BMJ Open

Digital Intervention Promoting Physical Activity among Obese people (DIPPAO) randomized controlled trial: study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058015
Article Type:	Protocol
Date Submitted by the Author:	05-Oct-2021
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Keywords:	SPORTS MEDICINE, SOCIAL MEDICINE, Diabetes & endocrinology < INTERNAL MEDICINE, HEALTH ECONOMICS

DIPPAO randomized controlled trial: study protocol

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Word count excluding title page, abstract, references, figures and tables: 4842

Tables/Figures: 6

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Abstract

Introduction: Physical inactivity and excessive sedentary behaviors are major preventable causes in both the development and the treatment of obesity and type 2 diabetes mellitus (T2DM). Nevertheless, current programs struggle to engage and sustain physical activity (PA) of patients over long periods of time. To overcome these limitations, the DIPPAO (Digital Intervention Promoting Physical Activity among Obese people) randomized controlled trial (RCT) aims to evaluate the effectiveness of a group-based digital intervention grounded on gamification strategies (i.e., the use of game elements in nongame contexts), enhanced by social features, and informed by the tenets of the self-determination theory and the social identity approach.

Methods and analysis: This trial is a two-arm parallel RCT testing the effectiveness of the Kiplin digital intervention on obese and T2DM patients in comparison to the usual supervised PA program of the University Hospital of Clermont-Ferrand, France. 50 patients will be randomized to one of the two conditions and will follow a 3-month program with a 6-month follow-up post-intervention. The primary outcome of the study is the daily step count change between the baseline assessment and the end of the intervention. Accelerometer data, self-reported PA, body composition, and physical capacities will also be evaluated. To advance our understanding of complex interventions like gamified and group-based ones, we will explore several psychological mediators relative to motivation, enjoyment, in-group identification, or perceived weight stigma. Finally, to assess a potential superior economic efficiency compared to the current treatment, we will conduct a cost-utility analysis between the two conditions. A mixed model approach will be used to analyze the change in outcomes over time.

Ethics and dissemination: The protocol study adheres to the principles of the Helsinki declaration. The research protocol has been reviewed and approved by the Local Human Protection Committee (CPP Ile de France XI, *N°* 21004-65219).

Trial registration: NCT04887077 *(ClinicalTrial.gov; Registered May 14, 2021)*

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Keywords: behavior change; cost-utility; e-health; gamification; intervention; mhealth; mobile app; obesity; physical activity; RCT; T2DM; weight stigma

Strengths and limitations of this study:

- This is the first study to compare a digital gamified intervention targeting PA to another existing non-drug treatment and to test its cost-utility.
- Between- and within-person level analyses of daily steps will provide insight on group differences and individual trajectories of behavior change.
- A 6-month follow-up will inform on the sustainability of the long-term intervention effect.
- One of the major limitations is that the intervention being complex integrating multiple components, it will be difficult to affirm which component is involved in the efficacy of the intervention.
- We will attempt to address this limitation by conducting in-depth mediation analyses, to identify the salient ingredients behind the effect.

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Introduction

Overweight and obesity, which concern one in two adults in western countries [1], are among the most important health risk factors, and is associated with comorbidities such as Type 2 diabetes mellitus (T2DM), which counts for 5% of the French population under 65 years of age, and 15% of people over 65 years old. If the roots of obesity and T2DM are complex and multifactorial, physical inactivity and sedentary behaviors (SB) are both major factors in the apparition and development of these diseases [2–7].

Positive effects of PA for these patients are recognized both at the scientific and institutional levels. Indeed, they can benefit from supervised PA programs suited to their disease (i.e., adapted physical activity, APA), which allow to improve functional capacity and muscle strength without having detrimental effects or complications on disease progression [8]. However, these programs can be difficult to access for patients, due to lack of availability on the scheduled sessions, lack of economic means, or geographical distance [9], and can be expensive for the healthcare system. As a result, a limited adherence to PA at the end of these programs is generally observed.

Given that PA of obese and T2DM patients remains very low [10–12], promoting their long-term PA participation is a major challenge for researchers, practitioners, and the global healthcare economic system [13]. A promising solution is to overcome the limitations of current face-to-face programs, by developing digital interventions. In this vein, this study will evaluate the efficacy of a digital intervention in subjects with chronic diseases, by comparing it to the gold standard (supervised face-to-face PA).

e-health and gamification

Digital tools may provide effective, cost effective, safe, and scalable interventions to improve health and healthcare [14]. These devices introduce a new care approach where patients participate in their treatment in a dynamic and interactive way, contributing to their empowerment. These interventions offer a wider and more individualized scope than face-to-face interventions, with potentially lower long-term costs [15]. Nevertheless, no rigorous trial has yet demonstrated the superiority of digital PA

interventions over existing ones. Although e-health interventions are gaining popularity for the treatment of obesity, appearing advantageous compared to current programs, no evidence of cost-effectiveness has been demonstrated [107]. In addition, concerns remain regarding the adherence rate and engagement in the long-term [16]. Therefore, the use of gamification appears as an interesting way to address these limits.

Defined as the use of game design elements in non-game contexts [17], gamification is the art of improving a routine activity in an engaging and motivating way, by the integration of specific ingredients that make games enjoyable. By gamifying PA, participants are encouraged to move and walk to play, and this tends to make their activity more playful and motivating [18]. A recent meta-analysis [19] revealed that gamified interventions improved PA with an increase of more than 1600 daily steps. Importantly, additional analyses indicated that a) gamified interventions appear more effective than equivalent non-gamified interventions and b) PA improvement persists in the long term. This suggests that gamification is more than a novelty effect, and that is a promising healthcare approach, as it can be easily implemented in daily life without adding demands to people's schedules. In sum, gamified interventions seem to be a critical strategy to engage participants in digital interventions. However, more rigorous trials are needed to confirm these promising results, to better understand the mechanisms explaining gamification effects, and to test the healthcare potential of gamified interventions [19].

Barriers to PA and determinants of behavior change in obese people

Another key driver to enhance the effectiveness of e-health interventions is the use of behavior change theories and techniques (BCTs), as they allow to target the active ingredients of behavior change [20]. Yet, the development of mobile applications, internet platforms, and connected objects designed to promote PA is rarely based on scientific knowledge [21,22] while they constitute an excellent opportunity to both develop and test such theories (e.g., theory of planned behavior [23], transtheoretical model [24], self-determination theory [25]) and BCTs [26].

In addition, recent research has emphasized the importance of precision medicine, which focus on individual variability and social and societal factors of behavior change in the development and evaluation of therapies [27]. In this vein, the social psychology approach can be promising as it highlights the importance of collective-level factors. Notably, it suggests that weight stigma is an important driver of the obesity increase [28]. Overweight and obese persons may face specific barriers related to weight stigma when they try to implement exercise in their daily life. They may indeed face or fear to face discrimination from a prejudiced person, or they may have internalized negative stereotypes into their self-perceptions, leading them to avoid activities in which they feel being stigmatized, such as PA [29]. For example, the more obese people perceive themselves negatively or feel discriminated because of their weight, the more they avoid PA [30]. Considering the impact of weight stigma in the development of obese-targeted interventions is therefore vital to optimize their effectiveness.

Theoretical framework

To address these challenges, the present intervention was built based on the tenets of the self-determination theory (SDT) [31] and the social identity approach (SIA) [32].

Self-determination theory. The SDT is an empirically validated framework which focuses on factors that promote sustained motivation and wellbeing [33]. At its core, this model proposes that motivation is regulated along a continuum from lack of motivation to a completely autonomous motivation, in which the behavior is spontaneous and comes from the individual's will. Research has revealed that an autonomous motivation has positive emotional, cognitive, and behavioral consequences, and is strongly associated with PA over time [34]. The most autonomous forms of motivation are the intrinsic ones, which occurs when people perform an activity for its own satisfaction, its inherent interest and enjoyment. Especially, practicing PA for the direct pleasure and the inherent satisfaction it provides is an important predictor of the long-term maintenance of physical practice [34]. This suggests that a game-

based intervention that provides fun and playful experiences would feed the autonomous motivation of participants and would be more correlated with long-term adherence of PA.

In parallel, SDT postulates that autonomous motivation increases when three basic psychological needs are satisfied [25]: the need for autonomy (i.e., need to feel responsible of one's own actions), for competence (i.e., need to feel effective in one's interactions with the environment), and for relatedness (i.e., need to feel connected to other people). Again, gamifying interventions seems particularly promising with this regard, as it can provide basic need satisfaction [18,35], leading to a significant intrinsic motivation improvement [36]. Firstly, gamification strategies such as points scores, badges, levels, and competitions, sustain the need for competence by providing feedbacks on the user's behavior. Secondly, customizable environments of the games or user choices may support autonomy. Finally, leaderboards, teams, groups, or communication functions may support the need for relatedness [18].

Social identity approach. It is now well-established that exercising in group-based settings may be effective to engage participants in PA and sustain their practice over time [37,38], regardless of the population characteristics [39]. However, results from group-based interventions are mixed, [40] suggesting that bringing people together does not systematically make interventions successful [41]. The SIA offers a relevant paradigm to explain these mixed results. It argues that social groups can affect health behaviors and outcomes only when individuals perceive they share the same identity with another individual or group [41]. SIA is the combination of two related theories - the social identity theory [42] and the self-categorization theory [43]. As social identity theory introduces the capacity for groups to be internalized into our sense of self (i.e., speaking and living situations in the name of 'we' and 'us' rather than just 'I' and 'me'), the self-categorization theory explains how people develop their social identity within groups. More especially, it proposes that the salience of a particular social identity results from a context-sensitive categorization process. Individuals categorize themselves according to a set of core attributes that are salient and observable such as age, gender, ethnicity, or weight status. The knowledge of these determinants is precious when designing group-based interventions in order to catalyze the effects of groups with shared social identities.

A recent body of work investigates the links between self-categorization theory and long-term adherence of PA programs. Dunlop, Beauchamp et al. [44–46] have shed light on important attributes that determine engagement in PA. These researchers found that age and gender are particularly relevant markers of shared social identity through PA. Importantly, moderator analyses revealed that adults who were overweight reported a particularly strong preference for exercising within same-gender groups relative to mixed-gender groups, in comparison to normal weight adults [45]. The consideration of these attributes that determine engagement in a PA program can inform and guide intervention choices. Moreover, based on the rejection-identification model [47], Jetten et al. [48] proposed that social identities derived from group membership can act as psychological resources when individuals are confronted with stigmatization. Thus, the shared identities forged during a group-based intervention regrouping individuals with the same stigma (e.g., weight status) could be the keystone for the emergence of a social identity and social support able to counteract the negative effects of group-based discrimination.

The study aims

The main objective of the DIPPAO randomized controlled trial (RCT) is to evaluate the effectiveness of the Kiplin intervention – a group-based digital program centered on gamification strategies and informed by the tenets of SDT and SIA – to promote PA among patients with obesity and/or T2DM. The Kiplin intervention is composed of four components embedded within a smartphone application: a) a gamification of PA through multiple games, b) a remote APA program with videoconferencing sessions, c) an interface for exchange and conversation and, d) an activity monitoring tool. The present study will investigate the short and long-term effects of the intervention over 3 and 9 months in comparison with the usual care provided at the University Hospital of Clermont-Ferrand, France (i.e., 3 months face-to-face supervised APA program). Additional objectives of this RCT will be to better understand the mechanisms underlying this digital intervention and to test its cost-utility compared to

the usual care. More specific hypotheses on the expected effects of the intervention are proposed in supplemental material 1.

Methods and analysis

Study design

This study will be a two-arm parallel RCT comparing the effectiveness of the Kiplin digital intervention to the usual supervised PA program of the University Hospital of Clermont-Ferrand, on patients with obesity and/or T2DM. Both arms will benefit from a 3-month program and assessments will be carried at baseline, 3 and 9 months. The conduct and reporting of the trial will follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines [49]. For an overview of the study design, see Figure 1.

[Please insert Figure 1 here]

Participants

Eligibility criteria. Participants will be voluntary patients affected for obesity (BMI ≥30 kg/m² and <45 kg/m²) and/or T2DM, aged 18 to 65 years, male or female, and referred to the department of sports medicine of the University Hospital of Clermont-Ferrand by their physician to benefit from supervised PA. The participants must have an iOS (at least iOS12 version) or Android (at least version 6) smartphone to be eligible. They must also be covered by health social security and be naive to any APA intervention. In order to ensure the understanding of the different questionnaires used in the study, sufficient proficiency of French will be required. The presence of one of the exclusion criteria listed in supplemental material 2 will lead to the exclusion of the participant.

Recruitment. A total of 50 patients (25 per group) will be recruited at the University Hospital of Clermont-Ferrand (department of sports' medicine). At their inclusion, patients meeting inclusion criteria will be proposed to participate to the study and the inclusion will be done during a medical consultation. The subject will sign a written consent form before being included in the study (see

supplemental material 3 for the patient consent form). Participants will not receive monetary compensation. However, the wearable device (Garmin Vivofit 3) distributed to all participants at the beginning of the study will be offered to them at its end.

Protocol

Procedure. There will be five visits for all participants: the selection visit, the inclusion visit, and three experimental visits (T0, T1, T2, see Figure 1). Visits will occur in the department of sports medicine (University Hospital) of Clermont-Ferrand. During the selection visit, one of the investigating physicians will check the patients' ability to complete the full protocol based on eligibility criteria. Only after signing the informed consent form, patients will move to the inclusion visit and will be given a wearable device (Garmin Vivofit 3) and an accelerometer (Actigraph GT3x) for the baseline assessment of PA for 7 days. At least one week after this visit, the T0 experimental visit will occur to complete baseline assessments before the start of the intervention. At the end of the 3-month program, the T1 experimental visit will be carried, and the T2 experimental visit will be placed 6 months after the end of the program in order to evaluate the follow-up of the intervention. Apart from a few questionnaires, the three experimental sessions will be identical. To ensure equal conditions for all participants, physical condition assessments will be conducted by the same APA coach, within the same day, at the same moment, and in the same order.

Randomization, allocation, and blinding. Following the first experimental visit, patients will be randomized in one of the two conditions with a 1:1 allocation. The associate biostatistician will carry out a permuted block randomization in advance by computer with randomly varying block sizes. The randomization list will be transmitted using sequentially numbered, opaque, sealed envelopes to the data collectors. Research assistants collecting data will be blinded to the treatment allocation. Double blinding is nevertheless not possible in such interventions because allocation concealment is impossible for participants.

Data management. All data will be entered electronically into REDCap (Research Electronic Data Capture), a secure, web-based software platform specifically designed to support data capture for research studies. Data will be reported as it is obtained. All Principal Investigators will be given access to the cleaned data sets. Investigators with direct access to the data will take all necessary precautions to ensure the confidentiality of information relating to the medical products, the trials, the participants involved and more particularly their identity and the obtained outcomes. A fully anonymized data set, statistical code, and all study materials will be made publicly available on the Open Science Framework.

Intervention

Preliminary testing. Feasibility of the gamified part of the Kiplin app has been previously assessed via a qualitative study among breast cancer survivors [50]. This study showed that the intervention was associated with positive feelings and was seen as a "motivational catalyzer promoting good habits" by the participants, suggesting that the intervention was ready to be tested in a RCT.

Intervention overview. To promote behavior change, we implemented within the Kiplin app 16 BCTs that have shown in previous meta-analyses to be effective in increasing walking behavior [51], to encourage behavior change of overweight and obese populations [52–54], and which were particularly suited for digital interventions [55]. Table 1 displays how BCTs have been implemented within the app. The Kiplin intervention is composed of four main features:

1) *APA sessions.* Participants of the Kiplin group will benefit from an APA program. Videoconferencing is an interesting perspective to reduce the organizational limitations of face-to-face programs. With this telemedicine approach, professionals can offer tailored interventions from a distance and propose a remote home-based APA program to patients in addition of providing monitoring, social support, and therapeutic education [56]. Thus, this program will be mainly remote and the number of sessions per week will decrease over 3 months. Patients will benefit of 3 sessions per week the first 2 weeks (1 face-to-face and 2 telecoaching sessions), 2 telecoaching sessions per week the next 6 weeks, and 1 telecoaching

session per week the third month, for a total of 22 sessions. Sessions conducted in face-to-face during the two weeks have the objective to ensure that the correct gestures are adopted by the patients. The telecoaching sessions will be group-based live remote APA classes of 60 minutes taught by a professional APA coach with a small group (between 5 and 7 patients). Each week, several sessions will be offered to patients who can register according to their preferences and availability (Figure 2A). Patients will see in advance the theme of the session. These sessions will have the particularity to be playful with the integration of quizzes, riddles, or tips on PA in addition to physical exercises (i.e., endurances exercises, muscle strengthening, and stretching). Thus, the sessions will integrate therapeutic education to inform participants on the benefits of PA, the deleterious consequences of SB, and some general knowledge like injury prevention.

2) *Gamification of PA.* In addition to the APA sessions, patients of the Kiplin group will benefit from three PA games. Patients will be able to participate in one game per month for an approximate duration of 14 days each. These settings seemed to be the most appropriate considering previous findings and recommendations [19] highlighting that gamified interventions of 12 weeks or more would be less efficient than shorter ones. These results suggest that multiple gamification doses would be better than only one long game. The three different games (i.e., the adventure (Figure 2B), the mission (Figure 2C) and the board game (Figure 2D); more details about the games in supplemental material 4) are structured in the same way: the daily step count performed by each participant is converted into points within the game and permits to progress by teams. Thus, the objective is to increase patients' daily activities through game mechanics and social interactions.

3) *Chat and messenger.* The messaging functions aimed to encourage social interactions are composed by an internal messaging space to communicate with the team and a general messaging system with all the patients of the program (Figure 2E). During the games, this messenger will be animated every day by "Pilot Kiplin" (i.e., a real Kiplin team member animating the app and who takes the form of a funny mascot) who launch challenges, announce results, and carry internal messages to motivate participants. In addition, regular notifications

will be sent by the app to mobilize and inform participants about the games or to remind them to participate to the telecoaching session they are registered.

4) *Activity monitoring tool.* Patients will be able to view their activity at any time of the day with their Garmin pedometer. The intervention focuses on daily step count rather than MVPA for several reasons. First, walking appears more adapted for obese people [57], and is statistically associated with declines in all-cause mortality [58,59] and improvement in body composition [60], regardless of its volume or intensity [58,61]. Along with the pedometer, a visual and numerical interface within the mobile app displays the daily activity (daily step count), the week average, and the graphical evolution of the number of daily steps (Figure 2F). This tool aims to give feedback on behavior and promote self-monitoring of PA. Self-monitoring and goal setting strategies have been pointed as major predictors of PA at short and long term in overweight and obese adults [53,54]. For this reason, another major element of the Kiplin app is the goal setting of PA. Recent research on goal setting revealed that interventions that set weekly or daily goals produced greater effects on PA than goals set over a longer time frame [62]. Moreover, it appears better to consider the achievement of the goals in "percentage of objective achieved" rather than in a binary way (success/fail) in order to inform that the objective is reached or close to being reached [63]. Following these recommendations, the initial step goal at the beginning of the program will be based on the daily step count of the evaluation week. By the end of the intervention participants will have to achieve 2000 more daily steps than baseline. To support this objective, daily goals during the games will be fixed on this objective. During time periods without games, participants' goal step will be increased progressively by 500 steps in order to reach the final step objective at the end of the 3-month program. The performances will be displayed each day as a percentage of the goal achieved in the form of a gauge that fills up. Each week, a new daily step goal will be settled based on the performance of the previous week. Participants will have the possibility to personalize their goal increase tier.

Finally, in addition to the collaborative teams, leaderboards, and the chat aimed to enhance social interactions, several elements have been adjusted in order to facilitate the development of a social

identity among Kiplin users. The team's allocation will be done in such a way that favors homogeneous groups in terms of gender and age. In addition, participants will complete a short and fun personality questionnaire upon entering their program. The answers will be additional elements allowing us to associate in teams people resembling each other. Other strategies will be implemented to facilitate social identification among the teams as the option to choose a team name, the option to see who is registered for APA sessions so patients can join their peers, and incentives by Pilot Kiplin to push participants to meet and walk together in real life.

[Please insert Figure 2 here]

Control condition. Participants allocated to the control condition will benefit from the usual PA care of the University Hospital of Clermont-Ferrand, which is a 3-month program of face-to-face APA, 3 sessions a week, for a total of 36 sessions. These individual sessions will be composed of a warm-up, followed by 50 minutes of endurance exercises, muscle strengthening exercises and stretching, all supervised by an APA coach in a dedicated room.

Table 1. Implementation of BCTs within the app

BCT	Related app feature or game mechanic

Goal setting behavior (1.1)	Set daily step goals.
Action planning (1.4)	Choose the goal according to several suggestions. Time-limited challenges encourage participants to maximize their activity at specific times.
Review behavior goals (1.5) Discrepancy between current behavior and goal (1.6)	Each week participants are encouraged to set a new goal considering their progress or difficulties.
Feedback on behavior (2.2)	Feedback on daily steps via the activity monitoring tool included in the app with weekly graph displaying progress towards goal.
Self-monitoring of behavior (2.3)	Self-monitoring tools with tips to use it.
Social support (unspecified, 3.1)	Team challenges where participants must collaborate to progress in the game.
Social support (practical, 3.2)	Incentives to push participants to walk together in real life.
Social support (emotional, 3.3)	Promote social connectedness through teamwork and games.
Instruction on how to perform a behavior (4.1) Information about health consequences (5.1)	Tips to plan and implement PA in daily life and information on the benefits of walking on health are given in the telecoaching sessions through infographics and quizzes.
Social comparison (6.2)	Individual and collective leaderboards.
Prompt/cues (7.1)	Push notifications, time-limited challenges
Cue signaling reward (7.4)	Virtual rewards such as trophies, clues, points.
Associative learning (7.8)	Via the playful experience.
Behavioral practice / rehearsal (8.1)	Game-based activities naturally lead to repetition and practice.

BCT: behavior change techniques corresponding to the Michie's taxonomy [64]

Table 2. Summary of the groups content

Intervention group (Kiplin)	**Control group (usual care)**
22 group-based APA sessions (1 face-to-face and 2 telecoaching sessions the first two weeks, 2 telecoaching sessions per week the next 6 weeks, and 1 telecoaching session per week the third month	36 individual APA sessions (3 sessions per week during 12 weeks)
Gamification of PA (3 games of 14 days each two weeks apart)	
Chat and messenger	
Activity monitoring tool (mobile app + Garmin Vivofit 3)	

Outcome measures

Primary outcome

The primary outcome will be the daily PA change measured as the daily step count assessed via the Garmin Vivofit 3 (Garmin International Inc., Olathe, KS, USA), a wearable activity tracker featuring an accelerometer that has been shown to accurately detect the number of steps under a variety of walking conditions [65]. The temporal zone of evaluation will extend from 7 days before the start of the intervention (i.e., baseline assessment), through the three months of intervention (i.e., evolution during the interventional phase), to 7 days after the end of the intervention (i.e., post-intervention assessment). Non-wear days will be defined as days with fewer than 1000 steps (as previous research suggested that daily step values less than 1000 may not represent full data capture [66,67]) and will be removed from the analysis. As using pedometers positively influence daily PA [68], the Garmin wearable will only display on its screen the time and date during the evaluation time. During the intervention period, as self-monitoring of PA is an integrated part of the digital intervention, participants of the Kiplin group will see their object unblocked (i.e., display of the daily number of steps, calories burned, distance traveled, and minutes of activity performed) following the randomization. The wearables of the usual supervised PA program group will stay unchanged during the intervention period.

Secondary outcomes

The secondary outcomes will be the changes in (1) *anthropometric measurements and body composition*, (2) *PA level and SB,* (3) p*hysical capacities, and (4) quality of life*. *Psychological mediators* and *program adherence* will also be examined. Finally, this study will include an evaluation of the cost-utility of the Kiplin intervention in comparison to the usual care. Table 3 provides an overview of all the outcomes measures and Table 4 provides the schedule of assessment (following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule template [69]).

Table 3. Outcomes measures of the DIPPAO RCT

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Outcome	Assessment method
Primary outcome	
Daily step count over 3 months	Via Garmin Vivofit 3
Secondary outcomes	
Anthropometric measurements and body composition	
Body mass, height and BMI	Body mass will be measured to the nearest 0.1 kg using a calibrated digital scale and height will be measured to the nearest 0.1 cm using a wall-mounted stadiometer. BMI will be calculated as body mass (kg) divided by height squared (m^2)
Body composition	Body composition will be assessed by bioelectrical impedance analysis, with the multi-frequency segmented body composition analyzer Tanita MC780 (Tanita, Hong Kong, China). Once the body mass has been evaluated by the scale, a foot/hand impedance measurement is performed (Hand-to-foot bioelectrical impedance analysis, BIA). This new BIA technology has recently been validated in adults of different levels of physical activity [70] as well as in overweight and obese children and adolescents [71].
Physical Activity and Sedentary Behaviors	
Objective PA	Accelerometer-based PA (Actigraph GT3X+; ActiGraph LLC, Pensacola, FL, USA) to measure the time spent in light-, moderate-, and vigorous-intensity PA over 7 days.
Objective SB	Accelerometer-based sedentary time (Actigraph GT3X+) over 7 days.
Self-reported PA and SB	Self-reported behaviors will be collected using the Recent Physical Activity Questionnaire (RPAQ) [72] that assess sitting time, number of stairs climbed, PA at home, active transportation, PA at work, leisure PA, and global transportation.
Daily step count and daily activity minutes over 9 months	Via Garmin Vivofit 3
Physical capacities	
Muscle strength	Muscular strength of the upper limbs will be assessed by a series of three handgrip test measurements for right and left hands, in the seated position. The best performance measured for each hand via the dynamometer (Takei Grip-D, Takei, Japan) will be conserved and the mean of both hands will be noted [73]. Muscular strength of lower limbs will be assessed by an isokinetic dynamometer that will measure the maximum knee extension torque at different speeds (30, 60 and 120°/s).
Cardiorespiratory fitness	Via the 6-minute walking test (6MWT). The 6MWT is a simple and convenient test that measures the distance in meters a patient can walk in six minutes in a standardized 30 meters long corridor. This test will be performed following the American Thoracic Society guidelines [74] and has been validated in the past [75].
Quality of life	
Quality of life	Via the EQ-5D-5L questionnaire [76] assessing 5 dimensions: mobility, autonomy of the person, current activity, pain/discomfort, anxiety/depression.
Psychological mediators	

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Perceived enjoyment	Perceived enjoyment of physical activity during the intervention will be evaluated using the Physical Activity Enjoyment Scale (PACES) [77]. This questionnaire consists of 16 items where participants have to rate "how you feel at the moment about the physical activity you have been doing" using a 7-point Likert scale ranged from 1 (not at all) to 7 (very much).
Psychological need satisfaction	The Psychological Need Satisfaction in Exercise Scale (PNSES) [78] will be used to measure perceived competence (e.g., I feel that I am able to complete exercises that are personally challenging), autonomy (e.g., I feel free to exercise in my own way), and relatedness (e.g., I feel attached to my exercise companion) while exercising during the program. Composed of 18 items, participants will have to rate their agreement on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Self-reported motivation	Autonomous and controlled motivation toward physical activity will be assessed using a short version of the Motivation Scale Towards Health-oriented Physical Activity [79]. This questionnaire is composed of 8 items with a 7-point Likert scale ranging from 1 (does not correspond at all) to 7 (corresponds totally), reflecting 4 motivational regulations: intrinsic, identified, introjected, and external regulation.
In-group identification	The existence of a shared identity within the PA group will be assessed via the In-group Identification Questionnaire [80] including 14 items on a 7-point Likert scale that ranged from 1 (not at all) to 7 (very much) and measuring five dimensions: solidarity, satisfaction, centrality, individual stereotypes and homogeneity within the group.
Weight stigma	Three forms of weight stigma will be evaluated. A modified version of the Everyday Discrimination Scale [81] will assess perceived discrimination. This questionnaire consists of 5 items (e.g., "In the past 12 months, how often have you been treated differently than others because of your weight?") rated on a 7-point Likert scale ranging from 1 (never) to 7 (all the time). Weight stigma concerns will be measured with the scale developed by Hunger and Major [81], composed of 3 items (e.g., "I am afraid of being excluded because of my weight") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The Modified Weight Bias Internalization Scale (WBIS-M) [82] will be used to assess weight bias internalization. This questionnaire is composed of 11 items (e.g., "I am less attractive than other people because of my weight") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Program adherence	
APA sessions attendance and perceived exertion	The number of APA sessions attended will be assessed for both groups. Perceived exertion of these sessions will be measured at the end of each session via the modified Borg Scale [83].
Application engagement	For the Kiplin group only, the application engagement and utilization will be noted by assessing the participation rates in games and challenges, the frequency of use of the mobile application, and the number of messages exchanged.
Economic evaluation	
Cost-utility analysis	The health economic evaluation will assess the economic impact of a 3-month digital intervention in an obese and/or T2DM population in comparison with the usual care. For this purpose, a cost-utility analysis will be performed with 1) identification and valuation of costs and 2) measurement of utility by the EQ-5D questionnaire. The perspective adopted will be the health insurance perspective. The measurement of resources, in physical quantities or in volume, will be part of the French health care context. Only direct medical costs will be identified and valued. The time horizon will extend from the date of inclusion (T0) to the end of the study (T3). Results will be presented in the form of an incremental cost-effectiveness ratio (ICER), which is the ratio between the average difference in cost (euros) and the average difference in effectiveness (QALY) observed between the two arms. Sensitivity analyses will be conducted to test the robustness of the results.
Control variables	

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Perceived vulnerability against COVID-19	An adapted version of the perceived vulnerability questionnaire [84] will be used. This questionnaire is composed of 6 items (e.g., "I feel concerned about the risk of contracting the COVID-19") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Perceived digitalization	Via one item (i.e., "I feel comfortable with the use of smartphones and digital objects") rated on a 7-point Liker scale ranging from 1 (strongly disagree) to 7 (strongly agree).

