Effectiveness of Guided Internet-Based Cognitive Behavior Therapy in Regular Clinical Settings

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Keywords
Internet-based cognitive behavior therapy · ICBT · Dissemination · Effectiveness · Efficacy trial · Anxiety and mood disorders

Summary
Therapist-guided internet-based cognitive behavior therapy (ICBT) has been tested in numerous controlled trials conducted in research settings. It is now established that this novel treatment format works for a range of clinical conditions. It is less well known if the promising results from efficacy studies can be transferred to routine clinical practice. In this paper we review the evidence from effectiveness studies and highlight challenges when implementing ICBT. Following literature searches we identified 4 controlled trials and 8 open studies, involving a total of 3,888 patients. There is now an increasing number of effectiveness studies on ICBT with studies on panic disorder, social anxiety disorder, generalized anxiety disorder, post-traumatic stress disorder, depression, tinnitus, and irritable bowel syndrome. All indicate that it is possible to transfer ICBT to clinical practice with sustained effects and moderate to large effect sizes. However, it is not clear which model to use for service delivery, and more work remains to be done on dissemination of ICBT. Moreover, the knowledge about outcome predictors from controlled efficacy trials is probably less relevant, and studies with large clinically representative samples are needed to investigate for which patients ICBT is suitable. In this work existing data could be combined and reanalyzed to study predictors of outcome.
Psychological treatment for mental and functional disorders has been around for a long time, and during the last 15 years there has been an expansion of technology-assisted psychological therapies [Marks et al., 2007]. The use of internet to deliver evidence-based psychological treatments has a short history, in spite of that there is now a large number of controlled trials for a range of conditions [Hedman et al., 2012a]. Indeed, since the first studies in the late 1990ies research on internet-based cognitive behavior therapy (ICBT) has grown steadily [Hedman et al., 2012a]. One problem with the existing literature is, however, that very different names have been used to describe fairly similar interventions, and sometimes the same term is used to describe very different interventions [Barak et al., 2009]. In this paper we will cover guided self-help interventions where the therapist interaction is asynchronous and the treatment is mainly delivered via websites in the form of text, pictures, and audio files [Andersson, 2009]. This treatment is being referred to as guided ICBT [Andersson et al., 2013]. There are other forms of internet treatments, such as real-time chat [Kessler et al., 2009], totally automated treatments with no clinician interaction before, during or after treatment [Klein et al., 2011], and other blended treatments where the internet is used as an adjunct or as aftercare following live treatment [Bauer et al., 2011]. These treatments are not covered in this review. One reason is that totally automated open access treatments are much easier to disseminate as they do not require any interaction with a clinician [Christensen et al., 2006], and the main obstacle with such treatments is the risk of non-adherence [Christensen et al., 2009]. To date, most evidence also indicates that guided internet treatments are more effective than totally automated treatments [Gellatly et al., 2007; Johansson and Andersson, 2012].

The topic of this paper is dissemination and how well guided ICBT works in routine clinical practice settings [Andersson et al., 2009a]. In the psychological literature, there are 2 types of research studies testing psychological treatments. The first type is often referred to as ‘efficacy studies’ [Seligman, 1995]. In efficacy studies internal validity is prioritized, which means that experimental control is important. In practice, this means that research participants tend to be highly selected, homogenous in clinical characteristics, self-referred, and therapists are well trained and monitored for adherence to treatment manuals [Shadish et al., 1997]. Moreover, efficacy studies tend to be conducted at research university clinics where therapists usually have smaller caseloads sometimes supported by students in training. In effect, it is often unclear if the results of such studies can be generalized to routine practice. As a response to the critique raised against efficacy trials [Westen et al., 2004], 'effectiveness studies' have been outlined and conducted [Hunsley and Lee, 2007]. These studies examine whether a treatment works in real-world settings and in situations that clinicians encounter in their daily routine practice [Lutz, 2003]. This type of study emphasizes the external validity of the research findings. However, there is no sharp distinction here, and it can be argued that clinical intervention research, e.g., trials on psychotherapy, always have elements of effectiveness as they include real patients with disorders that are indeed both comorbid and severe [Stirman et al., 2003]. Moreover, efficacy and effectiveness studies can be regarded as extremes on a continuum [Streiner, 2002]. For example, a study may be conducted in a specialist research clinic, but with regular patients referred to the treatment, and the therapists who provide the treatment may be both clinicians and researchers. When it comes to guided ICBT, things become even more complicated. Some of the criteria suggested for effectiveness trials are less relevant for guided ICBT. For example, when disseminating guided ICBT the actual treatment program remains the same and does not change with therapist. Another aspect of ICBT is that assessments are often embedded in the treatment. This facilitates outcome monitoring, and the difference seen between face-to-face efficacy versus effectiveness trials, where efficacy trials tend to have much more assessments than in clinical practice, is less present in ICBT effectiveness trials. Moreover, monitoring may increase treatment adherence. For the present review we defined effectiveness study as a study conducted in a setting equivalent or similar to routine clinical care where patients are not solely recruited through self-referral and treatments are delivered by staff with permanent employment.

