



Development and evaluation of a digital intervention based on gamification to promote physical activity of patients with chronic diseases

Alexandre Mazeas

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Alexandre Mazeas. Development and evaluation of a digital intervention based on gamification to promote physical activity of patients with chronic diseases. Education. Université Grenoble Alpes [2020-..], 2023. English. NNT: 2023GRALS005 . tel-04146764

HAL Id: tel-04146764

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THÈSE

Pour obtenir le grade de

DOCTEUR DE L'UNIVERSITÉ GRENOBLE ALPES

École doctorale : ISCE - Ingénierie pour la Santé la Cognition et l'Environnement
Spécialité : MCA - Mouvement et Comportement pour la santé et l'Autonomie
Unité de recherche : Sport et Environnement Social

**Development and evaluation of a digital intervention
based on gamification to promote the physical activity of
patients with chronic diseases**

**Développement et évaluation d'une intervention digitale
fondée sur la gamification pour promouvoir l'activité
physique de personnes atteintes de maladie chronique**

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Développement et évaluation d'une intervention digitale fondée sur la gamification pour promouvoir l'activité physique de personnes atteintes de maladie chronique

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Thesis submitted for the Degree of Doctor of Philosophy

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Acknowledgements

“Il n’y a pas de hasard,
Il n’y a que des rendez-vous”

Paul Eluard

Avant toute chose je voudrais remercier chaleureusement mes deux directrices pour tout ce qu’elles ont pu m’apporter durant cette thèse. Cette collaboration qui est venue d’une hasardeuse discussion lors d’un jury de thèse quand on y pense. Hasardeuse ? Non, un rendez-vous j’en suis sûr. Car je ne pouvais rêver d’un meilleur encadrement avec une doublette parfaitement raccord et complémentaire. Durant ces trois années, j’ai énormément appris à vos côtés et je suis très fier de vous avoir eu comme mentors. Aïna, merci de m’avoir pris sous ton aile il y a 5 ans déjà et de m’avoir accompagné jusqu’ici. Merci de ta confiance, de ta disponibilité et de ton écoute. Martine, merci pour ta disponibilité sans faille, ta confiance et merci surtout d’avoir partagé tes valeurs professionnelles et humaines avec moi.

I am very grateful to Dr Ann DeSmet, and Pr Nikos Ntoumanis for having agreed to be the rapporteurs of this doctoral work. I would also like to thank very much Pr Agnès Helme-Guizon, Pr Falko Sniehotta, and Pr Martin Hagger for accepting to expertise this work. It is a huge honor and privilege to have the opportunity to discuss with all of you the fruit of 3 years of research work.

Cette thèse n’aurait jamais eu le même intérêt et la même saveur pour moi sans cette collaboration avec l’entreprise Kiplin. Un grand merci à Vincent et Marine pour leur confiance et l’accueil qu’ils m’ont réservé dans l’entreprise. Merci à toute les équipes de Kiplin et plus particulièrement à tous ceux qui ont participé à faire de ces déplacements Nantais de réels moments de plaisir. Merci à tous pour votre accueil et votre engouement « *pour la science* ».

Merci aux Pr Marie Préau et Pr Julien Bois d’avoir accepté de faire partie de mon comité de suivi de thèse. Merci pour vos précieux conseils et votre écoute.

Merci à Bruno pour tes conseils statistiques.

Merci à Stéphane et Aliette pour votre précieuse aide dans le cadre de l'essai DIPPAO.
Merci également à mes jeunes stagiaires Félix, Lisa et Charlotte pour votre aide.

Merci au laboratoire SENS et tous ses membres pour tous les moments professionnels et extra-professionnels partagés ces dernières années. Une pensée toute particulière pour Valentin mon fidèle compagnon de thèse ainsi que Cyril et Margaux pour les nombreux week-end incroyables passés en terres mancelles pendant ces trois ans. Merci tout particulier à Silvio, David, Boris, Clément, Sandrine, Damien, Phillipe et les doctorants du labo.

Merci à mes amis Grenoblois, Carhaisiens, Badenois, Brestois.

Merci à la belle famille pour les moments de récupération pendant ces trois années de thèse dans des endroits aussi exotiques que la Corse, Le Pays Basque, La Palice ou l'impasse de la Roseaie.

Merci à ma famille et plus particulièrement à mes parents pour avoir cru en moi depuis le début et m'avoir permis d'en être la aujourd'hui.

Enfin merci à Lara de m'avoir supporté et fait rêver ces trois dernières années.

Résumé

Face à la prévalence grandissante de l'inactivité physique et des comportements sédentaires, il n'a jamais été aussi important de développer des interventions permettant de promouvoir efficacement et durablement un style de vie actif chez les patients atteints de maladies chroniques. Si un certain nombre d'initiatives existent dans ce sens, les programmes actuels se heurtent généralement à la difficulté d'engager les patients et de changer le comportement sur le long terme. De plus, ces programmes dispensés en présentiel sont associés à une série d'enjeux logistiques et économiques qui limitent leur impact et dissémination à grande échelle. Dans cette optique, la gamification et les nouvelles technologies apparaissent comme des outils prometteurs pour favoriser le changement de comportement en contexte écologique et proposer des interventions efficaces et fiables à distance. Néanmoins, à ce jour la littérature scientifique n'avait pas démontré l'efficacité de tels outils pour la prise en charge de l'activité physique. Ainsi, la question centrale de ce travail doctoral était de savoir si et dans quelles conditions l'utilisation d'intervention digitales et de la gamification pouvait être pertinente pour promouvoir l'activité physique de patients atteints de maladies chroniques. Au travers de 6 études, les résultats de ce travail doctoral soulignent les perspectives prometteuses de la gamification pour promouvoir l'activité physique de différentes populations, quel que soit leur âge ou état de santé, à la fois sur le court et le moyen terme. Les résultats de cette thèse suggèrent également qu'un programme digital intégrant de la gamification et du telecoaching pourrait être une plus-value intéressante dans la prise en charge de l'obésité et du diabète de type 2. Ces conclusions viennent enrichir la littérature dans le domaine et mettent en évidence un certain nombre d'implications cliniques, d'enjeux de développement et de perspectives de recherche afin de comprendre plus finement ces interventions et d'en optimiser leur efficacité.

Mots-clés : activité physique, changement de comportement, e-santé, gamification, intervention, m-santé

Abstract

Considering the growing prevalence of physical inactivity and sedentary behavior, it is of paramount importance to develop interventions that effectively and durably promote active lifestyles in patients with chronic diseases. While a number of initiatives already exist, current physical activity programs struggle to engage participants and change behavior over the long haul. In addition, these face-to-face programs are associated with a series of logistical and economic issues that limit their impact and widespread dissemination. In this context, the use of gamification and digital technologies appear to be promising tools for promoting behavior change in an ecological context and for providing effective and reliable interventions at a distance. Nevertheless, to date, the scientific literature has not demonstrated the effectiveness of such interventions. Therefore, the main objective of this doctoral work was to know if and under which conditions the use of digital interventions and gamification could be relevant to promote physical activity in patients with chronic diseases. Through 6 studies, the results of this doctoral work highlight the promising perspectives of gamification to improve both short and mid-term daily physical activity levels of various populations, regardless of their age or health status. The findings of this thesis also indicate that physical activity digital programs integrating gamification and telecoaching could be an interesting added value for the treatment of obesity and type 2 diabetes. This doctoral work presents new knowledge about the effectiveness of digital interventions and discusses the resulting clinical implications, design insights, and research perspectives to better understand these interventions and optimize their effectiveness.

Keywords: behavior change, eHealth, gamification, intervention, mHealth, physical activity

Introduction

Chronic diseases, also known as noncommunicable diseases (NCDs), constitute the leading cause of mortality in the world – killing 41 million people annually (Forouzanfar et al., 2016). More specifically, 17 million people die from a NCD before age 70 every year, and this trend is constantly increasing with the growth and aging of the population. In France, 87% of all deaths are due to noncommunicable diseases (World Health Organization, 2020). NCDs are characterized by the presence of a physical, psychological, or cognitive pathological state, which is expected to last and to have repercussions on the daily life of the patient (i.e., functional limitation, dependence on medication, diet, medical technology, or personal assistance, and the need for medical or paramedical care, psychological assistance, adaptation, monitoring). Cardiovascular diseases account for most NCD deaths (17.9 million annually), followed by cancers (9.3 million), chronic respiratory diseases (4.1 million), and diabetes (2.0 million).

There is now ample scientific evidence that NCDs are closely linked to the health behaviors of individuals. Especially, engaging in a suite of four healthy behaviors – not smoking, adopting a healthy diet, consuming alcohol moderately, and engaging in adequate physical activity – is associated with an estimated 11 to 14-year delay in all-cause mortality in healthy subjects (Ford et al., 2011) by preventing the emergence of chronic diseases. Recently Nyberg et al. reported that adopting these four healthy behaviors increased life expectancy without major chronic diseases (i.e., type 2 diabetes, coronary heart disease, stroke, cancer, asthma, and chronic respiratory diseases) by about nine years (Nyberg et al., 2020).

“If there is any deficiency in food or exercise, the body will fall sick”

Hippocrates, 460 - 370 BC

More particularly, the last report of the World Health Organization (WHO, 2022) concluded that almost 500 million people will develop heart disease, obesity, diabetes, or other NCDs attributable to physical inactivity between 2020 and 2030,

costing US\$ 27 billion annually. In France, the social cost of physical inactivity can be estimated at €140 billion per year, whereas prolonged daily sedentary behavior time costs €494 million to health insurance, and leads to 51,193 premature deaths per year (Commission Evaluation Economique et Santé Publique, 2022; Noël Racine et al., 2022). The aforementioned report also projected that the health savings for each individual who becomes sustainably active would be €840 for individuals aged 20 to 39 and €23,275 € for individuals aged 40 to 74 (Commission Evaluation Economique et Santé Publique, 2022).

In this sense, the promotion of physical activity and reduction of sedentary behavior are major concerns, as they are common factors in the development of all chronic diseases. On the one hand, physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure. It is an umbrella term that includes all types of movements such as active travel (i.e., walking, biking), occupational, sports, conditioning, or household (Biddle et al., 2015; Caspersen et al., 1985). In contrast, physical inactivity has been defined as “an insufficient physical activity level to meet present physical activity recommendations” (Bull et al., 2020). On the other hand, sedentary behavior refers to “any waking behavior characterized by an energy expenditure ≤ 1.5 metabolic equivalents (METs) while in a sitting or reclining posture” (Tremblay et al., 2017).

In recent years, scientific evidence has accumulated to support the health benefits of physical activity and the deleterious effects of prolonged sedentary behavior. Regular physical activity not only prevents the risk of developing chronic diseases (e.g., Manson et al., 2002; Wolin et al., 2009), but also limits their progression (e.g., Duclos et al., 2013; Pedersen & Saltin, 2015) and reduces early mortality (e.g., Ekelund et al., 2019). There is also scientific evidence of a dose-response relationship between mortality and the total time spent in sedentary behavior (Ekelund et al., 2019, 2020; Li et al., 2022). Recent epidemiological data suggest that high volumes of sedentary behavior are detrimental for cardio-metabolic health, even when combined with regular exercise (Le Roux et al., 2022), suggesting that the health effects of sedentary time are independent from those of physical activity.

For the greater part of human existence, physical activity was necessary for survival and individuals were naturally active. However, since the automation of industry and the tertiarization of the professional environment (at the end of the 19th century and mid-20th century, respectively), daily physical activity levels of the general

population have decreased while the time spent in sedentary behavior has skyrocketed – leading some authors to consider that “sitting is the new smoking”. As a consequence, nowadays most people need to consciously incorporate physical activity into their daily lives.

This lifestyle shift is reflected in the levels of physical activity of the general population, which are low to the point that researchers refer to a *physical inactivity pandemic*. It is estimated that one-third of the world’s population is insufficiently active (Guthold et al., 2018; Hallal et al., 2012), and the trend is downward, with adults performing on average 1000 fewer daily steps than two decades ago (Conger et al., 2022). In the *Nutrinet* study (i.e., a French web-based cohort on more than 35,000 adults), the authors estimated that the average time spent sitting during a workday was almost 12 hours and 9 hours during a day off (Saidj et al., 2015). These results are consistent with data reported in other European countries. Furthermore, while the global population is insufficiently active, the situation is even more alarming for some public. Indeed, patients with chronic diseases, women, and obese people have lower physical activity levels than the general population (e.g., Barker et al., 2019; Hallal et al., 2012).

In consequence, the scientific literature, as well as national and international reports, clearly highlight the need for efficient public health strategies to counteract both the constant decline in the level of physical activity at all ages and the alarming increase in time spent in sedentary behavior. In this vein, researchers have increasingly focused on promoting active living (Blair et al., 2010) – encouraging people to incorporate even small amounts of light activity (i.e., < 3 METs) into their daily routines (Jakicic et al., 2019). Indeed, a consistent number of scientific work suggested that the most important is global physical activity, regardless of the intensity (Ekelund et al., 2019; Piercy et al., 2018), even when this activity only includes walking (Lee et al., 2019). This idea is reflected in the slogan chosen by the WHO in 2020: “Every move count towards better health”. In addition, Le Roux et al. (2022) stated that “given the large amount of sedentary behavior in modern societies, the sole promotion of Moderate to Vigorous Physical Activity (i.e., MVPA) may be insufficient, and the promotion of daily living light-intensity activities may be a complementary approach to improve health”.

For these reasons, helping inactive and sedentary individuals adopt new habits appears to be an imperative challenge. But how can we intervene on the daily physical

activity of individuals in their natural context? How can we encourage individuals to walk to the grocery rather than take the car, or to take stairs instead of elevators? And how can we sustainably change these behaviors over time? These fundamental questions adorn the everyday work of behavioral scientists. At present, it appears critical to answer these questions in order to develop effective behavior change interventions that promote the initiation, engagement, and maintenance of regular daily living physical activity – especially among the most inactive populations, such as patients with chronic diseases.

In France, a series of actions have been initiated to promote the physical activity of patients with chronic diseases. They can benefit from supervised physical activity sessions (i.e., adapted physical activity), which include physical and sports activities, adapted to the person's abilities and illness. Adapted physical activity programs can be provided for prevention, rehabilitation, reinsertion, health education, or social inclusion purposes. Recently, the reach and potential impact of these programs have been strengthened thanks to the *modernization of the French health system* act of January 26, 2016, which allows physicians to prescribe adapted physical activity to patients with NCDs. This is a major advance, unique in the world, but insufficient to completely overcome the multiple limitations of these programs.

First, the adherence and observance rates of adapted physical activity programs are limited. Indeed, a significant number of patients do not participate in the programs offered as part of their care, and high drop-out rates are often reported during these programs (Boiché et al., 2020; Bonsaksen, 2013; King et al., 2006; Sharp & Freeman, 2009; Woodard & Berry, 2001). Second, several studies have reported that only a low percentage of patients maintain their physical activity at the end of these programs (Boiché et al., 2020; Campbell et al., 2001; Clark et al., 2011; Ries et al., 2003). Indeed, patients often fail to maintain regular physical activity at long term, and typically regress back to initial levels. More particularly, lapses and relapses are frequently observed among individuals attempting to maintain physical activity (Conroy et al., 2007; Dunton et al., 2021). Third, it is also important to note that the format of the sessions themselves is generally more focused on MVPA and has a limited impact on the overall daily physical activity of individuals.

More generally, supervised programs involve limitations for both patients and the healthcare system. For the patients, these programs are associated with logistical challenges such as scheduling, travel, childcare, and cost (e.g., “physical activity on

prescription” is not reimbursed by the National Social Security system) that limit their feasibility and impact (Jerant et al., 2005; Keefe et al., 2002; Tate & Zabinski, 2004). These limitations are exacerbated for patients whose mobility is particularly limited or who are geographically isolated. For hospitals and centers, time slots are difficult to multiply because of limited capacity and limited funding (Charles et al., 2019). Moreover, the growing number of patients with NCDs to be treated overloads the system, which does not have the capacity to take care of everybody. Additional limitations result from the COVID-19 outbreak that has plagued the world for the last two years. During this period, in-person visits were impossible due to the risk of contagion, which further highlighted the limitations of face-to-face programs.

In summary, adapted physical activity programs have difficulty engaging participants, have limited capacity to change behavior over the long term, and are associated with strong organizational and budgetary constraints that limit their broad deployment and dissemination. It is therefore of paramount importance to develop new interventions and treatments that overcome these limitations in order to tackle the public health issues of physical inactivity and sedentary behavior.

The last two decades have seen the rapid ascent of the use of technologies for health and behavior change. Commonly referred as digital health, this new scientific area opens fresh perspectives of care and innovative intervention development. More specifically, digital health interventions hold promise to better change behavior in real-life contexts and have the potential to extend the reach of evidence-based behavioral interventions at lower cost, while reducing patient burden. Indeed, mobile technologies are now equipped with powerful sensing, processing, storage, and visual display capacities, in addition to be widely available (Arigo et al., 2019; Johnson et al., 2016). Therefore, mobile phones and activity trackers offer a unique opportunity to intervene directly on daily-life physical activity of participants that is tracked. Their broad availability and lower cost appear as powerful means to alleviate pressure on the healthcare system (Fagherazzi et al., 2020; Gunasekeran et al., 2021).

