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A digital iCBT intervention for social anxiety disorder in Quebec and Ontario: protocol for a multi-phase effectiveness-implementation study

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Abstract

Background Social anxiety disorder (SAD) is one of the most prevalent anxiety disorders in Canada. Viable therapy options for the treatment of SAD include CBT being delivered virtually. In Australia, an innovative internet-delivered cognitive-behavioral therapy (iCBT) program for social anxiety has been developed, implemented, and demonstrated as effective. To make available high-quality and real-time evidence in response to the crucial need to access psychological services to meet population mental health needs, we propose to conduct a Canadian adaptation of the iCBT Shyness Program and to examine the program's effectiveness, and implementation in two Canadian provinces (Quebec and Ontario).

Methods The overall study design is a hybrid effectiveness-implementation study of a quasi-experimental parallel group trial. Prior to implementing the iCBT Shyness Program, it will undergo an initial adaptation to the Canadian context and focus groups will be conducted with key actor groups to discuss the adaptations to the graphics, narration of the lessons, and this to better reflect varying socio-cultural context among Canadian French- and English-speaking populations. We will evaluate the effectiveness of the program in three parallel pathways reflecting real-world pathways: (1) self-refer to the intervention; (2) recommended by a health professional without guidance; and (3) recommended by a health professional, with low-intensity guidance. Data collection will be carried out at baseline, at the beginning of each lesson, 12-week and 6-month follow-up. Outcomes measured will include anxiety and depressive symptoms, psychological distress, disability, as well as health service utilization and satisfaction. Semi-structured interviews will then be conducted with study participants and health care providers to explore facilitating factors and barriers to the implementation of the iCBT adapted program.

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Discussion This study will provide evidence on the effectiveness, barriers and facilitating factors to implementing a low-intensity iCBT in the Canadian context for SAD, which will bridge an important care gap for undeserved populations in Canada with SAD. Findings will inform the eventual scaling up of the program in community-based primary care across Canada. This would improve equity of the health care system by helping a large number of Canadians to timely access to mental health services.

Trial registration clinicaltrials.gov NCT06403995. Prospectively registered on 05/03/2024.

Keywords Anxiety, Social anxiety, Internet cognitive behavioral therapy, Community-based primary healthcare, Quasi-experimental design, Canada

Background

Social anxiety disorder (SAD) is one of the most prevalent psychiatric disorders [1]. Global estimates report lifetime prevalence reaching up to 12.1% in adults [2–5]. SAD is a chronic disorder in the absence of treatment [6] and has been associated with significant impairment in functioning, reduced school performance, loss of productivity, and decreased quality of life [1, 7, 8]. The Canadian community health survey showed that SAD was more prevalent in women, likely to be comorbid with major depression in men, and associated with lower income as well as lower and higher education (U shape) [3]. Canadians with SAD are also up to ten times more likely to report long-term limitations in activity and disability days [3]. In fact, anxiety disorders are the 6th highest cause of years lived with disability in Canada, with the burden of disease being more pronounced in those aged between 15 and 35 years [9].

SAD's key characteristics are persistent fear and avoidance of social situations and fear of scrutiny by others (e.g., social interactions) [10]. If left untreated, SAD may lead to the onset of psychiatric comorbidity with depression [11, 12] and other anxiety disorders [13] as well as substance use disorders [14, 15]. Further, evidence highlights that physical distancing and confinement measures implemented during the COVID-19 pandemic may have indirectly exacerbated SAD symptom severity for some individuals [16]. Research with adult university students [17] showed that social anxiety symptoms remained elevated even with the cessation of COVID-19-imposed physical distancing measures. The persistence of social anxiety in the context of reduced learning opportunities from exposure to social interactions has been suggested [17, 18]. A systematic review also showed the association between social isolation and social anxiety during the COVID-19 pandemic [19]. School closures during the pandemic may have put youth and young adults with social anxiety at increased risk of distress [20]. In a large college survey sample during COVID-19 in the United States of America [21], one-third of students reported moderate to severe anxiety symptoms, with racial discrimination and financial distress having the largest symptom effect [21].

Cognitive-behavioral therapy (CBT) is the most empirically supported psychological treatment for SAD [22, 23]. Meta-analyses of randomized controlled trials (RCTs) showed medium to large effect sizes of efficacy (Cohen's d=from 0.70 to 0.86) [24, 25]. In reviewing 21 studies, Boettcher et al. (2013) showed that guided and unguided internet-based cognitive behavioral therapy (iCBT) for SAD is as efficacious as face-to-face therapy and more efficacious than waiting list and online forum discussions control conditions [26]. In addition, internet-based psychological treatments for SAD have been shown to be cost-effective [27–31]. iCBT may also infer some advantage over face-to-face therapy for individuals who are highly fearful of face-to-face interactions with a therapist or who face significant geographical or financial barriers to in-person care [26, 32]. iCBT also serves as a stepping-stone to increase timely access to evidence-based treatment [33, 34].

