



# Pilot trial of a therapist-supported internet-delivered cognitive behavioural therapy program for health anxiety



Jill M. Newby<sup>a,b,\*</sup>, Alison E.J. Mahoney<sup>a</sup>, Elizabeth C. Mason<sup>a</sup>, Jessica Smith<sup>a</sup>, Shivani Uppal<sup>a</sup>, Gavin Andrews<sup>a</sup>

<sup>a</sup> Clinical Research Unit for Anxiety and Depression, School of Psychiatry, University of New South Wales at St Vincent's Hospital, Darlinghurst, NSW, Australia

<sup>b</sup> School of Psychology, University of New South Wales, Australia

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## ABSTRACT

Cognitive behavioural therapy (CBT) is an effective treatment for health anxiety, but more research is needed to evaluate accessible, low cost ways of delivering CBT. Internet CBT may be effective, but there are no iCBT programs available outside of Sweden. We developed the first English-language clinician-guided iCBT program for health anxiety and conducted an open pilot trial ( $n = 16$ ) to examine its acceptability, and impact on health anxiety and comorbidity, disability, and the cognitive and behavioural factors thought to maintain the disorder (e.g., catastrophising, hypervigilance). 13/16 participants completed the program (81% adherence). We found large and significant reductions in health anxiety, depression, distress, anxiety and disability ( $g$ 's  $> 1.0$ ), dysfunctional cognitions, behaviours and body vigilance between pre- and post-treatment, which were maintained at 3-month follow-up. The results provide preliminary support for the use of iCBT for health anxiety. Randomised controlled efficacy trials are now needed to evaluate this program.

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## 1. Introduction

Health anxiety is a disabling condition characterised by excessive fears of having or developing serious illnesses, misinterpretation of bodily symptoms and body hypervigilance, and maladaptive behaviours including body checking and excessive reassurance-seeking, (Fink et al., 2010). Health anxiety is a core feature of the new Illness Anxiety Disorder (IAD) and Somatic Symptom Disorder (SSD) diagnoses in DSM-5 (American Psychiatric Association, 2013), but is less restrictive and more clinically useful 'diagnosis' compared to the narrowly defined DSM-5 IAD criteria, which excludes individuals who experience somatic symptoms (Tyrer et al., 2016).

Epidemiological studies suggest that health anxiety is common in the community, with prevalence estimates ranging between 3.4% (Sunderland et al., 2012) and 7.7% (Creed and Barsky, 2004; Sunderland et al., 2013). Health anxiety is associated with a range of adverse consequences including high distress, poor occupational functioning, days out of role, and loss of quality of life, higher physical disability and greater rates of comorbid mental and physical disorders, and poor interpersonal relationships including the strained relationships with doctors (Conradt et al., 2006; Gureje et al., 1997; Sunderland et al., 2012). Health anxiety is also a key driver of health service use and linked

to high health care utilisation (Bobevski et al., 2016; Fink et al., 2010), and characterises patients who persistently and frequently attend primary care (Patel et al., 2015).

Cognitive Behavioural Therapy (CBT) has been shown to be effective for treating health anxiety (Thomson and Page, 2007), and is preferred over medications (Walker et al., 1999). CBT is based on cognitive behavioural models of health anxiety (Warwick, 1989; Warwick and Salkovskis, 1990) and uses techniques such as cognitive challenging, behavioural experiments and graded exposure to modify the cognitive (e.g., dysfunctional illness beliefs, and catastrophic misinterpretations of bodily symptoms), emotional (e.g., anxiety and depressed mood) and behavioural (e.g., reassurance-seeking, checking and avoidance) variables that are theorised to maintain health anxiety. CBT has been shown to be effective for patients with elevated health anxiety (Tyrer et al., 2013) and DSM-IV Hypochondriasis (Seivewright et al., 2008; Sorensen et al., 2011; Warwick et al., 1996). A recent meta-analysis of 13 randomised controlled trials (RCTs) of CBT interventions for health anxiety (Olatunji et al., 2014) found large between-groups differences between CBT and control conditions at post-treatment (mean  $g = 0.95$ ) and follow-up (mean  $g = 0.35$ ).

Although CBT is an established evidence-based treatment for health anxiety, it can be difficult to access and expensive to deliver (Seivewright et al., 2008). Because patients with health anxiety typically attribute their symptoms to medical rather than psychological causes, they tend to present to medical settings or medical health services (e.g., GPs, emergency, outpatient medical clinics) rather than psychological services. Referral to psychiatrists or psychologists can be fraught and difficult. It is now a

\* Corresponding author at: School of Psychology, 1302 Mathews Building, University of New South Wales, Kensington, NSW, 2052, Australia.

E-mail address: [j.newby@unsw.edu.au](mailto:j.newby@unsw.edu.au) (J.M. Newby).

priority to find innovative approaches to deliver CBT to people with health anxiety in a manner deemed acceptable to the patient.

One approach which has seen recent success is the use of the internet to deliver CBT. iCBT is low-cost, highly scalable and convenient, and private, and can be prescribed and supervised *within* general and medical practice (Newby et al., 2014). iCBT is effective for the treatment of a range of anxiety disorders, depression, and somatic conditions including irritable bowel syndrome (IBS), and chronic pain (Andrews et al., 2010; Hedman et al., 2012). Hedman and colleagues found that 12-weeks of therapist-supported iCBT was more effective than an online discussion forum control group in reducing health anxiety, and comorbid anxiety and depression ( $ds = 1.05$ – $1.62$ ), with gains maintained at 6-month and 12-month follow-up (see Hedman et al., 2013a, 2013b, and 2013c for 12-month outcomes). In a second RCT, Hedman et al. (2014) showed that iCBT was significantly more effective than an internet-delivered behavioural stress management (iBSM) program in reducing health anxiety at post-treatment, although both treatment groups showed large pre- to post-treatment improvements (iCBT:  $d = 1.78$ ; iBSM  $d = 1.22$ ). A recent RCT with participants with DSM-5 diagnoses of IAD or SSD conducted by Hedman et al. found that both guided iCBT and unguided iCBT demonstrated large effects sizes in reducing health anxiety, with benefits observed with limited therapist contact time ( $M = 64$  min in the guided condition) (Hedman et al., 2016). Together, these studies demonstrate that iCBT for either hypochondriasis or health anxiety is feasible and effective in reducing health anxiety symptoms. However, to our knowledge there are no existing programs for the online treatment of health anxiety outside of Sweden, and iCBT for health anxiety has never been evaluated by a research team independent from Hedman's research team.

