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ORIGINAL CONTRIBUTIONS

Acceptability and Feasibility of the Telehealth Bariatric Behavioral Intervention to Increase Physical Activity Before Bariatric Surgery: A Single-Case Experimental Study (Part I)

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Abstract

Background Physical activity (PA) can play an important role in optimizing metabolic/bariatric surgery (MBS) outcomes. However, many MBS patients have difficulty increasing PA, necessitating the development of theory-driven counseling interventions. This study aimed to (1) assess the feasibility and acceptability of the TELEhealth BARIatric behavioral intervention (TELE-BariACTIV) trial protocol/methods and intervention, which was designed to increase moderate-to-vigorous intensity physical activity (MVPA) in adults awaiting MBS and (2) estimate the effect of the intervention on MVPA.

Methods This trial used a repeated single-case experimental design. Twelve insufficiently active adults awaiting MBS received 6 weekly 45-min PA videoconferencing counseling sessions. Feasibility and acceptability data (i.e., refusal, recruitment, retention, attendance, and attrition rates) were tracked and collected via online surveys, and interviews. MVPA was assessed via accelerometry pre-, during, and post-intervention.

Results Among the 24 patients referred to the research team; five declined to participate (refusal rate = 20.8%) and seven were ineligible or unreachable. The recruitment rate was 1.2 participants per month between 2021–09 and 2022–07. One participant withdrew during the baseline phase, and one after the intervention (retention rate = 83.3%). No participant dropouts occurred during the intervention and 98.6% of sessions were completed. Participants' anticipated and retrospective acceptability of the intervention was 3.2/4 (IQR, 0.5) and 3.0/4 (IQR, 0.2), respectively. There was a statistically significant increase in MVPA [Tau-U = 0.32(0.11; 0.51)] from pre- to post-intervention.

Conclusion Despite a low recruitment rate, which could be explained by circumstances (COVID-19 pandemic), results support feasibility, acceptability, and preliminary efficacy of the TELE-Bari-ACTIV intervention for increasing MVPA in patients awaiting MBS.

Keywords Behavioral change intervention · Bariatric surgery · Physical activity · e-health · N-of-1 · Motivational interviewing

Key Points
1. Six weeks of physical activity (PA) tele-counseling is feasible for adults awaiting MBS.
2. Six weeks of PA tele-counseling (45 min/week) is acceptable for adults awaiting MBS.
3. A theory-based tele-counseling shows promise to increase MVPA in adults awaiting MBS.

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Introduction

Metabolic and bariatric surgery (MBS) is the most effective long-term treatment for severe obesity [1]. However, most adults are not meeting current physical activity (PA) recommendation before and after MBS, despite substantial weight loss and improvement in comorbid diseases, which appear to have little if any effect on moderate-to-vigorous intensity

physical activity (MVPA) levels [2, 3]. This is problematic given that MVPA can help enhance and sustain multiple MBS benefits, including physical and mental health both before and after MBS [4–6]. Yet, meeting MVPA guidelines can be challenging for many people due to various physical, psychological, and environmental barriers [7, 8]. Thus, patients may benefit from additional support before and after MBS to reach sustainable PA improvement, and to optimize MBS benefits [9].

PA behavioral change interventions warrant attention as their efficacy to increase PA has been established in adults with obesity [10]. Additionally, data showed that theory-driven interventions are effective to promote PA in adults [11, 12]. There is thus a clear need for theory-driven PA behavioral interventions to help patients overcome barriers to being more active. However, only a few interventions have been tested in MBS patients, and only one was delivered before MBS [13, 14]. The Bari-Active intervention, a randomized controlled study with 6-week PA behavioral intervention administered prior to MBS, led to noticeable improvements in device-measured MVPA levels as compared to usual care (+ 16.6 min per day vs. − 0.3 min per day) [13], but it was delivered face-to-face, which may limit access to the more affluent and those living in proximity to research or MBS centers.

Technology-based tools such as web-meeting software enable new ways for adults from everywhere to participate in behavioral interventions. With the wide reach of the Internet and the ubiquity of connected communication devices (e.g., computers, smart devices), a new age of convenient, scalable, personalized, and cost-effective telehealth interventions is emerging. Several studies have demonstrated the positive impact of telehealth interventions on health outcomes [15–17], and PA in adults with and without obesity [18, 19]. While the efficacy of telehealth interventions in MBS patients has been assessed [20–22], to our knowledge, few studies have investigated telehealth interventions where PA counseling is the primary intervention component. One feasibility study showed the feasibility of a smartphone app to promote PA before MBS [23], one randomized controlled study after MBS is an ongoing study with videoconferencing PA sessions or e-health online platform [24], and one randomized controlled trial reported no significant increases in step count after online monthly one-on-one 30-min PA telecoaching sessions during the six first month after MBS [25]. Further studies are needed, particularly in pre-MBS patients.

Current Study

Before investing human and financial resources in efficacy trials, a cautious approach is recommended by the staged approach to behavioral change intervention development (see the Obesity Related Behavioral Intervention Trials (ORBIT) model [26]). As a result, Bariactiv, which has previously demonstrated its effectiveness [13, 14], underwent revisions to strengthen its theory-based content, incorporate the users' perspectives, and align with the intervention's context, while also facilitating broader access through videoconferencing. Therefore, the aim of this study was to conduct a multicenter trial using a repeated single-case experimental study design to assess the feasibility and acceptability of the TELEhealth BARIatric behavioral intervention (TELE-BariACTIV) trial protocol/methods and intervention—a theory driven intervention—in adults awaiting MBS. The second aim was to estimate the effect of the TELE-BariACTIV behavioral intervention on MVPA (primary outcome for a future large-scale trial) prior to MBS (primary endpoint). The hypotheses were the following: (i) the protocol/methods and the intervention is feasible and acceptable based on the satisfaction criteria established a priori and (ii) device-measured MVPA is statistically significantly higher during (phase B1) and post-intervention (phase A2) compared to baseline (phase A1), with a small effect size.