The aim of this paper is to provide an updated review on how guided ICBT has been implemented and tested in regular clinical settings. First, we will briefly review what is known from efficacy studies with regard to therapist factors and patient characteristics predictive of treatment response. Then we will provide a review of the effectiveness studies that have been published on ICBT where some form of clinician contact has been included. Finally, we will discuss some challenges when implementing ICBT in routine clinical practice.

What Contributes to Good ICBT Outcomes? – Knowledge from Efficacy Studies

The empirical support for guided ICBT has been covered in many previous systematic reviews and meta-analyses [Andrews et al., 2010; Hedman et al., 2012a], not only for mood and anxiety disorders [Spek et al., 2007], but also for somatic problems [Cuijpers et al., 2008]. In general, these reviews have demonstrated that guided ICBT can be highly efficacious for several common psychiatric disorders with effect sizes similar to those of live CBT. When disseminating ICBT to routine care it is not only the treatment effects that are important, but also what is known regarding moderators and mediators of outcomes in efficacy trials. In contrast to the number of controlled trials, much less has been published on
what makes ICBT work, and most papers on the topic have been based on ideas and impressions [Andersson et al., 2009b; Ritterband et al., 2009], including practice guidelines [Abbot et al., 2008]. We will comment briefly on 2 aspects of treatment delivery that could be important to consider when implementing in routine clinical practice. The first is the role of the therapist who provides the guidance in ICBT, which is of interest as treatments that provide therapist support tend to produce better outcomes [Lewis et al., 2012]. As a starting point, we can conclude that the therapeutic alliance in guided ICBT is usually rated as high by patients [Knaevelsrud and Maercker, 2006; Andersson et al., 2012b; Bergman-Nordgren et al., 2013], but that it rarely predicts outcome. Second, we may conclude that the therapist factor probably only plays a minor role [Almlöv et al., 2009, 2011]. This is not the same as saying that it is unimportant what the therapist does [Paxling et al., 2013]. Even if most of the communication between the therapist and the patient is in the form of general support [Sanchez-Ortiz et al., 2011], there is room for therapist’s drift and a latent attitude towards homework completion. In one of the few controlled trials on the role of the therapist in ICBT, it was found that experienced therapists tended to devote less time to their clients, but there were no differences in outcome when compared to the inexperienced therapists in a trial on social anxiety disorder (SAD) [Andersson et al., 2012a]. Moreover, there are studies suggesting that guidance can be provided from a more technical point of view that does not require a clinician [Titov et al., 2010a]. A preliminary conclusion is that the therapist is important in ICBT, but that the firm structure of the treatment leaves less room for between-therapist effects and that it is probably the case that less training is needed than in regular CBT. In addition, another advantage of asynchronous contact in ICBT is that less experienced therapists can have good results because they can spend more time on their feedback (i.e. discuss with colleagues, reflect about the response, and ask for supervision). Overall there is not much written on the role of supervision in ICBT and how therapists should be trained [Hadjistavropoulos et al., 2012].

