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Telephone-based cognitive behavioural therapy for patients with postoperative bariatric surgery to manage COVID-19 pandemic-related mental health issues and distress (TELE-BARICARE): a protocol for a randomised controlled trial

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ABSTRACT

Introduction Bariatric surgery is currently the most effective treatment for obesity, and is performed yearly in over 8000 patients in Canada. Over 50% of those who live with obesity also have a history of mental health disorder. The COVID-19 pandemic has made it difficult for people living with obesity to manage their weight even after undergoing bariatric surgery, which combined with pandemic-related increases in mental health distress, has the potential to adversely impact obesity outcomes such as weight loss and quality of life. Reviews of virtual mental health interventions during COVID-19 have not identified any interventions that specifically address psychological distress or disordered eating in patients with obesity, including those who have had bariatric surgery.

Methods and analysis A randomised controlled trial will be conducted with 140 patients across four Ontario Bariatric Centres of Excellence to examine the efficacy of a telephone-based cognitive behavioural therapy intervention versus a control intervention (online COVID-19 self-help resources) in postoperative bariatric patients experiencing disordered eating and/or psychological distress. Patients will be randomised 1:1 to either group. Changes in the Binge Eating Scale and the Patient Health Questionnaire 9-Item Scale will be examined between groups across time (primary outcomes). Qualitative exit interviews will be conducted, and data will be used to inform future adaptations of the intervention to meet patients' diverse needs during and post-pandemic.

Ethics and dissemination This study has received ethics approvals from the following: Clinical Trials Ontario (3957) and the University Health Network Research Ethics Committee (22–5145), the Board of Record. All participants will provide written informed consent prior to enrolling in the study. Results will be made available to patients with bariatric surgery, the funders, the supporting organisations and other researchers via publication in peer-reviewed journals and conference presentations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To the best of our knowledge, this study will be the first multisite, randomised controlled trial examining the effects of a virtually delivered therapy for patients with post-bariatric surgery experiencing mental health distress and eating disorder symptoms during the COVID-19 pandemic.
⇒ The outcome measures have demonstrated strong psychometric properties in bariatric surgery patient populations.
⇒ The qualitative component of this study will help to further understand how virtually delivered psychological interventions during COVID-19 are experienced by diverse patient populations.
⇒ The main limitations of this study are the modest sample size and brief follow-up period, given the short time frame for conducting the study.

Trial registration number NCT05258578.

INTRODUCTION

The SARS-CoV-2 COVID-19 pandemic has had a catastrophic effect globally, causing over 4 million deaths and resulting in significant distress, social disruption and economic burden around the world.[1 2] High-risk patient populations, such as those with chronic or pre-existing medical conditions, including obesity, have experienced worsening mental health, distress and eating behaviours as a result of COVID-19.[3 4] The mental health distress associated with COVID-19 has the potential to adversely impact obesity outcomes, such as weight loss and quality of life, in patients

living with obesity or undergoing evidence-based obesity treatments (eg, bariatric surgery).[5] Specifically, patients with postoperative bariatric surgery have reported challenges with physical activity, eating behaviours, poor dietary adherence and disordered eating, all of which are associated with anxiety, depressive and stress symptoms secondary to the pandemic.[6–8] Indeed, studies have demonstrated unfavourable changes in dietary habits in people with obesity during the COVID-19 pandemic, with marked increases in the consumption of foods with limited or no nutritional value and a reduction in fresh produce.[9] Additionally, routine postoperative clinical visits have been significantly disrupted due to COVID-19, resulting in increased mental health distress and disordered eating as a result of decreased access to bariatric care teams post-surgery.[9 10] The worsening distress and disordered eating symptoms in the context of obesity can negatively impact obesity self-management and post-bariatric surgery care, specifically resulting in deteriorating mental health, physical health and quality of life.[11 12]

Emerging research has shown that the mental health disparities during COVID-19 are accentuated for more disadvantaged patient populations—specifically, greater mental health distress among females, people of lower socioeconomic status and some racialised groups.[13 14] However, limited data exist on bariatric surgery physical and mental health outcomes specific to diverse patient populations, which further complicates psychosocial care, including virtual psychosocial care, for individuals living with obesity during COVID-19. As a result, effective virtual psychosocial interventions are needed to treat patients' distress and eating difficulties in the context of obesity management during the current and recovery phases of the COVID-19 pandemic, especially for diverse patient populations.

