et al., 2016; Calear, Christensen, et al., 2016; Calear, Christensen, Mackinnon, & Griffiths, 2013; N. Wong et al., 2014)	—	—	—
Increases in anxiety for iCBT participants	1 measure used in 1 study of program 10 (Calear, Batterham, Poyser, et al., 2016)	—	—	—

iCBT: Internet-based cognitive behavioural therapy

Note: Multiple outcome measures may have been used in a single study. Also, some subgroup analyses were conducted. Please refer to individual studies for the results of each outcome measure.

Note: If two studies shared a partial or full dataset, results were counted as a single study, but both documents were cited. If one document contained two separate studies, two studies were reported but one document was cited.

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Chapter 5

Examining the usage, user experience and perceived impact of an Internet-based cognitive behavioural therapy program for adolescents with anxiety: Results from a randomized controlled trial

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Abstract

Background: Internet-based cognitive behavioural therapy (iCBT) increases access to treatment for adolescents with anxiety; however, many participants do not complete these programs. Understanding adolescents' program experiences may help explain and improve iCBT use and effectiveness based on program features and changes in anxiety (minimal clinically important difference; MCID) that are meaningful to users.

Objectives: Within a randomized controlled trial comparing a 6-session iCBT program for adolescent anxiety ('*Breathe*') to anxiety-based resource webpages, we aimed to: describe *Breathe* and webpage usage; describe and compare *Breathe* and webpage user experiences; calculate a user-defined MCID for anxiety symptoms; and among *Breathe* users, explore relationships between usage, experiences, and perceived changes in anxiety.

Methods: Enrolled adolescents, aged 13-19 years with mild-to-moderate anxiety, were randomly allocated to the interventions. Adolescents reported demographics and anxiety symptoms (Multidimensional Anxiety Scale for Children-2nd edition [MASC-2]) prior to intervention use. After intervention use, they reported symptoms, experiences (User Experience Questionnaire for Internet-based Interventions: satisfaction, acceptability, credibility, impact, adherence and usage), perceived change in anxiety (global ratings of change scale [GRCS]), and intervention use (number of *Breathe* sessions completed, webpages visited). We used descriptive statistics to summarize usage and experience outcomes, and independent sample t-tests, Pearson, Spearman or point-biserial correlations to test relationships between them. To calculate the MCID, we used MASC-2 mean change scores among adolescents reporting "somewhat better" anxiety on the GRCS.

Results: Adolescents (n=536) were mostly female (71.3%), aged 16.6 years (standard deviation [SD] 1.7) with 'very elevated' anxiety symptoms (Mean 92.2, SD 18.1). Intervention usage was low for adolescents allocated to *Breathe* (Mean 2.2 sessions, SD 2.3; n=258) and webpages (Mean 2.1 visits, SD 2.7; n=278). *Breathe* use was higher among the adolescents who reported their user experience after intervention use (*Breathe*: Median 6.0, Range 1-6, n=81/258; webpages: Median 2.0, Range 1-9, n=148/278). The total user experience was more positive for *Breathe* users than the webpage users ($P<.001$) and was correlated with *Breathe* use ($P's<.05$). Adolescents who used *Breathe* reported time constraints and program delivery factors (exposure activities, program support) as challenges to use. Program design features (surveys, graphs, videos) and learning activities (self-management skills) contributed to adolescents' enjoyment of *Breathe*. The MCID was determined to be a mean MASC-2 change score of 13.8 (SD 18.1). Using the MCID, 43% (n=35/81) of *Breathe* users were considered 'treatment responders'. Treatment response was not correlated with user experience scores or *Breathe* use ($P's>0.05$).

Conclusions: Overall, *Breathe* users reported positive experiences and changes in their anxiety following iCBT. *Breathe* program use was related to adolescents' reported iCBT experiences but not their treatment response. Users identified program design, activity and delivery factors that may influence their iCBT experience and use. Future studies can apply our measures to compare user experiences between Internet-based interventions, interpret treatment outcomes, optimize program development, and improve treatment decision-making for adolescents with anxiety.

5.1 Introduction

Anxiety disorders are the most prevalent mental health concern in children and adolescents, affecting about 8-11% of youth (Costello, Mustillo, Erkanli, Keeler, & Angold, 2003; Georgiades et al., 2019; Waddell, Offord, Shepherd, Hua, & McEwan, 2002). Children and adolescents with anxiety disorders are at increased risk of academic and social difficulties and have an increased likelihood of developing secondary anxiety disorders and depression (Essau, 2003; Kim-Cohen et al., 2003). There is strong research evidence supporting the efficacy of cognitive behaviour therapy (CBT) as first line treatment of mild-to-moderate child and adolescent anxiety disorders with numbers needed to treat (NNT) ranging from 3 to 6, but also some evidence that CBT is not significantly more effective than active control with support and education materials (James, James, Cowdrey, Soler, & Choke, 2015; James, Soler, & Weatherall, 2005). Understanding options for treatment delivery and for whom it may be best suited is a key area in CBT research as face-to-face CBT is not always accessible (Olthuis, Watt, Bailey, Hayden, & Stewart, 2016) and there are high drop-out rates of children and adolescents in traditional outpatient therapy treatment, ranging from 20-70% (De Haan, Boon, de Jong, Hoeve, & Vermeiren, 2013).

Internet-based cognitive behavioural therapy (iCBT), with its self-help format, can increase the access and availability of cognitive behavioural therapy (CBT) for adolescents with mild-to-moderate anxiety (Grist, Croker, Denne, Stallard, & Stallard, 2018; Orlowski et al., 2016). Recent systematic reviews and meta-analyses demonstrate that in reducing anxiety in adolescents, iCBT has comparable effectiveness to traditional, face-to-face CBT (Grist et al., 2018; Pennant et al., 2015; Rooksby, Elouafkaoui, Humphris, Clarkson, & Freeman, 2015; Ye et al., 2014) and is more effective than waiting for treatment (Ebert et al., 2015; Grist et al., 2018;

Hollis et al., 2017; Pennant et al., 2015; Podina, Mogoase, David, Szentagotai, & Dobrean, 2016; Vigerland, Lenhard, et al., 2016). Unlike face-to-face CBT where treatment may involve use of a workbook and in-person meetings with a therapist, iCBT provides therapeutic content and strategies through structured modules and activities (online or offline) that involve the use of multimedia (eg, video, audio) and other technological features (eg, drop-down response menus, animated demonstrations, interactive quizzes) (Andersson & Titov, 2014; Barak, Klein, & Proudfoot, 2009). Use of iCBT can be self-led or therapist-guided (synchronous or asynchronous support provided during use) and programs can include varied levels of additional communication, such as reminder emails or follow-up phone calls, to encourage use, troubleshoot issues or deliver feedback to users during the program.

Evaluations of adolescent experiences with various iCBT delivery and content formats have revealed 'good' program usability (eg, program had few errors; it was easy to learn to use) (Currie, Mcgrath, & Day, 2010; Patwardhan, 2016; Stoll, Pina, Gary, & Amresh, 2017; Wozney, Baxter, & Newton, 2015), moderate-to-strong credibility (eg, the program contained expert and reliable information), promising treatment expectancy (eg, users' expressed confidence in the benefits of the program) (Bradley, Robinson, & Brannen, 2012; Jolstedt et al., 2018; March, Spence, & Donovan, 2009; Spence et al., 2008, 2011; Spence, Holmes, March, & Lipp, 2006; Wozney et al., 2015), as well as moderate-to-high rates of satisfaction and acceptability (eg, users considered the content relatable; users would recommend the program to others) (Gerrits, van der Zanden, Visscher, & Conijn, 2007; March et al., 2009; Spence et al., 2006). Yet low usage patterns have been consistently reported in the literature with typically more than 50% of participants not completing an iCBT program as part of a research study (Christensen, Griffiths, & Farrer, 2009; Clarke, Kuosmanen, & Barry, 2014; Richardson, Stallard, & Velleman, 2010;

Rooksby et al., 2015; Vigerland, Lenhard, et al., 2016). These discordant outcomes contribute to a lack of clarity about how program usability, credibility, satisfaction, and usage relate to each other as part of an adolescent's iCBT experience.

Other aspects of the user experience, such as psychosocial barriers and facilitators to program usage, adolescents' perceived program impacts (eg, perceived effects on health outcomes) and adolescents' identification of the minimum change in anxiety symptoms that they would want to experience after completing an iCBT program (the minimal clinically important difference [MCID]; Jaeschke, Singer, & Guyatt, 1989), have not been explored. Yet, these aspects can deepen the understanding of how adolescent users of iCBT perceive programs and experience their use in day-to-day life. Establishing a MCID for the change in anxiety symptoms experienced following a program provides a preferred treatment effect among adolescent users (Guyatt et al., 2002). An adolescent-defined MCID could be used for user-centred treatment planning and to help advance methodological approaches in studies of iCBT effectiveness to guide the estimation of treatment effects (Guyatt et al., 2002; Jaeschke et al., 1989; Neely et al., 2007).

We conducted a prospective study of iCBT user experiences in the context of a large-scale randomized controlled trial (RCT). In this trial we evaluated the effectiveness of an iCBT program, *Breathe*, in reducing anxiety symptoms among adolescents aged 13-19 years as compared to webpages detailing anxiety resources ('resource-based webpages'; a usual self-help intervention). We had 4 objectives for the user experience study: (1) To determine the adolescents' usage of the *Breathe* program and resource-based webpages; (2) To define the adolescents' user experiences with the *Breathe* program and the resource-based webpages, and examine whether experiences differ between program and webpage use; and (3) To have

adolescent users of the *Breathe* program define a MCID for anxiety symptoms, the primary health outcome measured in the trial, after program use; and (4) To explore relationships among the user experiences, program usage, and the MCID among those adolescents who used the *Breathe* program. The overall intent of these objectives was to examine self-reported user experience data and automatically-captured program usage data together for a better understanding of the relationship between behavioural (objective usage) and experiential data (subjective usage, user experience, MCID) (Graham, Strawderman, Demment, & Olson, 2017; Kelders, Van Gemert-Pijnen, Werkman, Nijland, & Seydel, 2011; Mattila et al., 2016) to explain and improve iCBT outcomes.

5.2 Methods

5.2.1 Study design

The RCT was conducted across Canada. We embedded user experience outcome measures (user experience, MCID) and automatically captured intervention data (usage) into pre- and post-intervention time points of the trial. The Research Ethics Boards at the University of Alberta approved the trial (ClinicalTrials.gov Identifier: NCT02970734). The trial commenced November 21, 2016 and the final date of data collection was November 22, 2018.

5.2.2 Participant recruitment and eligibility

Adolescents were recruited for trial participation between November 21, 2016 and July 1, 2018. Recruitment was conducted through the trial's social media platforms (Facebook, Twitter, Tumblr, and Instagram) with posts and paid ads across Canada, and through healthcare professionals who provided study pamphlets to prospective participants seeking mental health care in specialty care clinics, primary care clinics and schools in Edmonton, Alberta; Hamilton, Ontario; and Halifax, Nova Scotia. Ads and pamphlets directed adolescents to view the trial

website (www.thebreathestudy.com), which provided details on the trial including eligibility criteria and the screening and enrolment process, information on anxiety, and the research team's contact information.

Adolescents interested in participation were screened for eligibility using a secure web-based application, Research Electronic Data Capture (REDCap). Inclusion criteria were: (i) a minimum score of ≥25 on the Screen for Child Anxiety Related Disorders (SCARED) (Birmaher et al., 1997) indicating the presence of clinical anxiety symptoms, (ii) the ability to read and write English, (iii) regular access to a telephone and a computer system with high speed Internet service, and (iv) the ability to use the computer to interact with web material. Adolescents were ineligible for participation if they: (i) screened as high-risk for self-harm via 4 items from the Ask Suicide-Screening Questionnaire (ASQ) (Horowitz et al., 2012) (a 'yes' answer to thoughts about killing oneself in the past week or a prior attempt), (ii) indicated the possible presence of a psychosis-related disorder via the 5-item Schizophrenia Test and Early Psychosis Indicator (STEPI) (Mulhauser, 2011) (an affirmative response to any item), (iii) screened positive for harmful and/or hazardous alcohol consumption via the 3-item Alcohol Use Disorders Identification Test Consumption subscale (AUDIT-C) (Saunders, Aasland, Babor, de la Fuente, & Grant, 1993) (a score of ≥3 for females; ≥4 for males), or (iv) resided outside of Canada. Ineligible adolescents were provided with suggestions for crisis services and other helplines (ie, Canadian Association for Suicide Prevention and Kids Help phone) and websites where evidence-based information on alcohol use, psychosis, and self-harm was available.

5.2.3 Procedures for informed consent and assent

The consent/assent process took place in REDCap. Adolescents were provided an information sheet on the trial and asked several yes/no questions to ensure consent/assent was

informed. Those aged 15 to 17 years were able to consent to the study on their own behalf; adolescents aged 13 and 14 years required online parental consent in addition to their assent to participate. Parental consent followed the same online process described for adolescents. Once consent and assent were obtained, adolescents were enrolled in the trial and randomly assigned using a computer-generated sequence to either the *Breathe* program or the resource-based webpages.