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357 **Table 4.** Schedule of enrollment, interventions, and assessments

		STUDY PERIOD						
	Selection visit	**Inclusion visit**	**T0**	**Intervention**			**T1**	**T2**
TIMEPOINT	***M-1***	***M-1***	***0***	***M1***	***M2***	***M3***	***M3***	***M9***
ENROLMENT:								
Eligibility screen	X							
Informed consent		X						
Randomization			X					
INTERVENTIONS:								
Kiplin intervention				←	—	→		
Usual care condition				←	—	→		
ASSESSMENTS:								
Height	X							
Weight			X				X	X
Body composition			X				X	X
6MWT			X				X	X
Handgrip			X				X	X
Isokinetic dynamometer			X				X	X
Step count and activity minutes		←	—	—	—	—	—	→
Accelerometry		←	→				X	X

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Self-reported PA			X				X	X
Motivation			X				X	X
Enjoyment							X	
Psychological needs							X	
Weight stigma			X				X	X
In-group identification							X	
Quality of life			X				X	X
Program adherence				←	—	→		
Control variables			X				X	X
Adverse events	At any time							

6MWT: 6-Minute Walk Test

Statistical analyses

Sample size and power analysis. Sample size estimations are based on the primary outcome measure of steps per day measured using the Garmin Vivofit 3. We conducted an a priori sample size estimation based on a previous meta-analysis [85] that have reported an effect size of $d = 0.51$, (95% CI [0.12,0.91], $I^2 = 90\%$) for PA interventions comprising wearables and smartphone applications compared to control groups. However, considerable statistical heterogeneity has been observed in the results of this meta-analysis. The authors therefore excluded studies with a high risk of bias in sensitivity analyses. The meta-analysis revealed a larger effect size of $d = 0.67$ (95% CI [0.48, 0.86], $I^2 = 0\%$). To conciliate these two results, we decided to base our sample size estimation on an intermediate effect size of $d = 0.60$.

In order to demonstrate a difference equivalent of an effect size of 0.6 on our primary outcome, we will require a sample size of 44 for 80 % power and a two-sided type I error at 0.05. More precisely, if we consider that the statistical individual is an individual-day and an intra-class correlation coefficient of 0.5 (in order to take into account the inter- and intra-individual variability), 2002 individual-days are

necessary per group (i.e., 22 participants per group). We propose to include 25 participants per group in order to foresee potential dropouts, inherent to such trial.

General points in data analyses. The statistical analyses will follow intention to treat and per protocol principles. Characteristics of participants will be described and compared between groups at inclusion according to the following variables: compliance with eligibility criteria, epidemiological characteristics, clinical characteristics, and possible treatments. A description of protocol deviations and causes of dropout will also be provided. Initial comparability of the two arms will be assessed on main participant characteristics and potential factors associated with the primary outcome. Statistical analyses will be performed using R (R Foundation for Statistical Computing, Vienna, Austria) and Stata (version 15; StataCorp, College Station, Texas, US).

Analyses of primary outcome. Longitudinal data will be assessed using linear mixed models in order to account for intra-individual differences. Differences in step count changes in function of the condition (group allocation) will be evaluated using models that include the following fixed effects: group, time, and group x time interaction. We will consider random intercepts for participants and random linear slopes for repeated measures at the participant level. The normality of residuals will be checked. When appropriate, a logarithmic transformation of the dependent variable will be performed. A Sidak's type I error correction will be applied to take into account multiple comparisons. The results will be expressed using effect-sizes and 95% confidence intervals.

Analyses of secondary outcomes. In a second phase, the primary analysis could be completed by a multivariate approach to take into account the possible confounding factors retained with regard to the results of the univariate analysis and to their clinical relevance (e.g., gender, age, BMI and engagement). Particular attention, primarily descriptive, will be paid to participants' adherence to different intervention programs. Moreover, an in-depth analysis of drop-outs occurrence will be proposed by considering the dropout as censored data (estimation by Kaplan-Meier method). As the primary analysis will be conducted following intention-to-treat principles, sensitivity analyses will be performed to evaluate the

statistical nature of missing data, and to propose, if necessary, the most appropriate data imputation method.

Finally, modelling analyses of longitudinal trajectory profiles could also be carried out, if possible, as well as multiple mediation modelling to examine the hypotheses according to which psychological mechanisms may partially or totally mediate the relationships between the intervention and the number of steps, the PA level and SB. Considering our lack of knowledge about intervention effect sizes on variables such as consequences of weight stigmatizations or in-group identification, Bayesian inferences could be applied in an exploratory perspective.

Continuous secondary outcomes will be analyzed as described above for the primary outcome. For non-repeated data, the following comparison tests will be used: Student's t test or Mann-Whitney test for quantitative data, and Chi2 test or Fisher's exact test for categorical variables.

Ethics and dissemination

The DIPPAO RCT adheres to the principles of the Helsinki declaration. The research protocol has been reviewed and approved by the Local Human Protection Committee (CPP Ile de France XI, *N*° 21004-65219) and has been registered on ClinicalTrial.gov (NCT04887077, Registered May 14, 2021). All participants will receive information sheets and consent forms to sign before the potential inclusion. Any modification of the research protocol must be subjected to an authorization agreement from the Ethics Committee.

The results of this study will be disseminated through international conference presentations and in relevant scientific journals. The three complementary but distinct objectives of the trial will be addressed in different publications at the end of the study.

Discussion

The Kiplin intervention is a group-based gamified digital program aim to promote behavior change and long-term PA among patients with obesity and/or T2DM. Backed by scientific knowledge, this intervention may change patient's behavior by improving their self-determined motivation toward PA, reducing weight stigma that usually act as PA barriers, and ultimately participating to improve program adherence. More globally, this intervention is the opportunity to address a wider audience though one unique program by responding to the limits and constraints of face-to-face programs. Findings will be of interest to researchers, practionners, and policy makers in future discussions on the relevance of digital interventions in the treatment of chronic diseases.

Abbreviations

6MWT: 6-minute walk test; APA: adapted physical activity; BCT: behavior change technique; BIA: bioelectrical impedance analysis; BMI: body mass index; Cm: centimeter; CONSORT: consolidated standards of reporting trials; CPP: comité de protection des personnes (Ethics committee); DIPPAO: digital intervention promoting physical activity among obese people; ICER: incremental cost-effectiveness ratio; Kg: kilogram; MVPA: moderate-to-vigorous physical activity; PA: physical activity; REDCap: Research Electronic Data Capture; RCT: randomized controlled trial; SB: sedentary behaviors; SDT: self-determination theory; SIA: social identity approach; T2DM: type 2 diabetes mellitus

Acknowledgments

The authors wanted to thank the challenge 3 I-SITE Clermont Auvergne Project 20-25 for their grant and all members of the Kiplin team involved in the development of the mobile application.

Contributors

AM, AC, MB, and MD conceptualized the project and obtained the funding. All authors have provided input into the study design. The first draft of the manuscript was written by AM and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding

This project is funded by a grant of the challenge 3 I-SITE Clermont Auvergne Project 20-25. The work of AM is supported by an ANRT grant (Cifre PhD Thesis) and by the company Kiplin. The funders had no input in the design of the trial and will have no influence on the collection, interpretation or publication of the study results. Trial sponsor: University Hospital CHU G. Montpied, Clermont-Ferrand.

Competing interests

AC, BP, and MD declare that they have no competing interests. AM's PhD Grant is funded by the French National Association for Research and Technology (ANRT) and Kiplin. MB is employed by Kiplin.

Ethics approval and consent to participate

The research protocol has been approved by the Protection of Persons Ethics Committee Ile de France XI (N° 21004-65219). Written informed consent will be obtained from participants prior their inclusion in the trial.

Provenance and peer review

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

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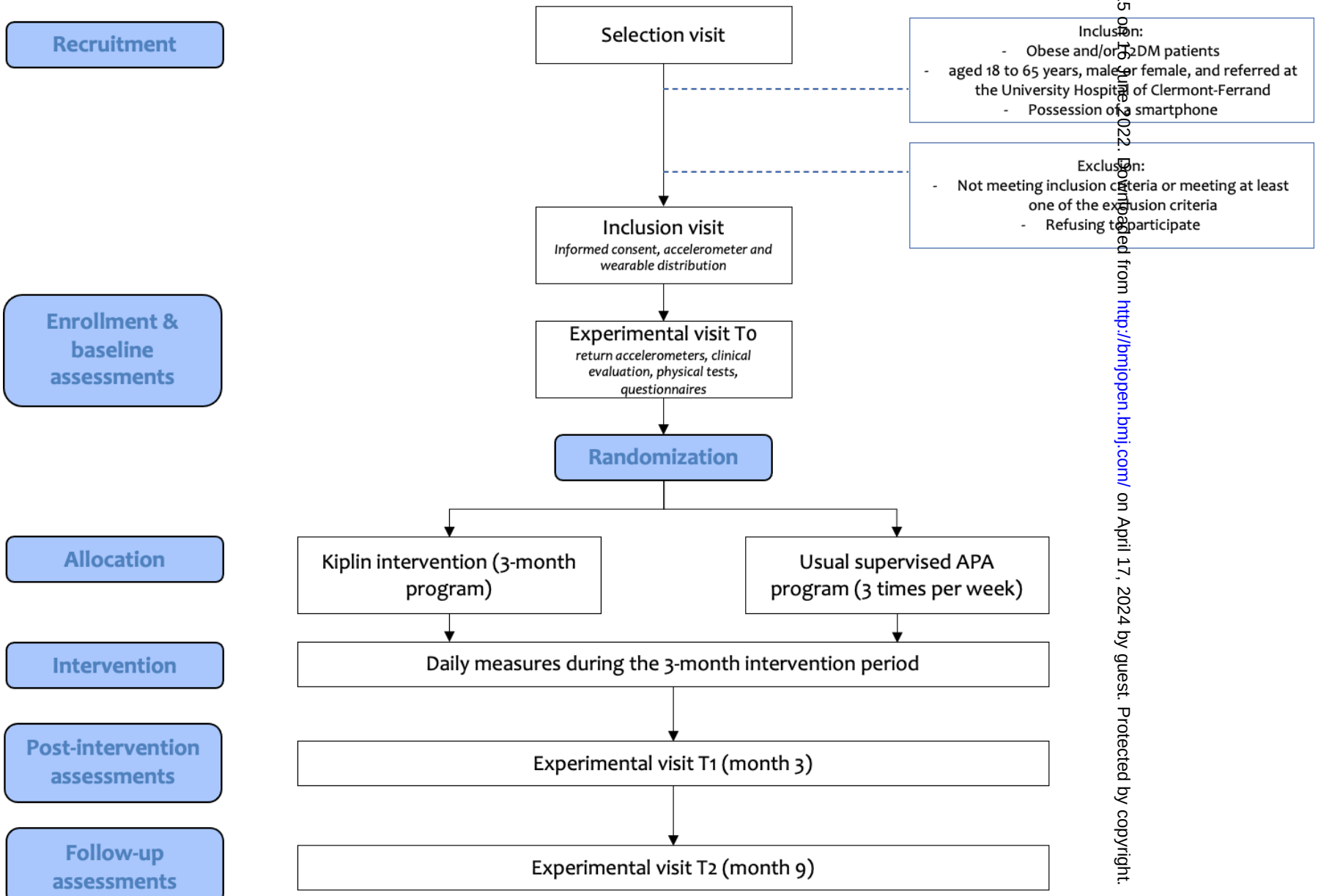
Figure 1. Study flowchart

Figure 2. Screenshots of the Kiplin app

Note. A. The telecoaching sessions reservation. B. The adventure. C. The investigation. D. The boardgame. E. The chat. F. The activity monitoring tool.



SUPPLEMENTARY ONLINE MATERIAL 1

Hypotheses on PA adherence

First, we argue that the Kiplin intervention will produce greater PA levels than the usual care (face-to-face supervised APA) during the whole intervention. More particularly, the Kiplin intervention will avoid the compensatory decrease between leisure PA time and supervised PA time frequently observed in traditional programs (King et al., 2007; Westerterp, 1998) by stimulating daily PA. This compensatory decrease is in line with the ActivityStat hypothesis (Gomersall et al., 2013), which suggests that an increase or decrease of PA in one domain will be compensated in another domain, in order to maintain an overall stable level of PA or energy expenditure over time. By stimulating daily PA with gamification features and goal setting, the Kiplin intervention may limit the decrease in total PA that could occur in compensation of an increase in PA in supervised sessions.

We also hypothesize that this improvement in PA will be sustained after the follow-up period.

> *Hypothesis 1a: Patients of the Kiplin group will demonstrate increased total PA over 3 months that will be superior to the total PA of patients in the face-to-face supervised APA condition.*
>
> *Hypothesis 1b: Patients of the Kiplin group will demonstrate improved PA over 9 months that will be superior to the total PA of patients in the face-to-face supervised APA condition.*

In parallel of these improvements, we expect to observe a decrease in the overall sedentary time resulting from a compensatory stimulation of the daily activity, notably led by gamification strategies.

> *Hypothesis 2: The Kiplin intervention will be effective in reducing SB. This effectiveness will be superior to the face-to-face supervised APA condition.*

Hypotheses on the intervention mechanisms

The Kiplin intervention including multiple components to change behavior, this trial will aim to identify the psychological mediators that can explain a potential improvement in PA. We argue that one of the potent ingredients of the Kiplin intervention will be its ability to promote a self-determined motivation toward PA. This motivation should be filled by basic needs' satisfaction and through the enjoyment of the playful activities experienced by the patients.

> *Hypothesis 3a: The Kiplin intervention will improve patients' self-determined motivation toward PA.*

Hypothesis 3b: The satisfaction of the three basic needs (autonomy, competence, and relatedness) and the enjoyment of the program will mediate the relationship between Kiplin intervention and patients self-determined motivation toward PA.

Hypothesis 3c: Kiplin intervention-related changes in motivation will increase PA.

The development of a self-determined motivation toward PA may limit the reduction of the effect of the Kiplin program on PA at the end of the intervention compared to the face-to-face supervised APA condition.

Hypothesis 3d: Kiplin intervention-related changes in motivation will sustain the PA improvement over the follow-up period compared to face-to-face supervised APA condition.

In parallel, we argue that this group-based digital intervention will encourage the emergence of a social identity in the group, being the basis for mutual and social support among the participants. Moreover, engaging in a group-based program in a co-operative setting with people sharing the same stigmatized characteristic (i.e., related to weight, pathology, and symptomatology) should allow individuals to overcome their fear of being discriminated, and more generally remove barriers related to the negative stereotypes that target them (Jetten et al., 2018; Olander et al., 2013). This would ultimately facilitate engagement in the proposed activities and promote behavior change.

Hypothesis 4a: The Kiplin intervention will reduce perceived discrimination, weight stigma concerns, and weight bias internalization compared to the usual care condition.

Hypothesis 4b: Kiplin intervention-related changes in weight stigma processes will increase PA.

Hypotheses on the cost-utility of the intervention

Finally, we hypothesize that the achievement of the aforementioned objectives associated with the advantages of e-health interventions (i.e., a broad accessibility though technology, permitting to address a large population) will allow to reduce the time of face-to-face supervised PA by an APA professional, for an identical number of patients, and to reduce the costs and constraints associated with a classic face-to-face care. In order to measure this potential increase in efficiency, we will integrate a health economic evaluation within this protocol.

Hypothesis 5: By requiring fewer face-to-face APA sessions, the Kiplin intervention may lead to economic benefits and health care saving in patient management compared to face-to-face supervised APA condition.

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SUPPLEMENTARY ONLINE MATERIAL 2

Exclusion criteria

Participants will be excluded if they meet anyone of the following criteria:

- Medical or surgical history judged by the investigator to be incompatible with the study.
- Subject with an unstable psychiatric condition.
- Pregnant or breastfeeding women.
- Heavy alcohol consumption (> 2 to 3 drinks per day depending on gender) or drug addiction.
- Disability or contraindication to PA.
- Subject with cardiorespiratory and/or osteoarticular disorders that limit their ability to perform physical tests or moderate PA for 30 minutes.
- Subject with progressive cardiovascular or neoplastic disease.
- Subject who has presented a major infection in the 3 months prior to inclusion.
- Subject with a known neuro-muscular pathology (i.e., myopathy, myasthenia, rhabdomyolysis, paraplegia, hemiplegia).
- Subject with chronic or acute inflammatory pathology within 3 months prior to inclusion.
- Subject diagnosed and/or treated for schizophrenia, bipolar disorder, major depression.
- Subject deprived of their liberty by judicial or administrative decision.
- Subject refusing to sign the written consent to participate.
- Subject participating in another study.

SUPPLEMENTARY ONLINE MATERIAL 3

Information letter and consent form in French (Version 3, 03/06/2021).

CLERMONT-FERRAND
CENTRE HOSPITALIER UNIVERSITAIRE

LETTRE D'INFORMATION

Etude DIPPAO : évaluation des effets d'une intervention connectée pour promouvoir l'activité physique et diminuer la sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2

Madame, Monsieur,

Nous vous proposons de participer au protocole de recherche intitulé « DIPPAO ».
Nous vous invitons à lire attentivement cette lettre d'information qui a pour but de répondre aux questions que vous seriez susceptible de vous poser avant de prendre votre décision de participation.

Ce document vous appartient et nous vous invitons à en discuter avec votre médecin et vos proches.

1) Objectif de la recherche

Selon de nombreuses études, le niveau d'activité physique de patients ayant un diabète de type 2 ou une obésité est particulièrement faible. Or la pratique régulière d'une activité physique permet non seulement de prévenir le risque de développer les maladies chroniques mais également de limiter leur progression et de diminuer la mortalité précoce liée à ces maladies. C'est pourquoi nous cherchons à développer à travers cette étude scientifique des interventions permettant d'augmenter l'activité physique de ces patients et que nous sollicitons votre participation.

L'objectif principal de ce projet est d'étudier l'effet d'une intervention digitale (Kiplin, https://www.kiplin.com/) composée de trois « briques » (des séances d'activité physique adaptée (APA) interactives en visio-conférence + animations connectées sous forme de jeux collectifs + suivi de l'activité physique avec un bracelet connecté et une application) sur l'activité physique globale et le temps de sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2 en comparaison avec la prise en charge classique au CHU de Clermont-Ferrand.
Les objectifs secondaires sont d'augmenter l'adhérence au programme et de diminuer le temps d'accompagnement en présentiel.

A travers une augmentation de l'activité physique, l'objectif est d'améliorer votre santé. En effet les études scientifiques et les sociétés savantes sont unanimes sur le fait que l'atteinte des recommandations en activité physique permet de conserver un bon état de santé et d'améliorer sa qualité de vie. Nous pensons que ces nouvelles méthodes pourraient être utiles mais nous aimerions le démontrer car rien n'est actuellement prouvé.

2) Méthodologie

Dans cette étude vous suivrez un programme de 3 mois. Nous testerons différentes variantes de l'intervention (intervention Kiplin ou séances d'activité physique adaptée en présentiel au CHU) afin d'évaluer quel format est le plus efficace pour augmenter et maintenir votre activité physique à la fin de l'intervention (3 mois de prise en charge au CHU) et 6 mois après la fin de l'intervention. Vous serez réparti dans l'un des deux groupes de l'étude aléatoirement selon une procédure de tirage au sort faite par ordinateur. Lors de votre prise en charge par un programme d'activité physique adaptée vous serez donc dans l'un des 2 groupes suivants :

- Groupe Kiplin

Groupe prise en charge traditionnelle

La méthodologie, les tests effectués ou encore la durée de votre participation seront strictement identiques qu'importe le groupe. Ces éléments sont décrits plus précisément ci-dessous. Au total, 48 patients seront inclus dans cette étude (24 par groupe).

3) Description des deux prises en charge

- Groupe Kiplin : 3 séances d'activité physique adaptée par semaine, d'abord en présentiel au CHU puis en visioconférence depuis chez vous via l'application mobile Kiplin. Parallèlement, vous pourrez, via l'application mobile Kiplin : suivre votre activité physique, participer à des animations sous forme de jeux par équipes où votre quantité d'activité physique vous permet de progresser dans le jeu, interagir avec les autres participants du Groupe Kiplin.

- Groupe prise en charge traditionnelle CHU : 3 séances d'activité physique adaptée par semaine en présentiel pendant 3 mois au CHU

4) Déroulement pratique

Si vous acceptez de participer à cette étude, vous serez suivi pendant 9 mois à partir de votre inclusion dans l'étude et vous aurez 5 visites (dont une seule supplémentaire par rapport à votre prise en charge originelle) :

- Visite de sélection : 1 mois avant le début de l'intervention *(environ 30 minutes)* : au cours de cette visite, le médecin investigateur vérifiera que vous pouvez participer au protocole et si tel est le cas vous proposera de participer à l'étude et vous remettra la lettre d'information. Suite à cette lecture, si vous souhaitez

participer à l'étude un formulaire de consentement vous sera transmis pour signature.

- Visite d'inclusion : 8 jours avant le début de votre programme (moins de 10 minutes) : Cette courte visite sera l'occasion pour vous de signer le formulaire de consentement avec le médecin investigateur. Vous repartirez avec un bracelet connecté Garmin ainsi que l'accéléromètre. Pendant cette semaine d'évaluation vous n'aurez pas accès aux données d'activité de la montre.

- Visite d'évaluation au début de l'intervention (M0) *(environ 45 minutes)* : Cette visite sera effectuée en amont de votre première séance d'APA afin de faciliter votre prise en charge. Vous ramènerez l'accéléromètre à cette occasion. Au cours de cette visite vous effectuerez les tests (détaillés ci-après) permettant l'évaluation de vos capacités physiques. Ces tests font partie de la prise en charge habituelle et ne vous demanderont pas plus de temps. Vous devrez également remplir plusieurs questionnaires évaluant notamment votre niveau d'activité physique, votre bien-être physique et émotionnel, votre motivation à la pratique d'activité physique.
  Vous serez informé à ce stade de votre groupe de prise en charge (Kiplin ou prise en charge traditionnelle) et pourrez dès lors planifier vos séances d'activité physique adaptée selon votre groupe.

- Visite d'évaluation à la fin de l'intervention (M3) (*environ 45min*) : Tests et questionnaires identiques aux précédentes visites.

- Visite M9 (6 mois après la fin de l'intervention) + évaluations (*environ 45min*) : Tests et questionnaires identiques aux précédentes visites.

5) Calendrier de suivi pour cette étude

Si vous acceptez de participer à cette étude et si vous remplissez toutes les conditions requises, vous serez suivi(e) dans le cadre du protocole du service de Médecine du sport du CHU de Clermont-Ferrand.

Le calendrier de votre suivi sera le suivant :

	Visite 1 Sélection	Visite 2 Inclusion	Visite 3 M0	Visite 4 M3	Visite 5 M9
	(30 min)	(10 min)	(45 min)	(45 min)	(45 min)
Consentement éclairé	X				

Critères d'inclusion et de non-inclusion	X		X		
Données sociodémographiques, poids, taille, tour de taille, pression artérielle, médicaments	X			X	X
Questionnaire activité physique			X	X	X
Échelle de douleur			X	X	X
Questionnaires bien-être psychologique et motivation à l'activité physique			X	X	X
Accéléromètre et bracelet Garmin		X		X	X
Composition corporelle			X	X	X
Endurance			X	X	X
Force musculaire			X	X	X
Pression artérielle			X	X	X

6) Description des tests réalisés

Les évaluations réalisées pour chacune des 3 visites (au début, à la fin des 3 mois et à la fin des 9 mois) sont les suivantes :

- Un bilan de vos capacités physiques sera effectué. Vous aurez pour cela 3 tests à réaliser :
  - Un test de force des membres supérieurs appelé « handgrip » durant lequel nous vous demanderons de serrer fort sur une poignée pendant 15 secondes. Deux essais seront enregistrés.
  - Un test de force des membres inférieurs sera réalisé grâce à un dynamomètre permettant de mesurer la force maximale d'extension du genou. Les mesures seront effectuées à trois vitesses différentes. Pour chaque vitesse, deux essais de 3 répétitions successives seront réalisés et la meilleure performance sera conservée. Vous disposerez de 2 minutes de repos entre chaque essai.
  - Un test d'endurance cardio respiratoire sera réalisé par l'intermédiaire du test de marche de six minutes ; l'objectif de ce test est de marcher aussi vite que vous pouvez pendant six minutes. La distance parcourue pendant les six minutes sera mesurée.

L'évaluation de la condition physique sera réalisée par la même personne, dans la même journée et toujours dans le même ordre.

- Suite aux tests de condition physique, vous devrez remplir plusieurs questionnaires
  - Le questionnaire RPAQ qui vous permet de préciser votre niveau d'activité physique.
  - Vous remplirez un deuxième questionnaire évaluant votre qualité de vie.
  - Le troisième questionnaire évaluera vos relations avec les autres patients durant l'intervention.
  - Plusieurs questionnaires permettront de mesurer votre motivation pour l'activité physique et vos sentiments envers cette activité.
    Un autre questionnaire vous demandera de décrire la discrimination que vous pouvez percevoir venant des autres personnes dans votre vie de tous les jours.
    Enfin un dernier questionnaire visera à évaluer l'impact émotionnel de la COVID-19.

- Un accéléromètre vous sera également remis. Il s'agit d'un petit boîtier (3 cm x 3 cm) que l'on fixe autour de la taille à l'aide d'une sangle élastique et qui permet d'enregistrer les mouvements. Sa petite taille et le fait que l'on peut porter le capteur sur ou ses vêtements rend l'appareil facile à porter et il s'oublie très vite. Ce capteur devra être porté pendant 7 jours du lever au coucher, sauf pendant les activités aquatiques (douche, bain, natation, etc.). Il va enregistrer sur 7 jours (enregistrement la journée) l'ensemble des mouvements que vous faites pour que nous puissions évaluer votre temps d'activité physique de faible, moyenne ou haute intensité

- Un bracelet connecté de la marque Garmin vous sera également remis. Il s'agit d'un appareil que vous porterez au poignet quotidiennement pendant la durée de l'étude, qui reconnaît et enregistre automatiquement vos différentes activités physiques. Si vous êtes dans le Groupe « prise en charge traditionnelle », l'affichage sera paramétré pour n'afficher que la date et l'heure pendant la durée de 'intervention (soit pendant 3 mois), et l'ensemble des fonctionnalités seront ensuite activées pour que vous puissiez continuer à utiliser l'objet.

- Bio-impédancemètre : vous monterez sur une balance qui permet de mesurer - en plus de votre poids - votre composition corporelle, c'est-à-dire la quantité de graisse (ou masse grasse), la quantité de muscles (ou masse musculaire) et la quantité d'eau de votre corps. Cela vous permet de mieux comprendre de quoi est fait votre poids quand vous vous pesez.