Trial results are reported in three parts. This paper reports on Part I, namely the main data collected before MBS on the primary outcomes (feasibility and acceptability), secondary outcomes (MVPA), and generalization measures (anxiety and depressive symptoms, quality of life, pain). Forthcoming Part II and III papers will present secondary data on the theoretical-construct measures assessed, and 1-year post-MBS follow-up data.

Materials and Methods

Study Design

The present open-label multicenter single-case experimental study with multiple baseline data (ABAB'A) is reported following recommendations for single-case protocols in behavioral interventions (Supplemental Files) [27]. This research design requires a small group of participants to test causal relationships between variables of interest, and allows rigorous experimental manipulation of independent variables and repeated measurements of dependent variables over time to enhance internal validity [28]. The observational phases "A" help control for maturation and historical variables, thus serving a function like a control group without intervention [27]. This design has been used with different clinical populations to study different behaviors, including PA [29–32] and adults before MBS [33], and is seen as a niche to test personalized obesity treatment [34].

The human research ethics committees approved the study protocol [35]. Informed consent was obtained from all individual participants included in the study prior to their participation.

Randomization and Procedures

The methods have been described in detail elsewhere [35], with any changes described in the Supplemental File. The following sections describe the methods relevant to the pre-MBS phases (phases A1, B1, and A2) reported in this paper. Participants were randomly assigned to either a 1- or 2-week baseline A1 phase; subsequent phases (phases B1 and A2) were of identical length for all participants. The A phases were observational phases without intervention, and the B phases were interventional with the TELE-BariACTIV. Daily MVPA was assessed for 7 (if randomized to 1-week baseline A1) or 14 days (if randomized to 2-week baseline A1) during the A1 phase, and then for 7 days in phases B1 and A2. The Actigraph Centerpoint was used to download and extract the data. Online Limesurvey© questionnaires were used to assess baseline sociodemographic data (before randomization and phase A1), clinical data, smoking status, and unhealthy alcohol consumption three times (before phases A1, B1, and A2), quality of life, including pain symptoms, anxiety, depressive symptoms, and self-reported MVPA four times (before phase A1, before, during and after phase B1). In addition, acceptability of the protocol and intervention was assessed using an online questionnaire before and after the intervention (phase B1), and with an online semi-structured individual interview after phase B1.

Recruitment and Participants

Twelve participants were recruited between September 2021 and July 2022 via referral from clinicians from three hospitals, i.e., two associated tertiary care (Quebec Heart and Lung Institute; Sacré Cœur Hospital, Montreal (Centre Intégré Universitaire de Soins et de Services de Santé (CIUSSS) du Nord-de-l'Île-de-Montréal); and one associated regional center (Chicoutimi Hospital, Chicoutimi (CIUSSS Saguenay–Lac-Saint-Jean)). The sample size is considered acceptable for this study, where sample sizes range from 2 to 12 [27, 36], due to the large number of repeated measurements within participants increasing statistical power.

Eligibility Criteria

To be included, participants had to (i) be aged ≥ 18 years, (ii) be scheduled to undergo a sleeve gastrectomy ≥ 12 weeks at one of the three participating hospitals, (iii) self-report ≤ 150 min of MVPA per week, and (iv) have access to a computer with Internet and an interface with a camera. Exclusion criteria were the following: (i) having a physical contraindication to PA, (ii) already enrolled in a supervised exercise intervention or PA behavioral change intervention, (iii) unable to speak and understand French, or (iv) needing a wheelchair, cane, walker, or other assistive device(s) to move.

The TELE-BariACTIV Intervention

Full details of the TELE-BariACTIV intervention have been described elsewhere [35]. Briefly, the intervention aimed to enhance participants' motivation to participate to PA (via satisfaction of their basic psychological needs of competence, autonomy, and relatedness) and self-efficacy in relation to PA to promote adoption and continuation of PA. To this end, the intervention was driven by key tenets of the self-determination theory [37]) and social cognitive theory (SCT; [38]), and embedded related motivational and behavioral change techniques (MBCT). The specific TELE-BariACTIV content- and relational-based techniques for each session are described in detail elsewhere [35]. Participants were offered six 45-min synchronous sessions before MBS via Zoom©. To facilitate learning and progress, as well as self-reflection, participants received information and worksheets by mail and/or email, depending on their preference. The intervention to all 12 participants was delivered by a woman with a master's degree in Kinesiology. She had received 5 h of training by the first and last authors beforehand and performed one random practice session that was recorded to receive feedback and better deliver the intervention and improve its fidelity. In addition to the sessions, participants received a PA monitor (A370 Polar© watch) and were encouraged to use it during the intervention to monitor their PA behavior.

Fidelity

The PA counselor documented several aspects for each session in a standardized form: attendance, session duration, topics covered, achievement of session goals, view of participant's response to the content, next steps, and personal reflections. The PA counselor reported that all topics were covered in the 45-min allotted time, supporting intervention fidelity (Supplemental Files).