Currently, high quality studies on the impact of virtual psychosocial interventions to prevent or treat mental health distress and eating disorders in patients with obesity during COVID-19 remain limited. Reviews to date, including a living systematic review of randomised controlled trials (RCTs), identified that self-guided internet-based cognitive behavioural therapy (CBT) and a layperson supportive telephone intervention improved mental health distress in non-bariatric populations.[15 16] Despite this preliminary evidence for virtual mental health interventions during COVID-19 in general and non-bariatric specific populations, these reviews did not identify any interventions that specifically addressed psychological distress or disordered eating in patients with obesity. This is a concern given significant shifts from in-person to virtual multidisciplinary visits across obesity and bariatric programmes during the pandemic.[17 18]

Previous research has demonstrated that a telephone-based CBT (Tele-CBT) intervention, developed specifically for patients who have undergone bariatric surgery, can improve depressive, anxiety and disordered eating symptoms in this population.[19–21] Furthermore, a recently published pilot study examining the effectiveness of this intervention in a subsample of patients with post-bariatric surgery during the COVID-19 pandemic showed that patients receiving Tele-CBT had significant improvements in depression, anxiety, binge eating and emotional eating symptoms immediately postintervention and at 3-month postintervention follow-up, whereas the control group did not.[22] Given that these results were preliminary and the study was not specifically designed to assess efficacy for COVID-19 related distress (ie, participation was not limited to those experiencing significant distress, the control group did not receive COVID-19-specific resources, the study was not sufficiently powered and adaptations for historically excluded and underserved populations were not considered), the current study proposes to test whether Tele-CBT is an efficacious intervention among patients managing obesity after bariatric surgery who are experiencing psychological distress or disordered eating associated with the COVID-19 pandemic.

Methods and analysis

Study overview

This is a prospectively registered (clinicaltrials.gov), multisite, two-arm RCT examining the efficacy of a Tele-CBT intervention versus a control intervention for patients with post-bariatric surgery experiencing disordered eating and/or mental health distress secondary to the COVID-19 pandemic. This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 recommendations (see online supplemental file 1; SPIRIT checklist).[23] The anticipated start date for this study is September 2022, with recruitment expected to finish by September 2023. Final data analyses for this study are expected to be complete by June 2024.

Study aims

The primary aim of this study is to examine the efficacy of Tele-CBT in improving disordered eating and psychological distress experienced by patients with postoperative bariatric surgery during COVID-19 in comparison to a control intervention (ie, online self-directed COVID-19 mental health resources).

The qualitative aim is to obtain input from patients to inform implementation of the Tele-CBT protocol to adapt it for diverse patient populations (ie, ethnicity, race and gender).

Study hypotheses

Co-primary hypotheses: individuals randomised to receive the Tele-CBT intervention will report significant improvements on the Binge Eating Scale (BES) and Patient Health Questionnaire-9 Item Scale (PHQ-9) immediately postintervention and at 3-month postintervention follow-up compared with the control group.

Secondary hypotheses: individuals randomised to receive the Tele-CBT intervention will report significant improvements on the Generalised Anxiety Disorder-7 Item Scale (GAD-7), Emotional Eating Scale (EES),

Loss of Control Over Eating Scale-Brief (LOCES-B) and Kessler Psychological Distress Scale (K6) immediately postintervention and at 3-month postintervention follow-up compared with the control group.

Study setting and participants

Patients with post-operative bariatric surgery (N=140 men, women and gender diverse individuals) will be referred to the study by treating clinicians from the University Health Network Bariatric Surgery Program (UHN-BSP), the Humber River Hospital Bariatric Surgery Program, The Ottawa Hospital Weight Management Clinic and the Thunder Bay Regional Bariatric Care Centre. To be eligible to receive bariatric surgery in Ontario, patients must be 18 years of age and older, have a body mass index (BMI) greater or equal to 40 kg/m^2 or a BMI greater than or equal to 35 kg/m^2 with at least one of the following comorbidities: coronary heart disease, type II diabetes, hypertension, diagnosed sleep apnea and/or gastro-oesophageal reflux disease. Patients are ineligible to receive bariatric surgery if they have a current drug or alcohol dependency, major life-threatening cancer within the last 2 years and untreated or inadequately treated psychiatric illness. Inclusion criteria to participate in the study include: patients with postoperative bariatric surgery (regardless of time since surgery), fluency in English, access to internet to complete online questionnaires and scores of ≥5 on the PHQ-9,[24] a measure of depressive symptoms, or ≥18 on the BES,[25] a measure of dysregulated eating in this patient population. All participants will be screened prior to study enrolment. Exclusion criteria include: (1) current active suicidal ideation and (2) current poorly controlled medical or psychiatric illness that would render Tele-CBT very difficult to conduct (eg, psychotic disorder and bipolar disorder).