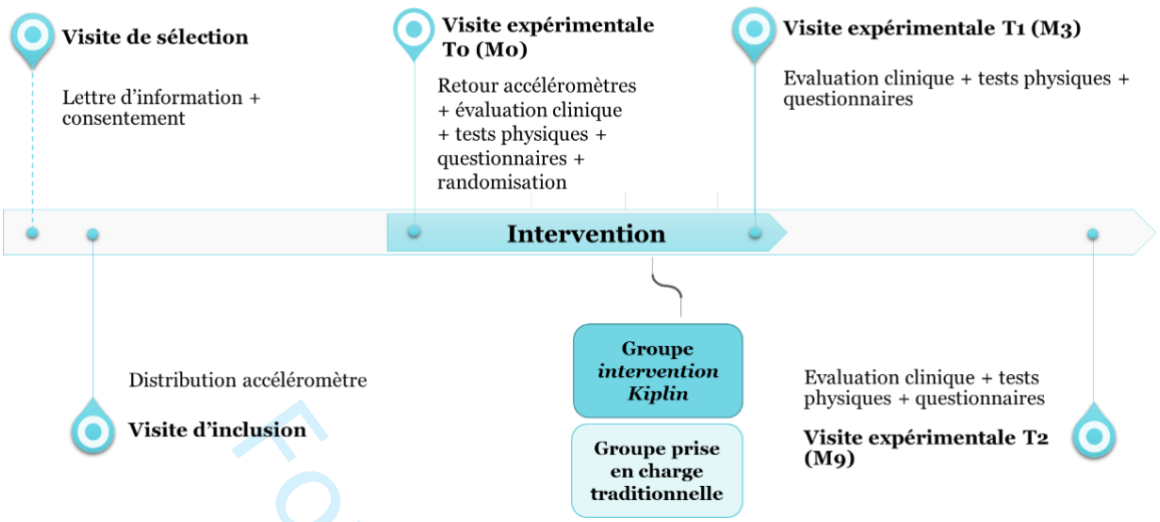


Schéma récapitulatif du protocole expérimental

Toutes les visites auront lieu au CHU.

7) Vos bénéfices à participer à cette étude

Vous aurez l'opportunité de tester de nouvelles méthodes originales de changement de comportement de manière gratuite.

⇨ L'avantage que vous pouvez attendre en participant à cette étude est une augmentation de votre activité physique, une meilleure gestion du stress, de la fatigue, du sommeil, une amélioration de votre condition physique et donc un bien-être physique et émotionnel. Ces résultats sont ceux attendus mais ne sont pas pour autant garantis.

8) Rémunération

⇨ Au début de l'étude vous sera distribué un objet connecté Garmin. Ce bracelet vous sera offert à la fin de l'étude. Toutes les fonctionnalités de l'objet ne seront pas accessibles par tous lors de l'étude mais seront bien évidemment débloquées et disponibles à l'issue de l'étude quand l'objet vous sera offert.

9) Risques et contraintes prévisibles

Risques liés à la pratique :

Les risques encourus lors des sessions d'activité du programme sont minimes compte tenu :

1) des faibles risques de traumatismes musculaires ou ostéo-articulaires induits par la nature des activités qui seront proposées et,

2) de l'intensité de l'exercice qui sera légère (pas de risque cardio-vasculaire).

Vous n'aurez pas plus de contraintes que d'habitude puisque les visites s'effectuent au CHU dans la continuité de votre prise en charge et que l'intervention vous est proposée gratuitement de manière intégrale. De potentielles contraintes peuvent survenir avec le port des matériels d'évaluation mais de nombreux conseils vous seront prodigués afin que vous ne ressentiez aucune gêne.

10) Informations utiles :

Votre participation à cette recherche n'engendrera aucun frais pour vous.

Toutefois, pour pouvoir participer à cette recherche vous devez être affilié(e) ou bénéficier d'un régime de sécurité sociale, et ne pas être placé(e) sous sauvegarde de justice.

Le CHU de Clermont-Ferrand, qui organise cette recherche en qualité de promoteur, a contracté une assurance conformément aux dispositions législatives, garantissant sa responsabilité civile et celle de tout intervenant auprès de la société d'assurances Biomedicinsure. Le numéro de contrat est 0840718730010. Dans le cas où votre état de santé serait altéré du fait de votre participation à l'étude, conformément à la loi n°2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine, vous seriez en droit de recevoir des dédommagements dans le cadre de ce contrat d'assurance spécifique.

Vous ne pourrez participer à aucune étude pendant toute la durée de la recherche et les 6 mois suivant la fin de la recherche. Vous ne devez pas non plus avoir participé à une recherche dans les 6 mois précédant votre participation à cette étude.

Cette recherche impliquant la personne humaine a reçu l'avis favorable du Comité de Protection des Personnes Ile de France XI en date du 27/01/2021.

Il est possible que cette recherche soit interrompue, si les circonstances le nécessitent, par le promoteur ou à la demande de l'autorité de santé.

Si vous considérez que vous avez subi un préjudice lors de votre participation à l'étude, vous devez immédiatement contacter l'investigateur coordonnateur :

Pr Martine Duclos

Chef de Service de Médecine du Sport et des Explorations Fonctionnelles et Respiratoires

CHU Gabriel Montpied - Clermont-Ferrand

mduclos@chu-clermontferrand.fr

11) Données personnelles recueillies :

Votre participation à cette étude implique la collecte et le traitement des données personnelles suivantes :

- État civil et coordonnées (nom, prénom, année de naissance, sexe, email)
- Composition corporelle et données anthropométriques (taille, poids, tour de taille)
- Pression artérielle systolique et diastolique
- Données de condition physique (résultats des tests physiques)
- Données d'activité physique et de sédentarité (questionnaire + niveau d'activité physique mesuré par l'objet connecté et par accéléromètre)
- Données de qualité de vie (questionnaire)
- Données relatives au soutien social perçu et aux relations partagées avec les autres patients (questionnaire)
- Données visant à évaluer votre motivation pour l'activité physique et vos sentiments envers cette activité (questionnaire)
- Données portant sur la discrimination que vous pouvez percevoir venant des autres personnes dans votre vie de tous les jours (questionnaire)
- Données de participation aux séances d'activité physique adaptée et aux animations connectées (si vous êtes dans le Groupe Kiplin)
- Contributions éventuelles sur les espaces de messagerie au sein de l'application mobile Kiplin (si vous êtes dans le Groupe Kiplin)

12) Protection de vos données personnelles :

Dans le cadre de cette recherche, le CHU de Clermont-Ferrand est responsable de la mise en œuvre du traitement de données à caractère personnel. Ce traitement informatique a pour but d'analyser les résultats de la recherche au regard de l'objectif de cette dernière qui vous a été présenté.

Le fondement juridique, au regard de l'article 6 du RGPD (Règlement Général sur la Protection des Données) est l'intérêt légitime du promoteur à mettre en œuvre le traitement de données médicales à des fins de recherche scientifique (article 9.2 du RGPD).

A cette fin, toutes les données médicales vous concernant et les données relatives à vos habitudes de vie nécessaires pour la recherche seront transmises au Promoteur, ou aux personnes ou sociétés agissant pour son compte, en France.

Ces données seront identifiées par un numéro de code et vos initiales. Ces données pourront également, dans des conditions assurant leur confidentialité, être transmises aux autorités de santé françaises, à d'autres entités du CHU de Clermont Ferrand.

Les données seront conservées au minimum 15 ans après la fin de la recherche, selon les dispositions légales en vigueur.

Le représentant du promoteur ou celui des Autorités de Santé, tenu au secret professionnel, peut avoir accès à votre dossier médical pour contrôle de conformité. En effet seules les données du dossier médical sont directement identifiantes. Leur consultation (par représentants autorisés) obéit à des règles strictes. Toutes les autres données "données de l'étude" sont des données codées transmises au promoteur qui les possède et peut les transmettre selon certaines règles. Les résultats de l'étude n'utilisent que ces données codées et leur publication respecte de ce fait l'anonymat.

Dans le cadre de cette recherche, la société Kiplin, éditrice de la solution connectée utilisée dans l'intervention, sera amenée à traiter certaines de vos données personnelles (coordonnées, sexe et année de naissance, données d'activité physique collectées par l'objet Garmin, contributions sur les espaces de messageries au sein de l'application, participation aux séances d'activité physique adaptée en visioconférence). Kiplin s'engage à mettre en œuvre toutes les mesures techniques et organisationnelles nécessaires pour assurer la sécurité et la confidentialité de vos données. En particulier, l'ensemble des données collectées via la solution Kiplin seront hébergées dans un environnement certifié pour l'hébergement de données de santé (hébergeur : Proginov – 44118 La Chevrolière).

Conformément aux dispositions du RGPD et de la loi informatique et libertés du 6 janvier 1978 modifiée, vous disposez d'un droit d'accès, de rectification et de limitation du traitement de vos données.

Conformément aux dispositions du RGPD, vous disposez également d'un droit d'opposition à la transmission des données couvertes par le secret professionnel susceptibles d'être utilisées dans le cadre de cette recherche et d'être traitées. Dans ce cas, l'exercice de ce droit vous empêchera de participer à la recherche.

Conformément à l'article 17.3 du RGPD, les données recueillies préalablement au retrait du consentement, le cas échéant, ne seront pas effacées et continueront à être traitées dans les conditions prévues par la recherche.

Pour exercer ces droits ou pour toute question sur le traitement de vos données, vous pouvez contacter notre délégué à la protection des données : CHU de Clermont-Ferrand – Direction de la Qualité – Gestion des Risques et Droits des Usagers – 58 rue Montalembert – 63003 Clermont-Ferrand cedex 1 (ou dpd@chu-clermontferrand.fr)

Vous pouvez également accéder directement ou par l'intermédiaire d'un médecin de votre choix à l'ensemble de vos données médicales en application des dispositions de l'article L. 1111-7 du code de la santé publique. Ces droits s'exercent auprès du médecin qui vous suit dans le cadre de la recherche et qui connaît votre identité.

Si vous estimez, après nous avoir contactés, que vos droits Informatique et Libertés ne sont pas respectés ou que le dispositif de contrôle d'accès n'est pas conforme aux règles de protection des données, vous pouvez adresser une réclamation auprès de la CNIL (https://www.cnil.fr/) par courrier.

13) Aspects légaux

Vous avez le droit de refuser de participer à cette recherche sans avoir à vous justifier. Votre choix n'influencera en rien le rapport que vous avez avec votre équipe soignante. Si vous acceptez de participer, vous avez le droit de retirer votre consentement à tout moment sans avoir à vous justifier.

Vous pourrez à tout moment durant l'essai vous adresser au Pr Martine Duclos et à son équipe pour leur poser toutes questions complémentaires.

Toute information nouvelle survenant pendant la participation et pouvant éventuellement modifier votre décision de participation, vous sera donnée.

Par ailleurs, vous pourrez être tenu(e) informé(e) des résultats globaux de cette recherche à la fin de l'étude.

Lorsque vous aurez lu cette lettre d'information et obtenu les réponses aux questions que vous vous posez en interrogeant le médecin investigateur, il vous sera proposé, si vous en êtes d'accord, de donner votre consentement écrit en signant le document préparé à cet effet. Vous disposez d'un délai de réflexion pour remettre ce document signé.

FORMULAIRE DE CONSENTEMENT DE PARTICIPATION A UNE RECHERCHE IMPLIQUANT LA PERSONNE HUMAINE

Etude DIPPAO : évaluation des effets d'une intervention digitale pour promouvoir l'activité physique et diminuer la sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2

Investigateur principal :

Pr Martine Duclos

Chef de Service de Médecine du Sport et des Explorations Fonctionnelles et Respiratoires

CHU Gabriel Montpied

Clermont-Ferrand

mduclos@chu-clermontferrand.fr

Je déclare :

- que le Docteur (*nom, prénom, téléphone*) …….. m'a proposé de participer à l'étude sus nommée,
- qu'il m'a expliqué en détail le protocole,
- qu'il m'a notamment fait connaître :
  - l'objectif, la méthode et la durée de l'étude
  - les contraintes et les risques potentiels encourus
  - mon droit de refuser de participer et en cas de désaccord de retirer mon consentement à tout moment
  - mon obligation d'inscription à un régime de sécurité sociale
  - que, si je le souhaite, à son terme, je serais informé(e) par le médecin investigateur de ses résultats globaux
  - que je ne serai pas autorisé(e) à participer à d'autres études cliniques pendant toute la durée du protocole, ni durant les 6 mois suivant la fin de ma participation,
  - que le Comité de Protection des Personnes Ile de France XI a émis un avis favorable en date du 27/01/2021,
  - que dans le cadre de cette étude le promoteur, le CHU de Clermont-Ferrand, a souscrit à une assurance couvrant cette recherche
  - que j'ai répondu en toute bonne foi aux questions concernant mon état de santé et ma participation à d'autres études
  - que je ne suis pas placé sous sauvegarde de justice,
- que je dois disposer d'un délai suffisant avant de signer ce consentement

Les informations relatives à l'étude recueillies par l'investigateur sont traitées confidentiellement. J'accepte que les données enregistrées à l'occasion de cette recherche puissent faire l'objet d'un traitement informatisé. J'ai bien noté que les droits d'accès, de rectification du traitement des données prévus par la loi informatique et libertés du 6 janvier 1978 modifiée s'exercent à tout moment auprès du médecin qui me suit dans le cadre de la recherche et qui connaît mon identité ou du délégué de protection des données du promoteur dont les coordonnées sont mentionnées dans la lettre d'information qui m'a été remise.
Après avoir discuté librement et obtenu réponse à toutes mes questions, j'accepte librement de participer à cette recherche impliquant la personne humaine dans les conditions précisées dans la lettre d'information et le formulaire de consentement.

Nom et prénom du patient : …… Date :……./……./……. Signature	Nom de l'investigateur : …… Date :……./……./……. Signature :

Ce document est à réaliser en 2 exemplaires originaux, dont le premier doit être gardé 15 ans par l'investigateur, un autre remis à la personne donnant son consentement.

SUPPLEMENTARY ONLINE MATERIAL 4

Kiplin Games

The Kiplin app collects the daily step count of participants by joining the API (Application Programming Interface) of the application used by the participants to track their activity (in the case of our study, the Kiplin app will use the Garmin Health API to collect the data measured via the Garmin Vivofit 3).

The adventure

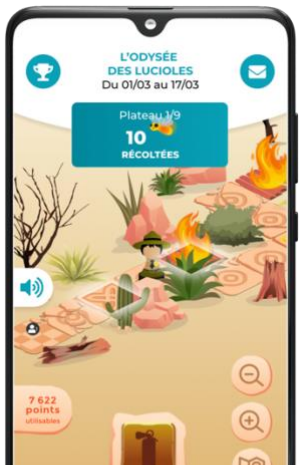
Through their journey, participants will be invited to be part of "the adventure", where the objective is to reach steps goals in order to collectively get to the final destination (players can visualize their progression on a map with checkpoints schematizing the remaining distances between different cities of a digital world tour; Figure 2B).

The investigation

The second game will be "the investigation", where participants will have to be physically active and succeed in collective challenges to unlock cues and try to solve the mission (Figure 2C).

The board game

Finally, "the board game" will put participants in the shoes of forest rangers having to put out a fire. Once again, the achievement of step goals will allow participants to progress by team on the board squares and to reach the next levels of the game to put out all the fires and save the forest residents (Figure 2D). The aim will be to put out as many fires as possible and save as many forest residents as possible by the end of the time limit.



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

Section/item	ItemNo	Description	Reported on page # (section)
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 *(Trial registration)*
	2b	All items from the World Health Organization Trial Registration Data Set	3 *(Trial registration)*
Protocol version	3	Date and version identifier	3 *(Trial registration)*
Funding	4	Sources and types of financial, material, and other support	24 *(Funding)*
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 23 *(Contributors)*
	5b	Name and contact information for the trial sponsor	24 *(Funding)*
	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	24 *(Funding)*
	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)	N/A

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 *(Introduction)*
	6b	Explanation for choice of comparators	4 *(Introduction)*
Objectives	7	Specific objectives or hypotheses	8-9 *(The study aims)*
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)	9-10 *(Study design, Randomization, allocation, and blinding)*
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	9 *(Study design)*
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)	9 *(Eligibility criteria)*
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-14 *(Intervention overview, control group)*
	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)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Table 3 *(Program adherence)*

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12 *(Eligibility criteria), supp. material 2*
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	16 *(Outcome measures), Table 3*
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)	10 *(Procedure)*, Figure 2
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	20 *(Sample size and power analysis)*
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9 *(Recruitment)*
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	10 *(Randomization, allocation, and blinding)*
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	10 *(Randomization, allocation, and blinding)*
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10 *(Randomization, allocation, and blinding)*

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10 *(Randomization, allocation, and blinding)*
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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	10 *(Procedure),* 21-25 *(Outcome measures),* *Table 2*
	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 *(Recruitment),* 21 *(Analyses of secondary outcomes)*
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	11 *(Data management)*
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	20-22 *(Statistical analyses)*
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21 *(Analyses of secondary outcomes)*
	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)	20-22 *(Statistical analyses)*
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	N/A
	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
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	Table 4
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	22 *(Ethics and dissemination)*
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)	22 *(Ethics and dissemination)*
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9 *(Recruitment)*
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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	11 *(Data management)*

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	24 *(Competing interests)*
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	11 *(Data management)*
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
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	22 *(Ethics and dissemination)*
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22 *(Ethics and dissemination)*
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplemental material 3
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

*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

Digital Intervention Promoting Physical Activity among Obese people (DIPPAO) randomized controlled trial: study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058015.R1
Article Type:	Protocol
Date Submitted by the Author:	15-Mar-2022
Complete List of Authors:	Mazéas, Alexandre; Univ. Grenoble Alpes, SENS; INRAE Centre Clermont-Auvergne-Rhône-Alpes, UNH, CRNH Chalabaev, Aïna; Univ. Grenoble Alpes, Laboratoire SENS Blond, Marine; Kiplin Pereira, Bruno; University Hospital Centre Clermont-Ferrand, Department of Biostatistics unit (DRCI) Duclos, Martine; University Hospital Centre Clermont-Ferrand, Department of Sport Medicine and Functional Exploration
Primary Subject Heading:	Sports and exercise medicine
Secondary Subject Heading:	Health informatics, Health economics, Rehabilitation medicine
Keywords:	SPORTS MEDICINE, SOCIAL MEDICINE, Diabetes & endocrinology < INTERNAL MEDICINE, HEALTH ECONOMICS, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS

DIPPAO randomized controlled trial: study protocol

Title: Digital Intervention Promoting Physical Activity among Obese people (DIPPAO) randomized controlled trial: study protocol

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Word count excluding title page, abstract, references, figures and tables: 5364

Tables/Figures: 6

DIPPAO randomized controlled trial: study protocol

Abstract

Introduction: Physical inactivity and excessive sedentary behaviors are major preventable causes in both the development and the treatment of obesity and type 2 diabetes mellitus (T2DM). Nevertheless, current programs struggle to engage and sustain physical activity (PA) of patients over long periods of time. To overcome these limitations, the DIPPAO (Digital Intervention Promoting Physical Activity among Obese people) randomized controlled trial (RCT) aims to evaluate the effectiveness of a group-based digital intervention grounded on gamification strategies, enhanced by social features, and informed by the tenets of the self-determination theory and the social identity approach.

Methods and analysis: This trial is a two-arm parallel RCT testing the effectiveness of the Kiplin digital intervention on obese and T2DM patients in comparison to the usual supervised PA program of the University Hospital of Clermont-Ferrand, France. A total of 50 patients will be randomized to one of the two interventions and will follow a 3-month program with a 6-month follow-up post-intervention. The primary outcome of the study is the daily step count change between the baseline assessment and the end of the intervention. Accelerometer data, self-reported PA, body composition, and physical capacities will also be evaluated. To advance our understanding of complex interventions like gamified and group-based ones, we will explore several psychological mediators relative to motivation, enjoyment, in-group identification, or perceived weight stigma. Finally, to assess a potential superior economic efficiency compared to the current treatment, we will conduct a cost-utility analysis between the two conditions. A mixed model approach will be used to analyze the change in outcomes over time.

Ethics and dissemination: The research protocol has been reviewed and approved by the Local Human Protection Committee (CPP Ile de France XI, *N°* 21004-65219). Results will inform the Kiplin app development, be published in scientific journals, and disseminated in international conferences.

Trial registration: NCT04887077 *(ClinicalTrial.gov; Registered May 14, 2021)*

Keywords: behavior change; cost-utility; e-health; gamification; intervention; mhealth; mobile app; obesity; physical activity; RCT; T2DM; weight stigma

DIPPAO randomized controlled trial: study protocol

Strengths and limitations of this study:

- Randomized controlled trial comparing a digital gamified intervention targeting PA to another existing non-drug treatment.
- Between- and within-person level analyses of daily steps will provide insight on group differences and individual trajectories of behavior change.
- A 6-month follow-up will inform on the sustainability of the long-term intervention effect.
- The intervention involving multiple components, it will be difficult to affirm which component is involved in the efficacy of the intervention.
- We will attempt to address this limitation by conducting in-depth mediation analyses, to identify the salient ingredients behind the effect.

DIPPAO randomized controlled trial: study protocol

Introduction

Overweight and obesity, which concern one in two adults in western countries [1], are among the most important health risk factors, and is associated with comorbidities such as Type 2 diabetes mellitus (T2DM), which affects 5% of the French population under 65 years of age, and 15% of people over 65 years old. If the roots of obesity and T2DM are complex and multifactorial, physical inactivity and sedentary behaviors (SB) are both major factors in the development of these diseases [2–7].

Positive effects of PA for these patients are recognized both at the scientific and institutional levels. Indeed, they can benefit from supervised PA programs suited to their disease (i.e., adapted physical activity, APA), which allow to improve functional capacity and muscle strength without having detrimental effects or complications on disease progression [8]. However, these programs can be difficult to access for patients, due to lack of availability on the scheduled sessions, lack of economic means, or geographical distance [9]. As a result, a limited adherence to PA at the end of these programs is generally observed [10].

Given that PA of obese and T2DM patients remains very low [11–13], promoting their long-term PA participation is a major challenge for researchers, practitioners, and the global healthcare economic system [14]. A promising solution is to overcome the limitations of current face-to-face programs, by developing digital interventions. In this vein, this study will evaluate the efficacy of a digital intervention in subjects with chronic diseases, by comparing it to the gold standard (supervised face-to-face PA).

e-health and gamification

Digital tools may provide effective, cost-effective, safe, and scalable interventions to improve health and healthcare [15]. These devices introduce a new care approach where patients participate in their treatment in a dynamic and interactive way, contributing to their empowerment. These interventions offer a wider and more individualized scope than face-to-face interventions, with potentially lower long-term costs [16]. Nevertheless, no rigorous trial has yet demonstrated the superiority of digital PA interventions over existing ones. Although e-health interventions are gaining popularity for the treatment

of obesity, appearing advantageous compared to current programs, no evidence of cost-effectiveness has been demonstrated [17]. In addition, concerns remain regarding the adherence rate and engagement in the long-term [18]. Therefore, the use of gamification appears as an interesting way to address these limits.

Defined as the use of game design elements in non-game contexts [19], gamification is the art of improving a routine activity in an engaging and motivating way, by the integration of specific ingredients that make games enjoyable. By gamifying PA, participants are encouraged to move and walk to play, and this tends to make their activity more playful and motivating [20]. A recent meta-analysis [21] revealed that gamified interventions improved PA with an increase of more than 1600 daily steps. Importantly, additional analyses indicated that a) gamified interventions appear more effective than equivalent non-gamified interventions and b) PA improvement persists in the long-term [21]. This suggests that gamification is more than a novelty effect, and that is a promising healthcare approach, as it can be easily implemented in daily life without adding demands to people's schedules. In sum, gamified interventions seem to be a critical strategy to engage participants in digital interventions. However, more rigorous trials are needed to confirm these promising results, to better understand the mechanisms explaining gamification effects, and to test the healthcare potential of gamified interventions [21].

Barriers to PA and determinants of behavior change in obese people

Another key driver to enhance the effectiveness of e-health interventions is the use of behavior change theories and techniques (BCTs), as they allow to target the active ingredients of behavior change [22]. In the early days of digital interventions, mobile apps, internet platforms, and connected objects designed to promote PA were rarely based on scientific knowledge, or at least the characteristics of the programs were not detailed enough to allow the mapping with evidence-based theories and techniques [23,24]. For example, Conroy et al. [25] evidenced that commercial apps released before 2014 do not contain a large amount of BCTs. Since then, recommendations provided by the CONSORT statement

[26] or the World Health Organization [27] have emphasized the need to systematically use a theory-based approach in the development of digital interventions. More especially, eHealth and mHealth devices constitute an excellent opportunity to both develop and test behavior change theories (e.g., theory of planned behavior [28], transtheoretical model [29], self-determination theory [30]) and BCTs [31].

In addition, recent research has emphasized the importance of precision medicine which focuses on individual variability and social and societal factors of behavior change in the development and evaluation of therapies [32]. In this vein, the social psychology approach can be promising as it highlights the importance of collective-level factors. Notably, it suggests that weight stigma is an important driver of the obesity increase [33]. Overweight and obese persons may face specific barriers related to weight stigma when they try to implement exercise in their daily life. They may indeed face or fear to face discrimination from a prejudiced person, or they may have internalized negative stereotypes into their self-perceptions, leading them to avoid activities in which they feel being stigmatized, such as PA [34]. For example, the more obese people perceive themselves negatively or feel discriminated because of their weight, the more they avoid PA [35]. Considering the impact of weight stigma in the development of obese-targeted interventions is therefore vital to optimize their effectiveness.

Theoretical framework

To address these challenges, the present intervention was built based on the tenets of the self-determination theory (SDT) [36] and the social identity approach (SIA) [37].

Self-determination theory. The SDT is an empirically validated framework which focuses on factors that promote sustained motivation and wellbeing [38]. At its core, this model proposes that motivation is regulated along a continuum from lack of motivation to a completely autonomous motivation, in which the behavior comes from the individual's will. Research has revealed that an autonomous motivation has positive emotional, cognitive, and behavioral consequences, and is strongly associated with PA over

time [39]. The most autonomous forms of motivation are the intrinsic ones, which occur when people perform an activity for its own satisfaction, its inherent interest and enjoyment. Especially, practicing PA for the direct pleasure and the inherent satisfaction it provides is an important predictor of the long-term maintenance of physical practice [39]. This suggests that a game-based intervention that provides fun and playful experiences would feed the autonomous motivation of participants and would be more correlated with long-term adherence of PA.

In parallel, SDT postulates that autonomous motivation increases when three basic psychological needs are satisfied [30]: the need for autonomy (i.e., need to feel responsible of one's own actions), for competence (i.e., need to feel effective in one's interactions with the environment), and for relatedness (i.e., need to feel connected to other people). Again, gamifying interventions seems particularly promising with this regard, as it can provide basic need satisfaction [20,40], leading to a significant intrinsic motivation improvement [41]. Firstly, gamification strategies such as points scores, badges, levels, and competitions, sustain the need for competence by providing feedbacks on the user's behavior. Secondly, customizable environments of the games or user choices may support autonomy. Finally, leaderboards, teams, groups, or communication functions may support the need for relatedness [20].

Social identity approach. It is now well-established that exercising in group-based settings may be effective to engage participants in PA and sustain their practice over time [42,43], regardless of the population characteristics [44]. However, results from group-based interventions are mixed, [45] suggesting that bringing people together does not systematically make interventions successful [46]. The SIA offers a relevant paradigm to explain these mixed results. It argues that social groups can affect health behaviors and outcomes only when individuals perceive they share the same identity with another individual or group [46]. SIA is the combination of two related theories - the social identity theory [47] and the self-categorization theory [48]. As social identity theory introduces the capacity for groups to be internalized into our sense of self (i.e., speaking and living situations in the name of 'we' and 'us' rather than just 'I' and 'me'), the self-categorization theory explains how people develop their social identity within groups. More especially, it proposes that the salience of a particular social identity results from a context-sensitive categorization process. Individuals categorize themselves according to a set of

core attributes that are salient and observable such as age, gender, ethnicity, or weight status. The knowledge of these determinants is precious when designing group-based interventions in order to catalyze the effects of groups with shared social identities.

A recent body of work investigates the links between self-categorization theory and long-term adherence of PA programs. Beauchamp et al. [49–51] have shed light on important attributes that determine engagement in PA. These researchers found that age and gender are particularly relevant markers of shared social identity through PA. Importantly, moderator analyses revealed that adults who were overweight reported a particularly strong preference for exercising within same-gender groups relative to mixed-gender groups, in comparison to normal weight adults [50]. The consideration of these attributes that determine engagement in a PA program can inform and guide intervention choices. Moreover, based on the rejection-identification model [52], Jetten et al. [53] proposed that social identities derived from group membership can act as psychological resources when individuals are confronted with stigmatization. Thus, the shared identities forged during a group-based intervention regrouping individuals with the same stigma (e.g., weight status) could be the keystone for the emergence of a social identity and social support able to counteract the negative effects of group-based discrimination.

