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Title: Effects of technology-based physical activity interventions for women after bariatric surgery: study protocol for a three-arm randomized controlled trial

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ABSTRACT

Introduction. A recent meta-analysis provided proof of efficacy for mobile technology to increase physical activity or weight loss in the short term. Videoconferencing may also be effective, especially as it reduces the barriers related to face-to-face physical activity interventions. Both technologies seem particularly interesting for bariatric surgery management, but their long-term effects on physical activity maintenance are unknown. Moreover, the mechanisms underlying their effectiveness, such as technology acceptability and motivational processes, have not been examined.

The objectives of this study are to determine the effects of two technology-based (mobile technology and videoconferencing) physical activity programs after bariatric surgery compared to standard care and to assess the contribution of acceptability and motivational mechanisms in explaining these effects on physical activity, physical measures, and health indicators.

Methods and analysis. One hundred and twenty young women who have undergone bariatric surgery in the last 3 to 6 months will be included. The volunteers will be randomly assigned to one of three arms: standard care (Control), access to an internet-based physical activity program delivered by an eHealth platform associated with an activity bracelet (ACTI-MOBIL), or access to a physical activity program delivered via videoconferencing (ACTI-VISIO). The primary outcome is the distance traveled during a 6-minute walk test relativized according to Capadaglio's theoretical distance. Secondary outcomes are behavioral measures of physical activity, physical measures, health indicators, technology acceptability, and motivational concepts. Data will be collected baseline (T0), 3 months (T3), and 6 months later (T6). The technology groups will receive a PA program for 12 weeks (between T0 and T3). A mixed model approach will be used to analyze the change in outcomes over time for each group.

Ethics and dissemination. This study protocol has been approved by the relevant Ethics Committees and the results will be disseminated through conference presentations and peer-reviewed publications.

Trial registration number. NCT04478331

KEYWORDS

Obesity; physical activity; information and communication technology (ICT); engagement; active lifestyle; bariatric surgery; technology-based program; eHealth; videoconferencing; mobile application

Strengths and limitations of this study

- Mobile technology and videoconferencing seem particularly interesting for promoting physical activity in bariatric surgery.
- Comparisons of the effects of two technology-based physical activity programs after bariatric surgery will lead to new recommendations for patients.
- This study will also provide a better understanding of the technology acceptability and motivational constructs in mediating the effects of the two technology-based physical activity programs.
- One potential challenge of this trial may include low compliance rates, especially toward physical activity recommendations, in bariatric surgery patients.

INTRODUCTION

Background

Bariatric surgery (BS) is currently the most effective treatment for severe obesity [1]. However, BS alone is insufficient to maintain weight loss and must be combined with physical activity (PA) lifestyle interventions [2,3]. Women are more concerned than men by physical inactivity and sedentary behaviors, both in the general population [4] and in obesity [5]. Therefore, promotion of PA is essential in the obesity management among women. Despite a multidisciplinary approach, long-term monitoring of BS recipients is poor, and this can lead to health complications. One year after BS, between 10 to 40% of patients are lost to follow-up, and young age is a main predictor of poor 5-year follow-up [6]. PA is the area with the lowest compliance rate, and new strategies that improve PA maintenance might help to sustain monitoring [7]. Technology-based PA promotion programs have been shown to be relevant for this aim [8,9], and several technologies for use in vulnerable populations have been investigated in recent years. Among them, active video games [10,11], virtual reality [12], connected devices [13], mobile applications [14], internet-based and social media [15,16], and videoconferencing [17] have been shown to increase the PA level in the short-term, but the medium and long-term effects of these technologies are not well known. These technologies may be relevant for promoting post-BS PA, but low-cost and widely used technologies such as smartphones should be preferred [18]. To classify potentially useful technologies, the 'Coventry, Aberdeen & London – Refined' (CALO-RE) taxonomy could be used to group them according to the behavioral change techniques they incorporate [19]. According to this taxonomy, mobile applications, internet-based platforms and devices like activity bracelets activate the main behavioral strategies like goal-setting, self-monitoring and personal feedback [20]. Recent meta-analyses have provided proof of efficacy for mobile technology compared to control condition [21] or offline interventions [20] to increase PA or decrease weight in the short term, but the long-term effects have been insufficiently studied [20,21]. Another review identified self-monitoring, feedback, goal-setting and shaping knowledge as key components of effective eHealth interventions for weight loss maintenance [22]. Based on these data, we assume that mobile technology will have long-term positive effects on PA in BS patients.

Furthermore, videoconferencing for PA includes monitoring by a professional, social support, teaching motivational strategies, use of communication skills, and goal-setting [23]. These features are part of both videoconferencing and face-to-face PA interventions [24], which may explain the lack of outcome differences between these two types of interaction [25]. Videoconferencing seems to be effective after BS, especially as it reduces some of the barriers of face-to-face PA interventions (e.g., travel time, distance of offers). Despite a limited sample size, videoconferencing proved to be effective in improving the physical fitness of women waiting for BS [17]. Both types of technology (mobile technology and videoconferencing) seem promising in BS, but their long-term effects on PA maintenance are unknown.

In addition, the mechanisms underlying the adoption or rejection of technologies in healthcare remain insufficiently studied. Indeed, acceptability is often reduced to a measure of satisfaction [26,27], which does not take into account the mechanisms underlying the adoption or rejection of a given technology. For this purpose, it is necessary to use models like the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) [28], which is the most comprehensive and parsimonious model [29] to measure acceptability in the early stages of use. As some technologies are better accepted than others, we can assume that the effects of these technologies may be mediated by their acceptability.

Furthermore, the effectiveness of PA interventions can be explained by motivation processes [30]. The role of motivational constructs in PA behavior in the field of obesity has been studied through self-determination theory (SDT) [31,32]. SDT is a macro-theory that notably highlights the types of motivation (i.e., intrinsic, extrinsic, amotivation) along a continuum [33], the needs that individuals attempt to satisfy (i.e., autonomy, competence, relatedness) [34], and the individual differences in motivation orientation (i.e., autonomy, control, impersonal) [35]. A systematic review of obesity studies showed that higher autonomous motivation, self-efficacy and self-regulation skills are predictors of increased PA [31]. Moreover, the use of motivational strategies can lead individuals to practice PA regularly and build habits [36]. To become a habit, a positive behavior must be integrated into the natural environment, disrupting old environmental cues and establishing new ones [37]. The changes associated with BS make this period ideal for the creation of new habits. The technologies we

have selected (mobile technology and videoconferencing) are not based on the same behavioral strategies, but both have the potential to lead to habit development, and we assume that they will be more suitable depending on motivational characteristics. Few randomized control trials (RCTs) have measured motivational concepts, and yet doing so might explain why some technologies are more effective for some people than for others.

The study aims

This study aims to investigate (1) the effects of two technology-based PA programs (mobile technology and videoconferencing) after BS compared to standard care and (2) the contribution of acceptability and motivational mechanisms in explaining these effects.

The main objective is to evaluate the effects of the two technology-based PA programs on the functional capacity of young women after BS. We expect that the technology groups (ACTI-MOBIL and ACTI-VISIO) will report a higher level of functional capacity at the end of the interventions (T3) compared with the control group, and that this effect will be sustained 3 months later (T6). We do not hypothesize the superiority of one technology over the other, because to our knowledge no study has yet compared them after BS.

The secondary objectives are (1) to evaluate the effects on behavioral measures of PA, physical measures, and health indicators in the technology groups compared with the control group, and (2) to explore the role of acceptability and motivational mechanisms in explaining these effects. We expect that participants in the technology groups (ACTI-MOBIL and ACTI-VISIO) compared with the control group will show: an improvement on the PA behavioral measures, an improvement on physical measures, and better health indicators. We also expect that these effects will be sustained 3 months later (T6). Technology acceptability based on theoretical models is not usually measured in RCTs [38,39], and acceptability as assessed by the UTAUT2 model has never been measured for technology-based PA interventions in the context of BS. In addition, few RCTs have measured motivational concepts. We assume that technology acceptability and motivational concepts may mediate the effects of technology-based interventions on PA behavioral measures, physical measures or health indicators.

METHODS AND ANALYSIS

Design

Participants will be randomly assigned to one of three groups: an eHealth platform associated with an activity bracelet (ACTI-MOBIL group), a PA program delivered via videoconferencing (ACTI-VISIO group), or standard care (Control group) (Figure 1). Outcomes will be assessed at baseline (T0), 3 months (T3), and 6 months later (T6). The technology groups will receive a PA program for 12 weeks (between T0 and T3). Each participant will be included for a period of 6 months, on average 3 to 6 months after the BS. Approximately 8 months of recruitment will be required to reach the target sample size. Thus, the total expected duration of the study is 14 months.

Participants

To be eligible for the study, individuals must be women between 18 and 40 years old and undergone BS 3 to 6 months ago at a tertiary referral center for BS (Nice University Hospital, France) with respect to the national recommendations [41]. Participants will not be included if they have a smartphone incompatible with the proposed technologies. They will be excluded from the study in cases of a serious adverse events, withdrawal of informed consent or violation of the protocol. A serious adverse event reporting form, validated for research, and a classification of serious and non-serious adverse events will be made available to those involved in the research protocol to assist them in the management of adverse events. Participants may participate in another research protocol if it does not involve new technologies and does not impact PA levels or fitness measurement.

Recruitment and randomization

Participants will be recruited by the clinicians at the Nice University Hospital in the south of France. Clinicians will give a general explanation of the study to potentially eligible patients, along with written information, and the participants can ask any questions before signing a written informed consent form. Individuals will then undergo all baseline measurements, supplemented by information on their professional occupation, education level, marital status, and a description of their PA in the

last 5 years. They will then be assigned by the last author to one of the three arms using MinimPy software [42] in a 1:1:1 ratio. The minimization randomization method will be used to avoid any imbalance between the three groups. We will stratify on age (≤ 30 years; > 30 years) and the type of BS (sleeve gastrectomy, gastric bypass, other). After randomization, participants will receive a second written information form with details on their allocation group and will be invited to sign a second informed consent form. This procedure of two times consent [43] will be used to avoid deceiving the participants about their allocation and preserve the validity and blinded aspect of the trial [44]. Recruitment has not yet started and will begin in the coming months.

Interventions

All interventions are similar in terms of recommended PA level: at least 150 minutes per week, with a goal of 300 minutes per week of moderate to vigorous PA including muscle strengthening exercises 2-3 times per week [3]. The technology groups will receive similar PA programs twice a week for 12 weeks (between T0 and T3), combined with advice and counseling about walking activities to achieve the recommendations.

Control group

The Control group will receive the usual care (also be provided in the ACTI-VISIO and ACTI-MOBIL groups) that includes two individual motivational interviews with a PA professional and a group workshop during the first year following BS to help participants achieve the PA recommendations. No face-to-face PA sessions will be offered as part of the usual care.

ACTI-VISIO group

The PA sessions will be delivered via videoconferencing system developed by Mooven™. The PA program consists in tailored adapted PA sessions led by a professional specialized in adapted PA. These sessions were specifically designed to be appropriate for the population and to ensure standardization of the recommended volume of PA. The PA sessions will be given live, individually at the beginning and then in groups of four women. During sessions, the professional and the participants will interact simultaneously, and the execution of the exercises will be monitored and adapted live by the professional. To ensure the safety of the PA, a rating of perceived exertion (RPE) will be requested

after each session on a 10-point scale. If the RPE exceed 7, the professional specialized in adapted PA will adjust the training load. In addition, the sessions will also include advice and tips for reaching the recommended PA level. After randomization, the women will receive registration details to create a personal account. Participants will then have to select practice times for two sessions per week. Technical assistance will be provided in cases of configuration difficulties. For participants who are absent for a scheduled session, a reminder will be made by phone for the next session.

ACTI-MOBIL group

The PA sessions will be delivered by an eHealth platform associated with an activity bracelet. The eHealth platform is a bariatric online module developed by BePatient™ in collaboration with the authors to enrich PA content and ensure standardization of the recommended volume of PA. The module used in the present trial consists of tips for reaching the PA level, PA questionnaires, PA feedback measured by the activity bracelet, and a video demonstration of PA sessions performed by a peer. To ensure the safety of the PA, the sessions were designed to be appropriate for this population and the RPE will be measured after each session on a 10-point scale. If the RPE exceeds 7 for 3 consecutive sessions, the training load will be adjusted. The platform will also include a variety of content, including dietary tips, obesity-related facts, information about surgery, and frequently asked questions. After randomization, the women will receive registration details to create a personal account and their activity bracelet synchronized to the platform to visualize their PA. Technical support will be provided in cases of configuration or synchronization difficulties. For the women whose activities have not been detected on the platform one week after the start of the program, a reminder will be given by phone.

Outcome measurements

Table 1 provides a summary of the measures to be collected. Outcomes will be assessed at baseline (T0), 3 months (T3), and 6 months later (T6). An outpatient visit will be scheduled in conjunction with routine care to perform physical assessments with a professional unaware of the allocation and hypotheses of the study. Self-report questionnaires will be completed directly by the participants

online using LimeSurvey CE, version 2.06+ or with paper-and-pencil. A reminder will be made by phone to schedule another visit in case of absence.

Table 1. Summary of measures to be collected

Outcomes	Instrument	Time of measurement
Primary outcome		
Functional capacity	6MWT distance [45,46]	T0, T3, and T6
Secondary outcomes		
Behavioral measures		
Physical activity level	GPAQ [47]	T0, T3, and T6
	7 days AX3 PA monitoring [48,49]	T0, T3, and T6
Stage of change	SOC [50]	T0, T3, and T6
Physical measures		
Energetic consumption	VO_2, VE, VCO_2, RER, HR measured using Cosmed K5 system [51]	T0, T3, and T6
Muscle strength	Maximal isometric knee extensor muscles strength (Newton) measured with MicroFET2 [52]	T0, T3, and T6
Health indicators		
Quality of life	EQ-5D, EQ-VAS [53]	T0, T3, and T6
Body mass index	Height	T0
	Body mass	T0, T3, and T6
Body composition	Muscle mass, fat mass, bone mineral content measured with Biody Xpert^{ZM}	T0, T3, and T6
Other measures		
Technology acceptability	eHealth acceptability scale [54]	T0, T3, and T6 except for control group
Program compliance	Rate of participation and RPE	T3 except for control group
Motivation for PA	EMAPS [55]	T0, T3, and T6
General causality orientation for PA	GCOS [56]	T0, T3, and T6
Basic psychological needs	BPN [57]	T0, T3, and T6

Notes. 6MWT, Six-Minute Walk Test; VO_2, oxygen uptake; VE, minute ventilation; VCO_2, carbon dioxide output; RER, respiratory exchange ratio; HR, heart rate; PA, physical activity; BS, bariatric surgery.

Primary outcome

The primary outcome is functional capacity assessed by distance traveled during a six-minute walk test (6MWT) performed according to guidelines [45] and with high reproducibility in obesity [58].

Due to weight loss during BS follow-up regardless of PA, the distance traveled in 6MWT increases after BS [59]. Therefore, we will use Capodaglio's formula including age, sex and body mass index (BMI) to relativize the walking distance [46].

Secondary outcomes

Behavioral measures of PA

PA level. PA will be measured using the Global PA Questionnaire (GPAQ) validated in the French language [47]. This scale comprises 16 items to assess the frequency and duration of PA during work, transportation, leisure time, and time spent sitting in a typical week. The items are used to calculate the energy expenditure score in metabolic equivalent tasks (METs), where 150 minutes per week of moderate to vigorous PA corresponds to 600 MET-min/week. This self-reported measure will be complemented by an objective evaluation using the Axivity AX3 triaxial accelerometer (AX3, Axivity, Newcastle, UK) worn on the wrist. The sensor will be set to begin recording at midnight the day after the appointment over a 7-day period at 100 Hz with a dynamic range of ±8g. The AX3 data will be downloaded, resampled, calibrated and analyzed using open-source AX3 OmGui software (OmGui Version 1.0.0.43, Open Movement, Newcastle University, UK). The AX3 sensor and its wrist location were chosen for their ease of use, reliability, accuracy, and validity, including in the field of obesity [48,49].

Stage of Change for PA. The stage of change for PA and exercise related to the Transtheoretical Model [60] will be measured using the French version [50] of the Stages of Change questionnaire [61]. Regular PA and exercise are defined as "at least 30 minutes per session, at least 5 days per week of moderate to vigorous PA." This questionnaire includes five items with a "yes" or "no" answer, transformed to attribute a score to each participant according to her stage (precontemplation=1, contemplation=2, preparation=3, action=4 or maintenance stage=5).

Physical measures.

Energetic consumption. Oxygen uptake (VO_2), minute ventilation (VE), carbon dioxide output (VCO_2), respiratory exchange ratio (RER) and heart rate (HR) will be measured during the 6MWT. These parameters will be measured using the Cosmed K5 system (Cosmed K5, Rome, Italy), which

consists of a mask and a portable unit. This equipment was chosen for its validity and reproducibility [51].