To address this gap, we developed a new online 6-lesson English-language CBT program for health anxiety (the *Health Anxiety Program*), and evaluated the feasibility and acceptability of the program in a small open pilot trial with participants who met DSM-5 criteria for either Illness Anxiety Disorder (IAD) or Somatic Symptom Disorder (SSD). We included participants with either IAD or SSD (rather than restricting our inclusion criteria to IAD only) because the new overly restrictive DSM-5 IAD criteria would exclude individuals with moderate to severe somatic symptoms, which is a common and defining feature of health anxious individuals. This is the first time iCBT for health anxiety has been evaluated by a research group independent from Hedman's research team. The iCBT program was modelled on existing research-tested iCBT programs developed and evaluated by our team (Mahoney et al., 2014; Newby et al., 2013; Perini et al., 2009), and comprised evidence-based CBT techniques drawn from existing CBT treatment protocols for health anxiety (Abramowitz and Braddock, 2011; Furer et al., 2007) and self-help texts (Anderson et al., 2011).

Our first aim was to assess the impact of the iCBT program on health anxiety, comorbid symptoms (depression, distress, and generalised anxiety), functional impairment, as well as the cognitive (e.g., hypervigilance, dysfunctional cognitions about health and illness, intolerance of uncertainty, mindful awareness) and behavioural (e.g., avoidance and safety behaviours such as checking and reassurance-seeking) processes that the iCBT program was designed to target. Our second aim was to explore the acceptability of this program, which we evaluated through adherence/completion rates, and patient satisfaction ratings. Because of the tendency for health anxious individuals to become overly anxious and amplify somatic symptoms when reading information about health and health concerns (Barsky et al., 1990; Ferguson et al., 2000), we also assessed whether any participants reported negative emotional reactions to the lessons, and/or unwanted side effects from participating in the program. In line with previous studies we expected large reductions in health anxiety and comorbid symptoms of depression and anxiety, good adherence (>70%) and that participants would find the program acceptable.

## 2. Method

### 2.1. Design

An open pilot trial design was used to explore the effects of the iCBT program. Participants were assessed at pre-, mid-treatment, post-treatment and at 3 months post-treatment.

### 2.2. Inclusion/exclusion criteria

Inclusion criteria were: (i) aged over 18, (ii) self-identified as experiencing symptoms of health anxiety and met criteria for a diagnosis of either DSM-5 IAD or SSD according to structured telephone diagnostic interview (if the participant met criteria for SSD, they must have endorsed criterion B2 of the DSM-5 criteria indicating the experience of persistently high level of anxiety about health or symptoms), (iii) prepared to provide their name, phone number and address, and the name and address of their local general practitioner, (iv) had attended a general practitioner for assessment of their physical health over the past 6 months, (v) had access to a phone, computer and printer, (vi) if taking antidepressant medications, were on a stable dose in the 2 months prior to assessment, and (vi) had not started psychological therapy in the 2 months prior to assessment. Exclusion criteria included psychosis or bipolar disorder, drug or alcohol dependence, current suicidality, current use of antipsychotic or regular benzodiazepine medications, or severe depression (PHQ-9 total scores >24).

### 2.3. Procedure

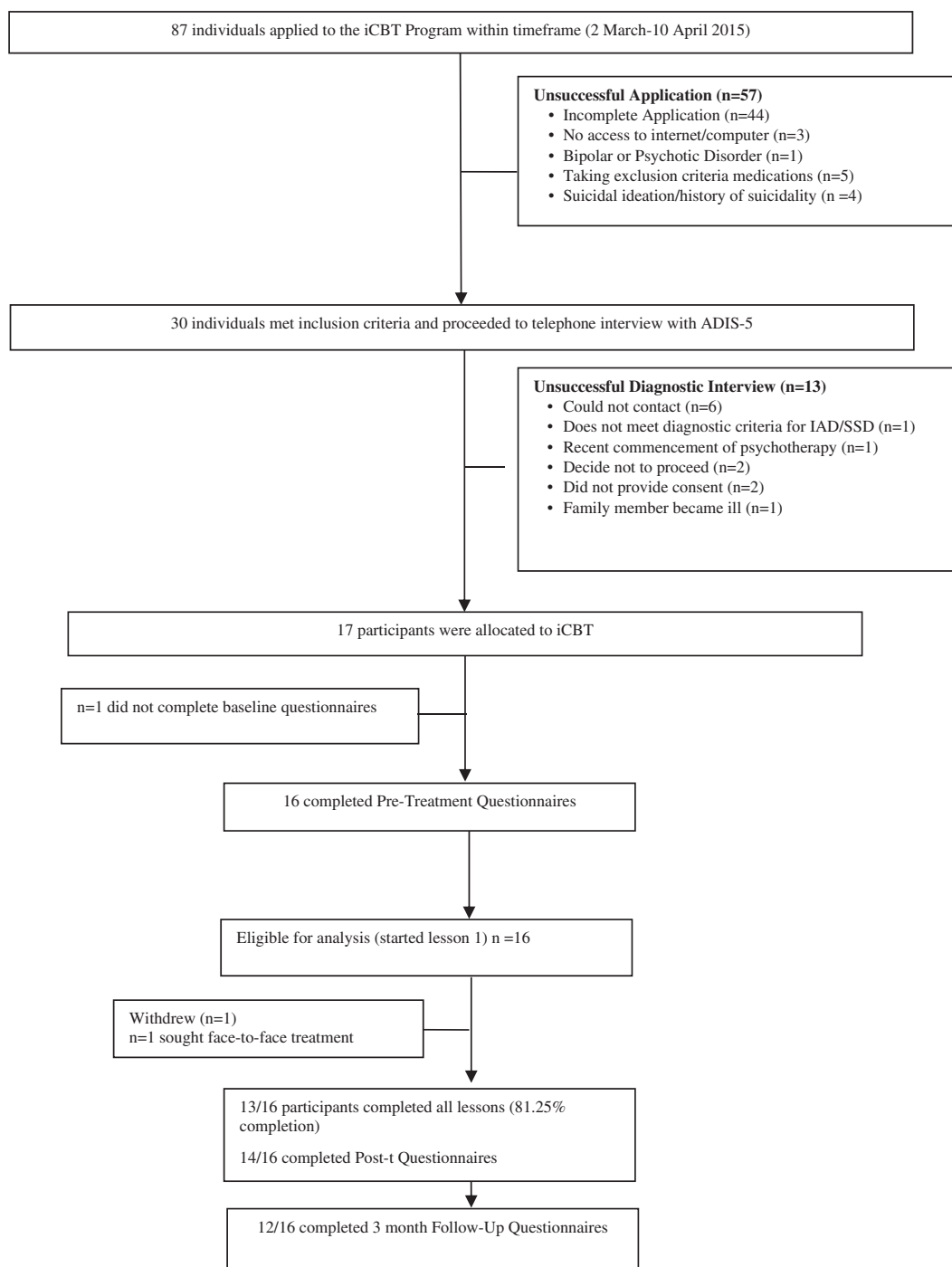
Participants applied online to [www.virtualclinic.org.au](http://www.virtualclinic.org.au) after reading details about the study. The online screening assessment comprised demographic questions, the Short Health Anxiety Inventory (Salkovskis et al., 2002) to assess health anxiety severity, the Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001) to assess depression severity and suicidal ideation. Participants who met online screening criteria then participated in a brief phone interview with a trained Clinical Psychologist with a PhD qualification in Clinical Psychology. The interviewer administered a structured diagnostic interview that consisted of an abbreviated version of the Anxiety Disorders Interview Schedule (ADIS-5) to confirm whether the applicant met DSM-5 criteria for IAD or SSD, supplemented with the modules from the Mini International Neuropsychiatric Interview Version 5.0.0 (Sheehan et al., 1998) to assess for the presence of current comorbid Panic Disorder, Agoraphobia, Generalised Anxiety Disorder (GAD), Obsessive Compulsive Disorder (OCD) and Major Depressive Disorder (MDD).