The study aims

The main objective of the DIPPAO randomized controlled trial (RCT) is to evaluate the effectiveness of the Kiplin intervention – a group-based digital program centered on gamification strategies and informed by the tenets of SDT and SIA – to promote PA among patients with obesity and/or T2DM. The Kiplin intervention is composed of four components embedded within a smartphone app: a) a gamification of PA through multiple games, b) a remote APA program with videoconferencing sessions, c) an interface for exchange and conversation and, d) an activity monitoring tool. The present study will investigate the short and long-term effects of the intervention over 3 and 9 months in comparison with the usual care provided at the University Hospital of Clermont-Ferrand, France (i.e., 3 months face-to-

face supervised APA program). Additional objectives of this RCT will be to better understand the mechanisms underlying this digital intervention and to test its cost-utility compared to the usual care. More specific hypotheses on the expected effects of the intervention are proposed in supplemental material 1.

Methods and analysis

Study design

This study will be a two-arm parallel RCT comparing the effectiveness of the Kiplin digital intervention to the usual supervised PA program of the University Hospital of Clermont-Ferrand, on patients with obesity and/or T2DM. Both arms will benefit from a 3-month program and assessments will be carried at baseline, 3 and 9 months. The conduct and reporting of the trial will follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines [26,54]. For an overview of the study design, see Figure 1.

[Please insert Figure 1 here]

Participants

Eligibility criteria. Participants will be voluntary patients affected by obesity (BMI ≥30 kg/m² and <45 kg/m²) and/or overweight/obesity and T2DM, aged 18 to 65 years, male or female, and referred to the department of sports medicine of the University Hospital of Clermont-Ferrand by their physician to benefit from supervised PA. The participants must have a smartphone with a compatible operating system (at least iOS12 or Android 6.0) to be eligible. They must also be covered by health social security and be naive to any APA intervention. In order to ensure the understanding of the different questionnaires used in the study, sufficient proficiency of French will be required. The presence of one of the exclusion criteria listed in supplemental material 2 will lead to the exclusion of the participant.

Recruitment. A total of 50 patients (25 per group) will be recruited at the University Hospital of Clermont-Ferrand (department of sports' medicine). At their inclusion, patients meeting inclusion

criteria will be invited to participate to the study and the inclusion will be done during a medical consultation. The subject will sign a written consent form before being included in the study (see supplemental material 3 for the patient consent form). Participants will not receive monetary compensation. However, the wearable device (Garmin Vivofit 3) distributed to all participants at the beginning of the study will be offered to them at its end. Recruitment began on June 2021 and the expected end date of recruitment is July 2022, for a start in spring 2022 depending on the sanitary situation. A total of 30 patients were recruited on February 2022.

Protocol

Procedure. There will be five visits for all participants: the selection visit, the inclusion visit, and three experimental visits (T0, T1, T2, see Figure 1). Visits will occur in the department of sports medicine (University Hospital) of Clermont-Ferrand. During the selection visit, one of the investigating physicians will check the patients' ability to complete the full protocol based on eligibility criteria. Only after signing the informed consent form, patients will move to the inclusion visit and will be given a wearable device (Garmin Vivofit 3) and an accelerometer (Actigraph GT3x) for the baseline assessment of PA for 7 days. At least one week after this visit, the T0 experimental visit will occur to complete baseline assessments before the start of the intervention. At the end of the 3-month program, the T1 experimental visit will be carried, and the T2 experimental visit will be placed 6 months after the end of the program in order to evaluate the follow-up of the intervention. Apart from a few questionnaires, the three experimental sessions will be identical. To ensure equal conditions for all participants, physical condition assessments will be conducted by the same APA coach, within the same day, at the same moment, and in the same order.

Randomization, allocation, and blinding. Following the first experimental visit, patients will be randomized in one of the two conditions with a 1:1 allocation. The associate biostatistician will carry out a permuted block randomization in advance by computer with randomly varying block sizes. The randomization list will be transmitted using sequentially numbered, opaque, sealed envelopes to the data

collectors. Research assistants collecting data will be blinded to the treatment allocation. Double blinding is nevertheless not possible in such interventions because allocation concealment is impossible for participants. Moreover, the APA coaches will not be aware of group allocation at baseline but blinding will be impossible afterward, as the coaches will have seen patients during the sessions.

Data management. All data will be entered electronically into REDCap (Research Electronic Data Capture), a secure, web-based software platform specifically designed to support data capture for research studies. Data will be reported as it is obtained. All Principal Investigators will be given access to the cleaned data sets. Investigators with direct access to the data will take all necessary precautions to ensure the confidentiality of information relating to the medical products, the trials, the participants involved and more particularly their identity and the obtained outcomes. A fully anonymized data set, statistical code, and all study materials will be made publicly available on the Open Science Framework.

Intervention

Preliminary testing. Feasibility of the gamified part of the Kiplin app has been previously assessed via a qualitative study among breast cancer survivors [55]. This study showed that the intervention was associated with positive feelings and was seen as a "motivational catalyzer promoting good habits" by the participants. Afterward, the full intervention including telecoaching APA sessions in a 12-week program has been pilot tested on different patient pathways (unpublished data), including obese and T2DM patients. Patients' feedbacks were all positive and enthusiastic and no organizational issues have been identified, suggesting that the intervention was ready to be tested in a RCT.

Intervention overview. To promote behavior change, we implemented within the Kiplin app 16 BCTs. Previous meta-analyses have shown these techniques to be effective in increasing walking behavior [56], to encourage behavior change of overweight and obese populations [57–59], and which were particularly suited for digital interventions [60]. Table 1 displays how BCTs have been implemented within the app. Patients will be offered a free download of the app as part of their treatment The Kiplin intervention is composed of four main features:

1) *APA sessions.* Participants of the Kiplin group will benefit from an APA program. Videoconferencing is an interesting perspective to reduce the organizational limitations of face-to-face programs. With this telemedicine approach, professionals can offer tailored interventions from a distance and propose a remote home-based APA program to patients in addition of providing monitoring, social support, and therapeutic education [61]. Thus, this program will be mainly remote and the number of sessions per week will decrease over 3 months. Patients will benefit of 3 sessions per week the first 2 weeks (1 face-to-face and 2 telecoaching sessions), 2 telecoaching sessions per week the next 6 weeks, and 1 telecoaching session per week the third month, for a total of 22 sessions. Sessions conducted in face-to-face during the two weeks have the objective to ensure that the correct movements are adopted by the patients. The telecoaching sessions will be group-based live remote APA classes of 60 minutes taught by a professional APA coach with a small group (between 5 and 7 patients). Each week, several sessions will be offered to patients who can register according to their preferences and availability (Figure 2A). Patients will see in advance the theme of the session. After registering on the app, they will receive a Livestorm link by e-mail allowing them to join the session on their smartphone, tablet, or computer. Some sessions will be playful with the integration of quizzes, riddles, or tips on PA in addition to physical exercises (i.e., endurances exercises, muscle strengthening, and stretching). Thus, the sessions will integrate therapeutic education to inform participants on the benefits of PA, the deleterious consequences of SB, and some general knowledge like injury prevention.

2) *Gamification of PA.* In addition to the APA sessions, patients of the Kiplin group will benefit from three PA games. Patients will be able to participate in one game per month for a duration of 14 days each. These settings seemed to be the most appropriate considering previous findings and recommendations [21] highlighting that gamified interventions of 12 weeks or more would be less efficient than shorter ones. These results suggest that multiple gamification doses would be better than only one long game. The three different games (i.e., the adventure (Figure 2B), the mission (Figure 2C) and the board game (Figure 2D); more details about the games in

supplemental material 4) are structured in the same way: the daily step count performed by each participant is converted into points within the game and permits to progress by teams. Thus, the objective is to increase patients' daily activities through game mechanics and social interactions. Participants will not be given specific instructions on how often they should log in to the app.

3) *Chat and messenger.* The messaging functions aimed to encourage social interactions are composed by an internal messaging space to communicate with the team and a general messaging system with all the patients of the program (Figure 2E). During the games, this messenger will be animated every day by "Pilot Kiplin" (i.e., a real Kiplin team member animating the app and who takes the form of a funny mascot) who launch challenges, announce results, and carry internal messages to motivate participants. In addition, regular notifications (which can be turned off) will be sent by the app to mobilize and inform participants about the games or to remind them to participate to the telecoaching session they are registered.

4) *Activity monitoring tool.* Patients will be able to view their activity at any time of the day with their Garmin pedometer. The intervention focuses on daily step count rather than MVPA for several reasons. First, walking appears more adapted for obese people [62], and is statistically associated with declines in all-cause mortality [63,64] and improvement in body composition [65], regardless of its volume or intensity [63,66]. Along with the pedometer, a visual and numerical interface within the mobile app displays the daily activity (daily step count), the week average, and the graphical evolution of the number of daily steps (Figure 2F). This tool aims to give feedback on behavior and promote self-monitoring of PA. Self-monitoring and goal setting strategies have been pointed as major predictors of PA at short and long term in overweight and obese adults [58,59]. For this reason, another major element of the Kiplin app is the goal setting of PA. Recent research on goal setting revealed that interventions that set weekly or daily goals produced greater effects on PA than goals set over a longer time frame [67]. Moreover, it appears better to consider the achievement of the goals in "percentage of objective achieved" rather than in a binary way (success/fail) in order to inform that the objective is reached or close to being reached [68]. Following these recommendations, the initial step goal at the beginning

of the program will be based on the daily step count of the evaluation week. By the end of the intervention participants will aim to achieve 2000 more daily steps than baseline. To support this objective, daily goals during the games will be fixed on this objective. During time periods without games, participants' goal step will be increased progressively by 500 steps in order to reach the final step objective at the end of the 3-month program. The performances will be displayed each day as a percentage of the goal achieved in the form of a gauge that fills up. Each week, a new daily step goal will be settled based on the performance of the previous week. Participants will have the opportunity to personalize their goal increase tier.

Finally, in addition to the collaborative teams, leaderboards, and the chat aimed to enhance social interactions, several elements have been adjusted in order to facilitate the development of a social identity among Kiplin users. The team's allocation will be done in such a way that favors homogeneous groups in terms of gender and age. In addition, participants will complete a short and fun personality questionnaire upon entering their program. The answers will be additional elements allowing us to associate in teams people resembling each other. Other strategies will be implemented to facilitate social identification among the teams as the option to choose a team name, the option to see who is registered for APA sessions so patients can join their peers, and incentives by Pilot Kiplin to push participants to meet and walk together in real life.

All these features are part of the standard Kiplin app, which will ensure the generalizability of the results outside the scope of this trial.

[Please insert Figure 2 here]

Control condition. Participants allocated to the control condition will benefit from the usual PA care of the University Hospital of Clermont-Ferrand, which is a 3-month program of face-to-face APA, 3 sessions a week on non-consecutive days, for a total of 36 sessions. These individual sessions will be composed of a warm-up, followed by 50 minutes of endurance exercises, muscle strengthening exercises and stretching, all supervised by an APA coach in a dedicated room. Aerobic and resistance exercises

will be performed in a circuit organized as a row of 6 exercise stations (3 aerobic and 3 resistance exercises). Aerobic exercises will be performed at 50% of VO2max the first week and the intensity will be gradually increased by 10% every two weeks to target at least 80% of VO2max over the last nine weeks. For resistance exercises, patients will perform a single set of 8-12 repetitions of unloaded exercises the first week and the number of sets will be gradually increased to 3. These exercises will be performed at 50% of 1RM during the first week and the load will be gradually increased by 10% every two weeks and remain at 80% of 1RM over the last five weeks.

The content of both groups is summarized in Table 2.

Table 1. Implementation of BCTs within the app

BCT	Related app feature or game mechanic

Goal setting behavior (1.1)	Set daily step goals.
Action planning (1.4)	Choose the goal according to several suggestions. Time-limited challenges encourage participants to maximize their activity at specific times.
Review behavior goals (1.5) Discrepancy between current behavior and goal (1.6)	Each week participants are encouraged to set a new goal considering their progress or difficulties.
Feedback on behavior (2.2)	Feedback on daily steps via the activity monitoring tool included in the app with weekly graph displaying progress towards goal.
Self-monitoring of behavior (2.3)	Self-monitoring tools with tips to use it.
Social support (unspecified, 3.1)	Team challenges where participants must collaborate to progress in the game.
Social support (practical, 3.2)	Incentives to push participants to walk together in real life.
Social support (emotional, 3.3)	Promote social connectedness through teamwork and games.
Instruction on how to perform a behavior (4.1) Information about health consequences (5.1)	Tips to plan and implement PA in daily life and information on the benefits of walking on health are given in the telecoaching sessions through infographics and quizzes.
Social comparison (6.2)	Individual and collective leaderboards.
Prompt/cues (7.1)	Push notifications, time-limited challenges
Cue signaling reward (7.4)	Virtual rewards such as trophies, clues, points.
Associative learning (7.8)	Via the playful experience.
Behavioral practice / rehearsal (8.1)	Game-based activities naturally lead to repetition and practice.

BCT: behavior change techniques corresponding to the Michie's taxonomy [69]

Table 2. Summary of the groups content

Intervention group (Kiplin)	**Control group (usual care)**
22 group-based APA sessions (1 face-to-face and 2 telecoaching sessions the first two weeks, 2 telecoaching sessions per week the next 6 weeks, and 1 telecoaching session per week the third month)	36 individual APA sessions (3 sessions per week during 12 weeks)
PA recommendations (during the intervention: personalized and evolving daily step goal + general PA guidelines; at the end of the program: video capsules to continue exercising in autonomy +	*PA recommendations* (at the start of the intervention: general PA guidelines; at the end of the program: assistance to plan an activity and find a club)

assistance to plan an activity and find a club)	
Gamification of PA (3 games of 14 days each two weeks apart)	
Chat and messenger	
Activity monitoring tool (mobile app + Garmin Vivofit 3)	

Outcome measures

Primary outcome

The primary outcome will be the daily PA change measured as the daily step count assessed via the Garmin Vivofit 3 (Garmin International Inc., Olathe, KS, USA), a wearable activity tracker featuring an accelerometer that has been shown to accurately detect the number of steps under a variety of walking conditions [70]. The temporal zone of evaluation will extend from 7 days before the start of the intervention (i.e., baseline assessment), through the three months of intervention (i.e., evolution during the interventional phase), to 7 days after the end of the intervention (i.e., post-intervention assessment). Non-wear days will be defined as days with fewer than 1000 steps (as previous research suggested that daily step values less than 1000 may not represent full data capture [71,72]) and will be removed from the analysis. As using pedometers positively influence daily PA [73], the Garmin wearable will only display on its screen the time and date during the evaluation time. During the intervention period, as self-monitoring of PA is an integrated part of the digital intervention, participants of the Kiplin group will see their object unblocked (i.e., display of the daily number of steps, calories burned, distance traveled, and minutes of activity performed) following the randomization. The wearables of the usual supervised PA program group will stay unchanged during the intervention period.

Secondary outcomes

The secondary outcomes will be the changes in (1) *anthropometric measurements and body composition*, (2) *PA level and SB,* (3) p*hysical capacities, and (4) quality of life*. *Psychological mediators* and *program adherence* will also be examined. Finally, this study will include an evaluation of the cost-utility of the Kiplin intervention in comparison to the usual care. Table 3 provides an

overview of all the outcomes measures and Table 4 provides the schedule of assessment (following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule template [74]).

Table 3. Outcomes measures of the DIPPAO RCT

Outcome	**Assessment method**
Primary outcome	
Daily step count over 3 months	Via Garmin Vivofit 3
Secondary outcomes	
Anthropometric measurements and body composition	
Body mass, height and BMI	Body mass will be measured to the nearest 0.1 kg using a calibrated digital scale and height will be measured to the nearest 0.1 cm using a wall-mounted stadiometer. BMI will be calculated as body mass (kg) divided by height squared (m^2)
Body composition	Body composition will be assessed by bioelectrical impedance analysis, with the multi-frequency segmented body composition analyzer Tanita MC780 (Tanita, Hong Kong, China). Once the body mass has been evaluated by the scale, a foot/hand impedance measurement is performed (Hand-to-foot bioelectrical impedance analysis, BIA). This new BIA technology has recently been validated in adults of different levels of physical activity [75] as well as in overweight and obese children and adolescents [76].
Physical Activity and Sedentary Behaviors	
Objective PA	Accelerometer-based PA (Actigraph GT3X+; ActiGraph LLC, Pensacola, FL, USA) to measure the time spent in light-, moderate-, and vigorous-intensity PA over 7 days.
Objective SB	Accelerometer-based sedentary time (Actigraph GT3X+) over 7 days.
Self-reported PA and SB	Self-reported behaviors will be collected using the Recent Physical Activity Questionnaire (RPAQ) [77] that assess sitting time, number of stairs climbed, PA at home, active transportation, PA at work, leisure PA, and global transportation.
Daily step count and daily activity minutes over 9 months	Via Garmin Vivofit 3
Physical capacities	
Muscle strength	Muscular strength of the upper limbs will be assessed by a series of three handgrip test measurements for right and left hands, in the seated position. The best performance measured for each hand via the dynamometer (Takei Grip-D, Takei, Japan) will be conserved and the mean of both hands will be noted [78]. Muscular strength of lower limbs will be assessed by an isokinetic dynamometer that will measure the maximum knee extension torque at different speeds (30, 60 and 120°/s).

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Cardiorespiratory fitness	Via the 6-minute walking test (6MWT). The 6MWT is a simple and convenient test that measures the distance in meters a patient can walk in six minutes in a standardized 30 meters long corridor. This test will be performed following the American Thoracic Society guidelines [79] and has been validated in the past [80].
Quality of life	
Quality of life	Via the EQ-5D-5L questionnaire [81] assessing 5 dimensions: mobility, autonomy of the person, current activity, pain/discomfort, anxiety/depression.
Psychological mediators	
Perceived enjoyment	Perceived enjoyment of physical activity during the intervention will be evaluated using the Physical Activity Enjoyment Scale (PACES) [82]. This questionnaire consists of 16 items where participants have to rate "how you feel at the moment about the physical activity you have been doing" using a 7-point Likert scale ranged from 1 (not at all) to 7 (very much).
Psychological need satisfaction	The Psychological Need Satisfaction in Exercise Scale (PNSES) [83] will be used to measure perceived competence (e.g., I feel that I am able to complete exercises that are personally challenging), autonomy (e.g., I feel free to exercise in my own way), and relatedness (e.g., I feel attached to my exercise companion) while exercising during the program. Composed of 18 items, participants will have to rate their agreement on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Self-reported motivation	Autonomous and controlled motivation toward physical activity will be assessed using a short version of the Motivation Scale Towards Health-oriented Physical Activity [84]. This questionnaire is composed of 8 items with a 7-point Likert scale ranging from 1 (does not correspond at all) to 7 (corresponds totally), reflecting 4 motivational regulations: intrinsic, identified, introjected, and external regulation.
In-group identification	The existence of a shared identity within the PA group will be assessed via the In-group Identification Questionnaire [85] including 14 items on a 7-point Likert scale that ranged from 1 (not at all) to 7 (very much) and measuring five dimensions: solidarity, satisfaction, centrality, individual stereotypes and homogeneity within the group.
Weight stigma	Three forms of weight stigma will be evaluated. A modified version of the Everyday Discrimination Scale [86] will assess perceived discrimination. This questionnaire consists of 5 items (e.g., "In the past 12 months, how often have you been treated differently than others because of your weight?") rated on a 7-point Likert scale ranging from 1 (never) to 7 (all the time). Weight stigma concerns will be measured with the scale developed by Hunger and Major [86], composed of 3 items (e.g., "I am afraid of being excluded because of my weight") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The Modified Weight Bias Internalization Scale (WBIS-M) [87] will be used to assess weight bias internalization. This questionnaire is composed of 11 items (e.g., "I am less attractive than other people because of my weight") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Program adherence	
APA sessions attendance and perceived exertion	The number of APA sessions attended will be assessed for both groups. Perceived exertion of these sessions will be measured at the end of each session via the modified Borg Scale [88].
App engagement	For the Kiplin group only, the app engagement and utilization will be noted by assessing the participation rates in games and challenges, the frequency of use of the mobile app, and the number of messages exchanged.
Economic evaluation	

Cost-utility analysis	The health economic evaluation will assess the economic impact of a 3-month digital intervention in an obese and/or T2DM population in comparison with the usual care. For this purpose, a cost-utility analysis will be performed with 1) identification and valuation of costs and 2) measurement of utility by the EQ-5D questionnaire. The perspective adopted will be the health insurance perspective. The measurement of resources, in physical quantities or in volume, will be part of the French health care context. Only direct medical costs will be identified and valued. The time horizon will extend from the date of inclusion (T0) to the end of the study (T3). Results will be presented in the form of an incremental cost-effectiveness ratio (ICER), which is the ratio between the average difference in cost (euros) and the average difference in effectiveness (QALY) observed between the two arms. Sensitivity analyses will be conducted to test the robustness of the results.
Control variables	
Perceived vulnerability against COVID-19	An adapted version of the perceived vulnerability questionnaire [89] will be used. This questionnaire is composed of 6 items (e.g., "I feel concerned about the risk of contracting the COVID-19") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Perceived digitalization	Via one item (i.e., "I feel comfortable with the use of smartphones and digital objects") rated on a 7-point Liker scale ranging from 1 (strongly disagree) to 7 (strongly agree).

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380 **Table 4.** Schedule of enrollment, interventions, and assessments

		STUDY PERIOD					
	Selection visit	**Inclusion visit**	**T0**	**Intervention**		**T1**	**T2**
TIMEPOINT	***M-1***	***M-1***	***0***	***M1***	***M2***	***M3***	***M3***	***M9***
ENROLMENT:								
Eligibility screen	X							
Informed consent		X						
Randomization			X					
INTERVENTIONS:								
Kiplin intervention				←	—	→		
Usual care condition				←	—	→		
ASSESSMENTS:								
Height	X							
Weight			X				X	X
Body composition			X				X	X

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6MWT			X			X	X
Handgrip			X			X	X
Isokinetic dynamometer			X			X	X
Step count and activity minutes		←	—	—	—	—	→
Accelerometry		←	—			X	X
Self-reported PA			X			X	X
Motivation			X			X	X
Enjoyment						X	
Psychological needs						X	
Weight stigma			X			X	X
In-group identification						X	
Quality of life			X			X	X
Program adherence				←	→		
Control variables			X			X	X
Adverse events	At any time						

6MWT: 6-Minute Walk Test

Statistical analyses

Sample size and power analysis. Sample size estimations are based on the primary outcome measure of steps per day measured using the Garmin Vivofit 3. We conducted an a priori sample size estimation based on a previous meta-analysis [90] that have reported an effect size of $d = 0.51$, (95% CI [0.12,0.91], $I^2 = 90\%$) for PA interventions comprising wearables and smartphone apps compared to control groups. However, considerable statistical heterogeneity has been observed in the results of this meta-analysis. The authors therefore excluded studies with a high risk of bias in sensitivity analyses. The meta-analysis

revealed a larger effect size of $d = 0.67$ (95% CI [0.48, 0.86], $I^2 = 0\%$). To conciliate these two results, we decided to base our sample size estimation on an intermediate effect size of $d = 0.60$.

In order to demonstrate a difference equivalent of an effect size of 0.6 on our primary outcome, we will require a sample size of 44 for 80 % power and a two-sided type I error at 0.05. More precisely, if we consider that the statistical individual is an individual-day and an intra-class correlation coefficient of 0.5 (in order to take into account the inter- and intra-individual variability), 2002 individual-days are necessary per group (i.e., 22 participants per group). We propose to include 25 participants per group in order to foresee potential dropouts, inherent to such trial.

General points in data analyses. The statistical analyses will follow intention to treat and per protocol principles. Characteristics of participants will be described and compared between groups at inclusion according to the following variables: compliance with eligibility criteria, epidemiological characteristics, clinical characteristics, and possible treatments. A description of protocol deviations and causes of dropout will also be provided. Initial comparability of the two arms will be assessed on main participant characteristics and potential factors associated with the primary outcome. Statistical analyses will be performed using R (R Foundation for Statistical Computing, Vienna, Austria) and Stata (version 15; StataCorp, College Station, Texas, US).

Analyses of primary outcome. Longitudinal data will be assessed using linear mixed models in order to account for intra-individual differences. Differences in step count changes in function of the condition (group allocation) will be evaluated using models that include the following fixed effects: group, time, and group x time interaction. We will consider random intercepts for participants and random linear slopes for repeated measures at the participant level. The normality of residuals will be checked. When appropriate, a logarithmic transformation of the dependent variable will be performed. A Sidak's type I error correction will be applied to take into account multiple comparisons. The results will be expressed using effect-sizes and 95% confidence intervals.

Analyses of secondary outcomes. In a second phase, the primary analysis could be completed by a multivariate approach to take into account the possible confounding factors retained with regard to the

results of the univariate analysis and to their clinical relevance (e.g., gender, age, BMI and engagement). Particular attention, primarily descriptive, will be paid to participants' adherence to different intervention programs. Moreover, an in-depth analysis of drop-outs occurrence will be proposed by considering the dropout as censored data (estimation by Kaplan-Meier method). As the primary analysis will be conducted following intention-to-treat principles, sensitivity analyses will be performed to evaluate the statistical nature of missing data, and to propose, if necessary, the most appropriate data imputation method.

Finally, modelling analyses of longitudinal trajectory profiles could also be carried out, if possible, as well as multiple mediation modelling to examine the hypotheses according to which psychological mechanisms may partially or totally mediate the relationships between the intervention and the number of steps, the PA level and SB. Considering our lack of knowledge about intervention effect sizes on variables such as consequences of weight stigmatizations or in-group identification, Bayesian inferences could be applied in an exploratory perspective.

Continuous secondary outcomes will be analyzed as described above for the primary outcome. For non-repeated data, the following comparison tests will be used: Student's t test or Mann-Whitney test for quantitative data, and Chi2 test or Fisher's exact test for categorical variables. Because of the potential for type 1 error due to multiple comparisons, findings from analyses of secondary outcomes will be interpreted as exploratory.

Patient and public involvement

The Kiplin intervention has been developed following an iterative process and a user-centered design philosophy. Interviews with patients and healthcare professionals along with usability tests informed us about the different user profiles, their needs, and their usage. These data then guided the development of the app. Patients were not involved in the development of the research question, the design, or the recruitment of the trial. Results will be reported individually through a personal report and a summary of the overall research findings on request to the principal investigator.

DIPPAO randomized controlled trial: study protocol

Ethics and dissemination

The DIPPAO RCT adheres to the principles of the Helsinki declaration. The research protocol has been reviewed and approved by the Local Human Protection Committee (CPP Ile de France XI, *N*° 21004-65219) and has been registered on ClinicalTrial.gov (NCT04887077, Registered May 14, 2021). All participants will receive information sheets and consent forms to sign before the potential inclusion. Any modification of the research protocol must be subjected to an authorization agreement from the Ethics Committee.

The results of this study will be disseminated through international conference presentations and in relevant scientific journals. The three complementary but distinct objectives of the trial will be addressed in different publications at the end of the study.

Discussion

The Kiplin intervention is a group-based gamified digital program aim to promote behavior change and long-term PA among patients with obesity and/or T2DM. Backed by scientific knowledge, this intervention may change patient's behavior by improving their self-determined motivation toward PA, reducing weight stigma that usually act as PA barriers, and ultimately participating to improve program adherence. More globally, this intervention is the opportunity to address a wider audience though one unique program by responding to the limits and constraints of face-to-face programs. Findings will be of interest to researchers, practionners, and policy makers in future discussions on the relevance of digital interventions in the treatment of chronic diseases.

Abbreviations

6MWT: 6-minute walk test; APA: adapted physical activity; BCT: behavior change technique; BIA: bioelectrical impedance analysis; BMI: body mass index; Cm: centimeter; CONSORT: consolidated

standards of reporting trials; CPP: comité de protection des personnes (Ethics committee); DIPPAO: digital intervention promoting physical activity among obese people; ICER: incremental cost-effectiveness ratio; Kg: kilogram; MVPA: moderate-to-vigorous physical activity; PA: physical activity; REDCap: Research Electronic Data Capture; RCT: randomized controlled trial; SB: sedentary behaviors; SDT: self-determination theory; SIA: social identity approach; T2DM: type 2 diabetes mellitus

Acknowledgments

The authors wanted to thank the challenge 3 I-SITE Clermont Auvergne Project 20-25 for their grant and all members of the Kiplin team involved in the development of the mobile application.