Muscle strength. The maximal isometric knee extensor muscles' strength of the left and right lower limb will be measured with the MicroFET2 (Hoggan Scientific, LLC, Salt Lake City, UT, USA). Women will be seated in a chair with the assessed limb placed at a knee angle of 90°. They will be asked to push as hard as possible for 5 seconds against the dynamometer held by a strap attached to the chair. The highest value in Newton (N) of three measurements will be recorded, and the average of both limbs results will be used for analysis. A similar measurement protocol has already been used in an obesity study [52].

Health indicators

Quality of life. Quality of life will be assessed with the French version of the EuroQoL-5-Dimensions (EQ-5D) and a EuroQoL-visual analog scale (EQ-VAS) [53]. The EQ-5D comprises five items measuring quality of life along five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each dimension, participants have five response options ranging from "no problems" to "unable." The EQ-VAS has a single item for which the women will be asked to rate their current health on a scale from 0: "worst imaginable" to 100: "best imaginable." This generic scale, which has previously been used in a BS study [62], was chosen to ensure consistency in the measurement of quality of life throughout weight loss.

Body mass index. Height (m) and body mass (kg) will be measured and used to calculate the BMI (kg/m^2).

Body composition. Body composition will be measured by bioimpedance using the Biody Xpert^{ZM} (Aminogram, France): muscle mass (kg), fat mass (kg), and bone mineral content (kg). For analyses these measures will be converted to percentages.

Other measures

Technology acceptability. The acceptability of technologies (ACTI-MOBIL and ACTI-VISIO groups) will be assessed by the French eHealth acceptability scale [54], including 25 items divided into eight subscales: performance expectancy, effort expectancy, social influence, facilitating conditions,

hedonic motivation, price value, habit, and behavioral intention. Women will rate each item on a 7-point scale ranging from 1: "strongly disagree" to 7: "strongly agree."

Program compliance. To measure technology-based program compliance, companies will be asked to report the presence or absence of women and their RPE at each session in a register (reported by the PA professional for ACTI-VISIO; completion, content consultation and validation statistics, PA level and number of days the activity bracelet is worn for ACTI-MOBIL).

Motivation for PA. The motivation for health-oriented PA will be measured with a French motivation scale for health-oriented PA [55]. This scale comprises 18 items, distributed across the six motivational constructs of SDT [33]: intrinsic motivation, integrated regulation, identified regulation, introjected regulation, external regulation, and amotivation. Participants will respond on a 7-point Likert scale ranging from 1: "strongly disagree" to 7: "strongly agree."

General Causality Orientations Scale for PA. Causality orientations will be measured using an adaptation of the General Causality Orientations Scale [56] to assess the strength of three motivational orientations (i.e., autonomy, control, impersonal) in the context of PA in a medical environment. The scale comprises seven vignettes and 21 items. Each vignette describes a situation and is followed by three items, one per motivational orientation, to which participants respond on a 7-point scale ranging from 1: "strongly disagree" to 7: "strongly agree."

Basic psychological needs. Basic psychological needs will be measured using a French scale validated in the sports context [57] where we replaced "sport" by "physical activity." This scale comprises 15 items distributed across the three needs: autonomy, competence, and relatedness. Participants will respond on a 7-point Likert scale ranging from 1: "strongly disagree" to 7: "strongly agree."

Data analysis and management

Sample size

Sample size for the study is based on the distance traveled during a 6MWT relativized with age, sex and BMI [46]. A recent meta-analysis showed an overall effect $Z = 2.52$ ($p = .01$) of change in functional walking after BS in an exercise group compared to a control group [64]. An overall effect $Z = 2.52$ correspond to $f = .20$ [65]. However, this effect size is probably minimized because it has not

been relativized according to BMI. Furthermore, eHealth PA programs for obese or sedentary individuals have an effect size of $d = .37$ [66], corresponding to $f = .19$ [65]. However, only 45% of eHealth interventions are based on theoretical models [67], which reduces their effectiveness. Given these limitations, a slightly larger effect size of $f = .25$ is considered. A total of 108 participants is necessary to keep power of 80% and alpha of 5% [68]. We anticipate that 10% of the participants will be lost to follow-up, will withdraw informed consent, or will be excluded from the study. Thus, with 120 women, 40 in each group, we consider our study to be sufficiently powered.

Data management

The recruiting clinicians will keep a register with a study number and all the identifiable data (name, phone number, pseudonymization code, and allocation group) for use during the follow-up. This register will be locked up with access only available to project investigators. Other data collected will be stored on a secured server with pseudonymization codes and no other personally identifiable information. The Department of Technology Systems at the University in collaboration with the Public Health Department of the University Hospital will handle the data management. To ensure the quality of the research, an audit may be carried out at any time by the Public Health Department of the University Hospital.

Data analysis

The level of significance for all statistical analyses will be set at .05 under the bilateral hypothesis. Missing data patterns will be analyzed and described. Less than 5% missing data is usually considered inconsequential [69], and simple methods will be used (e.g., last observation carried forward, mean, median). If more than 5% of the data is missing, these data will be handled by multiple imputation or maximum likelihood imputation [69,70]. The planning, implementation, analyses and final writing of the results will follow the recommendations of the CONSORT statements [71].

The normality of quantitative data will be assessed using a graphical method and a Shapiro test [72]. Simple mathematical transformations can be used if necessary to normalize non-normal data. The dimensional consistency of the subjective data will be calculated using Cronbach's alpha coefficient. To test the hypotheses, a mixed model procedure will be used. It should be noted that mixed models are highly recommended for repeated measurement analyses to take into account the non-

independence of the repeated measures [73,74]. Moreover, the mixed models can be used to analyze longitudinal mediated data [75]. The repeated measures will be considered as a longitudinal fixed factor. The condition (ACTI-MOBIL, ACTI-VISIO, CONTROL) representing the criterion of the analysis (the independent variable) will be considered as a fixed effect in the model. The intercept will be defined as a random factor that can vary for each participant. The acceptability of technologies and motivational constructs will be the mediating variables added to the mixed model.

ETHICS AND DISSEMINATION

This study was reviewed and approved by the French East 1 Protection of Persons Ethics Committee (number: 2020.A00172-37) and the French National Commission for Information Technology and Civil Liberties (number: UCA-R20-034). This study was registered in ClinicalTrials.gov Identifier: NCT04478331 (Registered July 15, 2020). The protocol (version 3, 15 October 2020) conforms to the principles of Good Clinical Practice and the Declaration of Helsinki and will be reported according to 2013 SPIRIT statement [40] (Additional file 1). Any modification of the research protocol must be subject to an authorization agreement from the Ethics Committee.

The datasets generated during the current study will be available from the corresponding author on reasonable request and archived for a period of 15 years.

A final scientific report of the research project, including the results and clinical outcomes of the study will be written by the principal investigator and sent to the Ethics Committees within one year of the research conclusion. Research summary results will be available to participants in accordance with the terms described in the information documents. The results of this trial will be disseminated through conference presentations and in peer-reviewed journals.

DISCUSSION

This study will provide insight into the effects of two technology-based PA programs (mobile technology and videoconferencing) post-BS. This study will also provide a better understanding of the acceptability and motivational constructs in mediating the effects of these technologies. Based on the

results, strategies to individually promote technology-based PA interventions and recommendations for implementing these programs will be developed.

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Competing Interests

The authors declare that they have no competing interests.

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Authors' contributions

FAL, MH, and VN conceived the project and procured the project funding. NC, AI, CP, SSC, AF contributed to the trial protocol. OD, JMG, AV, SSC, and MH conceptualized the interventions, developed the contents, and worked with the companies. FAL is leading the coordination of the trial. NC and AI are managing the trial including recruitment and data collection with the assistance of VN and MH. CP, FAL, and MH developed the plan for statistical analysis. MH and FAL drafted the

manuscript and coordinated the revisions. All other authors reviewed, edited, and approved the final manuscript.

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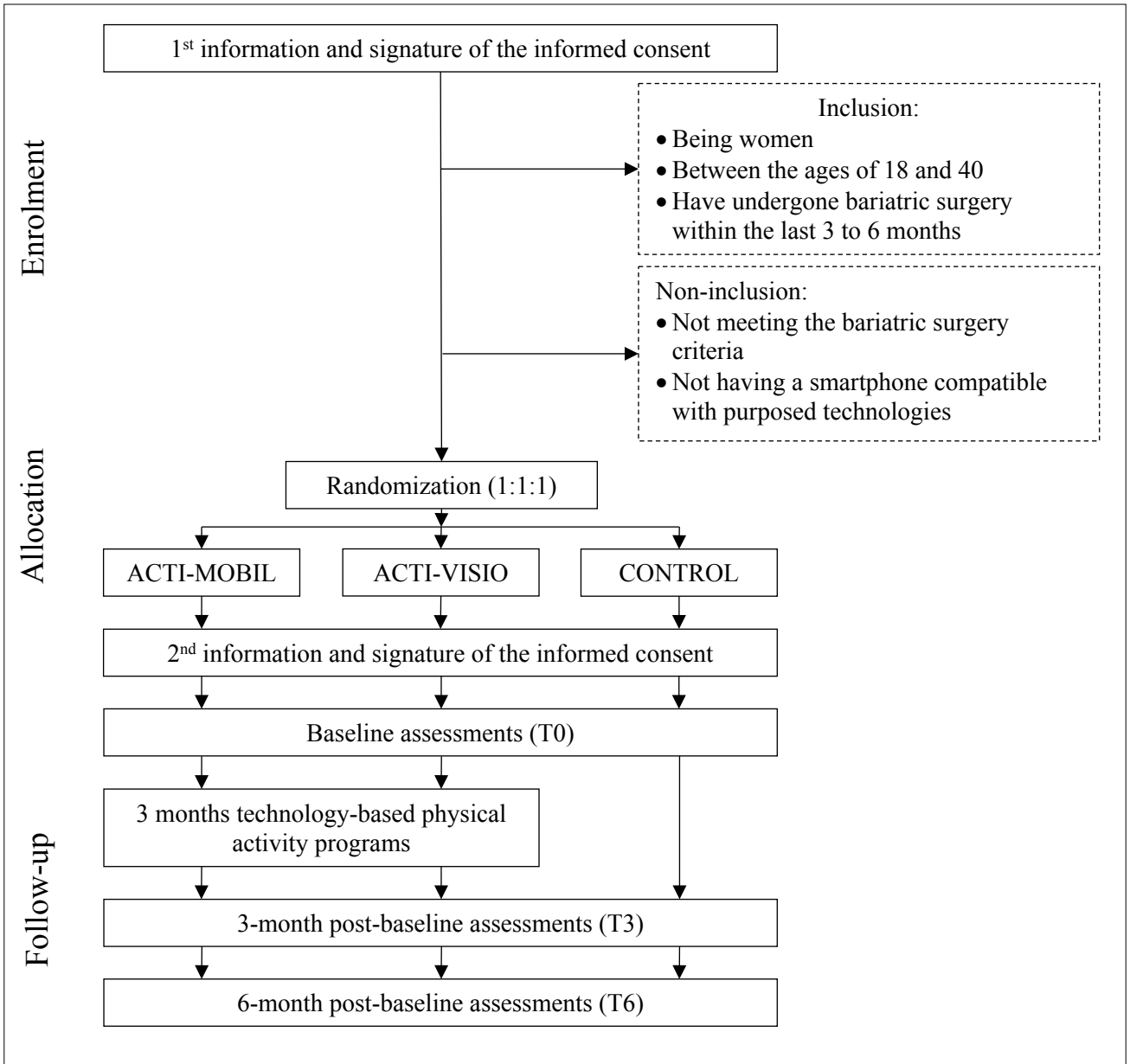
Figure legends

Fig. 1 Flow diagram of study protocol.

Additional material

Additional file 1 SPIRIT 2013 Checklist


Enrolment
1st information and signature of the informed consent
Inclusion:
• Being women
• Between the ages of 18 and 40
• Have undergone bariatric surgery within the last 3 to 6 months
Non-inclusion:
• Not meeting the bariatric surgery criteria
• Not having a smartphone compatible with purposed technologies
Allocation
Randomization (1:1:1)
ACTI-MOBIL
ACTI-VISIO
CONTROL
2nd information and signature of the informed consent
Baseline assessments (T0)
Follow-up
3 months technology-based physical activity programs
3-month post-baseline assessments (T3)
6-month post-baseline assessments (T6)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	15
Protocol version	3	Date and version identifier	15
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 17-18
	5b	Name and contact information for the trial sponsor	18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14; 17-18

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	10-11
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	7
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13-14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7-8
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7-8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7-8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8-9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A, blinding cannot be strictly guaranteed in this study, only strategies to limit potential bias were taken.

Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A, no interim analyses have been planned
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	7

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	14
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7-8, 17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A, no ancillary studies are planned
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17-18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A, no ancillary studies or post-trial care are planned
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	15
	31b	Authorship eligibility guidelines and any intended use of professional writers	17-18

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A consent form were written in French and revised by the French CPP.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A no biological specimens were collected as part of this trial

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Effects of technology-based physical activity interventions for women after bariatric surgery: study protocol for a three-arm randomized controlled trial

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Title: Effects of technology-based physical activity interventions for women after bariatric surgery: study protocol for a three-arm randomized controlled trial

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ABSTRACT

Introduction. A recent meta-analysis provided proof of efficacy for mobile technology to increase physical activity or weight loss in the short term. Videoconferencing may also be effective, especially as it reduces the barriers related to face-to-face physical activity interventions. Both technologies seem particularly interesting for bariatric surgery management, but their long-term effects on physical activity maintenance are unknown. Moreover, the mechanisms underlying their effectiveness, such as technology acceptability and motivational processes, have not been examined.

The objectives of this study are to determine the effects of two technology-based (mobile technology and videoconferencing) physical activity programs after bariatric surgery compared to standard care and to assess the contribution of acceptability and motivational mechanisms in explaining these effects on physical activity, physiological measures, and health indicators.

Methods and analysis. One hundred and twenty young women who have undergone bariatric surgery in the last 3 to 6 months will be included. The volunteers will be randomly assigned to one of three arms: CONTROL (standard care), ACTI-MOBIL (mobile technology), or ACTI-VISIO (videoconferencing). The primary outcome is the distance traveled during a 6-minute walk test relativized according to Capadaglio's theoretical distance. Secondary outcomes are behavioral measures of physical activity, physiological measures, health indicators, technology acceptability, and motivational concepts. Data will be collected at baseline (T0), 3 months (T3), and 6 months (T6). The technology groups will receive a physical activity program for 12 weeks (between T0 and T3). A mixed model approach will be used to analyze the change in outcomes over time for each group.

Ethics and dissemination. This study protocol was reviewed and approved by the French East 1 Protection of Persons Ethics Committee (number: 2020.A00172-37) and the French National Commission for Information Technology and Civil Liberties (number: UCA-R20-034). The results will be disseminated through conference presentations and peer-reviewed publications.

Trial registration number. NCT04478331

KEYWORDS

Physical activity; bariatric surgery; technology-based program; eHealth; videoconferencing; application

Strengths and limitations of this study

- Mobile technology and videoconferencing may improve the outcomes of bariatric surgery by promoting physical activity.
- Comparisons of the effects of two technology-based physical activity programs after bariatric surgery will lead to new recommendations for patients.
- This study will also provide a better understanding of the technology acceptability and motivational constructs in mediating the effects of the two technology-based physical activity programs.
- One potential challenge of this trial may include low compliance rates, especially toward physical activity recommendations, in bariatric surgery patients.

Abbreviations

6MWT, six-minute walk test; BS, bariatric surgery; MET, metabolic equivalent tasks; PA, physical activity.

INTRODUCTION

Background

Bariatric surgery (BS) is currently the most effective treatment for severe obesity [1]. However, BS alone is insufficient to maintain weight loss and must be combined with physical activity (PA) lifestyle interventions [2,3]. Women are more concerned than men by physical inactivity and sedentary behaviors, both in the general population [4] and in obesity [5]. Therefore, promotion of PA is essential in the obesity management among women. Despite a multidisciplinary approach, long-term monitoring of BS recipients is poor, and this can lead to health complications. One year after BS, between 10 to 40% of patients are lost to follow-up, and young age is a main predictor of poor 5-year follow-up [6]. PA is the area with the lowest compliance rate, and new strategies that improve PA maintenance might help to sustain monitoring [7]. Technology-based PA promotion programs have been shown to be relevant for this aim [8,9], and several technologies for use in vulnerable populations have been investigated in recent years. Among them, active video games [10,11], virtual reality [12], connected devices [13], mobile applications [14], internet-based and social media [15,16], and videoconferencing [17] have been shown to increase the PA level in the short-term, but the medium and long-term effects of these technologies are not well known. These technologies may be relevant for promoting post-BS PA, but low-cost and widely used technologies such as smartphones should be preferred [18]. To classify potentially useful technologies, the 'Coventry, Aberdeen & London – Refined' (CALO-RE) taxonomy could be used to group them according to the behavioral change techniques they incorporate [19].

