Waiting for Cognitive Behavioural Therapy (CBT): A Randomized Controlled Trial Evaluating the use of a Computerized CBT Program with Outpatients on a Waitlist in a University CBT Unit

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Abstract

Computerized Cognitive-Behavioural Therapy (cCBT) programs are a potential solution to decrease waiting lists for publicly-funded psychotherapy. However, assigning an appropriate program to individuals on a waiting list can be a challenge, given the heterogeneity of disorders presented and the timing of diagnostic assessments, which usually occur at the end of the waiting period. This study aimed to determine if a general cCBT program for depression and anxiety could reduce symptoms in outpatients referred for a wide variety of problems, while on a waiting list for CBT.

Sixty-seven outpatients with disparate diagnoses (anxiety, depression, obsessive-compulsive disorders, bipolar disorders, psychotic disorders and others), were randomized to one of two conditions: 1) the cCBT program "Good Days Ahead", which included weekly guidance and support, or 2) a control condition where patients were referred to an online self-help CBT workbook. The Clinical Outcomes in Routine Evaluations - Outcome Measure (CORE-OM), Beck Depression Inventory, Beck Anxiety Inventory, and an autonomous and controlled motivation for CBT scale were administered at start of study (T1), and at the end of the waiting period, when participants were formally assessed for face-to-face therapy (T2).

Mixed-design analyses of variance revealed no statistically significant changes in symptom measures over time, with the exception of the problems/symptoms and well-being subscales of the CORE-OM. Motivation changed in unexpected ways, with autonomous motivation decreasing from T1 to T2, and controlled motivation increasing over time. Non-significant interactions and modest effect sizes between groups across time suggested that the cCBT group did not do better than the control group. Interestingly, the majority of cCBT participants reported that the program was "very" or "extremely useful", while only a portion of

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the control group felt the same about the workbook. There were also notable differences in the completion rates of the two groups, in favour of the cCBT program.

Offering a general cCBT program to waiting list patients may not confer an advantage over simply referring them to an online workbook. In fact, our results suggest that changes in symptom severity and well-being were likely due to the passage of time rather than to the effects of either intervention. The decline in autonomous motivation for CBT could be explained, in part, to difficulties translating knowledge into practice, especially if participants' main problem was not directly addressed by the program or workbook. These findings suggest it might be more helpful to offer patients specific cCBT programs targeting their main complaints rather than assign them to a general cCBT program.

Résumé

L'emploi de programmes informatisés de thérapie cognitivo-comportementale (TCCi) pourrait être un moyen de réduire les longues listes de personnes en attente d'une psychothérapie financée par le gouvernement. Toutefois, proposer un programme approprié à ces personnes pose un problème compte tenu de la diversité des troubles présentés et du fait que l'évaluation diagnostique est habituellement effectuée à la fin de la période d'attente. La présente étude avait pour objet de déterminer si le recours à un programme général de TCCi axé sur la dépression et l'anxiété permettrait de réduire les symptômes de patients externes en attente d'une TCC qui avaient été orientés vers nos services et dont les problèmes variaient grandement.

Soixante-sept patients externes dont les diagnostics variaient (anxiété, dépression, trouble obsessionnel-compulsif, trouble bipolaire, trouble psychotique et autres troubles) ont participé à l'étude et ont été classés de façon aléatoire dans l'un de deux groupes : 1) le groupe de ceux qui allaient se servir du programme de TCCi Good Days Ahead, qui comportait une séance hebdomadaire d'orientation et de soutien; 2) le groupe témoin, dans lequel les patients allaient remplir en ligne, de manière autonome, un carnet de travail de TCC. Dans un premier temps (T1), soit au début de l'étude, les participants ont répondu au questionnaire de mesure systématique des résultats cliniques [The Clinical Outcomes in Routine Evaluations – Outcome Measure (CORE-OM)], aux questionnaires de dépression et d'anxiété de Beck et à un questionnaire de mesure de la motivation autonome et de la motivation contrôlée à l'égard de la TCC, puis, dans un deuxième temps (T2), soit à la fin de la période d'attente, ils ont fait l'objet d'une évaluation en bonne et due forme dans le cadre d'une thérapie face à face.

Les analyses de variance mixtes ont révélé qu'il n'y a eu aucun changement statistiquement significatif dans la mesure des symptômes au fil du temps, sauf pour ce qui est

des sous-échelles d'évaluation des problèmes ou symptômes et de bien-être du questionnaire de CORE-OM. Le degré de motivation a changé de façon inattendue : la motivation autonome a diminué du T1 au T2, alors que la motivation contrôlée a augmenté. Les interactions statistiquement non significatives et l'ampleur modeste de l'effet indiquent que le groupe ayant utilisé le programme de TCCi n'a pas obtenu de meilleurs résultats que le groupe témoin. Fait intéressant, une majorité des participants au programme de TCCi ont indiqué que le programme leur avait été « très » ou « extrêmement » utile, tandis qu'une faible partie seulement du groupe témoin ont eu la même impression par rapport au carnet de travail. Le taux d'achèvement du programme informatisé est nettement supérieur au taux d'achèvement du travail effectué à l'aide du carnet.

Il n'est peut-être pas plus avantageux d'offrir aux patients en attente d'une TCC de participer à un programme général de TCCi que de les inviter à utiliser un carnet de travail. En fait, les résultats de notre étude indiquent que les changements dans le degré de gravité des symptômes et dans le niveau de bien-être étaient probablement plus attribuables au passage du temps qu'à notre intervention. La diminution de la motivation autonome à l'égard de la TCC pourrait en partie s'expliquer par la difficulté à mettre en pratique les connaissances acquises, particulièrement dans le cas des patients dont le problème principal ne faisait pas directement l'objet d'une démarche dans le programme ou dans le carnet de travail. Les résultats obtenus indiquent qu'il vaudrait sans doute mieux offrir aux patients un programme de TCCi précis ayant un rapport direct avec les problèmes dont ils se plaignent que de leur faire suivre un programme général de TCCi.

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I also wish to send out a most special thanks to my friend Jesse Renaud. I do not believe I would be here today without her wisdom, professional guidance, and very, very generous heart. She, too, has believed in me from start to finish, even when I could not see it. The completion of my undergraduate thesis a few years ago had given me hope that graduate school would bring people just as inspiring and wonderful as she had been. As it turns out, it has...but only because she never really left my side.

Finally, I want to thank my parents for never pressuring me to accomplish grand things and for teaching me to be content, and humble, when I did achieve some things. I hope that with each milestone, they will continue to celebrate with me, no matter where I might go.

Thank you, Michael, for making me so, so happy.

Contribution of Authors

I, Rosanne Villemaire-Krajden, MSc Psychiatry student and research coordinator for the McGill University Health Centre CBT Unit, conducted the literature review for this study, wrote the research protocol, verbal consent script and consent form. I triaged participants, collected data, provided support phone calls to participants, and entered, analyzed and interpreted data. This thesis contains my own original and unpublished work.

Gail Myhr, my thesis supervisor, initiated and oversaw the development of this research project. As such, she planned its organization and implementation, formulated the research question and hypotheses, ensured that the content of the support phone calls was appropriate, provided guidance with regards to data analysis and interpretation, and revised and edited the manuscript.

Cognitive-Behavioural Therapy (CBT) has been widely recognized as an effective treatment for a variety of mental health disorders (Dusenberry and Hoffman, 2011; Sperry, 2006; Lovell and Richards, 2000). When compared to pharmaceutical treatment, CBT is equally effective for the treatment of anxiety disorders and mild to moderate depression, with fewer side effects and lower relapse and drop-out rates (Payne and Myhr, 2010). Similar findings have been reported for the treatment of obsessive-compulsive disorder, psychosis, and personality disorders (Antony et al., 2005; Hagen et al., 2011; Sperry, 2006). Importantly, CBT provides benefits that are maintained long after treatment has ended—something that medication cannot offer (Hollon et al., 2005; Antony et al., 2005). However, despite increasing demand for CBT services, face-to-face individual therapy remains relatively inaccessible (Cavanagh et al., 2006). This is due, in part, to a shortage of trained practitioners (Andrews et al., 2010; Comer, 2015) and to limitations in funding policies concerning mental health coverage. In many countries, including Canada, publicly-funded CBT remains limited (Payne and Myhr, 2010).

The recognition of a shortage of CBT services and of the concomitant increase in the number of individuals on treatment waitlists has led to a reconsideration of the delivery of CBT—that is, what it offers and how it is offered (Williams and Martinez, 2008). Most referrals for publicly-funded CBT involve a waiting period, followed by an assessment of the patient's problems and suitability for therapy, and finally, by twelve to twenty sessions with a CBT specialist (Williams and Martinez, 2008). Yet, the growing demand for CBT has rendered this delivery process insufficient. In an effort to improve the accessibility of CBT services, researchers and clinicians have therefore proposed that computerized CBT (cCBT) be administered, either as an alternative or as an adjunct to face-to-face therapy (Lovell and Richards; 2000; Cavanagh and Shapiro, 2004). Indeed, recent research has shown that cCBT

programs can be as effective as face-to-face CBT, while being less costly and time-consuming (e.g., Andersson and Titov, 2014; Purves et al., 2009; Thase et al., 2014; Wright et al., 2005).

A number of cCBT programs have been developed for the treatment of common mental health disorders. Users are typically required to login to a secure website or run a CD-ROM that allows them to access information and download material organized into a series of lessons or modules. Most if not all of these programs have been developed to address symptoms of depression and anxiety, and several meta-analyses of randomized controlled trials (RCTs) have shown evidence for their effectiveness (e.g., Andrews et al., 2010; Adelman et al., 2014; Thase et al., 2014). The National Institute for Clinical Excellence (NICE, 2006) has even recommended the interactive multimedia program Beating the Blues (BTB) as a stand-alone intervention of choice for treating depression of mild-to-moderate severity in primary care (Learmonth and Rai, 2008). A six-year long study on the use of BTB in a specialist CBT centre demonstrated the program's potential for decreasing the number of patients on a waitlist for face-to-face therapy (Learmonth et al., 2008). Of the 600 patients completing the program, 70% no longer needed subsequent face-to-face therapy, and were therefore fully discharged. In the past few years, a number of diagnostic-specific, internet-based CBT interventions (i.e., iCBT, which offers a non-interactive interface containing no videos) have been created to address other disorders, such as generalized anxiety, panic disorder or social anxiety disorder, and have been found to be effective (Andrews et al., 2010).

Different levels of patient guidance and support can be provided as an individual participates in cCBT. These include self-guidance, guidance by a non-clinical technician or practice nurse who sends reminders, and guidance by a clinician or non-clinician trainee who phones, emails, or comments on a private forum (Andrews et al., 2010). Studies which have

examined the effect of different types of patient guidance and support on the effectiveness of cCBT have had mixed results. In their seminal overview, Gellatly and colleagues (2007) concluded that cCBT may only be effective if a person guides and supports the patient throughout the therapy. They found no clear evidence that this supportive presence needed to be provided by a professional, however, or that it should consist of more than the monitoring and encouraging of patient progress. Other studies have shown that cCBT can be effective even when entirely self-guided (e.g., Lintvedt et al., 2013; Peck, 2010). According to the results of a meta-analysis of cCBT for depression and anxiety, however, cCBT delivered without guidance or support yielded, on average, a smaller effect size compared to cCBT delivered with a minimum of one hour of "knowledgeable assistance" throughout the entire therapy (Thase et al., 2014). Thase and colleagues concluded that offering some support, either in person, by telephone or e-mail, appears to be a requirement for maintaining patient involvement and for attaining good therapy outcomes.