Measurements

Primary Outcomes

Feasibility The following protocol/methods feasibility indicators were tracked by research assistants: (i) refusal rate (% of participants who declined to participate out of

participants referred by clinicians, and reasons); (ii) recruitment rate (number of participants recruited per month), and sources of referral (e.g., professionals, self via poster); (iii) retention rate (% of participants who complete the four assessments and the interview before MBS out of the participants consenting) with drop-out reasons; and (iv) % of missing data in the four assessment before MBS (overall/total, per participant, per outcome, and per assessment timepoint). Intervention feasibility indicators that were tracked were the following: (v) intervention attendance rate (% of the six pre-MBS sessions completed by each participant and overall) and (vi) intervention attrition rate (% of participants of those who started who did not complete the intervention as allocated). As previously described [35], the following a priori satisfaction criteria were chosen and used to analyze our results: (i) refusal rate ≤ 20% of participants who declined to participate, (ii) recruitment rate ≥ 1.8 participants recruited per month, (iii) retention rate ≥ 80% of participants who complete the four assessments and the interview before MBS, (iv) % of overall missing data ≤ 10% of data missing in the four assessments before MBS, (v) intervention attendance rate ≥ 80% of overall sessions completed, and (vi) intervention attrition rate ≤ 20% who did not complete the intervention.

Acceptability Participants were asked to complete a 7-item questionnaire developed by the authors based on the "Theoretical Framework of Acceptability" to evaluate the anticipated and retrospective acceptability of the intervention [39]. In addition, participants were invited to take part in a semi-structured individual interview via Zoom© to discuss their thoughts, feelings, and opinions regarding the protocol/methods and the intervention. Interviews were audio-recorded, and conducted by a trained research assistant guided by open-ended questions (Supplemental File).

After each session, the PA counselor also completed the Technical Quality Assessment Questionnaire to assess the quality and performance of the Zoom© technology platform and three additional questions to explore the quality of the relationship with the participant, session goal achievement, and global satisfaction [40].

Secondary outcomes

Device-Measured MVPA (Primary Outcome for a Future Large-Scale Trial) A triaxial accelerometer worn at the hip on the right side (Actigraph© wGT3X-BT) was used to assess daily MVPA (min per day) during phase A1 (7 to 14 days depending on participants' randomization), and during phases B1 and A2 (7 days). Participants were asked to wear the accelerometer during waking hours (except during water-based activities) and keep a log of wear times. Additionally, they were instructed to wear the accelerometer one or two additional days if they missed wear days.

Accelerometer data were extracted from the Actigraph© center point and downloaded (10-s epochs) using Actilife v.6.13.4 software. Only data from participants who wore the accelerometer ≥ 3 days (including at least 1 weekday and 1 weekend day) and ≥ 9 h per day were analyzed [2, 41]. Non-wear time was defined as a period of ≥ 120 min of consecutive zeros [42], and Freedson's threshold values of counts were used for the analyses (moderate intensity PA = 1952–5724 and vigorous intensity PA > 5,724) [43].

Generalization Measures (Secondary Outcomes for Future Large-Scale Trial) To increase the external validity of the study [44], generalization measures were performed to assess whether changes in health are generalized to other results in the scientific literature [29]. As detailed elsewhere [35], the Patient Health Questionnaire (PHQ-9) and the Generalized Anxiety Disorder Scale (GAD-7) were used to assess the severity of anxiety and depressive symptoms [45, 46], respectively. A minimal clinically important difference score ranging from 0 to 10 points on the GAD–7, and 0 to 14 points on the PHQ–9 depending on the range of baseline depressive or anxiety symptom severity was used to perform visual analysis on the effects of the intervention on these outcomes [47]. Also, quality of life was assessed using the physical and mental health scores of the 36-item RAND questionnaire [48]. A score of three was used as the minimal clinically important difference to perform the visual analysis of the quality of life data [49–52].

Covariables Baseline sociodemographic (age, sex, education, marital and professional status, number of children, income), clinical data (MBS date, medical conditions, height, weight), and smoking status (non-smoker, smoker, former smoker) were self-reported. Alcohol consumption was assessed using the Alcohol Use Disorder Identification Test-Concise (AUDIT-C) [53] and higher scores (out of 12) indicate a greater likelihood of a person's drinking habits negatively impacting their health and functional well-being. The Global Physical Activity Questionnaire (GPAQ, [54]) was used to calculate self-reported sitting time (hours per day), self-reported total MVPA, and self-reported MVPA per domain (work, travel to and from places, recreational activities) (minutes per week). Accelerometers were also used to measure sedentary time (hours per day), light PA (minutes per week), and daily steps. Sedentary time was defined as activity below < 100 counts per minute, whereas light-intensity PA was defined as activity with 100–1951 counts per minute [43]. Finally, pain was assessed using two RAND-36 Physical Pain subscale questions [48]. A mean score was calculated, with higher scores indicating greater pain intensity.

Internal Validity

To increase the internal validity of the study, participants were asked during the interviews whether they had life events that occurred during the study (e.g. illness, new job) that might have influenced the study results, and these were checked against the PA counselor's notes.

Statistical Analyses

Descriptive statistics were used to compute individual and group sociodemographic, clinical, feasibility, and acceptability data. A Tau-U test for each participant and for the group was performed to compare daily device-measured MVPA between phases A1 and B1, and phases A1 and A2 [55]. Individual effect sizes were aggregated in a meta-analysis to obtain a group-based effect size. A sensitivity analysis was performed with a randomization test [56]. All statistical analyses were performed with R 4.2 and the following packages: scan and SCRT [57].

The minimal clinically important difference scores were used to analyze the generalization measures (quality of life, anxiety, and depression symptoms) in descriptive purpose. The differences in individual scores between phases A1 and B1, and phases A1 and A2 were compared by visual inspection of the data [58].