According to this taxonomy, mobile applications, internet-based platforms and devices like activity bracelets activate the main behavioral strategies like goal-setting, self-monitoring and personal feedback [20]. Recent meta-analyses have provided proof of efficacy for mobile technology compared to control condition [21] or offline interventions [20] to increase PA or decrease weight in the short term, but the long-term effects have been insufficiently studied [20,21]. Another review identified self-monitoring, feedback, goal-setting and shaping knowledge as key components of effective eHealth

interventions for weight loss maintenance [22]. Based on these data, we assume that mobile technology will have long-term positive effects on PA in BS patients.

Furthermore, videoconferencing for PA includes monitoring by a professional, social support, teaching motivational strategies, use of communication skills, and goal-setting [23]. These features are part of both videoconferencing and face-to-face PA interventions [24], which may explain the lack of outcome differences between these two types of interaction [25]. Videoconferencing seems to be effective after BS, especially as it reduces some of the barriers of face-to-face PA interventions (e.g., travel time, distance of offers). Despite a limited sample size, videoconferencing proved to be effective in improving the physical fitness of women waiting for BS [17].

Mobile technology and videoconferencing are not based on the same behavioral strategies. Mobile applications incorporate strategies with technological regulations (e.g., self-monitoring, feedback, goal-setting, and shaping knowledge), while videoconferencing incorporates strategies with human regulations from both professional and other participants (e.g., social support, motivation strategies, communication skills, and goal-setting). The use of mobile applications is completely autonomous, while videoconferencing is regulated by pre-determined meetings. Both types of technology seem promising in BS, but their long-term effects on PA maintenance are unknown.

In addition, the mechanisms underlying the adoption or rejection of technologies in healthcare remain insufficiently studied. Indeed, acceptability is often reduced to a measure of satisfaction [26,27], which does not take into account the mechanisms underlying the adoption or rejection of a given technology. For this purpose, it is necessary to use models like the Unified Theory of Acceptance and Use of Technology 2 [28], which is the most comprehensive and parsimonious model [29] to measure acceptability in the early stages of use. As some technologies are better accepted than others, we can assume that the effects of these technologies may be mediated by their acceptability.

Furthermore, the effectiveness of PA interventions can be explained by motivation processes [30]. The role of motivational constructs in PA behavior in the field of obesity has been studied through self-determination theory [31,32]. Self-determination theory is a macro-theory that notably highlights the types of motivation (i.e., intrinsic, extrinsic, amotivation) along a continuum [33], the needs that individuals attempt to satisfy (i.e., autonomy, competence, relatedness) [34], and the

individual differences in motivation orientation (i.e., autonomy, control, impersonal) [35]. A systematic review of obesity studies showed that higher autonomous motivation, self-efficacy and self-regulation skills are predictors of increased PA [31]. Moreover, the use of motivational strategies can lead individuals to practice PA regularly and build habits [36]. To become a habit, a positive behavior must be integrated into the natural environment, disrupting old environmental cues and establishing new ones [37]. The changes associated with BS make this period ideal for the creation of new habits. The technologies we have selected (mobile technology and videoconferencing) are not based on the same behavioral strategies, but both have the potential to lead to habit development, and we assume that they will be more suitable depending on motivational characteristics. Few randomized control trials have measured motivational concepts, and yet doing so might explain why some technologies are more effective for some people than for others.

The study aims

This study aims to investigate (1) the effects of two technology-based PA programs (mobile technology and videoconferencing) after BS compared to standard care and (2) the contribution of acceptability and motivational mechanisms in explaining these effects.

The main objective is to evaluate the effects of the two technology-based PA programs on the walking capacity of young women after BS. We expect that the technology groups (ACTI-MOBIL and ACTI-VISIO) will report a higher level of walking capacity at the end of the interventions (T3) compared with the control group, and that this effect will be sustained 3 months later (T6). We do not hypothesize the superiority of one technology over the other, because to our knowledge no study has yet compared them after BS.

The secondary objectives are (1) to evaluate the effects on behavioral measures of PA, physiological measures, and health indicators in the technology groups compared with the control group, and (2) to explore the role of acceptability and motivational mechanisms in explaining these effects. We expect that participants in the technology groups (ACTI-MOBIL and ACTI-VISIO) compared with the control group will show: an improvement on the PA behavioral measures, an improvement on physiological measures, and better health indicators. We also expect that these effects will be

sustained 3 months later (T6). Technology acceptability based on theoretical models is not usually measured in randomized control trials [38,39], and acceptability as assessed by the Unified Theory of Acceptance and Use of Technology 2 model has never been measured for technology-based PA interventions in the context of BS. In addition, few randomized control trials have measured motivational concepts. We assume that technology acceptability and motivational concepts may mediate the effects of technology-based interventions on PA behavioral measures, physiological measures or health indicators.

METHODS AND ANALYSIS

Design

Participants will be randomly assigned to one of three groups: an eHealth platform associated with the Fitbit Inspire activity bracelet (ACTI-MOBIL group), a PA program delivered via videoconferencing (ACTI-VISIO group), or standard care (Control group) (Figure 1). Outcomes will be assessed at baseline (T0), 3 months (T3), and 6 months later (T6). The technology groups will receive a PA program for 12 weeks (between T0 and T3). Each participant will be included for a period of 6 months, on average 3 to 6 months after the BS. Approximately 8 months of recruitment will be required to reach the target sample size. Thus, the total expected duration of the study is 14 months.

Participants

To be eligible for the study, individuals must be women between 18 and 40 years old and have undergone BS 3 to 6 months earlier at a tertiary referral center for BS (Nice University Hospital, France) with respect to the national recommendations [40]. Participants will not be included if they have a smartphone incompatible with the proposed technologies. They will be excluded from the study in cases of a serious adverse events, withdrawal of informed consent or violation of the protocol. A serious adverse event reporting form, validated for research, and a classification of serious and non-serious adverse events will be made available to those involved in the research protocol to assist them

in the management of adverse events. Participants may participate in another research protocol if it does not involve new technologies and does not impact PA levels or fitness measurement.

Patient and Public Involvement

Patients were not involved in the development of the research question, the design, the recruitment or the conduct of the study. Results will be reported individually through a personal report of their measurements and a summary of the overall research findings upon request to the principal investigator. For this study, the burden will not be directly assessed by patients. However, measurements will be performed during routine care or according to patient availability.

Recruitment and randomization

Participants will be recruited by the clinicians at the Nice University Hospital in the south of France. Clinicians will give a general explanation of the study to potentially eligible patients, along with written information, and the participants can ask any questions before signing a written informed consent form (Additional file 2). Individuals will then undergo all baseline measurements, supplemented by information on their professional occupation, education level, marital status, and a description of their PA in the last 5 years. They will then be assigned by the last author to one of the three arms using MinimPy software [41] in a 1:1:1 ratio. The minimization randomization method will be used to avoid any imbalance between the three groups. We will stratify on age (≤ 30 years; > 30 years) and the type of BS (sleeve gastrectomy, gastric bypass, other). After randomization, participants will receive a second written information form with details on their allocation group and will be invited to sign a second informed consent form (Additional file 2). This procedure of two times consent [42] will be used to avoid deceiving the participants about their allocation and preserve the validity and blinded aspect of the trial [43]. Recruitment began on November 19, 2020.

Outcome measurements

Table 1 provides a summary of the measures to be collected. Outcomes will be assessed at baseline (T0), 3 months (T3), and 6 months later (T6) in conjunction with routine care in these same follow-up

periods. An outpatient visit will be scheduled to perform physical assessments with a professional unaware of the allocation and hypotheses of the study. Self-report questionnaires will be completed directly by the participants online using LimeSurvey CE, version 2.06+ or with paper-and-pencil. A reminder will be made by phone to schedule another visit in case of absence.

Table 1. Summary of measures to be collected

Outcomes	Instrument	Time of measurement
Primary outcome		
Walking capacity	6-minute walk test distance [44,45]	T0, T3, and T6
Secondary outcomes		
Behavioral measures		
Physical activity level	Global physical activity questionnaire [46]	T0, T3, and T6
	7 days AX3 physical activity monitoring [47,48]	T0, T3, and T6
Stage of change	Stage of change [49]	T0, T3, and T6
Physiological measures		
Energetic expenditure	Oxygen uptake, minute ventilation, carbon dioxide output, respiratory exchange ratio, heart rate measured using Cosmed K5 system [50]	T0, T3, and T6
Muscle strength	Maximal isometric knee extensor muscles strength (Newton) measured with MicroFET2 [51]	T0, T3, and T6
Health indicators		
Quality of life	EuroQoL-5-Dimensions and EuroQoL-visual analog scale [52]	T0, T3, and T6
Body mass index	Height	T0
	Body mass	T0, T3, and T6
Body composition	Muscle mass, fat mass, bone mineral content and their theoretical gap with reference values measured with Biody Xpert^{ZM}	T0, T3, and T6
Other measures		
Technology acceptability	eHealth acceptability scale [53]	T0, T3, and T6 except for control group
Program compliance	Rate of participation and rate of perceived exertion	T3 except for control group
Motivation for PA	Motivation scale for health-oriented physical activity [54]	T0, T3, and T6
General causality orientation for PA	General causality orientation scale[55]	T0, T3, and T6
Basic psychological needs	Basic psychological needs [56]	T0, T3, and T6

Primary outcome

The primary outcome is walking capacity assessed by distance traveled during a 6-minute walk test (6MWT) associated with measures of energy expenditure (e.g., heart rate, oxygen uptake) described in the secondary outcomes. The 6MWT, highly reproducible in obesity [57], will be performed according to guidelines [44]. Due to weight loss during BS follow-up regardless of PA, the distance traveled in 6MWT increases after BS [58]. Therefore, we will use Capodaglio's formula including age, sex and body mass index to relativize the walking distance [45].

Secondary outcomes

Behavioral measures of PA

PA level. PA will be measured using the Global PA Questionnaire validated in the French language [46]. This scale comprises 16 items to assess the frequency and duration of PA during work, transportation, leisure time, and time spent sitting in a typical week. The items are used to calculate the energy expenditure score in metabolic equivalent tasks (METs), where 150 minutes per week of moderate to vigorous PA corresponds to 600 MET-min/week. This self-reported measure will be complemented by an objective evaluation using the Axivity AX3 triaxial accelerometer (AX3, Axivity, Newcastle, UK) worn on the wrist. The sensor will be set to begin recording at midnight the day after the appointment over a 7-day period at 100 Hz with a dynamic range of ± 8 g. The AX3 data will be downloaded, resampled, calibrated and analyzed using open-source AX3 OmGui software (OmGui Version 1.0.0.43, Open Movement, Newcastle University, UK). The AX3 sensor and its wrist location were chosen for their ease of use, reliability, accuracy, and validity, including in the field of obesity [47,48].

Stage of Change for PA. The stage of change for PA and exercise related to the Transtheoretical Model [59] will be measured using the French version [49] of the Stages of Change questionnaire [60]. Regular PA and exercise are defined as "at least 30 minutes per session, at least 5 days per week of moderate to vigorous PA." This questionnaire includes five items with a "yes" or "no" answer, transformed to attribute a score to each participant according to her stage (precontemplation=1, contemplation=2, preparation=3, action=4 or maintenance stage=5).

Physiological measures.

Energetic expenditure. Oxygen uptake, minute ventilation, carbon dioxide output, respiratory exchange ratio and heart rate will be measured during the 6MWT. These parameters will be measured using the Cosmed K5 system (Cosmed K5, Rome, Italy), which consists of a mask and a portable unit. This equipment was chosen for its validity and reproducibility [50].

Muscle strength. The maximal isometric knee extensor muscle strength of the left and right lower limbs will be measured with the MicroFET2 (Hoggan Scientific, LLC, Salt Lake City, UT, USA). Women will be seated in a chair with the assessed limb placed at a knee angle of 90°. They will be asked to push as hard as possible for 5 seconds against the dynamometer held by a strap attached to the chair. The highest value in Newton (N) of three measurements will be recorded, and the average of both limb results will be used for analysis. A similar measurement protocol has already been used in an obesity study [51].

Health indicators

Quality of life. Quality of life will be assessed with the French version of the EuroQoL-5-Dimensions and a EuroQoL-visual analog scale [52]. The EuroQoL-5-Dimensions comprises five items measuring quality of life along five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each dimension, participants have five response options ranging from “no problems” to “unable.” The EuroQoL-visual analog scale has a single item for which the women will be asked to rate their current health on a scale from 0: “worst imaginable” to 100: “best imaginable.” This generic scale, which has previously been used in a BS study [61], was chosen to ensure consistency in the measurement of quality of life throughout weight loss.

Body mass index. Height (m) and body mass (kg) will be measured and used to calculate the body mass index (kg/m^2).

Body composition. Body composition will be measured by bioimpedance using the Biody Xpert^{ZM} (Aminogram, France): muscle mass (kg), fat mass (kg), and bone mineral content (kg). For analyses these measures will be converted to percentages. In addition, the theoretical gap with reference values will be measured for muscle mass (kg), fat mass (kg), and bone mineral content (kg).

Other measures

Technology acceptability. The acceptability of technologies (ACTI-MOBIL and ACTI-VISIO groups) will be assessed by the French eHealth acceptability scale [53], including 25 items divided into eight subscales: performance expectancy, effort expectancy, social influence, facilitating conditions, hedonic motivation, price value, habit, and behavioral intention. Women will rate each item on a 7-point scale ranging from 1: "strongly disagree" to 7: "strongly agree." This measure will not be assessed in the control group to avoid bias by giving individuals the idea of using a technology, disappointing participants without technology, or potentially removing blinding to the group assignment.

Program compliance. To measure technology-based program compliance, companies will be asked to report the presence or absence of women and their rate of perceived exertion at each session in a register (reported by the PA professional for ACTI-VISIO; completion, content consultation and validation statistics, PA level and number of days the activity bracelet is worn for ACTI-MOBIL).

Motivation for PA. The motivation for health-oriented PA will be measured with a French motivation scale for health-oriented PA [54]. This scale comprises 18 items, distributed across the six motivational constructs of the self-determination theory [33]: intrinsic motivation, integrated regulation, identified regulation, introjected regulation, external regulation, and amotivation. Participants will respond on a 7-point Likert scale ranging from 1: "strongly disagree" to 7: "strongly agree."

General Causality Orientations Scale for PA. Causality orientations will be measured using an adaptation of the General Causality Orientations Scale [55] to assess the strength of three motivational orientations (i.e., autonomy, control, impersonal) in the context of PA in a medical environment. The scale comprises seven vignettes and 21 items. Each vignette describes a situation and is followed by three items, one per motivational orientation, to which participants respond on a 7-point scale ranging from 1: "strongly disagree" to 7: "strongly agree."

Basic psychological needs. Basic psychological needs will be measured using a French scale validated in the sports context [56] for which we replaced "sport" by "physical activity." This scale comprises 15 items distributed across the three needs: autonomy, competence, and relatedness. Participants will respond on a 7-point Likert scale ranging from 1: "strongly disagree" to 7: "strongly agree."

Interventions

All interventions are similar in terms of the recommended PA level: at least 150 minutes per week, with a goal of 300 minutes per week of moderate to vigorous PA including muscle strengthening exercises 2-3 times per week [3]. The technology groups will receive similar PA programs twice a week for 12 weeks (between T0 and T3), combined with advice and counseling about walking activities to achieve the recommendations.

Control group

The Control group will receive the usual care (also provided to the ACTI-VISIO and ACTI-MOBIL groups) that includes two individual motivational interviews with a PA professional and a group workshop during the first year following BS to help participants achieve the PA recommendations. No face-to-face PA sessions will be offered as part of the usual care.

ACTI-VISIO group

The PA sessions will be delivered via a videoconferencing system developed by Mooven™. The PA program consists of tailored adapted PA sessions led by a professional specialized in adapted PA. These sessions were specifically designed to be appropriate for the population and to ensure standardization of the recommended volume of PA. The PA sessions will be given live, individually at the beginning and then in groups of four women. During sessions, all participants are able to see and interact with each other and with the professional. The execution of the exercises will be monitored and adapted live by the professional. The interactions between participants may constitute a form of peer support. To ensure the safety of the PA, a rating of perceived exertion will be requested after each session on a 10-point scale. If the rating exceeds 7, the professional specialized in adapted PA will adjust the training load. In addition, the sessions will also include advice and tips for reaching the recommended PA level. After randomization, the women will receive registration details to create a personal account. Participants will then have to select practice times for two sessions per week. Technical assistance will be provided in cases of configuration difficulties. For participants who are absent for a scheduled session, a reminder will be made by phone for the next session.