### 2.4. Participant flow

Details of participant flow are provided in Fig. 1. A total of 87 applicants applied to the program between 2 March 2015, and 10 April 2015. Of these, 57 applicants were excluded at online application, and a further 11 were excluded at the telephone interview, leaving 19 applicants who met inclusion criteria. Of these, two did not provide informed consent; one participant did not start the program (and had provided no baseline data). This left 16 participants who started the Health Anxiety Program, had baseline data and were included in the analysis. Data were collected from 14/16 participants at post-treatment, and 12/16 at follow-up. The study was approved by the Human Research Ethics Committee (HREC) of St Vincent's Hospital (Sydney, Australia) (HREC/14/SVH/294), and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN1261500033856).

### 2.5. Treatment program

The *Health Anxiety Program* consisted of 6 online lessons completed over 10 weeks, and was delivered via [www.virtualclinic.org.au](http://www.virtualclinic.org.au). The



**Fig. 1.** Participant flow diagram.

course content is presented in [Table 1](#). In each lesson, participants read an illustrated story of a fictional person with health anxiety who learned how to manage his symptoms using CBT skills. Each lesson also involves a downloadable lesson summary with recommended homework exercises and tasks. The course also includes a number of downloadable additional resources (see [Table 1](#)). All participants were sent a CD via post with the mindfulness of body sensations audio recording to listen to as part of the lesson 2 homework practice.

### 2.6. Clinician contact

All participants completing the iCBT course received email and/or phone contact with the clinician during the treatment period (JN, a

PhD-level Clinical Psychologist). All participants were contacted after lessons 1 and 2 either by email or phone call to encourage their progress throughout the course and to answer any questions they had about the program. After lesson 2, we employed a flexible approach to clinician contact, which was largely dependent on participants needs. Clinician contact occurred if either the participant initiated it (e.g., they sent an email asking questions about the program materials), if there was any evidence of deterioration on the K-10 (a rise in distress between lessons of 0.5SD or more), or little change in health anxiety scores between lessons (suggesting lack of improvement). In addition, the clinician contacted participants if they fell behind on lesson completion dates. Feedback on homework assignments was not routinely provided. Time spent contacting the participant (including telephone contact)

**Table 1**  
Lesson content and homework activities in the Health Anxiety Program.

Lesson title	Lesson content	Homework activities
1 Understanding health anxiety	<ul style="list-style-type: none"> <li>• Psychoeducation about health anxiety</li> <li>• Goal setting using the SMART principle</li> <li>• The Health Anxiety cycle</li> <li>• Identifying physiological, cognitive and behavioural symptoms of health anxiety</li> <li>• Psychoeducation about the fight or flight response</li> <li>• Understanding how cognitive behaviour therapy (CBT) can help</li> </ul>	<ul style="list-style-type: none"> <li>• Set goals for treatment</li> <li>• Complete my own health anxiety cycle</li> </ul>
2 Reducing your focus on health worries, and starting to reclaim your life	<ul style="list-style-type: none"> <li>• The noisy body, false alarms and explanations for physical sensations</li> <li>• The role of attention and attention focus experiment</li> <li>• Strategies to take the focus off your worries and your bodily sensations:               <ul style="list-style-type: none"> <li>○ Shifting attention</li> <li>○ Activity planning</li> <li>○ Worry-free zones</li> <li>○ Mindfulness</li> </ul> </li> <li>• Reducing checking and internet searching</li> </ul>	<ul style="list-style-type: none"> <li>• Activity planning</li> <li>• Bringing mindfulness into each day</li> <li>• Mindfulness of body sensations exercise</li> <li>• Checking prevention plan</li> </ul>
3 Becoming aware of your anxious thinking	<ul style="list-style-type: none"> <li>• Education about the cognitive model and unhelpful thinking errors</li> <li>• Alternative explanations for physical symptoms</li> </ul>	<ul style="list-style-type: none"> <li>• Thought monitoring</li> <li>• Thinking about alternative explanations for physical symptoms</li> <li>• Continue skills from previous lessons (activity planning, mindfulness of body sensations, worry-free zones, and cutting down checking and internet searching)</li> </ul>
4 Putting your thoughts and fears to the test	<ul style="list-style-type: none"> <li>• Thought challenging</li> <li>• Behavioural experiments (health anxiety experiments)</li> </ul>	<ul style="list-style-type: none"> <li>• Thought challenging</li> <li>• Behavioural experiments</li> </ul>
5 Tackling avoidance and safety behaviours	<ul style="list-style-type: none"> <li>• Education about avoidance and safety behaviours</li> <li>• Graded exposure</li> <li>• Tolerating uncertainty and doubt</li> </ul>	<ul style="list-style-type: none"> <li>• Create your own exposure stepladder</li> <li>• Graded exposure</li> </ul>
6 Learning how to stay well in the long-term	<ul style="list-style-type: none"> <li>• Evaluating progress</li> <li>• Overview/summary of skills</li> <li>• Lapses versus relapses</li> <li>• Relapse prevention plan</li> </ul> <p>Extra resources: Boosting motivation, controlled breathing, good sleep guide, helping your doctor help you, in case of emergency, information for family and friends, medications, panic attacks, progressive muscle relaxation, tackling low mood and keeping active, 100 things to do (pleasant activity planning ideas), labelling emotions, shifting your attention, structured problem solving, managing upsetting mental images, assertive communication, reassurance seeking frequently asked questions (FAQs)</p>	<p>Relapse prevention plan</p> <p>Worksheets (Extra resources): Thought monitoring worksheet, behavioural experiment form, thought challenging worksheet, pros and cons worksheet, activity planning and monitoring worksheet.</p>

