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# Randomized controlled trial of internet-delivered cognitive behaviour therapy comparing standard weekly versus optional weekly therapist support

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ABSTRACT

Internet-delivered cognitive behaviour therapy (ICBT) is effective for treating anxiety and depression. The relative benefits of offering standard weekly compared to optional weekly therapist support in conjunction with ICBT within routine care has not been examined. Patients seeking ICBT for depression and or anxiety in routine care were randomized to standard ($n$ = 92) or optional ($n$ = 88) weekly support. The optional approach resulted in therapists receiving half as many messages from (1.70 vs. 3.96) and sending half as many messages to patients (3.62 vs. 7.29). Optional Support was associated with lower completion rates (56.6% versus 82.4%), but, similar to Standard Support, resulted in large reductions on the GAD-7 (within Cohen's $d \geq 1.08$; avg. reduction ≥47%) and PHQ-9 (within Cohen's $d \geq 0.82$; avg. reduction ≥43%) at post-treatment and 3-month follow-up. Optional weekly support appears clinically effective and acceptable for many patients and may reduce costs, but safety requires monitoring given lower completion rates.

## 1. Introduction

Internet-delivered cognitive behavioural therapy (ICBT) has significant potential to improve patient access to care overcoming common barriers to attending face-to-face therapy (e.g., time, mobility, privacy, location; Andersson & Titov, 2014). In ICBT, patients access treatment materials designed to address mental health concerns on a weekly basis via the Internet; this is often accompanied by brief, but regular, weekly therapist support using secure emails or telephone calls (Andersson, 2016). Reviews of the ICBT literature are encouraging, especially for improvements in depression and anxiety (e.g., Andersson, Cuijpers, Carlbring, Riper, & Hedman, 2014; Andersson & Hedman, 2013; Hedman et al., 2012; Olthuis, Watt, Bailey, Hayden, & Stewart, 2015). Moreover, this form of treatment confers an implementation advantage, in that it requires considerably less time to deliver than face-to-face therapy (~15 min per week; Andersson, 2016).

While these results are promising, finite resources is a limiting factor in meeting demand for mental health services. Some research, therefore, has sought to examine efficient strategies for implementing ICBT. One strategy for increasing the efficiency of ICBT has been to introduce transdiagnostic ICBT programs that simultaneously address symptoms of depression and anxiety. Transdiagnostic ICBT has considerable appeal in routine practice as it takes less time for therapists to learn and deliver than disorder-specific ICBT (Hadjistavropoulos et al., 2016) and also addresses the high comorbidity between conditions (Kessler et al., 2005). Importantly, while efficient, transdiagnostic ICBT produces large symptom improvements that are similar to disorder-specific ICBT programs and face-to-face cognitive behaviour therapy (Dear, Staples et al., 2015; Newby, McKinnon, Kuyken, Gilbody, & Dalgleish, 2015; Newby, Twomey, Yuan Li, & Andrews, 2016; Titov et al., 2014; Titov, Dear, Staples, Terides et al., 2015). Furthermore, there is research showing that transdiagnostic ICBT is effective outside of research settings when offered in routine practice (Hadjistavropoulos et al., 2016).

Another potential option for reducing costs associated with ICBT is to reduce the degree of therapist support that accompanies ICBT. There has been considerable research comparing self-guided ICBT, where no therapist support is offered, to therapist-assisted ICBT (Baumeister, Reichler, Munzinger, & Lin, 2014). Systematic reviews have concluded that ICBT that includes therapist support produces greater reductions in

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symptoms than self-directed ICBT, due in part to lower adherence in self-directed ICBT (Baumeister et al., 2014; Spek et al., 2007). Recently, however, it has been noted that this conclusion may be overly simplified and that it may be possible to achieve positive results with self-directed ICBT (Berger et al., 2011). For example, simple automated reminders have been found to increase course completion rates (35%–58%) in self-directed ICBT (Titov et al., 2014). It has been hypothesized that therapist support may be less important "when the ICBT programs are sufficiently credible, engaging, of a high quality and involve some level of screening for suitability" (Dear, Gandy et al., 2015, p. 1921).

Recently, attention has turned to the concept of optional weekly therapist support with the prediction that this approach could reduce therapist time while maintaining treatment efficacy, acceptability and safety. In contrast to standard support where therapists contact patients weekly, patients receiving optional support are informed that the therapist is available weekly and may be contacted "as needed" (Dear, Gandy et al., 2015). This is consistent with the concept of *patient-centered care*, which refers to "providing care that is respectful of and responsive to individual patient preferences, needs, and values" (Institute of Medicine, 2001, p. 6). From a systems perspective, optional support could reduce time, and therefore costs, to deliver ICBT. Feedback from therapists suggests that substantial time is spent writing to patients who are enrolled in ICBT, but who do not respond to therapist support (Hadjistavropoulos, Alberts, Nugent, & Marchildon, 2014). When resources are constrained, offering standard weekly therapist support when it is not needed or wanted by a patient could represent an inefficient use of therapist time. On the other hand, it is possible that even though patients are not responding to support, this contact could still serve to assist patients with treatment completion and therapeutic change.