Although the mechanisms by which guidance and support modulate therapy outcomes remain unclear, it is possible that the presence of a supporting figure increases patients' motivation for therapy. According to self-determination theory, an environment that provides structure, autonomy support and a sense of involvement fosters autonomous motivation (Ryan and Deci, 2008). Autonomous motivation is experienced when individuals feel like they have freely and willingly chosen their goals, and that these goals have personal meaning. Providing autonomy support—that is, recognizing and acknowledging individuals' unique perspectives and feelings, abstaining from exerting pressure, and offering as much choice as possible— has been identified as being particularly important to enhance autonomous motivation. In the context of therapy, autonomous motivation has been shown to be a strong predictor of treatment outcome,

both in terms of symptom relief and symptom remission (Zuroff et al., 2007; 2012). Assessing whether patients feel autonomously motivated for therapy could help to identify which factors are most important for maintaining involvement and for achieving good cCBT therapy outcomes.

cCBT programs are a potential solution to the long waiting lists for publicly-funded CBT (Andrews et al., 2010). Individuals who seek psychotherapeutic treatment may be willing to engage in immediate efforts to change their state, but when confronted with treatment delays, might experience clinical deterioration or reduction in motivation. cCBT offers the possibility of earlier intervention by providing immediate accessibility to much needed services. The risk of symptom exacerbation could be reduced and for some, remission may even be achieved. This could potentially decrease the number of individuals needing subsequent face-to-face CBT, and reduce overall demand for expensive individual CBT services in the health care system.

Present Study: Rationale

At the McGill University health centre (MUHC) CBT unit, where CBT is funded by the provincial health service, wait times average seven months (range two weeks to 10 months). At our centre—and, indeed, in many real world practices—individuals seeking CBT present with a wide range of difficulties, from life disturbances to anxiety disorders, obsessive-compulsive disorders and major mental illnesses such as psychosis. With such a heterogeneous population, choosing a diagnostic-specific program to decrease the symptoms of patients on a waitlist can be challenging, especially given that diagnoses are usually established at the end of the waiting period when patients are met and formally assessed for the first time. Although it is feasible and somewhat commonplace in research to conduct structured diagnostic interviews over the phone (Andersson and Titov, 2014), most secondary or tertiary care CBT clinics proceed with comprehensive face-to-face interviews shortly before the start of therapy (Williams and

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Martinez, 2008). This usually allows for a more accurate assessment of patients' difficulties, which are often complex and might have evolved over the waiting period.

A potential solution to the challenge posed by the timing constraints of the referral and assessment process could be to offer a program that addresses symptoms of low mood and anxiety—two complaints characteristic of many mental health disorders. For a number of individuals referred for CBT and awaiting formal assessment, such a program might be quite beneficial. For some, it could even obviate the need for subsequent face-to-face therapy altogether, or at least increase its effectiveness.

Indeed, individuals with a range of diagnoses might be able to use many of the tools provided. A key premise of the CBT model is that, regardless of the mental health disorder, suffering and dysfunction often result from the cognitive interpretation and emotional response to primary phenomena, such as an upsetting event (adjustment disorder), voices (psychosis) or intrusive thoughts (obsessive-compulsive disorder) (Tsai, 2009; Taylor, 2011). For example, there is evidence that mood dysregulation and low self-esteem may initiate and maintain psychotic symptoms (Smith, 2006). For this reason, learning how to better manage mood and emotional distress using the cognitive-behavioural model of the interaction between thoughts, behavior and emotions may lead to increases in well-being and to a reduction of symptom severity for many individuals.

Examples of such programs include Good Days Ahead (GDA), which was recently investigated in a Randomized Controlled Trial (RCT) involving depressed outpatients at a University affiliated clinic. In nine sessions, this interactive multimedia cCBT program teaches users the basic principles of CBT, including the processes involved in modifying automatic thoughts and in taking action. Paired with weekly clinical guidance, GDA was found to be as

effective as face-to-face CBT in decreasing symptoms of depression and anxiety, while considerably reducing clinicians' amount of time and effort in the delivery of their services (Wright et al., 2005). Whether it could also benefit individuals with other mental disorders has not yet been investigated to our knowledge, and is the subject of the current study.

Study Objectives

The purpose of this pilot study was to test the effectiveness of Good Days Ahead with outpatients referred for CBT for a wide variety of problems. This study aimed to determine if offering such a CBT program could decrease symptoms of distress regardless of individuals' diagnosis. The rationale for this was two-fold. First, it was based on the logic underlying transdiagnostic treatment approaches, which maintain that the same basic principles can be applied across different disorders, with little to no need for tailoring methods according to specific diagnoses (McEvoy et al., 2009). Such logic lends itself particularly well to the CBT model, in which many of the methods used to change thoughts and behaviours can be applied to all disorders. Negative thinking causing distress is altered, and maladaptive behaviours such as avoidance or inactivity are addressed. Second, it is not uncommon for individuals with primary diagnoses other than depression or anxiety to also suffer from low mood and stress as a result of difficulties coping with their chief complaint (Rodriguez et al., 2005; Smith et al., 2006; Ricciardi, 1995). Providing a program that helps recognize the effect that thoughts and behaviours have on mood, and teaches methods for reappraising problematic situations could therefore be useful for many individuals, not just those diagnosed with a depressive or anxiety disorder. With staff support and guidance, an element that seems important for maximizing cCBT outcomes, it was expected that the program could be sufficiently tailored to individuals' needs to produce clinical improvements and perhaps even foster motivation for CBT.

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Research Design and Hypotheses

This pilot study used a prospective, longitudinal, randomized and controlled experimental design to evaluate the utility of cCBT for individuals on a waitlist for face-to-face CBT. Outpatients waiting for therapy at the MUHC CBT Unit were randomized to a cCBT treatment group, using the GDA program, or to a bibliotherapy control group. Individuals in the control group received an online CBT self-help workbook for depression and anxiety to control for the expectation of gain, a factor believed to be particularly important in modulating psychotherapy outcomes. We evaluated the effectiveness of the GDA self-help program in decreasing waitlist patients' symptoms of psychological distress as well as the number of patients requiring subsequent face-to-face CBT. More specifically, we hypothesized that:

1) For individuals in both groups, symptoms of psychological distress would decrease from the beginning (pre-wait; T1) to the end of the waiting period (post-wait; T2);

2) From T1 to T2, the delivery of cCBT to individuals on the waitlist would reduce symptoms of psychological distress to a greater extent that those of individuals in the control condition;

3) Fewer individuals in the cCBT condition would need subsequent face-to-face therapy compared to individuals in the bibliotherapy condition.

Participants

The McGill University Health Centre's Research Ethics Review Board approved the protocol. Participants were required to be able to read in English, operate a basic computer program (9th grade reading level), and have access to a computer on a weekly basis. All individuals referred to the MUHC CBT Unit by a physician for short-term CBT were eligible for the study. Patients referred for CBT for any indication were included. Substance misuse did not itself constitute an exclusion criterion, although if that was the sole issue, the patient was referred to a specialized addiction service instead. Acutely suicidal patients or others needing urgent care, detected during triage, were discussed with the principal investigator to facilitate a more appropriate care option (e.g., emergency department). All participants provided written informed consent prior to enrollment in the study.

Data was collected from a sample of 67 outpatients (45 females and 22 males) aged from 17-70 years old ($M = 38.21$; $SD = 12.71$). Figure 1 displays a flow chart with the number of participants in each group across time. Randomization allocated 34 participants to the control group and 33 to the cCBT group. Although the size of the sample at T2 for different measures varied according to the amount of missing data, 22 participants in the control group and 24 in the cCBT group completed the assessment interview as required by the study.

Participants who did not complete the assessment were considered to have dropped out. Pre-post analyses only included participants with data for both time points. No statistically significant differences were found between completers and drop outs for T1 baseline measures of COREOM (total without risk) $t(65) = 1.24$, $p > .05$, depressive symptoms $t(65) = .20$, $p > .05$,

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anxiety symptoms $t(65) = -.23$, $p > .05$, autonomous $t(64) = 1.07$, $p > .05$ or controlled motivation for CBT $t(64) = -1.11$, $p > .05$.

At T2, an approximately equal number of participants expressed the need for face-to-face CBT and were accepted in the program. Of note, four participants in the control group and two in the cCBT group were deemed unsuitable for CBT or required another type of treatment and were therefore referred elsewhere. One of these "unsuitable" cCBT participants nonetheless benefited from the computerized program, indicating no need for face-to-face CBT and believing a more prolonged use of the methods learned would be sufficient.

Procedure

Triage. All patients referred to the Unit were triaged by telephone, using the standard triage script used since the inception of the clinic (Appendix A). During this contact, it was ascertained if patients were willing to undergo a short-term course of individual, face-to-face CBT, and whether the problem(s) for which they were referred could be expected to be helped by CBT. The Unit functioning was described, and patients were advised of the usual six month wait before receiving services. The only change in the triage procedure for this study was to ask whether individuals were interested in participating in a research study during the waiting period.

Consent. If individuals expressed an interest in participating during the phone triage interview, they were asked to give preliminary verbal consent. A scripted introduction to the study was communicated, which included standardized study information such as the risks and benefits associated with participation (Appendix B). The verbal consent procedure and all dated contact details were noted, and the formal consent form (Appendix C) was emailed to the potential participants. Individuals were informed that they had a week to read the form and respond to the email with their decision to participate. They were also notified that they could

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withdraw from the study at any time and for any reason, without any consequence on their subsequent treatment in the Unit. They were provided with the investigators' contact information should they have any questions or concerns.

Individuals who formally consented to study participation were emailed a link to a secure website (REDCap) for the completion of their first set of questionnaires. Using block randomization, participants were then allocated to one of two conditions: the computerized CBT group or the bibliotherapy control group. They were notified of allocation by email, and those in the cCBT group were sent scripted instructions for starting the computerized program (Appendix D).

cCBT group. Participants in the treatment group received online access to the Good Days Ahead (GDA) cCBT program. This program consists of nine lessons, each taking approximately 30 minutes to complete. Each lesson contains videos featuring a licensed CBT therapist who provides explanations for the model and its application. Vignettes presenting case examples are offered, as well as quizzes and exercises to practice and consolidate learning. Individuals are taught to identify common biases in thinking (i.e., thoughts that serve to reinforce and perpetuate negative states), and to use a thought change record to analyze and reappraise problematic situations. Although the interventions are mostly cognitive, users are also introduced to a few behavioural techniques such as activity monitoring and scheduling.

Users were advised to do one lesson a week, although they were free to progress at their own pace and could take up to twelve weeks to complete the program (based on the recommendations of Jesse Wright, co-author of program, personal communication).