“Digital health will overtake prescription drug in 2035”

TLGG Consulting (2022)

The interventional perspectives are multiple with the democratization of digital tools. Among them, we can cite the concept of gamification. Gamification is the

use of game-based elements to foster behavior change, engagement, motivation, and soliciting participation in non-game contexts. By integrating game mechanisms such as points, levels, leaderboards, badges, challenges, or customization in interventions that are initially devoid of them, the purpose of gamification is to integrate into daily life activities the ingredients that make games enjoyable to motivate participants to engage in physical activity (Cugelman, 2013). Gamification therefore promises a double improvement by making activities more pleasant and ensuring the long-term engagement of people with tasks initially perceived as unmotivating (Sardi et al., 2017) – which is of great interest considering the limits of current programs.

Naturally, digital interventions and gamification gained popularity and rapidly spread in a wide range of domains that benefit from the increased engagement of their target users (Bassanelli et al., 2022) and are now breaking into the healthcare market. By one estimate, the global healthcare gamification industry generated \$3.3 billion in 2021, and is anticipated to generate \$9.0 billion by 2031 (Verified Market Research, 2021). Moreover, the US Food and Drug Administration (FDA) recently launched an initiative to accelerate the integration of digital health into conventional medical practice (US Food and Drug Administration, 2022).

Nevertheless, if digital health and gamification introduce an exciting roadmap for advancing care by addressing the many challenges to the field via technological innovations, there is to date no clear scientific evidence to justify their global effectiveness and use in healthcare. Moreover, there are some challenges associated with the use of digital health that must be addressed before any broad deployment. In particular, there are concerns about the ability of digital programs to engage participants once the novelty wears off or to be effective on any type of audience regardless of their age, sociodemographic, or health status. Essentially, one may wonder if these interventions are truly effective or if they are more of a fashion and novelty effect. More broadly, we can also ask whether the reduction of face-to-face contact may not have a negative motivational impact on patients.

This PhD thesis will attempt to answer these research gaps by developing and testing the effectiveness of a digital intervention – integrating gamification mechanisms – aimed to promote physical activity in subjects with chronic diseases. The central question of this thesis is whether this type of intervention is effective in promoting daily physical activity of participants in the short and mid-term, and in comparison with conventional care. We will also explore and test how digital

technologies can address the organizational constraints of current programs and improve healthcare delivery. We make the assumption that the use of gamification will act as a catalyst for digital intervention, allowing for practical implementation of behavioral change techniques and addressing the difficulties of engagement, often observed in digital programs.

This manuscript is organized into three parts: Part I: Theoretical background and aims of the thesis; Part II: Personal contributions; and Part III: General discussion. The two first chapters that constitute Part I will aim to review what is currently known about physical activity behavior change and about the use of digital means to promote physical activity in subjects with chronic diseases and facilitate care delivery. These two chapters will review the dominant theoretical models and state-of-the-art and will point out a number of limitations and challenges that this thesis will seek to address. These chapters will be followed by an interlude introducing the research program and the main questions of this thesis.

In Part II, six empirical studies will be presented. Study 1 proposes to evaluate the effectiveness of gamified interventions for physical activity promotion through a systematic review and meta-analysis of randomized controlled trials. Based on the results of the review, study 2 aims to test the impact of a gamified intervention outside the context of controlled trials, in real-life settings, by analyzing the longitudinal physical activity trajectories of 4800 individuals and exploring potential moderators implicated in the intervention effect. Studies 3 and 4 are respectively a pilot and a validation study aimed at developing and testing digital tools to remove the limits and barriers of in-person care. Study 3 evaluates the use of a mixed physical activity program including telecoaching among patients with various NCDs and compares it with the usual care whereas study 4 tests the validity and reliability of an innovative app-based medical device aimed to propose remote physical condition tests. Study 5 presents the protocol and methodology of the DIPPAO randomized controlled trial – a two-arm parallel clinical trial that seeks to compare the effectiveness, cost-effectiveness, and psychological mechanisms of the Kiplin digital intervention to the usual care among patients with obesity and type 2 diabetes. Lastly, study 6 presents the preliminary results of this trial.

Finally, Part III will propose a general discussion that will summarize the main results obtained, whilst discussing the limitations, research perspectives, and clinical implications of this thesis.

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PART I

Theoretical background and aims of the thesis

Chapter 1

Behavior change theories and the need to develop a precision medicine paradigm to improve physical activity

If physical activity and sedentary behaviors are nowadays the hearths of concerns in behavioral medicine and public health, the preoccupations of researchers on people's activity are nothing new. Physical activity promotion has been of paramount importance for several decades (Martin et al., 2006) as evidenced by the exponential growth in articles on this topic published since the 1950s (Blair et al., 2010). As a result, scientists became increasingly interested in the new challenge of trying to motivate individuals to become more active (Haslam et al., 2020). Hence, understanding the underlying mechanisms of these behaviors has naturally become crucial in helping individuals adopt an active lifestyle.

In response to this challenge, behavioral scientists have tried to identify the drivers and barriers to physical activity (Biddle, 2022). Thus, they classified a range of various outcomes influencing people's activity, and the first behavior change theories appeared in the 1980s (Rhodes et al., 2019). These theoretical frameworks are essential as they create a context for understanding, explaining, and ultimately intervening upon physical activity (Michie et al., 2014; Rothman, 2004). Models have accumulated over the years and the amount of behavior change theories available in the literature is now consequent. Several reviews have identified more than 80 available theories considering a large range of behavioral influences and mechanisms (Davis et al., 2015; Michie et al., 2014). In this chapter, we will first look at the dominant theoretical frameworks in the physical activity domain in order to apprehend their interest and limitations. We will then propose how a health precision medicine approach could

complement these theories to overcome some of these limitations and improve the effectiveness of behavior change interventions.

1.A brief overview of the dominant behavior change theories in the physical activity domain

1.1. The social cognitive framework

The social cognitive approach has been especially important in the field of physical activity. This framework considers that people act primarily upon reasoned cognitions when performing or not a specific behavior; in turn, behavior change is built into the reflective cognition of individuals. In that idea, our behaviors are determined above all by our beliefs and thoughts, and are guided by our goals and intention to perform desired actions. Prominent theories such as the *theory of planned behavior* (Ajzen, 1991), the *social cognitive theory* (Bandura, 1998), and the *transtheoretical model* (Prochaska & Di Clemente, 1982) are part of this framework.

As an example, the theory of planned behavior suggests that *attitude* (i.e., evaluation of a behavior), *subjective norm* (i.e., perceived social pressure to perform the behavior), and *perceived behavioral control* determine the strength of the intention, which in turn influence the probability to do the behavior (Hagger et al., 2002). In addition, each of these variables is predicted by specific antecedents. Attitudes are predicted by behavioral beliefs which are the person's subjective probability that performing the behavior of interest could lead to a certain outcome or involve a certain experience. Subjective norms are predicted by injunctive normative beliefs (i.e., the subjective probability that an important individual or group approves or not the target behavior) and descriptive normative beliefs (i.e., beliefs as to whether important others themselves perform the target behavior). Finally, perceived behavioral control is predicted by control beliefs which are defined as the individuals' subjective appreciation about the probability that some factors facilitating or impeding the realization of the behavior will be present in the situation of interest (Ajzen & Schmidt, 2020).

In the light of this theory, an individual is likely to engage in a certain physical activity if he has the intention to do so, and this intention will occur if the individual has a good evaluation of this activity, if he believes that his friends, family or physician

approves the behavior, and if he considers that he has the resources to be efficient in the activity. In the more recent formulation of this model, positive attitudes and subjective norms lead to the formation of the intention to perform the behavior, but only to the extent that individuals believe that they are capable of performing the behavior in question (Figure 1). Thus, perceived behavioral control moderates the effects of attitude and of subjective norm on intention (Ajzen & Schmidt, 2020).

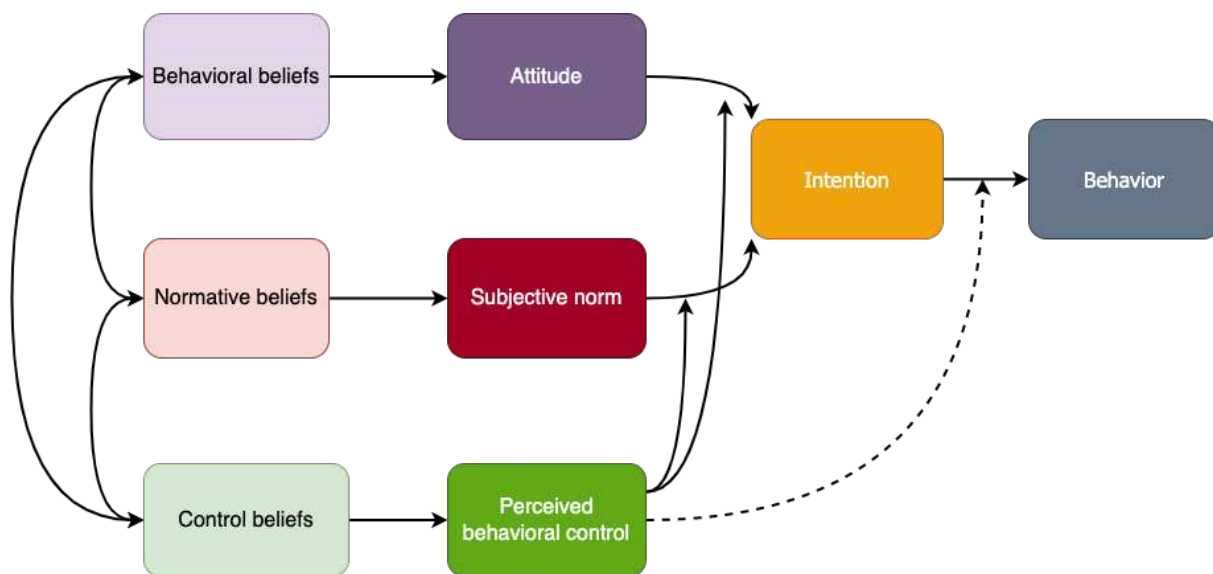


Figure 1. The theory of planned behavior (adapted from Ajzen & Schmidt, 2020)

This model and other social-cognitive models have been extensively tested in observational studies. They have demonstrated that these models have the potential to explain a high proportion of the variance in physical activity intention (Rhodes et al., 2019). For example, observational research showed that, in light of the theory of planned behavior, attitude ($\beta = 0.40$) and perceived behavioral control ($\beta = 0.33$) have medium effects on intention (McEachan et al., 2011).

However, despite hundreds of applications of social cognitive models in the field of physical activity (Cardinal, 2014; Rhodes & Nasuti, 2011), these models are not exempt from any criticism (Sniehotta et al., 2014). Specifically, research has revealed that intention has only a medium-size effect on physical activity (McEachan et al., 2011). Rhodes and de Bruijn (2013) confirmed this assumption, observing that 46% of individuals who intend to be physically active do not translate their intention into behavior. This phenomenon known under the name of the “*Intention-behavior gap*” (Sheeran & Webb, 2016) represents one of the main limitations of these models. In

other words, social cognitive models would explain the generation of the intention but not necessarily its translation into the behavior. Therefore, interventions only based on social cognitive frameworks aiming to increase the intention to exercise would not be sufficient to effectively change behaviors. In that idea, Webb and Sheeran (2006) found that a moderate to large increase in intention ($d = 0.66$) resulted in only a small to moderate change in behavior ($d = 0.36$). Then, other approaches focusing on factors that may explain when and how intention translates into behavior, such as self-regulatory skills (e.g., health action process approach, Schwarzer, 2008), and automatic processes (i.e., dual-process approaches) were proposed.

1.2. The dual-process framework

Dual-process models propose that behavior is determined not only by rational thoughts – as assumed by the social-cognitive approach – but also by automatic processes, which are non-intentional, efficient (i.e., not requiring effort), non-controllable, and/or unconscious processes (Bargh, 1994). Thus, a dichotomization is made between, on the one hand, reflective processes which are deliberate and effortful (e.g., self-efficacy, intention), and on the other hand non-conscious processes which are not dependent on cognitive resources (e.g., habits, implicit attitudes, affects). Models such as the *affective-reflective theory of physical inactivity and exercise* (Brand & Ekkekakis, 2018) or the *theory of effort minimization in physical activity* (TEMPA, Cheval & Boisgontier, 2021) are part of this framework.

The later model argues through an evolutionary perspective that people have evolved to have automatic attractions toward *effort minimization* – a natural tendency to avoid unnecessary physical effort and conserve energetic resources. In consequence, people having the intention to be active have to surpass this natural tendency to develop uneconomic behaviors (Figure 2). The TEMPA argues that *movement-related cues* are perceived as effortful and trigger automatic and controlled evaluations (e.g., intention and approach-avoidance tendencies) that in turn lead the individual to avoid or minimize his behavior (by influencing the decision to plan or perform the movement). The positive or negative evaluation of the movement-related cues is dependent on the physiological state of the individual at the moment of exposure, and on whether these cues are of a dispensable or necessary nature. *Perceived effort* (i.e., subjective experience/anticipation of the effortfulness of the behavior), itself influenced by the positive or negative evaluation of the cues, has a central role in this

model as it will influence the controlled and automatic processes. The TEMPA argues that to achieve the physical activity behavior, the automatic and controlled processes supporting this engagement should be stronger than the processes supporting the minimization of the perceived effort. The relative weight of the controlled and automatic precursors in the process is moderated by multiple factors (e.g., habitualness, fatigue, cognitive load).

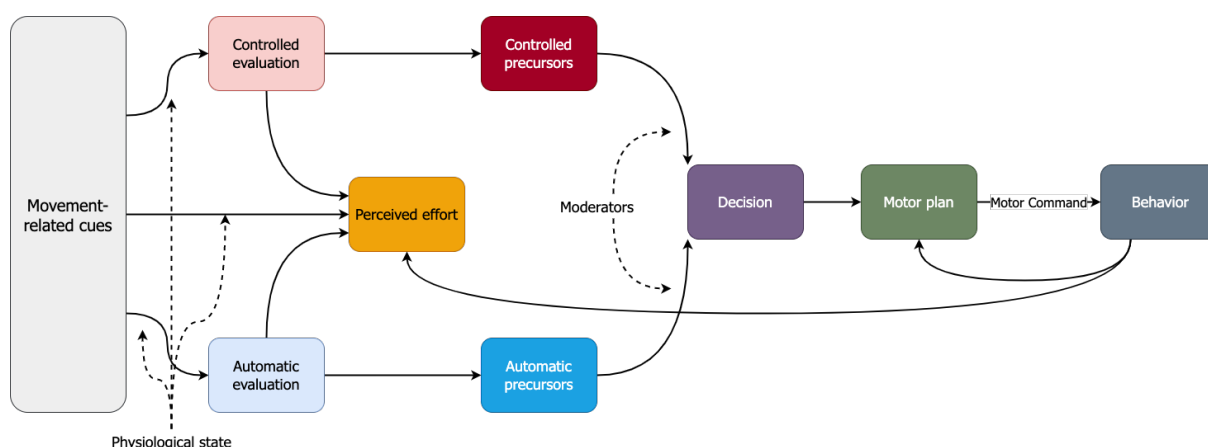


Figure 2. The theory of effort minimization in physical activity (adapted from Cheval & Boisgontier, 2021)

1.3. Humanistic framework

Humanistic theories posit that individuals are “innately driven toward fulfillment, personal growth, and strive toward achievement of full potential” (Goldstein, 1995; Maslow, 1943; Rogers, 1995). These models propose therefore that behaviors and activities that satisfy these elements and the needs of the individuals are naturally attracting and motivating (Deci & Ryan, 2000; Teixeira et al., 2012). The self-determination theory (SDT, Deci & Ryan, 2002) or the flow theory (Csikszentmihalyi, 1990) are part of this framework. The most popular model of this framework is undoubtedly the SDT.

Made up of six mini-theories, the SDT suggests that motivation can be pictured on a continuum of different types of motivations, ranging from lack of motivation to a completely autonomous motivation, in which the behavior comes from the individual’s will (Figure 3). These different forms of motivation reflect the reasons why a person will engage in an activity. While an intrinsic motivation (i.e., the highest form of

autonomous motivation) will push the individual to exercise for the inherent pleasure provided by the activity and for the fact of progressing and developing skills, a controlled motivation will lead the individual to practice for the consequences that the activity can bring (i.e., gain external reward or avoid punishments), or attaining a state valued by the person (e.g., physical appearance) and not for the activity itself.

SDT holds that the autonomous and controlled forms of motivation differentially affect their behaviors. Indeed, if both forms of motivation can initiate the behavior, people will be more likely to perform the behavior in the long-term when their motivation is autonomous (i.e., freely chosen) than controlled (e.g., by external pressures). This can be explained by the fact that when the external factors causing controlled motivation are less important to the person or no longer exist, the motivation disappears. In contrast, self-determined people performing an activity for themselves are more likely to keep this motivation in the future. Thus, autonomous forms of motivation represent higher quality and more sustainable drivers of the engagement (Deci & Ryan, 2000).

