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BMJ Open Effects of technology-based physical activity interventions for women after bariatric surgery: study protocol for a three-arm randomised 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 programmes after bariatric surgery compared with 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 3–6 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 travelled during a 6 min walk test relativised according to Capadaglio's theoretical distance. Secondary outcomes are behavioural 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 programme for 12 weeks (between T0 and T3). A mixed model approach will be used to analyse 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.

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 programmes 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 programmes.
- One potential challenge of this trial may include low compliance rates, especially towards 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 behaviours, both in the general population⁴ 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% and 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 programmes 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 videoconferencing¹⁷ have been shown to increase the PA level in the short term, but the medium-term 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' taxonomy could be used to group them according to the behavioural change techniques they incorporate.¹⁹

According to this taxonomy, mobile applications, internet-based platforms and devices like activity bracelets activate the main behavioural strategies like goal-setting, self-monitoring and personal feedback.²⁰ Recent meta-analyses have provided proof of efficacy for mobile technology compared with control condition²¹ or offline interventions²⁰ 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 patients with BS.

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 (eg, 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 behavioural strategies. Mobile applications incorporate strategies with technological regulations (eg, self-monitoring, feedback, goal setting and shaping knowledge), while videoconferencing incorporates strategies with human regulations from both professional and other participants (eg, social support, motivation strategies, communication skills and goal setting). The use of mobile applications is completely autonomous, while videoconferencing is regulated by predetermined 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 model²⁹ 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 behaviour in the field of obesity has been studied through self-determination theory.^{31 32} Self-determination theory is a macrotheory that notably highlights the types of motivation (ie, intrinsic, extrinsic, amotivation) along a continuum,³³ the needs that individuals attempt to satisfy (ie, autonomy, competence, relatedness)³⁴ and the individual differences in motivation orientation (ie, 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 behaviour 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 behavioural 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 randomised 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 programmes (mobile technology and videoconferencing) after BS compared with 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 programmes 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 hypothesise 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 behavioural 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

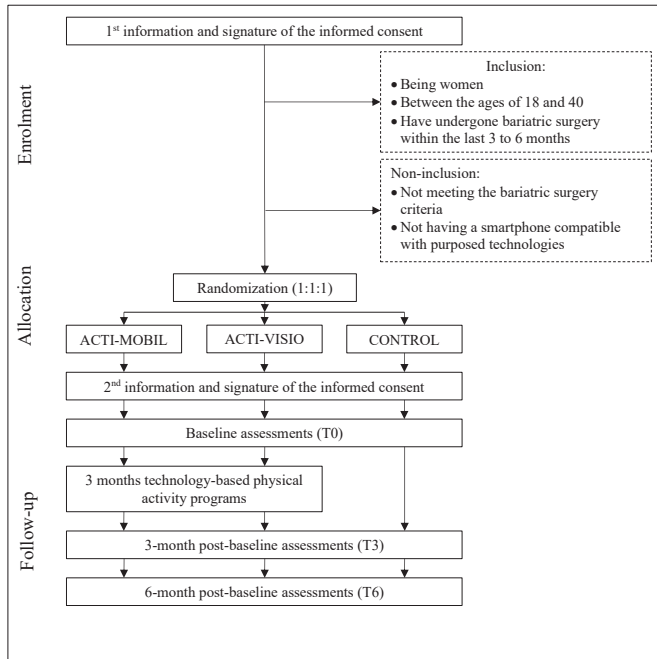


Figure 1 Flow diagram of study protocol.

the control group will show an improvement on the PA behavioural 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 randomised 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 randomised control trials have measured motivational concepts. We assume that technology acceptability and motivational concepts may mediate the effects of technology-based interventions on PA behavioural 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 programme 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 programme for 12 weeks (between T0 and T3). Each participant will be included for a period of 6 months, on average 3–6 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 3–6 months earlier at a tertiary referral centre 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 nonserious 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 online supplemental 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 on 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 randomisation

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 (online supplemental 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 software⁴¹ in a 1:1:1 ratio. The minimisation randomisation 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 randomisation, 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 (online supplemental additional file 2). This procedure of two times consent⁴² 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 19 November 2020.

Outcome measurements

Table 1 provides a summary of the measures to be collected. Outcomes will be assessed at baseline (T0), 3

**Table 1** Summary of measures to be collected

| Outcomes | Instrument | Time of measurement |
|--------------------------------------|--|--|
| Primary outcome | | |
| Walking capacity | 6 min walk test distance ^{45 47} | T0, T3 and T6 |
| Secondary outcomes | | |
| <i>Behavioural measures</i> | | |
| Physical activity level | Global physical activity questionnaire ⁴⁸ 7 days AX3 physical activity monitoring ^{49 50} | T0, T3 and T6 T0, T3 and T6 |
| Stage of change | Stage of change ⁵² | T0, T3 and T6 |
| <i>Physiological measures</i> | | |
| Energetic expenditure | Oxygen uptake, minute ventilation, carbon dioxide output, respiratory exchange ratio, heart rate measured using Cosmed K5 system ⁵⁴ | T0, T3 and T6 |
| Muscle strength | Maximal isometric knee extensor muscles strength (Newton) measured with MicroFET2 ⁵⁵ | T0, T3 and T6 |
| <i>Health indicators</i> | | |
| Quality of life | EuroQoL-5-Dimensions and EuroQoL-visual analogue scale ⁵⁶ | 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 Body Xpert | T0, T3 and T6 |
| Other measures | | |
| Technology acceptability | eHealth acceptability scale ⁵⁸ | T0, T3 and T6 except for control group |
| Programme compliance | Rate of participation and rate of perceived exertion | T3 except for control group |
| Motivation for PA | Motivation scale for health-oriented physical activity ⁵⁹ | T0, T3 and T6 |
| General causality orientation for PA | General causality orientation scale ⁶⁰ | T0, T3 and T6 |
| Basic psychological needs | Basic psychological needs ⁶¹ | T0, T3 and T6 |

PA, physical activity.