ACTI-MOBIL group

The PA sessions will be delivered by an eHealth platform associated with the Fitbit Inspire activity bracelet. The eHealth platform is a bariatric online module developed by BePatient™ in collaboration with the authors to enrich PA content and ensure standardization of the recommended volume of PA. The module used in the present trial consists of tips for reaching the PA level, PA questionnaires, PA feedback measured by the activity bracelet, and a video demonstration of PA sessions performed by a peer. To ensure the safety of the PA, the sessions were designed to be appropriate for this population and the rating of perceived exertion will be measured after each session on a 10-point scale. If the rating exceeds 7 for 3 consecutive sessions, the training load will be adjusted. The platform will also include a variety of content, including dietary tips, obesity-related facts, information about surgery, and frequently asked questions. After randomization, the women will receive registration details to create a personal account, and their activity bracelets will be synchronized to the platform to visualize their PA. Technical support will be provided in cases of configuration or synchronization difficulties. For the women whose activities have not been detected on the platform one week after the start of the program, a reminder will be given by phone.

Data analysis and management

Sample size

Sample size for the study is based on the distance traveled during a 6MWT relativized with age, sex and body mass index [45]. A recent meta-analysis showed an overall effect $Z = 2.52$ ($p = .01$) of change in walking distance after BS in an exercise group compared to a control group [62]. An overall effect $Z = 2.52$ correspond to $f = .20$ [63]. However, this effect size is probably minimized because it has not been relativized according to body mass index. Furthermore, eHealth PA programs for obese or sedentary individuals have an effect size of $d = .37$ [64], corresponding to $f = .19$ [63]. However, only 45% of eHealth interventions are based on theoretical models [65], which reduces their effectiveness. Given these limitations, a slightly larger effect size of $f = .25$ is considered. A total of 108 participants will be necessary to keep a power of 80% and alpha of 5% [66]. We anticipate that 10% of the participants will be lost to follow-up, drop out of testing, withdraw informed consent, or be

excluded from the study. Thus, with 120 women, 40 in each group, we consider our study to be sufficiently powered.

Data management

The recruiting clinicians will keep a register with a study number and all identifiable data (name, phone number, pseudonymization code, and allocation group) for use during the follow-up. This register will be locked up with access only available to project investigators. Other data collected will be stored on a secured server with pseudonymization codes and no other personally identifiable information. The Department of Technology Systems at the University in collaboration with the Public Health Department of the University Hospital will handle the data management. To ensure the quality of the research, an audit may be carried out at any time by the Public Health Department of the University Hospital.

Data analysis

The level of significance for all statistical analyses will be set at .05 under the bilateral hypothesis. Missing data patterns will be analyzed and described. Less than 5% missing data is usually considered inconsequential [67], and simple methods will be used (e.g., last observation carried forward, mean, median). If more than 5% of the data is missing, these data will be handled by multiple imputation or maximum likelihood imputation [67,68]. The planning, implementation, analyses and final writing of the results will follow the recommendations of the CONSORT statements [69].

The normality of quantitative data will be assessed using a graphical method and a Shapiro test [70]. Simple mathematical transformations can be used if necessary to normalize non-normal data. The dimensional consistency of the subjective data will be calculated using Cronbach's alpha coefficient. Baseline differences between groups (e.g., age, type of surgery, forms of motivation) will be tested prior to hypothesis testing. To test the hypotheses, a mixed model procedure will be used. It should be noted that mixed models are highly recommended for repeated measurement analyses to take into account the non-independence of the repeated measures [71,72]. Moreover, the mixed models can be used to analyze longitudinal mediated data [73]. The repeated measures will be considered as a

longitudinal fixed factor. The condition (ACTI-MOBIL, ACTI-VISIO, CONTROL) representing the criterion of the analysis (the independent variable) will be considered as a fixed effect in the model. The intercept will be defined as a random factor that can vary for each participant. The acceptability of technologies and motivational constructs will be the mediating variables added to the mixed model.

ETHICS AND DISSEMINATION

This study was reviewed and approved by the French East 1 Protection of Persons Ethics Committee (number: 2020.A00172-37) and the French National Commission for Information Technology and Civil Liberties (number: UCA-R20-034). This study was registered with ClinicalTrials.gov Identifier: NCT04478331 (Registered July 15, 2020). The protocol (version 3, 15 October 2020) conforms to the principles of Good Clinical Practice and the Declaration of Helsinki and will be reported according to the 2013 SPIRIT statement [74] (Additional file 1). Any modification of the research protocol must be subject to an authorization agreement from the Ethics Committee.

The datasets generated during the current study will be available from the corresponding author on reasonable request and archived for a period of 15 years.

A final scientific report of the research project, including the results and clinical outcomes of the study, will be written by the principal investigator and sent to the Ethics Committees within one year of the research conclusion. Research summary results will be available to participants in accordance with the terms described in the information documents. The results of this trial will be disseminated through conference presentations and in peer-reviewed journals.

DISCUSSION

This study will provide insight into the effects of two technology-based PA programs (mobile technology and videoconferencing) post-BS. This study will also provide a better understanding of the acceptability and motivational constructs in mediating the effects of these technologies. Based on the results, strategies to individually promote technology-based PA interventions and recommendations for implementing these programs will be developed.

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Competing Interests

The authors declare that they have no competing interests.

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Authors' contributions

FAL, MH, and VN conceived the project and procured the project funding. NC, AI, CP, SSC, AF, and PT contributed to the trial protocol. OD, JMG, AV, SSC, and MH conceptualized the interventions, developed the contents, and worked with the companies. FAL is leading the coordination of the trial.

NC and AI are managing the trial including recruitment and data collection with the assistance of VN and MH. CP, FAL, and MH developed the plan for statistical analysis. MH and FAL drafted the manuscript and coordinated the revisions. All other authors reviewed, edited, and approved the final manuscript.

Trial sponsor: Université Côte d'Azur, Nice, France

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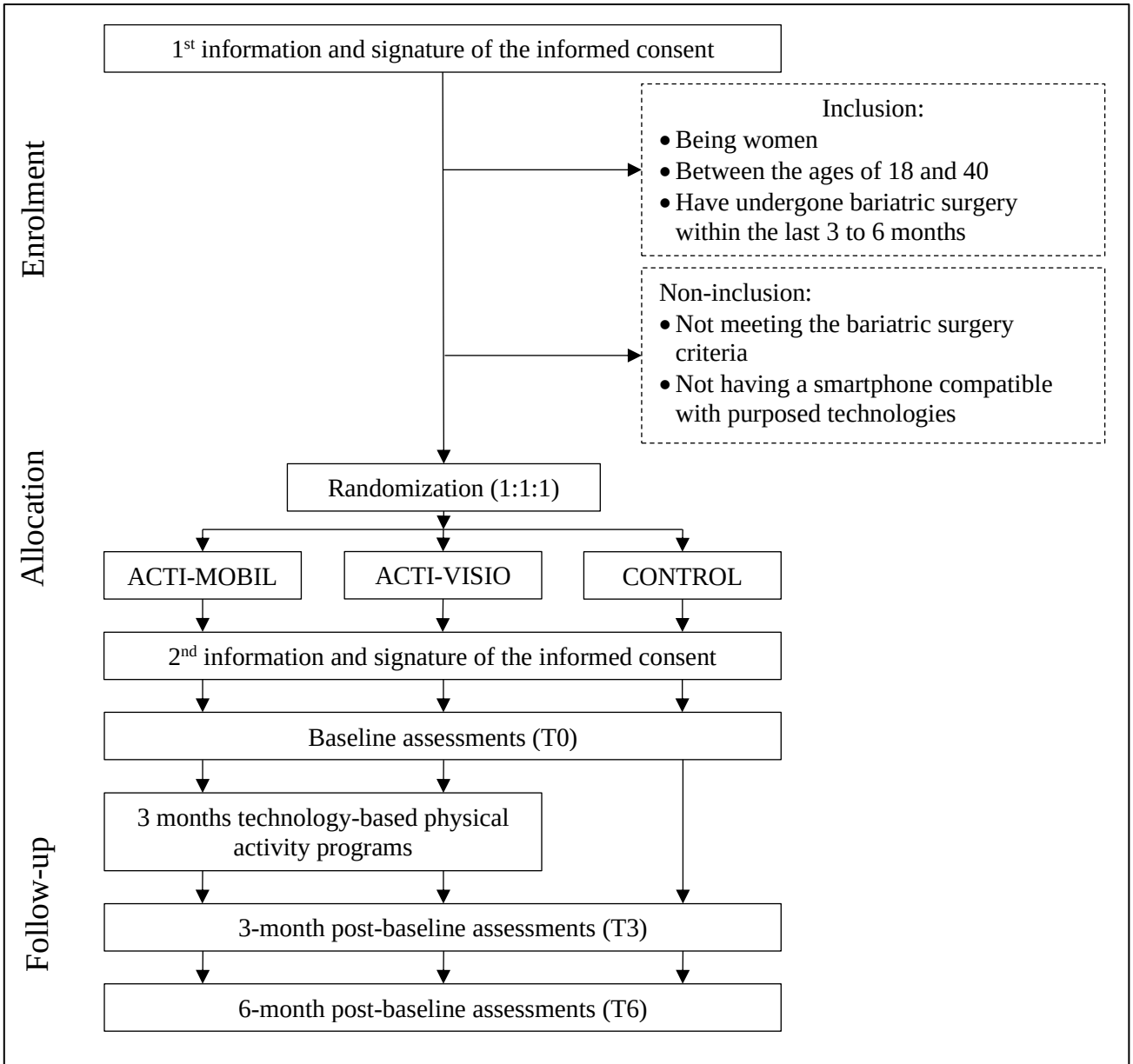
Figure legends

Fig. 1 Flow diagram of study protocol.

Additional material

Additional file 1 SPIRIT 2013 Checklist

Additional file 2 Informed consent materials


Enrolment
1st information and signature of the informed consent
Inclusion:
• Being women
• Between the ages of 18 and 40
• Have undergone bariatric surgery within the last 3 to 6 months
Non-inclusion:
• Not meeting the bariatric surgery criteria
• Not having a smartphone compatible with purposed technologies
Allocation
Randomization (1:1:1)
ACTI-MOBIL
ACTI-VISIO
CONTROL
2nd information and signature of the informed consent
Baseline assessments (T0)
Follow-up
3 months technology-based physical activity programs
3-month post-baseline assessments (T3)
6-month post-baseline assessments (T6)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	16
Protocol version	3	Date and version identifier	16
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 17-18
	5b	Name and contact information for the trial sponsor	18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17-18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15; 17-18

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	10-12
Objectives	7	Specific objectives or hypotheses	6-7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	13-14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	7-8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	13-14
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7-8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14-15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8-9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A, blinding cannot be strictly guaranteed in this study, only strategies to limit potential bias were taken.

Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13-14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15-16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15-16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	15
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A, no interim analyses have been planned
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	7-8

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	15
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8, 17-18
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A, no ancillary studies are planned
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16-18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A, no ancillary studies or post-trial care are planned
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	8, 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	17-18

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Translated consent forms are provided as a supplementary file.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A no biological specimens were collected as part of this trial

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Effects of technology-based physical activity interventions for women after bariatric surgery: study protocol for a three-arm randomized controlled trial

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Secondary Subject Heading:	Health informatics, Public health
Keywords:	Information technology < BIOTECHNOLOGY & BIOINFORMATICS, SPORTS MEDICINE, General endocrinology < DIABETES & ENDOCRINOLOGY, PUBLIC HEALTH

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Title: Effects of technology-based physical activity interventions for women after bariatric surgery: study protocol for a three-arm randomized controlled trial

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ABSTRACT

Introduction. A recent meta-analysis provided proof of efficacy for mobile technology to increase physical activity or weight loss in the short term. Videoconferencing may also be effective, especially as it reduces the barriers related to face-to-face physical activity interventions. Both technologies seem particularly interesting for bariatric surgery management, but their long-term effects on physical activity maintenance are unknown. Moreover, the mechanisms underlying their effectiveness, such as technology acceptability and motivational processes, have not been examined.

The objectives of this study are to determine the effects of two technology-based (mobile technology and videoconferencing) physical activity programs after bariatric surgery compared to standard care and to assess the contribution of acceptability and motivational mechanisms in explaining these effects on physical activity, physiological measures, and health indicators.

Methods and analysis. One hundred and twenty young women who have undergone bariatric surgery in the last 3 to 6 months will be included. The volunteers will be randomly assigned to one of three arms: CONTROL (standard care), ACTI-MOBIL (mobile technology), or ACTI-VISIO (videoconferencing). The primary outcome is the distance traveled during a 6-minute walk test relativized according to Capadaglio's theoretical distance. Secondary outcomes are behavioral measures of physical activity, physiological measures, health indicators, technology acceptability, and motivational concepts. Data will be collected at baseline (T0), 3 months (T3), and 6 months (T6). The technology groups will receive a physical activity program for 12 weeks (between T0 and T3). A mixed model approach will be used to analyze the change in outcomes over time for each group.

Ethics and dissemination. This study protocol was reviewed and approved by the French East 1 Protection of Persons Ethics Committee (number: 2020.A00172-37) and the French National Commission for Information Technology and Civil Liberties (number: UCA-R20-034). The results will be disseminated through conference presentations and peer-reviewed publications.

Trial registration number. NCT04478331

KEYWORDS

Physical activity; bariatric surgery; technology-based program; eHealth; videoconferencing; application

Strengths and limitations of this study

- Mobile technology and videoconferencing may improve the outcomes of bariatric surgery by promoting physical activity.
- Comparisons of the effects of two technology-based physical activity programs after bariatric surgery will lead to new recommendations for patients.
- This study will also provide a better understanding of the technology acceptability and motivational constructs in mediating the effects of the two technology-based physical activity programs.
- One potential challenge of this trial may include low compliance rates, especially toward physical activity recommendations, in bariatric surgery patients.

Abbreviations

6MWT, six-minute walk test; BS, bariatric surgery; MET, metabolic equivalent tasks; PA, physical activity.

INTRODUCTION

Background

Bariatric surgery (BS) is currently the most effective treatment for severe obesity [1]. However, BS alone is insufficient to maintain weight loss and must be combined with physical activity (PA) lifestyle interventions [2,3]. Women are more concerned than men by physical inactivity and sedentary behaviors, both in the general population [4] and in obesity [5]. Therefore, promotion of PA is essential in the obesity management among women. Despite a multidisciplinary approach, long-term monitoring of BS recipients is poor, and this can lead to health complications. One year after BS, between 10 to 40% of patients are lost to follow-up, and young age is a main predictor of poor 5-year follow-up [6]. PA is the area with the lowest compliance rate, and new strategies that improve PA maintenance might help to sustain monitoring [7]. Technology-based PA promotion programs have been shown to be relevant for this aim [8,9], and several technologies for use in vulnerable populations have been investigated in recent years. Among them, active video games [10,11], virtual reality [12], connected devices [13], mobile applications [14], internet-based and social media [15,16], and videoconferencing [17] have been shown to increase the PA level in the short-term, but the medium and long-term effects of these technologies are not well known. These technologies may be relevant for promoting post-BS PA, but low-cost and widely used technologies such as smartphones should be preferred [18]. To classify potentially useful technologies, the 'Coventry, Aberdeen & London – Refined' (CALO-RE) taxonomy could be used to group them according to the behavioral change techniques they incorporate [19].

According to this taxonomy, mobile applications, internet-based platforms and devices like activity bracelets activate the main behavioral strategies like goal-setting, self-monitoring and personal feedback [20]. Recent meta-analyses have provided proof of efficacy for mobile technology compared to control condition [21] or offline interventions [20] to increase PA or decrease weight in the short term, but the long-term effects have been insufficiently studied [20,21]. Another review identified self-monitoring, feedback, goal-setting and shaping knowledge as key components of effective eHealth

interventions for weight loss maintenance [22]. Based on these data, we assume that mobile technology will have long-term positive effects on PA in BS patients.

Furthermore, videoconferencing for PA includes monitoring by a professional, social support, teaching motivational strategies, use of communication skills, and goal-setting [23]. These features are part of both videoconferencing and face-to-face PA interventions [24], which may explain the lack of outcome differences between these two types of interaction [25]. Videoconferencing seems to be effective after BS, especially as it reduces some of the barriers of face-to-face PA interventions (e.g., travel time, distance of offers). Despite a limited sample size, videoconferencing proved to be effective in improving the physical fitness of women waiting for BS [17].

Mobile technology and videoconferencing are not based on the same behavioral strategies. Mobile applications incorporate strategies with technological regulations (e.g., self-monitoring, feedback, goal-setting, and shaping knowledge), while videoconferencing incorporates strategies with human regulations from both professional and other participants (e.g., social support, motivation strategies, communication skills, and goal-setting). The use of mobile applications is completely autonomous, while videoconferencing is regulated by pre-determined meetings. Both types of technology seem promising in BS, but their long-term effects on PA maintenance are unknown.