Despite available effective treatments including CBT, less than 40% of Canadians with a past year episode of SAD consulted a healthcare professional for their symptoms [3, 4]. Worldwide estimates have shown that on average 20% of individuals with a lifetime SAD received any treatment [35]. Barriers to health service use and access to psychological services for common mental disorders like anxiety disorders include those related to geography (living in rural communities), language, ethnicity and race (diverse groups), as well as age (older adults) [36–39]. Social inequities have also been shown in the use of pharmacological and psychological interventions for SAD [40]. During the pandemic, social and racial inequities associated with poorer health outcomes and reduced access to quality health care were identified in Canada [41–43]. These barriers are important to consider and address.

The Clinical Research Unit for Anxiety and Depression (CRUfAD) in Australia has developed, implemented, and demonstrated the efficacy and effectiveness of an innovative guided and unguided iCBT program in general practice for English-speaking adults with social anxiety (the 'Shyness Program') [26, 32, 44–49]. The Program's completion rates reached 78%, with an average of 5.2/6 lessons completed [46], and it was shown to be cost-effective

and acceptable to patients in Australia [49]. The Program was also shown to be effective when integrated into general clinical practice [32, 48]. For example, Williams et al. (2014) examined the effectiveness of the Program under two routine care pathways; first when the Program was prescribed and supervised by patients' primary care clinician, or second, when patients' primary care physician referred their patients to complete the Program at a specialist anxiety disorders clinic under the supervision of a mental health professional. Patients in both pathways reported similar improvements in symptoms of social phobia, psychological distress, major depression, and disability [32]. Among program completers, mean treatment satisfaction was close to four out of five, and confidence in recommending the program to others was over eight out of ten [32].

Studies highlight the importance of adapting digital, evidence-based interventions, including psychological interventions, to different contexts and groups [50]. Most empirically validated iCBT interventions for anxiety disorders in Canada are available in English. This is problematic for 85.4% and 3.8% of the population residing in Quebec and outside of Quebec for whom French is the first official language, respectively [51]. In Ontario, 4.1% of the population is French-speaking, of which 60% are from diverse groups. Similar rates have been observed in the Canadian Prairies [52].

The general objective of the current study is to assess the effectiveness, as well as barriers and facilitators to the implementation of the Canadian-adapted iCBT Shyness Program for SAD in community and primary care settings. We hypothesize that the Canadian-adapted iCBT Program will be associated with improvement in SAD symptoms and that its implementation will be associated with several barriers and facilitators. The first objective will be to translate and adapt iCBT Shyness Program to the Canadian context. The second objective will be to examine the completion and effectiveness of the Canadian-adapted, including the French translated and English iCBT Shyness Program, in improving SAD symptoms, within each three-pathway parallel group, which represent the most likely health service trajectory pathways where individuals would access the Program in the Canadian context. To use the program, people will: (1) self-refer to the intervention (self-referral, undirected iCBT); (2) have been recommended the intervention by a registered healthcare professional and will complete the program without guidance (recommended, undirected iCBT); or (3) have been recommended the intervention by a registered healthcare professional, with low-intensity guidance throughout the program (recommended, directed iCBT). The third objective will explore the implementation of the adapted iCBT Shyness Program in Quebec and Ontario, specifically, in each group, with emphasis on understanding the barriers and facilitating factors to the implementation of iCBT in both provinces from the perspective of participants and healthcare professionals.

Trial design

The overall study design is a type-1 hybrid effectiveness-implementation study [53] of a quasi-experimental parallel group trial reflecting real-world pathways (recommended and self-referrals).

Methods

The project includes three phases: a French-Canadian translation and English cultural adaptation of the Australian iCBT Shyness Program; testing the effectiveness of the translated and Canadian-adapted iCBT Shyness Program; and exploring barriers and facilitators in implementing the adapted iCBT program, which can inform further modifications to the program, its sustainability, and its scale-up. Table 1 presents the timeline of the study for each phase. The project will be conducted in two Canadian provinces: Quebec and Ontario. In Quebec, participants will be recruited in the *Montérégie* health and social services area, the second most populous region following the Montreal region in the province, that serves an urban and semi-urban and rural population of approximately 1.5 M inhabitants, which is 84% French-speaking and 16% English-speaking. The *Hôpital Montfort* serves approximately 1.2 M inhabitants of Eastern Ontario, with a 50% French-speaking and 50% English-speaking patient population.