Interviews were transcribed verbatim and analyzed by AB and JB with NVivo© using content analysis. The counselor's notes were also analyzed using content analysis. First, transcripts and notes were read, and then codes were generated that identified relevant features that aligned with the current objectives of assessing protocol/methods and intervention feasibility and acceptability. Next, similar codes were combined to form sub-themes and themes, which were labelled and defined. Last, illustrative quotes from the interviews and notes were selected to show links between the raw data and themes. All names were replaced with pseudonyms, any other identifying information was removed from the quotes, and the quotes were translated to English only after the coding process was finalized by a bilingual research assistant and reviewed by a native English-speaker (JB) for reporting purposes.

Results

Participant Characteristics

Eleven women and one man between 43 and 62 years of age consented to participate in this study. Baseline sociodemographic and medical data, smoking status, and alcohol use score of each participant are presented in Table 1.

Primary Outcomes

Feasibility

Recruitment lasted 10 months from September 2021 to July 2022. During this time, 24 patients awaiting MBS were referred to the research team by clinicians; five declined to participate (*refusal rate = 20.8%*), seven were ineligible or unreachable. In total, 12 were enrolled, consented, and completed baseline assessments post-randomization (*recruitment rate = 1.2 participant per month*). One participant dropped out during the baseline phase due to discomfort with the accelerometer, and one dropped out after completing the six pre-MBS intervention sessions, resulting in a *retention rate of 83.3%*.

Missing data were examined separately for self-reported (i.e., online survey) and device-measured (i.e., accelerometer) data. It was minimal for self-report as only baseline medication was missing for one participant in the Limesurvey questionnaires, but no other data were missing in the four assessment time points (Table 2). For accelerometer, missing data patterns are in Table 2. The percentage of participants with valid data (≥ 3 days including at least 1 weekday and 1weekend day, with ≥ 9 h per day) was 100% (11/11) for phase A1, 81.8% (9/11) for phase B1, and 54.5% (6/11) for phase A2.

No participant dropped during the phase B1 intervention offered prior to MBS (*interventionattrition rate = 0%*), and the *interventionattendance rate* was *98.6%* (65/66 sessions were completed); one participant missed the session 6 because their MBS was scheduled before the 6-week intervention end. In terms of length, 91.7% (11/12) of participants received one session per week across the 6-week period as planned; one participant delayed session 3, extending the intervention length to 7 weeks.

Acceptability

Participants anticipated and retrospective acceptability of the intervention were 3.2 (IQR: 0.5) and 3.0 (IQR: 0.2), respectively, on a scale of 4. The mean score for technical quality assessment of all sessions reported by the PA counselor was 2.8 ± 0.1 out of 3. The mean scores for the perceived relationship with participant, session goal achievement, overall satisfaction reported by the PA counselor were 10.0 ± 0.1, 9.7 ± 0.2, and 9.3 ± 0.4 out of 10, respectively. No adverse events occurred during the sessions. Session details are provided in the Supplemental Files.

Table 1 Participants characteristics ($n = 12$)

Participant	Age (years)	Sex	Marital status	Number of children	Professional status	Level of education	Income ($)	Ethnicity	Baseline BMI/postintervention BMI (k.m^2)	Medical conditions	Smoking status/alcohol consumption score
1 G1	56	F	Married	3	Full-time	Pre-university	50,000–74,999	White	44.4/44.4	HTN, Dys, OSA	Former smoker/1
2 G1	46	F	Civil union	4	Full-time	University	75,000–100,000	White	44.4/44.4	HTN, Dys, T2D, OSA, Ar, MH, Derma	Non-smoker/0
3 G1	50	F	Separated	2	Full-time	University	75,000–100,000	White	44.4/44.4	T2D, OSA, Ar, RespiD	Non-smoker/2
4 G2	51	F	Married	0	Full-time	High school	> 100,000	White	44.4/44.4	HTN, OSA, Ar, MH	Former smoker/0
5 G2	44	F	Civil union	3	Unemployed	High school	< 25,000	White	44.4/44.4	HTN, T2D, Ar	Non-smoker/0
6 G1	56	F	Married	3	Part-time	Pre-university	75,000–100,000	White	44.4/44.4	T2D, OSA, Ar, CVD, RespiD, MH	Former smoker/1
7 G2	59	F	Single	0	Retired	university	25,000–49,999	White	44.4/44.4	HTN, Dys, T2D, OSA, RespiD, Derma	Former smoker/3
8 G1	46	H	Single	0	Full-time	High school	50,000–74,999	White	44.4/ 44.4	Dys, OSA, CVD, MH	Non-smoker/0
9 G1	62	F	Married	2	Full-time	High school	> 100,000	White	44.4/44.4	HTN, OSA	Non-smoker/2
10 G2	61	F	Divorced	2	Full-time	University	> 100,000	White	44.4/44.4	OSA, Ar	Former smoker/2
11 G2	43	F	Married	3	Medical leave	Pre-university	75,000–100,000	White	44.4/44.4	HTN, OSA, Ar, RespiD, MH	Former smoker/3
12 G2	45	F	Married	2	Medical leave	High school	25,000–49,999	Hispanic	44.4/44.4	Dys, T2D, OSA, Ar, CVD, RespiD, MH	Smoker/0
Total	50.5	92% F	66.7% in couple	2	58% Full-time	66.7% ≥ pre-university	58.3% ≥ 75 000	91.7% White	46.6/45.2	83.3% ≥ 3 medical conditions	Smoker

G group, *HTN* hypertension, *Dys* dyslididemia, *T2D* type 2 diabetes, *OSA* obstructive sleep apnea, *Ar* arthritis/osteoarthritis, *CVD* cardiovascular disease, *MH* mental disorder, *Derma* dermatosis,