Contributors

AM, AC, MB, and MD conceptualized the project and obtained the funding. All authors have provided input into the study design. AM and BP designed the data analysis plan. The first draft of the manuscript was written by AM and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding

This project is funded by a grant of the challenge 3 I-SITE Clermont Auvergne Project 20-25. The work of AM is supported by an ANRT grant (Cifre PhD Thesis) and by the company Kiplin. The funders had no input in the design of the trial and will have no influence on the collection, interpretation or publication of the study results. Trial sponsor: University Hospital CHU G. Montpied, Clermont-Ferrand.

Competing interests

AC, BP, and MD declare that they have no competing interests. AM's PhD Grant is funded by the French National Association for Research and Technology (ANRT) and Kiplin. MB is employed by Kiplin.

Ethics approval and consent to participate

The research protocol has been approved by the Protection of Persons Ethics Committee Ile de France XI (N° 21004-65219). Written informed consent will be obtained from participants prior their inclusion in the trial.

Provenance and peer review

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

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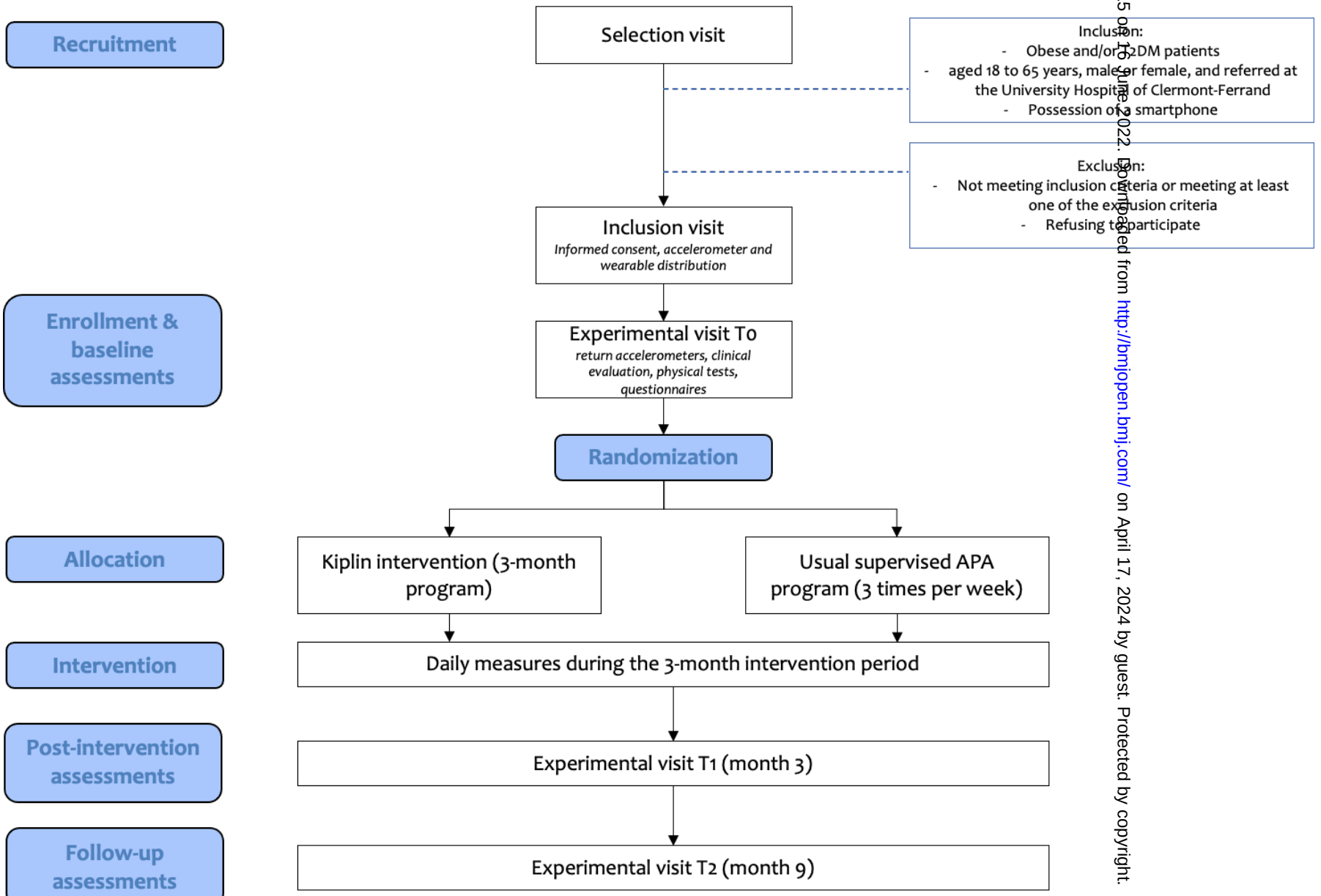
DIPPAO randomized controlled trial: study protocol

Figure 1. Study flowchart

Figure 2. Screenshots of the Kiplin app

Note. A. The telecoaching sessions reservation. B. The adventure. C. The investigation. D. The boardgame. E. The chat. F. The activity monitoring tool.



SUPPLEMENTARY ONLINE MATERIAL 1

Hypotheses on PA adherence

First, we argue that the Kiplin intervention will produce greater PA levels than the usual care (face-to-face supervised APA) during the whole intervention. More particularly, the Kiplin intervention will avoid the compensatory decrease between leisure PA time and supervised PA time frequently observed in traditional programs (King et al., 2007; Westerterp, 1998) by stimulating daily PA. This compensatory decrease is in line with the ActivityStat hypothesis (Gomersall et al., 2013), which suggests that an increase or decrease of PA in one domain will be compensated in another domain, in order to maintain an overall stable level of PA or energy expenditure over time. By stimulating daily PA with gamification features and goal setting, the Kiplin intervention may limit the decrease in total PA that could occur in compensation of an increase in PA in supervised sessions.

We also hypothesize that this improvement in PA will be sustained after the follow-up period.

> *Hypothesis 1a: Patients of the Kiplin group will demonstrate increased total PA over 3 months that will be superior to the total PA of patients in the face-to-face supervised APA condition.*
>
> *Hypothesis 1b: Patients of the Kiplin group will demonstrate improved PA over 9 months that will be superior to the total PA of patients in the face-to-face supervised APA condition.*

In parallel of these improvements, we expect to observe a decrease in the overall sedentary time resulting from a compensatory stimulation of the daily activity, notably led by gamification strategies.

> *Hypothesis 2: The Kiplin intervention will be effective in reducing SB. This effectiveness will be superior to the face-to-face supervised APA condition.*

Hypotheses on the intervention mechanisms

The Kiplin intervention including multiple components to change behavior, this trial will aim to identify the psychological mediators that can explain a potential improvement in PA. We argue that one of the potent ingredients of the Kiplin intervention will be its ability to promote a self-determined motivation toward PA. This motivation should be filled by basic needs' satisfaction and through the enjoyment of the playful activities experienced by the patients.

> *Hypothesis 3a: The Kiplin intervention will improve patients' self-determined motivation toward PA.*

Hypothesis 3b: The satisfaction of the three basic needs (autonomy, competence, and relatedness) and the enjoyment of the program will mediate the relationship between Kiplin intervention and patients self-determined motivation toward PA.

Hypothesis 3c: Kiplin intervention-related changes in motivation will increase PA.

The development of a self-determined motivation toward PA may limit the reduction of the effect of the Kiplin program on PA at the end of the intervention compared to the face-to-face supervised APA condition.

Hypothesis 3d: Kiplin intervention-related changes in motivation will sustain the PA improvement over the follow-up period compared to face-to-face supervised APA condition.

In parallel, we argue that this group-based digital intervention will encourage the emergence of a social identity in the group, being the basis for mutual and social support among the participants. Moreover, engaging in a group-based program in a co-operative setting with people sharing the same stigmatized characteristic (i.e., related to weight, pathology, and symptomatology) should allow individuals to overcome their fear of being discriminated, and more generally remove barriers related to the negative stereotypes that target them (Jetten et al., 2018; Olander et al., 2013). This would ultimately facilitate engagement in the proposed activities and promote behavior change.

Hypothesis 4a: The Kiplin intervention will reduce perceived discrimination, weight stigma concerns, and weight bias internalization compared to the usual care condition.

Hypothesis 4b: Kiplin intervention-related changes in weight stigma processes will increase PA.

Hypotheses on the cost-utility of the intervention

Finally, we hypothesize that the achievement of the aforementioned objectives associated with the advantages of e-health interventions (i.e., a broad accessibility though technology, permitting to address a large population) will allow to reduce the time of face-to-face supervised PA by an APA professional, for an identical number of patients, and to reduce the costs and constraints associated with a classic face-to-face care. In order to measure this potential increase in efficiency, we will integrate a health economic evaluation within this protocol.

Hypothesis 5: By requiring fewer face-to-face APA sessions, the Kiplin intervention may lead to economic benefits and health care saving in patient management compared to face-to-face supervised APA condition.

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SUPPLEMENTARY ONLINE MATERIAL 2

Exclusion criteria

Participants will be excluded if they meet anyone of the following criteria:

- Medical or surgical history judged by the investigator to be incompatible with the study.
- Subject with an unstable psychiatric condition.
- Pregnant or breastfeeding women.
- Heavy alcohol consumption (> 2 to 3 drinks per day depending on gender) or drug addiction.
- Disability or contraindication to PA.
- Subject with cardiorespiratory and/or osteoarticular disorders that limit their ability to perform physical tests or moderate PA for 30 minutes.
- Subject with progressive cardiovascular or neoplastic disease.
- Subject who has presented a major infection in the 3 months prior to inclusion.
- Subject with a known neuro-muscular pathology (i.e., myopathy, myasthenia, rhabdomyolysis, paraplegia, hemiplegia).
- Subject with chronic or acute inflammatory pathology within 3 months prior to inclusion.
- Subject diagnosed and/or treated for schizophrenia, bipolar disorder, major depression.
- Subject deprived of their liberty by judicial or administrative decision.
- Subject refusing to sign the written consent to participate.
- Subject participating in another study.

SUPPLEMENTARY ONLINE MATERIAL 3

Information letter and consent form in French (Version 3, 03/06/2021).

CLERMONT-FERRAND
CENTRE HOSPITALIER UNIVERSITAIRE

LETTRE D'INFORMATION

Etude DIPPAO : évaluation des effets d'une intervention connectée pour promouvoir l'activité physique et diminuer la sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2

Madame, Monsieur,

Nous vous proposons de participer au protocole de recherche intitulé « DIPPAO ».
Nous vous invitons à lire attentivement cette lettre d'information qui a pour but de répondre aux questions que vous seriez susceptible de vous poser avant de prendre votre décision de participation.

Ce document vous appartient et nous vous invitons à en discuter avec votre médecin et vos proches.

1) Objectif de la recherche

Selon de nombreuses études, le niveau d'activité physique de patients ayant un diabète de type 2 ou une obésité est particulièrement faible. Or la pratique régulière d'une activité physique permet non seulement de prévenir le risque de développer les maladies chroniques mais également de limiter leur progression et de diminuer la mortalité précoce liée à ces maladies. C'est pourquoi nous cherchons à développer à travers cette étude scientifique des interventions permettant d'augmenter l'activité physique de ces patients et que nous sollicitons votre participation.

L'objectif principal de ce projet est d'étudier l'effet d'une intervention digitale (Kiplin, https://www.kiplin.com/) composée de trois « briques » (des séances d'activité physique adaptée (APA) interactives en visio-conférence + animations connectées sous forme de jeux collectifs + suivi de l'activité physique avec un bracelet connecté et une application) sur l'activité physique globale et le temps de sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2 en comparaison avec la prise en charge classique au CHU de Clermont-Ferrand.
Les objectifs secondaires sont d'augmenter l'adhérence au programme et de diminuer le temps d'accompagnement en présentiel.

A travers une augmentation de l'activité physique, l'objectif est d'améliorer votre santé. En effet les études scientifiques et les sociétés savantes sont unanimes sur le fait que l'atteinte des recommandations en activité physique permet de conserver un bon état de santé et d'améliorer sa qualité de vie. Nous pensons que ces nouvelles méthodes pourraient être utiles mais nous aimerions le démontrer car rien n'est actuellement prouvé.

2) Méthodologie

Dans cette étude vous suivrez un programme de 3 mois. Nous testerons différentes variantes de l'intervention (intervention Kiplin ou séances d'activité physique adaptée en présentiel au CHU) afin d'évaluer quel format est le plus efficace pour augmenter et maintenir votre activité physique à la fin de l'intervention (3 mois de prise en charge au CHU) et 6 mois après la fin de l'intervention. Vous serez réparti dans l'un des deux groupes de l'étude aléatoirement selon une procédure de tirage au sort faite par ordinateur. Lors de votre prise en charge par un programme d'activité physique adaptée vous serez donc dans l'un des 2 groupes suivants :

- Groupe Kiplin

Groupe prise en charge traditionnelle

La méthodologie, les tests effectués ou encore la durée de votre participation seront strictement identiques qu'importe le groupe. Ces éléments sont décrits plus précisément ci-dessous. Au total, 48 patients seront inclus dans cette étude (24 par groupe).

3) Description des deux prises en charge

- Groupe Kiplin : 3 séances d'activité physique adaptée par semaine, d'abord en présentiel au CHU puis en visioconférence depuis chez vous via l'application mobile Kiplin. Parallèlement, vous pourrez, via l'application mobile Kiplin : suivre votre activité physique, participer à des animations sous forme de jeux par équipes où votre quantité d'activité physique vous permet de progresser dans le jeu, interagir avec les autres participants du Groupe Kiplin.

- Groupe prise en charge traditionnelle CHU : 3 séances d'activité physique adaptée par semaine en présentiel pendant 3 mois au CHU

4) Déroulement pratique

Si vous acceptez de participer à cette étude, vous serez suivi pendant 9 mois à partir de votre inclusion dans l'étude et vous aurez 5 visites (dont une seule supplémentaire par rapport à votre prise en charge originelle) :

- Visite de sélection : 1 mois avant le début de l'intervention *(environ 30 minutes)* : au cours de cette visite, le médecin investigateur vérifiera que vous pouvez participer au protocole et si tel est le cas vous proposera de participer à l'étude et vous remettra la lettre d'information. Suite à cette lecture, si vous souhaitez

participer à l'étude un formulaire de consentement vous sera transmis pour signature.

- Visite d'inclusion : 8 jours avant le début de votre programme (moins de 10 minutes) : Cette courte visite sera l'occasion pour vous de signer le formulaire de consentement avec le médecin investigateur. Vous repartirez avec un bracelet connecté Garmin ainsi que l'accéléromètre. Pendant cette semaine d'évaluation vous n'aurez pas accès aux données d'activité de la montre.

- Visite d'évaluation au début de l'intervention (M0) *(environ 45 minutes)* : Cette visite sera effectuée en amont de votre première séance d'APA afin de faciliter votre prise en charge. Vous ramènerez l'accéléromètre à cette occasion. Au cours de cette visite vous effectuerez les tests (détaillés ci-après) permettant l'évaluation de vos capacités physiques. Ces tests font partie de la prise en charge habituelle et ne vous demanderont pas plus de temps. Vous devrez également remplir plusieurs questionnaires évaluant notamment votre niveau d'activité physique, votre bien-être physique et émotionnel, votre motivation à la pratique d'activité physique.
  Vous serez informé à ce stade de votre groupe de prise en charge (Kiplin ou prise en charge traditionnelle) et pourrez dès lors planifier vos séances d'activité physique adaptée selon votre groupe.

- Visite d'évaluation à la fin de l'intervention (M3) (*environ 45min*) : Tests et questionnaires identiques aux précédentes visites.

- Visite M9 (6 mois après la fin de l'intervention) + évaluations (*environ 45min*) : Tests et questionnaires identiques aux précédentes visites.

5) Calendrier de suivi pour cette étude

Si vous acceptez de participer à cette étude et si vous remplissez toutes les conditions requises, vous serez suivi(e) dans le cadre du protocole du service de Médecine du sport du CHU de Clermont-Ferrand.

Le calendrier de votre suivi sera le suivant :

	Visite 1 Sélection	Visite 2 Inclusion	Visite 3 M0	Visite 4 M3	Visite 5 M9
	(30 min)	(10 min)	(45 min)	(45 min)	(45 min)
Consentement éclairé	X				

Critères d'inclusion et de non-inclusion	X		X		
Données sociodémographiques, poids, taille, tour de taille, pression artérielle, médicaments	X			X	X
Questionnaire activité physique			X	X	X
Échelle de douleur			X	X	X
Questionnaires bien-être psychologique et motivation à l'activité physique			X	X	X
Accéléromètre et bracelet Garmin		X		X	X
Composition corporelle			X	X	X
Endurance			X	X	X
Force musculaire			X	X	X
Pression artérielle			X	X	X

6) Description des tests réalisés

Les évaluations réalisées pour chacune des 3 visites (au début, à la fin des 3 mois et à la fin des 9 mois) sont les suivantes :

- Un bilan de vos capacités physiques sera effectué. Vous aurez pour cela 3 tests à réaliser :
  - Un test de force des membres supérieurs appelé « handgrip » durant lequel nous vous demanderons de serrer fort sur une poignée pendant 15 secondes. Deux essais seront enregistrés.
  - Un test de force des membres inférieurs sera réalisé grâce à un dynamomètre permettant de mesurer la force maximale d'extension du genou. Les mesures seront effectuées à trois vitesses différentes. Pour chaque vitesse, deux essais de 3 répétitions successives seront réalisés et la meilleure performance sera conservée. Vous disposerez de 2 minutes de repos entre chaque essai.
  - Un test d'endurance cardio respiratoire sera réalisé par l'intermédiaire du test de marche de six minutes ; l'objectif de ce test est de marcher aussi vite que vous pouvez pendant six minutes. La distance parcourue pendant les six minutes sera mesurée.

L'évaluation de la condition physique sera réalisée par la même personne, dans la même journée et toujours dans le même ordre.

- Suite aux tests de condition physique, vous devrez remplir plusieurs questionnaires
  - Le questionnaire RPAQ qui vous permet de préciser votre niveau d'activité physique.
  - Vous remplirez un deuxième questionnaire évaluant votre qualité de vie.
  - Le troisième questionnaire évaluera vos relations avec les autres patients durant l'intervention.
  - Plusieurs questionnaires permettront de mesurer votre motivation pour l'activité physique et vos sentiments envers cette activité.
    Un autre questionnaire vous demandera de décrire la discrimination que vous pouvez percevoir venant des autres personnes dans votre vie de tous les jours.
    Enfin un dernier questionnaire visera à évaluer l'impact émotionnel de la COVID-19.

- Un accéléromètre vous sera également remis. Il s'agit d'un petit boîtier (3 cm x 3 cm) que l'on fixe autour de la taille à l'aide d'une sangle élastique et qui permet d'enregistrer les mouvements. Sa petite taille et le fait que l'on peut porter le capteur sur ou ses vêtements rend l'appareil facile à porter et il s'oublie très vite. Ce capteur devra être porté pendant 7 jours du lever au coucher, sauf pendant les activités aquatiques (douche, bain, natation, etc.). Il va enregistrer sur 7 jours (enregistrement la journée) l'ensemble des mouvements que vous faites pour que nous puissions évaluer votre temps d'activité physique de faible, moyenne ou haute intensité

- Un bracelet connecté de la marque Garmin vous sera également remis. Il s'agit d'un appareil que vous porterez au poignet quotidiennement pendant la durée de l'étude, qui reconnaît et enregistre automatiquement vos différentes activités physiques. Si vous êtes dans le Groupe « prise en charge traditionnelle », l'affichage sera paramétré pour n'afficher que la date et l'heure pendant la durée de 'intervention (soit pendant 3 mois), et l'ensemble des fonctionnalités seront ensuite activées pour que vous puissiez continuer à utiliser l'objet.

- Bio-impédancemètre : vous monterez sur une balance qui permet de mesurer - en plus de votre poids - votre composition corporelle, c'est-à-dire la quantité de graisse (ou masse grasse), la quantité de muscles (ou masse musculaire) et la quantité d'eau de votre corps. Cela vous permet de mieux comprendre de quoi est fait votre poids quand vous vous pesez.

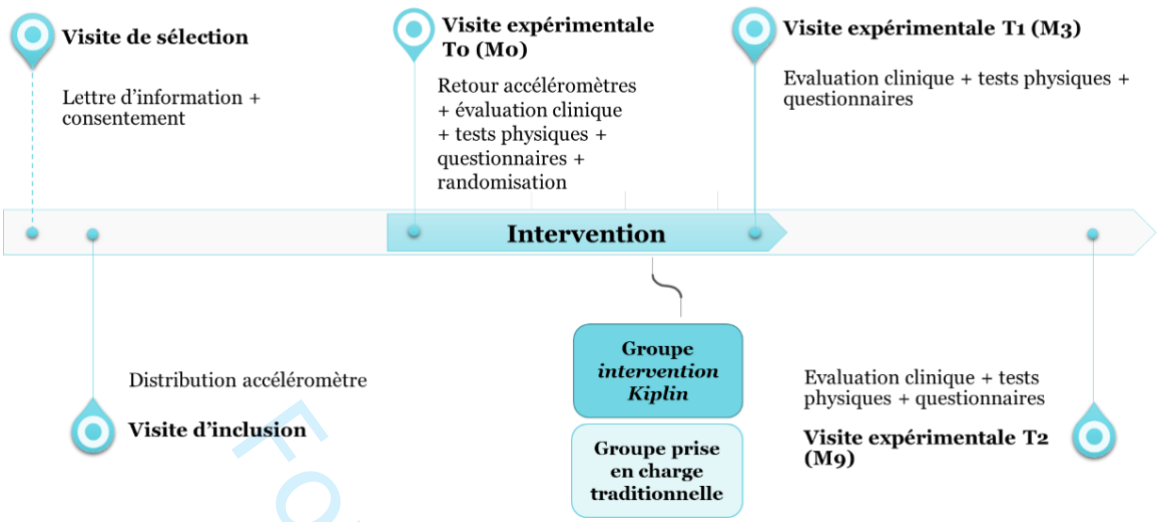

Schéma récapitulatif du protocole expérimental

Toutes les visites auront lieu au CHU.

7) Vos bénéfices à participer à cette étude

Vous aurez l'opportunité de tester de nouvelles méthodes originales de changement de comportement de manière gratuite.

⇨ L'avantage que vous pouvez attendre en participant à cette étude est une augmentation de votre activité physique, une meilleure gestion du stress, de la fatigue, du sommeil, une amélioration de votre condition physique et donc un bien-être physique et émotionnel. Ces résultats sont ceux attendus mais ne sont pas pour autant garantis.

8) Rémunération

⇨ Au début de l'étude vous sera distribué un objet connecté Garmin. Ce bracelet vous sera offert à la fin de l'étude. Toutes les fonctionnalités de l'objet ne seront pas accessibles par tous lors de l'étude mais seront bien évidemment débloquées et disponibles à l'issue de l'étude quand l'objet vous sera offert.

9) Risques et contraintes prévisibles

Risques liés à la pratique :

Les risques encourus lors des sessions d'activité du programme sont minimes compte tenu :

1) des faibles risques de traumatismes musculaires ou ostéo-articulaires induits par la nature des activités qui seront proposées et,

2) de l'intensité de l'exercice qui sera légère (pas de risque cardio-vasculaire).

Vous n'aurez pas plus de contraintes que d'habitude puisque les visites s'effectuent au CHU dans la continuité de votre prise en charge et que l'intervention vous est proposée gratuitement de manière intégrale. De potentielles contraintes peuvent survenir avec le port des matériels d'évaluation mais de nombreux conseils vous seront prodigués afin que vous ne ressentiez aucune gêne.

10) Informations utiles :

Votre participation à cette recherche n'engendrera aucun frais pour vous.

Toutefois, pour pouvoir participer à cette recherche vous devez être affilié(e) ou bénéficier d'un régime de sécurité sociale, et ne pas être placé(e) sous sauvegarde de justice.

Le CHU de Clermont-Ferrand, qui organise cette recherche en qualité de promoteur, a contracté une assurance conformément aux dispositions législatives, garantissant sa responsabilité civile et celle de tout intervenant auprès de la société d'assurances Biomedicinsure. Le numéro de contrat est 0840718730010. Dans le cas où votre état de santé serait altéré du fait de votre participation à l'étude, conformément à la loi n°2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine, vous seriez en droit de recevoir des dédommagements dans le cadre de ce contrat d'assurance spécifique.

Vous ne pourrez participer à aucune étude pendant toute la durée de la recherche et les 6 mois suivant la fin de la recherche. Vous ne devez pas non plus avoir participé à une recherche dans les 6 mois précédant votre participation à cette étude.

Cette recherche impliquant la personne humaine a reçu l'avis favorable du Comité de Protection des Personnes Ile de France XI en date du 27/01/2021.

Il est possible que cette recherche soit interrompue, si les circonstances le nécessitent, par le promoteur ou à la demande de l'autorité de santé.

Si vous considérez que vous avez subi un préjudice lors de votre participation à l'étude, vous devez immédiatement contacter l'investigateur coordonnateur :

Pr Martine Duclos

Chef de Service de Médecine du Sport et des Explorations Fonctionnelles et Respiratoires

CHU Gabriel Montpied - Clermont-Ferrand

mduclos@chu-clermontferrand.fr

11) Données personnelles recueillies :

Votre participation à cette étude implique la collecte et le traitement des données personnelles suivantes :

- État civil et coordonnées (nom, prénom, année de naissance, sexe, email)
- Composition corporelle et données anthropométriques (taille, poids, tour de taille)
- Pression artérielle systolique et diastolique
- Données de condition physique (résultats des tests physiques)
- Données d'activité physique et de sédentarité (questionnaire + niveau d'activité physique mesuré par l'objet connecté et par accéléromètre)
- Données de qualité de vie (questionnaire)
- Données relatives au soutien social perçu et aux relations partagées avec les autres patients (questionnaire)
- Données visant à évaluer votre motivation pour l'activité physique et vos sentiments envers cette activité (questionnaire)
- Données portant sur la discrimination que vous pouvez percevoir venant des autres personnes dans votre vie de tous les jours (questionnaire)
- Données de participation aux séances d'activité physique adaptée et aux animations connectées (si vous êtes dans le Groupe Kiplin)
- Contributions éventuelles sur les espaces de messagerie au sein de l'application mobile Kiplin (si vous êtes dans le Groupe Kiplin)

12) Protection de vos données personnelles :

Dans le cadre de cette recherche, le CHU de Clermont-Ferrand est responsable de la mise en œuvre du traitement de données à caractère personnel. Ce traitement informatique a pour but d'analyser les résultats de la recherche au regard de l'objectif de cette dernière qui vous a été présenté.

Le fondement juridique, au regard de l'article 6 du RGPD (Règlement Général sur la Protection des Données) est l'intérêt légitime du promoteur à mettre en œuvre le traitement de données médicales à des fins de recherche scientifique (article 9.2 du RGPD).

A cette fin, toutes les données médicales vous concernant et les données relatives à vos habitudes de vie nécessaires pour la recherche seront transmises au Promoteur, ou aux personnes ou sociétés agissant pour son compte, en France.

Ces données seront identifiées par un numéro de code et vos initiales. Ces données pourront également, dans des conditions assurant leur confidentialité, être transmises aux autorités de santé françaises, à d'autres entités du CHU de Clermont Ferrand.

Les données seront conservées au minimum 15 ans après la fin de la recherche, selon les dispositions légales en vigueur.

Le représentant du promoteur ou celui des Autorités de Santé, tenu au secret professionnel, peut avoir accès à votre dossier médical pour contrôle de conformité. En effet seules les données du dossier médical sont directement identifiantes. Leur consultation (par représentants autorisés) obéit à des règles strictes. Toutes les autres données "données de l'étude" sont des données codées transmises au promoteur qui les possède et peut les transmettre selon certaines règles. Les résultats de l'étude n'utilisent que ces données codées et leur publication respecte de ce fait l'anonymat.

Dans le cadre de cette recherche, la société Kiplin, éditrice de la solution connectée utilisée dans l'intervention, sera amenée à traiter certaines de vos données personnelles (coordonnées, sexe et année de naissance, données d'activité physique collectées par l'objet Garmin, contributions sur les espaces de messageries au sein de l'application, participation aux séances d'activité physique adaptée en visioconférence). Kiplin s'engage à mettre en œuvre toutes les mesures techniques et organisationnelles nécessaires pour assurer la sécurité et la confidentialité de vos données. En particulier, l'ensemble des données collectées via la solution Kiplin seront hébergées dans un environnement certifié pour l'hébergement de données de santé (hébergeur : Proginov – 44118 La Chevrolière).