Study design

The trial will use a two-arm parallel-group randomised controlled design (figure 1). Participants will enter the study on completion of written consent (see online supplemental file 2, consent form). After study entry, participants will be screened and if successful, asked to complete the baseline (preintervention) questionnaire packet. Randomisation will follow this baseline assessment. Participants randomised to the Tele-CBT group will then be assigned a therapist who will work with them over the next 10 weeks to deliver the manualised protocol. Participants assigned to the control group will be provided with the COVID-19 self-help resources available through the Centre for Addiction and Mental Health COVID-19 website and instructed on how to use the site. After this 10-week period, all participants will be asked to complete the postintervention questionnaire packet. A final 3-month follow-up questionnaire packet will be administered to patients 3 months following the postintervention questionnaire packet. Screening and all questionnaire packets will be completed online using Qualtrics survey software.

Randomisation

Using a parallel-group randomised design (figure 1), participants will be randomised 1:1 to either: (1) Tele-CBT Condition (ie, 7 sessions of Tele-CBT) or (2) control condition (ie, COVID-19 self-help and coping resources) once the baseline assessment is complete. The study biostatistician (CM) will generate the randomisation schedule prior to the start of the study. Randomisation, with random block sizes of 4, 6 or 8, will be stratified by sex, given the documented sex differences in bariatric surgery patients, and recruitment site. Randomised treatment assignments will occur via an independent central web-based system at all study sites. Each participant will be allocated a randomisation number, which will not be re-allocated if the participant drops out of the study.

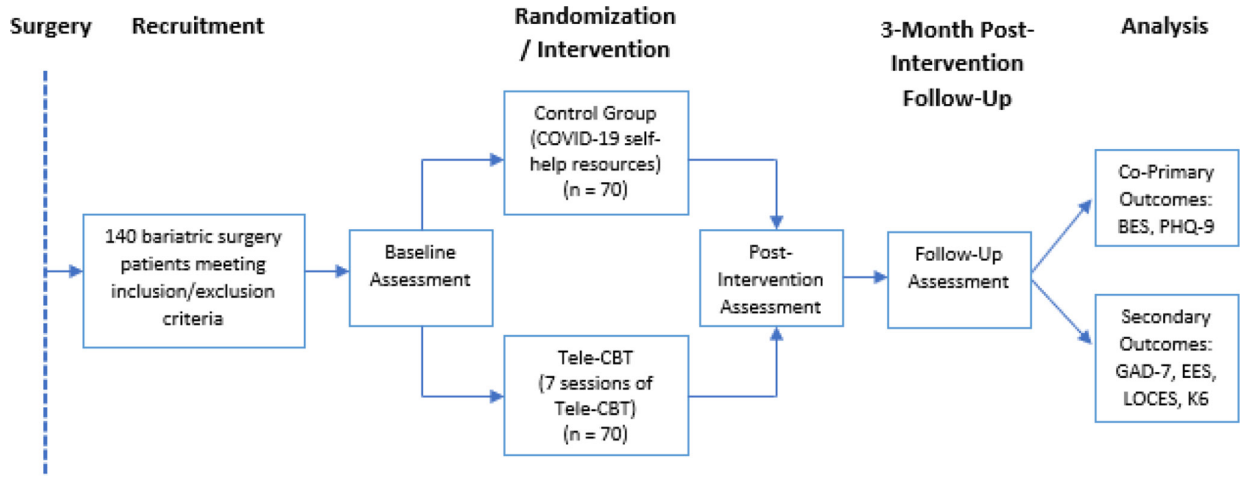

Figure 1 Study design. BES, Binge Eating Scale; EES, Emotional Eating Scale; GAD-7, Generalised Anxiety Disorder 7-Item Scale; K6, Kessler Psychological Distress Scale; LOCES, Loss of Control Over Eating Scale; PHQ-9, PHQ-9, Patient Health Questionnaire-9 Item Scale.