RespiD respiratory diseases. Total numbers are expressed in % or median

Table 2 Feasibility and acceptability outcomes

Participants	Counseling sessions					Research methods			
	Number of sessions completed	Duration of sessions (min)	Attrition (Y/N)	Acceptability anticipated score	Acceptability retrospective score	Number of online surveys completed (% missing data in completed survey)	Interviews completed (Y/N)	Number of accelerometer wear days: phases A1; B; A2	Number of days with valid accelerometer wear time (9 h per day): phases A1; B; A2
1 G1	5	36.0 (29.5–46.5)	N	3.4	3.5	4 (0%)	N	7; 7; 0	7; 7; 0
2 G1	6	41.5 (35.3–49.5)	N	3.4	2.9	4 (0%)	Y	7; 7; 7[a]	7; 7; 7
3 G1	6	40.5 (34.3–46.3)	N	3.1	2.9	4 (only medication)	N	5; 6; 6[a]	4; 5; 5
4 G2[b]	Did not receive the allocated intervention			-	-	1 (0%)	-	4; -	1; -
5 G2	6	42.0 (35.0–45.5)	N	-	3.0	4 (0%)	Y	13[a]; 0; 0	5; 0; 0
6 G1	6	49.0 (45–55.5)	N	3.3	3.4	4 (0%)	Y	7; 7; 0	6; 6; 0
7 G2	6	45.0 (41.3–49.8)	N	3.5	3.0	4 (0%)	Y	14; 7[a]; 9[a]	12; 7; 7
8 G1	6	45.5 (44.3–47.8)	N	2.1	3.1	4 (0%)	Y	7; 7; 7[a]	6; 6; 7
9 G1	6	34.0 (26.0–45.0)	N	3.0	3.0	4 (0%)	N	7; 0; 0	7; 0; 0
10 G2	6	47.5 (43.8–52.0)	N	3.5	2.9	4 (0%)	Y	11[a]; 7; 0	10; 7; 0
11 G2	6	47.0 (44.3–50.5)	N	2.5	2.9	4 (0%)	Y	14; 7; 7	14; 6; 6
12 G2	6	50.0 (48.8–57.5)	N	3.2	3.1	4 (0%)	Y	14; 7; 7	13; 7; 7
Total	98.5%	45.0	0%	3.2	3.0	98%	73%	94.6%;80.5%; 55.8%[c]	81.3%;75.3%;50.7%[c]

[a]Not on consecutive days

[b]Withdrew from the study because they disliked wearing the accelerometer; Total number are expressed in % or median

[c]Number of accelerometer wear days (or valid) /number of wear days required × 100 excluding participant who dropout

Qualitative Results Eight out of the 11 participants who completed the trial (72.7% of participants) were interviewed for 16 to 49 min (median 31.0 min (IQR: 11.8)). The transcribed data were summarized into eight themes (noted in boldface in Table 3), which contained several sub-themes (noted in italics in Table 3), and illustrative quotes are presented in the Supplemental Files.

Secondary Outcomes

Device-Measured Daily MVPA

The mean change for device-measured daily MVPA and statistical results are presented for each participant in Table 4; a graphical representation of these data is

Table 3 Themes and sub-themes based on content analysis of interviews ($n = 8$)