To date, there has been minimal research on ICBT that involves optional therapist support and as far as we are aware no such studies in routine clinical settings. One past trial of ICBT for panic disorder (8 lesson, 8 week) found poorer outcomes for optional ($n$ = 27) compared to standard weekly telephone support ($n$ = 25) in terms of dropout rates (33.3% vs. 20.8%) and symptom reduction (within −group effect size of 1.3 vs. 2.4; Oromendia, Orrego, Bonillo, & Molinuevo, 2016). Nevertheless, optional support was still better than a waiting list condition. Of note, only 4 of 27 patients made use of optional therapist support. In contrast to this research, a trial of ICBT for chronic pain (5-lesson, 8-week, with automated emails) found that optional support ($n$ = 141; 0.74 phone calls and 0.73 emails) was as effective as standard support ($n$ = 143; 6.4 phone calls and 5.63 emails), with both groups having similar completion rates (74% optional; 78% standard) and symptom improvement that was better than patients who received no treatment (Dear, Gandy et al., 2015). Similar to this study, Berger et al. (2011) compared therapist-guided ICBT for social phobia (5-lesson; 10 week) to unguided ICBT and unguided ICBT with the option to step-up to ICBT supported by emails or phone calls (~48% stepped-up care). In this trial, all three conditions were efficacious with no differences in completion among conditions (89% therapist-guided, 96% unguided, 93% optional). A number of explanations may account for positive outcomes in all conditions, including that in all conditions patients: 1) underwent pre-treatment screening; 2) had clear deadlines for module completion; and 3) participated in a discussion forum, which may have provided a source of support that is not available in self-guided programs.

Overall, the existing research suggests that optional support may be efficacious under some conditions, however, this has not been investigated in routine clinic settings. The current study sought to directly compare the efficacy of standard weekly versus optional patient-requested weekly therapist support on symptom improvement for patients enrolled in a transdiagnostic ICBT course for depression and anxiety. To assess for acceptability, groups were compared on completion rates, patient satisfaction, and therapeutic alliance. Use of therapist support (e.g., phone calls and emails) was also recorded, with the goal of understanding the impact of optional care on service delivery within routine care. Given the similarity of the current study to that of Dear, Gandy et al. (2015) in terms of program length, sample size, and use of automated emails it was hypothesized that optional support would be non-inferior to standard weekly therapist support and there would be strong symptom improvement, high completion rates and satisfaction with transdiagnostic ICBT regardless of whether patients received standard or optional weekly therapist support.

## 2. Method

### 2.1. Design and ethics

The study employed a two-arm, randomized, controlled, non-inferiority trial design. Patients were randomly assigned to receive transdiagnostic ICBT with weekly therapist: 1) Optional Support; or 2) Standard Support. Outcome was assessed at pre-treatment, post-treatment and 3-month follow-up. This trial received institutional research ethics board approval and was registered (ISRCTN14230906).

### 2.2. Patient recruitment, screening, and randomization

All patients applied for transdiagnostic ICBT through the Online Therapy Unit (www.onlinetherapyuser.ca), which is a government funded clinic that offers ICBT to patients throughout Saskatchewan, Canada. All patients who completed the eligibility screening process between February and July 2016 were included in the trial. Patients learned of treatment via medical professionals (47%; $n$ = 81), mental health professionals (32%; $n$ = 55), word of mouth (11%; $n$ = 20), online searches and email announcements (6%; $n$ = 11), media (2%; $n$ = 4), and printed posters/cards (2%; $n$ = 3).

Screening began with patients ($n$ = 382) completing an online questionnaire, which assessed whether patients met the basic inclusion criteria, including ensuring patients were: (1) 18 years of age or older; (2) residents of Saskatchewan, Canada; (3) self-reporting at least mild symptoms (above 5) on primary measures of depression and or anxiety (see measures below); (4) able to access and comfortable using computers and the Internet; (5) reporting no past diagnosis of schizophrenia; (6) available for the 8-week treatment period; and (7) willing to provide a medical provider as an emergency contact. If patients failed to endorse any one of these criteria ($n$ = 17), the online screening terminated and patients were encouraged to contact their family physician.

Patients who met these inclusion criteria ($n$ = 365) completed additional online questions about their background (e.g., name, age, sex, ethnicity, relationship status, education, employment) and symptoms. Following the completion of the online screening, staff contacted patients by telephone to discuss their responses to ensure the appropriateness of ICBT. At this stage, some patients could not be reached ($n$ = 25). Patients were excluded from treatment (and referred elsewhere if needed) if they: (1) were identified as having high suicide risk ($n$ = 33); (2) reported being in regular receipt of face-to-face therapy ($n$ = 9); (3) were no longer interested in treatment ($n$ = 9); (4) were primarily seeking treatment for alcohol or drug problems ($n$ = 5); (5) reported no symptoms of depression or anxiety ($n$ = 2); or (6) endorsed a medical condition that would interfere with treatment ($n$ = 1). See Fig. 1.

During telephone screening, accepted patients were randomly assigned to another trial ($n$ = 96) or to one of the two treatment groups for this trial. A permuted block design was used wherein randomization occurred by blocks of 18 patients to ensure approximately equal allocation among the three conditions. A total of 174 patients began at least one lesson and were eligible for analysis.