5.2.4 The Breathe program

The *Breathe* program for mild-to-moderate anxiety symptoms among adolescents is described in detail elsewhere (Newton et al., 2016). In brief, the program was delivered via IRIS (Intelligent Research Intervention Software), a secure, password-protected website. The program consisted of 6 iCBT sessions with each requiring approximately 30 minutes to complete; it was suggested that participants complete one session per week. Each *Breathe* session included four components. 'Check-in' involved adolescents rating their social-emotional functioning over the past week and indicating whether they had thoughts of self-harm or harming others. Check-in served as a risk management strategy. If a safety issue was flagged (eg, decompensation in anxiety symptoms between sessions, thoughts of self-harm), there was a trigger in IRIS to notify the Research Assistant to contact the adolescent (and potentially the parent(s) depending on the concern) by phone within 36 hours to assess whether the adolescent required more immediate care and provide resources to emergent or non-emergency resources. A safety video that included recommendations for immediate safety planning was also provided to adolescents. The 'Discover' component of the program introduced the session's key topics. 'Check-out' involved adolescents reflecting on their responses to session content. 'Try Out' outlined activities for

practicing the session's key concepts and skills prior to the next session. An overview of session content is provided in Table 1 and Figures 1-4 provide screenshots of the *Breathe* program.

Table 5.1. An overview of the content presented in the 6 sessions of the *Breathe* program.

SESSION	CONTENT COVERED	DESCRIPTION
1	Psychoeducation	• Introduction to the *Breathe* program • Psychoeducational information on anxiety and symptoms (eg, "fight or flight" response, normalization of anxiety) and how cognitive behavioural therapy can be used to treat these symptoms
2	Avoiding avoidance Constructing a fear hierarchy	• Identifying avoidant behaviour that might be fueling anxiety • Strategies for how to avoid avoiding (creating a rewards list) • Planning for how to face your worries ('exposure' activities)
3	Relaxation skills	• Presentation and practice of common relaxation strategies (eg, deep breathing, visualization, progressive muscle relaxation)
4	Cognitive distortions	• Identifying thinking traps • Understanding the 'thoughts-feelings-actions' cycle • Practice strategies to break out of thinking traps
5	Realistic thinking	• Recognizing unrealistic beliefs (eg, perfectionistic, control) and learning strategies for positively reframing them (eg, catch-challenge-change)
6	Fear hierarchy practice Concept integration Relapse prevention	• Completing exposure activities • Summarizing concepts learned in the *Breathe* program • Planning for the future and maintaining gains

Figure 5.1. A screenshot of a 'Check-in' activity within the *Breathe* program.

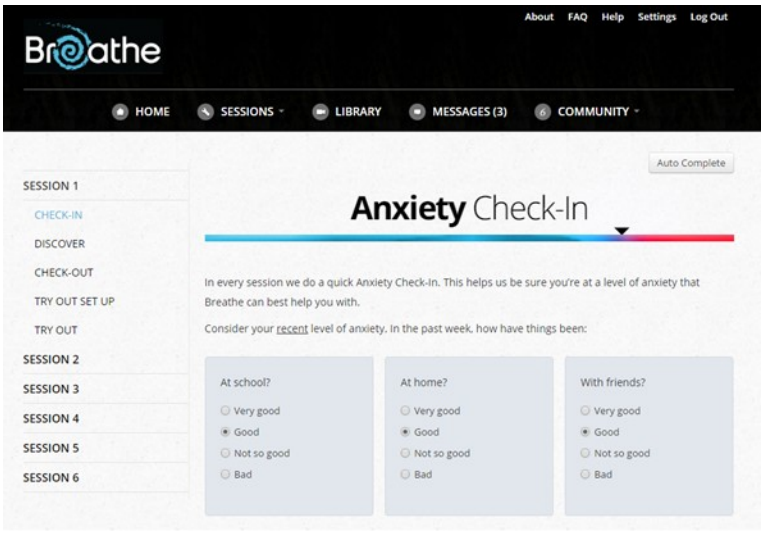


Figure 5.2. A screenshot of the 'Discover' section within the *Breathe* program.

Figure 5.3. A screenshot of the 'Check-out' activity within the *Breathe* program.

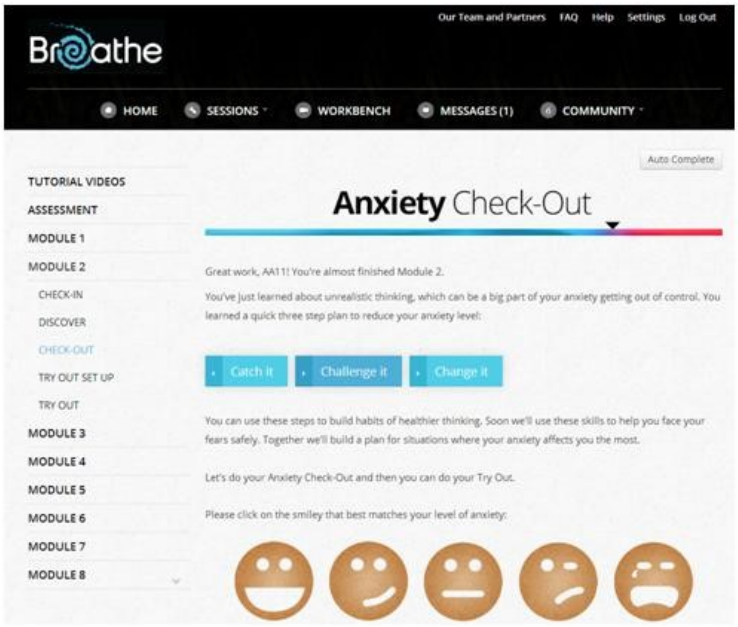
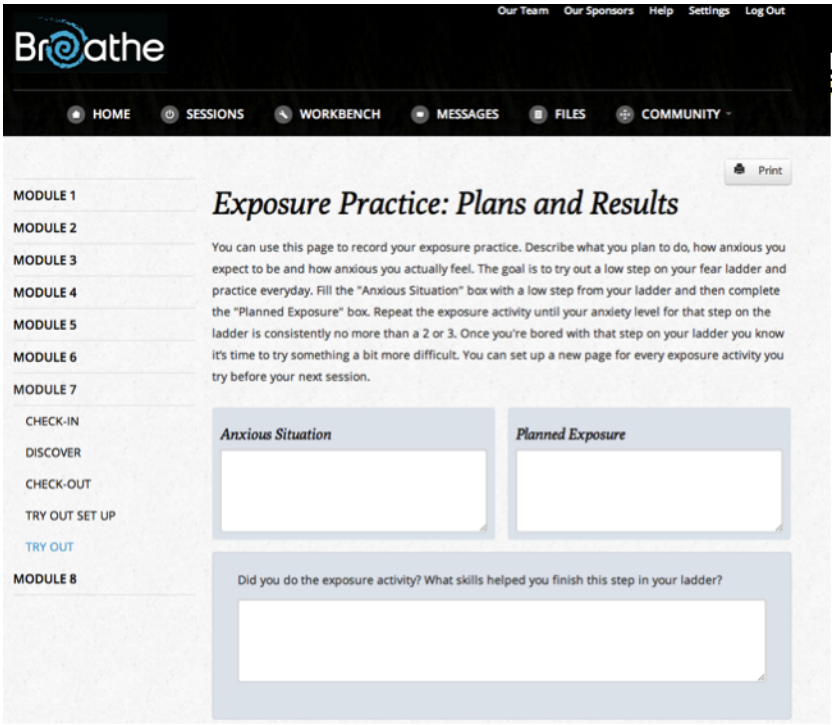


Figure 5.4. A screenshot of a 'Try Out' activity within the *Breathe* program.



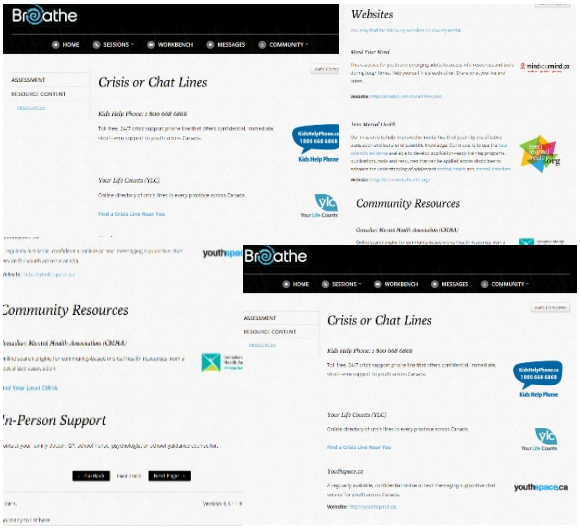
Animations, embedded video, audio playback, graphic novel style vignettes, image maps, timed prompts and on-screen pop-ups were embedded into the program to provide an interactive and multimodal experience. Features based on persuasive systems design (Oinas-Kukkonen & Harjumaa, 2008) were employed to promote program engagement and use: tailoring (provided customized content based on preferences or actions); self-monitoring (progress was tracked and presented virtually to encourage self-reflection); suggestions (key information was provided to help meet users' goals or needs); reminders (prompts were provided to help users continue with the program, provide notifications of the release of new sessions). Brief web-based and telephone support was also provided. Participants were assigned a *Breathe* coach who initiated a telephone coaching session after session 1 to answer any program questions and to help participants prepare to complete program activities. Users were also provided with the option for

a summary of each session to be emailed to an identified parent or guardian after each completed session.

5.2.5 Resource-based webpages

The resource-based webpages included suggestions of anxiety-based books and educational websites, contact information for local and national crisis lines, and information on the Emergency Department and other crisis mental health resources. Figure 5 provides a screenshot of the webpages. Webpage users were permitted unlimited access through IRIS over a 6-week period; the same timeframe the *Breathe* program was used. No safety or anxiety monitoring was provided during webpage use.

Figure 5.5. A collage of screenshots from the resource-based webpages.



5.2.6 Data Collection

We collected user experience data at the pre-intervention (baseline) and post-intervention (6 weeks following enrolment) assessment time points of the trial (Table 2); assessments were independent of an adolescent's intervention progress or use. We embedded data collection in IRIS to allow for electronically captured, securely stored, encrypted and password-protected

data. We provided adolescents who completed outcome measures at the post-intervention time point with a token of appreciation ($25 electronic gift card).

Table 5.2. A summary of the study's assessment time points.

	Time point	
Measure	Pre-intervention	Post-intervention
Demography	X	
Multidimensional Anxiety Scale for Children (MASC-2)	X	X
User Experience Questionnaire for Internet-based Interventions (UEQII)		X
Intervention usage		X
Global Rating of Change Scale (GRCS)		X

5.2.7 Measures

5.2.7.1 Demography

Adolescent demography included self-reported birth date (used to calculate participant's age), gender, and province of residence.

5.2.7.2 Multidimensional Anxiety Scale for Children (MASC)

Anxiety symptoms were reported using the Multidimensional Anxiety Scale for Children—2nd Edition (MASC-2; March, 2013). The MASC-2 is based on the original MASC (March, 1997) that was revised to assess a broader range of anxiety symptoms in children and adolescents 8-19 years. The MASC-2 is one of the most widely used self-report measures in trials involving adolescents with anxiety due to the brevity of the measure and simplicity of its administration (Fraccaro, Stelnicki, & Nordstokke, 2015). It consists of 50 items that assess emotional, physical, cognitive, and behavioural symptoms of anxiety utilizing six scales and four subscales. Adolescents respond using a 4-point Likert scale ranging from 0 ("Never true about me") to 4 ("Often true about me"). The questionnaire yields several scores including a total raw score and standardized t-scores based on 18,000 North American children and adolescents aged 8

to 19 years. The scale has acceptable internal consistency (a coefficient alpha of .92 for the self-reported Total Score) and test-retest reliability (all correlations >.80; *P*<.001) (Fraccaro et al., 2015), and strong convergent validity with other published measures of anxiety symptoms (Fraccaro et al., 2015).

5.2.7.3 Intervention usage

We defined intervention usage as adolescent's use of the *Breathe* program or the resource-based webpages during the 6-week intervention time period. Intervention usage was automatically recorded in IRIS using the number of: (1) *Breathe* sessions completed per allocated adolescent (a maximum of 6 sessions), and (2) webpages visited per allocated adolescent (no maximum).

5.2.7.4 User Experience Questionnaire for Internet-based Interventions (UEQII)

We developed the User Experience Questionnaire for Internet-based Interventions (UEQII) to evaluate and compare adolescents' self-reported user experience across Internet-based interventions (Appendix 5.1). UEQII items were informed by previously published questionnaires and key literature on user experiences (Ritterband et al., 2005, 2008; Thorndike et al., 2008). Items were tested for face and content validity (Streiner, Norman, & Cairney, 2015). The UEQII assesses the user experience through the 3 constructs: (1) Satisfaction and Acceptability: global satisfaction, helpfulness, expectations met, convenience, engagement, privacy, and preference for mode of delivery; (2) Credibility and Impact: confidence in treatment, skill development, perceived treatment effectiveness; and (3) Adherence and Usage: ease of use, including technical, psychosocial, and general barriers and facilitators to intervention use.