Participants were monitored on a weekly basis. GDA includes a dashboard feature that permits the monitoring of patient progress (e.g., track mood ratings, exercises, comprehension and completion rates), allowing for easy delivery of patient guidance and support. Participants received weekly phone calls (or, in rare occasions where calls could not be taken, were sent emails) during which progress and feedback were discussed. All calls were handled by the investigator, Rosanne Villemaire-Krajden, research coordinator and M.Sc psychiatry student, with the exception of one participant who was followed by a volunteer PhD psychology intern. The volunteer intern was oriented to the study, and observed two of the writer's calls to ensure consistency in support interventions.

Bibliotherapy control group. Participants in the control group received a PDF copy of an online CBT self-help workbook (Hertfordshire Partnership University NHS Foundation Trust, n.d.). This workbook contains both cognitive and behavioural techniques and exercises, such as thought-change recording, activity scheduling, and graded exposure to anxiety-provoking stimuli.

In this study, providing the control group with a CBT self-help workbook was used to help control for the expectation of gain during the wait. No monitoring of progress was offered to participants in the control group.

Assessment. Participants were evaluated at the end of the wait period (T2), and if deemed suitable for CBT, were offered face-to-face therapy. All patients were therefore required to undergo a comprehensive cognitive-behavioural assessment, even if they decided that they no longer wanted to receive face-to-face CBT. This assessment consisted of a two hour, semi-structured interview with three objectives: 1) to establish a diagnosis based on the fifth edition of the Diagnostic and Statistical Manual's criteria ([DSM-5]; American Psychiatry Association,

2013); 2) to determine whether short-term CBT would be appropriate for that patient, and 3) to begin case conceptualization. The interview (outline available upon request) identifies the patient's presenting problem(s), typical cognitions and behaviors, screens for various mental disorders and elicits pertinent past history.

Outcome data. Self-report measures were administered at two time points: at the start of study, about a week following triage (T1) and at the assessment at the end of the waiting period (T2).

Data management and confidentiality. Participants' names were written on their questionnaires which were collected by the research coordinator. Each participant was assigned an identification code for anonymously linking data. The identification information was only accessible to the research coordinator and principal investigator in a password-protected document.

The GDA program is in compliance with HIPAA regulations, which ensure that personal health information (PHI) remains private and secure. The confidential collection and management of data followed RedCAP's security practices, which rely both on the software itself and on the hosting institution's IT infrastructure and environment (Vanderbilt University, n.d.).

Measures

Participant characteristics. Information about participants' age, sex, marital status, level of education, employment status, previous therapy experience, and initial knowledge and hope in CBT were collected.

Motivation for therapy. Participants' autonomous and controlled motivation for CBT

(i.e., the extent to which participants feel like their engagement in therapy is a choice of their own as opposed to a consequence of external pressures and demands) was measured with an adapted version of the Autonomous and Controlled Motivations for Treatment Questionnaire (adapted from Williams et al., 1998). The adaptation entailed the specification of "CBT" as the treatment in question. This questionnaire includes two subscales, the first assessing autonomous motivation (6 items, e.g., "I personally believe that [participating in CBT] is the most important aspect of my becoming well") and the second assessing controlled motivation (6 items, e.g., "[I participate in CBT because] I don't want other people to be disappointed in me").

Psychological global distress and functioning. The Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM, Evans et al., 2010) was used to measure psychological distress experienced during the last week. This 34-item questionnaire was devised to be administered before and after therapy. Statements (e.g., "I have felt overwhelmed by my problems"; "I have felt tense, anxious or nervous"; "I have been able to do most things I needed to") are answered on a 5-point scale ranging from 0 "*Not at all*" to 4 "*Most or all of the time*" and items fall into four psychological domains: subjective well-being, problems/symptoms, life functioning difficulties, and risk/harm to self or others. It is to be noted that higher scores on the well-being subscale are indicative of lower well-being, which is counterintuitive. This is because scores are reversed for the calculation of the total main outcome measure, which consists of the summative item of the average scores for the first three domains (the risk/harm domain is considered separately and used as a clinical indicator rather than a subscale).

Depressive symptoms. The Beck Depression Inventory-Version II (BDI-II, Beck et al., 1996) was used to assess the presence of depressive symptoms in the last two weeks. The BDI-II

includes 21 items rated on a scale ranging from 0-3 measuring, for example, the extent to which individuals feel sad, guilty, agitated, worthless and suicidal.

Anxiety symptoms. Anxiety was measured with the Beck Anxiety Inventory (BAI, Beck et al., 1988). This 21-item scale measures how much individuals have been bothered by physical symptoms of anxiety during the past week (e.g., "Fear the worst happening"; "Heart pounding or racing"; "Shaky") with answers ranging from 0 "*Not at all*" to 3 "*Severely*".

Clinical severity. The Clinical Global Impression (CGI) (Guy, 1976) scale was used to assess participants' illness severity. The CGI score is a summary measure that is attributed based on clinician assessment of patients' symptoms, behavior, personal and familial history, and psychosocial circumstances. Scores indicate the severity of mental illness of a patient compared to other patients with similar diagnoses. The score allocated is therefore based on clinicians' experience with the population under which a patient falls. Scores range from 1 "*Normal, not at all ill*" to 7 "*Among the most extremely ill patients*".

Psychological, social and occupational functioning. The Global Assessment of Functioning (GAF) (American Psychological Association, 1994) scale was used to measure participants' overall level of functioning. Scores range from 1 "*Persistent danger of severely hurting self or others, or persistent inability to maintain minimal personal hygiene, or suicidal act with clear expectation of death*" to 100 "*Superior functioning in a wide range of activities, life's problems never seem to get out of hand, is sought out by others because of his or her many positive qualities. No symptoms*".

Data Analysis

Data was collected and managed using the web-based REDCap electronic data capture tool hosted at McGill University (Harris et al., 2009), and analyzed using IBM's SPSS statistical software package, version 22.

Data Cleaning Procedures

Data integrity. Data screening and "cleaning" procedures (e.g., reviewing frequency distributions) excluded errors such as the presence of impossible values. The presence of outliers was verified by identifying observations beyond 3.3 standard deviations from the mean (Tabachnick and Fidell, 2007). A visual inspection of the bivariate correlation matrix for all variables did not indicate multicollinearity. Normal distribution of scores was assessed for all variables by visually scanning z-score histograms and by following Kline's (2009) guidelines for interpreting skewness and kurtosis indexes. Although a few variables appeared slightly skewed on the histograms, all values of skewness were below 3 and all values of kurtosis were below 10, which confirmed the near normality of distributions.

Individual scatterplots showed unconditional linear relationships between all predictors and the outcome. No issues of multicollinearity were found. The maximum value for Cook's Distance was below 1, indicating no probable multivariate outlier issue (Tabachnick and Fidell, 2007). Inspection of the normal probability plot (P-P) of the regression standardized residuals showed that the distribution was reasonably linear and thus did not deviate from normality. The scatterplot of the standardized residuals also appeared normal (i.e., uniformly distributed in a rectangular shape), suggesting that the distribution was homoscedastic and that none of the assumptions had been violated (Pallant, 2010). Finally, as shown by the Durbin-Watson

Statistics approximating a value of 2, the assumption of independence of residuals was met (Field, 2009).

Although random sampling was not the method used and thus not all assumptions of tests of statistical significance were met according to Kline (2009), p values are nevertheless presented to facilitate the interpretation of results.

Power Analysis. An a priori power analysis was conducted using the average score on the main outcome measure, the CORE-OM. Using means and SDs from a clinical group $(M = 1.86, SD = 0.75)$, $(N = 863$, Evan et al., 2002), a shift of about 0.5 points on the CORE-OM represents an effect size of $0.6 - 0.7$. If the study had 30 subjects in each group for each time point, it would have an 80% probability of detecting this effect (one-tailed) (GPower 3.1.9.2). Unfortunately, due to time constraints for the production of this thesis, we were not able to enroll enough participants to counter for attrition rates at the second time point, which has led us to be underpowered when analyzing differences across time and between groups.

Statistical Analyses

Tests of baseline differences in demographic and clinical characteristics were evaluated using analyses of variances (ANOVAs) for continuous variables and chi-square tests of independence for categorical variables. To determine whether the delivery of cCBT to individuals on a waitlist could reduce symptoms of psychological distress compared to those of individuals in the control group, we used a mixed effect model for repeated measures that contained treatment group, time, and group-by-time interaction as fixed effects. We also examined effect sizes —a particularly important step given our sample size—within and between groups across time. Cohen's d was used to measure within-group effects, and obtained by calculating the difference between T1 and

T2 means, which were divided by their standard deviations and corrected for dependence using the correlation between these two means. Between-group effects were calculated with partial eta square by dividing the variance of the model by the sum of the variance of the model and of the variance of the error (SSm/(SSm + SSe)).

Results

Quantitative Analyses

Descriptive statistics. Participants waited an average of 6.9 months ($SD = 1.6$) between the time they were referred to the unit and the time they were assessed. Participants in the control group waited, on average, 3.8 months from the time they were enrolled in the study to the time they were assessed, while the corresponding average wait time for participants in the cCBT group was 4.3 months. The majority of participants (67%) had been in psychotherapy before, and about a third of those reported receiving some form of CBT (34%).

Table 1 displays baseline demographic information. The sample was highly educated, with almost two thirds (61%) of the sample having a university degree. Forty-three percent of participants were married or in a common-law relationship, approximately half (55%) of the sample was employed. There were no significant differences between groups with regards to distributions in gender ($\chi^2 = .007$ (1), $p > .05$), marital status ($\chi^2 = 2.32$ (3), $p > .05$), education level ($\chi^2 = 5.67$ (4), $p > .05$), or occupation status ($\chi^2 = 2.56$ (3), $p > .05$). Participants in the cCBT group were slightly older ($M = 42.03$; $SD = 13.27$) than those in the control group ($M = 34.50$; $SD = 11.10$) (F (1, 65) $= 6.36$, $p < .05$).

Table 2 shows participants' baseline level of knowledge of CBT and initial hope in therapy being of help to them. It also indicates participants' problem chronicity, clinical severity and level of functioning at the assessment at the end of the wait (T2).

Most participants (65%) reported having lived with a least one difficulty or complaint for at least ten years. At T2, the average Clinical Global Impression (CGI) score was 4.25, indicating moderate clinical severity, and the average Global Assessment of Functioning (GAF) score was 53.41, indicating moderate symptoms (e.g., flat affect and circumstantial speech, occasional panic attack) and moderate difficulty in social, occupational and school functioning (e.g., no friends, unable to keep a job).

Diagnostic information. Table 3 shows that at assessment, a quarter of the sample received a depressive disorder as a main diagnosis, and approximately the same proportion was diagnosed with an anxiety disorder. All anxiety disorders (e.g., generalized anxiety disorder, social anxiety disorder, panic disorder, illness anxiety disorder) were grouped into a single category. The third most common main diagnosis was obsessive-compulsive disorder (OCD) or related disorders (e.g., trichotillomania). A greater number of participants were diagnosed with a depressive disorder in the control condition compared to participants in the cCBT condition. Four participants in the cCBT condition were diagnosed with what is sometimes considered a "major mental illness", that is, bipolar I and II disorders or psychosis. No participants in the control condition received such a diagnosis.