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

Primary outcome

The primary outcome is walking capacity assessed by distance travelled during a 6 min walk test (6MWT) associated with measures of energy expenditure (eg, heart rate, oxygen uptake) described in the secondary outcomes. The 6MWT, highly reproducible in obesity,⁴⁴ will be performed according to guidelines.⁴⁵ Due to weight loss during BS follow-up regardless of PA, the distance travelled in 6MWT increases after BS.⁴⁶ Therefore, we will use Capodaglio's formula including age, sex and body mass index to relativise the walking distance.⁴⁷

Secondary outcomes

Behavioural measures of PA

PA level. PA will be measured using the Global PA Questionnaire validated in the French language.⁴⁸ 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 min/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 analysed using open-source AX3 OmGui software (OmGui V.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.^{49 50}

Stage of Change for PA. The stage of change for PA and exercise related to the transtheoretical model⁵¹ will be measured using the French version⁵² of the Stages of Change questionnaire.⁵³ Regular PA and exercise are defined as 'at least 30 min per session, at least 5 days per week of moderate to vigorous PA'. This questionnaire includes five items with an '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.⁵⁴

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, Utah). 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 5s 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.⁵⁵

Health indicators

Quality of life. Quality of life will be assessed with the French version of the EuroQoL-5-dimensions and a EuroQoL-visual analogue scale.⁵⁶ 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 analogue 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,⁵⁷ 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/m²).

Body composition. Body composition will be measured by bioimpedance using the Biody Xpert (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,⁵⁸ including 25 items divided into eight subscales: performance expectancy, effort expectancy, social influence, facilitating conditions, hedonic motivation, price value, habit and behavioural 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.

Programme compliance. To measure technology-based programme 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.⁵⁹ This scale comprises 18 items, distributed across the six motivational constructs of the self-determination theory³³: 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 Scale⁶⁰ to assess the strength of three motivational orientations (ie, autonomy, control and 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,⁶¹ 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 min per week, with a goal of 300 min per week of moderate to vigorous PA including muscle strengthening exercises 2–3 times per week.³ The



technology groups will receive similar PA programmes two times a week for 12 weeks (between T0 and T3), combined with advice and counselling 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 programme consists of tailored adapted PA sessions led by a professional specialised in adapted PA. These sessions were specifically designed to be appropriate for the population and to ensure standardisation 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 specialised 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 randomisation, 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 standardisation 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 seven for three 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 randomisation, the women will receive registration details to create a personal account, and their activity bracelets will be synchronised with the platform to visualise their PA. Technical support will be provided in cases of configuration or synchronisation difficulties. For the women whose activities have not been detected on the platform 1 week after the start of the programme, a reminder will be given by phone.

Data analysis and management

Sample size

Sample size for the study is based on the distance travelled during a 6MWT relativised with age, sex and body mass index.⁴⁷ A recent meta-analysis showed an overall effect $Z=2.52$ ($p=0.01$) of change in walking distance after BS in an exercise group compared with a control group.⁶² An overall effect $Z=2.52$ corresponds to $f=0.20$.⁶³ However, this effect size is probably minimised because it has not been relativised according to body mass index. Furthermore, eHealth PA programmes for obese or sedentary individuals have an effect size of $d=0.37$,⁶⁴ corresponding to $f=0.19$.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 $f=0.25$ 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, pseudonymisation 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 pseudonymisation 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 0.05 under the bilateral hypothesis. Missing data patterns will be analysed and described. Less than 5% missing data are usually considered inconsequential,⁶⁷ and simple methods will be used (eg, last observation carried forward, mean, median). If more than 5% of the data are 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 normalise non-normal data. The dimensional consistency of the subjective data will be calculated using Cronbach's alpha coefficient. Baseline differences between groups (eg, 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 nonindependence of the repeated measures.^{71 72} Moreover, the mixed models can be used to analyse 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 (Registered 15 July 2020). The protocol (V.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 statement⁷⁴ (online supplemental additional file 3). Any modification of the research protocol must be subjected to an authorisation agreement from the Ethics Committee.

The data sets 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 1 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 programmes (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 programmes will be developed.

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Contributors Fd'A-L, MH and VN conceived the project and procured the project funding. NC, AI, CP, SSC, AF and PT contributed to the trial protocol. OD, J-MG, AV, SSC and MH conceptualised the interventions, developed the contents, and worked with the companies. Fd'A-L 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, Fd'AL, and MH developed the plan for statistical analysis. MH and Fd'AL drafted the manuscript and coordinated the revisions. All other authors reviewed, edited and approved the final manuscript.

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