Moreover, SDT offers a deeper level of reading via the organismic integration theory (i.e., one of the 6 mini-theories), which posits the existence of different degrees of controlled and autonomous forms of motivation. On the continuum of self-determination, we can distinguish in order amotivation, external regulation, introjected regulation, identified regulation, integrated regulation, and intrinsic regulation. Each of these distinctions varies in its degree of self-determination. *Amotivation* is the complete absence of motivation. Then, SDT posits that some extrinsic motives are more adaptive than others. *External regulation* is the least self-determined form of extrinsic motivation. It occurs when individuals seek to obtain a reward or avoid a punishment. Here, the perceived locus of causality is external to the individual. In *introjected regulation*, the individual still tends to feel controlled or constrained but by internal pressures (i.e., partially internalized ideas such as to search approval or avoid guilt). *Identified regulation* constitutes a deeper level of internalization where motivation is more affected by individuals' values and priorities. *Integrated regulation* reflects the motivation to act in line with how people define themselves. Finally, *intrinsic motivation* is the motivation to perform a behavior for his own satisfaction and pleasure.

As mentioned above, the concept of "basic psychological needs" is the cornerstone of humanistic theories (Deci & Ryan, 2002). It is therefore natural that

these basic needs are represented in the SDT. In fact, three basic psychological needs are presumed to achieve self-determination: the need for *autonomy* (i.e., need to feel responsible of one's own actions), *competence* (i.e., need to feel effective in one's interactions with the environment), and *relatedness* (i.e., need to feel connected to other people). These needs are considered to be complementary and interrelated, and optimal growth and functioning require the satisfaction of most, if not all, of the needs (Ryan & Deci, 2017). Importantly, need satisfaction has been shown to be an important predictor of self-determined motivational regulations (Edmunds et al., 2006; Russell & Bray, 2009), physical self-worth and psychological well-being (Sebire et al., 2009), self-reported exercise behavior (Vlachopoulos et al., 2011), and long-term maintenance of physical practice (Teixeira et al., 2012). These results may explain why the SDT has been extensively applied to the sport and exercise domain (Bhavsar et al., 2020).

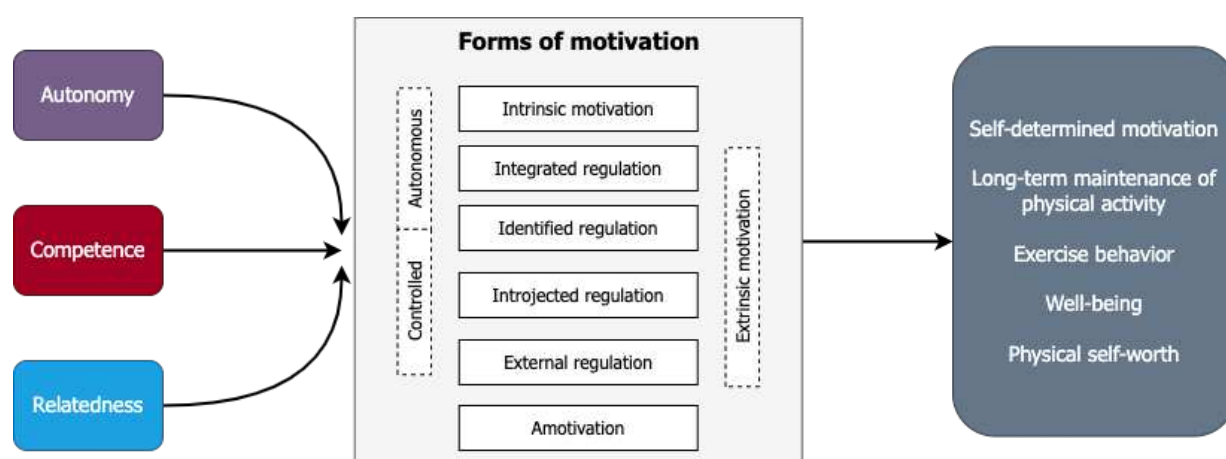


Figure 3. The self-determination theory (adapted from Sarrazin et al., 2011)

1.4. Integrated theories and taxonomies

In addition to the aforementioned suggestions, many integrated theories have been proposed to synthesize the content of multiple frameworks, or provide additional constructs to previous models to increase their parsimony and predictive value. We previously introduced the HAPA model which integrates situational and behavioral elements into traditional socio-cognitive theories. The trans-contextual model of motivation (Hagger & Chatzisarantis, 2007) or the COM-B (Capability, Opportunity, Motivation – Behavior) model (Michie et al., 2011) are other examples of integrated theories. In the COM-B model, the behavior is viewed as the result of a system evolving

multiple components (Figure 4). First, the *capacity* to perform the behavior which may be psychological (e.g., knowledge or skills) or physical (e.g., strength or stamina). Second, the *opportunity* to perform the behavior which may be social (e.g., social norms, interpersonal influences) or physical (e.g., time and resources necessary to perform the behavior). Third, the *motivation* to perform the behavior, which is defined as the brain processes that energize and direct the behavior. Motivation is divided into reflective motivation which involves conscious plans and evaluations (e.g., beliefs about consequences of the behavior, self-efficacy), and automatic motivation which includes emotional reactions, impulses, and habits.

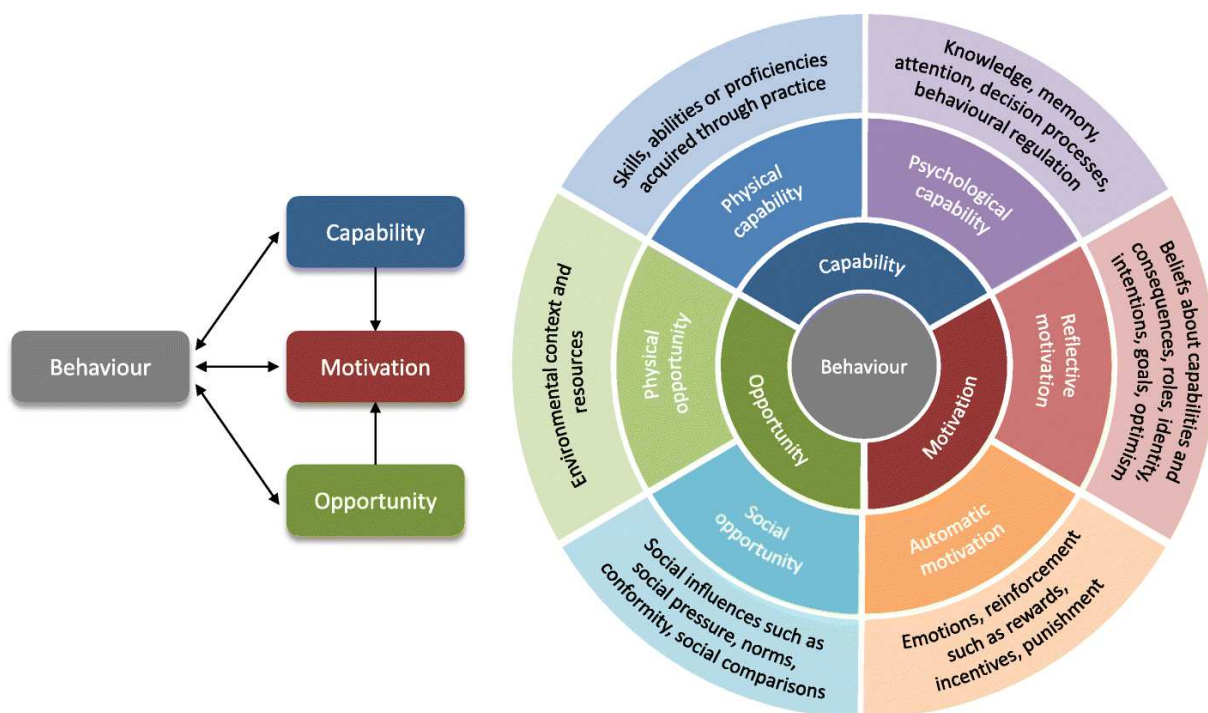


Figure 4. The COM-B (Capability, Opportunity, Motivation – Behavior) model (reproduced from McDonagh et al., 2018)

The COM-B model has also led to the development of the Behavior Change Intervention Ontology (Michie, Thomas, et al., 2017) and taxonomies of behavior change (e.g., the Behavior Change Technique (Michie et al., 2013) Taxonomy or the Behavior Change Wheel, Michie et al., 2011). Integrated theories can actually assist in identifying links between constructs and support the development of behavior change techniques (e.g., goal setting, self-monitoring, social support) that target the motivational levers proposed in these models (Michie et al., 2011). Behavior change

techniques comprise the “active ingredients” of behavior change interventions and can be combined in different ways by intervention developers. In addition to constituting a toolbox that can inform intervention development, these techniques provide a framework for accurately reporting the different components of an intervention – which is particularly useful in modern complex interventions. As an example, the taxonomy of behavior change techniques proposed by Michie et al. (2013) aims to identify, name and classify the different techniques that can be used in a behavior change intervention. This taxonomy inventories 93 techniques divided into subcategories according to their mode of operation (i.e., goals and planning, feedback and monitoring, social support, shaping knowledge, natural consequences, comparison of behavior, associations, repetition and substitution, comparison of outcomes, reward and threat, regulation, antecedents, identity, scheduled consequences, self-belief, covert learning).

1.5. Limits of the aforementioned models

Theoretical frameworks are generally recognized as essential features for physical activity promotion (Rhodes et al., 2019; Rhodes & Nigg, 2011). The aforementioned psychological frameworks and theories aim to structure the relations among variables, make overview assumptions for how the variables should operate, and are ultimately the basis of successful intervention development. As an illustration, the meta-analysis of Webb et al. (2010) evaluating the impact of theoretical basis on the efficacy of interventions delivered online revealed that interventions based on a theoretical framework were more effective in changing health-related behavior than non-theory-based interventions. In the physical activity domain, Gurlan et al. (2016) also found a significant difference in objective and self-reported physical activity between participants who have benefited from theory-based intervention compared to those who did not, highlighting the contribution of theoretical models for behavior change. In line with this conclusion, several authors advocated for a theory-driven approach to behavior change and provided frameworks and recommendations to rigorously guide decision-making in agile behavior change intervention development (Araújo-Soares et al., 2018; Sheeran et al., 2017).

However, in this process of theorization, these models may over-simplify the motivational processes and contextual factors involved in the physical activity behavior (Rebar et al., 2021). In consequence, these theoretical frameworks are not without

limitations and may explain why we still struggle to promote physical activity in current programs – even when they are evidence and theory-based. Indeed, if interventions based on theoretical models are efficient to promote physical activity, meta-analyses (e.g., Ntoumanis et al. (2021) for the SDT or Romain et al. (2018) for the transtheoretical model) consistently found only small-to-medium changes in physical outcomes at the end of the interventions, which lead to a limited practical relevance (Brand & Ekkekakis, 2021). Moreover, behavioral interventions often fail to produce sustainable effects in time (Kwasnicka et al., 2016), when this is what is more needed today according to public health recommendations. If traditional models focus on understanding why people engage or not in a specific behavior, little is known about the factors associated with behavior change maintenance in the long haul (Dunton et al., 2021).

It is therefore essential to question the limits of the dominant models to reach efficient and long-term behavior change. First, these models tend to analyze the behavior determinants for the average person and assume to be generalizable to the whole population, regardless of individuals' characteristics. However, as mentioned in the introduction, physical activity levels vary according to health status, gender, or weight of individuals. Moreover, the variables identified in these models better predict behavior when participants are young and healthy (Rebar et al., 2016; Sniehotta et al., 2014), contrasting with the characteristics of patients with chronic disease. As an illustration, recent meta-analyses conducted through the prism of the HAPA model suggested that intention is more correlated with health behavior in healthy adults than in clinical populations (Choi et al., 2018; Zhang et al., 2019). Therefore, there is a need to better identify the motivational levers and barriers to physical activity for the most inactive populations (Chalabaev et al., 2022). Specifically, the idiosyncratic nature of physical activity (i.e., the fact that people's activity can largely differ from one person to another) needs to be more considered in behavior change models.

Second, these models are often criticized as static, assuming additive, constant, and linear relationships between the different factors predicting a behavior (e.g., Riley et al., 2011). Heino et al. (2021) argued that this position led to an inaccurate and imprecise understanding of behavior change, as human behavior is associated with many non-linear interactions across different time scales, suggesting that the omission of these relationships can obscure important characteristics of behavior change. Physical activity is not exempt from this since it shares the particularity to fluctuate

over short timeframes at the individual level (Dunton, 2018; Maher et al., 2016; Pedersen et al., 2016) in response to a dynamic interplay of intra-individual (e.g., motivation, affects), inter-individual (i.e., interpersonal dynamics), and environmental/contextual factors (e.g., weather or urban planning) (Bauman et al., 2012; Chevance et al., 2021). Physical activity is therefore a complex, potentially non-linear, and dynamic behavior, and in consequence, traditional models cannot properly assess the factors involved in its initiation and maintenance. Complementary models and innovative methodologies are thus needed in association with traditional models to better understand the factors predicting the engagement and maintenance of physical activity once the program is finished and *in fine* help individuals to change this complex behavior.

In view of these two issues, the traditional “one-size-fits-all” approach to behavioral intervention theory and development seems inadequate to explore and intervene on complex, dynamic, multifactorial, and idiosyncratic behavior such as physical activity (Conroy et al., 2020). Rather, more tailored models adapted to individual preferences and the specific attributes of inactive populations are needed. In this perspective, the precision medicine paradigm can be inspiring for behavioral researchers and intervention developers as it proposes a new way of thinking about interventions – with a move into more individualized treatments through a deeper consideration of interpersonal determinants and individuals’ responses.

2. A precision medicine approach to behavior change

According to the US National Library of Medicine, precision medicine is “an emerging approach for disease treatment and prevention that takes into account individual variability, environment, and lifestyle for each person” (National Institutes of Health, 2020). Also referred as *precision health*, these initiatives aim to progressively move beyond approaches focused on average patient responses toward more individualized and contextualized ones (Chevance et al., 2021; Hekler et al., 2020). Precision medicine allows a) to improve patient screening, detection, and prevention for at-risk populations, and b) to propose bespoke interventions. More specifically, precision medicine offers new perspectives to build continuous-tuning interventions adapted to the complexity of health behavior such as physical activity, and facilitate the alignment

between research and practice through an iterative process to enable more equitable care and conduct mechanistic science in real-world context (Hekler et al., 2020).

This new paradigm can be a great source of inspiration to evolve our behavioral interventions, as it suggests ways of improving current treatments with better consideration of patients' individual variability and environment – the two main limits of traditional behavior change models identified in the last section. This vision tends to evolve health interventions into a more comprehensive and integrated approach that includes individuals and their context when selecting, building, or monitoring intervention programs (Hekler et al., 2020). Considering behavior change theories in the light of the precision medicine paradigm is therefore saying that frameworks and models need to be precisely adapted to the population and the target behavior. For this purpose, we need to associate traditional behavior change theories with other models or methodologies that allow us to respond to this challenge.

In the next sections, we propose to first consider social elements like the stereotypes and social identification processes in the intervention design, in order to implement programs that can better target patients and hard-to-reach stigmatized populations such as chronic disease patients and inactive individuals. In this perspective, the social identity approach can provide a precious foundation for developing and implementing tailored interventions. In addition, we suggest that considering the interconnected, idiosyncratic, and dynamic nature of physical activity along with the potential compensatory mechanisms that can occur during a physical activity program, and better monitoring the within-person evolution of the intervention effect across time could allow us to improve our evaluations of behavioral interventions and thus expand our capacities to match interventions to patients and contexts.

2.1. The health psychology of stereotypes: insights from the social identity approach

2.1.1. The importance of considering stereotypes from a behavior change perspective

Several researchers have stressed the importance of considering the numerous individual, environmental, policy, and social determinants of health behaviors in order to develop successful interventions (e.g., Sallis et al., 2015; Stevens et al., 2017). One

may argue that the socioecological approach (Bauman et al., 2012) already considers both individual and environmental factors. This multi-level model proposes that physical activity is determined by individual (e.g., psychological and biological characteristics), interpersonal (e.g., social support), environmental (e.g., social, built, natural), national (e.g., urban planning), and global (e.g., economic development) factors. Nevertheless, if these approaches are essential, they do not yet accurately specify how these different levels interact with each other (Chalabaev et al., 2022). In addition, these models assess physical activity in a holistic manner and tend to temper the influence of additional barriers specific to certain populations, such as patients with chronic diseases.

In order to address this limitation, Chabalaev et al. (2022) proposed to articulate the health psychology approach with the social psychology of stereotypes. This proposition is based on the observation that most inactive populations share one characteristic: they are targeted by negative stereotypes, such as: “patients lack physical abilities”, “older adults are fragile”, or “obese people are lazy”. Stereotypes are shared beliefs regarding the personal characteristics of a group of people (e.g., Leyens et al., 1994). Stereotypes are at the same time an environmental factor built in social interactions and an individual factor, captured by individual perceptions (Chalabaev et al., 2022). Therefore, they represent a real place of interaction between the intra and inter-individual levels. While these stereotypes may sometimes reflect reality, social psychology studies indicated that they influence behavior beyond biological factors, leading to their own realization. Stigmatized individuals 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 stigmatized, such as physical activity (Chalabaev & Sarrazin, 2020). These psychological processes are referred in the literature as *the social identity threat* and *the stereotype internalization processes* (Chalabaev et al., 2013; Chalabaev & Sarrazin, 2020).