Of note, comorbidities were common, with most participants (82%) having received more than one diagnosis. Approximately a quarter (23%) of participants was diagnosed with a depressive disorder, and the same proportion was diagnosed with an anxiety disorder. Personality traits or disorders were also commonly given as a secondary diagnosis (16%), followed by OCD and related disorders (13%).

Completion rates of cCBT program and workbook. Table 4 presents information about participants' completion rates of the cCBT program and CBT workbook, as well as their

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evaluation of the usefulness of the intervention to which they were exposed. At T2, participants in the cCBT program ($n = 21$) had completed, on average, a total of seven lessons. Most participants (61%) completed all nine lessons. The average number of follow-up phone calls provided was six (more than one lesson was sometimes reviewed with a phone call), of which the average length was 19 minutes.

At T2, approximately a quarter (29%) of participants in the control group ($n = 17$) completed the entire workbook. Most participants (65%) in the control condition either did not find the workbook useful at all or only somewhat useful, whereas half of the cCBT group found the program either very or extremely useful. Thirty-five percent of participants in the control group and 27% of participants in the cCBT group did not attend the assessment.

Correlations. Table 5 displays Pearson r and Spearman's rho correlations between participant demographics and T2 CORE-OM measures. Participants' age was negatively correlated with the well-being subscale of the CORE-OM, which, given the scoring of items on this subscale, indicated that younger individuals experienced less well-being. Younger individuals also tended to score higher on the total CORE-OM, and on the problems/symptoms subscale, as shown by the significant negative association between these variables. Participants' length of time living with their complaint or education level was not significantly correlated with any of the CORE-OM measures.

As shown in Table 6, the strength of statistically significant associations between baseline T1 measures and our main outcome measures at T2 (CORE-OM total mean without risk and its subscales' scores) varied from .49 to .72. All T1 variables were significantly and positively associated with T2 CORE-OM measures, with the exception of motivation for CBT, which did not significantly correlate with any other variable, and anxiety symptoms, which were

not associated with the well-being and functional difficulties subscales of the CORE-OM. This indicates that, in general, greater symptom severity at T1 was associated with poorer outcome at T2.

Table 7 also shows significant and positive associations of moderate strength between most variables at T2. Autonomous and controlled motivations for CBT were, again, not correlated with any other variable, and anxiety symptoms were not significantly correlated with functional difficulties.

Correlations between participants' Clinical Global Impression (CGI) score and T2 measures, and between participants' Global Assessment of Functioning (GAF) score are displayed in Table 8. All CORE-OM measures as well as the BDI (depressive symptoms) were significantly correlated with the CGI and GAF indicators of severity of illness and functioning. Of interest, T2 autonomous motivation was positively and moderately associated with GAF assessment scores, indicating that individuals with greater intrinsic motivation displayed higher levels of functioning.

Changes in outcome measures across time and differences between groups. Table 9 illustrates the results of a mixed design ANOVA conducted to assess changes between groups in scores over time (with "time" as a two level, within-subject variable, and "group" as a two-level, between-subject factor). Depressive symptoms, anxiety symptoms and CORE-OM indicators of functional difficulties and risk to self or others did not significantly change from T1 to T2 ($p > .05$). There was a significant effect of time on CORE-OM indicators of well-being and problems/symptoms, and on motivation for CBT, however. Scores on the well-being scale significantly decreased over time (reflecting an *increase* in well-being) ($F (1, 37) = 6.31$, $p < .05$), and this was also the case for participants' problems/symptoms ($F (1, 37) = 8.14$,

p < .05). Controlled motivation significantly increased (F (1, 38) = 5.07, p < .05), while, surprisingly, autonomous motivation significantly decreased (F (1, 38) = 4.48, p < .05). This indicates participants became less intrinsically and more extrinsically motivated as the wait period unfolded. No statistically significant interactions were found between time and group, suggesting that whether participants were in the cCBT group or the bibliotherapy control group made no difference in terms of well-being, symptom severity, functioning, or motivation for CBT.

Effect sizes are shown in Table 10. Within-group effect sizes calculated for changes across time were small to moderate in the cCBT group, and moderate to large in the control group, with the largest ones being for problems/symptoms (control group Cohen's d = .76) and well-being (control group Cohen's d = .58), which both reached statistical significance. There was no significant interaction between time and group for any outcome measures (p > .05), with interactions between group and outcome measures yielding very small effect sizes (the largest partial eta square of .05 was produced by the problems/symptoms severity subscale of the CORE-OM).

Given the wide variety of diagnoses in our sample, and considering that the cCBT program and CBT workbook were designed specifically for depression and anxiety, we decided to run a mixed-design ANOVA using the main diagnosis as one of the grouping variables. To do so, we combined all depressive and anxiety disorders in a single variable and all other diagnoses into another. This analysis did not change our findings that there was no significant change in symptoms over time according to diagnosis and intervention type. It is to be noted, however, that with such a small sample size (ten or less participants in each comparison group), reaching statistical significance would have been difficult.

Qualitative Analyses

A compilation of the comments collected from participants in the cCBT group at T2 allowed us to conduct a thematic analysis. In attempting to identify and categorize patterns of response, we discovered that most participants seemed to have appreciated four major aspects of the program: content, format, independence and support provided. The most common positive comments fell under a "content" category. Nineteen participants commented that the educational component of the program was valuable and that they had learned useful concepts and acquired new skills. Examples of such comments were: "I learned terms to define my experiences, and that helped me understand some of my negative automatic thoughts", "Some of the skills and concepts provided useful ways to think about my anxiety" and another liked "The educational component: [identifying] feelings, triggers and [separating] thoughts and feelings from perception".

Four comments regarded the general "format" or structure of the program. One commenter liked, for example, "The way it was broken down into manageable portions".

Another theme that emerged from the data was related to the fact that the program allowed for "independence", or autonomous use. Eight participants appeared to have appreciated being able to follow the program from a distance and at their own speed: "[No one] was watching [my work] so I wasn't forced to answer the questions fast".

Finally, three participants noted that they valued the support and guidance received over the phone, as illustrated by comments such as: "I had somebody with whom I could discuss my progress, ask questions, etc." and "The weekly calls kept me on track". Such comments were grouped under a "support" category.

Participants' negative feedback about the cCBT program was grouped into five similar themes: content, relevancy, format, independence and context. Four commentators complained about the "content" of the program, wishing that more video examples would have been provided, for example, or that "[The case examples were] a bit cheesy...not the best acting", while three participants felt the overall content was not relevant to their own difficulties. One participant explained, for example, that: "Examples in program videos usually did not seem relevant to my situation so it often felt like I had to do a lot of interpretative work in addition to the CBT exercises themselves, which was often more than I could manage given the severity of my anxiety and depression". It is noteworthy to mention that a few other participants who did not comment about the relevancy of the program directly on the questionnaires had shared similar remarks during phone conversations, either while they were completing or after they had completed the program.

Six participants observed negative aspects about the "format" of the program, with some being disappointed that no Smartphone application had been developed, which forced them to sit down at a computer to complete lessons.

Three participants viewed the independent work required as particularly challenging given the circumstances: "It was sometimes difficult to work independently and to monitor myself, especially when I was very anxious".

The final category grouped comments which might be applicable to the therapy context itself as opposed to the program. Two participants indicated that it was difficult for them to think about negative aspects of their lives and reveal sensitive information. As one of them mentioned: "I found it required me to concentrate on these negative things quite a bit" and another

explained: "I was raised in a conservative family, so I am not used to talk about my family issues in front of many people".

Of note, three participants thought there was nothing about the program that they did not like.

Discussion

Overall Findings

In testing the effectiveness of the GDA program with individuals with a range of disorders, we had hypothesized that: 1) symptoms of distress would decrease for individuals in both groups from the beginning of the waiting period, from triage (T1) to the end of the waiting period (at the assessment; T2), and that 2) the GDA program, in combination with weekly support and guidance, would help decrease the symptoms of distress of individuals in the cCBT group to a greater extent than those of individuals provided with a self-help bibliotherapy workbook; and that therefore, 3) less individuals in the cCBT group would be in need of subsequent face-to-face therapy than individuals in the bibliotherapy control group.

For the most part, our quantitative results indicate that, for individuals with a wide variety of disorders, neither a self-help workbook nor an interactive cCBT program designed for depression and anxiety were effective in reducing symptoms of distress. Our first hypothesis was only partially supported: the problems/symptoms subscale of the CORE-OM was the only psychological distress indicator to significantly decrease over time. In light of our overall findings, it might be reasonable to suggest that the significant decreases associated with the well-being and problems/symptoms subscale from T1 to T2 reflects the influence of the passage of time on participants' symptoms rather than the effect of our intervention.

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Our analysis of interactive effects suggest that providing a cCBT program with guidance and support did not confer an advantage over providing a self-help workbook, even when most participants did not complete this workbook. This contradicts our second hypothesis and much of the literature on the effectiveness of cCBT programs, which have been shown to benefit many individuals by substantially decreasing symptoms of distress. It seems, then, that the particularities of the program chosen might not have been adequate for the needs of our sample. Interestingly, a much greater proportion of individuals completed the cCBT program compared to the self-help workbook. There were also notable differences in participants' evaluation of the intervention's usefulness, with most individuals in the bibliotherapy control group finding the workbook minimally useful, and most individuals in the cCBT group finding the program very useful.

Our third hypothesis was contradicted by the fact that the proportion of individuals in need of subsequent face-to-face therapy was similar in both groups. However, the amount of knowledge gained might have been greater for individuals in the cCBT group—a result which, if found, could have an effect on the duration or effectiveness of face-to-face therapy.

Changes in Symptoms from Start of Study to Assessment

Although a lack of power might have contributed to the non-significant results for many symptom measures in both groups, the generally modest effect sizes yielded (and even more so for the cCBT group), suggest that power is probably not the main factor explaining these results. The significant decrease in problems/symptoms and in well-being from T1 to T2 is more likely attributable to a gradual improvement in individuals' symptoms throughout the waiting period, which might have peaked at the time of their referral to the Unit. Individuals could have felt at their worse when they consulted their referring doctor, and felt somewhat better a few months

later. Research has shown that it is not uncommon for mental health disorders to at least partially remit without treatment (e.g., Whiteford et al., 2012).

Interestingly, the size of the effect for the changes in well-being and problems/symptoms was only substantial for the control group, in which many participants did not complete the workbook. If the passage of time is indeed in part responsible for the decrease in symptoms and increase in well-being, partial remission might have been easier to achieve for individuals in the control group, as they were not actively encouraged to focus on their difficulties as were individuals in the cCBT group. If neither the self-help workbook nor the cCBT program were sufficiently effective to induce changes on more specific measures of distress, such as the Beck depression and anxiety inventories, improvements on the well-being and problem/symptoms subscales in the control group could be related to the extent to which participants had to focus on their issues. The problem/symptom subscale includes items such as "*I have been disturbed by unwanted thoughts and feelings*", and "*My problems have been impossible to put to one side*", which might have been affected by the amount of time participants spent thinking about their problems. The same logic could apply to items on the well-being subscale, which includes items measuring the extent to which participants felt like crying or overwhelmed by their problems.

