Online delivery of psychotherapy tailored to patients suffering from mental health problems due to the COVID-19 pandemic: Method/Study Design

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Abstract

Background: The impact of the COVID-19 pandemic has gone far beyond the direct overload of the hospital care system, with physical distancing, financial uncertainty, and the stress of well-being having largely negative consequences on individuals' mental health. Adding to these stressors is the personal and public trauma of lost lives, with an increasing fear of an unprecedented mental health epidemic with crushing effects on the public health sector and economy. To meet this overwhelming and growing demand for mental health care on an already strained health care system, we must have innovative approaches to significantly expand the capacity of care delivery. While it is not feasible in the short term to increase the number of mental health care providers or the number of hours they work, improving their time efficiency may be a viable solution. Virtual care and online delivery of psychotherapy, shown to be clinically effective, efficient, and cost-effective, presents itself as a promising means to address the ever-growing demand for mental health care. To our knowledge, we have established the first academic online psychotherapy clinic that aims to manage mental health problems secondary to the COVID-19 pandemic.

Objective: The goal of this research protocol is to evaluate the feasibility and efficacy of treating mental health issues aggravated by the stressors associated with the COVID-19 pandemic through an online platform.

Methods: This non-randomized control trial intervention will be delivered through the Online Psychotherapy Tool (OPTT), a secure, cloud-based, digital mental health platform. Participants will be offered a 9-week, diagnosis-specific, online cognitive behavioural therapy (e-CBT) program tailored to address mental health problems in the context of the COVID-19 pandemic. Participants (n = 80) will receive personalized feedback and interaction with a therapist throughout the program.

Results: The study received ethics approval in June 2020, and the recruitment of participants began in June 2020. Participant recruitment is being conducted via social media, web-based communities, and physician referrals. Data collection is expected to conclude by November 2020, and analyses are expected to be completed by December 2020 with linear regression analysis (for continuous outcomes) and binomial regression analysis (for categorical outcomes) being conducted.

Conclusions: If proven feasible, this method of care delivery could increase care capacity by four-folds. The findings from this

project have the potential to influence clinical practice and policy and increase accessibility to care during the COVID-19 pandemic, without sacrificing the quality of care. Clinical Trial: ClinicalTrials.Gov Protocol Registration and Results System (NCT0446667); https://clinicaltrials.gov/ct2/show/NCT04476667.

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ABSTRACT

Background: The impact of the COVID-19 pandemic has gone far beyond the direct

overload of the hospital care system, with physical distancing, financial uncertainty, and the stress of well-being having largely negative consequences on individuals' mental health. Adding to these stressors is the personal and public trauma of lost lives, with an increasing fear of an unprecedented mental health epidemic with crushing effects on the public health sector and economy. To meet this overwhelming and growing demand for mental health care on an already strained health care system, we must have innovative approaches to significantly expand the capacity of care delivery. While it is not feasible in the short term to increase the number of mental health care providers or the number of hours they work, improving their time efficiency may be a viable solution. Virtual care and online delivery of psychotherapy, shown to be clinically effective, efficient, and cost-effective, presents itself as a promising means to address the ever-growing demand for mental health care. To our knowledge, we have established the first academic online psychotherapy clinic that aims to manage mental health problems secondary to the COVID-19 pandemic. **Objective:** The goal of this research protocol is to evaluate the feasibility and efficacy of treating mental health issues aggravated by the stressors associated with the COVID-19 pandemic through an online platform. **Methods:** This non-randomized control trial intervention will be delivered through the Online Psychotherapy Tool (OPTT), a secure, cloud-based, digital mental health platform. Participants will be offered a 9-week, diagnosis-specific, online cognitive behavioural therapy (e-CBT) program tailored to address mental health problems in the context of the COVID-19 pandemic. Participants (n = 80) will receive personalized feedback and interaction with a therapist throughout the program. **Results:** The study received ethics approval in June 2020, and the recruitment of participants began in June 2020. Participant recruitment is being conducted via social media, web-based communities, and physician referrals. Data collection is expected to conclude by November 2020, and analyses are expected to be completed by December 2020 with linear regression analysis (for continuous outcomes) and binomial regression analysis (for categorical outcomes) being conducted. **Conclusions:** If proven feasible, this method of care delivery could increase care capacity by four-folds. The findings from

this project have the potential to influence clinical practice and policy and increase accessibility to care during the COVID-19 pandemic, without sacrificing the quality of care. **Trial Registration:** ClinicalTrials.Gov Protocol Registration and Results System (NCT0446667); https://clinicaltrials.gov/ct2/show/NCT04476667.