Study interventions

Tele-CBT condition

Participants in this group will receive 6 weekly Tele-CBT sessions and 1 final 'booster' session 1 month later, all approximately 55 min in duration and scheduled at a time convenient for the participants. The development, feasibility, acceptability and efficacy of the Tele-CBT protocol, as well as the content of the sessions, have been previously described by our team.[19–21 26] Briefly, the Tele-CBT sessions focus on introducing the cognitive behavioural model of overeating and obesity, scheduling healthy meals and snacks, scheduling pleasurable alternative activities to overeating, identifying and planning for difficult eating scenarios and problem solving and challenging negative thoughts. Participants are encouraged to complete CBT homework between sessions (ie, completing food records, pleasurable activities and worksheets). Five clinical psychology graduate students will work as study therapists under the supervision of the study principal investigators (SEC and SS) and will have biweekly case supervision meetings. Twenty per cent of audio recorded sessions will be rated for treatment adherence by an external reviewer with expertise in CBT. A total of five sessions will be considered as treatment completion. Participants will also be provided with the COVID-19 self-help resources detailed below.

Control condition

Participants in this group will be directed to the COVID-19 self-help webpage (www.camh.ca/COVID-19) to access coping tools to help with COVID-19 associated stress and anxiety, loss, grief and healing, stigma and physical isolation. Participants will receive weekly check-in/reminder emails for the duration of the intervention period that coincide with the weekly check-ins for the Tele-CBT condition.

Study outcomes

Primary outcomes

The multiple (two) primary endpoints are the BES and the PHQ-9. The BES is a 16-item self-report measure designed specifically for use with individuals with obesity and assesses the presence of binge eating characteristics indicative of an eating disorder. Scores on the BES range from 0 to 46 with moderate and severe levels of binge eating corresponding to cut-off scores of 18 and 27, respectively.[25] The PHQ-9 consists of 9 items assessing depressive symptoms on a scale ranging from 0 (not at all) to 3 (nearly every day). Scores on the PHQ-9 range from 0 to 27 with mild, moderate, moderately severe and severe levels of depressive symptoms corresponding to cut-off scores of 5, 10, 15 and 20, respectively.[24]

Secondary outcomes

Secondary outcomes are the EES, LOCES-B, GAD-7 and K6. The EES is a 25-item self-report measure that assesses a person's tendency to cope with negative affect through eating. The scale ranges from 0 (no desire) to 4 (overwhelming urge) and consists of questions that ask participants to rate the intensity of their urge to eat in response to 25 emotions. The EES is comprised of three subscales that reflect eating in response to anger/frustration, anxiety and depression.[27] The EES has been used in previous studies to examine emotional eating in post-bariatric surgery patients.[10] The LOCES-B is a brief, 7-item self-report measure that assesses loss of control eating. Patients indicate how often they tend to have difficulties controlling their eating on a scale ranging from 1 (never) to 5 (always).[28] The GAD-7 is a 7-item self-report questionnaire assessing anxiety symptoms on a scale ranging from 0 (not at all) to 3 (nearly every day). Scores on the GAD-7 range from 0 to 21 with mild, moderate and severe levels of anxiety symptoms corresponding to cut-off scores of 5, 10 and 15, respectively.[29 30] The K6 is a 6-item self-report questionnaire measuring psychological distress. Questions are scored from 0 (none of the time) to 4 (all of the time). Low scores indicate low levels of psychological distress, whereas high scores indicate high levels of psychological distress.[31] Sociodemographic data will also be collected from participants using the TC LHIN Hospitals Demographic Questionnaire, a standardised demographic questionnaire used by all Toronto hospitals (see http://torontohealthequity.ca/wp-content/uploads/2017/05/TC-LHIN-Hospitals-Demographic-Questions-English-visible-v2-1.pdf).[32–35]

Sample size and power considerations

The trial is powered to achieve at least 80% power to test each of the multiple primary endpoints (BES and PHQ-9). To account for ~15% patient attrition (as observed in our prior RCT), a total of N=140 participants (N=70 per arm) will be enrolled and randomised to ensure we have complete data on N=118 participants. The significance level (α) is set at 0.025 per multiple primary endpoint to account for two statistical tests. A total of N=118 participants (N=59 per arm) will achieve 80.0% power to detect a difference of mean changes of −3.1 between arms for BES, with a SD of 7.5 at preintervention and postintervention, and a correlation between measurement pairs of ρ=0.744. This sample size will achieve 96.2% power to detect a difference of mean changes of −3.4 between arms for PHQ-9, with SD=5.0 and ρ=0.597. The proposed effect sizes, SD and correlation between measurement pairs were estimated from the preliminary results in our current RCT.[22] While the trial is powered to detect differences in the multiple primary endpoints, a sample size of N=118 participants will achieve ≥90% power to detect differences in each of the secondary endpoints. Assuming an expected accrual rate of 11–12 participants per month across 4 sites, participant accrual is expected to complete in 12 months.