In addition, the mechanisms underlying the adoption or rejection of technologies in healthcare remain insufficiently studied. Indeed, acceptability is often reduced to a measure of satisfaction [26,27], which does not take into account the mechanisms underlying the adoption or rejection of a given technology. For this purpose, it is necessary to use models like the Unified Theory of Acceptance and Use of Technology 2 [28], which is the most comprehensive and parsimonious model [29] to measure acceptability in the early stages of use. As some technologies are better accepted than others, we can assume that the effects of these technologies may be mediated by their acceptability.

Furthermore, the effectiveness of PA interventions can be explained by motivation processes [30]. The role of motivational constructs in PA behavior in the field of obesity has been studied through self-determination theory [31,32]. Self-determination theory is a macro-theory that notably highlights the types of motivation (i.e., intrinsic, extrinsic, amotivation) along a continuum [33], the needs that individuals attempt to satisfy (i.e., autonomy, competence, relatedness) [34], and the

individual differences in motivation orientation (i.e., autonomy, control, impersonal) [35]. A systematic review of obesity studies showed that higher autonomous motivation, self-efficacy and self-regulation skills are predictors of increased PA [31]. Moreover, the use of motivational strategies can lead individuals to practice PA regularly and build habits [36]. To become a habit, a positive behavior must be integrated into the natural environment, disrupting old environmental cues and establishing new ones [37]. The changes associated with BS make this period ideal for the creation of new habits. The technologies we have selected (mobile technology and videoconferencing) are not based on the same behavioral strategies, but both have the potential to lead to habit development, and we assume that they will be more suitable depending on motivational characteristics. Few randomized control trials have measured motivational concepts, and yet doing so might explain why some technologies are more effective for some people than for others.

The study aims

This study aims to investigate (1) the effects of two technology-based PA programs (mobile technology and videoconferencing) after BS compared to standard care and (2) the contribution of acceptability and motivational mechanisms in explaining these effects.

The main objective is to evaluate the effects of the two technology-based PA programs on the walking capacity of young women after BS. We expect that the technology groups (ACTI-MOBIL and ACTI-VISIO) will report a higher level of walking capacity at the end of the interventions (T3) compared with the control group, and that this effect will be sustained 3 months later (T6). We do not hypothesize the superiority of one technology over the other, because to our knowledge no study has yet compared them after BS.

The secondary objectives are (1) to evaluate the effects on behavioral measures of PA, physiological measures, and health indicators in the technology groups compared with the control group, and (2) to explore the role of acceptability and motivational mechanisms in explaining these effects. We expect that participants in the technology groups (ACTI-MOBIL and ACTI-VISIO) compared with the control group will show: an improvement on the PA behavioral measures, an improvement on physiological measures, and better health indicators. We also expect that these effects will be

sustained 3 months later (T6). Technology acceptability based on theoretical models is not usually measured in randomized control trials [38,39], and acceptability as assessed by the Unified Theory of Acceptance and Use of Technology 2 model has never been measured for technology-based PA interventions in the context of BS. In addition, few randomized control trials have measured motivational concepts. We assume that technology acceptability and motivational concepts may mediate the effects of technology-based interventions on PA behavioral measures, physiological measures or health indicators.

METHODS AND ANALYSIS

Design

Participants will be randomly assigned to one of three groups: an eHealth platform associated with the Fitbit Inspire activity bracelet (ACTI-MOBIL group), a PA program delivered via videoconferencing (ACTI-VISIO group), or standard care (Control group) (Figure 1). Outcomes will be assessed at baseline (T0), 3 months (T3), and 6 months later (T6). The technology groups will receive a PA program for 12 weeks (between T0 and T3). Each participant will be included for a period of 6 months, on average 3 to 6 months after the BS. Approximately 8 months of recruitment will be required to reach the target sample size. Thus, the total expected duration of the study is 14 months.

Participants

To be eligible for the study, individuals must be women between 18 and 40 years old and have undergone BS 3 to 6 months earlier at a tertiary referral center for BS (Nice University Hospital, France) with respect to the national recommendations [40]. Participants will not be included if they have a smartphone incompatible with the proposed technologies. They will be excluded from the study in cases of serious adverse events, withdrawal of informed consent or violation of the protocol. A serious adverse event reporting form, validated for research, and a classification of serious and non-serious adverse events will be made available to those involved in the research protocol to assist them in managing adverse events (for more details on the management of adverse events, see Additional file

1). Participants may participate in another research protocol if it does not involve new technologies and does not impact PA levels or fitness measurement.

Patient and Public Involvement

Patients were not involved in the development of the research question, the design, the recruitment or the conduct of the study. Results will be reported individually through a personal report of their measurements and a summary of the overall research findings upon request to the principal investigator. For this study, the burden will not be directly assessed by patients. However, measurements will be performed during routine care or according to patient availability.

Recruitment and randomization

Participants will be recruited by the clinicians at the Nice University Hospital in the south of France. Clinicians will give a general explanation of the study to potentially eligible patients, along with written information, and the participants can ask any questions before signing a written informed consent form (Additional file 2). Individuals will then undergo all baseline measurements, supplemented by information on their professional occupation, education level, marital status, and a description of their PA in the last 5 years. They will then be assigned by the last author to one of the three arms using MinimPy software [41] in a 1:1:1 ratio. The minimization randomization method will be used to avoid any imbalance between the three groups. We will stratify on age (≤ 30 years; > 30 years) and the type of BS (sleeve gastrectomy, gastric bypass, other). After randomization, participants will receive a second written information form with details on their allocation group and will be invited to sign a second informed consent form (Additional file 2). This procedure of two times consent [42] will be used to avoid deceiving the participants about their allocation and preserve the validity and blinded aspect of the trial [43]. Recruitment began on November 19, 2020.

Outcome measurements

Table 1 provides a summary of the measures to be collected. Outcomes will be assessed at baseline (T0), 3 months (T3), and 6 months later (T6) in conjunction with routine care in these same follow-up

periods. An outpatient visit will be scheduled to perform physical assessments with a professional unaware of the allocation and hypotheses of the study. Self-report questionnaires will be completed directly by the participants online using LimeSurvey CE, version 2.06+ or with paper-and-pencil. A reminder will be made by phone to schedule another visit in case of absence.

Table 1. Summary of measures to be collected

Outcomes	Instrument	Time of measurement
Primary outcome		
Walking capacity	6-minute walk test distance [44,45]	T0, T3, and T6
Secondary outcomes		
Behavioral measures		
Physical activity level	Global physical activity questionnaire [46]	T0, T3, and T6
	7 days AX3 physical activity monitoring [47,48]	T0, T3, and T6
Stage of change	Stage of change [49]	T0, T3, and T6
Physiological measures		
Energetic expenditure	Oxygen uptake, minute ventilation, carbon dioxide output, respiratory exchange ratio, heart rate measured using Cosmed K5 system [50]	T0, T3, and T6
Muscle strength	Maximal isometric knee extensor muscles strength (Newton) measured with MicroFET2 [51]	T0, T3, and T6
Health indicators		
Quality of life	EuroQoL-5-Dimensions and EuroQoL-visual analog scale [52]	T0, T3, and T6
Body mass index	Height	T0
	Body mass	T0, T3, and T6
Body composition	Muscle mass, fat mass, bone mineral content and their theoretical gap with reference values measured with Biody Xpert^{ZM}	T0, T3, and T6
Other measures		
Technology acceptability	eHealth acceptability scale [53]	T0, T3, and T6 except for control group
Program compliance	Rate of participation and rate of perceived exertion	T3 except for control group
Motivation for PA	Motivation scale for health-oriented physical activity [54]	T0, T3, and T6
General causality orientation for PA	General causality orientation scale[55]	T0, T3, and T6
Basic psychological needs	Basic psychological needs [56]	T0, T3, and T6

Primary outcome

The primary outcome is walking capacity assessed by distance traveled during a 6-minute walk test (6MWT) associated with measures of energy expenditure (e.g., heart rate, oxygen uptake) described in the secondary outcomes. The 6MWT, highly reproducible in obesity [57], will be performed according to guidelines [44]. Due to weight loss during BS follow-up regardless of PA, the distance traveled in 6MWT increases after BS [58]. Therefore, we will use Capodaglio's formula including age, sex and body mass index to relativize the walking distance [45].

Secondary outcomes

Behavioral measures of PA

PA level. PA will be measured using the Global PA Questionnaire validated in the French language [46]. This scale comprises 16 items to assess the frequency and duration of PA during work, transportation, leisure time, and time spent sitting in a typical week. The items are used to calculate the energy expenditure score in metabolic equivalent tasks (METs), where 150 minutes per week of moderate to vigorous PA correspond to 600 MET-min/week. This self-reported measure will be complemented by an objective evaluation using the Axivity AX3 triaxial accelerometer (AX3, Axivity, Newcastle, UK) worn on the wrist. The sensor will be set to begin recording at midnight the day after the appointment over a 7-day period at 100 Hz with a dynamic range of ± 8 g. The AX3 data will be downloaded, resampled, calibrated and analyzed using open-source AX3 OmGui software (OmGui Version 1.0.0.43, Open Movement, Newcastle University, UK). The AX3 sensor and its wrist location were chosen for their ease of use, reliability, accuracy, and validity, including in the field of obesity [47,48].

Stage of Change for PA. The stage of change for PA and exercise related to the Transtheoretical Model [59] will be measured using the French version [49] of the Stages of Change questionnaire [60]. Regular PA and exercise are defined as "at least 30 minutes per session, at least 5 days per week of moderate to vigorous PA." This questionnaire includes five items with a "yes" or "no" answer, transformed to attribute a score to each participant according to her stage (precontemplation=1, contemplation=2, preparation=3, action=4 or maintenance stage=5).

Physiological measures.

Energetic expenditure. Oxygen uptake, minute ventilation, carbon dioxide output, respiratory exchange ratio and heart rate will be measured during the 6MWT. These parameters will be measured using the Cosmed K5 system (Cosmed K5, Rome, Italy), which consists of a mask and a portable unit. This equipment was chosen for its validity and reproducibility [50].

Muscle strength. The maximal isometric knee extensor muscle strength of the left and right lower limbs will be measured with the MicroFET2 (Hoggan Scientific, LLC, Salt Lake City, UT, USA). Women will be seated in a chair with the assessed limb placed at a knee angle of 90°. They will be asked to push as hard as possible for 5 seconds against the dynamometer held by a strap attached to the chair. The highest value in Newton (N) of three measurements will be recorded, and the average of both limb results will be used for analysis. A similar measurement protocol has already been used in an obesity study [51].

Health indicators

Quality of life. Quality of life will be assessed with the French version of the EuroQoL-5-Dimensions and a EuroQoL-visual analog scale [52]. The EuroQoL-5-Dimensions comprises five items measuring quality of life along five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each dimension, participants have five response options ranging from “no problems” to “unable.” The EuroQoL-visual analog scale has a single item for which the women will be asked to rate their current health on a scale from 0: “worst imaginable” to 100: “best imaginable.” This generic scale, which has previously been used in a BS study [61], was chosen to ensure consistency in the measurement of quality of life throughout weight loss.

Body mass index. Height (m) and body mass (kg) will be measured and used to calculate the body mass index (kg/m^2).

Body composition. Body composition will be measured by bioimpedance using the Biody Xpert^{ZM} (Aminogram, France): muscle mass (kg), fat mass (kg), and bone mineral content (kg). For the analyses, these measures will be converted to percentages. In addition, the theoretical gap with the reference values (derivative variables based on age, sex, weight and height provided by the French

company, Aminogram) will be measured to obtain estimations for muscle mass (kg), fat mass (kg), and bone mineral content (kg).

Other measures

Technology acceptability. The acceptability of technologies (ACTI-MOBIL and ACTI-VISIO groups) will be assessed by the French eHealth acceptability scale [53], including 25 items divided into eight subscales: performance expectancy, effort expectancy, social influence, facilitating conditions, hedonic motivation, price value, habit, and behavioral intention. Women will rate each item on a 7-point scale ranging from 1: "strongly disagree" to 7: "strongly agree." This measure will not be assessed in the control group to avoid bias by giving individuals the idea of using a technology, disappointing participants without technology, or potentially removing blinding to the group assignment.

Program compliance. To measure technology-based program compliance, companies will be asked to report the presence or absence of women and their rate of perceived exertion at each session in a register (reported by the PA professional for ACTI-VISIO; completion, content consultation and validation statistics, PA level and number of days the activity bracelet is worn for ACTI-MOBIL).

Motivation for PA. The motivation for health-oriented PA will be measured with a French motivation scale for health-oriented PA [54]. This scale comprises 18 items, distributed across the six motivational constructs of the self-determination theory [33]: intrinsic motivation, integrated regulation, identified regulation, introjected regulation, external regulation, and amotivation. Participants will respond on a 7-point Likert scale ranging from 1: "strongly disagree" to 7: "strongly agree."

General Causality Orientations Scale for PA. Causality orientations will be measured using an adaptation of the General Causality Orientations Scale [55] to assess the strength of three motivational orientations (i.e., autonomy, control, impersonal) in the context of PA in a medical environment. The scale comprises seven vignettes and 21 items. Each vignette describes a situation and is followed by three items, one per motivational orientation, to which participants respond on a 7-point scale ranging from 1: "strongly disagree" to 7: "strongly agree."

Basic psychological needs. Basic psychological needs will be measured using a French scale validated in the sports context [56] for which we replaced "sport" by "physical activity." This scale comprises 15 items distributed across the three needs: autonomy, competence, and relatedness. Participants will respond on a 7-point Likert scale ranging from 1: "strongly disagree" to 7: "strongly agree."

Interventions

All interventions are similar in terms of the recommended PA level: at least 150 minutes per week, with a goal of 300 minutes per week of moderate to vigorous PA including muscle strengthening exercises 2-3 times per week [3]. The technology groups will receive similar PA programs twice a week for 12 weeks (between T0 and T3), combined with advice and counseling about walking activities to achieve the recommendations.

Control group

The Control group will receive the usual care (also provided to the ACTI-VISIO and ACTI-MOBIL groups) that includes two individual motivational interviews with a PA professional and a group workshop during the first year following BS to help participants achieve the PA recommendations. No face-to-face PA sessions will be offered as part of the usual care.

ACTI-VISIO group

The PA sessions will be delivered via a videoconferencing system developed by Mooven™. The PA program consists of tailored adapted PA sessions led by a professional specialized in adapted PA. These sessions were specifically designed to be appropriate for the population and to ensure standardization of the recommended volume of PA. The PA sessions will be given live, individually at the beginning and then in groups of four women. During sessions, all participants are able to see and interact with each other and with the professional. The execution of the exercises will be monitored and adapted live by the professional. The interactions between participants may constitute a form of peer support. To ensure the safety of the PA, a rating of perceived exertion will be requested after each session on a 10-point scale. If the rating exceeds 7, the professional specialized in adapted PA will adjust the training load. In addition, the sessions will also include advice and tips for reaching the

recommended PA level. After randomization, the women will receive registration details to create a personal account. Participants will then have to select practice times for two sessions per week. Technical assistance will be provided in cases of configuration difficulties. For participants who are absent from a scheduled session, a reminder will be made by phone for the next session.

ACTI-MOBIL group

The PA sessions will be delivered by an eHealth platform associated with the Fitbit Inspire activity bracelet. The eHealth platform is a bariatric online module developed by BePatient™ in collaboration with the authors to enrich PA content and ensure standardization of the recommended volume of PA. The module used in the present trial consists of tips for reaching the PA level, PA questionnaires, PA feedback measured by the activity bracelet, and a video demonstration of PA sessions performed by a peer. To ensure the safety of the PA, the sessions were designed to be appropriate for this population and the rating of perceived exertion will be measured after each session on a 10-point scale. If the rating exceeds 7 for 3 consecutive sessions, the training load will be adjusted. The platform will also include a variety of content, including dietary tips, obesity-related facts, information about surgery, and frequently asked questions. After randomization, the women will receive registration details to create a personal account, and their activity bracelets will be synchronized with the platform to visualize their PA. Technical support will be provided in cases of configuration or synchronization difficulties. For the women whose activities have not been detected on the platform one week after the start of the program, a reminder will be given by phone.

Data analysis and management

Sample size

Sample size for the study is based on the distance traveled during a 6MWT relativized with age, sex and body mass index [45]. A recent meta-analysis showed an overall effect $Z = 2.52$ ($p = .01$) of change in walking distance after BS in an exercise group compared to a control group [62]. An overall effect $Z = 2.52$ corresponds to $f = .20$ [63]. However, this effect size is probably minimized because it has not been relativized according to body mass index. Furthermore, eHealth PA programs for obese or sedentary individuals have an effect size of $d = .37$ [64], corresponding to $f = .19$ [63]. However,

only 45% of eHealth interventions are based on theoretical models [65], which reduces their effectiveness. Given these limitations, a slightly larger effect size of $f = .25$ is considered. A total of 108 participants will be necessary to keep a power of 80% and alpha of 5% [66]. We anticipate that 10% of the participants will be lost to follow-up, drop out of testing, withdraw informed consent, or be excluded from the study. Thus, with 120 women, 40 in each group, we consider our study to be sufficiently powered.