Adolescents allocated to either the *Breathe* program or resource-based webpage responded to 21 items ('Core' items) on their user experience using a 4-point Likert scale ranging from 0 ("Really Worsened" or "Not at all") to 4 ("Really Improved" or "Completely"). Fifteen additional items specific to the *Breathe* program experience (items 22-36; 'Treatment' items) were completed by adolescents who used the *Breathe* program. If an adolescent responded "Not at all" or "Slightly" to items 30, 32 or 34, an open text box appeared (subsidiary questions 30a, 32a, 34a) for the adolescent to elaborate on their experience. Items 35 and 36 were also open text boxes where adolescents could describe what they considered to be the most challenging and enjoyable aspects of the *Breathe* program, respectively. There was not an option for adolescents to skip certain questions.

5.2.7.5 Global Rating of Change Scale (GRCS)

We used a global rating of change scale (GRCS) that contained a single question with an 11-point Likert scale (ranging from +5 to 0 to -5) to allow *Breathe* program users to indicate the degree to which their anxiety had changed for the better, for the worse, or whether they experienced no change at all as a result of participating in the *Breathe* program. Global ratings of change scales are widely used in clinical and research settings and are reproducible, clinically relevant and sensitive to change (Kamper, Maher, & Mackay, 2009). To validate the usefulness of the GRCS prior to calculating the MCID, we calculated the correlation between GRCS scores and pre- and post-intervention MASC-2 mean change scores among *Breathe* users. On the GRCS, the smallest change in anxiety symptoms that adolescents identified as important after completing the program (Guyatt, 2000; Jaeschke et al., 1989) was used to calculate the MCID.

5.2.8 Data analysis

We included all trial participants in the analysis of demographic, MASC-2 and intervention usage data; no data imputation strategies were used. For analysis of UEQII and GRCS data, including the MCID calculation, we included adolescents who accessed their assigned intervention at least once during the trial intervention period (ie, those allocated to the *Breathe* program completed at least one session; those allocated to the resource-based webpages visited at least one webpage). This criterion ensured that adolescents commented directly on their experience with the intervention they received. For adolescents who had some missing data among the measures, we used pairwise deletion to maximize the use of all available data on an analysis-by-analysis basis. Normality testing was conducted for all variables. We used means (standard deviations [SDs]), median (range), and/or number (proportion) to describe findings, as appropriate. To compare differences and explore relationships between variables, we conducted independent t-tests and Pearson correlations (r) for parametric data, and Spearman's rank-order correlation coefficients (Spearman's rho) and point-biserial correlations for non-parametric data (Pearson's product-moment correlation; r_{pb}). Data analysis was conducted with IBM SPSS Statistics 25. Significance level was set at $P \leq .05$.

5.2.8.1 Demography

We summarized participant demographics (age, gender, province of residence) using means (with SDs) and numbers (proportions).

5.2.8.2 Anxiety symptoms

We electronically scored the MASC-2 using the Multi-Health Systems (MHS) Online Assessment Center to generate total raw scores and validated t-scores. We calculated pre- and post-intervention symptom scores for each adolescent.

5.2.8.3 Intervention usage

We calculated the mean number (with standard deviation) of completed *Breathe* sessions and webpages visited at the post-intervention time point. We used interquartile ranges to establish data cut-offs (ie, high/low intervention users) to assist with data interpretation. We explored the relationship between intervention usage (the number of completed *Breathe* sessions or webpage visits) and user experience (UEQII total and subscale scores) using Pearson or Spearman correlations.

5.2.8.4 User experience

We summarized user experience data using means and standard deviations. Multiple construct and total scores were calculated (Appendix 5.2) with higher UEQII scores indicating a more highly rated (positive) user experience. For both *Breathe* program and resource-based webpage users, we calculated total scores for all 'Core' user experience items and total subscale scores for each of the three 'Core' constructs. Among *Breathe* program users, we calculated total scores for all 'Treatment' user experience items, total subscale scores for each of the three 'Treatment' constructs, and a total score of all UEQII items by summing the Core and Treatment items. We used interquartile ranges to establish cut-offs for the scores (i.e. 1st quartile= 'low', 2nd quartile= 'moderate', 3rd quartile= 'good', 4th quartile= 'very good' user experience) to assist with data interpretation; values were rounded up to the nearest whole number for categorization. We tested differences between the user groups for the core all items total score and the three subscale construct total scores using independent samples t-tests. Open-ended treatment UEQII data collected from *Breathe* users were extracted verbatim. We conducted a basic thematic analysis to group similar responses together; a minimum of two responses were required to generate a theme. Themes are described and we report the number of responses per theme.

5.2.8.5 Global Rating of Change

We summarized total and subgroup responses to the GRCS using means with SDs and numbers and proportions. We created 11 subgroups based on adolescents' responses to the GRCS (a subgroup for each response value on the scale). We also applied the following interpretation to the GRSC scores:

1) Adolescents who reported 0 on the GRCS were considered to have experienced "no change" in their anxiety.
2) Adolescents who reported +1 ("Almost the same, hardly better at all") were considered to have experience a "very small change", but one that may not be clinically relevant.
3) Adolescents who reported +2 ("Somewhat better") on the GRCS were considered to have experienced a "small change" in their anxiety.
4) Adolescents who reported +3 ("Much better") were considered to have experienced a "moderate change" in their anxiety.
5) Adolescents who reported +4 ("A great deal better") or +5 ("A very great deal better") were considered to have experienced a "large change" in their anxiety.

We grouped and classified the scores of adolescents who reported a worsening of anxiety symptoms (-1 to -5) in a similar manner.

5.2.8.6 Minimal Clinically Important Difference (MCID)

We used the anchor-based method, the most commonly used method, to calculate the MCID. This method involved comparing the change score on the MASC-2 to the GRCS score, which served as the 'anchor' (Copay, Subach, Glassman, Polly, & Schuler, 2007). MCID calculation involved 3 steps. First, we calculated the change in MASC-2 pre- and post-intervention total raw scores for each adolescent. Second, we calculated the mean change in the

MASC-2 total raw scores for each of the GRCS response subgroups that were created ("no change", "very small change", "small change", "moderate change", "large change"). Third, we identified the mean change in MASC-2 scores for adolescents who reported experiencing a "small change" in their anxiety (ie, a +2 response rating on the GRCS; "somewhat better") to provide the final MCID estimate (Guyatt, Juniper, Walter, Griffith, & Goldstein, 1998; Jaeschke et al., 1989; Juniper, Guyatt, Willan, & Griffith, 1994). The GRCS response rating used for the MCID estimate (+2) was based on the decision from research team clinicians who care for adolescents with anxiety and have experience using the MASC-2, who felt the +2 estimate (small change) would be relevant to informing their approach to treatment and be considered a positive response in the clinical setting. This GRCS change of 2 points on an 11-point scale is consistent with the MCID (change) of half a standard deviation from a large systematic review of health care outcome studies (Norman, 2003). In addition to the MCID estimate, the number (proportion) of adolescents who reached (or surpassed) the MCID threshold of a small change in their anxiety improvement was calculated to identify *Breathe* program 'treatment responders'. We used point-biserial correlations (a special case of Pearson's product-moment correlation; r_{pb}) to determine the relationship between treatment response (dichotomous variable: treatment responder or non-responder) and several user experience and usage variables (user experience construct and total scores; the number of *Breathe* sessions completed).

5.3 Results

5.3.1 Participants

The total number of adolescents enrolled in the trial was 536 (n=258 allocated to the *Breathe* program; n=278 allocated to the resource-based webpages). Table 3 presents the characteristics of the adolescents before intervention use. The average age of participants was

16.6 years (SD 1.7) and most participants identified themselves as female (71.3%). More than two-thirds of adolescents resided in the following 3 Canadian provinces: Ontario (27.1%), British Columbia (25.0%), and Alberta (15.1%). The average baseline MASC-2 total raw score was 92.2 (SD 18.1) with an associated t-score of 74.9 (SD 9.7; n=408) indicating a 'very elevated' level of anxiety.

Table 5.3. Pre-intervention characteristics for enrolled participants organized by total sample and intervention used.

		Intervention Group	
	All participants	***Breathe* program**	**Resource-based webpages**
Age, years, mean (SD)	16.6 (1.7)	16.5 (1.5)	16.7 (1.9)
No response, n (%)	6 (1.1%)	5 (1.9%)	1 (0.4%)
Gender, n (%)			
Female	382 (71.3%)	190 (73.6%)	192 (69.1%)
Male	24 (4.5%)	13 (5.0%)	11 (4.0%)
Other	14 (2.6%)	5 (1.9%)	9 (3.2%)
No response, n (%)	116 (21.6%)	50 (19.4%)	66 (23.7%)
Canadian province of residence, n (%)			
Alberta	81 (15.1%)	40 (15.5%)	41 (14.8%)
British Columbia	134 (25.0%)	69 (26.7%)	65 (23.4%)
Manitoba	17 (3.2%)	9 (3.5%)	8 (2.9%)
New Brunswick	8 (1.1%)	5 (1.9%)	3 (1.1%)
Newfoundland and Labrador	7 (1.3%)	4 (1.6%)	3 (1.1%)
Northwest Territories	1 (0.2%)	1 (0.4%)	0 (0.0%)
Nova Scotia	24 (4.5%)	10 (3.9%)	14 (5.0%)
Ontario	145 (27.1%)	68 (26.4%)	77 (27.7%)
Prince Edward Island	3 (0.6%)	2 (0.8%)	1 (0.4%)
No response, n (%)	116 (21.6%)	50 (19.4%)	66 (23.7%)
MASC 2 total raw score, mean (SD)	92.20 (18.1)	92.65 (16.9)	91.77 (19.3)
No response, n (%)	125 (23.3%)	54 (20.9%)	73 (25.5%)

5.3.2 Intervention usage

Figure 6 displays the total number of *Breathe* sessions completed by adolescents allocated to use the program. The average number of *Breathe* sessions completed by all 258 allocated adolescents was 2.2 (SD 2.3). Fifty users (19.4%) completed the entire 6-session program. Using interquartile ranges and the 75th percentile as a cut-point, 72 users (27.9%)

completed session 4 or more of the *Breathe* program and were considered 'program completers'. Figure 7 presents the total number of webpages visited by 278 adolescents allocated to access the webpages. The average number of webpages visited by users was 2.1 (SD 2.7). At least one webpage was visited by 196 users (70.5%).

Figure 5.6. The number of *Breathe* sessions completed by allocated participants.

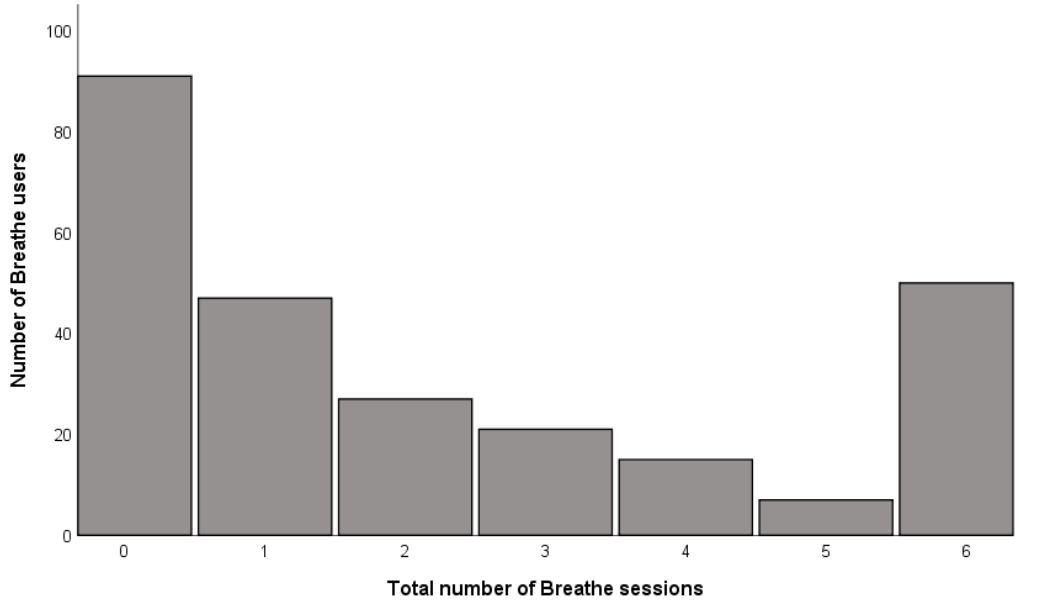
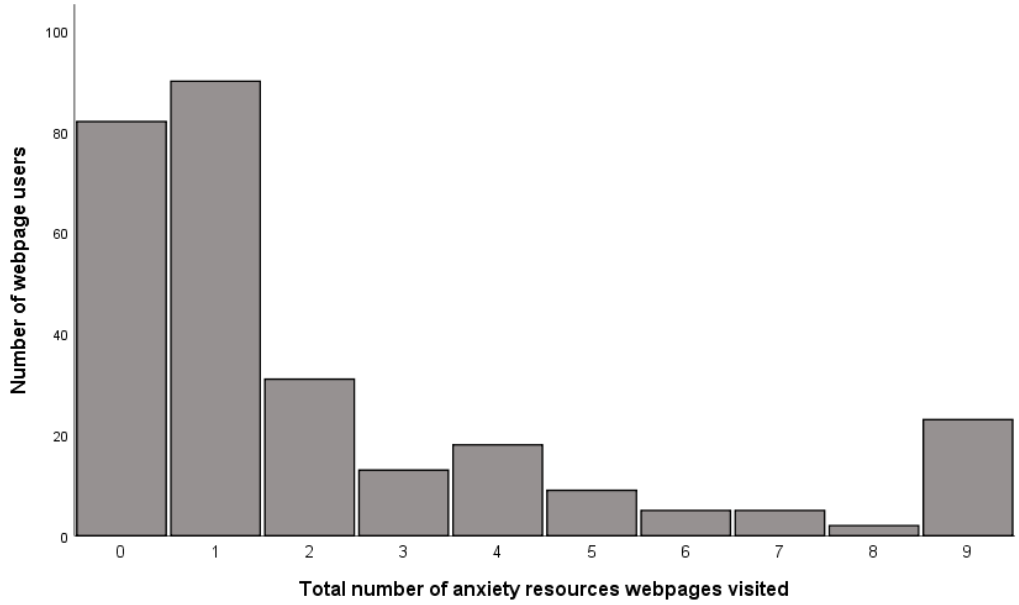


Figure 5.7. The number of resource-based webpages visited by allocated participants.