Conformément aux dispositions du RGPD et de la loi informatique et libertés du 6 janvier 1978 modifiée, vous disposez d'un droit d'accès, de rectification et de limitation du traitement de vos données.

Conformément aux dispositions du RGPD, vous disposez également d'un droit d'opposition à la transmission des données couvertes par le secret professionnel susceptibles d'être utilisées dans le cadre de cette recherche et d'être traitées. Dans ce cas, l'exercice de ce droit vous empêchera de participer à la recherche.

Conformément à l'article 17.3 du RGPD, les données recueillies préalablement au retrait du consentement, le cas échéant, ne seront pas effacées et continueront à être traitées dans les conditions prévues par la recherche.

Pour exercer ces droits ou pour toute question sur le traitement de vos données, vous pouvez contacter notre délégué à la protection des données : CHU de Clermont-Ferrand – Direction de la Qualité – Gestion des Risques et Droits des Usagers – 58 rue Montalembert – 63003 Clermont-Ferrand cedex 1 (ou dpd@chu-clermontferrand.fr)

Vous pouvez également accéder directement ou par l'intermédiaire d'un médecin de votre choix à l'ensemble de vos données médicales en application des dispositions de l'article L. 1111-7 du code de la santé publique. Ces droits s'exercent auprès du médecin qui vous suit dans le cadre de la recherche et qui connaît votre identité.

Si vous estimez, après nous avoir contactés, que vos droits Informatique et Libertés ne sont pas respectés ou que le dispositif de contrôle d'accès n'est pas conforme aux règles de protection des données, vous pouvez adresser une réclamation auprès de la CNIL (https://www.cnil.fr/) par courrier.

13) Aspects légaux

Vous avez le droit de refuser de participer à cette recherche sans avoir à vous justifier. Votre choix n'influencera en rien le rapport que vous avez avec votre équipe soignante. Si vous acceptez de participer, vous avez le droit de retirer votre consentement à tout moment sans avoir à vous justifier.

Vous pourrez à tout moment durant l'essai vous adresser au Pr Martine Duclos et à son équipe pour leur poser toutes questions complémentaires.

Toute information nouvelle survenant pendant la participation et pouvant éventuellement modifier votre décision de participation, vous sera donnée.

Par ailleurs, vous pourrez être tenu(e) informé(e) des résultats globaux de cette recherche à la fin de l'étude.

Lorsque vous aurez lu cette lettre d'information et obtenu les réponses aux questions que vous vous posez en interrogeant le médecin investigateur, il vous sera proposé, si vous en êtes d'accord, de donner votre consentement écrit en signant le document préparé à cet effet. Vous disposez d'un délai de réflexion pour remettre ce document signé.

FORMULAIRE DE CONSENTEMENT DE PARTICIPATION A UNE RECHERCHE IMPLIQUANT LA PERSONNE HUMAINE

Etude DIPPAO : évaluation des effets d'une intervention digitale pour promouvoir l'activité physique et diminuer la sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2

Investigateur principal :

Pr Martine Duclos

Chef de Service de Médecine du Sport et des Explorations Fonctionnelles et Respiratoires

CHU Gabriel Montpied

Clermont-Ferrand

mduclos@chu-clermontferrand.fr

Je déclare :

- que le Docteur (*nom, prénom, téléphone*) …….. m'a proposé de participer à l'étude sus nommée,
- qu'il m'a expliqué en détail le protocole,
- qu'il m'a notamment fait connaître :
  - l'objectif, la méthode et la durée de l'étude
  - les contraintes et les risques potentiels encourus
  - mon droit de refuser de participer et en cas de désaccord de retirer mon consentement à tout moment
  - mon obligation d'inscription à un régime de sécurité sociale
  - que, si je le souhaite, à son terme, je serais informé(e) par le médecin investigateur de ses résultats globaux
  - que je ne serai pas autorisé(e) à participer à d'autres études cliniques pendant toute la durée du protocole, ni durant les 6 mois suivant la fin de ma participation,
  - que le Comité de Protection des Personnes Ile de France XI a émis un avis favorable en date du 27/01/2021,
  - que dans le cadre de cette étude le promoteur, le CHU de Clermont-Ferrand, a souscrit à une assurance couvrant cette recherche
  - que j'ai répondu en toute bonne foi aux questions concernant mon état de santé et ma participation à d'autres études
  - que je ne suis pas placé sous sauvegarde de justice,
- que je dois disposer d'un délai suffisant avant de signer ce consentement

Les informations relatives à l'étude recueillies par l'investigateur sont traitées confidentiellement. J'accepte que les données enregistrées à l'occasion de cette recherche puissent faire l'objet d'un traitement informatisé. J'ai bien noté que les droits d'accès, de rectification du traitement des données prévus par la loi informatique et libertés du 6 janvier 1978 modifiée s'exercent à tout moment auprès du médecin qui me suit dans le cadre de la recherche et qui connaît mon identité ou du délégué de protection des données du promoteur dont les coordonnées sont mentionnées dans la lettre d'information qui m'a été remise.
Après avoir discuté librement et obtenu réponse à toutes mes questions, j'accepte librement de participer à cette recherche impliquant la personne humaine dans les conditions précisées dans la lettre d'information et le formulaire de consentement.

Nom et prénom du patient : …… Date :……./……./……. Signature	Nom de l'investigateur : …… Date :……./……./……. Signature :

Ce document est à réaliser en 2 exemplaires originaux, dont le premier doit être gardé 15 ans par l'investigateur, un autre remis à la personne donnant son consentement.

SUPPLEMENTARY ONLINE MATERIAL 4

Kiplin Games

The Kiplin app collects the daily step count of participants by joining the API (Application Programming Interface) of the application used by the participants to track their activity (in the case of our study, the Kiplin app will use the Garmin Health API to collect the data measured via the Garmin Vivofit 3).

The adventure

Through their journey, participants will be invited to be part of "the adventure", where the objective is to reach steps goals in order to collectively get to the final destination (players can visualize their progression on a map with checkpoints schematizing the remaining distances between different cities of a digital world tour; Figure 2B).

The investigation

The second game will be "the investigation", where participants will have to be physically active and succeed in collective challenges to unlock cues and try to solve the mission (Figure 2C).

The board game

Finally, "the board game" will put participants in the shoes of forest rangers having to put out a fire. Once again, the achievement of step goals will allow participants to progress by team on the board squares and to reach the next levels of the game to put out all the fires and save the forest residents (Figure 2D). The aim will be to put out as many fires as possible and save as many forest residents as possible by the end of the time limit.

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

Section/item	ItemNo	Description	Reported on page # (section)
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 *(Trial registration)*
	2b	All items from the World Health Organization Trial Registration Data Set	3 *(Trial registration)*
Protocol version	3	Date and version identifier	3 *(Trial registration)*
Funding	4	Sources and types of financial, material, and other support	24 *(Funding)*
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 23 *(Contributors)*
	5b	Name and contact information for the trial sponsor	24 *(Funding)*
	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	24 *(Funding)*
	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)	N/A

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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 *(Introduction)*
	6b	Explanation for choice of comparators	4 *(Introduction)*
Objectives	7	Specific objectives or hypotheses	8-9 *(The study aims)*
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)	9-10 *(Study design, Randomization, allocation, and blinding)*
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	9 *(Study design)*
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)	9 *(Eligibility criteria)*
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-14 *(Intervention overview, control group)*
	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)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Table 3 *(Program adherence)*

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12 *(Eligibility criteria), supp. material 2*
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	16 *(Outcome measures), Table 3*
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)	10 *(Procedure)*, Figure 2
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	20 *(Sample size and power analysis)*
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9 *(Recruitment)*
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	10 *(Randomization, allocation, and blinding)*
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	10 *(Randomization, allocation, and blinding)*
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10 *(Randomization, allocation, and blinding)*

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10 *(Randomization, allocation, and blinding)*
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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	10 *(Procedure),* 21-25 *(Outcome measures),* *Table 2*
	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 *(Recruitment),* 21 *(Analyses of secondary outcomes)*
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	11 *(Data management)*
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	20-22 *(Statistical analyses)*
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21 *(Analyses of secondary outcomes)*
	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)	20-22 *(Statistical analyses)*
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	N/A
	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
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	Table 4
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	22 *(Ethics and dissemination)*
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)	22 *(Ethics and dissemination)*
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9 *(Recruitment)*
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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	11 *(Data management)*

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	24 *(Competing interests)*
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	11 *(Data management)*
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
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	22 *(Ethics and dissemination)*
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22 *(Ethics and dissemination)*
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplemental material 3
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

*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

Digital Intervention Promoting Physical Activity among Obese people (DIPPAO) randomized controlled trial: study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058015.R2
Article Type:	Protocol
Date Submitted by the Author:	16-May-2022
Complete List of Authors:	Mazéas, Alexandre; Univ. Grenoble Alpes, SENS; INRAE Centre Clermont-Auvergne-Rhône-Alpes Chalabaev, Aïna; Univ. Grenoble Alpes, SENS Blond, Marine; Kiplin Pereira, Bruno; University Hospital Centre Clermont-Ferrand, Department of Biostatistics unit (DRCI) Duclos, Martine; University Hospital Centre Clermont-Ferrand, Department of Sport Medicine and Functional Exploration
Primary Subject Heading:	Sports and exercise medicine
Secondary Subject Heading:	Health informatics, Health economics, Rehabilitation medicine
Keywords:	SPORTS MEDICINE, SOCIAL MEDICINE, Diabetes & endocrinology < INTERNAL MEDICINE, HEALTH ECONOMICS, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS

DIPPAO randomized controlled trial: study protocol

Title: Digital Intervention Promoting Physical Activity among Obese people (DIPPAO) randomized controlled trial: study protocol

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Word count excluding title page, abstract, references, figures and tables: 5364

Tables/Figures: 6

DIPPAO randomized controlled trial: study protocol

Abstract

Introduction: Physical inactivity and excessive sedentary behaviors are major preventable causes in both the development and the treatment of obesity and type 2 diabetes mellitus (T2DM). Nevertheless, current programs struggle to engage and sustain physical activity (PA) of patients over long periods of time. To overcome these limitations, the DIPPAO (Digital Intervention Promoting Physical Activity among Obese people) randomized controlled trial (RCT) aims to evaluate the effectiveness of a group-based digital intervention grounded on gamification strategies, enhanced by social features, and informed by the tenets of the self-determination theory and the social identity approach.

Methods and analysis: This trial is a two-arm parallel RCT testing the effectiveness of the Kiplin digital intervention on obese and T2DM patients in comparison to the usual supervised PA program of the University Hospital of Clermont-Ferrand, France. A total of 50 patients will be randomized to one of the two interventions and will follow a 3-month program with a 6-month follow-up post-intervention. The primary outcome of the study is the daily step count change between the baseline assessment and the end of the intervention. Accelerometer data, self-reported PA, body composition, and physical capacities will also be evaluated. To advance our understanding of complex interventions like gamified and group-based ones, we will explore several psychological mediators relative to motivation, enjoyment, in-group identification, or perceived weight stigma. Finally, to assess a potential superior economic efficiency compared to the current treatment, we will conduct a cost-utility analysis between the two conditions. A mixed model approach will be used to analyze the change in outcomes over time.

Ethics and dissemination: The research protocol has been reviewed and approved by the Local Human Protection Committee (CPP Ile de France XI, *N°* 21004-65219). Results will inform the Kiplin app development, be published in scientific journals, and disseminated in international conferences.

Trial registration: NCT04887077 *(ClinicalTrial.gov; Registered May 14, 2021)*

Keywords: behavior change; cost-utility; e-health; gamification; intervention; mhealth; mobile app; obesity; physical activity; RCT; T2DM; weight stigma

DIPPAO randomized controlled trial: study protocol

Strengths and limitations of this study:

- Randomized controlled trial comparing a digital gamified intervention targeting PA to another existing non-drug treatment.
- Between- and within-person level analyses of daily steps will provide insight on group differences and individual trajectories of behavior change.
- A 6-month follow-up will inform on the sustainability of the long-term intervention effect.
- The intervention involving multiple components, it will be difficult to affirm which component is involved in the efficacy of the intervention.
- We will attempt to address this limitation by conducting in-depth mediation analyses, to identify the salient ingredients behind the effect.

DIPPAO randomized controlled trial: study protocol

Introduction

Overweight and obesity, which concern one in two adults in western countries [1], are among the most important health risk factors, and is associated with comorbidities such as Type 2 diabetes mellitus (T2DM), which affects 5% of the French population under 65 years of age, and 15% of people over 65 years old. If the roots of obesity and T2DM are complex and multifactorial, physical inactivity and sedentary behaviors (SB) are both major factors in the development of these diseases [2–7].

Positive effects of PA for these patients are recognized both at the scientific and institutional levels. Indeed, they can benefit from supervised PA programs suited to their disease (i.e., adapted physical activity, APA), which allow to improve functional capacity and muscle strength without having detrimental effects or complications on disease progression [8]. However, these programs can be difficult to access for patients, due to lack of availability on the scheduled sessions, lack of economic means, or geographical distance [9]. As a result, a limited adherence to PA at the end of these programs is generally observed [10].

Given that PA of obese and T2DM patients remains very low [11–13], promoting their long-term PA participation is a major challenge for researchers, practitioners, and the global healthcare economic system [14]. A promising solution is to overcome the limitations of current face-to-face programs, by developing digital interventions. In this vein, this study will evaluate the efficacy of a digital intervention in subjects with chronic diseases, by comparing it to the gold standard (supervised face-to-face PA).

e-health and gamification

Digital tools may provide effective, cost-effective, safe, and scalable interventions to improve health and healthcare [15]. These devices introduce a new care approach where patients participate in their treatment in a dynamic and interactive way, contributing to their empowerment. These interventions offer a wider and more individualized scope than face-to-face interventions, with potentially lower long-term costs [16]. Nevertheless, no rigorous trial has yet demonstrated the superiority of digital PA interventions over existing ones. Although e-health interventions are gaining popularity for the treatment

of obesity, appearing advantageous compared to current programs, no evidence of cost-effectiveness has been demonstrated [17]. In addition, concerns remain regarding the adherence rate and engagement in the long-term [18]. Therefore, the use of gamification appears as an interesting way to address these limits.

Defined as the use of game design elements in non-game contexts [19], gamification is the art of improving a routine activity in an engaging and motivating way, by the integration of specific ingredients that make games enjoyable. By gamifying PA, participants are encouraged to move and walk to play, and this tends to make their activity more playful and motivating [20]. A recent meta-analysis [21] revealed that gamified interventions improved PA with an increase of more than 1600 daily steps. Importantly, additional analyses indicated that a) gamified interventions appear more effective than equivalent non-gamified interventions and b) PA improvement persists in the long-term [21]. This suggests that gamification is more than a novelty effect, and that is a promising healthcare approach, as it can be easily implemented in daily life without adding demands to people's schedules. In sum, gamified interventions seem to be a critical strategy to engage participants in digital interventions. However, more rigorous trials are needed to confirm these promising results, to better understand the mechanisms explaining gamification effects, and to test the healthcare potential of gamified interventions [21].

Barriers to PA and determinants of behavior change in obese people

Another key driver to enhance the effectiveness of e-health interventions is the use of behavior change theories and techniques (BCTs), as they allow to target the active ingredients of behavior change [22]. In the early days of digital interventions, mobile apps, internet platforms, and connected objects designed to promote PA were rarely based on scientific knowledge, or at least the characteristics of the programs were not detailed enough to allow the mapping with evidence-based theories and techniques [23,24]. For example, Conroy et al. [25] evidenced that commercial apps released before 2014 do not contain a large amount of BCTs. Since then, recommendations provided by the CONSORT statement

[26] or the World Health Organization [27] have emphasized the need to systematically use a theory-based approach in the development of digital interventions. More especially, eHealth and mHealth devices constitute an excellent opportunity to both develop and test behavior change theories (e.g., theory of planned behavior [28], transtheoretical model [29], self-determination theory [30]) and BCTs [31].

In addition, recent research has emphasized the importance of precision medicine which focuses on individual variability and social and societal factors of behavior change in the development and evaluation of therapies [32]. In this vein, the social psychology approach can be promising as it highlights the importance of collective-level factors. Notably, it suggests that weight stigma is an important driver of the obesity increase [33]. Overweight and obese persons may face specific barriers related to weight stigma when they try to implement exercise in their daily life. They may indeed face or fear to face discrimination from a prejudiced person, or they may have internalized negative stereotypes into their self-perceptions, leading them to avoid activities in which they feel being stigmatized, such as PA [34]. For example, the more obese people perceive themselves negatively or feel discriminated because of their weight, the more they avoid PA [35]. Considering the impact of weight stigma in the development of obese-targeted interventions is therefore vital to optimize their effectiveness.

Theoretical framework

To address these challenges, the present intervention was built based on the tenets of the self-determination theory (SDT) [36] and the social identity approach (SIA) [37].

Self-determination theory. The SDT is an empirically validated framework which focuses on factors that promote sustained motivation and wellbeing [38]. At its core, this model proposes that motivation is regulated along a continuum from lack of motivation to a completely autonomous motivation, in which the behavior comes from the individual's will. Research has revealed that an autonomous motivation has positive emotional, cognitive, and behavioral consequences, and is strongly associated with PA over

time [39]. The most autonomous forms of motivation are the intrinsic ones, which occur when people perform an activity for its own satisfaction, its inherent interest and enjoyment. Especially, practicing PA for the direct pleasure and the inherent satisfaction it provides is an important predictor of the long-term maintenance of physical practice [39]. This suggests that a game-based intervention that provides fun and playful experiences would feed the autonomous motivation of participants and would be more correlated with long-term adherence of PA.

In parallel, SDT postulates that autonomous motivation increases when three basic psychological needs are satisfied [30]: the need for autonomy (i.e., need to feel responsible of one's own actions), for competence (i.e., need to feel effective in one's interactions with the environment), and for relatedness (i.e., need to feel connected to other people). Again, gamifying interventions seems particularly promising with this regard, as it can provide basic need satisfaction [20,40], leading to a significant intrinsic motivation improvement [41]. Firstly, gamification strategies such as points scores, badges, levels, and competitions, sustain the need for competence by providing feedbacks on the user's behavior. Secondly, customizable environments of the games or user choices may support autonomy. Finally, leaderboards, teams, groups, or communication functions may support the need for relatedness [20].

Social identity approach. It is now well-established that exercising in group-based settings may be effective to engage participants in PA and sustain their practice over time [42,43], regardless of the population characteristics [44]. However, results from group-based interventions are mixed, [45] suggesting that bringing people together does not systematically make interventions successful [46]. The SIA offers a relevant paradigm to explain these mixed results. It argues that social groups can affect health behaviors and outcomes only when individuals perceive they share the same identity with another individual or group [46]. SIA is the combination of two related theories - the social identity theory [47] and the self-categorization theory [48]. As social identity theory introduces the capacity for groups to be internalized into our sense of self (i.e., speaking and living situations in the name of 'we' and 'us' rather than just 'I' and 'me'), the self-categorization theory explains how people develop their social identity within groups. More especially, it proposes that the salience of a particular social identity results from a context-sensitive categorization process. Individuals categorize themselves according to a set of

core attributes that are salient and observable such as age, gender, ethnicity, or weight status. The knowledge of these determinants is precious when designing group-based interventions in order to catalyze the effects of groups with shared social identities.

A recent body of work investigates the links between self-categorization theory and long-term adherence of PA programs. Beauchamp et al. [49–51] have shed light on important attributes that determine engagement in PA. These researchers found that age and gender are particularly relevant markers of shared social identity through PA. Importantly, moderator analyses revealed that adults who were overweight reported a particularly strong preference for exercising within same-gender groups relative to mixed-gender groups, in comparison to normal weight adults [50]. The consideration of these attributes that determine engagement in a PA program can inform and guide intervention choices. Moreover, based on the rejection-identification model [52], Jetten et al. [53] proposed that social identities derived from group membership can act as psychological resources when individuals are confronted with stigmatization. Thus, the shared identities forged during a group-based intervention regrouping individuals with the same stigma (e.g., weight status) could be the keystone for the emergence of a social identity and social support able to counteract the negative effects of group-based discrimination.

The study aims

The main objective of the DIPPAO randomized controlled trial (RCT) is to evaluate the effectiveness of the Kiplin intervention – a group-based digital program centered on gamification strategies and informed by the tenets of SDT and SIA – to promote PA among patients with obesity and/or T2DM. The Kiplin intervention is composed of four components embedded within a smartphone app: a) a gamification of PA through multiple games, b) a remote APA program with videoconferencing sessions, c) an interface for exchange and conversation and, d) an activity monitoring tool. The present study will investigate the short and long-term effects of the intervention over 3 and 9 months in comparison with the usual care provided at the University Hospital of Clermont-Ferrand, France (i.e., 3 months face-to-

face supervised APA program). Additional objectives of this RCT will be to better understand the mechanisms underlying this digital intervention and to test its cost-utility compared to the usual care. More specific hypotheses on the expected effects of the intervention are proposed in supplemental material 1.

Methods and analysis

Study design

This study will be a two-arm parallel RCT comparing the effectiveness of the Kiplin digital intervention to the usual supervised PA program of the University Hospital of Clermont-Ferrand, on patients with obesity and/or T2DM. Both arms will benefit from a 3-month program and assessments will be carried at baseline, 3 and 9 months. The conduct and reporting of the trial will follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines [26,54]. For an overview of the study design, see Figure 1.

[Please insert Figure 1 here]

Participants

Eligibility criteria. Participants will be voluntary patients affected by obesity (BMI ≥30 kg/m² and <45 kg/m²) and/or overweight/obesity and T2DM, aged 18 to 65 years, male or female, and referred to the department of sports medicine of the University Hospital of Clermont-Ferrand by their physician to benefit from supervised PA. The participants must have a smartphone with a compatible operating system (at least iOS12 or Android 6.0) to be eligible. They must also be covered by health social security and be naive to any APA intervention. In order to ensure the understanding of the different questionnaires used in the study, sufficient proficiency of French will be required. The presence of one of the exclusion criteria listed in supplemental material 2 will lead to the exclusion of the participant.

Recruitment. A total of 50 patients (25 per group) will be recruited at the University Hospital of Clermont-Ferrand (department of sports' medicine). At their inclusion, patients meeting inclusion

criteria will be invited to participate to the study and the inclusion will be done during a medical consultation. The subject will sign a written consent form before being included in the study (see supplemental material 3 for the patient consent form). Participants will not receive monetary compensation. However, the wearable device (Garmin Vivofit 3) distributed to all participants at the beginning of the study will be offered to them at its end. Recruitment began on June 2021 and the expected end date of recruitment is July 2022, for a start in spring 2022 depending on the sanitary situation. A total of 30 patients were recruited on February 2022.

Protocol

Procedure. There will be five visits for all participants: the selection visit, the inclusion visit, and three experimental visits (T0, T1, T2, see Figure 1). Visits will occur in the department of sports medicine (University Hospital) of Clermont-Ferrand. During the selection visit, one of the investigating physicians will check the patients' ability to complete the full protocol based on eligibility criteria. Only after signing the informed consent form, patients will move to the inclusion visit and will be given a wearable device (Garmin Vivofit 3) and an accelerometer (Actigraph GT3x) for the baseline assessment of PA for 7 days. At least one week after this visit, the T0 experimental visit will occur to complete baseline assessments before the start of the intervention. At the end of the 3-month program, the T1 experimental visit will be carried, and the T2 experimental visit will be placed 6 months after the end of the program in order to evaluate the follow-up of the intervention. Apart from a few questionnaires, the three experimental sessions will be identical. To ensure equal conditions for all participants, physical condition assessments will be conducted by the same APA coach, within the same day, at the same moment, and in the same order.

Randomization, allocation, and blinding. Following the first experimental visit, patients will be randomized in one of the two conditions with a 1:1 allocation. The associate biostatistician will carry out a permuted block randomization in advance by computer with randomly varying block sizes. The randomization list will be transmitted using sequentially numbered, opaque, sealed envelopes to the data

collectors. Research assistants collecting data will be blinded to the treatment allocation. Double blinding is nevertheless not possible in such interventions because allocation concealment is impossible for participants. Moreover, the APA coaches will not be aware of group allocation at baseline but blinding will be impossible afterward, as the coaches will have seen patients during the sessions.

Data management. All data will be entered electronically into REDCap (Research Electronic Data Capture), a secure, web-based software platform specifically designed to support data capture for research studies. Data will be reported as it is obtained. All Principal Investigators will be given access to the cleaned data sets. Investigators with direct access to the data will take all necessary precautions to ensure the confidentiality of information relating to the medical products, the trials, the participants involved and more particularly their identity and the obtained outcomes. A fully anonymized data set, statistical code, and all study materials will be made publicly available on the Open Science Framework.

Intervention

Preliminary testing. Feasibility of the gamified part of the Kiplin app has been previously assessed via a qualitative study among breast cancer survivors [55]. This study showed that the intervention was associated with positive feelings and was seen as a "motivational catalyzer promoting good habits" by the participants. Afterward, the full intervention including telecoaching APA sessions in a 12-week program has been pilot tested on different patient pathways (unpublished data), including obese and T2DM patients. Patients' feedbacks were all positive and enthusiastic and no organizational issues have been identified, suggesting that the intervention was ready to be tested in a RCT.

Intervention overview. To promote behavior change, we implemented within the Kiplin app 16 BCTs. Previous meta-analyses have shown these techniques to be effective in increasing walking behavior [56], to encourage behavior change of overweight and obese populations [57–59], and which were particularly suited for digital interventions [60]. Table 1 displays how BCTs have been implemented within the app. Patients will be offered a free download of the app as part of their treatment The Kiplin intervention is composed of four main features:

1) *APA sessions.* Participants of the Kiplin group will benefit from an APA program. Videoconferencing is an interesting perspective to reduce the organizational limitations of face-to-face programs. With this telemedicine approach, professionals can offer tailored interventions from a distance and propose a remote home-based APA program to patients in addition of providing monitoring, social support, and therapeutic education [61]. Thus, this program will be mainly remote and the number of sessions per week will decrease over 3 months. Patients will benefit of 3 sessions per week the first 2 weeks (1 face-to-face and 2 telecoaching sessions), 2 telecoaching sessions per week the next 6 weeks, and 1 telecoaching session per week the third month, for a total of 22 sessions. Sessions conducted in face-to-face during the two weeks have the objective to ensure that the correct movements are adopted by the patients. The telecoaching sessions will be group-based live remote APA classes of 60 minutes taught by a professional APA coach with a small group (between 5 and 7 patients). Each week, several sessions will be offered to patients who can register according to their preferences and availability (Figure 2A). Patients will see in advance the theme of the session. After registering on the app, they will receive a Livestorm link by e-mail allowing them to join the session on their smartphone, tablet, or computer. Some sessions will be playful with the integration of quizzes, riddles, or tips on PA in addition to physical exercises (i.e., endurances exercises, muscle strengthening, and stretching). Thus, the sessions will integrate therapeutic education to inform participants on the benefits of PA, the deleterious consequences of SB, and some general knowledge like injury prevention.

2) *Gamification of PA.* In addition to the APA sessions, patients of the Kiplin group will benefit from three PA games. Patients will be able to participate in one game per month for a duration of 14 days each. These settings seemed to be the most appropriate considering previous findings and recommendations [21] highlighting that gamified interventions of 12 weeks or more would be less efficient than shorter ones. These results suggest that multiple gamification doses would be better than only one long game. The three different games (i.e., the adventure (Figure 2B), the mission (Figure 2C) and the board game (Figure 2D); more details about the games in

supplemental material 4) are structured in the same way: the daily step count performed by each participant is converted into points within the game and permits to progress by teams. Thus, the objective is to increase patients' daily activities through game mechanics and social interactions. Participants will not be given specific instructions on how often they should log in to the app.

3) *Chat and messenger.* The messaging functions aimed to encourage social interactions are composed by an internal messaging space to communicate with the team and a general messaging system with all the patients of the program (Figure 2E). During the games, this messenger will be animated every day by "Pilot Kiplin" (i.e., a real Kiplin team member animating the app and who takes the form of a funny mascot) who launch challenges, announce results, and carry internal messages to motivate participants. In addition, regular notifications (which can be turned off) will be sent by the app to mobilize and inform participants about the games or to remind them to participate to the telecoaching session they are registered.