A second point to consider before implementation is what the literature says about predictors of outcome. Even if mediators of outcome are important to consider for treatment development [Kazdin, 2007], it is probably the case that predictors of outcome are more important when moving an intervention to routine clinical practice. For example, if studies on ICBT mainly have included well-educated patients, and routine clinical practice is likely to involve patients who are less well educated, it is crucial to know if level of education is a predictor of outcome. Another example is comorbidity. If, e.g., persons with suicidal ideation have been excluded from efficacy trials (note that actual suicide risk is different from slightly elevated levels of suicidal thoughts), this can have implications for dissemination in routine practice. When it comes to predictors of outcome it is probably most important to locate the predictors of negative outcome and dropout, as this has implications for whom the treatment should be offered. Here the literature is scattered. For example, Hedman et al. [2012b] did find that genetic factors did not predict outcome in a study on SAD, whereas working full time, having children, less depressive symptoms, and higher expectancy of treatment effectiveness did. Some studies have found that adherence to treatment predicts outcome, but this is rather a moderator of outcome and ‘after the fact’; to be clinically useful pre-treatment predictors of subsequent adherence would be needed. A recently published predictor study using adherence as dependent variable showed that higher baseline symptom levels led to better adherence [Cleare et al., 2013]. Along the same lines it seems quite clear that more severe symptoms are not necessarily a negative predictor of outcome, which has been shown in studies on SAD [Nordgreen et al., 2012] and depression [Bower et al., 2013], although it might be the case that symptoms of personality disorder are a negative predictor [Andersson et al., 2008]. Another potential negative predictor of relevance in the treatment of personality disorder is number of previous depression episodes [Andersson et al., 2004]. To sum up, there is yet no established knowledge about predictors of outcome of guided ICBT, and indeed it is also the case that outcome can be hard to predict for face-to-face therapies [Driessen and Hollon, 2010]. Moreover, with more effectiveness data coming out knowledge about clinical outcome predictors in routine clinical practice settings will be obtained. An important potential advantage from those studies when it comes to prediction is that they will be less likely to have the restriction of range in terms of phenotype often inherent in randomized trials. This will in turn contribute a higher chance of detecting stable predictors of outcome.

An Overview of Effectiveness Studies

In this review we included effectiveness studies on ICBT where some form of therapist interaction had been involved. Moreover, we did not include studies where the setting and the contact with the clinicians were not directly related to the treatment program [Farrer et al., 2011]. We also excluded a study on problem solving therapy in which the treatment was presented as an option when waiting for face-to-face treatment [Kenter et al., 2013]. In total we describe 4 controlled trials and 8 open studies, involving a total of 3,888 patients. These studies were explicitly described as effectiveness studies and we acknowledge the possibility that studies may exist on guided ICBT which could be regarded as effectiveness studies but are not described as such. Although all studies were considered effectiveness studies trials using a randomized design and open studies are reported in separate tables as the open studies were judged to have been conducted in purely clinical routine care settings whereas RCTs always involve more rigorous procedures.
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Panic Disorder

The first condition for which effectiveness data exist is panic disorder. This condition has been the topic of several controlled efficacy studies [Andersson and Carlbring, 2011]. In table 1 we describe a controlled effectiveness trial by Bergström and colleagues [Bergström et al., 2010], in which live CBT was directly compared with ICBT. That study was preceded by a small effectiveness study on ICBT from the same group [Bergström et al., 2009], which is described in table 2. As shown in the tables within group effect sizes were large in these studies and differences between ICBT and live CBT were minimal. More recently, the Swedish research group at Karolinska Institutet has recently published effectiveness data from their ICBT unit [Hedman et al., 2013] with a total of 570 patients with panic disorder. The results showed that ICBT could be highly effective also when delivered as routine clinical care (table 2). Ruwaard and colleagues [Ruwaard et al., 2012] published data on a large series of clinical patients out of which 139 had been treated for panic disorder with their program ‘Interapy’. As displayed in table 2 effect sizes were large. Overall, the evidence from 1 controlled effectiveness trial and 3 open effectiveness trials clearly indicates that the results from the efficacy studies are sustained when delivered in routine practice.

SAD

For SAD there are even more controlled efficacy studies that have been published since the first trial on the ‘SOFIE’ program [Andersson et al., 2006], and also a few effectiveness studies. The first one was a small trial with 17 clinical patients who received ICBT for SAD [Aydos et al., 2009] with the ‘Shyness’ program [Titov et al., 2008] (table 2). There are also