Social identity threat occurs when individuals are concerned that they will be devalued because of their social identity (e.g., as a female, older adult, or overweight person). This psychological state arises in situations where negative stereotypes may apply: for example, when an overweight individual exercises with a group with only regular-weight people (Myre et al., 2020). Once triggered, stereotypic concerns generate unpleasant stress-related responses, including negative thoughts and affect,

increased cardiovascular responses, and avoidance behaviors. Stereotype internalization is the incorporation of negative societal views in the self-concept. It occurs when people perceive themselves in conformity with ingroup stereotypes. In consequence, the internalization of negative stereotypes can influence behavior as self-perceptions often shape the behavior. Thus, people tend to avoid activities in which they feel stigmatized, such as physical activity (Chalabaev & Sarrazin, 2020). For instance, the more obese people perceive themselves negatively, the more they avoid physical activity (Vartanian & Novak, 2011).

2.1.2. The social identity approach

In this context, the social identity approach (Haslam, 2004) can be interesting as it provides noteworthy insights on how group norms and social interactions can influence behavior change (Reynolds et al., 2020; Stevens et al., 2017). The social identity approach (comprises of two theories the social identity theory, Tajfel & Turner, 1979, and the self-categorization theory, Turner et al., 1987) argues that individuals can define themselves and behave as a function of idiosyncratic personal attributes (e.g., personal identity as “I” and “me”) or in terms of social categories (e.g., group membership as “we” and “us”). It is important to note that an individual may objectively feel a sense of belonging to a group based on salient factors (e.g., gender, ethnicity, nationality), but may also perceive himself or herself as a member because the group is self-relevant and self-defining (Turner et al., 1987). This approach posits that this distinction influence people’s beliefs, thoughts, and ultimately behaviors as they act differently depending on whether they define themselves as “I and me” or “we and us.”. Indeed, when the social identity derived from a group is salient for an individual, this one will focus more intensely on similarities with in-group members (e.g., people sharing the same disease) as well as differences from out-group members (e.g., healthy people). For instance, individuals will respond differently to stereotypes and stigma according to the social identity that is salient for the individual at a given time because each social identity shapes the attitudes, subjective norms, and behaviors of the individuals. The stronger a person’s identification with a particular group, the more likely the individual will behave in ways that align with the characteristics that define the group (Reynolds et al., 2020). These relationships between social identity, attitudes, and behavior are often explained through social influence processes. This is why the social identity approach suggests that social groups can affect health behaviors

and outcomes only when individuals perceive they share the same identity with another individual or group (Jetten et al., 2014). Therefore, an important mechanism for change is how people define themselves in a behavior change program.

2.1.3. Social identity offsets stereotype-related barriers

There are indeed important group-based factors that moderate the relationship between discrimination and health. Based on the rejection-identification model (Branscombe et al., 1999), Jetten et al. (2018) proposed that social identities derived from group membership can act as psychological resources when individuals are confronted with stigmatization. This can be viewed as a paradoxical situation because the group membership of stigmatized individuals is, in this context, both the problem and the key solution in helping them counteract the negative effects of group membership (Jetten et al., 2018). In line with this assumption, participants who share the same stigmatizing characteristic within a physical activity program (e.g., a certain pathology or weight status) may more easily identify with the group – allowing the emergence of social identity and social support. In other words, in specific conditions group belonging could help participants to overcome stereotype-related barriers (Olander et al., 2013) by attenuating the deleterious impact of stereotype internalization and social identity threat.

The self-categorization theory offers a relevant paradigm to conceive these assumptions. This theory attempts to explain the psychological processes by which people develop their social identities and proposes that the salience of a particular social identity results from a context-sensitive categorization process. Individuals categorize themselves and others according to a set of core attributes that are salient and observable such as age, gender, ethnicity, socioeconomic status, or weight status. These categorizations influence a) the inferences they make about those others, b) their perceptions of others' normative behaviors, and c) their attraction and engagement with in-group and out-group people (Beauchamp, 2019, Figure 5). When individuals perceive individuals of a particular social group to be similar to themselves, they are more likely to feel a greater sense of belonging, social connectivity, and cohesion toward those people. Two main mechanisms are proposed by the theory to explain how self-categorization. The first one is the social identity salience (i.e., the extent to which an attribute allowing self-categorization is salient for the individual) and the second one is the perception of intra-group similarities.

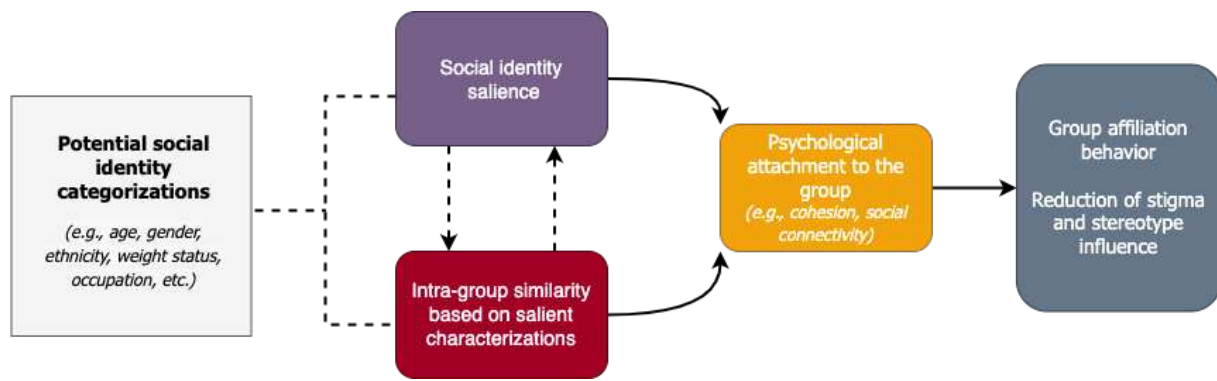


Figure 5. Self-categorization processes within exercise groups (adapted from Beauchamp, 2019)

In sum, when self-categorization as a stigmatized group member is salient (which occurs when certain attributes are salient and shared with the group), this affects not only perceptions of the stigmatized group but also the individual's own behaviors by unlocking cohesion, social connectivity, and support health and well-being by impacting the way that health conditions and health challenges are appraised, experienced, and responded by individuals (Jetten et al., 2014). Exercising in a group-based program specifically designed to facilitate the emergence of a social identity within it could act as a “social cure” (Jetten et al., 2012) affecting the availability and effectiveness of group-based support to counteract the negative effects of stigma and discrimination.

2.1.4. Social identity drives exercise engagement

Nevertheless, the contribution of group-based interventions aimed at promoting the emergence of social identity is not limited to their impact on stigma. Indeed, such interventions could also improve adherence to the physical activity program as recent research revealed that social identities could predict exercise adherence in group-based programs. By fitting people's preferences and unlocking social support, self-categorization within a group-based intervention can enhance engagement (Figure 5). For example, a series of studies by Beauchamp et al. (Beauchamp et al., 2018; Dunlop & Beauchamp, 2011a, 2011b) have shed light on important attributes determining physical activity engagement. These researchers found that age and gender are particularly relevant markers of shared social identity through physical activity. Their results suggested that both women ($d = 0.76$) and men ($d = 0.30$) reported a stronger

preference for same-gender rather than mixed-gender exercise group settings, and people consistently expressed positive preferences to exercise with people of the same age and a relative discontent of exercising with people either younger or older than themselves. Importantly for patients treated for obesity, moderator analyses revealed that overweight adults had an even more pronounced desire for exercising within same-gender groups relative to mixed-gender groups, compared to normal-weight adults (Dunlop & Beauchamp, 2011b). Stevens et al. recently replicated these findings, as their results suggested that exercise class attendees were more inclined to identify as members of classes in which they perceived the other members as similar to each other in general, and more particularly in terms of age, physical fitness, and attitude towards the class (Stevens et al., 2022). In consequence, group-based interventions that explicitly or implicitly target salient group identities can promote physical activity participation.

To conclude, if physical activity groups are psychologically meaningful for their members, engagement could be improved and barriers due to stigma could be reduced, ultimately leading to better intervention effects. The consideration of these social determinants in addition to traditional behavior change model insights could enhance intervention effectiveness by taking care of participants' environment and influences at the interpersonal level.

2.2. Considering physical activity behavior change under complexity: compensation mechanisms, idiosyncratic factors, and dynamic changes

2.2.1. Promoting physical activity from a complexity point of view

As previously mentioned, physical activity behaviors can be viewed as complex systems considering their non-linear, dynamic, multifactorial, and idiosyncratic nature. The necessity of considering health behaviors in this way has been recently highlighted by the UK Medical Research Council's guidance for developing and evaluating complex interventions (Skivington et al., 2018). Strictly speaking, physical activity is 1) influenced by multivariate factors because the context in which the individual evolves

matters, 2) manifesting idiosyncratically as people are different, and 3) dynamic as things naturally change across time (Hekler et al., 2019). In that respect, studying behavior change from a complexity point of view involves 3 key features: 1) changing physical activity behavior encompasses a multitude of variables and timescales which are interconnected, 2) behavior change involves non-ergodic psychological processes which are contextualized and specific to each individual, and 3) behavior change processes are dynamic and not systematically linear (Heino et al., 2021).

First, complexity science suggests that everything is intertwined (Heino et al., 2017). This implies that a change in the amount of physical activity due to an intervention effect can impact behaviors in other domains or at different timescales. This assumption joins the *ActivityStat Hypothesis* (Gomersall et al., 2013), which suggests that an increase or decrease of physical activity in one domain will be compensated in another domain, in order to maintain an overall stable level of physical activity or energy expenditure over time. This hypothesis is in harmony with frequent observations in physical activity programs that have pointed compensatory decreases in leisure physical activity time in favor of supervised physical activity sessions (King et al., 2007; Westerterp, 1998). As these compensatory mechanisms may exist, it is essential to a) set up methodological and statistical strategies to test their existence and, if they exist, b) set up interventions to counteract this phenomenon. It is also important to look at the detailed physical activity of participants after the end of the program, as these “isotemporal displacements” could also occur when individuals cease a structured physical activity program (Gomersall et al., 2015). Indeed, the time devoted to the physical activity sessions during a program is ‘liberated’ at its end and implicitly redistributed by individuals to other activities that can be beneficial in the best cases (i.e., alternative physical activity) or may negate or even counteract the impact of the program on people's habits at worst (e.g., if the liberated time is devoted to television viewing).

Second, the conditions under which a behavior change intervention can be effective may vary between individuals based on individual preferences, abilities, and constraints (Dunton et al., 2021). Most or all psychological phenomena involved in behavior change are nonergodic – which are characterized by non-homogeneity and non-stationarity (for a complete definition, see Heino et al., 2021; Ruissen et al., 2021). In consequence, group-level measurements do not correspond to those of individuals in time. Thus, we cannot take group-level large-sample results and draw conclusions

about individual-level processes (Hamaker, 2012). This emphasizes the need to adopt an idiographic approach (i.e., individual statistical modeling) with the aim to model individual trajectories rather than averaging them (Chevance et al., 2021; Heino et al., 2021). This idiographic approach may help to better explain the heterogeneity frequently observed in the effect of behavioral intervention between different individuals (Bolger & Zee, 2019; Michie et al., 2009) and “expand our capacities in matching interventions to people and contexts” (Hekler et al., 2020). Ultimately, this can lead to a better comprehension of the individual responses and “inform the development of highly tailored interventions in line with the objectives of precision medicine” (Chevance et al., 2021).

Lastly, the processes involved in behavior change are dynamic and potentially non-linear. Systems evolve as a function of both their past and present conditions and the effects of behavior change interventions can be considered as shocks to this system (Conroy et al., 2020; Heino et al., 2021). Therefore, an intervention effect may not be systematically linear as it could be imperceptible for a long time before exploding (as in exponential growth), or suddenly switch states upon reaching a threshold for example (Kelty-Stephen & Wallot, 2017). Moreover, even when an intervention is successful, stabilizing a system in a stable state may require at least as many resources as the initial change itself (Heino et al., 2021). This may explain why lapses and relapses are frequent among individuals attempting to maintain healthy behaviors such as physical activity and why people often fail to maintain long-term behavior change and typically regress back to baseline levels after the end of an intervention (Dunton et al., 2021). Complexity science can help as it aims to characterize and understand dynamics and discontinuous/irregular patterns of change in human behavior. In this line, Heino et al. (2021) argued that the most important factors in predicting behavior change may not be the strength of a variable’s relationship with behavior, but rather the type of fluctuation that the variable exhibits in response to an intervention, or how fast the dynamics recover after shocks. Conducting longer follow-up with intensive measurements seem essential in order to better understand the long-term intervention effect (Conroy et al., 2020).

2.2.2. The use of intensive longitudinal data methods to properly assess physical activity

These three issues make physical activity behavior difficult to assess through static, cross-sectional, or laboratory-based research methods (Dunton et al., 2021). The emergence of intensive longitudinal data methods, which collect and analyze high-frequency and high-density data across precise timescales in real-world settings, introduces interesting perspectives to tackle these issues. Indeed, these new methods can provide fine-grained insights about individual characteristics and can help better understand physical activity behavior change in real-life conditions (Carpenter et al., 2016; Dunton, 2018; Ruissen et al., 2021). Especially, intensive longitudinal data allows researchers to test bidirectional relationships in networks of variables, moves from group-only to group- and individual-level statistical inference, and move from low- to high-resolution behavioral assessments (Chevance et al., 2021; Ruissen et al., 2021).

First, as different variables involved in behavior change and timescales can be interconnected, it is necessary to model the dynamic of change of the different variables across time. Network modeling approaches (allowed by intensive longitudinal assessment) can be a valuable analytical approach in this perspective (Ruissen et al., 2021). Second, as idiographic approaches are needed, intensive longitudinal data using N-of-1 study designs (i.e., crossover experiments conducted with a single participant, Kwasnicka & Naughton, 2020; Tanious & Onghena, 2019), and adapted data analytic methods that can account for the non-stationarity of time series data, allows for individual statistical modeling. Ultimately, this introduces the possibility to dynamically tune interventions in real-time with methods developed in the field of control systems engineering (Conroy et al., 2020) or just-in-time adaptive interventions (i.e., “intervention design that adapts the provision of support over time to an individual’s changing status and contexts, with the goal to deliver support at the moment and in the context that the person needs it most and is most likely to be receptive”, Nahum-Shani et al., 2018). Third, as physical activity behavior change process is dynamic, it requires high-resolution measurements in order to capture its relative variability or stability over time and reduces the likelihood of erroneous conclusions due to the use of an inappropriate sampling frequency (Chevance et al., 2021). Indeed, following the “Nyquist Principle”, the sampling rate needs to be twice the degree to which meaningful variance and change are observed. As the effects of an

intervention can be non-linear and vary across timescales, the traditional measurement bursts conducted in physical activity trials (i.e., 7-day measurement before and after the intervention) are not adapted to properly assess the impact of a behavioral change intervention on physical activity (Chevance et al., 2021) and intensive longitudinal assessment can answer this issue.

In short, intensive longitudinal collection methods are needed in order to test the potential compensation mechanisms that could occur during or after a physical activity program, evaluate idiographic differences in the intervention effect between individuals, and measure the variables of interest at a high resolution in real-life context to be able to observe potential non-linear patterns in the intervention effects. These methods are likely to improve our behavior change models and provide tailored interventions to the participants. This rationale encourages us to think about how to measure physical activity as accurately as possible. If from a reliability point of view the current gold standard is the use of tri-axial accelerometers, the constraints and costs of this type of device do not allow to use them continuously over long periods of time. Although less accurate, the pedometers embedded in smartphones or wearables offer new proxies for physical activity that are adapted to intensive longitudinal collection. Especially, the use of these tools is riveting when the objective is to measure daily-life light-intensity activities.

Summary Chapter 1

Theoretical models of behavior change are essential for physical activity promotion as they depict and explain the determinants of behavior and ultimately offer strategies for intervention. A brief overview of the dominant theories has been proposed in this chapter. However, current behavior change theories are in the paradoxical situation of being in the same time essential and insufficient for physical activity promotion; these models being associated with a series of limitations. Behavioral intervention theory is indeed often based on a “one-size-fits-all” approach considering the insights of their models generalizable to all individuals regarding their age or health status. Associated models are often static and have difficulties in properly assessing complex behavior such as physical activity, which have the particularity to be dynamic, multifactorial, and

idiosyncratic. Finally, if these models are well suited to understand the initiation of the behavior, little is now on how to promote behavior maintenance across time. In this chapter, we propose to evolve these theoretical models and behavioral interventions by taking inspiration from the precision medicine approach. This paradigm can be inspiring for behavioral researchers and intervention developers as it proposes a new way of thinking about interventions with more individualized treatments through a deeper consideration of interpersonal determinants and individuals' responses. In that idea, the social identity approach can be a precious foundation to propose bespoke interventions limiting the impact of behavior change barriers linked to stereotypes and stigma. Moreover, intensive longitudinal assessments of the physical activity of participants could help to better understand the impact of behavioral interventions during and after the program.