was recorded by the clinician in each participant's case notes, and summed at the end of the study.

## 2.7. Measures

### 2.7.1. Diagnostic interviews

*The Anxiety Disorders Interview Schedule for DSM-5 (ADIS-5)* (Brown and Barlow, 2014). The ADIS-5 is a semi-structured diagnostic interview used to assess DSM-5 anxiety, depressive and somatic symptom diagnoses. In the absence of any validated diagnostic interviews to assess the new DSM-5 criteria for IAD and SSD at the start of the trial, we administered the IAD and SSD modules of the ADIS-5.

*Mini International Neuropsychiatric Interview Version 5.0.0* (Sheehan et al., 1998). The MINI is a semi-structured diagnostic interview that was employed to assess the presence of current comorbid Panic Disorder, Agoraphobia, GAD, OCD and MDD. The MINI possesses inter-rater reliability ranging between  $k = 0.88$ – $1.00$  and concurrent validity with the Composite International Diagnostic Interview (CIDI, see Kessler and Ustun, 2004).

### 2.7.2. Primary clinical outcomes

*The Short Health Anxiety Inventory (SHAI)* (Salkovskis et al., 2002). The SHAI is a validated 18-item self-report measure of the severity of health anxiety symptoms over the past week. The measure has good psychometric properties including good internal consistency, test-retest reliability and construct validity, and is sensitive to treatment (Abramowitz et al., 2007; Alberts et al., 2013). Participants are asked to rate each item with four response options to examine cognitive and behavioural features of health anxiety. Items are rated on a four point

scale, ranging from 0–3 (for example, the first item is: 0 = I do not worry about my health, 1 = I occasionally worry about my health, 2 = I spend much of my time worrying about my health, and 3 = I spend most of my time worrying about my health). In the current sample, the internal reliability estimate for the 18-item total score was 0.90.

### 2.7.3. Secondary clinical outcomes

*Body Vigilance Scale Short-Form (BVS-SF)* (Schmidt et al., 1997). The BVS-SF is a 3-item self-report measure of body vigilance, or the conscious monitoring and attention of internal states. Participants are instructed to rate over the past week (i) how much they paid close attention to internal bodily sensations, and (ii) how sensitive they were to changes in their internal bodily sensations (on a 1 = not at all, 5 = moderately, and 10 = extremely scale), and (iii) how much time they spent each day 'scanning' their body for sensations such as sweating, heart palpitations, and dizziness (where 0 = none, 5 = half of the time, and 10 = all of the time). The BVS has been shown to be elevated in patients with panic disorder, hypochondriasis and GAD, and has been associated with health care utilisation and health-related safety behaviours (Olatunji et al., 2007). In the original version of the BVS, an additional item is used to assess how much attention the individual pays to 15 symptoms of panic attacks, but we did not administer this item because our aim was to assess hypervigilance to bodily sensations more generally (rather than panic-specific sensations). In the current sample internal consistency of the 3-item measure was  $\alpha = 0.88$ .

*The Cognitions about Body and Health (CABAH)* (Rief et al., 1998) is a 31-item self-report measure of dysfunctional cognitions and assumptions related to the body, health, and illness behaviour, including catastrophising about minor bodily complaints. Participants rate their

general agreement with items (e.g., “A suddenly appearing joint pain can be a sign of a beginning paralysis”) on a 4-point scale ranging from 3 = completely right, 2 = mostly right, 1 = mostly wrong, and 0 = completely wrong. Internal consistency in the current study for the total scale at pre-treatment  $\alpha = 0.83$ .

The *Generalised Anxiety Disorder 7-item scale* (GAD-7, Spitzer et al., 2006) measured generalised anxiety disorder symptoms (e.g., “Feeling nervous, anxious, or on edge”) over the past fortnight on a scale ranging from 0 (not at all) to 3 (nearly every day), where 1 = several days, 2 = more than half of the days. The scale has good reliability and validity (0.85; Kroenke et al., 2007). In the current sample, internal consistency was  $\alpha = 0.83$ .

The *Intolerance of Uncertainty Scale – 12-item Short-Form* (IUS-12 Carleton, Norton & Asmundson, 2007) is a 12-item self-report measure of intolerance of uncertainty. Participants rate the degree to which each item is characteristic of them (e.g., I can't stand being taken by surprise) on a scale from 1 (not at all) to 5 (entirely characteristic of me).

The *Kessler 10-item Psychological Distress Scale* (K-10; Kessler et al., 2002) is a 10-item measure of non-specific psychological distress. Items (e.g., “About how often did you feel nervous?”) are assessed on a 5-point scale over the past fortnight. The K-10 has excellent psychometric properties (Furukawa et al., 2003), and higher scores indicate higher distress, with a score above 20 indicating clinical distress levels. In the current sample, internal consistency was  $\alpha = 0.90$ .