Outcome expectations
Participants had several reasons for participating in this study, which related to the *intervention* and *research*. For the former, they regarded the intervention as a means to receive support from a professional, gain knowledge, improve their physical condition and health, and get help initiating and maintaining an active lifestyle. For the latter, they believed they could help others and contribute to research. However, some participants indicated they had not expectations driving their motivation to participate in the intervention or study
Intervention likes
Participants talked about 5 main components they liked about the intervention and that motivated them to engage in increasing their PA. These were: *Engagement and interaction with the PA counselor*, *Content*, *Material*, *Modalities*, and *Non-specific*. Participants valued the counselor and referred to her attributes and acting qualities. By being encouraging, non-judgmental, helpful, empathetic, attentive, positive attitude, confident in participants, accessible, and available, it was much easier for them to connect with her and share their experiences, feelings, and obstacles. They discussed ways in which the counselor delivered content energetically, passionately, humorously, and competently, which acted as a means of motivation for them to remain in the intervention
Besides the counselor, participants talked about how the *Content* met their specific needs; while covering considerable breadth, the content was flexible enough for the counselor to adapt it to each participant's own lifestyle. Participants noted that the intervention was a source of relevant information for them learn from or review that happened to be motivating, relevant, interesting, understandable, and pleasant, and they found it useful to receive related tips and examples. Additionally, participants talked about two main components that would motivate them in-between sessions with the counselor. The first was having access to different tool, such as videos, which could then assist participants in making decisions about PA. The second was the activity sheets, which they could complete in real time with the counselor (e.g., setting goals) and/or consult as needed (e.g., diary to see their progress or problems). Relatedly, participants liked receiving a PA monitor as *Material* because it was a motivating way for them to track their PA behavior. Participants also valued the *Modalities*. They indicated that the length and pace were appropriate, especially because the counselor could adjust timeframes as necessary, and they felt it was easy to connect because they could schedule sessions at their convenience and join from wherever. They also discussed the importance of receiving it both prior to and after MBS. Finally, their high satisfaction ratings with the intervention and support for future implementation provide further evidence to suggest that the intervention was acceptable to participants
Research likes
Participants talked about 4 main components they liked about the protocol/study methods and that motivated them to engage in increasing their PA. These were: *Interaction with research staff*, *Content*, *Material*, and *Non-specific*. Participants remarked that the research staff available, effective in their communication, offered understandable instructions, and conducted assessments professionally as they were courteous, respectful, and sympathetic. Additionally, the *Content* (i.e., written instructions) were understandable and participants reported that they were comfortable following the protocol for the accelerometer because they did not view it as too burdensome or invasive. Finally, their high satisfaction ratings with the research and support for future implementation also suggest that the research protocol/study methods were acceptable to participants
Intervention dislikes
Participants discussed dislikes about the intervention that could thwart their motivation to engage in the intervention. These formed 3 subthemes: *Content*, *Material*, and *Modalities*. One identified dislike was that participants were interested in receiving supervised PA training, and thus commented that it was lacking from the intervention content. Also, participants reported skipping doing activity sheets if they believed they were redundant; they did not view them as useful. In terms of the *Material*, participants noted that they were not comfortable using the Polar watch. They indicated that, due to its features, functionality, and poor perceived accuracy, they felt that other devices would be better. Furthermore, as *Modalities* preferences vary among participants, some participants found it difficult to engage in sessions because their children disrupted their concentration. Dosage (i.e., session duration, intervention length, amount and pacing of sessions) was also an issue for some participants. In particular, they noted that it was 'not long enough' and not spread out enough for them to adapt their own lifestyle and routine
Dislike about research
Participants provided 3 subthemes for dislikes about the protocol/study methods: *Content*, *Material*, and *Modalities*. Identified issues with the content were that the questionnaires were long, comprised redundant, unclear, or ambiguous items, and information provided about the intervention components was incomplete. Some participants viewed some of the *Material* as bothersome and non-user friendly (i.e., accelerometer) or burdensome and pointless (i.e., journals). Last, in terms of *Modality*, one issue some participants noted was that research staff did not provide clear instructions about the accelerometer protocol, which led them to feel guilty about not adhering to the protocol. It was also noted that frequency of communication was insufficient, and, there was not enough follow-up by research staff to ensure participants completed research-related tasks on time
Benefits to participants
Participants described how the intervention positively impacted their *Physical*, *Psychosocial*, and *Behavioral* functioning. They indicated reduced fatigue, improved general and heart health, and enhanced physical condition as a result of engaging in more PA. Additionally, participants reported that the intervention allowed them to release negative emotions and improve their mood and wellbeing. They also felt the intervention facilitated interactions with others, including family, which in turn led them and their families to become more motivated collectively to engage in PA. In turn, participants engaged in more PA with their families, allowing them to spend more time together while moving more, sitting less, and doing new activities
Still, being involved in the intervention did not change *Physical*, *Psychosocial*, and *Behavioral* functioning for some participants, which they believe were attributable to their PA behavior remaining unchanged or not having changed for long enough. As well, one participant reported worsened pain
Recommendations for future
While participants were generally satisfied with the intervention and protocol/study methods they provided suggestions that could help better align the *Intervention* and *Research* with their needs and preferences. First, participants felt to further promote PA behavior change and improvements in functioning they would require psychological care *and* exercise training sessions. Second, participants noted that making sessions longer and offering them across a longer timeframe (especially after MBS) could facilitate further changes for those seeking additional support. Third, future research should employ a variety of strategies to help participants successfully complete research tasks and provide participants with a comprehensive user-friendly schedule of activities/tasks. Fourth, participants highlighted the importance of having someone who could: support participants while they perform assessments and communicate with participants more often. Last, they indicated that they should be more opportunities for participants to share their perspectives and suggested adding open-ended questions

PA physical activity

provided in the Supplemental Files. The global results for the nine participants with valid phase A1 and phase B1 accelerometer data showed a significant reduction in MVPA from phase A1 to B1 [Tau-$U_{A1\ vs.\ B} = -0.30$ (CI lower; CI higher, -0.37; -0.75) with a MVPA mean change $= -0.9$ min per day (min, -6.2 min per day; max, 9.7 min per day)], and a significant increase from phase A1 to A2 [Tau-$U_{A1\ vs.A2} = 0.32$ (CI lower; CI higher,

Table 4 Comparison of moderate-vigorous physical activity accelerometry data between phases A1 and B1, between phases A1 and A2

Participants	A1 vs. B1			A1 vs. A2		
	Mean change (minutes per day)	Tau (CI lower; CI higher)	Randomization test p-value	Mean change (minutes per day)	Tau (CI lower; CI higher)	Randomization test *p*-value
1	−2.48	−0.37 (−0.75; −0.20)	.60			-
2	9.67	0.14 (−0.42; 0.63)	.60	26.21	**0.63 (0.15; 0.87)***	.13
3	−6.24	**−0.80 (−0.96; −0.29)***	.80	−0.64	0.11 (−0.60; 0.72)	.66
6	−1.86	0.11 (−0.64; 0.49)	.80			-
7	−8.21	−0.40 (−0.73; 0.06)	.31	−9.52	−0.12 (−0.54; 0.35)	.13
8	−1.06	−0.39 (−0.79; 0.24)	.40	8.79	0.10 (−0.48; 0.61)	.33
10	5.19	0.17 (−0.34; 0.60)	.17			-
11	−0.64	−0.04 (−0.47; 0.41)	.08	6.94	**0.63 (0.27; 0.84)***	.08
12	−2.75	**−0.72 (−0.88; −0.41)***	.50	1.52	0.29 (−0.17; 0.65)	.17
Total	−0.93	**−0.30 (−0.37; −0.75)***	.09	5.55	**0.32 (0.11; 0.51)***	**<.002**

*$p \leq .05$; *CI* coefficient interval

Bold values are statistically significant values

0.11; 0.51) with a MVPA mean change = 5.6 min per day (min, −9.5 min per day; max, 26.2 min per day)] (Table 3). Findings from sensitivity analyses (randomization test) are provided in Table 3.