Keywords

Mental health; COVID-19; depression; anxiety; psychotherapy; cognitive behavioural therapy; online; internet; electronic; mental health care

Introduction

Background and Rationale:

The COVID-19 pandemic is a source of high degrees of uncertainty, anxiety, and stress, and is ultimately affecting mental health on a global scale. In fact, according to a recent survey, 75% of Canadians report feeling anxious, 37% report feeling lonely, and 32% say they are having a hard time falling asleep because of the stressors associated with the COVID-19 pandemic (AbacusData). Experience of previous public disasters shows that the psychological scars of these events go far beyond the official end of the disaster. For instance, the mental health effects observed following Hurricane Katrina lasted for over 4 years after the disaster with a 35% increase in substance abuse hospitalization in New Orleans (Moise & Ruiz 2016). This shows that addressing the mental health aspect of this pandemic is as important as addressing the immediate medical emergency. The increase in demand for mental health care services caused by the COVID-19 pandemic comes in the backdrop of a system already in crisis, which necessitates devising innovative approaches to stretch the current care capacity to cover more patients.

Cognitive behavioural therapy (CBT) is a promising solution to treating depression and anxiety disorders related to the COVID-19 pandemic. CBT is widely regarded as a first-line treatment for Major Depressive Disorder (MDD) and Generalized Anxiety Disorder (GAD) as supported by Randomized Controlled Trials (RCTs), meta-analysis, and recommendations of most clinical guidelines (Carl et al., 2019; Hall et al., 2016; Swedish Council on Health Technology Assessment, 2005) with long-term effects (Kodal et al., 2018; Salzer et al., 2011). CBT has been proven to be effective in relieving depressive and anxiety-related symptoms, improve overall functioning and prevent relapses of these conditions (Carl et al., 2019; Hall et al., 2016; Swedish Council on Health Technology Assessment, 2005) with long-term effects (Kodal et al., 2018; Salzer et al., 2011).

One downfall to CBT however, is that it is a very time-consuming and costly treatment

modality. Fortunately, replacing live and in-person CBT (i.e. synchronous care) with electronically-delivered and non-simultaneous therapy techniques (i.e. asynchronous care) appears to be a viable solution. The online delivery of CBT (iCBT or e-CBT) is a promising option that has been proven to be efficacious in treating both anxiety and depressive disorders while offering more accessible treatment with comparable results to in-person therapy (Andersson & Cuijpers 2009; Musiat & Tarrier 2014; Saddichha et al. 2014; Sztein et al. 2018). Moreover, through using pre-designed therapy content, clinicians may reduce their clinical time to a quarter of their initial practice time, making this a more affordable and scalable form of care delivery (Alavi et al., 2018).

In this study, we aim to develop an online psychotherapy clinic centred around e-CBT to assist patients with stress caused by the COVID-19 pandemic. The e-CBT program consists of 9 modules, 1 module per week, that will focus on coping skills and building resilience, which are effective in the treatment of mood and anxiety disorders. We will use the Online Psychotherapy Tool (OPTT), a secure, cloud-based platform, to interact with patients and to deliver therapy. We hypothesize that delivering these psychotherapeutic interventions through an online platform will improve the quality of life and decrease symptoms of depression and anxiety during this pandemic.

Objectives:

The first objective of this study is to design and implement an online psychotherapy clinic to address mental health problems related to the COVID-19 pandemic. The second objective is to evaluate the feasibility and efficacy of treating COVID-19 related mental health problems by offering specific e-CBT modules through an online clinic. The third and final objective is to rapidly disseminate the knowledge gained from this study to practices that could facilitate effective and reliable scaling of this solution across the country.

Methods

Study Design:

A non-randomized controlled trial study design will be employed. Qualitative focus groups

will be conducted to gather personal demographic information as well as information about the feasibility of implementing an online psychotherapy clinic. Additionally, quantitative analyses of online psychotherapy treatment efficacy will be conducted using standardized symptomology questionnaires.