The *Patient Health Questionnaire-9* (PHQ-9). The PHQ-9 (Kroenke et al., 2001) is a widely used 9-item measure of depression symptoms experienced over the past 2 weeks. Participants rate the frequency of symptoms (e.g., “Feeling down, depressed, or hopeless”) over the past fortnight on a scale ranging from 0 (not at all) to 3 (nearly every day), where 1 = several days, 2 = more than half of the days. The measure has good internal consistency ( $\alpha = 0.86$ – $0.89$ ), test-retest reliability ( $r = 0.84$  over 48 h), and construct validity (Kroenke et al., 2001). It is also sensitive to change across CBT (Kroenke et al., 2001; Perini et al., 2009). In the current sample, internal consistency was  $\alpha = 0.78$ .

The *Patient Health Questionnaire 15-item Scale* (PHQ-15) (Kroenke et al., 2002) is a 15-item scale of the severity of a range of somatic symptoms experienced over the past four weeks. Items (e.g., stomach pain, back pain, headaches) are rated on a 3-point scale (where 0 = not bothered at all, 1 = bothered a little, 2 = bothered a lot) over the past four weeks. This measure has been demonstrated to have good internal consistency ( $\alpha = 0.80$ ), (Gierk et al., 2015), and is predictive of functional impairment, and health care utilisation in medical outpatient samples (Kroenke et al., 2002). Scores of 5, 10 and 15 represent cut-off points for low, medium and high severity of somatic symptoms. In the current sample, internal consistency was  $\alpha = 0.77$  at baseline.

The *Mindful Awareness and Attention Scale* (MAAS) (Brown and Ryan, 2003) is a 15-item self-report measure of the core characteristic of trait mindfulness (awareness of and attention to what is happening in the present moment). Items (e.g., “I find it difficult to stay focused on what's happening in the present”) are rated on a 7-point scale regarding the degree to what each item reflects their experience ranging from 1 (almost always) to 6 (almost never). Higher scores indicate higher trait or dispositional mindfulness. The MAAS has demonstrated to have good internal consistency (0.80–0.90, and 0.83 in the current sample), test-retest reliability, and discriminant validity (Brown and Ryan, 2003).

The *12-item World Health Organisation Disability Assessment Schedule* (WHODAS -II). The WHODAS-II (Rehm et al., 1999) assesses functional impairment and disability due to health conditions (including mental or emotional difficulties) over the past month. Reliability (current  $\alpha = 0.83$ ) and validity are sound (Andrews et al., 2009).

*Worry Behaviours Inventory Short-Form* (WBI-SF) (adapted from Mahoney et al., 2016). The WBI is a new self-report measure of safety behaviours and avoidant behaviours associated with worry. Five of the 6 items administered in the short-form were drawn from the original 20-item WBI, with the 6th item added to assess body checking because of its critical role in health anxiety. Participants are asked to rate the

frequency of 6 behaviours over the past week, including reassurance-seeking, distraction, avoidance, reassurance-seeking through information (e.g., internet searching), general checking, and body checking. While there are no published psychometric evaluations of the short form, Mahoney et al. (2016) provide evidence for internal reliability ( $\alpha = 0.86$ ), construct validity, and discriminant validity of the WBI. In the current sample, internal consistency of the WBI-SF was  $\alpha = 0.75$  at baseline.

#### 2.7.4. Acceptability ratings

**2.7.4.1. Time spent reading lessons.** To assess engagement in the program, we asked participants how long they spent (in minutes) reading the previous lesson and practicing the skills they had learnt.

**2.7.4.2. Emotional reactions and unwanted side effects.** After each lesson, participants completed a 2-item measure of their emotional and physical reactions to the lesson content. They were asked to compare: (i) how anxious they felt after the lesson compared to how they felt before they started reading the lesson on a 5-point scale (a lot less anxious/a little bit less anxious/no change/a little more anxious/a lot more anxious), and (ii) how intense their physical sensations felt after the lesson compared to before (a lot less intense/a little less intense/no change/a little bit more intense/a lot more intense). In addition, participants were asked at post-treatment whether they had experienced any unwanted side effects or negative events that occurred because of the program, and were asked to provide brief details in an open text field.

**2.7.4.3. Treatment satisfaction questionnaire.** At post-treatment, participants were asked to rate how satisfied they were with the program on a 5-point scale ranging from 0 = very dissatisfied to 5 = very satisfied. They were also asked to rate the quality of the material in each lesson and the quality of their contact with the clinical team (excellent/good/satisfactory/unsatisfactory), as well as how they found the amount of time (10 weeks) allocated to the entire program (much too little time/a bit too little time/exactly the right amount of time/a bit too much time). Finally, they were asked to rate how logical the program was, their confidence that the program was successful in teaching them skills to manage their anxiety, and their confidence in recommending the program to a friend with health anxiety, on a scale from 1–10 (where 1 = not very, and 10 = very).

#### 2.8. Outcome measurement

All participants completed the SHAI, K-10, WBI-SF, and the BVS-SF before they commenced each lesson, and these measures were also administered at post-treatment and 3-month follow-up. The K-10 was used as a measure to alert the clinician if participants' scores rose by  $>0.5SD$  between lessons, indicating a significant increase in distress, or if their scores rose above 30 (severe range). The PHQ-9 and PHQ-15 were administered at pre-, mid- (before lesson 4), post-treatment and 3-month follow-up. The GAD-7, WHODAS, CABAII, IUS-12 and MAAS were administered at baseline, post-treatment and 3-month follow-up.<sup>1</sup>

#### 2.9. Power calculation

We used G\*Power to conduct a power calculation and determine sample size (Faul et al., 2007): a sample size of  $n = 10$  was needed to detect a large within-group (pre to post) effect size of  $d = 1.0$  at 80% power, alpha set at 0.05 (two-tailed).

<sup>1</sup> The GAD-7, WHODAS, CABAII, IUS-12 and MAAS were not administered at mid-treatment because we wanted to minimise the burden placed on participants from completing questionnaires during the treatment program.