The overarching framework used to guide the three project phases was inspired by Hwang's (2009) [54] framework, which highlights five main areas: "(a) generating knowledge and collaborating with stakeholders, (b) integrating generated information with theory, and empirical and clinical knowledge, (c) reviewing the initial culturally adapted clinical intervention with stakeholders and revising the culturally adapted intervention, (d) testing the culturally adapted intervention, and (e) finalizing the culturally adapted intervention" (Hwang, 2009, page 369). We aligned some of these areas with the three phases of our project. Specifically, Phase 1 of the project (adaptation) will include Hwang's (2009) steps related to the generation of knowledge, in our case, via focus groups, and the use of generated knowledge to inform edits and modifications for future adaptations of iCBT programs for the Canadian context [50, 54]. Phase 2 (effectiveness) will include examining the outcomes of the iCBT intervention when delivered via three ecologically valid clinical pathways, and Phase 3 (implementation) will aim to better understand barriers and facilitators to iCBT program's implementation, including to inform further modifications, sustainability, and scale-up.

Table 1 Timeline of the study and assessments

	Baseline	Intervention Before each lesson						Follow-up	
	T0	T1	T2	T3	T4	T5	T6	T7	T8
Initial sociodemographic and clinical characteristics									
Sociodemographic variables	X								
Self-reported physical chronic conditions	X								
Self-reported psychiatric disorders (e.g., depression, anxiety-related disorders, psychotic disorder, bipolar disorder)	X								
Past 3-month health service & medication use	X								
Symptom assessment									
Psychological Distress scale (K10)		X	X	X	X	X	X	X	X
Patient Health Questionnaire (PHQ-8)	X							X	X
Generalized Anxiety Scale (GAD-7)	X							X	X
Social Phobia Inventory (SPIN)	X							X	X
Functionality and quality of life assessment									
World Health Organization Disability Assessment Schedule (WHODAS 2.0)	X							X	X
AQoL-4D	X							X	X
Psychological assessment									
6-item Revised UCLA Loneliness Scale	X							X	X
Satisfaction with program									
Satisfaction with the iCBT program								X	
Health care use & contact with referring health professional									
Past 6-month health and social service use									X
Contacts with referring health professional									X

Phase 1: Canadian adaptation of the Australian iCBT shyness program

The Shyness Program is presented in the form of illustrated stories of a working woman and young man with SAD and their health professional (a psychologist). The program comprises six online lessons that teach core cognitive and behavioral principles and skills, including psychoeducation about the symptoms and treatment of SAD (Lesson 1 and 2); graded exposure and behavioral experiments (Lesson 3); cognitive restructuring (Lesson 4 and 5); relapse prevention (Lesson 6). The program also includes lesson summaries, homework assignments, and regular scheduled emails to support program users in applying the CBT skills themselves [46]. It is recommended that lessons are completed every one to two weeks with the full program completed within 90 days (see https://thiswayup.org.au/courses/the-social-anxiety-course/).

The adaptation of the Australian iCBT Shyness Program to the Canadian context will follow a stepwise process. First, research team members with previous experience in translating iCBT lessons will conduct a French translation of the iCBT Shyness Program and a first review/adaptation of the French/English program, specifically for language and visuals. Second, to inform on further program edits and modifications for the Canadian context, we will conduct focus groups with consultants (i.e., patient-partners, community leaders, and service providers) with experience pertaining to social anxiety, including those who self-identify as belonging to diverse groups (e.g., gender identity, visible minorities) [55]. Focus groups will be guided by questions developed by our research team to better understand perceptions on "peripheral components" of the iCBT Shyness Program [56], such as, for example, language (verbal style, narration), objects or items included in the program (relevant graphics or images), program content, such as length, structure, examples provided, activities and homework, program goals.

Focus group participants will be recruited in two ways. First, purposeful sampling [57] will be used to identify participants who have lived experience of social anxiety and who have worked with people with lived experience of social anxiety. We will collaborate with patient partner initiatives (*Hôpital Montfort* and *Université de Sherbrooke*). We will also rely on our network of collaborators, who have ties with community organizations serving diverse groups, as well as health centers. Recruitment flyers for the project will be distributed within these sites. We will aim to recruit participants from diverse ethnic, socio-cultural and linguistic groups (French/English) in each province.