4) *Activity monitoring tool.* Patients will be able to view their activity at any time of the day with their Garmin pedometer. The intervention focuses on daily step count rather than MVPA for several reasons. First, walking appears more adapted for obese people [62], and is statistically associated with declines in all-cause mortality [63,64] and improvement in body composition [65], regardless of its volume or intensity [63,66]. Along with the pedometer, a visual and numerical interface within the mobile app displays the daily activity (daily step count), the week average, and the graphical evolution of the number of daily steps (Figure 2F). This tool aims to give feedback on behavior and promote self-monitoring of PA. Self-monitoring and goal setting strategies have been pointed as major predictors of PA at short and long term in overweight and obese adults [58,59]. For this reason, another major element of the Kiplin app is the goal setting of PA. Recent research on goal setting revealed that interventions that set weekly or daily goals produced greater effects on PA than goals set over a longer time frame [67]. Moreover, it appears better to consider the achievement of the goals in "percentage of objective achieved" rather than in a binary way (success/fail) in order to inform that the objective is reached or close to being reached [68]. Following these recommendations, the initial step goal at the beginning

of the program will be based on the daily step count of the evaluation week. By the end of the intervention participants will aim to achieve 2000 more daily steps than baseline. To support this objective, daily goals during the games will be fixed on this objective. During time periods without games, participants' goal step will be increased progressively by 500 steps in order to reach the final step objective at the end of the 3-month program. The performances will be displayed each day as a percentage of the goal achieved in the form of a gauge that fills up. Each week, a new daily step goal will be settled based on the performance of the previous week. Participants will have the opportunity to personalize their goal increase tier.

Finally, in addition to the collaborative teams, leaderboards, and the chat aimed to enhance social interactions, several elements have been adjusted in order to facilitate the development of a social identity among Kiplin users. The team's allocation will be done in such a way that favors homogeneous groups in terms of gender and age. In addition, participants will complete a short and fun personality questionnaire upon entering their program. The answers will be additional elements allowing us to associate in teams people resembling each other. Other strategies will be implemented to facilitate social identification among the teams as the option to choose a team name, the option to see who is registered for APA sessions so patients can join their peers, and incentives by Pilot Kiplin to push participants to meet and walk together in real life.

All these features are part of the standard Kiplin app, which will ensure the generalizability of the results outside the scope of this trial.

[Please insert Figure 2 here]

Control condition. Participants allocated to the control condition will benefit from the usual PA care of the University Hospital of Clermont-Ferrand, which is a 3-month program of face-to-face APA, 3 sessions a week on non-consecutive days, for a total of 36 sessions. These individual sessions will be composed of a warm-up, followed by 50 minutes of endurance exercises, muscle strengthening exercises and stretching, all supervised by an APA coach in a dedicated room. Aerobic and resistance exercises

will be performed in a circuit organized as a row of 6 exercise stations (3 aerobic and 3 resistance exercises). Aerobic exercises will be performed at 50% of VO2max the first week and the intensity will be gradually increased by 10% every two weeks to target at least 80% of VO2max over the last nine weeks. For resistance exercises, patients will perform a single set of 8-12 repetitions of unloaded exercises the first week and the number of sets will be gradually increased to 3. These exercises will be performed at 50% of 1RM during the first week and the load will be gradually increased by 10% every two weeks and remain at 80% of 1RM over the last five weeks.

The content of both groups is summarized in Table 2.

Table 1. Implementation of BCTs within the app

BCT	Related app feature or game mechanic

Goal setting behavior (1.1)	Set daily step goals.
Action planning (1.4)	Choose the goal according to several suggestions. Time-limited challenges encourage participants to maximize their activity at specific times.
Review behavior goals (1.5) Discrepancy between current behavior and goal (1.6)	Each week participants are encouraged to set a new goal considering their progress or difficulties.
Feedback on behavior (2.2)	Feedback on daily steps via the activity monitoring tool included in the app with weekly graph displaying progress towards goal.
Self-monitoring of behavior (2.3)	Self-monitoring tools with tips to use it.
Social support (unspecified, 3.1)	Team challenges where participants must collaborate to progress in the game.
Social support (practical, 3.2)	Incentives to push participants to walk together in real life.
Social support (emotional, 3.3)	Promote social connectedness through teamwork and games.
Instruction on how to perform a behavior (4.1) Information about health consequences (5.1)	Tips to plan and implement PA in daily life and information on the benefits of walking on health are given in the telecoaching sessions through infographics and quizzes.
Social comparison (6.2)	Individual and collective leaderboards.
Prompt/cues (7.1)	Push notifications, time-limited challenges
Cue signaling reward (7.4)	Virtual rewards such as trophies, clues, points.
Associative learning (7.8)	Via the playful experience.
Behavioral practice / rehearsal (8.1)	Game-based activities naturally lead to repetition and practice.

BCT: behavior change techniques corresponding to the Michie's taxonomy [69]

Table 2. Summary of the groups content

Intervention group (Kiplin)	**Control group (usual care)**
22 group-based APA sessions (1 face-to-face and 2 telecoaching sessions the first two weeks, 2 telecoaching sessions per week the next 6 weeks, and 1 telecoaching session per week the third month)	36 individual APA sessions (3 sessions per week during 12 weeks)
PA recommendations (during the intervention: personalized and evolving daily step goal + general PA guidelines; at the end of the program: video capsules to continue exercising in autonomy +	*PA recommendations* (at the start of the intervention: general PA guidelines; at the end of the program: assistance to plan an activity and find a club)

assistance to plan an activity and find a club)	
Gamification of PA (3 games of 14 days each two weeks apart)	
Chat and messenger	
Activity monitoring tool (mobile app + Garmin Vivofit 3)	

Outcome measures

Primary outcome

The primary outcome will be the daily PA change measured as the daily step count assessed via the Garmin Vivofit 3 (Garmin International Inc., Olathe, KS, USA), a wearable activity tracker featuring an accelerometer that has been shown to accurately detect the number of steps under a variety of walking conditions [70]. The temporal zone of evaluation will extend from 7 days before the start of the intervention (i.e., baseline assessment), through the three months of intervention (i.e., evolution during the interventional phase), to 7 days after the end of the intervention (i.e., post-intervention assessment). Non-wear days will be defined as days with fewer than 1000 steps (as previous research suggested that daily step values less than 1000 may not represent full data capture [71,72]) and will be removed from the analysis. As using pedometers positively influence daily PA [73], the Garmin wearable will only display on its screen the time and date during the evaluation time. During the intervention period, as self-monitoring of PA is an integrated part of the digital intervention, participants of the Kiplin group will see their object unblocked (i.e., display of the daily number of steps, calories burned, distance traveled, and minutes of activity performed) following the randomization. The wearables of the usual supervised PA program group will stay unchanged during the intervention period.

Secondary outcomes

The secondary outcomes will be the changes in (1) *anthropometric measurements and body composition*, (2) *PA level and SB,* (3) p*hysical capacities, and (4) quality of life*. *Psychological mediators* and *program adherence* will also be examined. Finally, this study will include an evaluation of the cost-utility of the Kiplin intervention in comparison to the usual care. Table 3 provides an

overview of all the outcomes measures and Table 4 provides the schedule of assessment (following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule template [74]).

Table 3. Outcomes measures of the DIPPAO RCT

Outcome	**Assessment method**
Primary outcome	
Daily step count over 3 months	Via Garmin Vivofit 3
Secondary outcomes	
Anthropometric measurements and body composition	
Body mass, height and BMI	Body mass will be measured to the nearest 0.1 kg using a calibrated digital scale and height will be measured to the nearest 0.1 cm using a wall-mounted stadiometer. BMI will be calculated as body mass (kg) divided by height squared (m^2)
Body composition	Body composition will be assessed by bioelectrical impedance analysis, with the multi-frequency segmented body composition analyzer Tanita MC780 (Tanita, Hong Kong, China). Once the body mass has been evaluated by the scale, a foot/hand impedance measurement is performed (Hand-to-foot bioelectrical impedance analysis, BIA). This new BIA technology has recently been validated in adults of different levels of physical activity [75] as well as in overweight and obese children and adolescents [76].
Physical Activity and Sedentary Behaviors	
Objective PA	Accelerometer-based PA (Actigraph GT3X+; ActiGraph LLC, Pensacola, FL, USA) to measure the time spent in light-, moderate-, and vigorous-intensity PA over 7 days.
Objective SB	Accelerometer-based sedentary time (Actigraph GT3X+) over 7 days.
Self-reported PA and SB	Self-reported behaviors will be collected using the Recent Physical Activity Questionnaire (RPAQ) [77] that assess sitting time, number of stairs climbed, PA at home, active transportation, PA at work, leisure PA, and global transportation.
Daily step count and daily activity minutes over 9 months	Via Garmin Vivofit 3
Physical capacities	
Muscle strength	Muscular strength of the upper limbs will be assessed by a series of three handgrip test measurements for right and left hands, in the seated position. The best performance measured for each hand via the dynamometer (Takei Grip-D, Takei, Japan) will be conserved and the mean of both hands will be noted [78]. Muscular strength of lower limbs will be assessed by an isokinetic dynamometer that will measure the maximum knee extension torque at different speeds (30, 60 and 120°/s).

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Cardiorespiratory fitness	Via the 6-minute walking test (6MWT). The 6MWT is a simple and convenient test that measures the distance in meters a patient can walk in six minutes in a standardized 30 meters long corridor. This test will be performed following the American Thoracic Society guidelines [79] and has been validated in the past [80].
Quality of life	
Quality of life	Via the EQ-5D-5L questionnaire [81] assessing 5 dimensions: mobility, autonomy of the person, current activity, pain/discomfort, anxiety/depression.
Psychological mediators	
Perceived enjoyment	Perceived enjoyment of physical activity during the intervention will be evaluated using the Physical Activity Enjoyment Scale (PACES) [82]. This questionnaire consists of 16 items where participants have to rate "how you feel at the moment about the physical activity you have been doing" using a 7-point Likert scale ranged from 1 (not at all) to 7 (very much).
Psychological need satisfaction	The Psychological Need Satisfaction in Exercise Scale (PNSES) [83] will be used to measure perceived competence (e.g., I feel that I am able to complete exercises that are personally challenging), autonomy (e.g., I feel free to exercise in my own way), and relatedness (e.g., I feel attached to my exercise companion) while exercising during the program. Composed of 18 items, participants will have to rate their agreement on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Self-reported motivation	Autonomous and controlled motivation toward physical activity will be assessed using a short version of the Motivation Scale Towards Health-oriented Physical Activity [84]. This questionnaire is composed of 8 items with a 7-point Likert scale ranging from 1 (does not correspond at all) to 7 (corresponds totally), reflecting 4 motivational regulations: intrinsic, identified, introjected, and external regulation.
In-group identification	The existence of a shared identity within the PA group will be assessed via the In-group Identification Questionnaire [85] including 14 items on a 7-point Likert scale that ranged from 1 (not at all) to 7 (very much) and measuring five dimensions: solidarity, satisfaction, centrality, individual stereotypes and homogeneity within the group.
Weight stigma	Three forms of weight stigma will be evaluated. A modified version of the Everyday Discrimination Scale [86] will assess perceived discrimination. This questionnaire consists of 5 items (e.g., "In the past 12 months, how often have you been treated differently than others because of your weight?") rated on a 7-point Likert scale ranging from 1 (never) to 7 (all the time). Weight stigma concerns will be measured with the scale developed by Hunger and Major [86], composed of 3 items (e.g., "I am afraid of being excluded because of my weight") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The Modified Weight Bias Internalization Scale (WBIS-M) [87] will be used to assess weight bias internalization. This questionnaire is composed of 11 items (e.g., "I am less attractive than other people because of my weight") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Program adherence	
APA sessions attendance and perceived exertion	The number of APA sessions attended will be assessed for both groups. Perceived exertion of these sessions will be measured at the end of each session via the modified Borg Scale [88].
App engagement	For the Kiplin group only, the app engagement and utilization will be noted by assessing the participation rates in games and challenges, the frequency of use of the mobile app, and the number of messages exchanged.
Economic evaluation	

Cost-utility analysis	The health economic evaluation will assess the economic impact of a 3-month digital intervention in an obese and/or T2DM population in comparison with the usual care. For this purpose, a cost-utility analysis will be performed with 1) identification and valuation of costs and 2) measurement of utility by the EQ-5D questionnaire. The perspective adopted will be the health insurance perspective. The measurement of resources, in physical quantities or in volume, will be part of the French health care context. Only direct medical costs will be identified and valued. The time horizon will extend from the date of inclusion (T0) to the end of the study (T3). Results will be presented in the form of an incremental cost-effectiveness ratio (ICER), which is the ratio between the average difference in cost (euros) and the average difference in effectiveness (QALY) observed between the two arms. Sensitivity analyses will be conducted to test the robustness of the results.
Control variables	
Perceived vulnerability against COVID-19	An adapted version of the perceived vulnerability questionnaire [89] will be used. This questionnaire is composed of 6 items (e.g., "I feel concerned about the risk of contracting the COVID-19") rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
Perceived digitalization	Via one item (i.e., "I feel comfortable with the use of smartphones and digital objects") rated on a 7-point Liker scale ranging from 1 (strongly disagree) to 7 (strongly agree).

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380 **Table 4.** Schedule of enrollment, interventions, and assessments

		STUDY PERIOD					
	Selection visit	**Inclusion visit**	**T0**	**Intervention**		**T1**	**T2**
TIMEPOINT	***M-1***	***M-1***	***0***	***M1***	***M2***	***M3***	***M3***	***M9***
ENROLMENT:								
Eligibility screen	X							
Informed consent		X						
Randomization			X					
INTERVENTIONS:								
Kiplin intervention				←	—	→		
Usual care condition				←	—	→		
ASSESSMENTS:								
Height	X							
Weight			X				X	X
Body composition			X				X	X

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6MWT			X			X	X
Handgrip			X			X	X
Isokinetic dynamometer			X			X	X
Step count and activity minutes		←	—	—	—	—	→
Accelerometry		←	—			X	X
Self-reported PA			X			X	X
Motivation			X			X	X
Enjoyment						X	
Psychological needs						X	
Weight stigma			X			X	X
In-group identification						X	
Quality of life			X			X	X
Program adherence				←	→		
Control variables			X			X	X
Adverse events	At any time						

6MWT: 6-Minute Walk Test

Statistical analyses

Sample size and power analysis. Sample size estimations are based on the primary outcome measure of steps per day measured using the Garmin Vivofit 3. We conducted an a priori sample size estimation based on a previous meta-analysis [90] that have reported an effect size of $d = 0.51$, (95% CI [0.12,0.91], $I^2 = 90\%$) for PA interventions comprising wearables and smartphone apps compared to control groups. However, considerable statistical heterogeneity has been observed in the results of this meta-analysis. The authors therefore excluded studies with a high risk of bias in sensitivity analyses. The meta-analysis

revealed a larger effect size of $d = 0.67$ (95% CI [0.48, 0.86], $I^2 = 0\%$). To conciliate these two results, we decided to base our sample size estimation on an intermediate effect size of $d = 0.60$.

In order to demonstrate a difference equivalent of an effect size of 0.6 on our primary outcome, we will require a sample size of 44 for 80 % power and a two-sided type I error at 0.05. More precisely, if we consider that the statistical individual is an individual-day and an intra-class correlation coefficient of 0.5 (in order to take into account the inter- and intra-individual variability), 2002 individual-days are necessary per group (i.e., 22 participants per group). We propose to include 25 participants per group in order to foresee potential dropouts, inherent to such trial.

General points in data analyses. The statistical analyses will follow intention to treat and per protocol principles. Characteristics of participants will be described and compared between groups at inclusion according to the following variables: compliance with eligibility criteria, epidemiological characteristics, clinical characteristics, and possible treatments. A description of protocol deviations and causes of dropout will also be provided. Initial comparability of the two arms will be assessed on main participant characteristics and potential factors associated with the primary outcome. Statistical analyses will be performed using R (R Foundation for Statistical Computing, Vienna, Austria) and Stata (version 15; StataCorp, College Station, Texas, US).

Analyses of primary outcome. Longitudinal data will be assessed using linear mixed models in order to account for intra-individual differences. Differences in step count changes in function of the condition (group allocation) will be evaluated using models that include the following fixed effects: group, time, and group x time interaction. We will consider random intercepts for participants and random linear slopes for repeated measures at the participant level. The normality of residuals will be checked. When appropriate, a logarithmic transformation of the dependent variable will be performed. A Sidak's type I error correction will be applied to take into account multiple comparisons. The results will be expressed using effect-sizes and 95% confidence intervals.

Analyses of secondary outcomes. In a second phase, the primary analysis could be completed by a multivariate approach to take into account the possible confounding factors retained with regard to the

results of the univariate analysis and to their clinical relevance (e.g., gender, age, BMI and engagement). Particular attention, primarily descriptive, will be paid to participants' adherence to different intervention programs. Moreover, an in-depth analysis of drop-outs occurrence will be proposed by considering the dropout as censored data (estimation by Kaplan-Meier method). As the primary analysis will be conducted following intention-to-treat principles, sensitivity analyses will be performed to evaluate the statistical nature of missing data, and to propose, if necessary, the most appropriate data imputation method.

Finally, modelling analyses of longitudinal trajectory profiles could also be carried out, if possible, as well as multiple mediation modelling to examine the hypotheses according to which psychological mechanisms may partially or totally mediate the relationships between the intervention and the number of steps, the PA level and SB. Considering our lack of knowledge about intervention effect sizes on variables such as consequences of weight stigmatizations or in-group identification, Bayesian inferences could be applied in an exploratory perspective.

Continuous secondary outcomes will be analyzed as described above for the primary outcome. For non-repeated data, the following comparison tests will be used: Student's t test or Mann-Whitney test for quantitative data, and Chi2 test or Fisher's exact test for categorical variables. Because of the potential for type 1 error due to multiple comparisons, findings from analyses of secondary outcomes will be interpreted as exploratory.

Patient and public involvement

The Kiplin intervention has been developed following an iterative process and a user-centered design philosophy. Interviews with patients and healthcare professionals along with usability tests informed us about the different user profiles, their needs, and their usage. These data then guided the development of the app. Patients were not involved in the development of the research question, the design, or the recruitment of the trial. Results will be reported individually through a personal report and a summary of the overall research findings on request to the principal investigator.

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Ethics and dissemination

The DIPPAO RCT adheres to the principles of the Helsinki declaration. The research protocol has been reviewed and approved by the Local Human Protection Committee (CPP Ile de France XI, *N*° 21004-65219) and has been registered on ClinicalTrial.gov (NCT04887077, Registered May 14, 2021). All participants will receive information sheets and consent forms to sign before the potential inclusion. Any modification of the research protocol must be subjected to an authorization agreement from the Ethics Committee.

The results of this study will be disseminated through international conference presentations and in relevant scientific journals. The three complementary but distinct objectives of the trial will be addressed in different publications at the end of the study.

Discussion

The Kiplin intervention is a group-based gamified digital program aim to promote behavior change and long-term PA among patients with obesity and/or T2DM. Backed by scientific knowledge, this intervention may change patient's behavior by improving their self-determined motivation toward PA, reducing weight stigma that usually act as PA barriers, and ultimately participating to improve program adherence. More globally, this intervention is the opportunity to address a wider audience though one unique program by responding to the limits and constraints of face-to-face programs. Findings will be of interest to researchers, practionners, and policy makers in future discussions on the relevance of digital interventions in the treatment of chronic diseases.

Abbreviations

6MWT: 6-minute walk test; APA: adapted physical activity; BCT: behavior change technique; BIA: bioelectrical impedance analysis; BMI: body mass index; Cm: centimeter; CONSORT: consolidated

standards of reporting trials; CPP: comité de protection des personnes (Ethics committee); DIPPAO: digital intervention promoting physical activity among obese people; ICER: incremental cost-effectiveness ratio; Kg: kilogram; MVPA: moderate-to-vigorous physical activity; PA: physical activity; REDCap: Research Electronic Data Capture; RCT: randomized controlled trial; SB: sedentary behaviors; SDT: self-determination theory; SIA: social identity approach; T2DM: type 2 diabetes mellitus

Acknowledgments

The authors wanted to thank the challenge 3 I-SITE Clermont Auvergne Project 20-25 for their grant and all members of the Kiplin team involved in the development of the mobile application.

Contributors

AM, AC, MB, and MD conceptualized the project and obtained the funding. All authors have provided input into the study design. AM and BP designed the data analysis plan. The first draft of the manuscript was written by AM and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding

This project is funded by a grant of the challenge 3 I-SITE Clermont Auvergne Project 20-25. The work of AM is supported by an ANRT grant (Cifre PhD Thesis) and by the company Kiplin. The funders had no input in the design of the trial and will have no influence on the collection, interpretation or publication of the study results. Trial sponsor: University Hospital CHU G. Montpied, Clermont-Ferrand.

Competing interests

AC, BP, and MD declare that they have no competing interests. AM's PhD Grant is funded by the French National Association for Research and Technology (ANRT) and Kiplin. MB is employed by Kiplin.

Ethics approval and consent to participate

The research protocol has been approved by the Protection of Persons Ethics Committee Ile de France XI (N° 21004-65219). Written informed consent will be obtained from participants prior their inclusion in the trial.

Provenance and peer review

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

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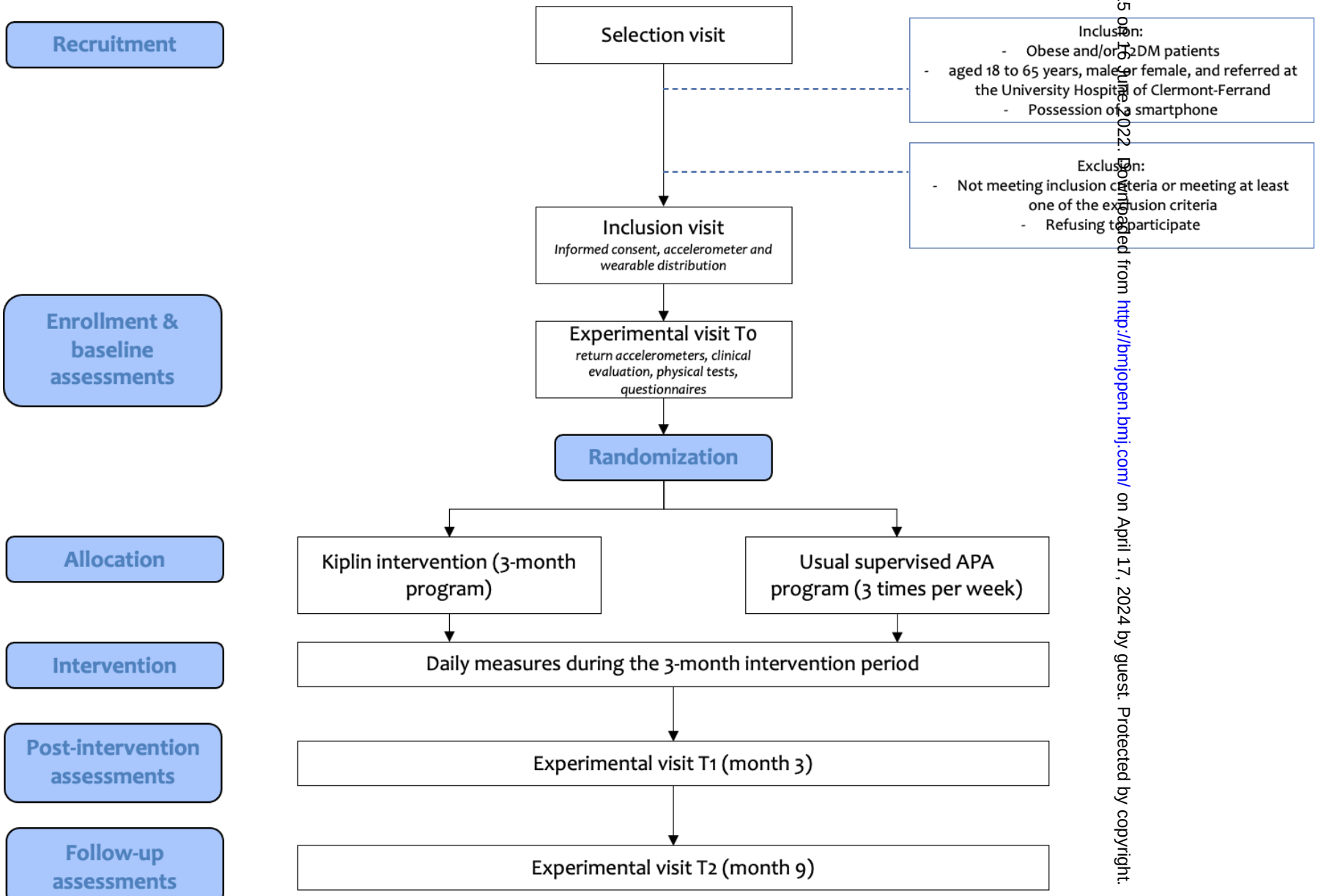
DIPPAO randomized controlled trial: study protocol

Figure 1. Study flowchart

Figure 2. Screenshots of the Kiplin app

Note. A. The telecoaching sessions reservation. B. The adventure. C. The investigation. D. The boardgame. E. The chat. F. The activity monitoring tool.



SUPPLEMENTARY ONLINE MATERIAL 1

Hypotheses on PA adherence

First, we argue that the Kiplin intervention will produce greater PA levels than the usual care (face-to-face supervised APA) during the whole intervention. More particularly, the Kiplin intervention will avoid the compensatory decrease between leisure PA time and supervised PA time frequently observed in traditional programs (King et al., 2007; Westerterp, 1998) by stimulating daily PA. This compensatory decrease is in line with the ActivityStat hypothesis (Gomersall et al., 2013), which suggests that an increase or decrease of PA in one domain will be compensated in another domain, in order to maintain an overall stable level of PA or energy expenditure over time. By stimulating daily PA with gamification features and goal setting, the Kiplin intervention may limit the decrease in total PA that could occur in compensation of an increase in PA in supervised sessions.

We also hypothesize that this improvement in PA will be sustained after the follow-up period.

> *Hypothesis 1a: Patients of the Kiplin group will demonstrate increased total PA over 3 months that will be superior to the total PA of patients in the face-to-face supervised APA condition.*
>
> *Hypothesis 1b: Patients of the Kiplin group will demonstrate improved PA over 9 months that will be superior to the total PA of patients in the face-to-face supervised APA condition.*

In parallel of these improvements, we expect to observe a decrease in the overall sedentary time resulting from a compensatory stimulation of the daily activity, notably led by gamification strategies.

> *Hypothesis 2: The Kiplin intervention will be effective in reducing SB. This effectiveness will be superior to the face-to-face supervised APA condition.*

Hypotheses on the intervention mechanisms

The Kiplin intervention including multiple components to change behavior, this trial will aim to identify the psychological mediators that can explain a potential improvement in PA. We argue that one of the potent ingredients of the Kiplin intervention will be its ability to promote a self-determined motivation toward PA. This motivation should be filled by basic needs' satisfaction and through the enjoyment of the playful activities experienced by the patients.

> *Hypothesis 3a: The Kiplin intervention will improve patients' self-determined motivation toward PA.*

Hypothesis 3b: The satisfaction of the three basic needs (autonomy, competence, and relatedness) and the enjoyment of the program will mediate the relationship between Kiplin intervention and patients self-determined motivation toward PA.

Hypothesis 3c: Kiplin intervention-related changes in motivation will increase PA.

The development of a self-determined motivation toward PA may limit the reduction of the effect of the Kiplin program on PA at the end of the intervention compared to the face-to-face supervised APA condition.

Hypothesis 3d: Kiplin intervention-related changes in motivation will sustain the PA improvement over the follow-up period compared to face-to-face supervised APA condition.

In parallel, we argue that this group-based digital intervention will encourage the emergence of a social identity in the group, being the basis for mutual and social support among the participants. Moreover, engaging in a group-based program in a co-operative setting with people sharing the same stigmatized characteristic (i.e., related to weight, pathology, and symptomatology) should allow individuals to overcome their fear of being discriminated, and more generally remove barriers related to the negative stereotypes that target them (Jetten et al., 2018; Olander et al., 2013). This would ultimately facilitate engagement in the proposed activities and promote behavior change.

Hypothesis 4a: The Kiplin intervention will reduce perceived discrimination, weight stigma concerns, and weight bias internalization compared to the usual care condition.

Hypothesis 4b: Kiplin intervention-related changes in weight stigma processes will increase PA.

Hypotheses on the cost-utility of the intervention

Finally, we hypothesize that the achievement of the aforementioned objectives associated with the advantages of e-health interventions (i.e., a broad accessibility though technology, permitting to address a large population) will allow to reduce the time of face-to-face supervised PA by an APA professional, for an identical number of patients, and to reduce the costs and constraints associated with a classic face-to-face care. In order to measure this potential increase in efficiency, we will integrate a health economic evaluation within this protocol.