Participants:

Participants (n = 80) aged 18-65 years will be enrolled in the study based on referrals from the outpatient clinics of Hotel Dieu Hospital and Providence Care Hospital located in Kingston, Ontario, Canada. Those invited and interested in participating will provide informed consent before evaluation by one of the psychiatrists on the research team through a secured video appointment. Diagnosis of Major Depressive Disorder (MDD) and/or Generalized Anxiety Disorder (GAD) will be confirmed using the Diagnostic and Statistical Manual of Mental Disorders – 5th Edition (DSM-5) and approved through the Mini-International Neuropsychiatric Interview (MINI), Version 7.0.2, DSM-5. The inclusion criteria for the study will include the capacity to consent; a diagnosis of MDD and/or GAD, the ability to speak and read English, and having consistent and reliable access to the Internet. Exclusion criteria will include active psychosis, acute mania, severe alcohol or substance use disorder, and/or active suicidal or homicidal ideation. Additionally, if a participant is receiving another form of psychotherapy, they will be excluded from the study. If eligible for the study, participants will be assigned to the electronic psychotherapy (e-psychotherapy) group. Individuals with a diagnosis of either MDD and/or GAD that do not wish to participate in the e-psychotherapy group will continue to receive treatment as usual (TAU) and will be a part of the control group. Both groups will be stratified by sex, gender, and group.

Procedures:

Participants enrolled in the e-psychotherapy group will participate in a 9-week program that will include a combination of CBT, mindfulness, and problem-based therapy, in addition to TAU. The content of the e-psychotherapy program will be customized to reflect the challenges that

individuals may face during the COVID-19 pandemic and will be developed into interactive and engaging therapy modules. All online sessions and interactions will occur through OPTT.

All participants will be assigned to a therapist on the team. The therapist will assign a pre-designed therapy module to their patient through OPTT on a specific day of the week, granting the participant access to the therapy content at any time throughout the week. Each weekly module will highlight a different topic and include general information, an overview of skills, and homework that is to be completed by a specific day that week. Completing each weekly module will require an average time commitment of 40 minutes, which can be completed all at once or in several blocks of time. The homework will be directly submitted through OPTT to the clinician who will then provide personalized feedback to the patient. To maintain consistency, therapists will use pre-designed session-specific feedback templates to respond to each homework submission. Each patient's care team will be able to securely communicate through OPTT to make decisions regarding each patient's care path. The control group will receive TAU for the first 9 weeks. If control group participants continue to present significant symptoms (less than 50% reduction in symptoms from baseline), they will be offered the option to receive the e-psychotherapy program.

Outcome Evaluation:

Primary outcomes measured will be stress level changes based on the Depression, Anxiety, and Stress Scale – 21 Item Questionnaire (DASS-21), resilience based on the Resilience Scale – 14 Item Questionnaire (RS-14), and quality of life which will be based on the Quality of Life and Enjoyment Questionnaire (Q-LES-Q). Additional measurement will be made based on participant diagnosis [Patient Health Questionnaire – 9 Item (PHQ-9), Montgomery Asberg Depression Rating Scale (MADRS), and Generalized Anxiety Disorder – 7 Item Questionnaire (GAD-7)]. All questionnaires will be collected directly through OPTT before treatment (baseline), after session 5, after the final session, and after a 6-month follow up. Health care providers will be asked about the feasibility of providing e-psychotherapy, how it compared to in-person psychotherapy concerning

time commitment, feelings of ‘connectedness’ to the participant, and any perceived benefits/drawbacks to e-psychotherapy. From focus groups, personal, social, and cultural factors (gender, sexuality, background, supportive resources, structural/social barriers, etc.) will be extracted using an Interpretive Phenomenological Analysis (IPA) approach.

Online Module Content:

The first 3 sessions will be designed to address the symptoms caused by the fear of illness, and concerns about personal safety in the context of a pandemic. e-CBT modules will focus on problem-solving techniques with mindfulness practices, to help build healthy coping skills that address the uncertainties surrounding the COVID-19 pandemic. e-CBT modules will involve guiding participants to develop constructive and balanced coping strategies through 5 focuses: stimulus control, cognitive therapy, sleep hygiene, relaxation therapy, and sleep restriction. Additional focus will be placed on the connection between thoughts, behaviours, emotions, physical reactions and the environment.