## 2.10. Statistical analyses

All analyses were implemented in SPSS v. 22. To investigate reductions in the primary and secondary outcome measures from pre- to post-treatment, and from pre-treatment to 3-month follow-up, a linear mixed model for each of the outcome measures was implemented using the MIXED procedure with a random intercept for subject. Mixed models estimate parameters in repeated measures studies with unbalanced data using maximum likelihood estimation. This makes use of the incomplete data in a way that does not bias the parameter estimates (West et al., 2006). For each outcome, time was treated as a categorical variable, and an identity covariance structure was specified to model the covariance structure of the random intercept. Initial model building focused on the selection of the most appropriate covariance structure for the residual correlation matrix. Model fit indices and inspection of the variance-covariance matrix supported the selection of the identity covariance structure for each of the outcome measures. Effect sizes (Hedges  $g$ , adjusted for sample size) were calculated to determine the size of the within-group reduction between pre-treatment to post-treatment, and pre-treatment to 3-month follow-up. Finally, based on Jacobson and Truax (1991), reliable change (RCI) values were calculated for SHAI scores to determine the proportion of participants who evidenced clinically reliable improvements between baseline and post-treatment. We used test-retest reliability estimates of 0.87 from Olatunji et al. (2011), and SD of 7.24 derived from the current sample to calculate these values.

## 3. Results

### 3.1. Participant characteristics

Participants ( $N = 16$ , 81% females) were adults (mean age: 41.4 years,  $SD = 16.27$ , range = 19–69) with a DSM-5 diagnosis of either IAD ( $n = 10$ , 62.5%) or SSD ( $n = 6$ , 37.5%). Participants met criteria for an average of 2 diagnoses (range = 1–4 diagnoses,  $SD = 0.89$ ); three participants met criteria for MDD (18.8%), 5 had GAD (31.3%), 4 had panic disorder (25%), three had agoraphobia (18.8%), and one had OCD (6.3%). The mean score on the SHAI was 32.94 ( $SD = 7.64$ , range = 22–45), which is in the clinical range (Alberts et al., 2013). One participant was receiving concurrent psychological treatment (CBT), and two were taking medications for anxiety or depression (both were on selective serotonin reuptake inhibitors).

The majority of the sample were either married or living in a de facto relationship ( $n = 11$ , 68.8%), 4 were single/never married (25%), and one participant was divorced (6.3%). Thirteen participants (81.3%) were in paid employment, two were retired (12.5%), and one was registered sick/disabled (6.3%). All reported that English was the main language spoken at home. The majority were born in Australia ( $n = 10$ , 62.5%), with the remaining participants from England ( $n = 4$ , 25%), or other European countries ( $n = 2$ , 12.6%). In terms of education, 9 had attained tertiary level education (56.3%), 4 participants completed year 12 or equivalent (25%), and the remaining either had no qualification ( $n = 1$ , 6.3%), or other certificate/diploma level education ( $n = 2$ , 12.6%).

Participants found out about the program from a variety of sources including social media ( $n = 6$ , 37.6%), from mental health professionals or general practitioners ( $n = 3$ , 18.9%), internet searches ( $n = 3$ , 18.9%), word of mouth ( $n = 2$ , 12.6%), or other sources ( $n = 1$ , 6.3%).

### 3.2. Adherence

Of the 16 participants who started the program, 13 participants completed all 6 lessons of the program (81.25% completion rate). Of the non-completers, one participant withdrew from the program after completing two lessons to seek face-to-face treatment. The remaining two participants completed two lessons each.

### 3.3. Primary and secondary outcomes at post-treatment

Table 2 includes the estimated marginal means and the linear mixed model results for each of the outcome measures at pre- and post-treatment, and at 3-month follow-up. For all outcome measures, the reduction in symptoms from pre- to post-treatment was statistically significant at the  $p < 0.001$  level, except for IUS-12 scores which were significant at the  $p < 0.01$  level. Table 2 also reports the effect sizes of the pre- to post-treatment changes on outcome measures. Effect sizes were moderate for CABA scores ( $g = 0.78$ ), and the remaining effect sizes were large (Hedges  $gs = 1.04$ – $1.67$ ).

### 3.4. Proportion of participants who achieved clinically reliable change in health anxiety

Twelve out of the fourteen participants with post-treatment data (86%) showed clinically reliable improvements on SHAI scores between baseline and post-treatment.

### 3.5. Primary and secondary clinical outcomes at 3-month follow-up

For all outcome measures, the reduction in symptoms from pre-treatment to 3-month follow-up was statistically significant at the  $p < 0.001$  level, except for IUS-12 scores which were significant at the  $p < 0.05$  level. Pre-treatment to follow-up effect sizes were large for all variables (Hedges  $gs = 0.84$ – $1.65$ ).

### 3.6. Clinician contact

The clinician (JN) spent an average of 27 min ( $SD = 11.7$ , range = 15–59) emailing and calling each participant in the iCBT group during the treatment course (including the follow-up period).

### 3.7. Participants' engagement with program

On average, the participants spent between 39 to 55 min reading each lesson, and between 60–112 min practicing the skills. However, there was a large degree of variability in the self-reported time spent on the program, with the time spent ranging from 2 to 220 min reading (and re-reading) the lessons, and between 0 and 300 min practicing the skills.

### 3.8. Emotional reactions to the lessons

There were only three instances of reported mild increases in anxiety, and three instances of reported mild increases in the intensity of physical sensations after reading the program lessons. Of those who reported increased anxiety after the lessons, only two participants reported feeling a “little more” anxious and “a little more intense physical sensations” after reading lesson 1 (13.3%), and one participant felt a “little more anxious” and “a little more intense physical sensations” after lesson 3 (10%). In contrast, the majority of participants reported feeling less anxious after reading the lessons (lesson 1:  $n = 9/15$ , 60%; lesson 2:  $n = 5/12$ , 41.7%; lesson 3:  $7/10$ ,  $n = 70\%$ ; lesson 4:  $6/10$ ,  $n = 60\%$ ; lesson 5:  $4/11$ , 36.4%; lesson 6:  $n = 7/10$ , 70%).<sup>2</sup>

### 3.9. Treatment satisfaction

Of the 14 participants who completed the post-treatment questionnaires, all participants reported that they were either mostly ( $n = 8$ , 57.1%) or very ( $n = 6$ , 42.9%) satisfied with the program, and rated the quality of both the lesson content and contact with the clinical team as either good or excellent (lesson content: good:  $n = 7$ , 50%,

<sup>2</sup> Due to a technical issue (browser incompatibility) with the administration of this questionnaire, the questionnaire was not administered to all participants.