Differences between Groups from Start of Study to Assessment

The absence of a significant interaction between the two time points and the group to which participants were assigned indicates that the results observed in one group did not significantly differ from those of the other group. Participants' trajectories, with regards to depressive symptoms, anxiety symptoms, CORE-OM measures and motivation for CBT, were not dependent on the type of intervention. The workbook had been given to individuals in the control condition to control for any expectation of gain; it was unsurprising to find that it was not

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very useful, especially in the absence of guidance and support. What was surprising was that the cCBT program, in combination with weekly support, conferred no advantage over the workbook.

cCBT programs, including GDA, had previously been tested with individuals selected to participate based on their diagnosis, which was matched to the program's targeted diagnosis. Yet, given the wide applicability of the basic CBT model, we had anticipated that a program for depression and anxiety could be helpful for individuals with other diagnoses, in that they could adapt what they learned to their own difficulties. Contrary to expectations, the specificities of the GDA program seem to have prevented participants from benefiting, at least in terms of symptom reduction. Although participants were provided with information about the CBT model, which included an explanation and examples for the role of thoughts and behaviour in fostering and maintaining emotional states, participants might have had difficulties understanding how to apply this knowledge to their own problems, and perhaps even more so to translate it into practice. Indeed, if individuals' main complaint was neither depressive nor anxiety symptoms, they might have found the illustrative case examples differed considerably from their own experiences.

If a number of processes contributing to and maintaining mental health problems are common across disorders, the range or type of methods offered by GDA to identify and address these processes may not have been adequate for all participants, which might have been discouraging. Although the program did offer insight into anxiety symptoms and their relationship to certain thoughts and behaviours, the techniques and exercises aimed at reducing anxiety were mostly cognitive. Individuals with specific anxiety disorders, such as social anxiety disorder or panic disorder, and with obsessive-compulsive disorders might have needed to be provided with more behavioural tools, such as exercises aimed at reducing avoidance and safety-

seeking behaviours, and at initiating graded exposure to anxiety-provoking stimuli. Given the large proportion of participants who were diagnosed with obsessive-compulsive and related disorders at the assessment, this hypothesis is rather plausible. Moreover, although it is common for individuals with a wide range of primary diagnoses to report low mood and anxiety as a result of difficulties coping with their main problem, these secondary symptoms might have been experienced and expressed very differently depending on the type of problem causing them. Confusion about the relevance and applicability of the program to participants' main difficulty could have discouraged a number of participants from investing effort into adapting the methods to their own problems, even when guided and encouraged to do so during weekly phone calls.

From the investigator's perspective, support phone calls often posed a challenge when participants' main problem was not directly targeted by the program. Calls were provided to follow-up on lessons rather than to prepare or prime participants for upcoming content, and this might have complicated efforts to adapt the program to participants' needs. Indeed, scheduling calls at such a time meant that any suggestion made for adjusting an exercise was only considered by participants after they had completed it. Sufficiently tailoring the program to participants' needs might have required more than 20 minutes per week, and perhaps changes in the wording and type of exercises as well.

Compared to the program, the workbook may have contained more behaviourally-oriented exercises such as graded exposure. Yet, low compliance, in the absence of guidance and support, might have prevented individuals from benefitting from these important behavioural strategies. For some participants, the realization that the workbook was targeted solely towards anxiety and mood might have deterred them from using it at all. Importantly, for both groups, the methods taught—such as recognizing and identifying common cognitive errors and finding more

accurate ways to think about themselves and their environment—might not have been presented in a way that elicited active involvement in recovery.

Changes in Motivation for CBT from Start of Study to Assessment

This study also examined the effect of both interventions on motivation for CBT. Autonomous motivation represents the extent to which individuals engage in treatment by free will and in a way that has personal meaning, while controlled motivation reflects how much individuals believe this engagement results from external pressures such as guilt, or a desire to please others. We had anticipated that participants' autonomous motivation would increase from start of study to assessment, and even more so for those in the cCBT group. This was based on our knowledge of self-determination theory, which suggests that autonomous motivation can be enhanced in a context where individuals are provided with a structure in which their autonomous support and involvement are actively encouraged—an environment we attempted to create with weekly follow-up phone calls.

Contrary to our expectations, participants in both groups experienced a decrease in autonomous motivation for CBT, and an increase in their controlled motivation over time. Although we did not directly measure the extent to which participants felt autonomously supported, it appears that the phone calls provided to participants in the cCBT group to help them identify their main problems while validating their feelings and encouraging the attainment of their goals, was not sufficient to enhance autonomous motivation. In fact, in this respect it might not have made a difference at all: the same directional changes in motivation were observed across time in the control group in which participants did not receive any guidance and support.

Yet, given the apparent lack of effectiveness of both the workbook and cCBT program in alleviating symptoms, the decrease in autonomous motivation and the increase in controlled motivation are somewhat logical. A study conducted by Zuroff and colleagues (2012) had identified both types of motivation as important predictors of treatment outcomes, with higher levels of autonomous motivation being correlated with greater symptom reduction, and controlled motivation inversely correlated with symptom reduction. Surprisingly, we did not find significant associations between autonomous and controlled motivation at T1 or at T2 and any of the CORE-OM measures, including the problems/symptoms subscale. There was also no association between autonomous and controlled motivation at T1 or T2 and depressive symptoms at T2. Of interest, Zuroff and colleagues had found that between-person differences in autonomous and controlled motivation served to predict the extent of change in depressive symptoms. Given the very small standard deviations yielded by the motivation scales, and especially by its autonomous counterpart, it is possible that differences in motivation levels between participants were too negligible to consistently vary with changes in the problem/symptoms subscale. Moreover, we had not measured participants' perceived autonomy support, which was found to strongly predict autonomous motivation and which might, as such, also play a direct or mediating role in modulating depressive severity.

A comparison of completion rates between the two groups and an observation of some of participants' comments about their use of the cCBT program suggest that support and guidance could be important at least for treatment adherence. The finding that autonomous motivation decreased despite efforts to foster autonomous support suggests that a supportive context may only exert a positive influence on motivation in conjunction with a treatment that is in itself "adequate". Without the pairing of these two factors, support might be helpful for maintaining

involvement, but not for attaining good therapy outcomes. In both groups, the disjunction between some of participants' experiences and the ones portrayed in the cCBT program or workbook could have negatively affected levels of perceived self-efficacy, which could, in turn, have reduced participants' autonomous motivation for CBT.

Although self-efficacy was not measured in our study, two recent studies have shown that it can mediate the effectiveness of online therapy interventions through symptom improvement (Warmerdam et al., 2010; Clarke et al., 2014). From the perspective of Bandura's social learning theory, perceived self-efficacy reflects the belief an individual has about his or her capacity to engage in certain behavioural changes; a factor that has been identified as a strong contributor to psychotherapy outcomes (Bandura, 1977). The presumption is that therapeutic outcomes are influenced by the amount of effort and time individuals expend and how much they persevere in the face of challenges when coping with negative experiences. As mentioned by Clarke and colleagues (2014), as well as by Warmerdam and colleagues (2010), examining the role of self-efficacy might be particularly important in assessing the effectiveness of computerized therapy, given that individuals' active cognitive and behavioural engagement through self-monitoring are of utmost importance in this context. In the present study, the content of both interventions could have led participants to question the usefulness of the exercises and homework, and altered their beliefs about initiating change autonomously, leading to reductions in autonomous motivation. Possible decreases in participants' levels of perceived self-efficacy might have been mirrored by a belief that they were mostly engaging in treatment for extrinsic reasons, such as to contribute to research advances, or even to please the Unit's personnel—personnel who might later evaluate their suitability for face-to-face CBT— which could explain the observed increase in participants' controlled motivation for CBT.

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Clinical Implications

Research has shown that cCBT programs can be as effective as face-to-face therapy, while offering several advantages such as increasing accessibility to services while reducing clinician time and mental health care costs. As such, cCBT programs are a potential solution to the long waiting lists for face-to-face therapy. In many clinical settings, conducting diagnostic assessments at the beginning of the waiting period is often impractical, and can affect the accuracy of treatment plans, which would only be applied months later. This can make it difficult for clinicians to decide which program to offer patients during their wait. The findings from this study nonetheless highlight the importance of providing an intervention targeted towards patients' main complaint or which at least provides examples and exercises easily adaptable to a number of different mental health problems. Although transdiagnostic cCBT programs for a wide range of disorders have not yet been created, perhaps conducting a short triage interview by phone and asking patients to identify the main problem they wish to resolve could be sufficient in selecting a program targeted to patients' needs. Recent research has shown that when patients' chief complaint is at least partly successfully addressed by an online program, benefits can extend to secondary complaints despite them not being directly targeted (Hofman, 2016). Finally, support and guidance appear to play an important role at least for compliance with treatment, and might be of particular benefit to patients more prone to drop out in the face of challenges, such as individuals more severely ill or less motivated to work on their own.

Limitations and Future Directions

A number of limitations can be raised. First and foremost, given that sample size has an effect on statistical power, significant findings were likely difficult to achieve across all study measures, including our main outcome measure. This inevitably blurs conclusions about the true

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effectiveness of interventions. Second, it is also worthy to mention that despite the advantageous ability of RCTs to yield unbiased and consistent estimates of effect, they are somewhat restricted in their external validity (Clay, 2010). With this RCT, we attempted to be representative of and generalizable to "real-world" populations of individuals seeking CBT, and thus, to maximize external validity. Our study was based on extremely wide inclusion criteria, resulting in a very heterogeneous group of outpatients who greatly varied in diagnosis. Combined with our restricted sample size, diagnostic heterogeneity posed an even greater challenge for the analysis and interpretation of our data. Finally, although we offered suggestions about the possible roles of autonomous support and perceived self-efficacy in altering motivation for therapy, these factors were not directly measured and no firm conclusions can be drawn about their involvement in the explanation of our results.

Future research on the use of cCBT programs for outpatients on waitlists for face-to-face CBT should explore ways to effectively alleviate distress in populations with a wide range of difficulties, and in a way that is time and cost-effective. Improving knowledge about which factors are most important for achieving good cCBT outcomes would also be important. We regret not having measured participants' perception of self-efficacy, as we were not aware of the few studies which had recently examined this concept. For our part, we will be assessing whether there might be differences in face-to-face therapy outcomes according to the group to which participants were assigned. Although the type of intervention did not have a differential effect on symptomatology, differences in participants' evaluation of the usefulness of each intervention could predict the length of subsequent therapy or the extent of its benefit.