<table>
<thead>
<tr>
<th>Reference</th>
<th>Country</th>
<th>Disorder</th>
<th>N</th>
<th>Outcome</th>
<th>Effect sizesa (pre/post d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bergström et al. [2010]</td>
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<td>panic disorder</td>
<td>20</td>
<td>PDSS</td>
<td>2.5</td>
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<td>social anxiety disorder</td>
<td>570</td>
<td>PDSS-SR</td>
<td>1.07</td>
</tr>
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<td>Ruwaard et al. [2012]</td>
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<td>panic disorder</td>
<td>139</td>
<td>a) PDSS-SR</td>
<td>1.36</td>
</tr>
<tr>
<td>Aydos et al. [2009]</td>
<td>Australia</td>
<td>social anxiety disorder</td>
<td>17</td>
<td>a) SIAS</td>
<td>1.51</td>
</tr>
<tr>
<td>Newby et al. [2013]</td>
<td>Australia</td>
<td>mixed anxiety and depression</td>
<td>136</td>
<td>a) GAD-7</td>
<td>1.15</td>
</tr>
<tr>
<td>Mewton et al. [2012]</td>
<td>Australia</td>
<td>general anxiety disorder</td>
<td>588</td>
<td>a) PHQ-9</td>
<td>0.86</td>
</tr>
<tr>
<td>Williams and Andrews [2013]</td>
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<td>depression</td>
<td>359</td>
<td>PHQ-9</td>
<td>0.98</td>
</tr>
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<td>Kaldo et al. [2004]</td>
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<td>tinnitus</td>
<td>77</td>
<td>TRQ</td>
<td>0.56</td>
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<tr>
<td>Kaldo et al. [2013]</td>
<td>Sweden</td>
<td>tinnitus</td>
<td>293</td>
<td>TRQ</td>
<td>0.58</td>
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ICBT = internet-based cognitive behavior therapy; PDSS = Panic Disorder Severity Scale; SIAS = Social Interaction Anxiety Scale; GAD-7 = Generalized Anxiety Disorder Scale, 7-item version; PHQ-9 = Patient Health Questionnaire 9; PDSS-SR = Panic Disorder Severity Scale Self-Report; IES = Impact of Event Scale; BDI = Beck Depression Inventory; DASS = Depression Anxiety Stress Scales; TRQ = Tinnitus Reaction Questionnaire.

a Effect sizes have been recalculated from summary statistics in the original papers.
2 controlled effectiveness trials. In Australia, Andrews and colleagues [Andrews et al., 2011] conducted a small controlled effectiveness trial where they compared ICBT with face-to-face group CBT. As seen in table 1 both treatments were equally effective. In a larger trial, ICBT was compared with group CBT and in this trial there was even a tendency for the ICBT group to improve more [Hedman et al., 2011a]. For this study there is also a separate report showing that ICBT is cost-effective compared to live CBT [Hedman et al., 2011b]. Thus, data from effectiveness studies indicate that the promising effects from the efficacy studies clearly replicate when the treatment is delivered in routine practice settings. Larger series of patients should however be examined, as the 2 controlled trials involved randomization which is not a characteristic of regular practice.

Generalized Anxiety Disorder

To our knowledge there is only 1 effectiveness study on the treatment of generalized anxiety disorder (GAD), which is a test of the ‘Worry’ program from Australia [Titov et al., 2009]. As seen in table 2, a large series of patients have been treated [Mewton et al., 2012], and it is clear that the large treatment effects from the relatively few efficacy trials on GAD are replicated [Titov et al., 2009; Paxling et al., 2011; Andersson et al., 2012c]. With regards to posttraumatic stress disorder there are controlled efficacy trials [Andersson, 2010], but to our knowledge effectiveness data have only been reported for the Interapy program [Lange et al., 2003], as presented in table 2. The results of that study however show that ICBT for posttraumatic stress can yield large effects when delivered in routine care. For other specific anxiety disorders, such as obsessive compulsive disorder, specific phobia, and severe health anxiety, there are controlled efficacy trials, but no effectiveness trials on guided ICBT.

Mixed Anxiety and Depression

It is widely acknowledged that there is an overlap between mood and anxiety disorders, and in a recent effectiveness trial on mixed anxiety and depression [Newby et al., 2013] it was found that the ICBT treatment worked in a general practice setting. From the Swedish research group there is an ongoing controlled effectiveness study [Bergman Nordgren et al., 2012], in which tailored ICBT has been tested [Carlbring et al., 2011] for patients with mixed anxiety and depression in primary care. Unpublished data from that trial show clear benefits of treatment. Overall, however there are still very few studies on tailored and transdiagnostic ICBT when delivered in routine practice.