5.3.3 User experiences

Eighty-one *Breathe* users provided user experience data after program use; these users accessed the program at least once (31.4% of allocated adolescents). Among webpage users, 148 users provided user experience data after webpage use; these users visited at least one webpage (53.6% of allocated adolescents). The median number of sessions completed by '*Breathe* users' was 6.0 (Range: 1-6). Sixty-one (75.3%) *Breathe* users were 'program completers' with 43 (53.1%) completing the entire program. The median number of webpages visited was 2.0 (Range: 1-9).

Table 4 presents the responses to user experience questions and differences in experiences between *Breathe* and webpage users (score range 0 "not at all" to 4 "completely"). Across both interventions, adolescents reported that the information was easy to understand (*Breathe* users: Mean 3.5, SD 0.7; webpage users: Mean 2.8, SD 1.2), adolescents trusted the information from the intervention (*Breathe* users: Mean 3.6, SD 0.7; webpage users: Mean 3.1, SD 1.0), the Internet was a good method for delivering the information (*Breathe* users: Mean 3.7, SD 0.6; webpage users: Mean 2.9, SD 1.3), and the intervention was easy to use (*Breathe* users: Mean 3.3, SD 0.6; webpage users: Mean 2.4, SD 1.2). Adolescent users of *Breathe* or the webpages did not consider computer access or availability, Internet or technical problems as major barriers to using the interventions. Adolescents who used *Breathe* reported that personal (*Breathe* users: Mean 1.8, SD 1.2; webpage users: Mean 2.5, SD 1.4) and school (*Breathe* users: Mean 1.9, SD 1.4; webpage users: Mean 2.4, SD 1.5) commitments limited their intervention use more so than adolescents who used the webpage (*P*'s<.001).

Table 5.4. The differences in core items of the User Experience Questionnaire for Internet-based Interventions between *Breathe* users (n=81) and webpage users (n=148).

User experience item	Mean (SD)		Test statistic, t-test (df)	*P* value
	Breathe users	webpage users		
1. Was it easy to use? [c]	3.3 (0.6)	2.4 (1.2)	8.1 (222.2)	.00
2. Was it convenient to use? [c]	3.0 (0.9)	1.8 (1.3)	8.2 (215.5)	.00
3. Was the information easy to understand? [c]	3.5 (0.7)	2.8 (1.2)	5.8 (222.8)	.00
4. Was the Internet a good method for delivering this information? [c]	3.7 (0.6)	2.9 (1.3)	6.2 (217.5)	.00
5. Were you eager to use it? [c]	2.9 (0.9)	1.9 (1.3)	6.9 (217.5)	.00
6. Were you satisfied? [c]	3.0 (0.8)	1.8 (1.3)	8.8 (222.7)	.00
7. Did it meet your expectations? [c]	3.0 (0.8)	1.7 (1.5)	9.4 (227.0)	.00
8. Did it keep your interest? [c]	2.7 (1.0)	1.4 (1.3)	8.7 (203.7)	.00
9. Did you trust the information from it? [c]	3.6 (0.7)	3.1 (1.0)	4.7 (217.8)	.00
10. Did concerns about your privacy (eg, friends or family knowing about your online activities) affect your use of it? [b]	3.0 (1.1)	3.3 (1.0)	-2.4 (227.0)	.00
11. Did access or availability of a computer affect your use of it? [b]	3.4 (1.1)	3.4 (1.1)	0.3 (227.0)	.74
12. Did technical computer problems (eg, trouble logging in, clicking to the next page) affect your use of it? [b]	3.6 (0.8)	3.6 (0.9)	-0.4 (227.0)	.74
13. Did Internet problems (eg, slow or poor connection) affect your use of it? [b,c]	3.6 (0.7)	3.5 (0.9)	1.0 (208.3)	.34
14. Did personal commitments (eg, family time, extracurricular activities) affect your use of it? [a,b,c]	1.8 (1.2)	2.5 (1.4)	-4.0 (187.8)	.00
15. Did school commitments (eg, class time, homework) affect your use of it? [a,b]	1.9 (1.4)	2.4 (1.5)	-2.4 (226.0)	.02
16. How likely would you be to come back to it if difficulties with your anxiety continue or return? [a,c]	2.6 (1.1)	1.9 (1.4)	4.0 (202.2)	.00
17. How did your ability to manage your anxiety change by using it? [a,c]	2.9 (0.5)	2.3 (0.6)	8.1 (195.4)	.00
18. How did you anxiety with activities at school (eg, speaking up in class, taking a test) change by using it? [a,c]	2.7 (0.6)	2.1 (0.6)	7.8 (163.5)	.00
19. How did your relationship with friends and peers change by using it? [a,c]	2.5 (0.6)	2.2 (0.6)	3.9 (166.1)	.00
20. How did your relationships with family members change by using it? [a,c]	2.4 (0.6)	2.1 (0.6)	2.6 (156.0)	.01
21. How did your overall anxiety change by using it? [a,c]	2.8 (0.6)	2.2 (0.8)	6.7 (204.6)	.00

SD= Standard deviation; df= Degrees of freedom

[a] N=147 for this analysis

[b] Item is reverse-scored so that a higher rating now indicates a more positive experience

[c] Equal variances not assumed based on Levene's Test for Equality of Variances

Table 5 presents and compares the total UEQII scores for the core user experience constructs and for all core user experience items (items 1-21) for *Breathe* and webpage users. *Breathe* users had significantly higher total Construct 1, Construct 2 and Core items total scores than webpage users. We found that the Construct 3 total score was higher among webpage users compared to *Breathe* users, but this difference was not statistically significant.

Table 5.5. The differences between *Breathe* (n=81) and webpage (n=148) users in the construct and core item total scores of the User Experience Questionnaire for Internet-based Interventions.

	Score Range	***Breathe* users, mean (SD)**	**User Experience Indicator[a]**	**Webpage users, mean (SD)**	**User Experience Indicator[a]**	**Test Statistic, t-test (df)**	***P* value**
Construct 1: Satisfaction and Acceptability	0-32	25.2 (4.2)	Good	16.6 (7.9)	Moderate	9.2 (227.0)	.00
Construct 2: Credibility and Impact	0-24	16.9 (2.2)	Very good	14.0 (3.0)[b]	Moderate	7.7 (226.0)	.00
Construct 3: Adherence and Usage	0-28	19.9 (4.2)	Moderate	20.7 (4.4)[b]	Good	-1.4 (226.0)	0.18
All Core Items	0-84	62.0 (8.2)	Good	51.2 (11.1)[b]	Moderate	7.6 (226.0)	.00

SD= Standard deviation; df= Degrees of freedom
[a] Based on quartiles using all adolescent users (*Breathe* program + webpage users): 1st quartile= low; 2nd quartile= moderate; 3rd quartile= good; 4th quartile= very good
[b] N=147 for this analysis

Tables 6 and 7 present the *Breathe* users' experiences with the program (Treatment items). The most positive user experiences involved how the *Breathe* program looked, the relevance of the information to the user's situation, and the likelihood of the program being recommended to others. The lowest rated user experience items were the time required to complete the program, exposure activities ('facing your fears'), and whether the program helped users meet their treatment goals.

Table 5.6. *Breathe* user ratings (n=81) from the User Experience Questionnaire for Internet-based Interventions.

***Breathe* user experience item**	**Mean (SD)**
22. Was it a good fit for you?	2.6 (0.8)

23. Did you like the way it looked?	3.2 (0.9)
24. Did the information relate to you and your situation?	2.8 (1.1)
25. Did it help you meet your treatment goals?	2.3 (1.0)
26. Did the reminder emails affect your use of it?	3.0 (1.2)
27. Did the time required to complete the program affect your use of it? [b]	1.9 (1.2)
28. Did concerns about 'facing your fears' affect your use of it? [b]	2.2 (1.3)
29. How likely would you be to recommend it to others?	3.0 (0.8)
30. Were the follow-up emails and telephone calls helpful? [a]	2.7 (1.1)
31. Were the homework ('Try Out') exercises helpful? [a]	2.4 (1.0)
32. Were the homework ('Try Out') exercises easy to complete? [a]	2.7 (0.9)
33. Was the worry ladder helpful? [a]	2.4 (1.1)
34. Was the worry ladder easy to complete? [a]	2.4 (1.0)

SD= Standard deviation
[a] N=80 for this analysis
[b] Item is reverse-scored so that a higher rating now indicates a more positive experience

Table 5.7. *Breathe* user experiences (n=81) presented by user experience construct, treatment items and all items total scores from the User Experience Questionnaire for Internet-based Interventions.

	Total Score, mean (SD)	**Score Range**	**User Experience Indicator[a]**
Construct 1: Satisfaction and Acceptability	11.6 (2.6)	0-16	Good
Construct 2: Credibility and Impact	9.8 (2.8)[b]	0-16	Good
Construct 3: Adherence and Usage	12.2 (2.9)[b]	0-20	Good
Treatment Items	33.5 (6.4)[b]	0-52	Good
All Items (Core + Treatment items)	95.3 (13.5)[b]	0-136	Good

[a] Indicator is based on quartiles of *Breathe* users only: 1st quartile= low; 2nd quartile= moderate; 3rd quartile= good; 4th quartile= very good
[b]N=80 for this analysis

Breathe users provided open-ended responses for UEQII items 30a, 32a, 34a, 36 and 36. Themes associated with these responses are identified in Table 8 with example responses. Adolescents described nervousness or discomfort around completing (or thinking about completing) the telephone coaching call after session 1, limited time or forgetting to complete the sessions and homework activities (Try Outs), and difficulty in understanding the instructions for planned exposure activities (the worry ladder), including breaking down the anxious situation they wanted to overcome. A major theme surrounding program enjoyment related to users

learning about anxiety and the new coping strategies or techniques to help them manage their worries.

Table 5.8. Themes and responses from open-ended items from the User Experience Questionnaire for Internet-based Interventions.

Open-ended question (number of respondents)	Theme (number of responses contributing to each theme)[a]	Example verbatim response
30a. Why were the follow-up emails and telephone calls not very helpful? (n=10)	Anticipating the telephone coaching call was stressful (n=8)	"I was self motivated so the emails just filled my inbox" (User 4992)
	Emails did not motivate program use (n=4)	"Emails didn't motivate me, made me want to ignore it even more" (User 1191)
	Lack of comfort during the telephone coaching call (n=3)	"I like to do things independently and I find it difficult to interact with strangers" (User 1447)
32a. Why was it a challenge to complete the homework? (n=7)	Lack of time for program workload (n=4)	"Hard to make time and to remember to go back to things everyday" (User 2930)
	Forgetting (n=2)	"I'd forget to do them" (User 107)
	Feasibility (n=2)	"The boxes were small and it was hard to read all of the text" (User 1483)
34a. Why was it a challenge to complete the worry ladder? (n=12)	Instructions/activities were hard to understand (n=4)	"For me there wasn't enough instructions for it and I was confused" (User 2449)
	Uncertainty in completing (n=3)	"It was difficult coming up with all the steps, i didn't have a creative mind with creative ideas" (User 1253)
	Difficulty focusing/articulating worries (n=2)	"I felt my worries were too complex to fit into it" (User 1825)
35. What was the most challenging part of the program? [d] (n=80)	Time management (n=24)	"Trying to complete the tasks on time with my schedule" (User 894)
	Preparing for and/or implementing skills outside of the program (n=23)	"Finding the courage to do exposure activities. Also remembering and putting effort into coping strategies while in an anxious situation" (User 606)
	Difficulty working with anxiety concerns (thoughts, feelings, behaviours) on their own (n=20)	"Facing my fears and organizing my thoughts was a challenge because sometimes I would have to dig deep to find answers" (User 215)
	Regular program use (n=18)	"Remembering to participate in the program" (User 1102)
	Program format (n=2)	"Reading the format was hard to follow" (User 1006)
36. What was the most enjoyable part of the program? [d] (n=80)	Learning new information and skills (n=31)	"Learning more about what I can do to help myself" (User 1103)
	Not feeling alone (n=10)	"I think just knowing that I'm not alone with anxiety. Knowing that other people go through it and some people want to

		help makes me not feel so alone and helpless" (User 215)
	Program activities (n=10)	"I really liked the worry ladder and the surveys" (User 215)
	Noticing improvement or impact (n=9)	"Seeing what improvements I may have as well as how this program works" (User 371)
	Progress monitoring and feedback activities (n=7)	"I think answering the journals, and keeping track of my anxiety every week from school, family and friends" (User 1253)
	Developing insights (n=5)	"Introspection and the ability to actually think about the things I'm doing" (User 1282)
	Program format or features (n=5)	"Being able to do it online and not have to talk with anyone face to face" (User 2209)
	Positive emotions while working on the program (n=4)	"Finishing the session successfully" (User 752)
	Telephone coaching call (n=2)	"My phone call with my coach" (User 1102)

[a]Adolescents' responses may have been coded under more than one theme if there were multiple components (themes) to their response.