We estimate conducting four focus groups in each province. The first will include four to six French-speaking patient-partners, the second, four to six English-speaking patient partners, and the third and fourth, three

to four community leaders and healthcare professionals in each language. Focus groups will last approximately 90 to 120 min. Interested participants will be screened for eligibility (i.e., lived experience of social anxiety among, for example, patient-partners, or community leaders, service providers working with this population) by a team member and will be invited to read and sign the Inform Consent Form for this phase. Eligible consultants and partners will be provided with information about the project. Participants will then be invited to review program materials (stored on a Web platform [e.g., testing version of the ēquilia virtual clinic, Moodle]) over a couple of weeks. During this time, a research team member will be available to support patient partners and community leaders and healthcare professionals. After this period, participants will be invited to their respective focus groups to comment on the lessons according to pre-determined questions and to share any other comments about the lessons/program materials. Community leaders and health professionals will also review available resources and support documentation for clinicians. Focus groups will follow a semi-structured interview guide and will be conducted by members of the research team via secure online video conferencing system and will be audio-recorded.

Focus group interviews will be transcribed verbatim and thematic data analyses will be conducted, using both inductive and deductive processes [58]. Members of the research team will re-read the focus group transcriptions. Transcriptions will be coded using NVivo Software (version 12) according to a pre-determined codebook, developed based on the focus group interview guide, all the while allowing for new themes and codes to be identified while coding. The coding process will be shared with the research team at multiple steps for feedback and validation. The research team will use findings to inform further edits and modifications to the iCBT Shyness Program. This adapted program to the Canadian context (in French and English) will be used to inform phases 2 and 3 of the research.

Phase 2: effectiveness of the adapted iCBT program

The adapted SAD program (i.e., Canadian adaptation of both French and English versions) will be available to consenting participants on the ēquilia virtual clinic (www.c.equilia.ca). Interested participants will be able to visit the ēquilia website for more details about the research project. The website presents information on symptoms of depression and anxiety, stress, and well-being; the different online programs offered; mental health resources and supports, telephone numbers to health and social services available in the community; and the possibility to register for the newsletter and programs. Eligible participants will provide electronic consent and personal details, including their contact information, and be invited to complete the online screening questionnaire for eligibility. Technical support will be available for those needing assistance in accessing the SAD program.

Recruitment and patient assignment

To be eligible for the study, participants must be aged ≥ 18 years, speak and write in French or English and have access to the Internet and a digital device. Participants will be eligible if they screen positive for social anxiety using the 17-item Social Phobia Inventory (SPIN) questionnaire, where symptoms are rated on a 5-point scale from 0 (not at all) to 4 (extremely), with a possible score range from 0 to 68 [59]. A cut-off > 20 has been shown to reflect a probable case of SAD [60].

Participants will be excluded if they self-report severe symptoms of depression (Patient Health Questionnaire [PHQ-9] score ≥ 23) or thoughts they would be better off dead or hurting themselves on the 9th item of PHQ-9 (score > 0 on the item) in the past two weeks or thoughts or wishes to kill themselves on the 9th item of the Beck Depression Inventory (BDI-II) (score > 0 on the item) [61, 62]; a diagnosis of schizophrenia, bipolar disorder or active problems related to substance use or dependence; beginning psychological therapy (< 4 weeks ago) or medication (< 8 weeks ago) for depression/anxiety; or currently using benzodiazepines. Excluded participants will receive a list of references to health and social services in the community. A previous trial conducted by our research team on CBT for anxiety disorders has demonstrated the feasibility of the recruitment strategies [63].

Participants will be in one of three treatment groups for ecological validity to reflect real-world treatment trajectory pathways:

(1) **Self-referred**, **undirected iCBT**: Recruitment strategies will include self-referral following advertisements (e.g., clinic waiting rooms, bulletin boards, institutional and ēquilia websites, geolocated online advertising and social media), and recommendations from providers (e.g., family physician, nurse practitioner, community organizations, support groups). For ecological validity, this recruitment approach is consistent with the delivery model for undirected programs at the ēquilia Web platform. These individuals will not receive follow-up contact during the program. In case of severe distress (i.e., score ≥ 30 on Kessler's 10-item psychological distress scale (K10) [64, 65], participants will receive an automated email with a list of resources and emergency contact numbers.