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Figure 1

Flowchart of participants

Consented &
randomized to
study
N = 67

T1 control
n = 34

T1 cCBT
n = 33

Finished
workbook
n = 5

Finished
program
n = 20

Dropped out
n = 12

Completed
assessment
n = 22

Dropped out
n = 9

Completed
assessment
n = 24

Accepted for
face-to-face
therapy
n = 18

Accepted for
face-to-face
therapy
n = 21
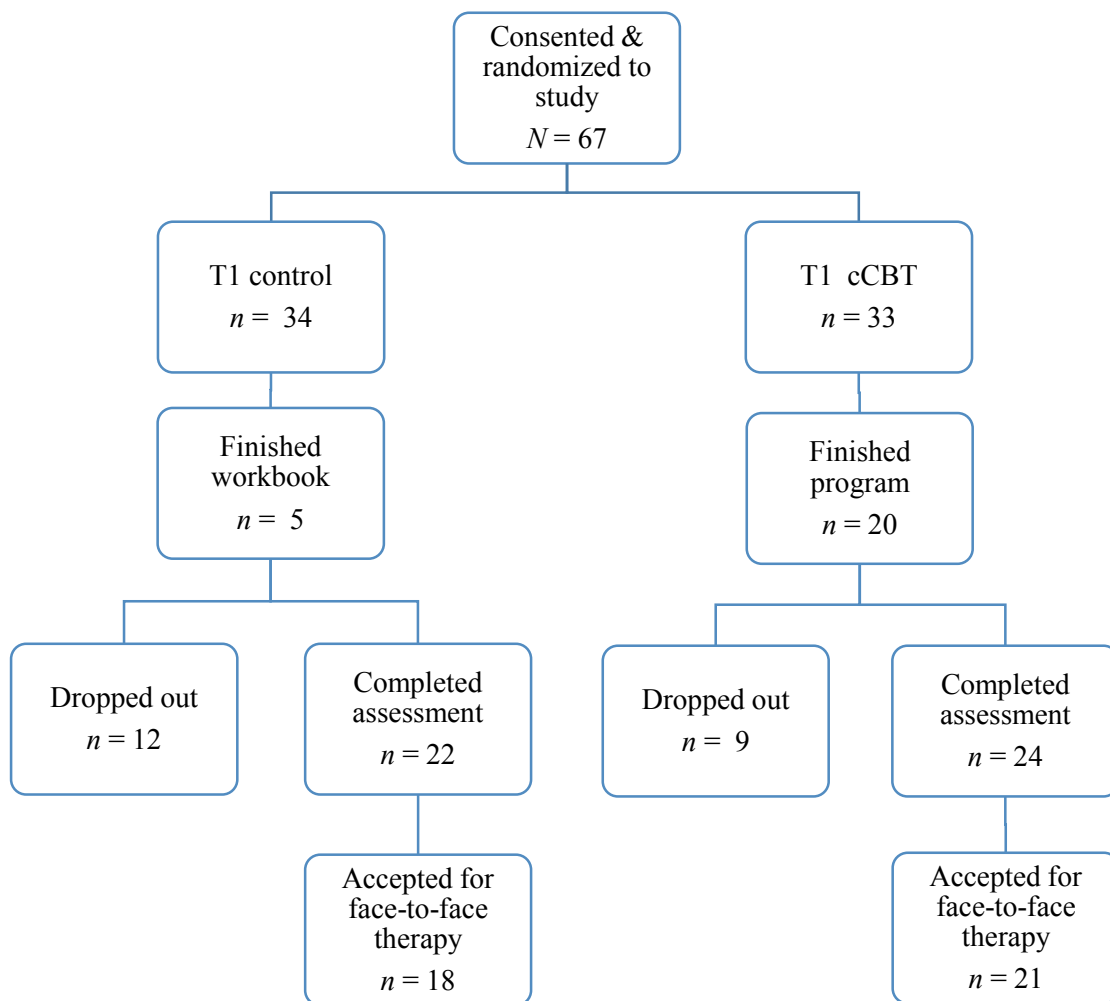
Table 1

Demographic Information

	Control % (*n*)	cCBT % (*n*)	Total % (*n*)
Sex			
Female	67.6 (23)	66.7 (22)	67.2 (45)
Male	32.4 (11)	33.3 (11)	32.8 (22)
Marital Status			
Single	50.0 (17)	40.6 (13)	45.5 (30)
Common-Law	20.6 (7)	12.5 (4)	16.7 (11)
Married	20.6 (7)	31.3 (10)	25.8 (17)
Divorced	8.8 (3)	15.6 (5)	12.1 (8)
Highest education completed			
Elementary school	0.0 (0)	3.1 (1)	1.5 (1)
High school	35.3 (12)	12.5 (4)	24.2 (16)
College/Cegep	11.8 (4)	15.6 (5)	13.6 (9)
Bachelor's degree	35.3 (12)	50.0 (16)	42.4 (28)
Master's/doctorate	17.6 (6)	18.8 (6)	18.2 (12)
Occupation status			
Student	17.6 (6)	12.5 (4)	15.2 (10)
Employed	52.9 (18)	56.3 (18)	54.5 (36)
Unemployed	29.4 (10)	25.0 (8)	27.3 (18)
Retired	0.0 (0)	6.3 (2)	3.0 (2)

Table 2

Knowledge, Hope in CBT and Problem Chronicity at Start of Study (T1), and Clinical Severity and Functioning at Assessment (T2)

	Control % or *M* (*SD*)	cCBT % or *M* (*SD*)	Total % or *M* (*SD*)
Knowledge of CBT (T1)	(*n* = 34)	(*n* = 32)	(*n* = 66)
None	20.6	12.5	16.7
Just what referring MD explained	23.5	12.5	18.2
Some reading on it	38.2	46.9	42.4
Extensive readings, self-help exercises	2.9	12.5	7.6
Previous CBT	14.7	15.6	15.2
Hope in CBT being helpful (T1)	(*n* = 34)	(*n* = 32)	(*n* = 66)
Not hopeful at all	2.9	0.0	1.5
Somewhat hopeful	5.9	15.6	10.6
Moderately hopeful	32.4	37.5	34.8
Very hopeful	50.0	34.4	42.4
Extremely hopeful	8.8	12.5	10.6
Time with main problem (T1)	(*n* = 32)	(*n* = 31)	(*n* = 63)
Lifelong (at least 10 years)	68.8	61.3	65.4
At least 5 years	12.5	19.4	15.9
2 years	6.3	6.5	6.3
> 6 months, but < 2 years	6.3	12.9	9.5
< 6 months	6.3	0.0	3.2
Clinical Global Impression score (CGI; T2)	(*n* = 21)	(*n* = 20)	(*n* = 41)
	4.36 (.69)	4.13 (.76)	4.25
Global Assessment of Functioning score (GAF, T2)	(*n* = 21)	(*n* = 20)	(*n* = 41)
	52.95 (7.51)	53.90 (7.64)	53.41

Table 3

Frequencies of Main Diagnosis at Assessment (n = 44)

	Control	cCBT	Total
Depressive disorders (MDD and PDD, recurrent, single episodes)	8	3	11
Anxiety disorders (social, generalized)	4	6	10
Bipolar I & II disorders	0	2	2
OCD & related disorders	4	3	7
Insomnia disorder	1	0	1
Somatic symptom disorder	1	0	1
V code	1	0	1
Psychosis & related disorders	0	2	2
Adjustment disorder	0	1	1
Substance-related disorders	0	1	1
Personality disorders/traits	2	3	5
Autism spectrum disorder	1	0	1
Total	22	22	44

Table 4

Completion Rates for and Evaluation of Usefulness of Workbook and cCBT Program

	Control group (n = 17) %	cCBT group (n = 21) %
Amount of workbook completed		—
None	11.8	—
Only a few pages/chapters	17.6	—
Less half	29.4	—
More than half	11.8	—
The entire book (or almost)	29.4	—
Proportion of program completed		
All 9 lessons	—	60.6
At least 7 lessons	—	75.8
At least 3 lessons	—	93.9
Usefulness of intervention		
Not useful at all	35.3	4.8
Somewhat useful	29.4	14.3
Moderately useful	23.5	28.6
Very useful	5.9	38.1
Extremely useful	5.9	14.3

Table 5

Correlations (Pearson r and Spearman's rho) between Participant Characteristics and T2
CORE-OM Mean Scales (N = 67)

	Total without risk	Well-being	Problems/ symptoms	Functional difficulties	Risk
Age	-.26*	-.46*	-.33*	-.30	-.04
Education level	-.15	.01	-.04	-.12	.17
Amount of time living with problem	.07	-.01	.02	.01	.11

Note. * = $p < .05$.

Table 6

Correlations of Depressive Symptoms, Anxiety Symptoms, and Motivation for CBT at T1, with T2 Main Outcome Measures (CORE-OM) at T2 (N = 67)

Variables	1	2	3	4	5	6	7	8
1. CORE-OM mean total without risk (T2)	—							
2. CORE-OM mean well-being (T2)	.68*	—						
3. CORE-OM mean problems/symptom severity (T2)	.77*	.77*	—					
4. CORE-OM mean functional difficulties (T2)	.66*	.64*	.69*	—				
5. Depressive symptoms, BDI (T1)	.72*	.50*	.60*	.59*	—			
6. Anxiety symptoms, BAI (T1)	.64*	.25	.49*	.25	.50*	—		
7. Autonomous motivation (T1)	-.12	-.00	-.02	-.01	-.09	-.05	—	
8. Controlled motivation (T1)	.10	.05	.20	.23	.20	.11	.13	—

Note. * = *p* < .05. BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory.

Table 7

Correlations of T2 Depressive Symptoms, Anxiety Symptoms, and Motivation for CBT with T2 Main Outcome Measure (CORE-OM) (N = 67)

Variables	1	2	3	4	5	6	7	8
1. CORE-OM mean total without risk (T2)	—							
2. CORE-OM mean well-being (T2)	.68*	—						
3. CORE-OM mean problems/symptom severity (T2)	.77*	.77*	—					
4. CORE-OM mean functional difficulties (T2)	.66*	.64*	.69*	—				
5. Depressive symptoms, BDI (T2)	.55*	.51*	.75*	.65*	—			
6. Anxiety symptoms, BAI (T2)	.41*	.37*	.46*	.16	.53*	—		
7. Autonomous motivation (T2)	-.26	-.02	-.08	-.12	-.11	.11	—	
8. Controlled motivation (T2)	-.21	-.27	-.06	-.04	.03	-.14	-.07	—

Note. $* = p < .05$. BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory.

Table 8

Correlations between Clinical Global Impression (CGI), Global Assessment of Functioning (GAF) and T2 measures (N = 67)

Variables	CGI	GAF
COREOM mean total without risk	.52*	-.69*
COREOM mean well-being	.38*	-.64*
COREOM mean problems/symptoms	.46*	-.51*
COREOM mean functional difficulties	.51*	-.59*
Depressive symptoms (BDI)	.45*	-.56*
Anxiety symptoms (BAI)	.24	-.20
Autonomous motivation	-.27	.39*
Controlled motivation	-.29	.24

Note. * = *p* < .05. BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory.