Hypothesis 5: By requiring fewer face-to-face APA sessions, the Kiplin intervention may lead to economic benefits and health care saving in patient management compared to face-to-face supervised APA condition.

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SUPPLEMENTARY ONLINE MATERIAL 2

Exclusion criteria

Participants will be excluded if they meet anyone of the following criteria that limit their ability to use the app or perform exercise:

- Medical or surgical history judged by the investigator to be incompatible with the study.
- Subject with an unstable psychiatric condition.
- Pregnant or breastfeeding women.
- Heavy alcohol consumption (> 2 to 3 drinks per day depending on gender) or drug addiction.
- Disability or contraindication to PA.
- Subject with cardiorespiratory and/or osteoarticular disorders that limit their ability to perform physical tests or moderate PA for 30 minutes.
- Subject with progressive cardiovascular or neoplastic disease.
- Subject who has presented a major infection in the 3 months prior to inclusion.
- Subject with a known neuro-muscular pathology (i.e., myopathy, myasthenia, rhabdomyolysis, paraplegia, hemiplegia).
- Subject with chronic or acute inflammatory pathology within 3 months prior to inclusion.
- Subject diagnosed and/or treated for schizophrenia, bipolar disorder, major depression.
- Subject deprived of their liberty by judicial or administrative decision.
- Subject refusing to sign the written consent to participate.
- Subject participating in another study.

SUPPLEMENTARY ONLINE MATERIAL 3

Information letter and consent form in French (Version 3, 03/06/2021).

CLERMONT-FERRAND
CENTRE HOSPITALIER UNIVERSITAIRE

LETTRE D'INFORMATION

Etude DIPPAO : évaluation des effets d'une intervention connectée pour promouvoir l'activité physique et diminuer la sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2

Madame, Monsieur,

Nous vous proposons de participer au protocole de recherche intitulé « DIPPAO ».
Nous vous invitons à lire attentivement cette lettre d'information qui a pour but de répondre aux questions que vous seriez susceptible de vous poser avant de prendre votre décision de participation.

Ce document vous appartient et nous vous invitons à en discuter avec votre médecin et vos proches.

1) Objectif de la recherche

Selon de nombreuses études, le niveau d'activité physique de patients ayant un diabète de type 2 ou une obésité est particulièrement faible. Or la pratique régulière d'une activité physique permet non seulement de prévenir le risque de développer les maladies chroniques mais également de limiter leur progression et de diminuer la mortalité précoce liée à ces maladies. C'est pourquoi nous cherchons à développer à travers cette étude scientifique des interventions permettant d'augmenter l'activité physique de ces patients et que nous sollicitons votre participation.

L'objectif principal de ce projet est d'étudier l'effet d'une intervention digitale (Kiplin, https://www.kiplin.com/) composée de trois « briques » (des séances d'activité physique adaptée (APA) interactives en visio-conférence + animations connectées sous forme de jeux collectifs + suivi de l'activité physique avec un bracelet connecté et une application) sur l'activité physique globale et le temps de sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2 en comparaison avec la prise en charge classique au CHU de Clermont-Ferrand.
Les objectifs secondaires sont d'augmenter l'adhérence au programme et de diminuer le temps d'accompagnement en présentiel.

A travers une augmentation de l'activité physique, l'objectif est d'améliorer votre santé. En effet les études scientifiques et les sociétés savantes sont unanimes sur le fait que l'atteinte des recommandations en activité physique permet de conserver un bon état de santé et d'améliorer sa qualité de vie. Nous pensons que ces nouvelles méthodes pourraient être utiles mais nous aimerions le démontrer car rien n'est actuellement prouvé.

2) Méthodologie

Dans cette étude vous suivrez un programme de 3 mois. Nous testerons différentes variantes de l'intervention (intervention Kiplin ou séances d'activité physique adaptée en présentiel au CHU) afin d'évaluer quel format est le plus efficace pour augmenter et maintenir votre activité physique à la fin de l'intervention (3 mois de prise en charge au CHU) et 6 mois après la fin de l'intervention. Vous serez réparti dans l'un des deux groupes de l'étude aléatoirement selon une procédure de tirage au sort faite par ordinateur. Lors de votre prise en charge par un programme d'activité physique adaptée vous serez donc dans l'un des 2 groupes suivants :

- Groupe Kiplin

Groupe prise en charge traditionnelle

La méthodologie, les tests effectués ou encore la durée de votre participation seront strictement identiques qu'importe le groupe. Ces éléments sont décrits plus précisément ci-dessous. Au total, 48 patients seront inclus dans cette étude (24 par groupe).

3) Description des deux prises en charge

- Groupe Kiplin : 3 séances d'activité physique adaptée par semaine, d'abord en présentiel au CHU puis en visioconférence depuis chez vous via l'application mobile Kiplin. Parallèlement, vous pourrez, via l'application mobile Kiplin : suivre votre activité physique, participer à des animations sous forme de jeux par équipes où votre quantité d'activité physique vous permet de progresser dans le jeu, interagir avec les autres participants du Groupe Kiplin.

- Groupe prise en charge traditionnelle CHU : 3 séances d'activité physique adaptée par semaine en présentiel pendant 3 mois au CHU

4) Déroulement pratique

Si vous acceptez de participer à cette étude, vous serez suivi pendant 9 mois à partir de votre inclusion dans l'étude et vous aurez 5 visites (dont une seule supplémentaire par rapport à votre prise en charge originelle) :

- Visite de sélection : 1 mois avant le début de l'intervention *(environ 30 minutes)* : au cours de cette visite, le médecin investigateur vérifiera que vous pouvez participer au protocole et si tel est le cas vous proposera de participer à l'étude et vous remettra la lettre d'information. Suite à cette lecture, si vous souhaitez

participer à l'étude un formulaire de consentement vous sera transmis pour signature.

- Visite d'inclusion : 8 jours avant le début de votre programme (moins de 10 minutes) : Cette courte visite sera l'occasion pour vous de signer le formulaire de consentement avec le médecin investigateur. Vous repartirez avec un bracelet connecté Garmin ainsi que l'accéléromètre. Pendant cette semaine d'évaluation vous n'aurez pas accès aux données d'activité de la montre.

- Visite d'évaluation au début de l'intervention (M0) *(environ 45 minutes)* : Cette visite sera effectuée en amont de votre première séance d'APA afin de faciliter votre prise en charge. Vous ramènerez l'accéléromètre à cette occasion. Au cours de cette visite vous effectuerez les tests (détaillés ci-après) permettant l'évaluation de vos capacités physiques. Ces tests font partie de la prise en charge habituelle et ne vous demanderont pas plus de temps. Vous devrez également remplir plusieurs questionnaires évaluant notamment votre niveau d'activité physique, votre bien-être physique et émotionnel, votre motivation à la pratique d'activité physique.
  Vous serez informé à ce stade de votre groupe de prise en charge (Kiplin ou prise en charge traditionnelle) et pourrez dès lors planifier vos séances d'activité physique adaptée selon votre groupe.

- Visite d'évaluation à la fin de l'intervention (M3) (*environ 45min*) : Tests et questionnaires identiques aux précédentes visites.

- Visite M9 (6 mois après la fin de l'intervention) + évaluations (*environ 45min*) : Tests et questionnaires identiques aux précédentes visites.

5) Calendrier de suivi pour cette étude

Si vous acceptez de participer à cette étude et si vous remplissez toutes les conditions requises, vous serez suivi(e) dans le cadre du protocole du service de Médecine du sport du CHU de Clermont-Ferrand.

Le calendrier de votre suivi sera le suivant :

	Visite 1 Sélection	Visite 2 Inclusion	Visite 3 M0	Visite 4 M3	Visite 5 M9
	(30 min)	(10 min)	(45 min)	(45 min)	(45 min)
Consentement éclairé	X				

Critères d'inclusion et de non-inclusion	X		X		
Données sociodémographiques, poids, taille, tour de taille, pression artérielle, médicaments	X			X	X
Questionnaire activité physique			X	X	X
Échelle de douleur			X	X	X
Questionnaires bien-être psychologique et motivation à l'activité physique			X	X	X
Accéléromètre et bracelet Garmin		X		X	X
Composition corporelle			X	X	X
Endurance			X	X	X
Force musculaire			X	X	X
Pression artérielle			X	X	X

6) Description des tests réalisés

Les évaluations réalisées pour chacune des 3 visites (au début, à la fin des 3 mois et à la fin des 9 mois) sont les suivantes :

- Un bilan de vos capacités physiques sera effectué. Vous aurez pour cela 3 tests à réaliser :
  - Un test de force des membres supérieurs appelé « handgrip » durant lequel nous vous demanderons de serrer fort sur une poignée pendant 15 secondes. Deux essais seront enregistrés.
  - Un test de force des membres inférieurs sera réalisé grâce à un dynamomètre permettant de mesurer la force maximale d'extension du genou. Les mesures seront effectuées à trois vitesses différentes. Pour chaque vitesse, deux essais de 3 répétitions successives seront réalisés et la meilleure performance sera conservée. Vous disposerez de 2 minutes de repos entre chaque essai.
  - Un test d'endurance cardio respiratoire sera réalisé par l'intermédiaire du test de marche de six minutes ; l'objectif de ce test est de marcher aussi vite que vous pouvez pendant six minutes. La distance parcourue pendant les six minutes sera mesurée.

L'évaluation de la condition physique sera réalisée par la même personne, dans la même journée et toujours dans le même ordre.

- Suite aux tests de condition physique, vous devrez remplir plusieurs questionnaires
  - Le questionnaire RPAQ qui vous permet de préciser votre niveau d'activité physique.
  - Vous remplirez un deuxième questionnaire évaluant votre qualité de vie.
  - Le troisième questionnaire évaluera vos relations avec les autres patients durant l'intervention.
  - Plusieurs questionnaires permettront de mesurer votre motivation pour l'activité physique et vos sentiments envers cette activité.
    Un autre questionnaire vous demandera de décrire la discrimination que vous pouvez percevoir venant des autres personnes dans votre vie de tous les jours.
    Enfin un dernier questionnaire visera à évaluer l'impact émotionnel de la COVID-19.

- Un accéléromètre vous sera également remis. Il s'agit d'un petit boîtier (3 cm x 3 cm) que l'on fixe autour de la taille à l'aide d'une sangle élastique et qui permet d'enregistrer les mouvements. Sa petite taille et le fait que l'on peut porter le capteur sur ou ses vêtements rend l'appareil facile à porter et il s'oublie très vite. Ce capteur devra être porté pendant 7 jours du lever au coucher, sauf pendant les activités aquatiques (douche, bain, natation, etc.). Il va enregistrer sur 7 jours (enregistrement la journée) l'ensemble des mouvements que vous faites pour que nous puissions évaluer votre temps d'activité physique de faible, moyenne ou haute intensité

- Un bracelet connecté de la marque Garmin vous sera également remis. Il s'agit d'un appareil que vous porterez au poignet quotidiennement pendant la durée de l'étude, qui reconnaît et enregistre automatiquement vos différentes activités physiques. Si vous êtes dans le Groupe « prise en charge traditionnelle », l'affichage sera paramétré pour n'afficher que la date et l'heure pendant la durée de 'intervention (soit pendant 3 mois), et l'ensemble des fonctionnalités seront ensuite activées pour que vous puissiez continuer à utiliser l'objet.

- Bio-impédancemètre : vous monterez sur une balance qui permet de mesurer - en plus de votre poids - votre composition corporelle, c'est-à-dire la quantité de graisse (ou masse grasse), la quantité de muscles (ou masse musculaire) et la quantité d'eau de votre corps. Cela vous permet de mieux comprendre de quoi est fait votre poids quand vous vous pesez.

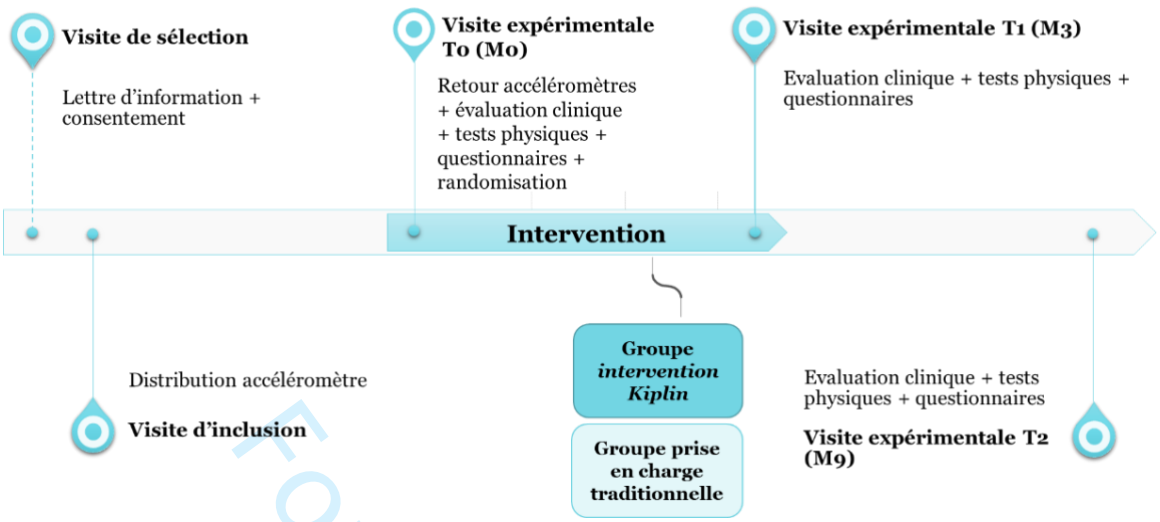

Schéma récapitulatif du protocole expérimental

Toutes les visites auront lieu au CHU.

7) Vos bénéfices à participer à cette étude

Vous aurez l'opportunité de tester de nouvelles méthodes originales de changement de comportement de manière gratuite.

⇨ L'avantage que vous pouvez attendre en participant à cette étude est une augmentation de votre activité physique, une meilleure gestion du stress, de la fatigue, du sommeil, une amélioration de votre condition physique et donc un bien-être physique et émotionnel. Ces résultats sont ceux attendus mais ne sont pas pour autant garantis.

8) Rémunération

⇨ Au début de l'étude vous sera distribué un objet connecté Garmin. Ce bracelet vous sera offert à la fin de l'étude. Toutes les fonctionnalités de l'objet ne seront pas accessibles par tous lors de l'étude mais seront bien évidemment débloquées et disponibles à l'issue de l'étude quand l'objet vous sera offert.

9) Risques et contraintes prévisibles

Risques liés à la pratique :

Les risques encourus lors des sessions d'activité du programme sont minimes compte tenu :

1) des faibles risques de traumatismes musculaires ou ostéo-articulaires induits par la nature des activités qui seront proposées et,

2) de l'intensité de l'exercice qui sera légère (pas de risque cardio-vasculaire).

Vous n'aurez pas plus de contraintes que d'habitude puisque les visites s'effectuent au CHU dans la continuité de votre prise en charge et que l'intervention vous est proposée gratuitement de manière intégrale. De potentielles contraintes peuvent survenir avec le port des matériels d'évaluation mais de nombreux conseils vous seront prodigués afin que vous ne ressentiez aucune gêne.

10) Informations utiles :

Votre participation à cette recherche n'engendrera aucun frais pour vous.

Toutefois, pour pouvoir participer à cette recherche vous devez être affilié(e) ou bénéficier d'un régime de sécurité sociale, et ne pas être placé(e) sous sauvegarde de justice.

Le CHU de Clermont-Ferrand, qui organise cette recherche en qualité de promoteur, a contracté une assurance conformément aux dispositions législatives, garantissant sa responsabilité civile et celle de tout intervenant auprès de la société d'assurances Biomedicinsure. Le numéro de contrat est 0840718730010. Dans le cas où votre état de santé serait altéré du fait de votre participation à l'étude, conformément à la loi n°2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine, vous seriez en droit de recevoir des dédommagements dans le cadre de ce contrat d'assurance spécifique.

Vous ne pourrez participer à aucune étude pendant toute la durée de la recherche et les 6 mois suivant la fin de la recherche. Vous ne devez pas non plus avoir participé à une recherche dans les 6 mois précédant votre participation à cette étude.

Cette recherche impliquant la personne humaine a reçu l'avis favorable du Comité de Protection des Personnes Ile de France XI en date du 27/01/2021.

Il est possible que cette recherche soit interrompue, si les circonstances le nécessitent, par le promoteur ou à la demande de l'autorité de santé.

Si vous considérez que vous avez subi un préjudice lors de votre participation à l'étude, vous devez immédiatement contacter l'investigateur coordonnateur :

Pr Martine Duclos

Chef de Service de Médecine du Sport et des Explorations Fonctionnelles et Respiratoires

CHU Gabriel Montpied - Clermont-Ferrand

mduclos@chu-clermontferrand.fr

11) Données personnelles recueillies :

Votre participation à cette étude implique la collecte et le traitement des données personnelles suivantes :

- État civil et coordonnées (nom, prénom, année de naissance, sexe, email)
- Composition corporelle et données anthropométriques (taille, poids, tour de taille)
- Pression artérielle systolique et diastolique
- Données de condition physique (résultats des tests physiques)
- Données d'activité physique et de sédentarité (questionnaire + niveau d'activité physique mesuré par l'objet connecté et par accéléromètre)
- Données de qualité de vie (questionnaire)
- Données relatives au soutien social perçu et aux relations partagées avec les autres patients (questionnaire)
- Données visant à évaluer votre motivation pour l'activité physique et vos sentiments envers cette activité (questionnaire)
- Données portant sur la discrimination que vous pouvez percevoir venant des autres personnes dans votre vie de tous les jours (questionnaire)
- Données de participation aux séances d'activité physique adaptée et aux animations connectées (si vous êtes dans le Groupe Kiplin)
- Contributions éventuelles sur les espaces de messagerie au sein de l'application mobile Kiplin (si vous êtes dans le Groupe Kiplin)

12) Protection de vos données personnelles :

Dans le cadre de cette recherche, le CHU de Clermont-Ferrand est responsable de la mise en œuvre du traitement de données à caractère personnel. Ce traitement informatique a pour but d'analyser les résultats de la recherche au regard de l'objectif de cette dernière qui vous a été présenté.

Le fondement juridique, au regard de l'article 6 du RGPD (Règlement Général sur la Protection des Données) est l'intérêt légitime du promoteur à mettre en œuvre le traitement de données médicales à des fins de recherche scientifique (article 9.2 du RGPD).

A cette fin, toutes les données médicales vous concernant et les données relatives à vos habitudes de vie nécessaires pour la recherche seront transmises au Promoteur, ou aux personnes ou sociétés agissant pour son compte, en France.

Ces données seront identifiées par un numéro de code et vos initiales. Ces données pourront également, dans des conditions assurant leur confidentialité, être transmises aux autorités de santé françaises, à d'autres entités du CHU de Clermont Ferrand.

Les données seront conservées au minimum 15 ans après la fin de la recherche, selon les dispositions légales en vigueur.

Le représentant du promoteur ou celui des Autorités de Santé, tenu au secret professionnel, peut avoir accès à votre dossier médical pour contrôle de conformité. En effet seules les données du dossier médical sont directement identifiantes. Leur consultation (par représentants autorisés) obéit à des règles strictes. Toutes les autres données "données de l'étude" sont des données codées transmises au promoteur qui les possède et peut les transmettre selon certaines règles. Les résultats de l'étude n'utilisent que ces données codées et leur publication respecte de ce fait l'anonymat.

Dans le cadre de cette recherche, la société Kiplin, éditrice de la solution connectée utilisée dans l'intervention, sera amenée à traiter certaines de vos données personnelles (coordonnées, sexe et année de naissance, données d'activité physique collectées par l'objet Garmin, contributions sur les espaces de messageries au sein de l'application, participation aux séances d'activité physique adaptée en visioconférence). Kiplin s'engage à mettre en œuvre toutes les mesures techniques et organisationnelles nécessaires pour assurer la sécurité et la confidentialité de vos données. En particulier, l'ensemble des données collectées via la solution Kiplin seront hébergées dans un environnement certifié pour l'hébergement de données de santé (hébergeur : Proginov – 44118 La Chevrolière).

Conformément aux dispositions du RGPD et de la loi informatique et libertés du 6 janvier 1978 modifiée, vous disposez d'un droit d'accès, de rectification et de limitation du traitement de vos données.

Conformément aux dispositions du RGPD, vous disposez également d'un droit d'opposition à la transmission des données couvertes par le secret professionnel susceptibles d'être utilisées dans le cadre de cette recherche et d'être traitées. Dans ce cas, l'exercice de ce droit vous empêchera de participer à la recherche.

Conformément à l'article 17.3 du RGPD, les données recueillies préalablement au retrait du consentement, le cas échéant, ne seront pas effacées et continueront à être traitées dans les conditions prévues par la recherche.

Pour exercer ces droits ou pour toute question sur le traitement de vos données, vous pouvez contacter notre délégué à la protection des données : CHU de Clermont-Ferrand – Direction de la Qualité – Gestion des Risques et Droits des Usagers – 58 rue Montalembert – 63003 Clermont-Ferrand cedex 1 (ou dpd@chu-clermontferrand.fr)

Vous pouvez également accéder directement ou par l'intermédiaire d'un médecin de votre choix à l'ensemble de vos données médicales en application des dispositions de l'article L. 1111-7 du code de la santé publique. Ces droits s'exercent auprès du médecin qui vous suit dans le cadre de la recherche et qui connaît votre identité.

Si vous estimez, après nous avoir contactés, que vos droits Informatique et Libertés ne sont pas respectés ou que le dispositif de contrôle d'accès n'est pas conforme aux règles de protection des données, vous pouvez adresser une réclamation auprès de la CNIL (https://www.cnil.fr/) par courrier.

13) Aspects légaux

Vous avez le droit de refuser de participer à cette recherche sans avoir à vous justifier. Votre choix n'influencera en rien le rapport que vous avez avec votre équipe soignante. Si vous acceptez de participer, vous avez le droit de retirer votre consentement à tout moment sans avoir à vous justifier.

Vous pourrez à tout moment durant l'essai vous adresser au Pr Martine Duclos et à son équipe pour leur poser toutes questions complémentaires.

Toute information nouvelle survenant pendant la participation et pouvant éventuellement modifier votre décision de participation, vous sera donnée.

Par ailleurs, vous pourrez être tenu(e) informé(e) des résultats globaux de cette recherche à la fin de l'étude.

Lorsque vous aurez lu cette lettre d'information et obtenu les réponses aux questions que vous vous posez en interrogeant le médecin investigateur, il vous sera proposé, si vous en êtes d'accord, de donner votre consentement écrit en signant le document préparé à cet effet. Vous disposez d'un délai de réflexion pour remettre ce document signé.

FORMULAIRE DE CONSENTEMENT DE PARTICIPATION A UNE RECHERCHE IMPLIQUANT LA PERSONNE HUMAINE

Etude DIPPAO : évaluation des effets d'une intervention digitale pour promouvoir l'activité physique et diminuer la sédentarité chez des patients atteints d'obésité et/ou de diabète de type 2

Investigateur principal :

Pr Martine Duclos

Chef de Service de Médecine du Sport et des Explorations Fonctionnelles et Respiratoires

CHU Gabriel Montpied

Clermont-Ferrand

mduclos@chu-clermontferrand.fr

Je déclare :

- que le Docteur (*nom, prénom, téléphone*) …….. m'a proposé de participer à l'étude sus nommée,
- qu'il m'a expliqué en détail le protocole,
- qu'il m'a notamment fait connaître :
  - l'objectif, la méthode et la durée de l'étude
  - les contraintes et les risques potentiels encourus
  - mon droit de refuser de participer et en cas de désaccord de retirer mon consentement à tout moment
  - mon obligation d'inscription à un régime de sécurité sociale
  - que, si je le souhaite, à son terme, je serais informé(e) par le médecin investigateur de ses résultats globaux
  - que je ne serai pas autorisé(e) à participer à d'autres études cliniques pendant toute la durée du protocole, ni durant les 6 mois suivant la fin de ma participation,
  - que le Comité de Protection des Personnes Ile de France XI a émis un avis favorable en date du 27/01/2021,
  - que dans le cadre de cette étude le promoteur, le CHU de Clermont-Ferrand, a souscrit à une assurance couvrant cette recherche
  - que j'ai répondu en toute bonne foi aux questions concernant mon état de santé et ma participation à d'autres études
  - que je ne suis pas placé sous sauvegarde de justice,
- que je dois disposer d'un délai suffisant avant de signer ce consentement

Les informations relatives à l'étude recueillies par l'investigateur sont traitées confidentiellement. J'accepte que les données enregistrées à l'occasion de cette recherche puissent faire l'objet d'un traitement informatisé. J'ai bien noté que les droits d'accès, de rectification du traitement des données prévus par la loi informatique et libertés du 6 janvier 1978 modifiée s'exercent à tout moment auprès du médecin qui me suit dans le cadre de la recherche et qui connaît mon identité ou du délégué de protection des données du promoteur dont les coordonnées sont mentionnées dans la lettre d'information qui m'a été remise.
Après avoir discuté librement et obtenu réponse à toutes mes questions, j'accepte librement de participer à cette recherche impliquant la personne humaine dans les conditions précisées dans la lettre d'information et le formulaire de consentement.

Nom et prénom du patient : …… Date :……./……./……. Signature	Nom de l'investigateur : …… Date :……./……./……. Signature :

Ce document est à réaliser en 2 exemplaires originaux, dont le premier doit être gardé 15 ans par l'investigateur, un autre remis à la personne donnant son consentement.

SUPPLEMENTARY ONLINE MATERIAL 4

Kiplin Games

The Kiplin app collects the daily step count of participants by joining the API (Application Programming Interface) of the application used by the participants to track their activity (in the case of our study, the Kiplin app will use the Garmin Health API to collect the data measured via the Garmin Vivofit 3).

The adventure

Through their journey, participants will be invited to be part of "the adventure", where the objective is to reach steps goals in order to collectively get to the final destination (players can visualize their progression on a map with checkpoints schematizing the remaining distances between different cities of a digital world tour; Figure 2B).

The investigation

The second game will be "the investigation", where participants will have to be physically active and succeed in collective challenges to unlock cues and try to solve the mission (Figure 2C).

The board game

Finally, "the board game" will put participants in the shoes of forest rangers having to put out a fire. Once again, the achievement of step goals will allow participants to progress by team on the board squares and to reach the next levels of the game to put out all the fires and save the forest residents (Figure 2D). The aim will be to put out as many fires as possible and save as many forest residents as possible by the end of the time limit.

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

Section/item	ItemNo	Description	Reported on page # (section)
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 *(Trial registration)*
	2b	All items from the World Health Organization Trial Registration Data Set	3 *(Trial registration)*
Protocol version	3	Date and version identifier	3 *(Trial registration)*
Funding	4	Sources and types of financial, material, and other support	24 *(Funding)*
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 23 *(Contributors)*
	5b	Name and contact information for the trial sponsor	24 *(Funding)*
	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	24 *(Funding)*
	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)	N/A

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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 *(Introduction)*
	6b	Explanation for choice of comparators	4 *(Introduction)*
Objectives	7	Specific objectives or hypotheses	8-9 *(The study aims)*
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)	9-10 *(Study design, Randomization, allocation, and blinding)*
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	9 *(Study design)*
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)	9 *(Eligibility criteria)*
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-14 *(Intervention overview, control group)*
	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)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Table 3 *(Program adherence)*

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12 *(Eligibility criteria), supp. material 2*
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	16 *(Outcome measures), Table 3*
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)	10 *(Procedure)*, Figure 2
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	20 *(Sample size and power analysis)*
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9 *(Recruitment)*
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	10 *(Randomization, allocation, and blinding)*
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	10 *(Randomization, allocation, and blinding)*
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10 *(Randomization, allocation, and blinding)*

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10 *(Randomization, allocation, and blinding)*
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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	10 *(Procedure),* 21-25 *(Outcome measures),* *Table 2*
	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 *(Recruitment),* 21 *(Analyses of secondary outcomes)*
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	11 *(Data management)*
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	20-22 *(Statistical analyses)*
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21 *(Analyses of secondary outcomes)*
	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)	20-22 *(Statistical analyses)*
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	N/A
	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
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	Table 4
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	22 *(Ethics and dissemination)*
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)	22 *(Ethics and dissemination)*
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9 *(Recruitment)*
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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	11 *(Data management)*

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	24 *(Competing interests)*
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	11 *(Data management)*
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
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	22 *(Ethics and dissemination)*
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22 *(Ethics and dissemination)*
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplemental material 3
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

*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.