Depression

Mild to moderate depression is another field for which there have been many controlled efficacy trials [Richards and Richardson, 2012]. We have not located any controlled effectiveness trial on depression, but open studies have been published. In a large sample of 359 patients it was found that the treatment ‘Sadness’ worked [Williams and Andrews, 2013], and the authors also reported that health condition of more severe and suicidal patients also improved. A separate report has been published by the same group showing that suicidal ideation should not be an exclusion criterion; these patients make substantial reductions of depressive symptoms following ICBT [Watts et al., 2012]. The second data set on depression presented in table 2 comes from the Interapy group, who have treated both depression and burnout with large within group effects sizes [Ruwaard et al., 2012]. For both of these conditions there have been previous controlled efficacy trials [Ruwaard et al., 2007, 2009]. There is clearly a need for more effectiveness studies on guided ICBT for depression, but the ones available suggest that the treatment can be transferred to clinical practice.

Somatic Conditions

In the field of somatic disorders there has been an active research with a large number of controlled trials on therapist-guided ICBT. One of the first conditions to be treated with ICBT was tinnitus, which is ringing or buzzing in the ears with no external origin [Baguley et al., 2013]. The first controlled trial on ICBT for tinnitus was published more than 10 years ago [Andersson et al., 2002], but even before that the treatment was implemented in regular clinical practice in Uppsala, Sweden. An early effectiveness study showed that the treatment worked [Kaldo-Sandström et al., 2004], and table 2 also presents the outcomes of a recently published effectiveness study from the same clinic [Kaldo et al., 2013]. As with live CBT for tinnitus effect sizes are slightly smaller in ICBT for tinnitus compared to ICBT for anxiety disorders. Finally, there is one controlled effectiveness trial on ICBT for irritable bowel syndrome (IBS), which is a condition characterized by abdominal pain or discomfort combined with diarrhea and/or constipation [Blanchard, 2001]. The controlled trial [Ljótsson et al., 2011] (table 1) largely replicated the findings from a previous efficacy trial demonstrating large within group effect sizes [Ljótsson et al., 2010]. As with the anxiety disorders, there are several health conditions for which there are only efficacy studies on guided ICBT and no investigations on effectiveness, including, e.g., chronic pain, headache, diabetes, psychological distress in cancer patients, eating disorders, and erectile dysfunction [Hedman et al., 2012a].

Discussion

Overall, this review suggests that the effects found in controlled efficacy trials on guided ICBT tend to be replicated in clinical practice in ICBT for panic disorder, SAD, GAD, post-traumatic stress disorder, burn out, depression, mixed anxiety and depression, tinnitus, and IBS. This is in line with what has been observed when face-to-face therapies have been tested.
[Stewart and Chambless, 2009]. There are however few studies on the effectiveness of guided ICBT, and for many conditions there are no effectiveness studies at all, which should be seen in the light of more than 100 controlled efficacy trials [Hedman et al., 2012a].