5.3.3.1 Relationships between intervention usage and user experience

Table 9 presents the relationships between intervention usage and user experience scores for *Breathe* and webpage users. The number of *Breathe* sessions completed was significantly correlated with the Adherence and Usage construct scores for both the core and treatment items, the total score for all treatment items, and the total score for all user experience items.

Table 5.9. The relationship between intervention usage and the user experience.

	Total number of *Breathe* sessions (n=81)	**Number of webpage visits (n=148)**
UEQII Core items (1-21)		
Construct 1: Satisfaction and Acceptability	rho=0.10, *P*=0.37	rho=0.07, *P*=0.42
Construct 2: Credibility and Impact	rho=0.12, *P*=0.28	rho=-0.02, *P*=0.84[b]
Construct 3: Adherence and Usage	rho=0.22, *P*=0.05	rho=0.08, *P*=0.36[b]
All Core Items	rho=0.18, *P*=0.10	rho=0.07, *P*=0.42[b]
UEQII Treatment items (22-34)		

Construct 1: Satisfaction and Acceptability	rho=0.15, *P*=0.17	--
Construct 2: Credibility and Impact	rho=0.22, *P*=0.06[a]	--
Construct 3: Adherence and Usage	rho=0.37, *P*<0.00[a]	--
All Treatment Items	rho=0.33, *P*<0.00[a]	--
All UEQII items (1-34)		
All Core and Treatment Items	rho=0.30, *P*<0.00[a]	--

[a]N=80 for this analysis
[b]N=147 for this analysis

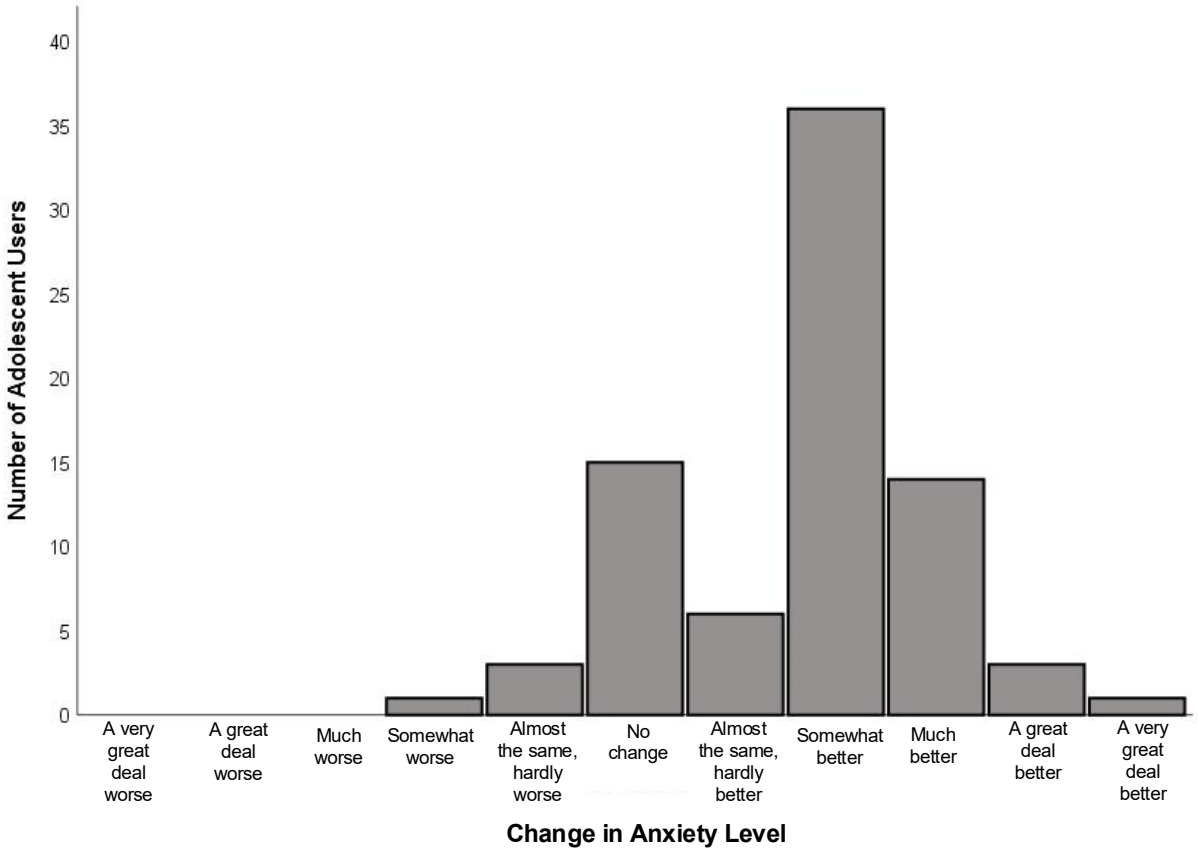
5.3.4 Breathe user ratings of changes in anxiety

Eighty *Breathe* users (30.6% of allocated adolescents) reported their change in anxiety using the GRCS (score range -5 to +5, with 0=no change). Among these adolescents, 60 (75.0%) reported that their anxiety level improved after they had used the program with an average improvement of 2.3 (somewhat better; SD 0.8). For the 5.0% of adolescents who reported that their anxiety was worse after the program (n=4), the average worsening rating was 1.3 (mostly same/hardly worse; SD 0.5). Twenty percent of adolescents (n=16) reported no change in their anxiety after the program. The mean GRCS response among respondents was 1.7 (SD 1.3). Figure 8 presents an overview of the GRCS responses from *Breathe* users.

5.3.4.1 Relationships between the global ratings of anxiety change, *Breathe* program use, and the Breathe user experience

We did not find a statistically significant relationship between the number of sessions completed (program use) and *Breathe* users' reported changes in anxiety on the GRCS (rho=0.02, *P*=.83). We found that the GRCS was related to the average user experience including core total score (r=0.41, *P*<.000), treatment total score (r=0.50, *P*<.000) and the all items total score (r=0.49, *P*<.000).

Figure 5.8. The change in anxiety levels as reported by adolescent users (n=80) of the *Breathe* program using the global rating of change scale (GRCS).



5.3.5 Minimal clinically important difference

We found a significant positive correlation between the GRCS scores and the MASC-2 change scores among *Breathe* users (r=0.27, *P*=.02) validating the usefulness of the MCID approach. To calculate the MCID, we used the mean change in MASC-2 raw scores among *Breathe* users (n=36; 45.6%) who reported a "Somewhat better" change in their anxiety (+2; "small change") on the GRCS. This mean MASC-2 change score was 13.8 (SD 18.1). Therefore, the MCID for the improvement of adolescents' anxiety following the *Breathe* program was 13.8 points. Using this estimate, the number of *Breathe* users who reached (or surpassed) the MCID threshold and were considered 'treatment responders' was 35/81 (43.2%).

5.3.5.1 Relationships between treatment response, *Breathe* program use, and the *Breathe* user experience

We found no significant point-biserial correlations (r_{pb}) between the treatment response of *Breathe* program users (treatment responder or non-responder) and: (1) the number of sessions completed (r_{pb}=0.05, *P*=.66); (2) UEQII core total score (r_{pb}=-0.04, *P*=.76); (3) UEQII treatment total score (r_{pb}=0.02, *P*=.82); (4) UEQII Satisfaction and Adherence total score (Construct 1; r_{pb}=-0.03, *P*=.32); (5) UEQII Credibility and Impact total score (Construct 2; r_{pb}=0.02, *P*=.88); (6) UEQII Adherence and Usage total score (Construct 3; r_{pb}=0.02, *P*=.88), and (7) UEQII all items total score (r_{pb}=-0.03, *P*=.82).

5.4 Discussion

Interest in the *Breathe* program was high, particularly given recruitment was primarily through social media and required adolescents to self-identify as wanting help for their anxiety. About one-third of the participants in the iCBT intervention completed the post intervention evaluation and three quarters of them completed more than half the program. For iCBT programs designed and delivered to adolescents with anxiety, program evaluations should aim to understand how iCBT is experienced by users to further ensure its relevance, use and impact as a self-help treatment (Barbic et al., 2019; Brown, Ford, Deighton, & Wolpert, 2014; Feather et al., 2016; Short et al., 2018). As part of a large-scale evaluation of *Breathe*, an iCBT program for mild-to-moderate anxiety symptoms among adolescents, we utilized user-report measures to improve our understanding of adolescents' use of, and experiences with, iCBT as compared to standard resource-based webpages, and what perceived impact users experience following iCBT. In the study, we recognized that multiple interacting components influence the user experience (Litvin, Abrantes, & Brown, 2013; Short et al., 2015; Yardley, Spring, & Riper, 2016). By using

complementary measures—automatically captured administrative data (eg, session completion data), self-report data detailing program experience and program impacts—we described and compared distinct but essential parts of the user experience. As a result, we discovered: (1) how iCBT program delivery may influence iCBT use and the user experience; (2) technological features and program activities associated with user satisfaction and acceptability; and (3) what adolescents report to be an important change in their anxiety after program use.

5.4.1 Program delivery, iCBT use, and the user experience

Similar to previously published studies (Radomski et al., 2019), program use was low among all adolescents allocated to the *Breathe* program. On average, adolescents completed a little more than one-third of the program and about 20% completed the entire 6-session program, a completion rate that falls within the range of 5-50% reported by other iCBT studies (Radomski et al., 2019). Program use was higher among *Breathe* users who provided user experience data (ie, approximately one-third of allocated users), 75% of whom were considered 'program completers'. What can we learn from this engaged user group to increase program use among other adolescent iCBT users? While other studies have looked to user demographics to provide explanations in low program use, explanations have been mixed (Ebert et al., 2015; Hollis et al., 2017; Pennant et al., 2015; Podina et al., 2016), which suggests new approaches to understanding program use are needed.

Consistent with the literature, *Breathe* users described difficulty remembering to work on the program (L. M. Ritterband et al., 2008; S. H. Spence et al., 2008), concerns with privacy and stigma (eg, others knowing about or judging their help seeking) (Bradley et al., 2012; Gulliver, Griffiths, & Christensen, 2010; Steeves, 2014), time constraints and conflicting commitments (Gerrits et al., 2007; Iloabachie et al., 2011; Kaltenthaler et al., 2008; Nielsen et al., 2018), and

delaying or avoiding tasks they found challenging (Ciuca, Berger, & Miclea, 2017; Schulz, Vincent, & Berger, 2017) as the biggest obstacles to program adherence and use. The majority of previously studied iCBT programs with completion rates greater than 50% involved regular therapist and/or parent involvement to support program use (Anderson et al., 2012; Keller, 2009; March et al., 2009; Spence et al., 2008; Vigerland et al., 2013, 2017; Vigerland, Ljótsson, et al., 2016). It may be that this type of support, as well as the degree of support provided, may help adolescents manage their time and complete challenging program activities (Nordh et al., 2017; Shahnavaz et al., 2018; Silfvernagel, Gren-Landell, Emanuelsson, Carlbring, & Andersson, 2015; Spence et al., 2011; Vigerland et al., 2013). In our study, *Breathe* users received one telephone-based coaching call after completing their first session to prepare adolescents for the skills-based program activities to follow, including exposure activities, that would begin in session two. Almost half of the adolescents allocated to *Breathe* did not go on to complete the next program session and the personalized exposure activities they had set up in session one (ie, a hierarchy of activities specific to their worries and fears). While some adolescents described the call as a positive experience, others considered it "stressful" because they did not know the coach and some adolescents described avoiding and delaying the call. This mixed response to coach involvement suggests that *how* support is provided is a key aspect of program delivery and the user experience.