Table 9

Changes across Time: Outcome Measures at Baseline (T$_1$) and Assessment (T$_2$)

Measure	Control Mean (SD)		cCBT Mean (SD)		Repeated-measures ANOVAs F values	
	T$_1$	T$_2$	T$_1$	T$_2$	Time (*df*)	Time x Group (*df*)
CORE-OM						
Total without risk (mean)	2.36 (.52)	2.22 (.59)	2.22 (.74)	2.12 (.73)	3.76 (1, 37)	.10 (1, 37)
Well-being	2.86 (.77)	2.53 (.74)	2.58 (.95)	000000000002.44 (.88)	6.31* (1, 37)	1.06 (1, 37)
Problem/symptoms	2.79 (.69)	2.41 (.86)	2.43 (.94)	2.29 (1.01)	8.74* (1, 37)	1.84 (1, 37)
Functional difficulties	2.07 (.51)	2.17 (.55)	2.12 (.74)	2.05 (.63)	.05 (1, 37)	.28 (1, 37)
Risk/harm	.69 (.71)	.57 (.48)	.51 (.55)	.48 (.53)	.73 (1, 37)	.32 (1, 37)
Motivation for CBT						
Controlled	16.90 (9.31)	19.50 (9.33)	13.80 (6.88)	17.00 (8.78)	5.07* (1, 38)	.05 (1, 38)
Autonomous	35.00 (4.35)	33.35 (5.73)	36.15 (5.73)	34.85 (4.69)	4.48* (1, 38)	.06 (1, 38)
BDI, depression scale	29.27 (11.85)	28.59 (14.70)	25.50 (11.94)	24.14 (12.50)	.46 (1, 42)	.01 (1, 42)
BAI, anxiety scale	19.86 (10.61)	18.32 (11.65)	22.33 (14.38)	20.00 (13.42)	1.00 (1, 41)	.05 (1, 41)

Note. * = *p* <.05. BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory.

Table 10

Within-group Effect Sizes (Cohen's d) and Between-group Effect Sizes (Partial Eta Squared)

| | Within-Group Effect Sizes | | | | Between-Group Effect sizes |
| | Control | | cCBT | | |
	t (df)	d	t (df)	d	Partial Eta Square
CORE-OM total without risk	1.81 (18)	.41	1.05 (19)	.24	.00
CORE-OM well-being	2.46* (18)	.58	1.07 (19)	.24	.03
CORE-OM problems/symptoms	3.20* (18)	.76	1.09 (19)	.27	.05
CORE-OM functioning difficulties	-1.13 (18)	-.28	-.55 (19)	-.13	.03
BDI, depressive scale	.34 (21)	.07	.63 (21)	.13	.00
BAI, anxiety scale	.68 (21)	.14	.83 (20)	.18	.00
Controlled motivation	-1.81 (19)	-.29	-2.00 (19)	-.47	.00
Autonomous motivation	1.56 (19)	.36	4.43 (19)	.33	.00

Note. $*= p <.05$. BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory.

Triage Script, English version

Introduction

Hello, my name is Rosanne Villemaire-Krajden, and I am the research coordinator at the MUHC Cognitive Behavioural Therapy Unit, calling on behalf of Dr. Myhr. We received a referral from Dr. Y, suggesting that you might benefit from Cognitive Behavioural Therapy (CBT). Were you aware of this? Are you interested in pursuing a therapy at our Unit?

Main problem

We offer short term CBT, which usually lasts between 12 – 20 weeks, and which is focused on addressing specific problems. Although we have a waiting list of about 6 months from the time you were referred to the time you will be assessed and start therapy, meanwhile we call everyone on our wait list to ask them to provide us with a bit of information about the main difficulties that they are experiencing, so that we can prepare the questionnaires that need to be completed at the assessment. Could you briefly explain the main problem for which you would like help with?

- Could you give me a specific example?

- How long have you had this problem?

- How does this problem affect you? (At work? At home? Anywhere else?)

Other problems

Any other problems you would want help with?

Medication

Do you take any medication for this problem? What medication?

Substances

Do you take any alcohol? Do you take alcohol to calm your anxiety? Has alcohol ever been a problem for you? Do you take any street drugs? Have these ever posed a problem for you?

Procedure

Assessment procedure. I will be discussing what you told me with Dr. Myhr. I may call you back to gather more information. Right now, as I explained earlier, we have a wait of several months, but it may be shorter or longer. You will be called back with an appointment for the initial assessment. This assessment usually occurs on Tuesday afternoons and involves being interviewed by our team of CBT therapists. Specifically, this means that usually two people interview you, and other members of the team may observe behind a one-way mirror. The

interview lasts about 2 hours. During this interview, your specific problems will be discussed, and you will be given an idea of what receiving CBT would be like.

Individual therapy. If you and the team feel that CBT might be useful for you, you will be assigned a therapist. Most of our therapists are senior residents or experienced therapists, who are undergoing specialized training in CBT. For this reason, your therapy sessions may be videotaped, but for supervision purposes only. The videotapes are kept under key at all times and are deleted between sessions.

Do you have questions so far?

Research project. Before I let you go, I would like to know whether you would be interested in participating in a research project while you are waiting for treatment at our Unit. The project involves reading about CBT or using a computerized version of CBT while you are waiting for face-to-face therapy, to see if either of these things could help with your difficulties. Would you like to hear more about this?

If no: Can I ask why this is not of interest to you?

If still no: Okay, thank you. So for now, I will suggest that you read "Mind Over Mood" by Dennis Greenberger and Christine A. Padesky while you are waiting, to get an idea of what CBT for your problem is like. Do you want to write that down? You can order it on Amazon, or pick it up in most bookstores. It might also be available to borrow at the library. We will be calling you for an assessment as soon as we have an opening. Do you have any other questions? Let me give you our number in case you have any further questions about our Unit or about participating in our study. 514-934-1934 ext. 35533 (MJ) or 35510 (RVK).

If yes: Okay, so let me tell you a little more about the study. This study is testing whether or not reading about CBT (also called bibliotherapy) or following a CBT program on a computer can help people's symptoms while they wait for face-to-face, individual CBT. The process is very simple. You would complete a questionnaire package, which you could receive by email and fill in online, or you could fill it in on paper by receiving the questionnaires through regular mail, or you could come into the hospital to fill it in with our help. This would take about 30 minutes to fill out.

Once the questionnaires will have been completed, you will be assigned, at random, to one of two groups. At random means that neither you nor I know which group you will be assigned to until the questionnaires are filled in. It is like flipping a coin: you have a 50/50 chance of being in either group.

If you are assigned to the **bibliotherapy** group, you would receive a copy of a CBT self-help workbook which might help you with your difficulties.

If you are assigned to the **computerized CBT group,** you will be granted access to an online CBT program, delivered to you by computer. This would give you access to nine weekly computer CBT sessions that last about 30 minutes each. This program would be available to you at no cost.

At the end of the wait period and regardless of which group you will have been assigned to, you would receive face-to-face therapy as was planned in the first place, if you still wish to do so.

Are you still interested in participating in this research project?

If no: Why not?

If yes: Okay. The first step to enroll you in the study will be to get your formal consent. I will give you a bit more details about the study now, and then I will call you back in a few days to see if you have come up with a decision. If you agree to participate, I will send you a copy of the consent form by email or regular mail for you to read. (Research coordinator proceeds with the Verbal Consent Script presented in Appendix B).

Appendix B

Verbal Consent Script, English version

Goal of Study

As I mentioned, the goal of this study is to find out if bibliotherapy (a self-help workbook about CBT) or a self-help computerized CBT program called Good Days Ahead, will help decrease symptoms of depression, anxiety, or any other type of symptoms or distress you may be experiencing while waiting for individual, face-to-face CBT. It will also evaluate the effectiveness of these interventions in producing direct cost savings to the health care system.

Study Location

The study will take place at the Cognitive-Behavioural Therapy Unit of the McGill University Health Centre in Montreal, QC, Canada. Most tasks that you will be asked to complete will be doable from home, however.

Duration of Study

The duration of the study will be equal to the length of the normal wait period for individual CBT, which is on average two to six months.

If you are randomly assigned to the bibliotherapy group, the workbook can be easily finished within this time. If you are randomly assigned to the computerized CBT program, Good Days Ahead, it will consist of nine weekly interactive therapy sessions of about 30 minutes each. If you want, you can complete more than one session per week, or you can decide to go a little more slowly and take up to twelve weeks to complete the program.

The Clinical Assessment

After the waiting period is up, you will be invited for a complete psychiatric and cognitive behavioural assessment, of about two hours in duration. This is the same assessment that I mentioned at the beginning of this phone call, and which all patients undergo prior to starting individual CBT, whether they participate in the research study or not. If this assessment allows us to determine that CBT would be of help to you, you will be assigned a therapist, and your individual CBT will soon begin.

Questionnaires

You will be asked to complete a questionnaire package three times during the study:

1) At the start of the study.

2) At the time of the assessment, which will be after the wait period.

3) After your individual therapy is over. If for some reason, you don't wish to have individual CBT after the waitlist is over, we will ask that your third set of questionnaires be filled out five to six months after the second set.

Potential Benefits

Learning about and practicing CBT using a workbook, a computerized cognitive-behavioral therapy program or an individualized therapy could help improve the symptoms you are experiencing. Your participation in this study may also help society at large by advancing knowledge about mental health treatments.

Potential Risks and Discomforts

By participating in this study, you will not be exposed to any serious risk. In the course of your waitlist interventions or individual CBT, you may feel some discomfort as you are encouraged to reflect on your thinking and emotions in problematic situations. If you feel worse during the waitlist portion of the study, you can contact me, and I will advise the Principal Investigator, Dr. Gail Myhr. Dr. Myhr is a psychiatrist with many years of experience in mental disorders and CBT, and she will help you decide what needs to be done, and make any necessary referrals. Should you feel worse during your individual CBT, your therapist will help you.

Cost and Compensation

There is no financial cost to you for your participation, and you will not be given compensation.

Other Requirements

While you are participating in the study, we request that you don't start any other new psychological treatments during the wait period or during individual CBT. We also ask that if your doctor decides to change your medication or change the dosage, you inform us of this change.

Confidentiality: Protection of Your Personal Information

The researchers will need to consult your medical file for information useful to this study. This means that they will have access to the questionnaires you will fill out (which will include information such as your name, sex, and date of birth) and to information about your progress, such as the number of therapy sessions you will have received.

Rest assured that all information obtained during this study will be kept strictly confidential, in the extent that they comply with applicable laws and regulations. The results of this study may be published, but your name will never be published. It will be replaced by a code that will keep your identification anonymous. This code will be password-protected and will only be accessible to the researchers of this study.

Voluntary Participation and Withdrawal from Study

It is important that you understand that your decision to participate in this study is entirely voluntary. You can refuse to participate. If you accept to participate, you can cease at

any given time without having to give an explanation. There will be no penalty or loss of benefit if you chose to not participate or if you decide to stop participating.

Questions

Do you have any questions? Are some things unclear to you?

Next Step

As I explained earlier, I will give you some time to let you think about whether participating in this study is something you would like to do. I will be calling you back in a few days to see if you have come up with a decision. Is there a day and time you would prefer for me to call?

Thank you for your time and I will be in touch.