Recommended iCBT

Participants will have received a recommendation to the intervention by a healthcare professional (e.g., family physician, nurse or social worker, psychologist). Recruitment packages (e.g., posters, introduction letter and clinician guide to recommending program) will be sent to clinics. Clinicians participating in the study will recommend the program to patients, whether they are in their respective caseloads or seen in walk-in clinics. To be able to recommend the intervention, healthcare professionals will need to register and complete the electronic informed of the research bank on the platform (dashboard). Clinicians will provide the name and email of the patients they want to recommend the program to. Once patients register for the program, referring physicians will receive an email indicating that their patient registered themselves and giving them the option to provide low-intensity guidance (e.g. email or brief phone contact (5 to 10 min)) after Lesson 1 and 2, and then on an as-needed basis or patient request. Physicians will respond by email to indicate the option they have chosen. If guided, they will be sent further support documentation. Participants having been recommended the program will therefore be in one of the two following groups:

(2) **Recommended**, **undirected iCBT.** Participants will have received recommendation from a healthcare professional (e.g., family physician, nurse or social worker, psychologist) to complete the adapted program and this without guidance. Clinicians will provide the name and email of the patients they are referring the program to without providing participants with in-program support but will consult the dashboard as they have clinical responsibility for the patient. In case of severe distress (i.e., K10 score ≥ 30), the referring healthcare professional will receive an automated email informing them to go to their dashboard to identify that patient. Participants will also receive an automated email with a list of resources and emergency contact numbers. To support the generalization of findings to the real-world (ecological validity), clinicians may follow-up with patients at their discretion.

(3) **Recommended**, **directed iCBT**. Participants will have received recommendation to complete the intervention by a healthcare professional and be provided low-intensity guidance (e.g., email or brief phone contact [5 to 10 min] after Lesson 1 and 2, and then on an as-needed basis or patient request). Clinicians will be able to recommend the adapted program to their patients, will remain responsible for their patients and, will check their dashboard to see how their patients are progressing through the program. In the event of severe distress (i.e., K10 score ≥ 30) in a patient, the referring healthcare professional will receive an automated email informing them to go to their dashboard to identify that patient and assess the appropriate action to take. Participants will also receive an automated email with a list of resources and emergency contact numbers.

If needed, we will adjust the advertising to encourage recruitment in the different treatment trajectory pathways to meet the required sample size in each arm in a balanced manner. During this trial, participants will be able to stop or start any new pharmacological or psychological therapies.

Data collection

Interested participants will be invited to read and sign the electronic informed consent form to participate in the current research project and the research Bank of the ēquilia platform. Informed consent form, questionnaires assessing eligibility, socio-demographic and clinical characteristics (age, gender, self-identifying as a visible minority, education, income, region of residence, self-reported presence of physical chronic conditions, depression, attention deficit hyperactivity disorder, anxiety disorders), past 3-month health service (any emergency department visit, any hospitalization, visit to a health professional, receipt of services from local community service center (LCSC) and psychotropic drug use (e.g., antidepressant, antipsychotic, stimulant or non-stimulant for attention deficit hyperactivity disorder) will be collected in the Research Electronic Data Capture (REDCap) research platform at baseline (T0). Prior to the start of each of the six lessons (T1-T6), and at the 12-week (T7, i.e. post-treatment) and 6-month follow-up (T8, i.e. 6-month post-treatment), participants will be asked to complete the K10 questionnaire on the ēquilia Web platform (T1-T6) and the REDCap platform (T7-T8).

Kessler psychological distress scale (K10):

The 10-item scale assesses psychological distress on a 5-point scale with scores ranging from 10 to 50 [64]. Scores ≥ 30 correspond to severe distress, and an alert is sent to the study team, the participant and referring health professional. As in the This Way Up clinic, participants will have to answer the questionnaire based on the last two weeks. At baseline (T0), 12-week (T7) and 6-month follow-up (T8), participants will also complete the following self-reported questionnaires in the REDCap research platform:

Social phobia inventory (SPIN):
The 17-item SPIN questionnaire will be used to assess past week social anxiety symptoms, which are rated on a 5-point scale from 0 (not at all) to 4 (extremely), with a possible score range from 0 to 68 [59]. A cut-off >20 has been shown to reflect a probable case of SAD [60].

Patient health questionnaire (PHQ-8):
The 8-item questionnaire will be used to assess depressive symptoms. Symptoms are rated on a 0 (not at all) to 3 (nearly every day) point scale, with scores ranging from 0 to 24, during the last two weeks. A cut-off score≥10 is used to identify a probable major depressive disorder [67].

Generalized anxiety scale (GAD-7):
The 7-item questionnaire will be used to assess generalized anxiety symptoms during the last two weeks with scores ranging from 0 to 21. A cut-off score≥10 is used to identify probable anxiety [68].

World health organization disability assessment schedule (WHODAS 2.0):
The 12-item schedule measures activity limitations in the past 30 days in 6 domains (possible score range 0 to 60), will also be used to assess disability [69].

Four-dimension assessment of quality of life (AQoL-4D):
Health-related quality of life (HRQOL) in the past week will be assessed with the AQoL-4D [70, 71] including 12 items on four dimensions: independent living, mental health, relationships, senses. Scoring will be based on available weights and utility scores range from 0 to 1.0 [70, 72].