Data management

The recruiting clinicians will keep a register with a study number and all identifiable data (name, phone number, pseudonymization code, and allocation group) for use during the follow-up. This register will be locked up with access only available to project investigators. Other data collected will be stored on a secured server with pseudonymization codes and no other personally identifiable information. The Department of Technology Systems at the University in collaboration with the Public Health Department of the University Hospital will handle the data management. To ensure the quality of the research, an audit may be carried out at any time by the Public Health Department of the University Hospital.

Data analysis

The level of significance for all statistical analyses will be set at .05 under the bilateral hypothesis. Missing data patterns will be analyzed and described. Less than 5% missing data is usually considered inconsequential [67], and simple methods will be used (e.g., last observation carried forward, mean, median). If more than 5% of the data is missing, these data will be handled by multiple imputation or maximum likelihood imputation [67,68]. The planning, implementation, analyses and final writing of the results will follow the recommendations of the CONSORT statements [69].

The normality of quantitative data will be assessed using a graphical method and a Shapiro test [70]. Simple mathematical transformations can be used if necessary to normalize non-normal data. The dimensional consistency of the subjective data will be calculated using Cronbach's alpha coefficient. Baseline differences between groups (e.g., age, type of surgery, forms of motivation) will be tested

prior to hypothesis testing. To test the hypotheses, a mixed model procedure will be used. It should be noted that mixed models are highly recommended for repeated measurement analyses to take into account the non-independence of the repeated measures [71,72]. Moreover, the mixed models can be used to analyze longitudinal mediated data [73]. The repeated measures will be considered as a longitudinal fixed factor. The condition (ACTI-MOBIL, ACTI-VISIO, CONTROL) representing the criterion of the analysis (the independent variable) will be considered as a fixed effect in the model. The intercept will be defined as a random factor that can vary for each participant. The acceptability of technologies and motivational constructs will be the mediating variables added to the mixed model.

ETHICS AND DISSEMINATION

This study was reviewed and approved by the French East 1 Protection of Persons Ethics Committee (number: 2020.A00172-37) and the French National Commission for Information Technology and Civil Liberties (number: UCA-R20-034). This study was registered with ClinicalTrials.gov Identifier: NCT04478331 (Registered July 15, 2020). The protocol (version 3, 15 October 2020) conforms to the principles of Good Clinical Practice and the Declaration of Helsinki and will be reported according to the 2013 SPIRIT statement [74] (Additional file 3). Any modification of the research protocol must be subject to an authorization agreement from the Ethics Committee.

The datasets generated during the current study will be available from the corresponding author on reasonable request and archived for a period of 15 years.

A final scientific report of the research project, including the results and clinical outcomes of the study, will be written by the principal investigator and sent to the Ethics Committees within one year of the research conclusion. Research summary results will be available to participants in accordance with the terms described in the information documents. The results of this trial will be disseminated through conference presentations and in peer-reviewed journals.

DISCUSSION

This study will provide insight into the effects of two technology-based PA programs (mobile technology and videoconferencing) post-BS. This study will also provide a better understanding of the acceptability and motivational constructs in mediating the effects of these technologies. Based on the results, strategies to individually promote technology-based PA interventions and recommendations for implementing these programs will be developed.

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Competing Interests

The authors declare that they have no competing interests.

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trials, the association contributed to the trial protocol, but they had no role in the collection, analysis, and interpretation of data, nor in the decision to publish the manuscript.

Authors' contributions

FAL, MH, and VN conceived the project and procured the project funding. NC, AI, CP, SSC, AF, and PT contributed to the trial protocol. OD, JMG, AV, SSC, and MH conceptualized the interventions, developed the contents, and worked with the companies. FAL is leading the coordination of the trial. NC and AI are managing the trial including recruitment and data collection with the assistance of VN and MH. CP, FAL, and MH developed the plan for statistical analysis. MH and FAL drafted the manuscript and coordinated the revisions. All other authors reviewed, edited, and approved the final manuscript.

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Figure legends

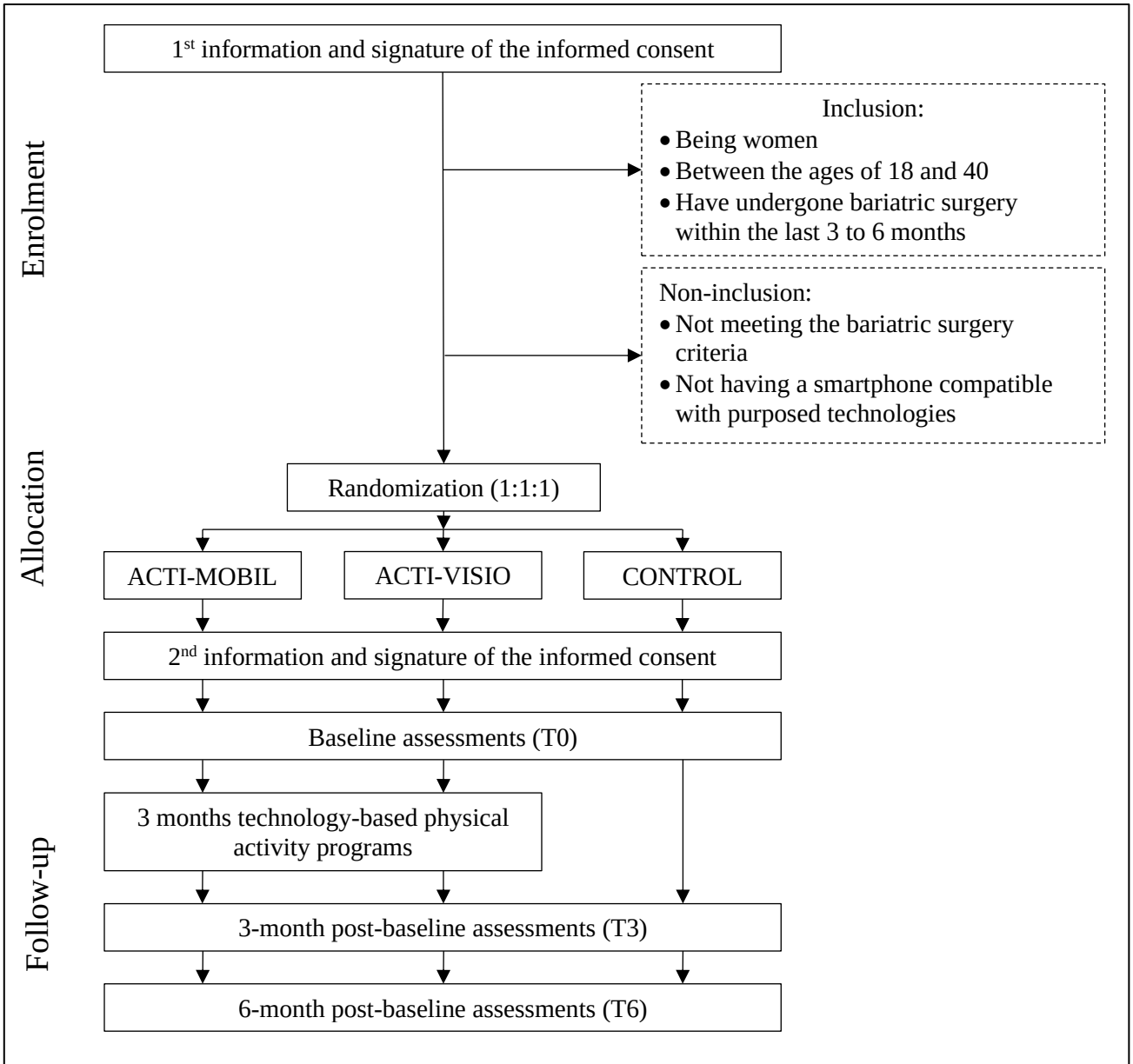
Fig. 1 Flow diagram of study protocol.

Additional material

Additional file 1 Management of adverse events

Additional file 2 Informed consent materials

Additional file 3 SPIRIT 2013 Checklist


Enrolment
Allocation
Follow-up
1st information and signature of the informed consent
Inclusion:
• Being women
• Between the ages of 18 and 40
• Have undergone bariatric surgery within the last 3 to 6 months
Non-inclusion:
• Not meeting the bariatric surgery criteria
• Not having a smartphone compatible with purposed technologies
Randomization (1:1:1)
ACTI-MOBIL
ACTI-VISIO
CONTROL
2nd information and signature of the informed consent
Baseline assessments (T0)
3 months technology-based physical activity programs
3-month post-baseline assessments (T3)
6-month post-baseline assessments (T6)

Additional file 1. Management of adverse events

1. Definition

Adverse event (AE) (article R1123-46 of the public health code): Any harmful event occurring in a person who undergoes research, whether or not this event is related to the research or the product on which this research is based.

Serious Adverse Event / Effect (SAE) (article R1123-46 of the public health code and ICH E2B guide): Any adverse event that:

- Leads to death.
- Endangers the life of the person undergoing the research.
- Leads to hospitalization or prolongation of hospitalization.
- Leads to significant or lasting disability or handicap.
- Results in a congenital anomaly or malformation.
- Does not meet the qualifications listed above but may be considered "potentially serious" (certain biological abnormalities), is considered a relevant drug in the judgment of the investigator, and requires medical intervention to prevent progression to a precipitous condition.

The term "life-threatening" is reserved for an immediate life-threatening situation at the time of the adverse event, regardless of the consequences of corrective or palliative therapy.

Unexpected Adverse Reaction (UAR): Any adverse reaction whose nature, severity or course is not consistent with the information contained in the guidelines recognized by the authorities.

Suspected Unexpected Severe Adverse Reaction (SUSAR): An adverse reaction whose nature, severity/intensity or course is not consistent with the information contained in Investigator's Brochure or Protocol.

Expected Serious Adverse Effect (EIGA): Any effect defined in the protocol as expected.

New fact (article R1123-46 of the public health code): Any new data that may lead to a reassessment of the benefit/risk ratio of the product under investigation, to changes in the use of this product, in the conduct of the research, or in the documents relating to the research, or to the suspension or interruption or modification of the research protocol or similar research.

The following will NOT be considered as an SAE:

- An event resulting in a transient move to a hospital consultation, door-to-door service, or day hospital.
- Hospitalizations (more than one night on site) or prolongations of hospitalizations for the following reasons:
    - Scheduled hospitalization for routine procedures or treatments that are part of a pre-defined monitoring or therapy program.
    - Hospitalization or intervention required by protocol.
    - Hospitalization for comfort or for a social reason (e.g., hospitalization of an elderly person in a relationship of dependence with a spouse who has just been hospitalized).
    - Elective hospitalization not associated with a worsening of the clinical condition and not related to the objective of the clinical study and taking place during the clinical study (e.g., cosmetic surgery).
    - Infectious complications treated on an outpatient basis and not leading to hospitalization.

2. Types of adverse events

Risks related to bariatric surgery:

In the event of too much stress during physical activity due to the very reduced food intake and rapid weight loss, vagal discomfort, benign dizziness, and functional hypoglycemia may rarely occur.
Dumping syndrome, a discomfort specifically linked to bariatric surgery, could potentially occur during physical activity without any direct link with it.

Expected risks related to the study procedures:

Muscle contractures may occur during the physical activity program or during the 6-minute walk test.

3. Behavior to be observed

In order to avoid the occurrence of an adverse event, patients are asked not to carry out the exercises alone, to always have someone close to them available in case of an adverse event and, especially if discomfort has already occurred, to be attentive to the first signs in order to adopt the appropriate course of action.

The action to be taken for each adverse event is:

Vagal malaise or functional hypoglycemia: the patient becomes pale during exercise and more often during recovery, may complain of nausea and lightheadedness, may present sweating and hot flashes, and describes sudden fatigue.
1. Stop the effort.
2. Lie flat with legs elevated or bent.
3. Notify a doctor (call 15).

Dumping syndrome: the patient becomes pale, has hot flashes, sweats, palpitations and tachycardia, and complains of abdominal pain or gagging.
1. Stop the effort.
2. Lie flat with legs raised or bent.
3. In conjunction with the health care team, adapt dietary and behavioral measures (e.g., increase time allocated to eating, avoid foods identified as triggers, limit simple sugars in favor of complex sugars (Di Vetta et al., 2017).

4. Procedures for recording and reporting adverse events

Any non-serious adverse event, as defined above, observed during the research and its aftermath must be reported in the observation book in the section provided for this purpose. Only one event should be reported per item. The event may correspond to a symptom, a diagnosis or a result of a complementary examination deemed significant. All clinical or paraclinical elements that best describe the corresponding event must be reported.
A form for reporting a serious adverse event, validated for research, and a classification grid for serious and non-serious adverse events will be made available to the persons involved in the research protocol to help them manage adverse events (i.e., to help them differentiate between events according to their seriousness and their expected nature). The grid will be drawn up and validated by all those involved in the research. It may be modified during the course of the research, depending on the reports received by the sponsor.
The sponsor, informed by the intervener, is obliged to notify the Steering Committee immediately of all serious adverse events except those listed in the grid as not requiring immediate notification. For each serious adverse event, the Steering Committee must issue an opinion on the causal link of the event with any experimental element of the research, whether it concerns the procedures performed or the products used. Obtaining information relating to the description and evaluation of an adverse event may not be possible within the time allowed for the initial report. Therefore, the clinical course, as well as the results of any clinical check-ups and diagnostic and/or laboratory examinations, or any other information allowing an adequate analysis of the causal link, will be reported:

- Either on the initial report of the SAE if they are immediately available.
- Or subsequently and as quickly as possible, by sending a new completed SAE report by fax (and specifying that it is a follow-up to a declared SAE and the follow-up number).

All reports made by investigators should identify each subject participating in the research by a unique code number assigned to each subject.
In the event of a notified death of a research subject, the investigator should provide the sponsor with any additional information requested (e.g., hospital report, autopsy results).
Any new fact occurring in the research or in the context of the research, from data in the literature or from ongoing research, must be notified to the sponsor.

5. Reporting of adverse events to the Health Authorities

All suspected serious unexpected adverse events will be reported by the sponsor to the competent authorities within the legal deadlines.
In the event of a serious unexpected adverse reaction due to an experimental element of the research, whether it concerns the procedures performed or the products used, the competent authorities, the Personal Protection Committee and the research investigators must be informed.

6. Follow-up procedures for individuals following the occurrence of adverse events

Any patient presenting an adverse event should be followed up until the event is resolved or stabilized.
If the event is not serious, the progress of the event should be noted on the relevant page of the case report form in the section provided for this purpose.

INFORMATION NOTICE FOR PATIENTS FOR PARTICIPATION IN THE OCAPAS STUDY

Study of Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

Trial sponsor: Côte d'Azur University

Head of research: Prof. Fabienne d'Arripe-Longueville, Laboratoire Motricité Humaine, Expertise, Sport Santé [*Laboratory of Human Motricity, Expertise, Sport, and Health*] (EA 6312), Côte d'Azur University

Principal investigators: Prof. Nicolas Chevalier, University Professor – Hospital Practitioner at the Nice University Hospital; Prof. Antonio Iannelli, University Professor – Hospital Practitioner at the Nice University Hospital

Madam,

We would like to offer you the opportunity to participate in a clinical research study because you are undergoing a bariatric surgery procedure.

This information notice will tell you more about the study.

You have a 7-day reflection period during which you can take the time to read and understand this information, reflect on your participation, and ask the principal investigators of the study to explain what you did not understand.

PURPOSE OF THE STUDY

The "OCAPAS" scientific study is conducted in partnership with the Laboratoire Motricité Humaine, Expertise, Sport, Santé (LAMHESS) of Côte d'Azur University, the Specialised Obesity Center of the Provence Alpes Côte d'Azur East, the DARE [*Digestive-Anesthesia-Resuscitation-Endocrinology*] pole of the Nice University Hospital, the Public Health Department of the Nice University Hospital, Azur Sport Santé, the Laboratoire d'Anthropologie, Psychologie Cliniques, Cognitives et Sociales (LAPCOS) [*Laboratory of Anthropology, Clinical, Cognitive and Social Psychology*] of Côte d'Azur University, and the companies *Be Patient* and *Mooven*.

Its main objective is to study patient engagement in physical activity during bariatric surgery follow-up.

The secondary objectives are to study the impact of your physical activity practice on different engagement and health indicators. Your perception of various mechanisms which could help to strengthen your commitment to physical activity will also be measured.