Generalization Measures

At least one minimal clinically important difference for psychosocial outcomes (anxiety and depressive symptoms, quality of life) was reached by 10/11 (90.9%) participants during phase B1 (during the intervention) and during phase A2 (post-intervention) (Supplemental Files). At least one minimal clinically important difference for anxiety and depressive symptoms was reached by 4/5 (80.0%) participants with mental health disorder during phase A2 (post-intervention) (Supplemental Files).

Regarding self-reported *overall* MVPA, only 1/11 (9.1%) participant reached ≥ 150 min per week during phase A2 (post-intervention), and 3/11 (27.3%) had an increase of 30 min per week during phase A2 compared to phase A1 (baseline) (Supplemental Files). In terms of self-reported *leisure-time* MVPA, 5/11 (45.5%) participants increased their MVPA by 30 min per week from phase A1 to A2 (Supplemental Files). All participants showed stable self-reported sitting time.

Internal Validity

Supplemental Files describe significant life events that occurred during the study period for each participant, which may have impacted any reported results. Briefly, one participant reported helping for house renovation during phase A1 (baseline), four reported significant life events during phase B1 (during intervention) (i.e., worrying medical results, severe anemia and wrist surgery, COVID-19, and two family members passing), and one reported having COVID-19 during the phase A2 (post-intervention).

Discussion

The aims of the present study were to assess the feasibility and acceptability of the TELE-BariACTIV protocol/methods, test the intervention, and acquire preliminary data on its effects on MVPA among adults prior to MBS.

Feasibility and Acceptability

The quantitative results provide support for the first hypotheses on the feasibility and acceptability of the TELE-BariACTIV protocol/methods and intervention as evidenced by meeting or exceeding a priori satisfaction criteria. The data collection and intervention were designed to eliminate the need for face-to-face meetings to enhance accessibility, ease, and inclusivity, while addressing barriers to PA and research-reported adults awaiting MBS. This approach appeared to be effective in this regard as evidenced by satisfactory refusal, retention, intervention attendance, and intervention attrition rates.

While the recruitment rate of 1.2 participants per month was below the target rate of 1.8, it was likely explained by COVID-19 pandemic circumstances—i.e., MBS procedures were stopped in Quebec during the winter months of 2021–2022 so it was not possible to include participants, the increased workload of nurses or dieticians involved in

the recruitment led to lack of time for research, and flyers and posters were not allowed in the clinic waiting rooms. Moreover, participants were possibly apprehensive about social contact and worried they could not engage in PA in isolation (especially if they did not have PA equipment in their household).

Missing data from the questionnaires were below the expected 10%, possibly due to the close monitoring of the research assistants by email and telephone reminders, as well as the ability for participants to complete questionnaires remotely via Limesurvey. However, missing data for accelerometer based daily MVPA was higher than 10%, which worsened across phases. This amount of missing data was due to the low compliance with wear time guidelines as opposed to device failure. Nonetheless, analysis of each timepoint showed that 100% of participants complied with guidelines, regardless of randomization, and thus had valid data that could be analyzed for phase A1. This dropped to 81.8% of participants for phase B1, and 54.5% of participants for phase A2. As a result, this meant that data for only nine participants could be considered when comparing phases A1 and B1, and only six participants when comparing phases A1 and A2. Larger longitudinal cohort studies in participants after MBS reported that 78% (baseline assessment) to 57% (1-year post-MBS assessment) of participants had valid accelerometer data [59, 60]. Comparisons with other studies conducted in MBS adults are difficult, due to variability in protocols (e.g., design, valid wear time criteria, time of assessment).

Qualitative results also provide further support for high acceptability of the TELE-BariACTIV protocol/methods and intervention. Participants who enrolled reported high levels of satisfaction with the research process and the intervention. Participants expressed appreciation for being able to engage and interact with the PA counselor and the research staff. The acceptability of the intervention was also confirmed by the PA counselor, having reported good relationships with participants, and high levels of global and technology satisfaction. Intervention timing (pre-MBS), flexibility in scheduling, accessibility with online sessions, and content (motivating, relevant, interesting, understandable, and pleasant) were also appreciated by participants. Other studies reveal adults before and after MBS appreciate telemedicine and telehealth intervention [21, 61]. Another aspect that contributed to participants' satisfaction was the benefits they perceived from their participation, such as health, physical fitness, well-being, and mood, which align with past research [7, 62]. Desirable behavioral changes were also noted by participants (less sitting, moving more) in their interview, though the self-report data did not support less sitting time.

Lessons Learned and Participant Suggestions for Improvement

The use of qualitative data enabled the identification of areas for improvements to optimize the TELE-BariACTIV protocol/methods and intervention. Regarding the intervention, participants suggested that adding telehealth supervised exercise training would enhance their experiences. The addition of this component is possible, especially given our previous work that shows it is feasible and acceptable in adults awaiting MBS [61]. Increasing the length (from 6 weeks) to have more sessions and spreading out sessions (from weekly) was also suggested. However, adding more sessions would require additional resources, and it is unclear whether such additions would translate into larger behavioral changes. Stepped care interventions could be an alternative for non-responders without engaging excessive additional resources [63]. Future studies should assess the cost of the intervention to determine if it is cost-effective and in turn have cost data to share with stakeholders. The polar watch (A370 Polar© watch), offered to participants to self-monitor their PA, was not extensively appreciated. As self-monitor PA is effective [64], the choice of another monitor with the help of patient partners seems justified for future studies.