Training:

All therapists will learn the standard care pathway, the aim, and the content of each therapeutic session. Moreover, they will be provided sample homework from a patient and will be asked to provide feedback as practice for the sessions. Feedback templates will vary from session to session and therapists will personalize each template for each patients’ homework. Training will occur through webinars and exercises with feedback.

Ethics and Data Privacy:

All procedures have been approved and comply with the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. Only the care providers involved in the care of the participant will have access to their information. Participants will only be identifiable by an ID number on the OPTT platform and hard copies of consent forms with participant identity will be stored securely on-site and will be destroyed 5 years after study completion. Only anonymized

data will be provided to the analysis team members.

OPTT is compliant with the Health Insurance Portability and Accountability Act (HIPAA), Personal Information Protection and Electronic Documents Act (PIPEDA), and Service Organization Control - 2 (SOC-2). Additionally, all servers and databases are hosted in Amazon Web Service (AWS) Canada cloud infrastructure which is managed by Medstack to assure all provincial and federal privacy and security regulations are met. OPTT will not collect any identifiable personal information or Internet Protocol (IP) addresses for privacy purposes. OPTT will only collect anonymized metadata to improve its service quality and provide advanced analytics to the clinician team. All data is encrypted by OPTT and no employee has direct access to patient data. All encrypted backups are kept in the S3 storage that is dedicated to Queen's University located in Kingston, Ontario, Canada.

Data Analysis:

Initially, all data will be examined for missing, nonsensical, and outlying variables. Missing data will be treated as missing and not imputed (i.e., will be analyzed on a per-protocol basis). Given the likelihood of participant drop-out or withdrawal, we have purposely over-sampled our study and control groups to obtain meaningful and statistically significant results at the end of the study. Based on previous experience with CBT and e-CBT in similar patient populations, we anticipate up to 30% drop-out by the end of the treatment or TAU phases. Using the GAD-7 as the primary outcome, a 30% change is considered clinically significant. Therefore, a sample size of 40 participants in each arm of the study would be sufficient for detecting significant results with $p=0.05$, and a power of 0.95. Data collection will occur at three separate time points; baseline (pre-intervention), in the middle of the study (week five) and immediately post-intervention (week nine). Using Mann-Whitney-U tests, baseline demographic data from individuals who drop out will be compared to those who finish identifying any fundamental differences between completers and non-completers. Linear regression analysis (for continuous outcomes) and binomial regression analysis (for

categorical outcomes), will be used to identify variables associated with the two outcome measures over the three measurement time points while controlling for demographic variables such as age and gender, and to compare the differences between the study arms.

Discussion

General Progress:

The study has received ethics approval from the Queen's University Health Science and Affiliated Teaching Hospitals Research Ethics Board (HSREB) in June 2020, and the recruitment of participants began in June 2020. Participant recruitment has been conducted through social media advertisements, physical advertisements, and physician referrals. Data collection is expected to conclude by November 2020, and data analyses are expected to be completed by December 2020 with linear regression analysis (for continuous outcomes) and binomial regression analysis (for categorical outcomes) being conducted.

Conclusions:

Addressing the extensive mental health problems caused by the COVID-19 pandemic requires rapid and easily accessible solutions. An online psychotherapy clinic with pre-designed therapy modules could be used to rapidly scale up the clinical capacity to address mental health problems caused by the COVID-19 pandemic while ensuring a high quality of care. We will share the outcomes of our study as a preprint on bioRxiv.org for the rapid dissemination of our findings. We will also hold multiple online workshops for other clinicians interested in implementing this approach and provide technical and academic support to deploy this solution in their respective practices. This would ensure that our findings could be rapidly incorporated into clinical practice across the country. This approach would provide major financial savings to the health care system

through efficient use of clinician time and provide a more equitable and accessible method of delivery for patients.

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Conflicts of Interest

Drs. Nazanin Alavi and Mohsen Omrani have co-founded the care delivery platform in use (i.e. OPTT) and have ownership stakes in OPTT Inc.

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