There are many topics to discuss when considering dissemination of ICBT into daily routine practice. One first crucial issue, not touched upon in this review, is the role of data security [Bennett et al., 2010] and the need for a robust web solution in order to handle large number of participants. A second issue has to do with assessment procedures, as ICBT inherently involves computerized online assessment procedures alongside the treatment [Andersson et al., 2010]. Overall, evidence suggests that psychometric measurement characteristics are maintained when measures are administered online [Carlbring et al., 2007; Hedman et al., 2010], but to our knowledge there is not much written about how well online measures work in routine clinical practice. A third related aspect of ICBT in routine clinical settings is how diagnostic interviews are conducted. For example, at the ICBT unit at Karolinska Institutet, Psychiatry Southwest, ICBT is always preceded and followed by a psychiatric diagnostic interview in vivo, but whether this is needed apart from the obvious benefits in terms of risk assessment and possibilities to directly refer patients to other treatment alternatives (e.g., medication) is not clear. For example, in one study on SAD there were no differences in effects whether a diagnostic pre-treatment interview was included or not [Boettcher et al., 2012]. In many efficacy studies the diagnostic interviews have been administered over telephone, which is one alternative [Crippa et al., 2008]. Overall, dissemination of ICBT is not only about treatment provision, but also concerns referral routes, assessments, management of patients less suitable for ICBT, and outcome monitoring including follow-ups. In addition, there is initial evidence suggesting that ICBT can prevent relapse in depression [Holländare et al., 2011], and in the future it is possible that longer ICBT treatments (extending over years) and booster treatments will be developed for more chronic conditions and where there is a risk of relapse. A fourth point to consider is the training of therapists in ICBT and if there should be separate therapists who work with guidance (perhaps less in need of training but under supervision), or if ICBT should be seen as one of many tools in the therapist toolbox. We referred earlier to the observation that therapist factors are probably less important in ICBT, but this does not necessarily mean that just anyone is a suitable internet therapist as there is always a risk for mistakes in text communication. Even if there are preliminary guidelines on how to best guide patients in ICBT [Titov, 2010; Hadjistavropoulos et al., 2011], more work is needed when it comes to practice guidelines. A fifth related issue is if therapists and patients are interested in and want ICBT. There is an emerging literature on clinicians’ attitudes towards ICBT [Wangberg et al., 2007; Gun et al., 2011], and with the possible exception of clinicians treating children and adolescents [Stallard et al., 2010], attitudes appear to be positive. When it comes to patient attitudes data is not consistent and potentially there are differences between countries and settings, with some studies showing more positive attitudes [Spence et al., 2011; Wootton et al., 2011] than others [Mohr et al., 2010]. A sixth important point is the role of healthcare regulation and reimbursement issues that are instrumental when implementing ICBT in clinical practice. For example in Norway, it has not been allowed to communicate with patients over internet [Nordgreen et al., 2010], and funding of services differs widely between countries where some countries offer services free of charge and others are linked with insurance companies who may have their own preferences and regulations. A related factor is the role of professional organizations such as unions and how they influence services and license to practice. A final point to discuss, which has bearings on the distinction between efficacy and effectiveness studies, is how much the clinic should mimic the research setting (e.g., if the number of outcome measures should be kept the same or cut down). It is obviously much easier to retain aspects of the efficacy study in the field of ICBT, such as routine administration of measures and the treatment staying intact, but there are also things that can differ. One thing is that clinicians who have not been part of treatment development may feel more detached from the treatment and hence it may be a good idea to include clinician input in treatment planning and the actual treatment content. Indeed, there is preliminary evidence that tailored treatment, where the treatment modules are individually prescribed, might benefit patients with more severe disorders [Johansson et al., 2012]. In any case the tailoring procedures and pre-treatment case conceptualization may be something that would make ICBT more attractive to clinicians and indeed patients as well.

This review has limitations. First, the search for literature was complicated by the fact that there is no real consensus on how to describe and report ICBT studies. For example, there are efficacy studies where the clinician handling the patients has been a practitioner [Shandley et al., 2008], and in our review we rather focused on the setting in which ICBT was delivered (i.e., routine care), which is just one aspect of effectiveness. Second, many ICBT efficacy trials have recruited participants from the general public and it may be that the research participants in those trials are more representative for the public than clinic patients [Titov et al., 2010b]. This would make the distinction between efficacy and effectiveness blurred. As a third limitation we acknowledge that we did not code our retrieved studies for clinical representativeness [Stewart and Chambless, 2009]. As a fourth limitation we note that most effectiveness studies covered in this review have been delivered in specialist clinics, and in some cases ICBT has been the only treatment delivered [Ruwaard et al., 2012], whereas in others ICBT has been one of several treatment options [Kaldo et al., 2013].

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Verhaltenstherapie 2013;23:140–148
ICBT involving clinician contact has been tested in efficacy trials with most studies indicating that the treatment works when it is transported to routine care. Studies on panic disorder, SAD, GAD, posttraumatic stress disorder, depression, mixed anxiety and depression, tinnitus, and IBS all indicate that it is possible to transfer ICBT to clinical practice with sustained effects. There are however several knowledge gaps and many conditions for which efficacy data has not been reported. Moreover, clinical predictors of outcome should be reported in large series of patients, and there is a need to study the implementation process when ICBT is spread to routine care.

Conclusions

The preparation of this paper was supported in part by grants from the Swedish council for working and life research, the Swedish research council, and Linköping University.

Acknowledgement

The authors declare that there is no conflict of interests concerning this paper.

Disclosure Statement

The authors declare that there is no conflict of interests concerning this paper.

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Published online by Elsevier Ltd on 21 June 2013 in VCH (Formerly Verlag Chemie GmbH)

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