Statistical analyses

All randomised participants will be analysed, adhering to the intent-to-treat principle. Descriptive statistics will summarise participant baseline characteristics and

outcomes by study arm. Normality of the change scores or the residuals in the model will be checked, and non-normally distributed endpoints will be transformed using log(x) or log(x+1) transformations. The pre–post change in the primary and secondary endpoints will be compared between the treatment and control groups using linear regression, adjusting for sex, race, socioeconomic status and study site. As an exploratory analysis, linear mixed models will test the change in the primary and secondary endpoints between groups across the postintervention and 3-month follow-up timepoint, with adjustment for the baseline timepoint. Statistical analyses will be performed using SAS Enterprise Guide V.7.1 and SPSS V.24. Two-sided p values of <0.05 will be considered statistically significant.

Qualitative interviews

Qualitative exit interviews will be conducted via telephone with a purposive sample of 25–30 participants of diverse gender, age, race and ethnicity who have completed Tele-CBT. The aim of these interviews is to understand the unique needs of patients and address barriers to implementation from a patient-centred lens. The estimated number of interviews will allow for a broad representation from diverse groups. Interview audio will be transcribed and analysed using Nvivo qualitative software (QSR International Pty, Victoria, Australia) and using an inductive approach as outlined by Braun and Clarke.[36] Thematic analyses will include familiarising oneself with the data, assigning codes, searching for themes, reviewing themes and generating a report. The qualitative data will be used to create a plan for implementation and adaptations for use in diverse populations, including young adults/transitional age youth, racialised, gender diverse and ethnocultural populations.

Data management, storage and security

The primary research study team at the UHN-BSP (SS, SEC and SEL) will supervise the day-to-day operation of the project and ensure that all ethics and guidelines are being followed. Data will be stored on network drives within the University Health Network with firewalls and security measures in place. Hard copy records will be stored in a locked cabinet in a secure location. Access to records and data will be limited to study team members only. All study data will be de-identified and a master log with identifiers will be kept and stored separately from the data.

Patient and public involvement

None.

Ethics and dissemination

This study has received ethics approvals from the following: Clinical Trials Ontario (3957) and the University Health Network Research Ethics Committee (22–5145), the Board of Record. All participants will provide written informed consent, obtained by the study research coordinator, prior to enrolling in the study (see online supplemental file 2; consent form). Results will be made available to bariatric surgery patients, the funders, the supporting organisations and other researchers via publication in peer-reviewed journals and conference presentations.

DISCUSSION

Given the increase in mental health distress and obesogenic behaviours related to the COVID-19 pandemic, it is critical that patients have consistent access to psychosocial care. The rapid expansion of virtual care across obesity programmes provides opportunities to extend the reach of psychosocial care beyond the pandemic.[17 37] Building off previous research, this study aims to demonstrate that Tele-CBT is an efficacious intervention for those experiencing distress secondary to the COVID-19 pandemic and to mitigate pandemic-related deteriorations in mental health, disordered eating and weight management in obesity care. Moreover, the qualitative component of this study will increase understanding of how to adapt this psychological intervention for diverse patient populations living with obesity and mental health challenges. By understanding how remotely delivered psychological interventions during COVID-19 are received and affect diverse patient populations, these study findings will be used to inform the development and application of psychosocial treatments and services during COVID-19 and its recovery phase.

It is important to note that the modest sample size and brief follow-up duration are limitations of this study. Given that recruitment will be limited to a 1-year period, a target sample of 140 participants was determined to be feasible for recruitment within that time frame yet still provide sufficient power to detect changes in the multiple primary endpoints. Future studies could include a larger sample size to ensure accuracy of results and to allow for more generalisability of findings. Additionally, due to the short time frame in which the study will need to be conducted, the follow-up period for this study is limited to 3-month postintervention. Although previous research has shown that this short follow-up duration is sufficient in demonstrating the efficacy of the Tele-CBT intervention,[22] future studies could include additional follow-up timepoints to determine how the outcome measures change over prolonged periods of time.

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Contributors All authors contributed to the conception of the study and the writing and editing of this manuscript. SS, SEL, BA, RH, SW, SD, TJ, NA, MF and SEC were involved in the planning of the study design. SEL conducted screening and data collection. Analysis was performed by SS, SEL, CM and SEC. Conduction and reporting of the study was led by SS, SEL, BA, CM and SEC.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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