Six-item revised UCLA loneliness scale:
The six-item questionnaire will be used to assess loneliness on a four-level Likert scale (I often/sometimes/rarely/never feel this way) with a total score ranging from 0 to 24 [73, 74].

Satisfaction with program questionnaire:
As in Williams et al., (2014) [32], self-reported satisfaction with the adapted SAD iCBT program will also be assessed at follow-up (T7) with a 5-point scale assessing how satisfied individuals were with the program: 1=very dissatisfied to 5=very satisfied; and how confident participants are in recommending the program to a family member/friend with social anxiety (1=not at all to 10=extremely confident).

Health service utilization:
At 6-month follow-up (T8), past 6-month health and social service use (any emergency department visit, any hospitalization, visit to a health professional, receipt of services from LCSC, psychotropic drug use) and number of contacts (i.e., consultations) with referring health professional of the program will be collected in the REDCap research platform.

The REDCap electronic data capture tool is hosted at the Research Center of the Centre Hospitalier Universitaire de Sherbrooke [75, 76]. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources. Data will be accessible through REDCap only to designated research team members (access ID and password needed). After data extraction, the statistician will have access to nominative data and linking code in a distinct encrypted file. The datasets will be depersonalized with participants only identified by a code for statistical analyses. Data will still be accessible through the REDCap platform as a backup. Data collected within the equilia research databank are also secured in the Research Center of the Centre Hospitalier Universitaire de Sherbrooke servers. Direct identifiers will be replaced by a code by the CRED Informatics platform and kept separate from other data. Data will be encoded by the CRED Informatics platform using an encryption algorithm. Access to the computerized server is secure, with up-to-date antivirus software and data encryption. CRED's staff have signed a confidentiality agreement. Active data monitoring will ensure the quality of data.

Statistical analyses

Sample size

Sample size was calculated using G*Power v3.1. The sample size was calculated for an ANOVA with repeated measures considering the interaction between time (within-factor) and program completion (between-factor). The calculation considered an α of 0.05, a β of 0.20, as well as an assumed correction for nonsphericity of 1 (sphericity assumption met) and a moderate conservative (0.50) correlation among repeated measures. We will consider baseline, post-treatment, and follow-up measures, and three group completion status per program definition. The Shyness unguided iCBT program has shown large within-group effect size on social anxiety-related outcomes [44, 49] with available data for 60% of participants at the 6-month follow-up [49]. Consequently, the sample size calculation assumed a medium Cohen's f of 0.25 and an attrition rate of 40%. Accordingly, for the current study, the recruitment of at least

84 individuals will be required by treatment trajectory pathway.

Principal and descriptive analyses

For each treatment trajectory pathway, descriptive analyses of socio-demographic and clinical factors, and health service utilization will be carried out. Measures of central tendency and distribution will be calculated according to the type and normality of the data. Categorical variables will be reported with count and percentage data. Normal continuous data will be reported with the mean and associated standard deviation, while nonnormal continuous data, with median and interquartile range.

The main analysis will evaluate the change in scores on the SPIN from baseline (T0) to post-treatment (T7) and 6-month follow-up (T8) using generalized linear mixed regression models for repeated measures accounting for within-subject variations [77, 78]. This allows for participants with missing follow-up data to be included in the analyses as well as to consider the change in study variables at follow-up. The choice of distribution family and link will be data driven. Change in the outcome will be predicted by testing interaction terms between time × program completion and potential confounders (socio-demographic, clinical study variables). Additional analyses will consider secondary outcomes, namely: K10, PHQ-8, GAD-7, WHODAS 2.0 and AQoL-4D. The choice of covariates in these models will be informed by bivariate analyses, from which independent variables associated with the outcome at a significance level of $p=0.10$ will be considered. Treatment effect sizes will also be calculated with Cohen's *d*. Reliable change indexes will also be calculated for study outcomes [79]. Analyses will be carried out for each pathway.

Secondary analyses

Differences among participants of the different treatment trajectory pathways will be assessed with Chi-square or Fisher's exact test for categorical variables. For continuous variables, ANOVAs will be used for normally distributed variables or Kruskal-Wallis for non-normally distributed variables. Multinomial logistic regression models will assess program completion (i.e., completers, partial-completers, and non-completers), for each pathway, as a function of baseline socio-demographic, clinical and health service use factors to identify potential determinants of completion. These will inform the third phase of this study.

Sensitivity analyses will also be carried out to test the robustness of conclusions by restricting analyses to completers.