**Table 2**

Estimated marginal means at pre-, mid- post-treatment and 3 months following internet CBT for health anxiety.

	Pre-treatment	Mid-treatment	Post-treatment	3-month follow-up	Pre- to post-treatment			Pre-treatment to follow-up		
	Mean (SD) n = 16	Mean (SD) n = 13	Mean (SD) n = 13	Mean (SD) n = 11	F(df)	r	Effect size: Hedges g (95% CI)	F(df)	R	Effect size: Hedges g (95% CI)
<i>Symptoms</i>										
Health Anxiety (SHAI)	32.94 (7.24)	23.67 (7.10)	18.70 (6.89)	18.01 (6.77)	F(2, 26.35) = 25.44**	0.31	1.64 (0.80–2.49)	F(3, 37.61) = 24.41**	0.42	1.60 (0.73–2.48)
Distress (K–10)	26.19 (6.00)	16.86 (5.99)	15.83 (5.99)	16.01 (5.27)	F(2, 76.46) = 18.27**	0.004	1.67 (0.82–2.52)	F(3, 37.15) = 17.06**	0.40	1.36 (0.51–2.21)
Depression (PHQ-9)	8.31 (3.36)	3.71 (3.35)	3.36 (3.24)	2.30 (2.98)	F(2, 25.69) = 14.38**	0.35	1.20 (0.40–1.99)	F(3, 37.02) = 13.75**	0.27	1.35 (0.50–2.20)
Somatic Symptoms (PHQ-15)	13.56 (4.76)	8.71 (4.40)	7.88 (4.36)	7.53 (4.11)	F(2, 24.27) = 39.31**	0.73	1.27 (0.48–2.08)	F(3, 35.04) = 27.18**	0.66	1.30 (0.45–2.14)
Generalised Anxiety (GAD-7)	10.81 (4.04)	–	4.78 (3.97)	4.62 (3.78)	F(1, 12.25) = 25.09**	0.40	1.52 (0.69–2.35)	F(2, 23.98) = 16.89**	0.38	1.27 (0.47–2.07)
Disability (WHODAS)	20.25 (4.76)	–	14.72 (4.72)	13.35 (3.91)	F(1, 9.72) = 16.25*	0.38	1.24 (0.45–2.04)	F(2, 18.21) = 19.30**	0.58	1.12 (0.33–1.90)
<i>Cognitive and behavioural processes:</i>										
Worry Behaviours (WBI-SF)	12.31 (3.88)	6.90 (3.89)	6.63 (3.75)	3.86 (3.52)	F(2, 24.85) = 13.27**	0.47	1.04 (0.26–1.82)	F(3, 36.39) = 16.31**	0.08	1.65 (0.77–2.54)
Body Vigilance (BVS-SF)	21.31 (6.04)	11.67 (6.04)	10.90 (5.80)	11.17 (5.97)	F(2, 27.79) = 17.76**	0.22	1.46 (0.64–2.28)	F(3, 39.48) = 12.28**	0.29	1.26 (0.42–2.10)
Cognitions (CABAH)	45.50 (8.96)	–	37.84 (8.29)	31.42 (8.99)	F(1, 12.45) = 40.03**	0.90	0.78 (0.03–1.54)	F(2, 24.40) = 23.64**	0.71	1.03 (0.25–1.81)
Intolerance of Uncertainty (IUS-12)	35.69 (9.88)	–	25.71 (9.84)	25.17 (10.81)	F(1, 13.60) = 9.53*	0.26	1.04 (0.26–1.82)	F(2, 26.25) = 5.10#	0.09	0.84 (0.08–1.61)
Mindful Awareness and Attention (MAAS)	50.94 (9.52)	–	61.24 (9.12)	63.27 (8.89)	F(1, 12.50) = 24.82**	0.67	1.12 (0.34–1.91)	F(2, 23.92) = 18.84**	0.62	1.05 (0.27–1.83)

\*\* p < 0.001 \* p < 0.01 # p < 0.05.

excellent: n = 7, 50%; clinical contact: good: n = 5, 35.7%, excellent: n = 9, 64.3%). In terms of the tempo of the program (the scope of the program in relation to its length), more than half felt they had too little time (n = 9, 64.3%), two thought it was too much time (14.3%), and three felt it was the right amount of time (21.4%).

Overall, participants rated the program as logical (M = 8.36, SD = 1.69), endorsed high levels of confidence in having the techniques to manage health anxiety (M = 7.5, SD = 1.40), and confidence in recommending the iCBT course to a friend with health anxiety (where 1 = not at all and 10 = very) (M = 8.5, SD = 1.09).

### 3.10. Side effects

Of 14 participants who completed the questionnaire, 8 did not report any side effects, leaving 6 who reported experiencing unwanted side effects as a result of the program. One participant for example reported increased anxiety at the start of the program (Participant Quote: "I think I went through a phase where I was more anxious than ever because of things that the program brought up but I didn't yet have the tools to cope with them. The first few weeks were very tough."). Three reported 'setbacks' in response to graded exposure (Participant Quote: "I did have a very bad week, partly related to the commencement of graded exposure but also to the onset of a new 'symptom'. It certainly gave me an opportunity to practice!") Participant Quote: "The effects of the materials in lesson 5 that encouraged participants to exposure to the source of fear: I was uncomfortable with some of my reactions..." Participant Quote: "Had a significant backslide – possibly owing to the exposure that I wasn't ready for. Conversations with the clinician at this point were particularly useful, however"). There was also one participant who reported thinking about their health more ("There were times when I was thinking about health things more and the fact I was running behind on my lessons made me feel more anxious, but nothing dramatic or ongoing."). Finally, the remaining participant reported a non-specific set back ("I've had a setback but it wasn't unwanted: I used the skills I had learned and got through it, and I'll get through any other setbacks I may have in the course of my life.").