The way that a program facilitates the development of a strong therapeutic alliance between the user and the support person is thought to be key for increasing program use (Anderson et al., 2012; Liber et al., 2010; Spence et al., 2008). Flexible support options within iCBT program delivery may include:

- Ongoing support for those with difficulty working with their anxiety concerns independently (supervisory support),
- Available-as-needed support for users who request reminders, comments on their performance or further instruction (feedback or nudging), and/or
- Timely support during key activities such as exposure activities and an adolescent's preparation to use skills outside of the program (targeted support).

These different levels of support alongside different user-selected communication strategies (eg, in-person, email, text messages, discussion forums) may improve adolescents' use of and experiences with an iCBT program. To this end, prior to iCBT program use, there may be value in parents, clinicians, and/or an online process guiding adolescents through a comparative review of iCBT program delivery features so that adolescents choose the program that best fits their social and relational preferences. Under this approach, adolescents could choose between iCBT programs that leverage pre-existing relationships (eg, parent, current therapist), foster a new virtual relationship (eg, virtual coach that provides real-time feedback online), or introduce a new relationship (eg, program coach).

It is important to note that the stage of the program at which user experiences are measured may provide more or less information on the relationship between adolescents' use of and experiences with a program. In this study, we administered our user experience measures after program use. However, moving forward in the field, there is value in formative evaluation during program use. Such evaluations may reveal how the user experience changes over time, how it can be optimized (Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009), and how to improve the accuracy of collected data on the user experience (eg, reduce recall bias, link user experience domains to specific program sessions). For example, repeated measurement,

using log data or routine monitoring of points of program stoppage among users, may help to identify the relationship between program continuation or discontinuation, adolescents' anxiety states, or program content or features. Use of factor analysis (eg, O'Brien, Cairns, & Hall, 2018) or multiple regression (eg, Beintner et al., 2018) could help to illuminate how different constructs of user experience relate to one another, to intervention use and how the constructs change over the course of treatment.

5.4.2 Program features and activities and the user experience

Overall, in this study, user experiences were rated as significantly more positive for *Breathe* program users than for those who accessed the resource-based webpages. The only user experience questionnaire construct for which we found no difference between the two intervention groups was the adherence and usage construct—both the *Breathe* program and webpage users reported few concerns with technology or Internet accessibility or functionality during the study. Like other iCBT studies, *Breathe* users reported that the program was easy to understand (Calear, Christensen, Brewer, Mackinnon, & Griffiths, 2016), met their needs (Vigerland, Ljótsson, et al., 2016), and that they were satisfied overall (Jolstedt et al., 2018; Pramana, Parmanto, Kendall, & Silk, 2014; Spence et al., 2008). Nearly half of users stated that the most enjoyable parts of the program were learning about anxiety, developing new coping strategies, and feeling like others could relate to their situation or worries and vice-versa. However, *Breathe* users' satisfaction and acceptability with the program was not correlated with their use of it, suggesting that other program factors need to be explored for their association with iCBT use. A distinguishing feature of *Breathe* as compared to the resource webpages was that *Breathe* incorporated instruction and interaction (providing opportunities for 'doing') in addition to information (providing opportunities for 'knowing') as part of the intervention,

helping users develop their capacity and competency for self-management rather than redirecting them to alternative resources. *Breathe* users liked activities that improved their ability to self-manage their anxiety, either by informing them, empowering them or normalizing their experiences. Users reported the greatest interest in developing skills that were relatively easier to learn and had a timelier impact (eg, "deep breathing exercises", "watching videos of other teens with anxiety and relating to them"). When designing an iCBT program it may be helpful to consider 'balancing' the variety and sequence of program content and activities included according to their expected level of effort from the user and the immediacy of benefit. The following categorization can support program developers using this approach: (1) Immediate relief tasks: foundational and straightforward behavioural strategies that focus on reducing physiological arousal (eg, relaxation or mindfulness techniques) to have a relatively quick effect on anxiety; (2) Immediate, short-term and long-term relief tasks: cognitive strategies that help users find 'perspective' with their anxiety (eg, psychoeducation, normalization, affirmation of support), and develop awareness and self-efficacy of their ability to modify their thoughts and behaviours (eg, self-monitoring, practice activities), to ameliorate anxiety for extended periods of time; (3) Short-term and long-term relief tasks: more complex, multi-step behavioural and cognitive strategies that focus on developing new habits and adaptive responses to previously feared stimuli (eg, exposure activities, homework) that have a more enduring impact on anxiety. *Breathe* users reported positive experiences with more immediate and short-term relief tasks, suggesting that when long-term relief tasks are presented in sessions, some immediate and short-term relief tasks should also be included (eg, revisited or presented) to maintain users' interest and sense of self-mastery or achievement with the program. Combining immediate and short-term relief tasks with long-term ones could potentially off-set the discomfort and effort required

to persist through more demanding tasks (ie, exposure), making it easier for users to continue with the program.

In addition to program content and activities, technological features are also inherent aspects of iCBT. The *Breathe* program was developed using persuasive system design components to increase program engagement, use, and effectiveness (Iloabachie et al., 2011). Yet, on average, program use was still low for all allocated users. Persuasive design features are embedded within the program itself making use of the program a prerequisite for users to experience these features and their 'persuasive effects'. The majority of *Breathe* adolescents did not access the first session ('non-users') and were not exposed to such features. Among the adolescents who did use the *Breathe* program, they described specific persuasive design features to be among the most enjoyable features of the program. These features included interactive surveys and graphs (designed to provide feedback, increase users' awareness of their changes over time and help with goal setting) (Dombrowski et al., 2012; Lentferink et al., 2017; Michie, Abraham, Whittington, McAteer, & Gupta, 2009), and video clips showing in-vivo exposure and diaphragmatic breathing (designed to provide step-by-step peer simulations of therapeutic activities) (Radomski et al., 2019). Based on adolescent feedback in this study, it may be that the design features did have a positive influence on program use as intended. However, what remains an important question is how to promote adolescent users' initiation engagement with a persuasive system design-based program so that they can experience the program's features?

One strategy may involve the use of pre-intervention activities, such as readying adolescents for the iCBT program, or assessing the fit between adolescents and the program, to improve program initiation and use. For example, a 'preview' of an iCBT program could be provided to adolescents' prior to eligibility screening to pique their interest in the program. This

preview could showcase the positively rated program activities and design features, informing adolescents of what they can expect if they were to use the program, helping them to decide whether they would like to pursue accessing the program. Incorporating an iCBT program preview can have many benefits to the entire treatment (or research study) process for adolescents and their families as well as researchers and clinicians involved in program implementation. For example, this preview approach can promote a user-centred, decision-making treatment process (adolescents can self-select programs that meet their needs and preferences), streamline the recruitment and eligibility screening process (identifying adolescents who may be unlikely to use the program early on, saving time and resources by redirecting them to treatment alternatives), uphold research or clinical practice ethics (adolescents can avoid a treatment that may be unusable, ineffective or potentially harmful to them), and stimulate or 'kick start' adolescents use of the program (adolescents becomes intrigued and interested in commencing the program).

Another strategy to promote initial program engagement is to incorporate an assessment of beliefs and attitudes prior to program use. Persuasive technology aims to reinforce, change or shape users' attitudes or behaviours toward their health goal (Fogg, 2002; Oinas-Kukkonen & Harjumaa, 2008), suggesting that a clear understanding of users' psychology precedes selection and use of an intervention. Assessing adolescents' existing health beliefs and attitudes (eg, treatment expectations, health and technology literacy, self-efficacy) and treatment goals (eg, desired change in knowledge, skills or symptoms) pre intervention may help determine: (1) the potential for successful 'persuasion' to occur (an attitude or behaviour change) with use of the iCBT program, and (2) if a positive potential exists, what persuasive system design components may be most appropriate to match the beliefs and goals of the adolescent. Feedback on the fit

(persuasive potential) between the adolescent and the program can be provided to the adolescent. Once an adolescent decides to begin the program, the persuasive design features used in the program can be tailored to the goals of the user. Being able to assess and appropriately tailor a program's persuasive features based on adolescents' beliefs, attitudes and goals could improve users' experience and use of iCBT.

Considering that multiple iCBT components work together to form a complex intervention (Craig et al., 2008), we recommend connecting the persuasive system design features known to relate to a positive user experience (program reminders, progress and feedback tools, multimedia demonstrations, flexible program support) with proposed mechanisms of change (CBT content [psychoeducation, skills training], attitude or behaviour change processes [techniques that target users' motivation, sense of mastery]) (Radomski et al., 2019). Future studies that systematically test the relationship between iCBT features, behaviour change processes, user experience, and health outcomes would help to develop working models of iCBT effectiveness. Standardized interviews and patient-reported measures (eg, Ratings of Perceived Helpfulness in Behavior Change, Iloabachie et al., 2011; Zabinski et al., 2001) may also help researchers determine how iCBT program features have or have not engaged adolescents in behavior change, the reliability of adolescents' self-awareness/reports on their fit with a program and adolescent to determine the self-reports, and what features were most effective for improving program use.

5.4.3 Changes in adolescents' anxiety following iCBT use

Previous iCBT studies have measured whether program participation was perceived as 'effective or useful' by adolescents (Calear et al., 2016; Vigerland et al., 2013), but have not formally measured the degree of meaningful change in anxiety as experienced by users of a

program. This study is the first to quantify a user-reported improvement to a MCID for anxiety symptoms, a common primary outcome of trials to date. Establishing this MCID is an important step in informing future sample sizes for trials of iCBT effectiveness (eg, can provide a clinically meaningful effect size) and interpreting adolescent outcomes (eg, presenting results with clear meaning behind anxiety changes and implications, such as whether an adolescent is a positive responder to iCBT). Reporting whether changes in anxiety across different programs met a MCID can also assist adolescents, parents, and clinicians in deciding which program best matches their expected treatment response (Neely et al., 2007; Wright, Hannon, Hegedus, & Kavchak, 2012).

In this study, most adolescents reported that their anxiety was 'better' after using the *Breathe* program. Based on the MCID estimate generated from adolescents' ratings, 43% of *Breathe* users were considered treatment responders. Previous iCBT studies have used clinical severity ratings (ratings have ranged from 0=none to 8=extremely severe) as a proximal indicator of treatment response (Spence et al., 2008, 2011; Vigerland et al., 2013; Vigerland, Ljótsson, et al., 2016). However, a clinician has assigned these ratings. For programs used outside a research or clinical setting, use of a MCID to determine treatment response can reduce costs and time associated with clinician involvement and better reflects the experience of the youth.

For *Breathe* users, we did not find a statistically significant relationship between treatment response and the number of program sessions completed. There is conflicting evidence as to whether a causal relationship between iCBT use and change in anxiety (a 'dose-response' relationship) exists—some studies have found evidence for this relationship (March, 2008; March et al., 2018) whereas others have not (Liber et al., 2010; Spence, Donovan, S, Kenardy, & Hearn, 2017). In our study, adolescents may have discontinued their use of a program

(temporarily or definitively) once they felt their symptoms had improved, regardless of their progress in the program. Perceived impact may also be based on unique individual factors such as treatment expectancy, pre-intervention anxiety severity, self-regulation abilities and/or motivational factors (Institute of Medicine [U.S.] Committee on Prevention of Mental Disorders and Substance Abuse Among Children, O'Connell, Boat, Warner, & National Research Council Board on Children, 2009; March, 2008; Yardley et al., 2016), factors that we did not assess. The lack of association between treatment response and program use further emphasizes the importance of incorporating users' perspectives in the evaluation of iCBT since commonly used methods (eg, standardized symptom questionnaires) may not fully capture the health and social benefits adolescents want or need from an iCBT program. More research is required to determine what treatment outcomes are important to adolescent users of iCBT apart from those that researchers and clinicians typically administer.

5.4.4 Strengths and Limitations

This study has several strengths related to the assessment of user experiences of iCBT for adolescents with anxiety. Currently, there is considerable heterogeneity in how the user experience is defined and evaluated, with most research being conducted with adult populations (Perski et al., 2019; Perski, Blandford, West, & Michie, 2017; Short et al., 2018; Yardley et al., 2016). To target our users, we used current, key literature (Bradley et al., 2012; Morrison, Yardley, Powell, & Michie, 2012; Radomski et al., 2019; Rickwood et al., 2019; Ritterband et al., 2008; Thorndike et al., 2008; Wozney et al., 2017) to develop the User Experience Questionnaire for Internet-based Interventions (UEQII). This self-report measure includes 3 major user experience constructs (Construct 1: satisfaction and acceptability; Construct 2: credibility and impact; Construct 3: adherence and usage). Each construct provided diverse

information to understand the adolescent experiences with iCBT as well as our comparison intervention. With the growing number of RCTs evaluating iCBT using a technology-based intervention as a control, a method to compare the user experience between two Internet-based interventions for adolescents is becoming increasingly important. Although this measure is subject to response bias (recall or social desirability) and relies on adolescents' insights of their own behaviours or attitudes (experiential data), it provides information that is not directly observable and cannot be captured by traditional diagnostic assessments, a proxy respondent (ie, parent), or digital log data (objective data). In the future, other researchers can use the UEQII by administering the *core* items to other Internet-based interventions and adapting the *treatment* items for their intervention under study to narrow in on what specific intervention components meet the needs and preferences of their target users. As a first step prior to broader use, we recommend that the UEQII undergo further psychometric testing to assess its feasibility and transferability in other contexts, ages and patient groups and iCBT programs.