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Chapter 2

The promise of digital interventions

Digital products have become an inevitable element of our daily life over the course of the 21st century. The widespread accessibility of smartphones (14 billion mobile devices in the world in 2021), wearable devices (722 million connected wearable devices in 2019), and internet access (4.9 billion internet users in 2021) (Statista, 2022) opens the perspective to propose new kinds of intervention that take advantage of these means to support health behavior change (Arigo et al., 2019; Walsh & Groarke, 2019). Indeed, whether they are efficient, these tools can improve health by supporting behaviors involved in chronic disease prevention such as physical activity. They also introduce a large range of organizational assets bringing new approaches to the management of health conditions. Following this idea, there has been an explosion in the development and use of digital health products in behavioral medicine over the past two decades. Broadly speaking, the number of health apps has doubled since 2013, and the equivalent of 250 eHealth solutions have been added to app stores each day in 2020 (Genève, 2020). This popularity is also reflected in the scientific dynamic around digital health. We can notice the publication of more than 2,000 studies since 2007 on this topic, including almost 1,500 published articles in the last few years (IQVIA Institute for Human Data Science, 2021).

Most often, the different digital tools and interventions are categorized under the headings of electronic health (eHealth) or mobile health (mHealth). The European Commission defines *eHealth* or telemedicine, as "the use of information and communication technologies to all health-related activities, and/or the delivery of care at a distance". *mHealth* is generally described as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" (Kay et al., 2011). In addition, *digital therapeutics* is another term increasingly used in the area. Following the Digital Therapeutics Alliance, digital therapeutics "deliver medical interventions directly to

patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of diseases and disorders”. Among digital interventions, digital therapeutics are therefore the ones that focus on a specific clinical indication, propose fixed, sure, and reproducible content, and have demonstrated proof of high-quality evidence on clinical effectiveness (IQVIA Institute for Human Data Science, 2021). In other words, digital therapeutics are eHealth and mHealth proven-interventions that have undergone a rigorous scientific validation approved by regulatory agencies, which then open reimbursement possibilities and sustainable access to the health market.

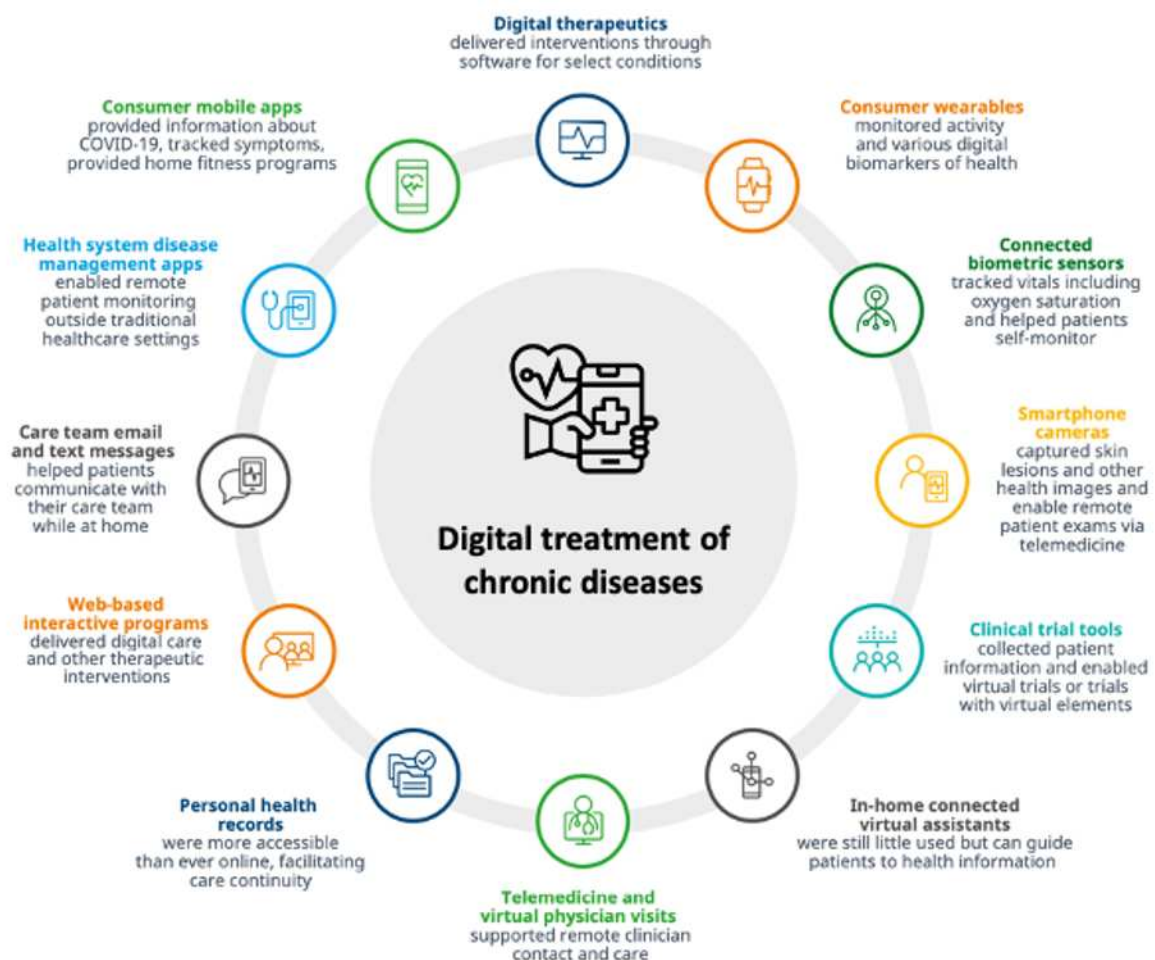


Figure 6. Overview of the different perspectives offered by digital interventions (adapted from IQVIA Institute for Human Data Science, 2021)

Today, digital interventions comprise a multitude of tools and potential applications (Figure 6), among which products dedicated to a) digital diagnostic (which use sensors to diagnose disease), b) the regulation, monitoring, or tracking of the use and delivery of treatments, c) the monitoring and visualization of data collected via a connected sensor (e.g., device-connected apps), and d) treatments facilitated by

digital devices (i.e., telemedicine programs). The appropriate use of the different modules in the treatment of chronic diseases is likely to improve health and healthcare by fostering physical activity behavior change through a safe, scalable, wide-reaching, and cost-effective intervention. In this chapter, we will outline in depth the assets that make digital health an unprecedented promise for the treatment of chronic diseases. Nevertheless, despite these apparent exciting perspectives, a series of challenges face the route of digital interventions and we must address them to enhance the effectiveness and implementation of such programs. These challenges and research gaps will be described in the second section of this chapter.

3. Promises of digital interventions for behavior change, health, and healthcare

3.1. Promising solutions for physical activity promotion

If the penetration of digital health solutions on the health market is relatively recent, researchers have been interested in the effects of digital products to increase physical activity for several decades so far. The association between behavioral medicine and technology is indeed nothing new as pedometers have been increasingly used for the quantification of physical activity engagement in behavioral research since the 1960s (Arigo et al., 2019). These portable motion-sensitive devices, enabling real-time measurement of the steps count, were quickly adopted because of their capacity to provide real-time, inexpensive, and intuitive individual self-monitoring of physical activity (Arigo et al., 2019; Tudor-Locke & Lutes, 2009), which is interesting in improving the effectiveness and reach of behavioral interventions. Technological advances have since permitted the development of modern wearables and smartwatches. These devices provide a finer granularity of measurement with the ability to collect a large range of behavioral and physiological data, at a high resolution.

Behavioral medicine scientists quickly appropriated these tools to design self-monitoring interventions. A considerable number of systematic reviews and meta-analyses have been conducted to assess the effectiveness of pedometers, wearables, and activity trackers to promote physical activity. Recently, Ferguson et al. (2022) published an umbrella review, which is a review of systematic reviews or meta-analyses. They identified a total of 39 systematic reviews and meta-analyses, reporting

results from 163,992 participants covering all age groups of healthy and clinical populations. The results of this review revealed that activity trackers improved physical activity and health with on average 1800 extra daily steps, +40 min per day walking, and -1 kg in body weight, in a variety of age groups and populations. Interestingly, this review suggests good sustainability on daily step count at 4–6 months (+1127 steps per day), and more modest but statistically significant effects on longer follow-up, up to 4 years (+494 steps per day). Thus, the magnitude of the behavior change benefits is clinically important, and the benefits seem to last at least six months. Nevertheless, the studies reviewed rarely looked at very long-haul time periods which was a limitation of the included studies. It also must be mentioned that other measures of physiological (i.e., blood pressure, cholesterol, glycosylated hemoglobin) and psychological (i.e., quality of life, pain) effects were generally small and often non-significant.

Beyond these direct interventional perspectives, activity trackers progressively provided the ability to “digitize” the physical activity of individuals and allowed researchers and designers to integrate these data in more advanced and complex interventions – notably in mHealth applications. Indeed, smartphone apps offer new interesting and exciting opportunities for the creation of physical activity interventions, through embedded tools measuring activity such as pedometers, accelerometers, gyroscopes, and GPS (Wu et al., 2012). These devices allow imaging of more individualized and interactive interventions thanks to their internet access, visual/graphical options, and ability to collect real-time data (Riley et al., 2011).

Several meta-analyses investigated the effectiveness of smartphone apps in increasing physical activity. Gal et al. (2018) reviewed 18 randomized controlled trials and found that the use of wearables and smartphone apps led to a small to moderate increase in physical activity minutes per day (SMD = 0.43, 95%CI [0.03-0.82]) and a moderate increase in daily steps (SMD = 0.51, 95%CI [0.12-0.91]). These findings contrast with those observed by Romeo et al. (2019). Indeed, these authors found that smartphone apps produced a nonsignificant increase in participants’ average daily steps, with a mean difference of 476.75 steps per day between experimental and control groups. In a counter-intuitive way, sensitivity analyses suggested that physical activity programs with a duration of fewer than 3 months were more effective than apps evaluated after a longer period. The meta-analysis of Kirk et al. (2018) also found that shorter mHealth physical activity interventions (<16 weeks) were more effective than longer ones.

Furthermore, Mönninghoff et al. (2021) conducted a systematic review and meta-analysis of randomized controlled trials focusing on the long-term effectiveness of mHealth physical activity interventions. They found that, in addition to having significantly increased physical activity (across all outcome measures: walking standardized mean difference, moderate-to-vigorous physical activity (MVPA), total physical activity (TPA), and energy expenditure) at the end of the programs, the intervention effects were significantly maintained over time, but with decreasing effect sizes. In the short term (i.e., ≤ 6 months after the end of intervention), effects were sustained for walking (SMD = 0.26, 95%CI [0.09-0.42]), MVPA (SMD = 0.20, 95%CI [0.05-0.35]), and TPA (SMD = 0.53, 95%CI [0.13-0.93]) whereas in the long term (i.e., > 6 months after the end of intervention), effects were sustained for walking (SMD = 0.25, 95%CI [0.10-0.39]) and MVPA (SMD = 0.19, 95%CI [0.11-0.27]). Overall, the authors observed higher effect scores in sick and at-risk populations. However, while these results are particularly promising, the authors emphasized that statistical heterogeneity was significant, resulting in low to very low quality of evidence.

In sum, digital interventions seem interesting to promote physical activity at both short- and mid-terms but further research is needed to confirm these results. In addition to offering interesting prospects for behavior change, digital interventions also appear to be valuable in other regards, which we will discuss in the following sections.

3.2. Promising opportunities to build precision medicine behavioral interventions

In addition to provide effective interventions, new technologies afford new possibilities of personalization that make a behavior change precision medicine approach feasible. This personalization capacity is made possible thanks to different factors. First, coded systems can be more easily improved than non-numerical interventions and internet access allows updating programs remotely in real-time. Then, as we have seen in the last section, advances in mobile and sensor technologies have made it conceivable to capture intensive longitudinal data on physical activity and associated psychological processes in the natural context of daily life (Conroy et al., 2020). Thus, digital means are data-driven solutions that feed on personal data and can take advantage of it to tailor the intervention content – which is, as argued in the first chapter, essential to

adapt the program in function of idiosyncratic personal attributes and individual responses to the intervention.

Data collection through digital means can be either active (i.e., requires active input from the users) or passive (i.e., collected without requiring any active participation from the users). When passive, data is usually collected via mobile sensing of the technologies (e.g., physical activity via accelerometers, geographical position via GPS, sleep via heart rate). When active, data is usually collected through questionnaires and ecological momentary assessment (Shiffman et al., 2008). These ambulatory monitoring methods offer new ways of monitoring real behavior in various situations from everyday life, in real-time, over time, on large samples, and with limited expense for researchers or burden for participants (Conner & Mehl, 2015; Dunton et al., 2021). This process of quantification of the individual in situ using data from personal digital devices is nowadays called *digital phenotyping* (Torous et al., 2016).

Digital phenotypes are interesting from an interventional point of view, as they allow 1) intervening in real-time, and 2) taking into consideration the dynamic changes within individuals and adapting the intervention in consequence. This large amount of collected data can be used in two different ways. First, it is possible to use data from prior participants or patients to make decisions and personalize the interventions of future individuals. Second, the data being collected in real-time, it is possible to use data from the individual to build a real-time optimization intervention for that individual in particular. The last approach is particularly interesting as it allows to consider the idiosyncratic individual factors and the fact that people are, act, and respond differently to interventions. It also opens new possibilities to perpetually adapt the intervention to the dynamic process of behavior change – especially by identifying individual inputs associated with the maintenance of daily physical activity (Conroy et al., 2020; Hekler et al., 2013). From this perspective, the field of control systems engineering and the use of system identification are promising avenues to provide micro-adjustments within programs and help people move toward the desired behavior.

A first example of such individualized approach is the provision of automated and tailored responses by messaging or chatbot. These virtual assistants can be used to deliver innovative programs that provide appealing, personalized, and convenient health advice and can support health behaviors such as physical activity (Curtis et al.,

2021; Maher et al., 2020). Text messages can also be personalized in function of behavioral responses via a control systems engineering approach, as demonstrated by Conroy et al. (2019). Other kinds of intervention, called just-in-time adaptive interventions are made possible by digital means. For example, the *Choosing Health* randomized controlled trial (Kwasnicka et al., 2020) evaluates the efficacy of a digital intervention – aimed to promote weight loss – coupled with ecological momentary assessment in order to identify behavioral determinants for each participant and therefore tailor evidence-based behavior change techniques and intervention content. Hardeman et al. (2019) conducted a systematic review of just-in-time adaptive interventions to promote physical activity. Their findings suggested that such interventions were feasible and acceptable for the participants. Regarding the effectiveness, they found mixed evidence for intervention effects on behavior. Nevertheless, the authors highlighted that these adaptive interventions are in their early stages and that future research is needed.

To summarize, by their digital flexible nature and by gathering a large amount of ecologically valid data, digital interventions can be adaptive and meaningfully personalized to the users' needs. However, despite promising perspectives, the control system engineering methods are yet largely unfamiliar to the physical activity promotion community (Conroy et al., 2020) and this sort of software is still rarely applied.

3.3. Promising scalable and wide-reaching practical interventions at a lower cost

As introduced before, some of the limitations of current treatments in chronic disease management are organizational issues. Some authors argued that “the healthcare system is not well designed for the management of chronic conditions” (Steinhubl et al., 2013) with the presence of limitations for patients, practitioners, and the healthcare system in general. On the one hand, physical activity programs can be difficult to access for patients, due to lack of availability on the scheduled sessions, lack of economic means, or geographical distance from the care center (Jerant et al., 2005). On the other hand, hospitals and clinics are overloaded, waiting lists for care appear, and the current system cannot handle the rising number of patients with chronic diseases who need adapted physical activity. In this context, digital health services are promising to tackle

the patients' inconveniences and healthcare difficulties as digital tools have been presented as potentially powerful means to alleviate pressure on existing health and social care systems (Fagherazzi et al., 2020; Gunasekeran et al., 2021).

In the first instance, digital tools can improve patients' experience by ensuring better management of chronic conditions and allowing for more rapid diagnosis and treatment of common chronic conditions. By integrating self-monitoring tools and systems allowing remote consultations or care, the number of unnecessary visits to physicians' offices and hospitals could be substantially decreased (Steinhubl et al., 2013). The ability of mHealth services to track pertinent data, collected passively through sensors or actively via questionnaires, associated with the capacity of eHealth services to automatically transmit in real-time the data to the patient's physician when desired are factors enabling this transition. Delivering behavioral interventions via digital tools reduces or eliminates barriers such as scheduling, transportation, and childcare conflicts, given that individuals can participate anywhere and anytime of the day (Arigo et al., 2019).