Regarding areas for improvement for the methods/protocol, given the negative ethical, scientific, and economic implications of an ineffective recruitment strategy [65], all other strategies not used in this study need to be carefully considered and could be added in future trials, such as incentives for clinicians assisting with recruitment (e.g., payment, authorship on research papers), involvement of patient partners in designing recruitment materials design and procedures, telephone reminders, and better communication about the time commitment, potential harms and benefits of the trial [66–68]. Missing accelerometer data is also a major concern in research that could bias results [69]. Based on the qualitative data and studies conducted in children with obesity and in adults, additional strategies to improve compliance with accelerometer wearing should be implemented in future studies among MBS patients such as scheduled reminders for research assistants and participants, clear instructions for participants, comprehensive user-friendly schedule of activities/tasks, wrist-worn rather than hip-worn accelerometer, 24-h wearing protocol, and financial prorated incentives [70, 71].

Secondary Outcomes

Promoting stronger engagement and continued participation in MVPA among adults receiving MBS is a crucial focus for clinicians. The current results provide preliminary evidence that a theory-based intervention can

increase MVPA before MBS. However, there was a significant reduction in daily MVPA during the intervention (phases A1 vs. B1), although sensitivity analysis did not confirm this significant decrease with a *p*-value above 0.05 ($p = 0.09$). This significant decrease of daily MVPA during the intervention may be explained by life events occurring before (house renovation) and during the intervention (COVID-19, relatives' passing). Also, a reaction effect to accelerometer assessments has been previously observed. It may explain a relatively high level of MVPA during the baseline phase [72]. Overall, the TELE-BariACTIV intervention yielded a statistically significant increase in MVPA after the intervention (phases A1 vs. A2) that represented a small effect size (Tau-$U_{A1\ vs.A2} = 0.32$). While the practical significance of this effect magnitude is unknown, it is in line with the effect size reported in a meta-analysis on the efficacy of theory-based interventions promoting PA in adults ($d = 0.31$, 95% CI [0.24, 0.37], $k = 82$) [11]. As evidence supporting the importance of PA for MBS patients and the effectiveness of interventions supporting behavior change interventions [4–6, 10–12], more studies that aim to implement and evaluate how such interventions can be implemented efficiently in practice are warranted.

Although not one of the primary aims of this study, the results support that behavioral interventions can have positive effects on quality of life, anxiety, and depressive symptoms. Nearly all (91%) participants reported clinically important improvements in one or more outcomes after the intervention. This finding is in line with previous meta-analyses showing positive effects of PA increases on mental health among adults with obesity or chronic diseases [73, 74]. However, further investigations are needed to confirm these findings and add to the current low level of evidence in a perioperative context [75].

Study Strengths and Limitations

This study is one of the first steps in the rigorous development of a behavioral intervention aimed at increasing MVPA in adults awaiting MBS. The evidence-based, patient-centerd, and theory-based intervention, as well as the use of distance-based means to collect data and to deliver the intervention, are strengths of this study. In addition, the use of complementary quantitative and qualitative methods ensured that participants were given a voice to optimize the intervention and research procedures, and to understand the perceived benefits of the intervention. Finally, the device-based assessment of MVPA limited recall bias and other limitations of self-report questionnaires. However, the present study has some limitations. Given the small sample size, recruited in the province of Quebec during the COVID-19 pandemic, and the inclusion of only one man and one Hispanic woman, the generalization of the results to a larger population and other contexts is limited. Finally, some participants did not have valid accelerometer data, and thus were excluded from the statistical analysis comparing phase A1 to B1, and A1 to A2. Thus, the conclusions could be biased because the characteristics of participants with and without valid data could be different.

Conclusions

Both quantitative and qualitative results support the feasibility, and acceptability of the TELE-BariACTIV protocol/methods and intervention, despite a low recruitment rate, which may be partly explained by the unique circumstances of the COVID-19 pandemic. This study provides the first evidence of a potential effect of the TELE-BariACTIV on daily MVPA. These promising findings warrant testing of the TELE-BariACTIV intervention in a future efficacy trial.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11695-024-07161-0.

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Data Availability The R syntax for main analyses is provided on the Open Sciences Framework (https://osf.io/vpmzf/). Raw MVPA, light PA, sedentary time, daily steps, and pain score data are available in Supplemental Files. Other data described in the manuscript and code book will be made available on request pending application.

Declarations

Ethics Approval Ethics approval was obtained from three institutions: Quebec Heart and Lung Institute, Sacré Cœur Hospital, Montreal [Centre Intégré Universitaire de Soins et de Services de Santé (CIUSSS) du Nord-de-l'Île-de-Montréal] and Chicoutimi Hospital, Chicoutimi [CIUSSS Saguenay–Lac-Saint-Jean]. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Conflicts of Interest AT and LB received funding from Johnson & Johnson, Medtronic, and GI Windows for studies on bariatric surgery. AT has been a consultant for Biotwin, Bausch Health, Novo Nordisk, and Eli Lilly. MFL has been a consultant for Eli Lilly, Novo Nordisk, Rhythm, and Takeda and received research funding from Merck Canada and Novo Nordisk. AT and LB are codirectors of the Research

Chair in Bariatric and Metabolic Surgery at Laval University. AB, MA, PB, JL, DB, PYG, JB, PB, and AJR have no conflict of interest.

Human Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Study Registration and Analytic Plan Registration The study protocol with analytic plan was previously registered in Baillot et al. (2022). Acceptability and Feasibility of the Telehealth Bariatric Behavioral Intervention to Increase Physical Activity: Protocol for a Single-Case Experimental Study. *JMIR Res Protoc*, *11*(9), e39633.

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