Data imputation

Efforts will be made to increase sample size and keep losses to follow-up at a minimum, including by monitoring data collection to enhance participation with reminders and education strategies to increase patient engagement. Notably, automated reminders are sent when individuals do not begin their program, when a new lesson is available, when a lesson is not started within specific timeframes, and to keep track of the time to program expiration. To reflect treatment dose-response [66], participants will be categorized and studied as a function of whether they are completers (i.e., if all six lessons are completed); partial-completers (i.e., completed four or five lessons); and non-completers (i.e., completed one to three lessons). Eligible individuals with missing baseline questionnaires or not having commenced the program (i.e., 0 lesson completed) will not be considered in the analyses.

As it is expected to have more than 5% of missing data [80], multiple imputation by chained equations will be used for multiple imputations and the number of imputations will depend on the percentage of missing data at follow-up [81]. Data predicting attrition will be added to the multiple imputation model. Complete case and multiple imputation analyses (overall dataset; dataset including participants who completed at least one lesson and contributed to follow-up but not to any data collection (T1 – T6) and therefore excluding individuals who contributed only to T0) will be carried out, and limitations will be discussed.

Phase 3: barriers and facilitators in implementing the adapted iCBT program

Study participants who participated in phase 2 and agreed to be recontacted (in the consent form of the research Bank) and healthcare professionals who recommended the program to a patient in phase 2, corresponding to purposeful sampling [57], will be contacted and interviewed to better understand their experiences with the adapted iCBT program during Phase 2. We aim to recruit 45 patients (15 from each pathway) and 20 healthcare professionals with diverse socio-demographic characteristics (gender, age, visible minority groups, languages, province), as well as program completers and non-completers.

Qualitative descriptive research [82, 83] will be employed to explore barriers and facilitating factors to the uptake and implementation of the adapted iCBT program in the community and primary care and referral arm in Quebec and in Ontario. We will conduct semi-structured interviews with participants and healthcare professionals who participated in Phase 2, via a secure video conferencing system or in person. Interview guides will be developed based on frameworks including those

to (1) guide the cultural adaptations [84, 85] of "peripheral components" of the iCBT Shyness Program [56] and explore its acceptability and participant perceptions of the adapted program used [86]; and, (2) explore the contextual factors via elements of the Consolidated Framework for Implementation Research (CFIR) [87, 88] and the Expert Recommendations for Implementing change (ERIC) [89, 90], to better understand implementation barriers and facilitators and factors related to the sustainability and scale-up of the intervention.

We aim to conduct semi-structured interviews at the end of the follow-up period from Phase 2 (post-treatment). Semi-structured interviews will be conducted by members of the research team in French or in English. They will last approximately between 45 and 60 min.

Semi-structured interviews will be transcribed verbatim and analyzed using a thematic analysis approach [58] with NVivo (version 12). The developed interview guide will be used as a structure to code broad interview passages into over-arching themes, after which they will be coded into smaller units of analysis [58]. New themes identified through the coding process will be added to the pre-determined coding structure, which will be discussed at multiple steps with the research team members, including patient partners. Findings will then be organized into barriers or facilitating factors to the implementation of the Canadian-adapted iCBT program in Quebec and in Ontario. Findings will be used to inform additional edits and modifications to the iCBT Shyness Program for the Canadian context. Further, barriers and facilitators identified through our study will help to better understand primary and secondary outcomes identified in Phase 2, as well as inform implementation strategies for the sustainability and scaling-up of the iCBT in community-based and primary care settings across Quebec and Ontario, as well as provide recommendations for its implementation across Canada for French- and English-speaking populations.

Trial coordination

An executive committee formed by the principal investigators, a knowledge user, and a research coordinator will coordinate the study. The committee will meet online every month and more frequently, if needed, during key moments of the study (start of the recruitment, end of recruitment, paper publication). The executive committee will consult the steering committee, including co-investigators, patient-partners, and co-knowledge users, throughout the project for methodological and strategic decision-making points. The trial coordination will also be informed by a Data Safety Monitoring Board (DSMB).

Data safety monitoring board

An independent data monitoring committee will be constituted of three researchers with expertise relevant to the task, such as statistics, common mental health disorders, digital intervention, and health services. The DSMB will oversee recruitment, adherence and adverse events and inform the trial coordination of their recommendations. Solicited and spontaneously reported adverse events will be documented. These will be defined as high psychological distress as assessed with the K10, which could be causally associated with the intervention, will be reported to the ERB and the DSMB. The committee will audit and meet every three months. No interim analyses will be conducted. The K10 scores will be monitored weekly by the research team and resources will be sent automatically via email.

Dissemination policy

The investigators will be consulted and involved in each scientific article that uses data from this trial. Other members from the steering committee will also be invited to contribute.