In addition, digital health interventions are flexible and allow fast and direct access to health content in everyday life settings (Knox et al., 2021). Several studies focused on the acceptability of these interventions for the participants. Acceptability is a concept embedded in the Technology acceptance model (Davis, 1989), which posits that perceived ease of use and perceived usefulness of a technology positively influence usage intention, which in turn leads to the adoption of the technologies. In two studies using quantitative and qualitative approaches, Hayotte et al. recently demonstrated that the acceptability of several digital health technologies (i.e., smartphone apps, active video games, physical activity via videoconference) was high among patients with severe obesity. For the three technologies studies, patients reported many positive perceptions (Hayotte, 2021) and the authors found that only 8% of respondents had a low level of acceptability of all technologies (Hayotte et al., 2021). The use of technologies being a prerequisite for the effectiveness of digital interventions, these results underline the feasibility of the use of digital interventions for health purposes.

On another perspective, eHealth and mHealth tools have been reported as comparatively low-cost or even cost-saving compared with other intervention delivery modes, such as face-to-face intervention delivery via group or individual sessions (Brown et al., 2020). Digital interventions can reduce healthcare costs in many ways, including decreasing transportation costs for patients or healthcare workers,

addressing inefficient practices, decreasing time to diagnosis, keeping patients in their home longer versus costly healthcare facilities, or reducing hospital visits (Steinhubl et al., 2013). By rebound effect, digital interventions would be highly scalable thanks to their relatively low cost. Their large-scale deployment would also be facilitated by the fact that, due to their digital nature, eHealth and mHealth tools are highly reproducible and accessible for the patients as we will see in the next section.

In addition, digital tools could enhance the reach of the interventions to isolated or stigmatized individuals. First, digital programs can help to take care of geographically isolated people who are far from health care centers. Secondly, technologies could reduce the barriers due to stereotypes and allow individuals who are stigmatized to better engage in a physical activity program, notably by making individuals more anonymous (Griffiths et al., 2006) and reducing the stigma and potential stress associated with help-seeking in person.

Moreover, digital means introduce a new opportunity to exercise or bring care through virtual groups (e.g., exercising from home but being connected to other patients with digital means). Through platforms such as messaging, text messages, videoconferencing, or social networks, digital interventions can easily create group-based settings and be the cornerstone of the ‘social cures’ developed in the first chapter of this thesis. There is a growing body of evidence that online communities can offer new groups for people to join and these ones might have beneficial effects for patients (Jetten et al., 2014). Through mixed methods, Johnston et al. (2013) observed that online communities were beneficial by developing information utility and social support. These digital groups thus helped community participants to better understand their health condition and also provided a place for sharing and receiving support. Recent research supported this idea, with some systematic reviews suggesting promise for social media-delivered interventions. As an example, a Cochrane review published in 2021 concluded that social media interventions may be effective to increase physical activity and improve well-being (Petkovic et al., 2021).

In short, digital means offer prospects for revolutionizing the management of chronic pathologies, allowing to improve the experience of patients via practical solutions and alleviate pressure on the health system by rapidly increase scale at minimal cost, being cheaper than their face-to-face counterparts.

3.4. Alternative and innovative solutions for care during the COVID-19 pandemic

The impacts of the COVID-19 pandemic have been particularly notable on the management of chronic diseases (Chudasama et al., 2020). Indeed, most of the in-person or physical healthcare was unfeasible and both researchers and clinicians had to innovate to be able to continue providing adapted physical activity programs. This particular period has been a real accelerator for the world of digital health, with increased use and consideration of eHealth and mHealth tools (Scott et al., 2020). For instance, the download and use of telemedicine apps and exercise apps significantly increased in 2020. The weekly downloads of physical activity apps increased 5x from an already high baseline of 3,7 million and a telemedicine app such as *Doximity* (i.e., an online networking service for medical professionals), increased their downloads by 38 (IQVIA Institute for Human Data Science, 2021).

In these times where efforts rapidly shifted from face-to-face to remote delivery (Kwasnicka et al., 2022), the potentialities of digital health intervention to propose safe, effective, and informed management from home were welcome. In this context, the ability of digital means to connect people and create online communities is also valuable in pandemic times – where social interactions are restricted because of lockdowns or teleworking. The democratization of these tools has also been notable in primary care. In the midst of COVID-19, employers of big companies have in fact established relationships with developers of digital health apps directly or through payers to protect employees' health and mental health. This was particularly notable in the field of physical activity, as the impact of “forced” telework for the general population emphasized the health issues related to time spent sitting, sedentary behaviors, and physical inactivity.

The impact of the COVID-19 pandemic has also been reflected in research projects and clinical trials that had to be suspended or adapted during this period due to the burden of recruitment and data management. This has resulted in the acceleration of the shift to decentralized and partially-offsite “hybrid” trials (IQVIA Institute for Human Data Science, 2021). During the pandemic, clinical trials rapidly shifted to decentralized or “hybrid” studies, with the use of some remote monitoring and home-based visits enabled by technologies. These new forms of trials will also be interesting in the post-COVID-19 era, as they will answer some of the current limits of

randomized controlled trials (i.e., which are lengthy, costly, logistically challenging, and not always representative of real-life treatments, Vincent, 2010) by reducing patient burden, streamlining operational execution, reducing the time of inclusion and recruitment, and focusing on real-life measurements.

In summary, the pandemic has amplified the need for the development of digital therapeutics that can deliver remote interventions and remote patient monitoring outside traditional healthcare settings. This crisis has also accelerated the digital transition of the health system and the world of research with the progressive implementation of hybrid or decentralized trials.

4. Challenges in the development and evaluation of digital interventions

4.1. The engagement crisis

At this time, one of the main limitations in digital interventions is the limited engagement rates observed (Karekla et al., 2019). Despite a certain willingness and curiosity from the general population to test eHealth and mHealth interventions as illustrated by the many downloads measured, usage is usually limited in time. Indeed, digital services or apps are generally subject to significant dropout rates, with a considerable sample of users not adhering as intended (Eysenbach, 2005; Hesser, 2020).

In their systematic review, Kelders et al. (2012) found that only 50% of participants engaged with the interventions in the manner desired by the designers (i.e., have used all the features offered), with estimates varying between 10-90% across studies. In the same idea, Meyerowitz-Katz et al. (2020) demonstrated that up to 80% of all participants in mHealth interventions only engage at a minimum level, do not log into the mHealth app more than once, and do not consistently use the app in the long term. In the physical activity domain, Bort-Roig et al.'s (2014) systematic review of smartphone-based interventions aimed to monitor and promote physical activity, the typical duration of use of the app ranged from 2 to 6 months across trials.

In addition to being observed in scientific studies, data from commercial apps seem to describe the same difficulty to engage users in the long haul. For instance, it has been estimated that 25% of health apps are only used once by each user, with less

than 10% of users returning to the app seven days after their first login session (Appboy, 2016). A recent survey of thousands of U.S. Americans revealed that individuals abandon their wearable 6 months after purchasing it (Endeavour, 2014). Another study that examined the use of mHealth applications in more comprehensive environments reported low retention rates, with only 3.9% of participants using mHealth apps for more than 15 days (Baumel et al., 2019). Finally, an analysis centered on a database of 37,000 apps data suggested that 21% of users abandon an app after one use and 71% of users are estimated to disengage within 90 days after onboarding (Localytics, 2018).

All of this data reveals a real struggle to engage participants within digital interventions over the long term, once the novelty wears off. We can therefore talk about a real crisis of engagement, which tends to be problematic as engagement is assumed to be essential to the effectiveness of digital interventions (Donkin et al., 2011; Yardley et al., 2016). As this research suggested the existence of a dose-response relationship or a minimum ‘effective dose’ needed to obtain a clinically meaningful effect of digital interventions, engagement is thus essential as it is positively associated with the intervention effectiveness. Edney et al. (2019) observed that engagement in a physical activity app was associated with increases in objective physical activity levels. In a recent meta-analysis evaluating the relationships between digital intervention engagement, physical activity, and sedentary behaviors, McLaughlin et al. (2021) found a small but positive association between digital engagement and physical activity (0.08, 95%CI [0.01-0.14]). Better understanding participants’ engagement in physical activity digital interventions appears therefore essential to maximize app retention and intervention effectiveness.

Hence, researchers in behavioral science, computer science, and human-computer interaction science had a growing interest in the conceptualization of the digital engagement. These different scientific fields having different objectives, backgrounds, and epistemologies, there is no real consensus or shared definition of the concept of engagement (Karekla et al., 2019; Perski et al., 2017). Whereas in the behavioral science literature engagement can be defined as the intervention usage (e.g., number of logins, time spent in frequency and duration, interaction with the modules), engagement is seen as the subjective experience of flow in computer science and human-computer interaction sciences (Perski et al., 2017). The flow is the ability of an activity to absorb and fully engage an individual in it (Csikszentmihalyi, 1990). It

occurs when the level of competence is perfectly adapted to the challenge and is characterized by focused attention and enjoyment. The flow theory (Csikszentmihalyi, 1990) belongs to the humanistic framework (see chapter 1).

In an effort to harmonize the fields' visions, Perski et al. (2017) proposed an integrative conceptualization of engagement with digital interventions (Figure 7). In their model, engagement is defined as a multidimensional construct directly or indirectly influenced by the context of use, the mechanisms of action, and the nature of the target behavior (suggesting the existence of a positive feedback loop between engagement and the behavior). Thus, there are both direct and indirect factors that can predict user engagement in a specific intervention.

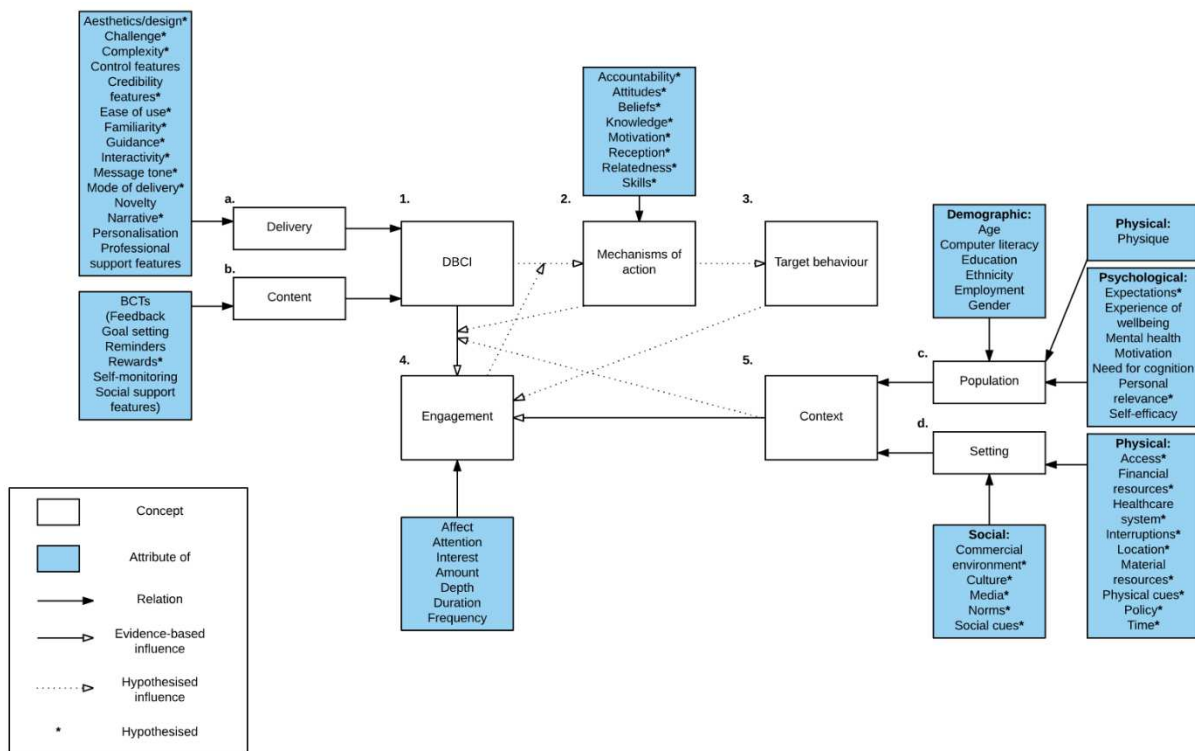


Figure 7. Conceptual framework of direct and indirect influences on engagement with digital behavior change interventions (reproduced from Perski et al., 2017)

We can then naturally ask how to improve adherence and engagement in digital interventions. Pratap et al. (2020) identified 4 factors that were significantly associated with increased participant retention in a cross-study evaluation of 100,000 participant app use data from 8 different studies. Their results suggested that the presence of a clinician referral led to an increase of 40 days in median retention time, the use of a monetary compensation for participation led to an increase of 22 days, the

congruence between the patient's clinical condition and the condition targeted by the intervention led to an increase of 7 days compared with controls, and older age of participants led to an increase of 4 days.

In parallel, in a recent systematic review exploring the factors influencing adherence to mHealth apps targeted for chronic diseases, Jakob et al. (2022) showed that 4 main intervention-related factors were positively associated with adherence, including personalization or tailoring of the content to the individual needs of the user, reminders in the form of individualized push notifications, user-friendly and technically stable app design, and personal support. They also found that social and gamification features enhanced app adherence across several health domains. Amagai et al. (2022) also suggested that gamifying mHealth apps and using reminders such as notifications and SMS text messages could be interesting affordances to enhance engagement in digital interventions. This idea was also endorsed by a systematic review published in 2017 (Looyestyn et al., 2017), in which the authors found that gamification is effective in increasing engagement in online programs.

4.2. The lack of use of behavior change theories in digital interventions development

In the early days of digital interventions, mobile apps, internet platforms, and connected objects designed to promote physical activity were rarely based on scientific knowledge (Cowan et al., 2012; Rabin & Bock, 2011). This can be explained by the fact that these products are widely developed in the private sector. On the one hand, private companies' development has many advantages, such as the ability to raise money from investors, key skills in design and development, expertise in market access, and tools for interoperability (e.g., application programming interfaces). If these abilities contributed to the acceleration and growth of the digital health field, the extent to which private companies incorporate clinical guidelines and evidence-based behavioral change theories in technology development seems to be low (Arigo et al., 2019).

Although some technologies integrate effective behavior change techniques, most only include a limited amount (McKay et al., 2019). For example, Conroy et al. (2014) evidenced that top-ranked commercial apps for physical activity released before

2014 do not contain a large amount of behavior change techniques – with fewer than 4 techniques in most of the cases examined. This represents an interesting marker of the lack of diversity in the behavior change strategies proposed by digital interventions. In the same approach but this time with apps designed for obesity and weight management, Nikolaou & Lean (2017) found that only 17 apps (0.05% of their sample) were developed with identifiable professional expertise. In a similar vein, studies of Pagoto et al. (2013) and Rivera et al. (2016) revealed that weight-loss mobile apps generally included only a minority of the behavioral strategies found in evidence-based weight-loss interventions.

The involvement of behavioral scientists in the product development of commercial apps is then insufficient. This tends to be problematic as, as we have seen in the first chapter of this manuscript, behavior change theories guide intervention development by lighting up the active ingredients and lever for change, and are therefore an essential basis to develop successful interventions. As a reminder, in their systematic review of 85 online interventions for health behavior change, Webb et al. (2010) found that more extensive use of theory was associated with increases in effect size and that interventions that incorporated more behavior change techniques also tended to have larger effects. Another review found that the use of relevant behavior change techniques significantly increased the success of weight loss programs (Hartmann-Boyce et al., 2014).

Naturally, some authors progressively argued that the reason some meta-analyses report a modest effect of digital interventions on physical activity is due to a lack of use of health behavior change theories (e.g., Patel et al., 2019). Guidelines and recommendations provided by the Consolidated Standards of Reporting Trials (CONSORT) statement (Eysenbach & Consort-ehealth Group, 2011) or the World Health Organization (Agarwal et al., 2016) have since emphasized the need to systematically use a theory-based approach in the development and reporting of digital interventions.

In order to reduce the gap between what is known about the determinants of behavior change and what is actually implemented in digital interventions, the first step would be to expand collaborations between the academic and industry worlds. Arigo et al. (2019) pointed out that “the digital health industry emerged with the shared goal of creating behavioral solutions for health, which presented an enormous and unprecedented opportunity for academic-industry collaboration”. Working on design

thinking involving developers, designers, marketers, clinicians, and behavioral scientists would let conceiving the implementation of behavioral change techniques within the digital product in an optimal way.

In a second step, the psychological mechanisms of digital interventions need to be more studied. Most studies evaluating digital interventions have not focused on the component techniques mobilized in interventions and thus, current theories struggle to explain how exactly eHealth and mHealth interventions for physical activity work (Aromatario et al., 2019; Romeo et al., 2021). This lack of interest in the underlying mechanisms of digital programs limits their comprehension and potential. The investigation of these elements in parallel with their effectiveness is thus crucial.

Finally, another perspective would be to use gamification techniques to facilitate the implementation of behavior change techniques. Indeed, several authors suggested that most gamification strategies can be mapped to established theories and behavior change techniques. For example, Cheek et al. (2015) proposed a coherent framework between gamification mechanics and the three basic psychological needs of self-determination theory. From another perspective, Cugelman (2013) mapped 27 behavior change techniques to the 7 most common gamification strategies, demonstrating that there were some interesting links and proximity between gamification principles and digital health behavior change science. This author added that gamification architecture was very similar to the structure of change theorized in the self-regulatory theory (Carver & Scheier, 2000), which is based on feedback loops. Therefore, these reflections suggest that if we rely on taxonomies of gamification elements, the implemented mechanics could easily match established behavior change strategies derived from models in health psychology.