ANTICIPATED BENEFIT(S)

This study, through the physical activity that will be recommended to you, should help improve your health, quality of life and well-being.

CONDUCTING THE STUDY

You will be monitored through physical and psychological assessments. You will be included in a group at random. This random selection will be made by the person in charge of the study as soon as you return this information letter and the signed consent form. In order to guarantee the scientific validity of the study, you will then receive the information corresponding to the group in which you are assigned.

Assessments will take place upon inclusion in a group (T0), then at 3 months (T3), and 6 months (T6) after inclusion. Only the physical assessments requiring a measurement will be required to take place at the Archet 2 University Hospital in Nice.

Physical assessments will be based on a 6-minute walking test (carried out under standardised conditions), a strength test, and the wearing of an accelerometer for 7 days positioned at the time of the assessments (and returned at the end of the 7-day period by post with a stamped envelope provided). Height, weight and impedance measurements will be carried out by a doctor or nurse as part of the standard monitoring.

The questionnaires to which you will be submitted can be filled in online on the *LimeSurvey* platform. You will receive an e-mail with the link to the questionnaire and a reminder of your anonymity number. If you have difficulty completing the questionnaires on the *LimeSurvey* platform, you can also complete them on paper during the physical assessments. The questionnaires will be used to evaluate:

- Self-reported physical activity level
- Observance and motivation:
  - The number, duration and type of physical activity sessions per week according to international recommendations.
  - Physical exercise habits and history
  - The stage of engagement in practice
  - Motivation for physical activity, how you feel during physical activity, and your reactions to various situations.
- Your perception of the solution to strengthen your commitment to physical activity
- Quality of life and health.

POTENTIAL RISKS

The respect of the protocol and contra-indications, the specific training of the adapted physical activity professional, as well as the carrying out of the evaluations at the Archet 2 Nice University Hospital, will guarantee your safety during the evaluations.

The risks that may arise during these assessments are those of possible and classic discomforts during the sessions (vaso-vagal episode, drop in blood pressure, shortness of breath, dizziness)

for which the assessors are trained and which are the same as those related to practising physical or sports activities of daily life.
However, the scientific committee reserves the right to terminate the experiment in case of poor adaptation or intolerance.

CONSTRAINTS

You are free to participate in another research protocol, provided it does not involve new technologies and does not have an impact on physical activity levels or fitness measurement.

FINANCIAL PARTICIPATION

Your collaboration in this research protocol will not involve any financial participation on your part.
All costs (medical, supervision, equipment, insurance, etc.) related to the study will be covered by the researchers.
Only an uncashed cheque used as a security deposit for the loan of the equipment will be requested from you and then destroyed upon the return of the equipment.

LEGISLATION - CONFIDENTIALITY

In accordance with Articles L. 1121-1 et seq. of the French Public Health Code, the Committee on Human Research studied this research project and issued a favourable opinion on 01/04/2020.
An insurance policy, number 146 177 524, was taken out by the sponsor of the trial, the Côte d'Azur University - 20 avenue Valrose - BP 2135 - 06103 Nice Cedex 2, with the company MMA Entreprise, to cover the risks linked to this research.
Any information about you collected during this trial will be treated confidentially.
Only those responsible for the study and possibly the health authorities will have access to this data. With the exception of these people - who will treat the information in the strictest respect of medical secrecy - your anonymity will be preserved. The publication of the results of the study will not include any individual results.
The data recorded over the course of this study will be subject to computerised processing by the sponsor. As this is personal data, you have the right of access, rectification, portability, deletion or limitation in the processing of data concerning you at any time by contacting the Data Protection Officer, Mr. Didier Martin at the Côte d'Azur University and those in charge of the study. As regards information of a medical nature, this right is exercised through the intermediary of Professor Nicolas Chevalier at the University Hospital of Nice, in accordance with France's law on Information Technology, Data Files and Civil Liberties, No. 78-17 of 6 January 1978, amended by law No. 94-548 of the 1st of July 1994, and Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation). The project received a

notification of compliance with reference to methodology, and an analysis of the impact on privacy delivered by the Data Protection Officer of the Côte d'Azur University on 28/04/2020. In accordance with Article L. 1122-1, as amended, of the French Public Health Code (law of March 2002 on patients' rights), the overall results of the study can be communicated to you if you wish.

If you have any questions during your participation in this study, you may contact the principal investigators of this study:

- Prof. Nicolas Chevalier, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice
- Prof. Antonio Iannelli, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice

Or the scientific head of research:

- Prof. Fabienne d'Arripe-Longueville, phone: 04.89.15.39.55 at the LAMHESS of the Côte d'Azur University.

Or the Data Protection Officer:

- Mr. Didier Martin, phone: 04.89.15.11.99 at the Côte d'Azur University

You are free to accept or refuse to participate in this study. This will in no way affect the quality or the level of care you will receive, which will be the same as it has been thus far. During the course of the study, you may also decide to discontinue your participation without having to justify your decision.
Thank you for taking the time to read this newsletter. If you agree to participate in this research study, we invite you to sign the attached consent form.

Consent – Pre-registration phase (all) – V3 (04/03/2020)
ID No. – RCB: 2020-A00172-37

CONSENT FORM
FOR PARTICIPATION IN THE OCAPAS STUDY

Study on Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

I the undersigned …… (*Last name and first name of the volunteer*), accept to participate in the "**OCAPAS**" study.

The objectives and terms of the study were clearly explained to me by Prof. Nicolas Chevalier and Prof. Antonio Iannelli.

I have read and understood the information sheet given to me.

I accept that the documents in my medical file that relate to the study may be accessible to those responsible for the study and possibly to the health authorities. With the exception of these persons, who will treat the information in the strictest respect of medical confidentiality, my anonymity will be preserved.

I accept that my personal data collected during this study may be subject to automated processing by the research organisers. I may exercise my right of access, rectification, portability, deletion or limitation of the processing of data concerning me by contacting the data protection representative Mr. Didier Martin at the Côte d'Azur University, and as regards information of a medical nature by contacting Professor Nicolas Chevalier at the Nice University Hospital.

I understand that my participation in the study is voluntary.

I am free to accept or refuse to participate, and I am free to stop my participation at any time during the course of the study. This will not affect the quality of care I will receive.

My consent does not relieve the organisers of this study of their responsibilities. I retain all my rights under the law.

Having discussed it and having obtained the answers to all my questions, I freely and voluntarily agree to participate in the research study proposed to me.

Prepared in Nice, on _ _ / _ _ / _ _ _ _

Name and signature of the investigator *Signature of the volunteer*

INFORMATION NOTICE FOR PATIENTS FOR PARTICIPATION IN THE OCAPAS STUDY

Study of Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

Trial sponsor: Côte d'Azur University

Head of research: Prof. Fabienne d'Arripe-Longueville, Laboratoire Motricité Humaine, Expertise, Sport Santé [*Laboratory of Human Motricity, Expertise, Sport, and Health*] (EA 6312), Côte d'Azur University

Principal investigators: Prof. Nicolas Chevalier, University Professor – Hospital Practitioner at the Nice University Hospital; Prof. Antonio Iannelli, University Professor – Hospital Practitioner at the Nice University Hospital

Madam,

We would like to offer you the opportunity to participate in a clinical research study because you are undergoing a bariatric surgery procedure.

This information notice will tell you more about the study.

You have a 7-day reflection period during which you can take the time to read and understand this information, reflect on your participation, and ask the principal investigators of the study to explain what you did not understand.

PURPOSE OF THE STUDY

The "OCAPAS" scientific study is conducted in partnership with the Laboratoire Motricité Humaine, Expertise, Sport, Santé (LAMHESS) of Côte d'Azur University, the Specialised Obesity Center of the Provence Alpes Côte d'Azur East, the DARE [*Digestive-Anesthesia-Resuscitation-Endocrinology*] pole of the Nice University Hospital, the Public Health Department of the Nice University Hospital, Azur Sport Santé, the Laboratoire d'Anthropologie, Psychologie Cliniques, Cognitives et Sociales (LAPCOS) [*Laboratory of Anthropology, Clinical, Cognitive and Social Psychology*] of Côte d'Azur University, and the companies *Be Patient* and *Mooven*.

Its main objective is to study patient engagement in physical activity during bariatric surgery follow-up. To support your commitment to physical activity, the *MyBody* mobile application proposed by *Be Patient* will be made available to you.

The secondary objectives are to study the impact of your physical activity practice on different engagement and health indicators. Your perception of various mechanisms which could help to strengthen your commitment to physical activity will also be measured.

ANTICIPATED BENEFIT(S)

This study, through the physical activity that will be recommended to you, should help improve your health, quality of life and well-being.

CONDUCTING THE STUDY

To support your commitment to physical activity, you will benefit from the *MyBody* mobile application proposed by *Be Patient* and a connected watch that will allow you to view the number of steps you've taken each day, week and month. The mobile application is composed of advice sheets with quizzes, and a guided adapted physical activity program to be begun between the 3rd and 6th month following bariatric surgery. The adapted physical activity programme will respect international recommendations, i.e. it will accompany you in achieving 150 minutes per week with the goal of reaching 300 minutes per week. On the mobile application, you will be proposed two sessions per week, lasting from 30 to 50 minutes, consisting of endurance exercises and resistance strength-conditioning exercises in the form of a training circuit which will evolve progressively over the course of the programme. In addition, you will also be encouraged to walk regularly so as to reach the recommendations. After each session, you will record your participation on the application and evaluate your rating of perceived exertion on a scale from 0 to 10.

You will be monitored through physical and psychological assessments in the form of questionnaires. Assessments will take place at the beginning of inclusion (T0), then at 3 months (T3), and 6 months (T6) after inclusion. Only the physical assessments requiring a measurement will be required to take place at the Archet 2 University Hospital in Nice.

Physical assessments will be based on a 6-minute walking test (carried out under standardised conditions), a strength test, and the wearing of an accelerometer for 7 days positioned at the time of the assessments (and returned at the end of the 7-day period by post with a stamped envelope provided). Height, weight and impedance measurements will be carried out by a doctor or nurse as part of the standard monitoring.

The questionnaires to which you will be submitted can be filled in online on the *LimeSurvey* platform. You will receive an e-mail with the link to the questionnaire and a reminder of your anonymity number. If you have difficulty completing the questionnaires on the *LimeSurvey* platform, you can also complete them on paper during the physical assessments. The questionnaires will be used to evaluate:

- Self-reported physical activity level
- Observance and motivation:
  - The number, duration and type of physical activity sessions per week according to international recommendations.
  - Physical exercise habits and history
  - The stage of engagement in practice
  - Motivation for physical activity, how you feel during physical activity, and your reactions to various situations.

- Your perception of the solution to strengthen your commitment to physical activity
- Quality of life and health.

POTENTIAL RISKS

The respect of the protocol and contra-indications, the specific training of the adapted physical activity professional, as well as the carrying out of the evaluations at the Archet 2 Nice University Hospital, will guarantee your safety during the evaluations.

The risks that may arise during these assessments are those of possible and classic discomforts during the sessions (vaso-vagal episode, drop in blood pressure, shortness of breath, dizziness) for which the assessors are trained and which are the same as those related to practising physical or sports activities of daily life.

When carrying out the physical activities guided by the mobile application, the recommended perceived intensity must be strictly respected so as to avoid any risk during the practice (vaso-vagal episode, drop in blood pressure, shortness of breath...). Even if the risk of occurrence is low, it is advisable to always have a trusted person nearby to be able to react in the event of an undesirable event.

However, the scientific committee reserves the right to terminate the experiment in case of poor adaptation or intolerance.

CONSTRAINTS

You are free to participate in another research protocol, provided it does not involve new technologies and does not have an impact on physical activity levels or fitness measurement.

FINANCIAL PARTICIPATION

Your collaboration in this research protocol will not involve any financial participation on your part.

All costs (medical, supervision, equipment, insurance, etc.) related to the study will be covered by the researchers.

Only an uncashed cheque used as a security deposit for the loan of the equipment will be requested from you and then destroyed upon the return of the equipment.

LEGISLATION - CONFIDENTIALITY

In accordance with Articles L. 1121-1 et seq. of the French Public Health Code, the Committee on Human Research studied this research project and issued a favourable opinion on 01/04/2020.

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Only those responsible for the study and possibly the health authorities will have access to this data. With the exception of these people - who will treat the information in the strictest

respect of medical secrecy - your anonymity will be preserved. The publication of the results of the study will not include any individual results.
The data recorded over the course of this study will be subject to computerised processing by the sponsor. As this is personal data, you have the right of access, rectification, portability, deletion or limitation in the processing of data concerning you at any time by contacting the Data Protection Officer, Mr. Didier Martin at the Côte d'Azur University and those in charge of the study. As regards information of a medical nature, this right is exercised through the intermediary of Professor Nicolas Chevalier at the University Hospital of Nice, in accordance with France's law on Information Technology, Data Files and Civil Liberties, No. 78-17 of 6 January 1978, amended by law No. 94-548 of the 1st of July 1994, and Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation). The project received a notification of compliance with reference to methodology, and an analysis of the impact on privacy delivered by the Data Protection Officer of the Côte d'Azur University on 28/04/2020. In accordance with Article L. 1122-1, as amended, of the French Public Health Code (law of March 2002 on patients' rights), the overall results of the study can be communicated to you if you wish.

If you have any questions during your participation in this study, you may contact the principal investigators of this study:

- Prof. Nicolas Chevalier, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice
- Prof. Antonio Iannelli, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice

Or the scientific head of research:

- Prof. Fabienne d'Arripe-Longueville, phone: 04.89.15.39.55 at the LAMHESS of the Côte d'Azur University.

Or the Data Protection Officer:

- Mr. Didier Martin, phone: 04.89.15.11.99 at the Côte d'Azur University

You are free to accept or refuse to participate in this study. This will in no way affect the quality or the level of care you will receive, which will be the same as it has been thus far. During the course of the study, you may also decide to discontinue your participation without having to justify your decision.
Thank you for taking the time to read this newsletter. If you agree to participate in this research study, we invite you to sign the attached consent form.

CONSENT FORM
FOR PARTICIPATION IN THE OCAPAS STUDY

Study on Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

I the undersigned …… (*Last name and first name of the volunteer*), accept to participate in the "**OCAPAS**" study.

The objectives and terms of the study were clearly explained to me by Prof. Nicolas Chevalier and Prof. Antonio Iannelli.

I have read and understood the information sheet given to me.

I accept that the documents in my medical file that relate to the study may be accessible to those responsible for the study and possibly to the health authorities. With the exception of these persons, who will treat the information in the strictest respect of medical confidentiality, my anonymity will be preserved.

I accept that my personal data collected during this study may be subject to automated processing by the research organisers. I may exercise my right of access, rectification, portability, deletion or limitation of the processing of data concerning me by contacting the data protection representative Mr. Didier Martin at the Côte d'Azur University, and as regards information of a medical nature by contacting Professor Nicolas Chevalier at the Nice University Hospital.

I understand that my participation in the study is voluntary.

I am free to accept or refuse to participate, and I am free to stop my participation at any time during the course of the study. This will not affect the quality of care I will receive.

My consent does not relieve the organisers of this study of their responsibilities. I retain all my rights under the law.

Having discussed it and having obtained the answers to all my questions, I freely and voluntarily agree to participate in the research study proposed to me.

Prepared in Nice, on _ _ / _ _ / _ _ _ _

Name and signature of the investigator *Signature of the volunteer*

INFORMATION NOTICE FOR PATIENTS FOR PARTICIPATION IN THE OCAPAS STUDY

Study of Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

Trial sponsor: Côte d'Azur University

Head of research: Prof. Fabienne d'Arripe-Longueville, Laboratoire Motricité Humaine, Expertise, Sport Santé [*Laboratory of Human Motricity, Expertise, Sport, and Health*] (EA 6312), Côte d'Azur University

Principal investigators: Prof. Nicolas Chevalier, University Professor – Hospital Practitioner at the Nice University Hospital; Prof. Antonio Iannelli, University Professor – Hospital Practitioner at the Nice University Hospital

Madam,

We would like to offer you the opportunity to participate in a clinical research study because you are undergoing a bariatric surgery procedure.

This information notice will tell you more about the study.

You have a 7-day reflection period during which you can take the time to read and understand this information, reflect on your participation, and ask the principal investigators of the study to explain what you did not understand.

PURPOSE OF THE STUDY

The "OCAPAS" scientific study is conducted in partnership with the Laboratoire Motricité Humaine, Expertise, Sport, Santé (LAMHESS) of Côte d'Azur University, the Specialised Obesity Center of the Provence Alpes Côte d'Azur East, the DARE [*Digestive-Anesthesia-Resuscitation-Endocrinology*] pole of the Nice University Hospital, the Public Health Department of the Nice University Hospital, Azur Sport Santé, the Laboratoire d'Anthropologie, Psychologie Cliniques, Cognitives et Sociales (LAPCOS) [*Laboratory of Anthropology, Clinical, Cognitive and Social Psychology*] of Côte d'Azur University, and the companies *Be Patient* and *Mooven*.