This study also has several limitations. First, we used adolescent ratings on a global rating scale (a GRCS) to calculate the MCID. There is no standard for how to calculate the MCID, therefore a variety of methods exist and can be used depending on the study sample and data collected (for a review of the different methods see Beaton, Boers, & Wells, 2002; Copay et al., 2007; Ebrahim et al., 2017; Wells et al., 2001). In this study, the anchor-based approach was considered optimal because it maintains the user's perspective (Ebrahim et al., 2017; King, 2011; Morse, 1994), an essential perspective with a primarily self-led intervention for an internalizing disorder. The GRCS significantly correlated with the MASC-2 change scores, considered a 'gold standard' screen of adolescent-reported anxiety symptoms, providing support for the validity of the MCID estimate. Disadvantages of the anchor-based method, however, include the selection

of the anchor itself (ie, GRCS) and the potentially arbitrary nature of the MCID 'cut-point' for a small change in anxiety (ie, "somewhat better"), although the GRCS change is consistent from other studies (Norman, 2003). Thus, the MCID estimate calculated can vary between samples with different participant characteristics (eg, baseline severity, previous treatment experiences) (Copay et al., 2007; Kamper et al., 2009; King, 2011). Moving forward, we recommend that MCIDs be calculated using the same measures (GRCS, MASC-2) for adolescent users of other iCBT programs. A composite MCID estimate can then be generated by amalgamating MCID data across multiple studies to increase the generalizability and validity of the estimate (Song, Lin, Ward, & Fine, 2013) and/or provide a range of critical MCID values can be provided. The composite and ranges can be corroborated using Delphi (eg, clinical or expert opinion) or distribution-based methods (eg, effect size, standard error of measurement) (Beaton et al., 2002; Copay et al., 2007), triangulating multiple approaches to calculating the MCID to improve the robustness of the estimate (Wright et al., 2012).

Finally, in this study there was a large rate of attrition, which resulted in only about one-third of enrolled adolescents included in the user experience analysis. Attrition is said to be a fundamental characteristic and methodological limitation of longitudinal iCBT studies (Eysenbach, 2005; Lal & Adair, 2014; Melville, Casey, & Kavanagh, 2010). It is also consistent with drop out in outpatient therapy settings (deHaan, 2013). As well, participants reported high levels of anxiety on standard screening tools (MASC-2, "very elevated") which reflects a higher severity of anxiety symptoms in those seeking help than in most iCBT studies. This study was inclusive of youth at any stage in their treatment journey, and it is possible that some youth were exploring multiple options to access help and that iCBT was not the option of best fit at that time. It is also possible that the limits in timing of the evaluation at baseline and 6 weeks from

enrolment may also have impacted the number of users as some may have been excluded who would have engaged further with a longer time course. Thus, our user experience findings may be based on adolescents who are different than those who dropped out of the study. *Breathe* users who used the program and completed the post-intervention assessments may have had a preference for self-help programs, greater motivation or commitment to treatment, or viewed the program to be highly relevant or beneficial to them (Calear, Christensen, Mackinnon, & Griffiths, 2013; Eysenbach, 2005; Iloabachie et al., 2011). Since the perceptions of adolescents who dropped out were not captured by our evaluation, we are limited in understanding of why an iCBT program is unlikely to be used once accessed.

5.5 Conclusions

Given the high prevalence of anxiety disorders, the challenges in accessing CBT, and the interest of young people in internet interventions, iCBT is an important area of clinical research. In this study, we used user-report measures, including a new measure, the UEQII, to examine the multiple components that influence anxious adolescents' experiences with iCBT as compared to that of resource-based webpages. How iCBT is delivered may influence and help explain the relatively low number of session use, perception of time constraints and other commonly reported challenges to completing a program. The more positive experience *Breathe* users reported as compared to webpage users may be attributed to the interactive technological features and program activities (eg, graphs, video demonstrations, learning about anxiety) with specific focus on anxiety coping skills incorporated into iCBT. Although most adolescent users experienced benefit from iCBT, the relationship between adolescents' use, their experiences and perceived impact on anxiety is still unclear, indicating that further understanding of what adolescents find challenging and enjoyable about iCBT, as well as the characteristics of those

who would most benefit from this delivery mode, is necessary to optimize its delivery. Future studies can validate the UEQII, test and integrate our program suggestions, and apply our user experience measures toward creating robust treatment-planning guidelines including mechanisms to engage more youth in treatment completion.

Abbreviations

Breathe: Being Real, Easing Anxiety: Tools Helping Electronically

CBT: cognitive behavioural therapy

df: degrees of freedom

GRCS: global ratings of change scale

iCBT: Internet-based cognitive behavioural therapy

MASC-2: Multidimensional Anxiety Scale for Children—2nd Edition

MCID: minimal clinically important difference

RCT: randomized controlled trial

SD: standard deviation

UEQII: User Experience Questionnaire for Internet-based Interventions

Appendix 5.1. The User Experience Questionnaire for Internet-based Interventions (UEQII).

Please think about your experience with the [*Breathe* program/ anxiety resources webpage] intervention and rate the following:

1.	Was it easy to use?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
2.	Was it convenient to use?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
3.	Was the information easy to understand?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
4.	Was the Internet a good method for delivering this information?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
5.	Were you eager to use it?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
6.	Were you satisfied?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
7.	Did it meet your expectations?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
8.	Did it keep your interest?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
9.	Did you trust the information from it?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
10.	Did concerns about your privacy (eg, friends or family knowing about your online activities) affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		4	3	2	1	0
11.	Did access or availability of a computer affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		4	3	2	1	0
12.	Did technical computer problems (eg, trouble logging in, clicking to the next page) affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		4	3	2	1	0
13.	Did Internet problems (eg, slow or poor connection) affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		4	3	2	1	0

14.	Did personal commitments (eg, family time, extracurricular activities) affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		4	3	2	1	0
15.	Did school commitments (eg, class time, homework) affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		4	3	2	1	0
16.	How likely would you be to come back to it if difficulties with your anxiety continue or return?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
17.	How did your ability to manage your anxiety change by using it?	Really Worsened	Somewhat Worsened	No Change	Somewhat Improved	Really Improved
		0	1	2	3	4
18.	How did your anxiety with activities at school (eg, speaking up in class, taking a test) change by using it?	Really Worsened	Somewhat Worsened	No Change	Somewhat Improved	Really Improved
		0	1	2	3	4
19.	How did your relationships with friends and peers change by using it?	Really Worsened	Somewhat Worsened	No Change	Somewhat Improved	Really Improved
		0	1	2	3	4
20.	How did your relationships with family members change by using it?	Really Worsened	Somewhat Worsened	No Change	Somewhat Improved	Really Improved
		0	1	2	3	4
21.	How did your overall anxiety change by using it?	Really Worsened	Somewhat Worsened	No Change	Somewhat Improved	Really Improved
		0	1	2	3	4
22.	Was it a good fit for you?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
23.	Did you like the way it looked?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
24.	Did the information relate to you and your situation?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
25.	Did it help you to meet your Treatment goals?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
26.	Did the reminder emails affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4

27.	Did the time required to complete the program affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		4	3	2	1	0
28.	Did concerns about 'facing your fears' affect your use of it?	Not at all	Slightly	Somewhat	Mostly	Completely
		4	3	2	1	0
29.	How likely would you be to recommend it to others?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
30.	Were the follow-up emails and telephone calls helpful?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
30a.	If you answered 'Not at all' or 'Slightly' to the question above, why were the emails and telephone calls not very helpful?	Open text box				
31.	Were the homework ('Try Out') exercises helpful?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
32.	Were the homework ('Try Out') exercises easy to complete?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
32a.	If you answered 'Not at all' or 'Slightly' to the question above, why was it a challenge to complete the homework?	Open text box				
33.	Was the worry ladder helpful?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
34.	Was the worry ladder easy to complete?	Not at all	Slightly	Somewhat	Mostly	Completely
		0	1	2	3	4
34a.	If you answered 'Not at all' or 'Slightly' to the question above, why was it a challenge to complete the worry ladder?	Open text box				
35.	What was the most challenging part of the program?	Open text box				
36.	What was the most enjoyable part of the program?	Open text box				

Appendix 5.2. Scoring of the UEQII.

Questionnaire for the Control and Treatment groups (Items 1-21):				
		Items	**Reverse Scored Items**	**Total Score Range**
'Core' items total score		1-21	10-15	0-84
Construct 1 total score: Satisfaction and Acceptability		1-8	None	0-32
Construct 2 total score: Credibility and Impact		9, 17-21	None	0-24
Construct 3 total score: adherence and Usage		10-16	10-15	0-28
Questionnaire for the Treatment group only (Items 22-36):				
	Open-field Responses	**Items**	**Reverse Scored Items**	**Total Score Range**
'Treatment' items total score	N/A	22-34	27, 28	0-52
Construct 1 total score: Satisfaction and Acceptability	35, 36	22-24, 29	None	0-16
Construct 2 total score: Credibility and Impact	30a	25, 30, 31, 33	None	0-16
Construct 3 total score: Adherence and Usage	32a, 34a	26, 27, 28, 32, 34	27, 28	0-20

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Chapter 6

Discussion

6.1 Overview of Findings

The three research studies presented in this dissertation were based on explorations of program designs and the user experience of iCBT for adolescents with anxiety. The first study was a realist synthesis that examined what iCBT program content, interaction, and technologies may lead to moderate-to-high program use for child and adolescent users. The second study was a realist synthesis with a focus on what iCBT program content, interaction, and technologies may contribute to reductions in anxiety symptoms among users. The third study was a multiple methods study that involved the examination of the use, experiences, and perceived impact of an iCBT program for adolescents with anxiety, and how user experiences with iCBT compared to those experiences with another Internet-based intervention. Based on this novel research, I generated hypotheses for how key program activities, technological features, delivery contexts may support desired health outcomes—program use, symptom reductions, positive user experiences—among adolescents who use iCBT.

6.1.1 Main findings from study 1

My aim for study 1 was to explore how, why and for whom iCBT programs for children and adolescents with anxiety may produce the program use outcomes reported in the literature. My examination maintained the perspective that iCBT programs have multiple interacting technology-based components (are complex interventions) and are designed to drive behaviour change (are persuasive systems). I adopted a realist synthesis approach that allowed me to identify 5 possible relationships as to how the use of specific persuasive system design features (technology-based mechanisms) supported by some key user and delivery features (context) may

generate moderate-to-high program use (outcomes) in iCBT for children and adolescents with anxiety. The 5 context-mechanism-outcome configurations provided support for multiple persuasive strategies to improve iCBT program use: tailoring and personalization (primary task supports); rewards, reminders and social role features (dialogue supports); and trustworthiness, expertise and authority features (system credibility supports). This study provided support for the use of PSD features that have been previously reported in the literature (eg, primary task and dialogue support features), but also suggested potentially beneficial features that have been under-recognized or used (eg, rewards, system credibility support features). I hypothesized that utilizing multiple PSD features, both within and across the different support categories, may produce additive or synergistic effects on program use; however, there was insufficient evidence available to explain the impact of specific combinations of PSD features. Adjunct program support was an important aspect of the iCBT delivery context that seemed to improve program use. I found indications that the adjunct support person (eg, teacher, online therapist, in-person parent) and the communication approach the support person used with the user (eg, email, telephone) may have influenced program use. Both factors varied based on the level of prevention the program was designed for (universal prevention, indicated prevention, treatment) and on the age of program users. Children completing treatment-based iCBT programs generally received the most extensive adjunct support (ie, regular involvement from a therapist and/or parent), and program use was often greater among children than adolescents. Recognizing that multiple PSD features are incorporated in iCBT program designs, and that individual features may affect each other differently, further knowledge and testing of the purpose and function of these features will help determine the number and combination to use in certain delivery

contexts. With formal testing, these hypotheses may become evidence-based principles that can guide the design and development of future iCBT programs for this population.

6.1.2 Main findings from study 2

My aim for study 2 was similar to study 1 in that I sought to explore how iCBT programs for children and adolescents with anxiety work from a complex intervention and persuasive systems design perspective. However, my outcomes of interest were different for this study. The focus of study 2 was on understanding how changes in anxiety symptoms post-intervention are produced. Using a realist synthesis approach, I developed 11 context-mechanism-outcome configurations that hypothesize the PSD features (technological mechanisms) that may contribute to the reported reductions in anxiety symptoms (outcomes), as they relate to key user and delivery features (context). The 11 configurations were developed and organized according to 'program type' (universal prevention [3 configurations], indicated prevention [4 configurations], or treatment programs [4 configurations])—recognizing that the level of prevention or treatment that a program is designed for has different target users and design elements, and these differences may be a defining aspect of iCBT programs; thus, program type should be accounted for in my analysis. Across the configurations for each program type, some key PSD features recurred, indicating that there may be some features that are universally beneficial in iCBT: self-monitoring, simulation, social role, similarity, social learning and rehearsal. Tailoring was a feature unique to indicated prevention programs, and personalization, trustworthiness, expertise and authority were unique to treatment programs. Adjunct program support was an important part of the delivery context of all programs, with the support person, their expertise, and their frequency of involvement differing according to program type (and therefore user characteristics [eg, anxiety severity] and program design [eg, CBT techniques,

PSD features] did as well). In this study I proposed that the function (proposed purpose), and not necessarily the quantity, of key PSD features may be most important in reducing users' anxiety. A description of the proposed purpose of key PSD features was provided. Examining Internet-based treatments as tools for behaviour change helps us understand how anxiety symptomology is addressed via program activities and features and which attitudes or beliefs are targeted in iCBT programs. Formal testing of the individual and combined components presented in the 11 configurations (hypotheses) is now required to determine their effectiveness in reducing anxiety for child and adolescent iCBT users and how these programs can be further improved.