Study findings will be made available on social media, equilia newsletter, the research team websites, patient associations, and through presentations adapted to the general public. The scientific community will have access to study results by way of scientific papers submitted in peer-reviewed journals. The CRediT (Contributor Roles Taxonomy) and International Committee of Medical Journal Editors guidelines will be used to define authorship and roles.

Discussion

This protocol describes the translation and adaptation process of the iCBT Australia Shyness Program to the Canadian context (French, English), as well as the evaluation of its effectiveness and implementation in primary care settings in Quebec and Ontario. We hypothesize a significant reduction in symptoms of social anxiety (primary outcome) with the use of the iCBT adapted program to the Canadian context, as well as psychological distress, depressive symptoms, and disability, as well as HRQOL (secondary outcomes).

The study protocol may include some limitations. First, focus groups could result in social desirability bias. To help minimize this type of bias, we aim to organize focus groups for patient-partners, as well as community leaders and service providers, respectively. Second, although the study findings may be subject to selection bias, we tried to minimize the effect by including pathways where individuals without a family physician or not wishing to get referred from a health professional may also self-refer. We will compare the characteristics of participants in each pathway group with respect to program completion,

socio-demographic and clinical characteristics and health service use factors to assess the potential selection bias. Changes in study outcomes will be assessed through self-reports. Findings may be subject to social desirability; however, we do not expect this to be differential from baseline to follow-up. Finally, to control for potential confounders, socio-demographic, clinical and health service use factors will be controlled for in the multivariate analyses.

The current study will address an important and timely gap in service delivery as Canada considers stepped-care models like the United Kingdom's "Increased Access to Psychological Therapies" (IAPT) [91, 92], which includes low-intensity interventions as a first-line treatment. One such Canadian model includes the Montfort Hospital's Community-based Stepped-Care Tele-Mental-Health Program which includes the use of iCBT as a first step in the model for Francophones living in a minority context in Ontario. There is, at present, a need for available therapy options in primary care, as there are long waiting lists for mental health services and timely access to treatment options continues to be challenged by barriers to mental health care [93–95]. Hence, this project will help inform and contribute to improving the efficiency of the healthcare system by meeting population mental health needs equitably and by offering real-time solutions and tools to clinicians and decision-makers to meet population mental health needs. Additionally, through implementation analysis, we will better understand how a digital program offering psychological treatment like for SAD can be further integrated within routine and general care and scaled-up.

Abbreviations

AQoL-4D	Assessment of Quality of Life
BDI-II	Beck Depression Inventory
CFIR	Consolidated Framework for Implementation Research
CRUfAD	Clinical Research Unit for Anxiety and Depression
CBT	Cognitive-behavioral therapy
ERIC	Expert Recommendations for Implementing change
GAD-7	Generalized Anxiety Scale
HRQOL	Health related quality of life
IAPT	Increased Access to Psychological Therapies
iCBT	Internet-based cognitive-behavioral therapy
K10	Kessler's 10-item psychological distress scale
LCSC	Local community service center
PHQ	Patient Health Questionnaire
RCT	Randomized controlled trials
REDCap	Research Electronic Data Capture
SAD	Social anxiety disorder
SPIN	Social Phobia Inventory
WHODAS 2.0	World Health Organization Disability Assessment Schedule

Author contributions

HMV: Conceptualization, Funding acquisition, Methodology, Writing – Original Draft, Writing – Review & Editing. PR: Conceptualization, Funding acquisition, Methodology, Writing – Review & Editing. JS: Conceptualization, Methodology, Funding acquisition, Writing – Review & Editing. CLL: Methodology, Writing – Review & Editing. AC: Methodology, Writing – Review & Editing. MB: Funding acquisition, Writing – Review & Editing. JG: Funding acquisition, Writing – Review & Editing. AM: Funding acquisition, Writing – Review & Editing. DK: Funding acquisition, Writing – Review & Editing. MHC: Funding acquisition, Writing – Review & Editing. MD: Funding acquisition, Writing – Review & Editing. RL: Funding acquisition, Writing – Review & Editing. MDP: Funding acquisition, Writing – Review & Editing. MCI: Funding acquisition, Writing – Review & Editing. JAN: Funding acquisition, Writing – Review & Editing. AL: Funding acquisition, Writing – Review & Editing. All authors read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study was approved by the institutional research ethics board of the Centre intégré universitaire de santé et de services sociaux de l'Estrie – Centre hospitalier universitaire de Sherbrooke (CIUSSSE-CHUS) (#2023–4843). For all phases of the study, written or verbal consent will be obtained.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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