Its main objective is to study patient engagement in physical activity during bariatric surgery follow-up. To support your commitment to physical activity, adapted physical activity sessions by videoconference will be made available to you.

The secondary objectives are to study the impact of your physical activity practice on different engagement and health indicators. Your perception of various mechanisms which could help to strengthen your commitment to physical activity will also be measured.

ANTICIPATED BENEFIT(S)

This study, through the physical activity that will be recommended to you, should help improve your health, quality of life and well-being.

CONDUCTING THE STUDY

To support your commitment to physical activity, following your bariatric surgery, you will benefit from an adapted physical activity program delivered via videoconferencing by a trained professional. Initially, you will have one-on-one videoconferences with an adapted physical activity professional, and then you will be given the opportunity to participate in group sessions with a group of young women included in this study like you. This group will be composed of a maximum of 4 people. The adapted physical activity program carried out by videoconference will comply with international recommendations, i.e. it will accompany you in achieving 150 minutes per week with the goal of reaching 300 minutes per week. You will be proposed two videoconference sessions per week, lasting from 30 to 50 minutes, consisting of endurance exercises and resistance strength-conditioning exercises in the form of a training circuit which will evolve progressively over the course of the programme. For each exercise, the professional will show you the exercise and explain it to you, and then you will carry out the number of repetitions planned together. As the sessions will be carried out live, the professional will be able to correct your posture and give you advice. In addition, he will encourage you to walk regularly so as to reach the recommendations. After each session, the professional will record your participation on a monitoring form and will ask you to evaluate your rating of perceived exertion on a scale from 0 to 10.

You will be monitored through physical and psychological assessments in the form of questionnaires. Assessments will take place at the beginning of inclusion (T0), then at 3 months (T3), and 6 months (T6) after inclusion. Only the physical assessments requiring a measurement will be required to take place at the Archet 2 University Hospital in Nice.

Physical assessments will be based on a 6-minute walking test (carried out under standardised conditions), a strength test, and the wearing of an accelerometer for 7 days positioned at the time of the assessments (and returned at the end of the 7-day period by post with a stamped envelope provided). Height, weight and impedance measurements will be carried out by a doctor or nurse as part of the standard monitoring.

The questionnaires to which you will be submitted can be filled in online on the *LimeSurvey* platform. You will receive an e-mail with the link to the questionnaire and a reminder of your anonymity number. If you have difficulty completing the questionnaires on the *LimeSurvey* platform, you can also complete them on paper during the physical assessments. The questionnaires will be used to evaluate:

- Self-reported physical activity level
- Observance and motivation:
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- Physical exercise habits and history
- The stage of engagement in practice
- Motivation for physical activity, how you feel during physical activity, and your reactions to various situations.

- Your perception of the solution to strengthen your commitment to physical activity
- Quality of life and health.

POTENTIAL RISKS

The respect of the protocol and contra-indications, the specific training of the adapted physical activity professional, as well as the carrying out of the evaluations at the Archet 2 Nice University Hospital, will guarantee your safety during the evaluations.

The risks that may arise during these assessments are those of possible and classic discomforts during the sessions (vaso-vagal episode, drop in blood pressure, shortness of breath, dizziness) for which the assessors are trained and which are the same as those related to practising physical or sports activities of daily life.

When carrying out the physical activities guided by the adapted physical activity professional by videoconference, the recommended perceived intensity must be strictly respected so as to avoid any risk during the session (vaso-vagal episode, drop in blood pressure, shortness of breath...). Even if the risk of occurrence is low, it is advisable to always have a trusted person nearby to be able to react in the event of an undesirable event.

However, the scientific committee reserves the right to terminate the experiment in case of poor adaptation or intolerance.

CONSTRAINTS

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FINANCIAL PARTICIPATION

Your collaboration in this research protocol will not involve any financial participation on your part.

All costs (medical, supervision, equipment, insurance, etc.) related to the study will be covered by the researchers.

Only an uncashed cheque used as a security deposit for the loan of the equipment will be requested from you and then destroyed upon the return of the equipment.

LEGISLATION - CONFIDENTIALITY

In accordance with Articles L. 1121-1 et seq. of the French Public Health Code, the Committee on Human Research studied this research project and issued a favourable opinion on 01/04/2020.

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The data recorded over the course of this study will be subject to computerised processing by the sponsor. As this is personal data, you have the right of access, rectification, portability, deletion or limitation in the processing of data concerning you at any time by contacting the Data Protection Officer, Mr. Didier Martin at the Côte d'Azur University and those in charge of the study. As regards information of a medical nature, this right is exercised through the intermediary of Professor Nicolas Chevalier at the University Hospital of Nice, in accordance with France's law on Information Technology, Data Files and Civil Liberties, No. 78-17 of 6 January 1978, amended by law No. 94-548 of the 1st of July 1994, and Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation). The project received a notification of compliance with reference to methodology, and an analysis of the impact on privacy delivered by the Data Protection Officer of the Côte d'Azur University on 28/04/2020.

In accordance with Article L. 1122-1, as amended, of the French Public Health Code (law of March 2002 on patients' rights), the overall results of the study can be communicated to you if you wish.

If you have any questions during your participation in this study, you may contact the principal investigators of this study:

- Prof. Nicolas Chevalier, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice
- Prof. Antonio Iannelli, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice

Or the scientific head of research:

- Prof. Fabienne d'Arripe-Longueville, phone: 04.89.15.39.55 at the LAMHESS of the Côte d'Azur University.

Or the Data Protection Officer:

- Mr. Didier Martin, phone: 04.89.15.11.99 at the Côte d'Azur University

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course of the study, you may also decide to discontinue your participation without having to justify your decision.

Thank you for taking the time to read this newsletter. If you agree to participate in this research study, we invite you to sign the attached consent form.

CONSENT FORM
FOR PARTICIPATION IN THE OCAPAS STUDY

Study on Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

I the undersigned …… (*Last name and first name of the volunteer*), accept to participate in the "**OCAPAS**" study.

The objectives and terms of the study were clearly explained to me by Prof. Nicolas Chevalier and Prof. Antonio Iannelli.

I have read and understood the information sheet given to me.

I accept that the documents in my medical file that relate to the study may be accessible to those responsible for the study and possibly to the health authorities. With the exception of these persons, who will treat the information in the strictest respect of medical confidentiality, my anonymity will be preserved.

I accept that my personal data collected during this study may be subject to automated processing by the research organisers. I may exercise my right of access, rectification, portability, deletion or limitation of the processing of data concerning me by contacting the data protection representative Mr. Didier Martin at the Côte d'Azur University, and as regards information of a medical nature by contacting Professor Nicolas Chevalier at the Nice University Hospital.

I understand that my participation in the study is voluntary.

I am free to accept or refuse to participate, and I am free to stop my participation at any time during the course of the study. This will not affect the quality of care I will receive.

My consent does not relieve the organisers of this study of their responsibilities. I retain all my rights under the law.

Having discussed it and having obtained the answers to all my questions, I freely and voluntarily agree to participate in the research study proposed to me.

Prepared in Nice, on _ _ / _ _ / _ _ _ _

Name and signature of the investigator *Signature of the volunteer*

Information notice – Group C – V4 (15/10/2020)
ID No. – RCB: 2020-A00172-37

INFORMATION NOTICE FOR PATIENTS FOR PARTICIPATION IN THE OCAPAS STUDY

Study of Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

Trial sponsor: Côte d'Azur University

Head of research: Prof. Fabienne d'Arripe-Longueville, Laboratoire Motricité Humaine, Expertise, Sport Santé [*Laboratory of Human Motricity, Expertise, Sport, and Health*] (EA 6312), Côte d'Azur University

Principal investigators: Prof. Nicolas Chevalier, University Professor – Hospital Practitioner at the Nice University Hospital; Prof. Antonio Iannelli, University Professor – Hospital Practitioner at the Nice University Hospital

Madam,

We would like to offer you the opportunity to participate in a clinical research study because you are undergoing a bariatric surgery procedure.

This information notice will tell you more about the study.

You have a 7-day reflection period during which you can take the time to read and understand this information, reflect on your participation, and ask the principal investigators of the study to explain what you did not understand.

PURPOSE OF THE STUDY

The "OCAPAS" scientific study is conducted in partnership with the Laboratoire Motricité Humaine, Expertise, Sport, Santé (LAMHESS) of Côte d'Azur University, the Specialised Obesity Center of the Provence Alpes Côte d'Azur East, the DARE [*Digestive-Anesthesia-Resuscitation-Endocrinology*] pole of the Nice University Hospital, the Public Health Department of the Nice University Hospital, Azur Sport Santé, the Laboratoire d'Anthropologie, Psychologie Cliniques, Cognitives et Sociales (LAPCOS) [*Laboratory of Anthropology, Clinical, Cognitive and Social Psychology*] of Côte d'Azur University, and the companies *Be Patient* and *Mooven*.

Its main objective is to study patient engagement in physical activity during bariatric surgery follow-up. To support your commitment to physical activity, you will be monitored and receive advice from the adapted physical activity professional from the bariatric surgery service.

The secondary objectives are to study the impact of your physical activity practice on different engagement and health indicators. Your perception of various mechanisms which could help to strengthen your commitment to physical activity will also be measured.

ANTICIPATED BENEFIT(S)

This study, through the physical activity that will be recommended to you, should help improve your health, quality of life and well-being.

CONDUCTING THE STUDY

To support your commitment to physical activity, you will be monitored and receive advice to help you achieve 150 minutes per week of physical activity with the goal of reaching 300 minutes per week. This advice and recommendations will be given to you by the adapted physical activity professional from the bariatric surgery service. You will be encouraged to walk regularly in order to reach the recommendations and to carry out two sessions per week dedicated to physical activity including muscle strengthening exercises adapted to the bariatric surgery course.

You will be monitored through physical and psychological assessments in the form of questionnaires. Assessments will take place at the beginning of inclusion (T0), then at 3 months (T3), and 6 months (T6) after inclusion. Only the physical assessments requiring a measurement will be required to take place at the Archet 2 University Hospital in Nice.

Physical assessments will be based on a 6-minute walking test (carried out under standardised conditions), a strength test, and the wearing of an accelerometer for 7 days positioned at the time of the assessments (and returned at the end of the 7-day period by post with a stamped envelope provided). Height, weight and impedance measurements will be carried out by a doctor or nurse as part of the standard monitoring.

The questionnaires to which you will be submitted can be filled in online on the *LimeSurvey* platform. You will receive an e-mail with the link to the questionnaire and a reminder of your anonymity number. If you have difficulty completing the questionnaires on the *LimeSurvey* platform, you can also complete them on paper during the physical assessments. The questionnaires will be used to evaluate:

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  - The number, duration and type of physical activity sessions per week according to international recommendations.
  - Physical exercise habits and history
  - The stage of engagement in practice
  - Motivation for physical activity, how you feel during physical activity, and your reactions to various situations.
- Your perception of the solution to strengthen your commitment to physical activity
- Quality of life and health.

POTENTIAL RISKS

The respect of the protocol and contra-indications, the specific training of the adapted physical activity professional, as well as the carrying out of the evaluations at the Archet 2 Nice University Hospital, will guarantee your safety during the evaluations.

The risks that may arise during these assessments are those of possible and classic discomforts during the sessions (vaso-vagal episode, drop in blood pressure, shortness of breath, dizziness) for which the assessors are trained and which are the same as those related to practising physical or sports activities of daily life.

When carrying out the recommended physical activities, the recommended perceived intensity must be strictly respected so as to avoid any risk during the practice (vaso-vagal episode, drop in blood pressure, shortness of breath...).

However, the scientific committee reserves the right to terminate the experiment in case of poor adaptation or intolerance.

CONSTRAINTS

You are free to participate in another research protocol, provided it does not involve new technologies and does not have an impact on physical activity levels or fitness measurement.

FINANCIAL PARTICIPATION

Your collaboration in this research protocol will not involve any financial participation on your part.

All costs (medical, supervision, equipment, insurance, etc.) related to the study will be covered by the researchers.

Only an uncashed cheque used as a security deposit for the loan of the equipment will be requested from you and then destroyed upon the return of the equipment.

LEGISLATION - CONFIDENTIALITY

In accordance with Articles L. 1121-1 et seq. of the French Public Health Code, the Committee on Human Research studied this research project and issued a favourable opinion on 01/04/2020.

An insurance policy, number 146 177 524, was taken out by the sponsor of the trial, the Côte d'Azur University - 20 avenue Valrose - BP 2135 - 06103 Nice Cedex 2, with the company MMA Entreprise, to cover the risks linked to this research.

Any information about you collected during this trial will be treated confidentially.

Only those responsible for the study and possibly the health authorities will have access to this data. With the exception of these people - who will treat the information in the strictest respect of medical secrecy - your anonymity will be preserved. The publication of the results of the study will not include any individual results.

The data recorded over the course of this study will be subject to computerised processing by the sponsor. As this is personal data, you have the right of access, rectification, portability, deletion or limitation in the processing of data concerning you at any time by contacting the

Data Protection Officer, Mr. Didier Martin at the Côte d'Azur University and those in charge of the study. As regards information of a medical nature, this right is exercised through the intermediary of Professor Nicolas Chevalier at the University Hospital of Nice, in accordance with France's law on Information Technology, Data Files and Civil Liberties, No. 78-17 of 6 January 1978, amended by law No. 94-548 of the 1st of July 1994, and Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation). The project received a notification of compliance with reference to methodology, and an analysis of the impact on privacy delivered by the Data Protection Officer of the Côte d'Azur University on 28/04/2020. In accordance with Article L. 1122-1, as amended, of the French Public Health Code (law of March 2002 on patients' rights), the overall results of the study can be communicated to you if you wish.

If you have any questions during your participation in this study, you may contact the principal investigators of this study:

- Prof. Nicolas Chevalier, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice
- Prof. Antonio Iannelli, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice

Or the scientific head of research:

- Prof. Fabienne d'Arripe-Longueville, phone: 04.89.15.39.55 at the LAMHESS of the Côte d'Azur University.

Or the Data Protection Officer:

- Mr. Didier Martin, phone: 04.89.15.11.99 at the Côte d'Azur University

You are free to accept or refuse to participate in this study. This will in no way affect the quality or the level of care you will receive, which will be the same as it has been thus far. During the course of the study, you may also decide to discontinue your participation without having to justify your decision.

Thank you for taking the time to read this newsletter. If you agree to participate in this research study, we invite you to sign the attached consent form.

Consent – Group C – V3 (04/03/2020)
ID No. – RCB: 2020-A00172-37

FORMULAIRE DE CONSENTEMENT POUR LA PARTICIPATION A L'ETUDE OCAPAS

Etude Activité Physique et Chirurgie Bariatrique

Research title: "OCAPAS" Scientific study

I the undersigned …… (*Last name and first name of the volunteer*), accept to participate in the "**OCAPAS**" study.

The objectives and terms of the study were clearly explained to me by Prof. Nicolas Chevalier and Prof. Antonio Iannelli.

I have read and understood the information sheet given to me.

I accept that the documents in my medical file that relate to the study may be accessible to those responsible for the study and possibly to the health authorities. With the exception of these persons, who will treat the information in the strictest respect of medical confidentiality, my anonymity will be preserved.

I accept that my personal data collected during this study may be subject to automated processing by the research organisers. I may exercise my right of access, rectification, portability, deletion or limitation of the processing of data concerning me by contacting the data protection representative Mr. Didier Martin at the Côte d'Azur University, and as regards information of a medical nature by contacting Professor Nicolas Chevalier at the Nice University Hospital.

I understand that my participation in the study is voluntary.

I am free to accept or refuse to participate, and I am free to stop my participation at any time during the course of the study. This will not affect the quality of care I will receive.

My consent does not relieve the organisers of this study of their responsibilities. I retain all my rights under the law.

Having discussed it and having obtained the answers to all my questions, I freely and voluntarily agree to participate in the research study proposed to me.

Prepared in Nice, on _ _ / _ _ / _ _ _ _

Name and signature of the investigator

Signature of the volunteer

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	16
Protocol version	3	Date and version identifier	16
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 17-18
	5b	Name and contact information for the trial sponsor	18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17-18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15; 17-18

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	10-12
Objectives	7	Specific objectives or hypotheses	6-7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	13-14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	7-8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	13-14
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7-8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14-15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8-9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A, blinding cannot be strictly guaranteed in this study, only strategies to limit potential bias were taken.

Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13-14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15-16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15-16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	15
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A, no interim analyses have been planned
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	7-8

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	15
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8, 17-18
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A, no ancillary studies are planned
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16-18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A, no ancillary studies or post-trial care are planned
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	8, 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	17-18

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Translated consent forms are provided as a supplementary file.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A no biological specimens were collected as part of this trial

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.