6.1.3 Main findings from study 3

One aim for study 3 was to understand adolescents' use of, experiences with, and perceived impact of an iCBT program for anxiety (the *Breathe* program). A combination of automatically captured data and user-report measures, including a user experience questionnaire that I developed (the multi-construct User Experience Questionnaire for Internet-based Interventions [UEQII]), were collected within a national RCT of the *Breathe* program. My 'user experience' study was embedded in the trial to help other research teams interpret program iCBT study outcomes and inform the optimization of this type of treatment in the future. Understanding adolescents' perceived impact of iCBT involved defining the minimal change that adolescents experience (ie, feeling 'somewhat better') following their use of iCBT, indicating whether a meaningful improvement in adolescents' anxiety had occurred (determining a MCID). This was the first study in the field of iCBT for adolescent anxiety to calculate a MCID for a commonly used standardized anxiety symptom questionnaire (MASC-2). A second aim of the study was to explore how the experiences of iCBT (*Breathe*) users compared to that of users of another Internet-based intervention (resource-based webpages). Intervention use was low for

adolescents allocated to *Breathe* or the webpages. Overall, among adolescents who provided user experience data, experiences with *Breathe* were rated significantly more positive than the experience of webpage users. Significant relationships between *Breathe* use and the Adherence and Usage construct and total item scores of the UEQII were found. *Breathe* users' feedback indicated that their use of and experiences with the program may have been hindered by their lack of comfort with the coaching call, difficulty with comprehension or initiation of the exposure and/or homework activities, conflicting personal commitments. Users' enjoyment in learning about anxiety, developing new coping strategies and feeling a sense of normalization about their experiences may have promoted iCBT use and provided a more satisfying program experience for some users. The majority of *Breathe* users reported that their anxiety was 'better' following program use and I calculated the MCID to be an average change score of 13.8 points (SD 18.1) on the MASC-2. Using the MCID as a cut-off, 43% of *Breathe* users were 'positive treatment responders'. Treatment response was not related to program use or users' ratings of their *Breathe* experience. The lack of relationships between most measures used in this study suggests that program use, experience, and perceived impact each play an important, but perhaps distinct, role in understanding what an effective or successful iCBT program means. User-report measures can be used to interpret and explain treatment outcomes and to gain valuable feedback to optimize iCBT programs and their evaluations to better meet the needs of adolescent users.

6.2 Strengths and Limitations

In two of my dissertation studies, I applied a relevant, comprehensive, and increasingly studied model, the PSD model (Oinas-Kukkonen & Harjumaa, 2008), to guide my analyses of the design and evaluation of iCBT programs. My use of this model helped me to organize and systematize my analyses (Abbott, Foster, Marin, & Dykes, 2014) and increase the interpretability

and application of my findings. With increasing emphasis being placed on the need for theory to guide Internet-based intervention development (Kok, Gottlieb, Bartholomew, & Parcel, 2013; Lippke & Ziegelmann, 2008; Michie & Johnston, 2012), my findings provide new PSD-based ideas around program components and activities to test in future clinical trials of iCBT programs. The approach I took to bring together diverse data of iCBT programs was systematic and focused. However, because my syntheses were focused on PSD, how other factors (ie, mediators or moderators) may affect how iCBT programs work—such as user's psychological characteristics (eg, cognitive processing style, beliefs or attitudes, skills and literacy; Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009), user engagement (eg, adherence, satisfaction, motivation; Barello et al., 2016), and environmental and cultural influences (eg, healthcare policies, user's location, societal perceptions of health)—was not a focus, but can be explored in future studies building on my PSD work.

When evaluations take place matters. In all three of my studies, I relied on the availability of post-treatment data for my analysis. As is common with iCBT programs, poor rates of program completion and/or study attrition were observed for included studies (Radomski et al., 2019). Participants who provided study data may be characteristically different (eg, in terms of motivation, accountability, enjoyment of iCBT, suitability for a self-help program) than those who did not provide data (Calear, Christensen, Mackinnon, & Griffiths, 2013; Eysenbach, 2005; Iloabachie et al., 2011). Therefore, participants who I needed to understand in terms of helping them to stay engaged or benefit from an iCBT program, for example, were insufficiently examined. To bridge this limitation, in study 3 I used data from program 'completers' to hypothesize reasons for low use and suggest solutions to help adolescents use a program in a way that was meaningful for them.

At this time, there is considerable heterogeneity in how the user experience is defined and evaluated, with most research being conducted with adult populations or in-person treatments (Perski et al., 2019; Perski, Blandford, West, & Michie, 2017; Short et al., 2018; Yardley, Spring, & Riper, 2016). Strengths of my third study include my multidimensional definition of the adolescent user experience of an iCBT program and my use of multiple data sources to understand user experiences. This approach helped me to explore unexamined aspects of iCBT programs that may explain or interpret usage or effectiveness findings. A limitation in this approach is that the self-report tools I used, the UEQII and MCID, are subject to inherent reporting biases (eg, recall or social desirability). Despite this, the tools provided me with unique insights into adolescents' perceptions of an Internet-based intervention and of their anxiety which may not otherwise be captured using other methods (eg, electronic behavioural data). Psychometric testing is now required to determine the validity and reliability of the tools and to assess their feasibility and transferability in other delivery settings and for other populations and iCBT programs.

6.3 Recommendations

6.3.1 Determining what program components are most effective in different delivery contexts

There is a need to develop an evidence base recognizing iCBT as a complex intervention (Craig et al., 2013)—an intervention that is embedded in varied delivery contexts and comprised of multiple approaches to engage users (mechanisms) (Barak, Klein, & Proudfoot, 2009; Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012). Relatively few iCBT studies have examined how content, interactions, and technologies work together to produce iCBT outcomes (ie, program use, anxiety reductions) (Calear et al., 2013; Lenhard et al., 2016; March, Spence, & Donovan, 2009; Neil, Batterham, Christensen, Bennett, & Griffiths, 2009; Patwardhan, 2016;

Spence, Holmes, March, & Lipp, 2006; Stoll, Pina, Gary, & Amresh, 2017; Tillfors et al., 2011). Future studies can advance the findings from my realist syntheses to determine: (1) which candidate mechanisms are strongly associated with program contexts and its outcomes; and (2) that the relationships are plausible, are in the expected directions, and the mechanisms precede the outcome(s) (Kazdin, 2007; Kazdin & Weisz, 2003). Systematically evaluating the usefulness of a few program components at a time with nimble, adaptive, and explanatory approaches (eg, sequential multiple assignment randomized trials [SMART]; Multiphase Optimization Strategy [MOST]) can contribute to a quicker accumulation of program design knowledge and iteration of design or development solutions for effective, usable, and enjoyable programs. These approaches can involve assessing the mechanisms and outcomes at multiple time points to isolate the mechanisms ideal 'dose', function, 'point of action' or peak usefulness (Baker, Gustafson, & Shah, 2014; Collins, Murphy, & Strecher, 2007; Holmes et al., 2018; Kazdin, 2007; Kazdin & Weisz, 2003). These approaches can also help to establish set criterion with which to compare the effectiveness of new iCBT programs to improve the efficiency of program evaluation.

6.3.2 Further development of a theory-based repository of effective program components that address psychotherapy techniques

Theories or models provide some operationalization and standardization of terms, can increase reproducibility of similar classification among researchers, and can support program comparisons between studies as developers and researchers so that they can begin 'speaking the same language'. The Persuasive Systems Design (PSD) and Institute of Medicine (IOM) models that I used in my dissertation research provided a systematic way to identify and evaluate iCBT program components. Other design frameworks are also available such as the CeHRes roadmap (van Gemert-Pijnen et al., 2011), BIT Model (Mohr, Schueller, Montague, Burns, & Rashidi,

2014), U-FADE (Wiafe, 2013), TUDER (Wang, Fadhil, Lange, & Reiterer, 2018), and BCTT (Michie et al., 2013). These models describe the use of technology for behaviour change and may provide new insights into the iCBT field if used in the design and evaluation of iCBT programs. Identification and analysis of CBT techniques in relation to behaviour change (eg, goal setting, problem solving) and technological techniques (eg, virtual rewards, video demonstrations) could advance our understanding of iCBT from a psychological perspective, offering unique insights into psychological (user) mechanisms of change. Researchers in the iCBT field may come to recognize crucial 'CBT mechanisms' as part of these interventions or realize that they can be relatively 'psychotherapy-agnostic' (not adhere to any formal psychotherapy clinical guidelines) and still be effective.

6.3.3 Post-intervention user experience evaluations to confirm projected solutions

There has been relatively little formal consideration of how users' needs, preferences and experiences are incorporated into a model for iCBT design. The majority of adolescent involvement in the design and evaluation of iCBT programs has been in initial design stage activities (Patwardhan, 2016; Verdaguer, Mateo, Wyka, Dennis-Tiwary, & Leung, 2018; Whittemore, Grey, Lindemann, Ambrosino, & Jaser, 2010; Wozney, Baxter, & Newton, 2015) such as:

(1) Co-design, where developers seek the opinions of users on what features or characteristics they would like to have included in a program;

(2) Think-aloud interviews, where users give their immediate reaction to the program and its features or researchers observe how users use the program (Van den Haak, De Jong, & Schellens, 2007); and

(3) Usability testing, where users provide feedback on what works or does not work and/or identify technical, content, navigation or aesthetic issues that may affect user satisfaction (Breakey et al., 2013). However, we have not closed the loop on whether adolescents found their design suggestions to be beneficial, enjoyable, usable, etc., after they experience a program as part of a research study (ie, did their input, and researchers/developers use of it effect program outcomes, like program usage or effectiveness?). Asking adolescents to report directly on their experience with a program can help ensure the relevance, use and impact of a program from a user's perspective.

Future studies need to include adolescents' input about program design components and outcomes that they consider important to them post-intervention. Incorporating post-intervention user-report measures into a larger study of an iCBT program effectiveness would provide information about how different users perceive and act on different components of an iCBT program—what was satisfactory, acceptable, credible, impactful (asking adolescents what their 'user experience' was)—and whether or how use of the program and its components lead to important changes in the users' anxiety (asking adolescents what they consider to be an important change in their anxiety and did they experience it?). User-report measures should also capture information that is not directly observable (subjective) and that cannot be captured by objective measures or third-party respondents. This would help differentiate between the program components that are considered effective based on statistical significance as compared to those that have practical or clinical significance (are important or meaningful to adolescents).

6.3.4 Comparison with other Internet-based interventions to isolate iCBT components

Mechanisms of psychotherapy programs are most rigorously evaluated when the treatment of interest is closely matched to a comparison treatment/condition (Horvath, 1988;

Lohr, DeMaio, & McGlynn, 2003; Safer & Hugo, 2006; Stevens, 2000). Future studies need to compare iCBT with an appropriate Internet-based comparator as opposed to a waitlist or inactive comparator to better identify important iCBT program components. An appropriate comparison treatment may include some of the general therapeutic factors that the treatment of interest includes (eg, psychoeducation, credible resources) while omitting the unique active ingredients (mechanisms) of the treatment under investigation (eg, exposure activities, interactive surveys) (Horvath, 1988; Stevens, 2000). The comparison of two active treatment condition helps control for the influence of 'common factors' on treatment outcome (e.g. in face-to-face CBT common factors may be therapeutic alliance or rationale; in iCBT common factors may be accessing the Internet for anxiety management or adolescents deciding when to login online) (Safer & Hugo, 2006), and increases the likelihood of assessing whether the proposed mechanisms were effective. An active comparator can also help protect against inflated treatment effects that can be found with the use of an inactive comparator (ie, waitlist) (Kiluk et al., 2011) to provide a more accurate representation of effect sizes.

Not only is inclusion of a well-matched comparison group important to determine the effectiveness of an iCBT program, but an appropriate assessment tool that can compare both Internet-based intervention groups is important also. Such an assessment tool can inquire more deeply into the technological, content, and 'user experience' aspects of the interventions more specifically since a participant will be able to directly comment on their interactions (versus have no interactions in the case of a waitlist participant, or no technology interactions in the case of face-to-face CBT). As an example, future studies can include the UEQII as part of the evaluation of an iCBT program, tailoring the questionnaire to their specific intervention groups (adapting 'treatment' items as needed). Incorporating the UEQII in future studies also provides an

opportunity to assess the UEQII's feasibility and transferability in other contexts, ages and patient groups and iCBT or Internet-based programs.

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