## 4. Discussion

This study aimed to explore the acceptability of an internet CBT program for the treatment of health anxiety, and its impact on health anxiety, comorbid symptoms and key cognitive and behavioural maintaining factors including illness-related cognitions, hypervigilance to bodily sensations, and avoidance and safety behaviours (e.g., checking, reassurance-seeking and internet searching). In a sample of 16 individuals who met criteria for DSM-5 Illness Anxiety Disorder or Somatic Symptom Disorder, we found large and significant reductions between baseline and post-treatment on measures on health anxiety (g = 1.64), depression (g = 1.20), distress (g = 1.67), generalised anxiety (g = 1.57), disability (g = 1.24), and somatic symptom severity (g = 1.27), which were maintained until 3 months following the program. The majority of participants (86%) experienced clinically reliable met improvements in health anxiety scores between baseline and post-treatment (Jacobson and Truax, 1991). As predicted, most participants completed the iCBT program (adherence = 81%), and treatment satisfaction ratings were high.

These positive results were observed with minimal clinician input, with the clinician spending on average 27 min per participant. While most of the previous evaluations of iCBT for health anxiety have involved weekly support from a therapist (e.g., Hedman et al., 2011), our results support those of Hedman and colleagues (Hedman et al., 2016) who showed that both unguided iCBT and therapist-guided iCBT (as well as CBT-based bibliotherapy for health anxiety) produce large and positive reductions in health anxiety. Together, these studies suggest that iCBT can improve symptoms of health anxiety with relatively minimal clinician contact time.

Our results also showed that the iCBT program led to improvements on the key cognitive and behavioural maintaining factors that are hypothesised to maintain health anxiety according to existing theoretical models of the condition (Warwick, 1989). We found significant reductions in dysfunctional health-related cognitions, behaviours (including reassurance-seeking, avoidance and internet searching) and body vigilance, as well as increases in mindful awareness and the ability

to tolerate uncertainty. Because of the small sample size, we were unable to assess the mechanism by which iCBT produced symptom improvements. Future studies should include mediation analyses to examine whether changes in important theoretical constructs (e.g., intolerance of uncertainty, hypervigilance to bodily sensations) mediate reductions in health anxiety. Preliminary evidence from Hedman et al. suggested that reductions in perceptions of risk of disease, intolerance of uncertainty and body hypervigilance may mediate improvements in health anxiety symptoms during iCBT (Hedman et al., 2013a), but this finding is yet to be replicated. It is also currently unknown whether changes in maladaptive behaviours such as reductions in body checking, reassurance-seeking or internet searching mediate symptom improvements during iCBT.

This study assessed unwanted side effects or negative reactions to internet CBT for health anxiety, which is in line with calls for increased assessment of unwanted side effects of internet interventions (Rozenlat et al., 2014). Hedman and colleagues have previously collected data on adverse events via self-report questionnaire at post-treatment, and found adverse events were reported by a small minority of individuals undergoing therapist-supported iCBT (19% in Hedman et al., 2016; 12% in Hedman et al., 2014) with the most common being an increase in anxiety. In the current study, we collected information about unwanted reactions to iCBT after each lesson and at post-treatment.

Despite the potential for health-related information to trigger fears of illness and amplify the perceived intensity of somatic symptoms in health anxious individuals, the majority of participants said that they felt less anxious and less intense physical sensations as a direct result of completing the lessons. It is possible that these findings are a reflection of the distraction afforded by reading the lessons, which may have in turn reduced body vigilance, and therefore reduced anxiety. Interestingly, instances of increased anxiety whilst completing the lessons were less common, and only reported to be mild. However, 6 of 14 individuals who completed post-treatment assessments reported some unwanted negative effects of the program, with the most common reported including setbacks after starting exposure; most used the unwanted side effects as an opportunity to practice their new skills. Future research should focus on examining the nature of unwanted side effects of iCBT for health anxiety in larger samples, how patients perceive these side effects in balance of the 'wanted side effects' or improvements they typically experience as a result of iCBT, and explore whether the experience of side effects predicts drop-out, or influences outcomes.

The results of this pilot trial need to be interpreted in the context of some limitations. The small sample size precluded a thorough analysis of predictors of treatment adherence and outcome. In future, it would be useful to examine whether there are any important differences in treatment response between individuals with DSM-5 IAD versus SSD, and whether patients who experience health anxiety in the context of diagnosed medical illnesses (e.g., cancer survivors who fear cancer recurrence) or physical pathology, respond as well to iCBT as those without diagnosed illnesses and/or medically unexplained symptoms. Hedman et al. (2013b) found that higher baseline health anxiety predicted larger improvements in health anxiety, although higher baseline depression predicted a poorer response to iCBT for health anxiety. These latter findings are in line with a meta-analysis showing that comorbid depression may moderate the effects of CBT, with higher depression associated with smaller effect sizes (Olatunji et al., 2014). Our sample was too small (with only three individuals meeting criteria for MDD) to determine whether comorbid depression predicted outcomes. Future RCTs are needed to examine this issue, and to compare the Health Anxiety Program to control groups to rule out the influence of other non-specific factors in the improvements in symptoms observed in this sample (e.g., non-specific treatment factors, assessment and clinician support).

Furthermore, we did not conduct inter-rater reliability estimates for the diagnoses made in the current study. Although the mean ratings on

the self-report questionnaires attest to the clinical nature of the sample, future studies are needed to determine the inter-rater reliability of the IAD and SSD diagnoses using the ADIS-5 interview. Although Axelsson and colleagues found evidence of the reliability of the Health Preoccupation Interview (a new structured interview for DSM-5 IAD and SSD diagnoses, yielding inter-rater agreement of 0.85) in diagnosing IAD and SSD, this finding is yet to be replicated, and the inter-rater reliability of the IAD and SSD modules of the ADIS-5 is not yet known. The assessment of treatment outcomes also relied on self-report data. While such outcome measures are valid and widely used, additional measures related to objective reductions in health care utilisation, as well as diagnostic status and clinician severity ratings would have augmented the current findings. Finally, the representativeness of the sample who received iCBT to the general population of individuals with health anxiety is not yet known.

In summary, the results of this pilot trial show that internet CBT for health anxiety is acceptable, and yields large and significant improvements on health anxiety and comorbid symptoms. This program now needs to be evaluated in a RCT with long-term follow-up to evaluate the efficacy of the program, and how long the symptom improvements are maintained.

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