Appendix C

Consent Form, English version

Title of study:	Waiting for Cognitive Behavioural Therapy (CBT): A Randomized Controlled Trial Evaluating the use of a Computerized CBT Program for Outpatients on a Waitlist in a University CBT Unit
Principal Investigator:	Dr. Gail Myhr**,** MD, FRCPC McGill University Health Centre 1025 Pine Ave West Office P2.085 C Montreal, QC, H3A 1A1 Tel. 514-934-1934 ext. 35533
Research Coordinator:	Rosanne V. Krajden, B.A. Psychology McGill University Health Centre 1025 Pine Ave West Office P2.088 Montreal, QC, H3A 1A1 Tel. 514-934-1934 ext. 35510

1. Introduction

You have been invited to take part in a study called **"Waiting for Cognitive Behavioural Therapy (CBT): A Randomized Controlled Trial Evaluating the use of a Computerized CBT Program for Outpatients on a Waitlist in a University CBT Unit".**

Please read this form carefully before you decide if you want to participate in the study. This form contains information about what you will be expected to do if you decide to participate. It is important that you clearly understand the study's requirements and potential risks and benefits. If you do not understand some of the words, or if you find that some information is unclear, we encourage you to ask the study staff any questions you may have.

2. Goal of Study

The goal of this study is to find out if bibliotherapy (a self-help workbook about CBT) or a self-help computerized CBT program, Good Days Ahead, will help decrease symptoms of depression, anxiety, or any other type of symptoms or distress you may be experiencing while waiting for individual CBT. This study will also evaluate the effectiveness of these interventions in producing direct cost savings to the health care system.

We are inviting you to take part in this study because you have been referred by a doctor to the MUHC CBT Unit to receive cognitive-behavioural therapy (CBT). Because we cannot offer you therapy immediately, you have been put on the waitlist. While you are waiting, you could benefit from reading a self-help workbook about CBT (bibliotherapy) or using a computerized

cognitive-behavioral therapy program. Either condition could help improve the symptoms you are experiencing.

3. Study Procedures

3.1 Duration

The duration of the study will be equal to the length of the wait period for your individual CBT, which is on average two to six months depending on demand and availability of MUHC CBT Unit therapists. The bibliotherapy workbook can be easily finished within this time frame. The computerized CBT program, Good Days Ahead, delivers nine weekly interactive therapy sessions of about 30 minutes each. If you wish, you may complete more than one session per week, or decide to go a little more slowly and take up to twelve weeks to complete the program.

3.2 Procedure

The study will take place at the Cognitive-Behavioural Therapy Unit of the McGill University Health Centre in Montreal, QC, Canada. You may also be asked to complete some tasks from home. If you decide to participate in this study, you will be <u>randomly assigned to one of two groups</u> – the Bibliotherapy Group or the Computerized CBT Program Group. This means that you cannot choose in which group you will belong: it will be determined by chance, just like flipping a coin.

Bibliotherapy Group. If you are assigned to this group, you will be given a copy of a CBT self-help workbook which consists of reading material and a series of worksheets and exercises to complete. You can do them at your own pace. At the end of the wait period, you will be asked about your experience with the book.

Computerized CBT Program Group. If you are assigned to this group, you will receive therapy from a computerized cognitive-behavioral therapy program, entitled Good Days Ahead. This is a proprietary (protected by copyright) CBT program, which has helped many people, and will be supplied at no cost to you. You will be given a password and the address of an online site which you can access securely from any computer. If you don't have access to a personal computer, you are welcome to come to the hospital and use one of our research computers for your sessions. We will check in with you for about 15 minutes once a week to see how you are getting on.

Individual, Face-to-Face CBT. CBT is a psychotherapy which is focussed on problems in the here and now. It involves examining the connection between your thoughts, emotions and behaviour in problematic situations. Between sessions there are often exercises to do, in order to strengthen what you learn in therapy. The end of therapy is arrived at in discussion with your therapist, when the problems which you have chosen to work on have been resolved, or you decide to stop. Most therapies in the unit consist of between 12-20 one hour sessions.

You were referred to the MUHC CBT Unit for face-to-face therapy and you will still be entitled to receive this therapy whether you agree to participate in this study or not. If you begin the

study, and you decide to withdraw from it, you are still entitled to individual CBT once the wait period is up. Participation in this program will not affect the length of your wait.

After the waiting period is up, you will be invited for a complete psychiatric and cognitive behavioural assessment, of about two hours in duration. This is the same assessment all patients undergo prior to starting individual CBT, whether they are in the research project or not. If this assessment allows us to determine that CBT will be helpful to you, you will be assigned a therapist, and your individual CBT will soon begin. It is possible that the assessment will indicate that CBT is no longer needed or suitable for you. It is also possible that after finishing your bibliotherapy or computer program you will decide you no longer need or want to receive individual CBT. In these cases, we would still ask that you remain in the study. Specifically, we would like you to fill out a third set of questionnaires five to six months later.

Questionnaires

You will complete a questionnaire package three times during the study:

1) At the start of the study.

2) At the time of the assessment, which will be after the wait period.

3) After your individual therapy is over. If for some reason, you don't wish to have individual CBT after the waitlist is over, we will ask that your third set of questionnaires be filled out five to six months after the second set.

4. Concurrent Treatments

Many individuals undergoing therapy at the MUHC CBT Unit take medications prescribed by their doctors for their psychological difficulties. There is no need to change any of your medications if you are undergoing CBT. Medications and CBT do not interfere with each other. However, if your doctor decides to change your medication or change the dosage, you are advised to please inform your therapist or the Research Coordinator if you are still on the waitlist.

While you are participating in the study, we request that you don't start any other new **psychological** treatments during the wait period or during individual CBT without first discussing it with the research team. Starting another psychological treatment could interfere with the effectiveness of CBT, and make it hard to know the effects of our interventions on your progress. If you are already undergoing a long term therapy with another therapist, we will discuss this with you and decide what to do about this on an individual basis, as we would with all MUHC CBT Unit patients. Rest assured that your well-being will be prioritized at all times during your participation in this study, and that you will not be prevented from receiving the treatment you need.

5. Potential Benefits

Learning about and practicing CBT using a workbook, a computerized cognitive-behavioral therapy program or an individualized therapy could help improve the symptoms you are

experiencing. Your participation in this study may also help society at large by advancing knowledge about mental health treatments.

6. Potential Risks and Discomforts

By participating in this study, you will not be exposed to any serious risk. In the course of your waitlist interventions or individual CBT, you may feel some discomfort as you are encouraged to reflect on your thinking and emotions in problematic situations. If you feel worse during the waitlist portion of the study, you can contact the Research Coordinator, Rosanne Villemaire Krajden, who will advise the Principal Investigator, Dr. Gail Myhr. Dr. Myhr is a psychiatrist with many years of experience in mental disorders and CBT, and she will help you decide what needs to be done, and make any necessary referrals. If you feel worse during your individual CBT, your therapist will help you.

7. Cost and Compensation

There is no financial cost to you for your participation, and you will not be given compensation.

8. Confidentiality: Protection of Your Personal Information

The researchers will need to consult your medical file for information useful to this study. This means that they will have access to the questionnaires you will fill out (which will include information such as your name, sex, and date of birth) and to information about your progress, such as the number of therapy sessions you will have received.

Rest assured that all information obtained during this study will be kept strictly confidential, in the extent that they comply with applicable laws and regulations. The results of this study may be published, but your name will never be published. It will be replaced by a code that will keep your identification anonymous. This code will be password-protected and will only be accessible to the researchers of this study.

The computerized CBT program, GDA, is in compliance with HIPAA regulations, which ensure that personal health information (PHI) remains private and secure. The providers of the computerized CBT program may use coded data for research purposes, but it will remain anonymous. The data will be stored for a period of 25 years by the researchers and by the providers of the computerized CBT program.

The data may be published in medical journals or shared with other individuals during scientific meetings; however it will not be possible to identify you. The data may also be used for further analysis related to the project or to help in the development of future research projects.

For surveillance and control purposes, your study file as well as your medical charts may be examined by a person mandated by the Research Ethics Board of McGill University Health Centre, by the institution, by a person mandated by regulatory authorities as well as by the sponsor's representatives. All these individuals and organizations have agreed with a policy on confidentiality.

For safety purposes, especially to be able to communicate with you rapidly, your name and

surname, contact information as well as the start and end date of your participation in this project will be stored for one year after the termination of the project in a separate registry maintained by the study doctor or by the institution.

In compliance with the *Act respecting Access to documents held by public bodies and the Protection of personal information*, you have the right to consult your study file in order to verify the information gathered and to have it rectified it if necessary. You may exercise this right as long as the study doctor or the institution holds this information. However, in order to protect the scientific integrity of the research project, you may have access to certain information only once this project has come to an end.

9. Voluntary Participation and Withdrawal from Study

Your decision to participate in this study is entirely voluntary. You can refuse to participate. If you accept to participate, you can cease at any given time without having to give an explanation. There will be no penalty or loss of benefit if you chose to not participate or if you decide to stop participating. If, at any time, the researchers feel that it is best for you that you stop participating in this study, they may decide to cease your participation.

10. Indemnification

If you should suffer any injury following any procedure related to the research project, you will receive the appropriate care and services for your medical condition. By accepting to participate in this research project, you are not waiving any of your legal rights nor discharging the researchers, or the institution, of their civil and professional responsibility.

11. Funding of the Research Project

The costs of this study will be borne by the MUHC CBT Unit teaching and research fund.

Contact Information

If you have any questions, concerns or complaints about your participation in this study, please contact the principal investigator, Dr. Gail Myhr, tel. 514-934-1934, extension 35533, or the Research Coordinator, Rosanne Villemaire-Krajden, tel. 514-934-1934, extension 35510.

If you have any questions, concerns or complaints about your rights as a participant, please contact the Ombudsman, tel. 514-934-1934, extension 48306.

DECLARATION OF CONSENT

"I have carefully read this consent form, and I agree to participate in this research study. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I have been given sufficient time to consider the above information and to seek advice if I chose to do so."

Appendix D

Instructions to GDA program (email), English version

Dear [participant's name],

Thank you for completing your questionnaires. You have been randomized to the computerized CBT option. I just created an account for you to start using the program, Good Days Ahead. You should be receiving an email with your login information (you may want to check your junk mail folder).

You can navigate through the lessons and explore the site as you wish. Each lesson offers videos, readings and exercises, and some form of homework. The lessons are simple and straightforward, and you need to complete them in the right sequence.

Users are also strongly advised to do one session a week, although you are free to progress at your own pace. This means that you can complete more than one session a week or do them more slowly and take **up to twelve weeks (maximum)** to complete the program. If you are "absent" for more than three weeks' worth of lessons, your participation from the study will be withdrawn (but you will remain on our wait list for face-to-face therapy).

Doing the interactive exercises and homework is important, as it ensures that you reflect on how you typically feel, think and act in problematic situations. As you will soon learn, our thoughts, emotions and physical symptoms as well as the way we behave all influence each other. By maintaining the way we think and react to situations, our mood is also maintained. Learning to use Cognitive-Behavioural Therapy tools to develop the skills needed to improve our well-being involves homework, as it encourages us to think about how we react to situations, and to discover new ways of interpreting and feeling about them.

We will be providing you with some guidance and support as you complete the program. This means that a member of the CBT team will be keeping an eye on your progress and well-being on a weekly basis, asking you how things are going **by phone**. Please note that these phone calls should be viewed in a similar way as face-to-face appointments; once we have agreed on a day and time for a call, we ask that you tell us as soon as possible if you cannot take the call so that we can adjust our schedules accordingly.

Please do not hesitate to contact me should you have any questions or concerns.

Again, I thank you for your participation in our study!