4.3. Are digital interventions more effective and cost-effective than traditional interventions?

Another limitation of digital intervention is its incomplete evaluation at this time. The number of digital health tools rigorously evaluated in clinical trials is relatively low (Zhao et al., 2016). In 2017, only 0.18% of 325,000 published health apps on consumer platforms had undergone formative scientific evaluation (IQVIA Institute for Human Data Science, 2021). In the same idea, Rivera et al. (2016) remarked in their scoping review that, of the 393 identified apps destined to manage obesity and weight, only 3

(0.8%) underwent a scientific evaluation. Despite the proliferation of digital tools in the health market, there remains a lack of rigorous, high-quality evidence on the efficacy and effectiveness of such interventions.

This tends to be problematic as this calls into question the validity of apps regarding their effectiveness and safety (Rivera et al., 2016). Beyond all the apparent advantages associated with digital interventions previously mentioned, we can legitimately ask whether these interventions are truly effective and if so, whether they are superior to current treatments.

Although digital interventions have been extensively tested in comparison to passive or active control groups, no rigorous trial has yet demonstrated the superiority of digital physical activity interventions over existing ones (e.g., supervised physical activity programs). As an example, a systematic review (Muellmann et al., 2018) revealed that eHealth interventions were effective to promote physical activity in older adults aged >55 years but the results were inconclusive regarding the question of whether eHealth interventions had a greater impact on physical activity than non-eHealth interventions. Also, evidence regarding long-term effects was inconclusive too. This point is also critical as interventions that can change and sustain behavior change are needed. In addition, whereas digital programs appear economically advantageous compared with current programs, no evidence of cost-effectiveness has been demonstrated yet (Brown et al., 2021; Iribarren et al., 2017).

In this context, the digital health domain needs more rigorous evaluations and comparisons with usual care. The gold-standard evaluation method, namely the randomized controlled trial, can be helpful to evaluate the efficacy and effectiveness of digital health tools (van Beurden et al., 2019; Wunsch et al., 2020). However, evaluation processes must go further as there is the need to follow patients for longer times (to assess the long-term effects) and report both between-group differences in benefit and within-person evolutions (IQVIA Institute for Human Data Science, 2021; Kwasnicka et al., 2022). Within-person evaluations are needed in order to better assess individual longitudinal patterns and comprehend the key determinants allowing to tailor digital programs to patients' needs. As discussed in the first chapter of this thesis, conducting intensive longitudinal assessments to assess within-person evolutions and individual changes appears essential considering the idiosyncratic and dynamic nature of physical activity.

Moreover, as digital health tools must meet individual needs, it is a reasonable assumption that they must be adapted to individual needs in order to maximize their effectiveness (Kwasnicka et al., 2022). To this end, alternative assessment methods, such as N-of-1 trials, could be helpful. As digital health interventions are often expected to be evaluated in traditional parallel-arm randomized controlled trials by key stakeholders (e.g., funders, reviewers, and regulators, Kwasnicka et al., 2022), an integration of intensive longitudinal measures with N-of-1 methods within a randomized controlled trial could be interesting.

Finally, the evaluations should also include user-retention measures to determine the durability of the clinical effect, and cost-effectiveness analyses (e.g., cost-utility analysis comparing digital intervention versus standard of care) to test their economic pertinence in the healthcare system. In evaluating both effectiveness and cost-effectiveness, digital health intervention developers could provide evidence to policymakers and organizations on the comparison between these interventions and conventional delivery models (Michie et al., 2017). Furthermore, to better ensure rigorous evaluation, there is a concern for better reporting the content of digital interventions in sufficient detail to ensure adequate description of the technical components of the intervention and to ensure comparability, transparency, and reproducibility (Agarwal et al., 2016; Eysenbach & Consort-ehealth Group, 2011; Michie et al., 2017).

4.4. Are digital interventions adapted to all types of users?

One last question that we may ask is whether digital interventions are suitable for all types of users and patients. Before moving the healthcare system from face-to-face to a more technology-supported care, we must ensure this issue in order to avoid the introduction of new health inequalities, while one of the promises of digital interventions is to reduce them. If a patient does not have the knowledge, skills, or motivation to use digital health technologies this will naturally affect the observance and effectiveness of the intervention.

In this perspective, an essential construct to consider is digital health literacy, which is defined as: ‘the ability to seek, find, understand, appraise, and apply information from digital sources to manage and cope with health issues’ (Dunn &

Hazzard, 2019). A lack of digital health literacy has been associated with a lack of access to relevant health information, resulting in a lack of ability to use preventive digital health tools (Ehrari et al., 2022). Estacio et al. (2017) also found a strong association between health literacy, internet access, and use. They noticed that some socio-demographic variables (i.e., age, education, income, perceived health) were also associated with internet access.

The consideration of these socio-demographic variables in the development and evaluation of digital interventions appears essential. Despite the widespread adoption of digital technologies among the global population, it is important to notice that some populations remain poorly digitalized and digitally isolated. For example, in the UK, 79% of all digitally excluded people are aged 65 years or older, and more than half of people older than age 75 years do not use the internet regularly (Digital Inclusion Evidence Review, 2018). Through a survey-based study, Gordon & Hornbrook (2018) observed that the older people and some sub-groups (i.e., Black, Latino, and Filipino seniors) had less access to digital tools, less experience performing a variety of online tasks, and were less likely to believe that they would be capable of using it compared to younger and white seniors. In line with this data, recent research postulated that older adults may experience lower digital self-efficacy and computer anxiety than younger people (Koivisto & Malik, 2020; White et al., 2022). This lower digital self-efficacy, associated with the fact that older adults may take more time to learn new skills and systems, can be an additional barrier to the implementation of digital programs for the elderly.

The effects of digital interventions may also vary across individuals on the basis of their socio-economic status. The results of a recent meta-analysis (Western et al., 2021) suggested that digital interventions targeting physical activity would not have the same effects on people with low socioeconomic status compared to high socioeconomic status. For people with low socioeconomic status, the authors found no evidence that digital interventions were effective to promote physical activity, irrespective of the behavior change techniques used, whereas interventions in high socioeconomic status populations were significantly effective. The authors suggested that these divergent results may be explained by participants' digital literacy and that future research should focus on incorporating intervention components to facilitate the onboarding of participants and boost their eHealth literacy.

Based on the results of their systematic review, Stowell et al. (2018) provided several recommendations to improve mHealth tools destined for vulnerable groups. Their review highlighted that personalization of the content and gamification techniques were interesting usage facilitators and could serve as an entry point for participants with low digital literacy. In line with this idea, prior research has also concluded that digital gameplay can provide various benefits for older adults, especially in the health domain (Kaufman et al., 2016; Koivisto & Malik, 2020). However, in gamification research, most studies have been conducted with young adults and the impact of gamified interventions on other populations has been seldom evaluated (Koivisto & Malik, 2020; Stowell et al., 2018).

Summary Chapter 2

The widespread accessibility of new technologies and digital products holds great promise for improving behavior change and allows to develop precision medicine solutions. By their omnipresence in our lives, their relatively low-cost, their ability to access content anywhere quickly, and their capacity to collect real-time data in natural context, digital means allow for personalized, scalable, wide-reaching, and cost-effective interventions. They therefore have unique potential to overcome current face-to-face programs' limitations by delivering more effective and affordable solutions. However, to date, there is no clear scientific evidence of the superiority of such interventions. If digital interventions appear advantageous compared with current programs, no evidence of better effectiveness or cost-effectiveness has been demonstrated. In addition, there are concerns about the ability of digital programs to engage participants once the novelty wears off or to be effective on any type of audience regardless of their age, sociodemographic, or health status. Finally, digital interventions are not always evidence-based and the mechanisms underlying the effect of these programs are poorly understood. Addressing these research gaps and challenges will allow the deployment of scientifically validated digital therapeutics at large scale, with the promise to improve patients' health and healthcare.

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Interlude – Research Program

5. Research gaps and aims of the thesis

Considering the prevalence and growth of NCDs and the role of physical inactivity and excessive sedentary behavior in the development of these pathologies, there is an urgent need to promote daily-living light physical activity among inactive populations such as patients with NCDs. If interventions to reduce NCDs have been relatively successful in helping individuals make initial changes in health behaviors (Glasgow et al., 1999), current programs struggle to engage participants and promote long-term physical activity. In addition, the usual care in the treatment of NCDs composed of *in-person* face-to-face supervised physical activity is associated with several economic and organizational constraints for both patients and the healthcare system, which tend to limit the impact and generalization of these programs.

From this perspective, theoretical frameworks from health psychology are essential, as they create a context for understanding, explaining, and ultimately intervening upon physical activity. However, dominant models are not without limitations and we proposed in the first chapter of this thesis that thinking behavior change from a precision medicine perspective would help us better consider the environment and idiosyncratic personal attributes within physical activity programs. Also, proposing group-based interventions informed by the tenets of the social identity approach could be helpful to enhance engagement in physical activity programs and reduce stereotype-related barriers. In addition, we suggested that intensive longitudinal physical activity assessments could help better understand the impact of behavioral interventions during and after the program.

In this context, digital interventions hold great promise to foster behavior change and enhance the reach of physical activity programs. Digital means allow to passively record or track a rich range of psychological, social, and contextual variables that can be used to, at the same time, understand processes and outcomes of behavioral health interventions (Hekler et al., 2013) and propose new forms of intervention highly adaptative and deployable in real-world settings at a lower cost. Interestingly, these

technologies can 1) facilitate intensive longitudinal assessments in real-life contexts, and 2) connect participants within a program facilitating group-based interventions.

However, important caveats remain. To date there is no clear scientific evidence of the superiority of such interventions. If digital interventions appear advantageous compared with current programs, no evidence of better effectiveness or cost-effectiveness has been demonstrated. In addition, digital interventions are associated with a series of uncertainties. We can mention the difficulty to engage the individuals once the novelty wears off, the fact that digital programs may not be suited to every typology of user and could increase health inequalities. In addition, several authors have highlighted that these interventions are rarely based on theories of behavior change and their mechanisms poorly understood.

As proposed in the last sections, gamification appears as a promising solution to overcome these challenges by enhancing engagement, facilitating the implementation of behavior change techniques, supporting the adoption of digital interventions by populations with lower digital health literacy, and promoting long-term behavior change.

However, there is a current dearth of literature relating to the use of gamification to promote physical activity in healthcare settings. Early literature reviews on this topic revealed the existence of mixed results (Johnson et al., 2016; Koivisto & Hamari, 2019; Seaborn & Fels, 2015). More alarmingly, some authors observed that the effects were more nuanced when more rigorous experiments were conducted (Koivisto & Hamari, 2019). Thus, the effectiveness of gamified interventions to promote physical activity needs to be evaluated in further rigorous scientific studies.

Beyond the capacity of gamified interventions to increase physical activity in the short term, we may question the effectiveness of these programs once the novelty has worn off and when participants stop the intervention. To date, most of the gamified digital services investigated in the literature have been proven to yield solely short-term engagement through extrinsic rewards (Sardi et al., 2017). According to the self-determination theory, gamification techniques could potentially increase intrinsic motivation – by enhancing the pleasure related to the activity and fulfilling the needs for autonomy, competence, and relatedness – or reduce intrinsic motivation because external rewards such as gamified elements are known to reduce intrinsic motivation (Deci et al., 2001; Johnson et al., 2016; Zuckerman & Gal-Oz, 2014). Also, we may ask

if the nature of gamification techniques, which might be closely related to behavior change techniques, could promote long-term behavior adoption.

Finally, as to date most studies on gamification have been conducted among young adults (Koivisto & Malik, 2020), we may question the generalizability of gamified interventions: are gamification techniques adapted to any type of public regardless of their age or health condition? More globally, we need to pay attention to the determinants and settings that can explain engagement in gamified interventions. What are the users' characteristics, settings, and environment where the gamification takes place, and how do these variables interact with the intervention effect?

Therefore, the aim of this PhD was to provide some answers to these important questions notably by developing and evaluating the effectiveness of a digital intervention based on gamification to promote the physical activity of patients with NCDs. Thus, the research program proposed in this doctoral work aims to answer the following questions not yet explored in the literature:

- *Objective 1:* Is gamification effective to promote physical activity?
- *Objective 2:* Can eHealth and mHealth provide effective and reliable adapted physical activity care at a distance?
- *Objective 3:* Is a digital intervention more effective and cost-effective than the usual care in promoting physical activity among patients with NCDs?
- *Objective 4:* What are the moderating variables of these interventions?

6. Collaboration Academia/Industry

As highlighted in the last chapter, digital health research would benefit greatly from closer collaboration between academia and industry. According to Arigo et al. (2019), “some of the biggest challenges to realizing the potential of behavioral medicine in digital health arise from the fact that industry and academia are working in parallel, with very little collaboration”. This is problematic, as both parties have complementary skills and strengths that, if combined, would allow for the development of more robust and effective interventions with broader reach (Figure 8).

eHealth and mHealth development are associated with several constraints such as a high monetary and time cost (i.e., app development is estimated to require in average \$270,000 and between 7 and 12 months, Turner-McGrievy et al., 2017) and the need for a panoply of varied professional skills (ranging from theoretical and

engineering backgrounds for the research and development phase, information technology (IT) development, user experience (UX) and user interface (UI) design for the technological development and the iterative phase, marketing and medical background for the deployment of the solution). Moreover, health market access is highly regulated and health products must have demonstrated scientific evidence of efficacy and safety through rigorous evaluation to be considered for admission to the healthcare system.

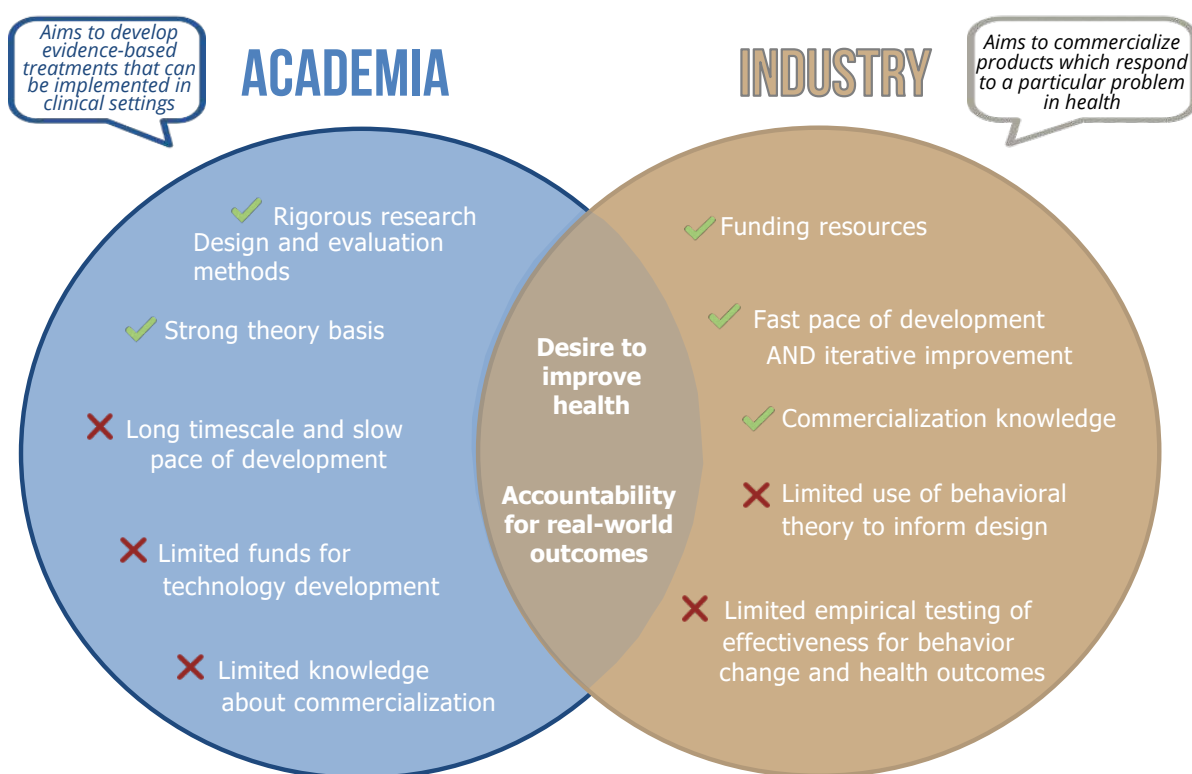


Figure 8. Strengths and weaknesses in digital health development in academia and industry sectors (adapted from Arigo et al., 2019)

While academic work is typically funded through research grants (Arigo et al., 2019), these budgets do not allow such investment and timescales, making it difficult for academic researchers to develop truly mature products. Additionally, researchers alone do not have the necessary professional competencies to meet the technical challenges of digital development. If the industry can more easily respond to these limitations through its ability to raise funds and recruit professionals with varied skills, private companies usually have limited theoretical knowledge and skills in rigorous evaluation methods, as opposed to academic researchers. We thus clearly see the need

to bridge the gap between academia and industry and call for more collaboration; and it is around this idea that this PhD thesis was built.

This PhD work was conducted in close collaboration with the Kiplin company, a health game publisher founded in 2014 in Nantes, France. Kiplin proposes digital interventions aimed to promote physical activity – especially via gamification principles – in primary prevention with programs deployed for employees within companies or in tertiary prevention within the context of health programs for patients with chronic diseases. During these three years of doctoral work, the aim of our collaboration was to 1) strengthen the theoretical basis of the solution by implementing scientific knowledge from behavioral medicine and health psychology disciplines, 2) contribute to the development of the solution modules, and 3) rigorously evaluate each module and then the full solution in order to improve its efficiency. This thesis was funded by the French National Association for Research and Technology (ANRT), which supports the development of academic/industry research partnerships.

7. Research program

Digital programs are complex interventions involving a myriad of different interconnected elements. To answer this issue, this PhD work followed an iterative development and incremental evaluation philosophy employing various experimental designs. Hence, the several modules which aim to compose the final Kiplin digital therapeutic were first developed and evaluated independently before being evaluated together within a randomized controlled trial.

Chapter 3 is composed of two studies aimed to answer the first and fourth objectives of this thesis. More particularly, they aimed to evaluate the effectiveness of gamified interventions on physical activity during the intervention and follow-up periods, test the generalizability to different publics and settings, and investigate potential moderators of the effect. To this end, we first conducted a systematic review and meta-analysis of randomized controlled trial to quantify the effect size of gamified interventions evaluated in previous studies (study 1). Informed by the results of this review, we conducted a retrospective analysis of 4800 participants who were proposed to perform a gamified intervention (study 2). The main purpose of this study was to test the effectiveness of a gamified intervention in real-life conditions. In this one, we conducted mixed-effect models in order to analyze the within-person evolution of

physical activity across time and between-person evolution across participants and nonparticipants. In addition, we examined the associations between intervention parameters, exposure to the intervention, participants' characteristics and settings, and the physical activity evolution. These two studies focused on the effect of gamification for both healthy and patients with chronic diseases.

Chapter 4 consists of two pilot studies aimed at evaluating two technological modules that have for objective to enable remote adapted physical activity programs and answer the questions raised in the second objective of this thesis. In study 3, we pilot-tested the effectiveness of a hybrid adapted physical activity program involving face-to-face sessions and telecoaching on physical activity, physical condition, and body composition of 20 patients with various chronic diseases. In a secondary analysis, we compared the results of this program to 100 similar patients who had benefited from the usual care (i.e., in-person supervised physical activity program). Study 4 aimed to assess the validity and reliability of an app-based medical device to propose remote physical condition tests. In a pre-clinic study, 53 healthy participants performed the 6-meter walking test and the 30-second-sit-to-stand test with this app, in three different sessions, in order to evaluate the test-retest reproducibility and the correspondence of the medical device measures in comparison to gold standard measures.

Finally, we conducted a randomized controlled trial which aimed to provide evidence to answer all the objectives but more specifically to answer objectives 3 and 4 of this thesis. The main purpose of this clinical trial was to test the effectiveness of group-based digital intervention – including gamification and telecoaching, enhanced by social features, and informed by the tenets of the self-determination theory and the social identity approach – among patients with obesity and type 2 diabetes in comparison to the usual care. In order to try to answer the various limits mentioned in the first part of this thesis, this trial included intensive longitudinal assessment of physical activity, both between-group differences in benefit and within-person evolutions analyses, user-retention measures, cost-effectiveness analyses, and psychological measures. Study 5 introduces the background, objectives, and study design of this tow-arm parallel randomized controlled trial whereas study 6 reveals the preliminary results.

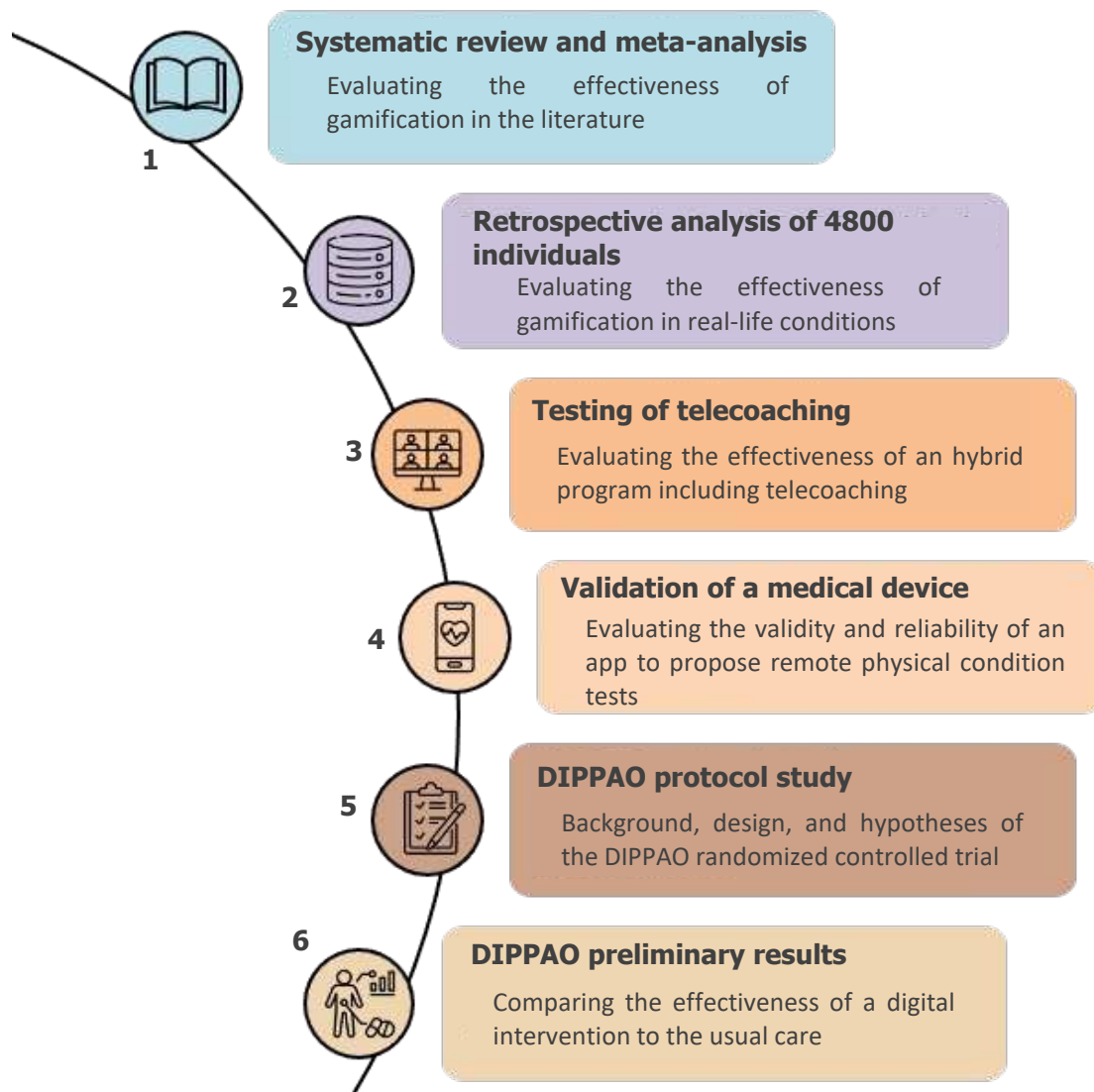


Figure 9. Overview of the different studies of the thesis with their main objective.

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PART II

Personal contributions

Chapter 3

Gamification: a way to catalyze behavior change

Since its introduction in 2008, the concept of gamification has increasingly gained attention and has been adopted by practitioners and researchers in various domains such as workplace, education, marketing, and healthcare. As introduced earlier, the potential of gamification lies in the restructuring of daily tasks and activities with game elements and gameful affordances and appears as an interesting way of promoting daily physical activity.

Nevertheless, an examination of the literature revealed numerous inconsistent results with gamification use. Several authors argued that these mixed results were the consequence of a lack of adequate methodological rigor (such as sample size selection and controlled experimental research methods). In this context, conducting a meta-analysis appears as timely, as there are now enough randomized controlled trials (considered as the “gold standard” of experimental design) to conduct such an analysis. However, the question of the generalization of the results in real-life contexts (i.e., outside the controlled environment of scientific studies) may also be discussed.

The two studies presented in this chapter are part of this process and aim to evaluate the effectiveness and generalizability of gamification to promote physical activity.

8. Study 1: evaluating the effectiveness of gamification on physical activity: systematic review and meta-analysis of randomized controlled trials

Published in Journal of Medical Internet Research:

Mazeas A, Duclos M, Pereira B, Chalabaev A. Evaluating the Effectiveness of Gamification on Physical Activity: Systematic Review and Meta-analysis of Randomized Controlled Trials. J Med Internet Res. 2022 Jan 4;24(1):e26779. doi: 10.2196/26779. PMID: 34982715.

Review

Evaluating the Effectiveness of Gamification on Physical Activity: Systematic Review and Meta-analysis of Randomized Controlled Trials

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Abstract

Background: Gamification refers to the use of game elements in nongame contexts. The use of gamification to change behaviors and promote physical activity (PA) is a promising avenue for tackling the global physical inactivity pandemic and the current prevalence of chronic diseases. However, there is no evidence of the effectiveness of gamified interventions with the existence of mixed results in the literature.

Objective: The aim of this systematic review and meta-analysis is to evaluate the effectiveness of gamified interventions and their health care potential by testing the generalizability and sustainability of their influence on PA and sedentary behavior.

Methods: A total of 5 electronic databases (PubMed, Embase, Scopus, Web of Science, and the Cochrane Central Register of Controlled Trials) were searched for randomized controlled trials published in English from 2010 to 2020. Eligibility criteria were based on the components of the participants, interventions, comparators, and outcomes framework. Studies were included when they used gamified interventions in daily life with an active or inactive control group and when they assessed a PA or sedentary behavior outcome. We conducted meta-analyses using a random-effects model approach. Sensitivity analyses, influence analyses, and publication bias analyses were performed to examine the robustness of our results.

Results: The main meta-analysis performed on 16 studies and 2407 participants revealed a small to medium summary effect of gamified interventions on PA behavior (Hedges $g=0.42$, 95% CI 0.14-0.69). No statistical difference among different subgroups (adults vs adolescents and healthy participants vs adults with chronic diseases) and no interaction effects with moderators such as age, gender, or BMI were found, suggesting good generalizability of gamified interventions to different user populations. The effect was statistically significant when gamified interventions were compared with inactive control groups, such as waiting lists (Hedges $g=0.58$, 95% CI 0.08-1.07), and active control groups that included a nongamified PA intervention (Hedges $g=0.23$, 95% CI 0.05-0.41). This suggests that gamified interventions are not only efficient in changing behavior but also more effective compared with other behavioral interventions. The long-term effect (measured with follow-up averaging 14 weeks after the end of the intervention) was weaker, with a very small to small effect (Hedges $g=0.15$, 95% CI 0.07-0.23).

Conclusions: This meta-analysis confirms that gamified interventions are promising for promoting PA in various populations. Additional analyses revealed that this effect persists after the follow-up period, suggesting that it is not just a novelty effect caused by the playful nature of gamification, and that gamified products appear effective compared with equivalent nongamified PA interventions. Future rigorous trials are required to confirm these findings.

KEYWORDS

behavior change; eHealth; gamification; health behavior; intervention; meta-analysis; mobile phone; physical activity; systematic review

Introduction

Background

Physical inactivity and sedentary behavior (SB) are among the leading risk factors for global mortality [1]. Each year, physical inactivity is responsible for >5 million deaths worldwide [2]. In contrast, regular physical activity (PA) prevents the risk of developing chronic diseases [3,4], limits their progression [5,6], and reduces early mortality [7]. In parallel, there is a dose-response relationship between total sedentary time per day and overall mortality [7]. Meta-analyses demonstrate that the risk of mortality in adults increases steadily with a sedentary lifestyle of >3 hours per day and more significantly when this time exceeds 7 hours per day [8]. However, recent studies have suggested that high levels of PA could attenuate or even eliminate the deleterious effects of SB on overall mortality [9].

In this context, it is urgent to develop interventions that can effectively change PA. Therefore, digital health interventions constitute a new opportunity to take care of patients by involving them in their treatment in a dynamic and interactive way. Gamification is a promising avenue to capitalize on the efficacy of digital interventions. Gamification is defined as the use of game design elements in nongame contexts [10]. By integrating game mechanisms in interventions that are initially devoid of them, the purpose of gamification is to integrate into daily life the ingredients that make games enjoyable to motivate participants to engage in PA [11]. The use of *motivational affordances* created by gamification can influence psychological (eg, motivation, attitude, and enjoyment) and physical outcomes (eg, physical capacities) [12] and therefore appears as a potentially powerful technique for behavior change.

By gamifying PA, participants are encouraged to move and walk to play, which tends to make their activities more enjoyable and playful [13]. Unlike serious games, which refer to the use of a full-fledged video game for educational or health purposes (ie, a video game in its entirety as opposed to selected elements or individual features of a game) [10] and require a dedicated time, a location, and implementation [14], gamification techniques are relatively open to varying situational modes of engagement [10] and concern instead global PA in all aspects of daily life (eg, walking, running, or gardening). Gamification is made possible by mobile technologies and wearable devices that can track and collect daily activities in a continuous and web-based manner. This allows for intervening directly on the lifestyle of individuals without adding material or time constraints for the participants.

However, several literature reviews [13,15,16] have reported inconsistent results concerning the use of gamification in behavioral interventions, with some studies demonstrating positive effects and other studies providing more mixed effects. These reviews also emphasized the lack of high-quality studies

and highlighted the need for more rigorous trials to isolate the impact of gamification (ie, randomized controlled trials [RCTs]). Importantly, Koivisto and Hamari [15] suggested that the effects of gamification could be smaller when using rigorous experimentation. In sum, these reviews indicate that there is no clear evidence of the effectiveness of gamified interventions. Nevertheless, no meta-analysis has been conducted yet. Quantifying the effect size of gamified interventions and identifying moderators of this effect would provide important information about the effectiveness of such interventions. Moreover, a meta-analysis appears as timely, as there are now enough RCTs to conduct such an analysis.

This Study

This study is the first to quantify the effects of gamified interventions on PA. Beyond the effect during or just after the intervention, we also seek to evaluate the long-term effects to determine the health relevance of these interventions. Indeed, we reasoned that to be considered effective, gamification must sustain its impacts over the long term and offer more than a short-term novelty effect [11]. The generalizability of gamification to different user populations is also a major issue because it would determine whether gamification can be introduced in health care settings with patients or it is more suited in prevention for healthy audiences.

The objectives of this systematic review and meta-analysis are to answer these research gaps by (1) evaluating the effect of gamified interventions on PA and SB, (2) assessing the long-term or sustained effects of gamified programs, and (3) evaluating the generalizability of gamification across different populations.

Methods

Design

This review was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [17]. Following recommendations to minimize bias and provide evidence of a priori analysis intentions [18], the study was preregistered under the international prospective register of systematic reviews (PROSPERO; registration number: CRD42020186882) and on the Open Science Framework (OSF) [19]. Moreover, all materials and data are available on the OSF page of the project to facilitate reproducibility and transparency of this review [20].

Search Strategy and Information Sources

We conducted a systematic literature search using five electronic databases: PubMed, Embase, Scopus, Web of Science, and the Cochrane Central Register of Controlled Trials. We combined alternate terms and keywords representing synonyms for the outcomes (PA or SB), intervention (gamification), device (eHealth), and trial (see Table S1 in [Multimedia Appendix 1](#)

[21-36] for an overview of the terms used). The search strategy was reviewed by an academic librarian. All databases were searched individually from January 1, 2010 (2010 being the date of the widespread adoption of the term *gamification* [10]), to December 31, 2020, and the research was restricted to English-language texts. The complete search equations for all databases are available in [Multimedia Appendix 1](#). In addition, we complemented our search with reference harvesting from the included studies and overview articles.

Eligibility Criteria

Studies were eligible for inclusion if they were RCTs and if they met other criteria based on the participants, interventions, comparators, and outcomes framework.

Participants

This review focused on the general population regardless of age, gender, or health status (ie, patients with chronic diseases were also included). We excluded studies involving participants with contraindications to PA or with diseases preventing them from engaging in PA or understanding the principles of the game (intellectual and cognitive impairments).

Intervention

Digital interventions targeting PA or SB and incorporating game elements and gamification techniques, such as points, levels, rewards, leaderboards, narratives, and teams, were of interest. We clearly distinguished between gamification and related constructs, such as serious games. Therefore, we excluded interventions based on active video games (ie, electronic games that allow players to physically play with the images on screen) that are more comparable with serious games than with gamified products.

Comparators

Studies that attempted to compare gamified interventions with control groups without gamification elements in a randomized design were integrated in the review. These groups could be either inactive (nonexposed control group, such as a waiting list) or active (another nongamified intervention).

Outcomes

In this review, we included studies assessing change in total PA or leisure PA (quantity in metabolic equivalent of task [MET] hour per week or MET minute per week or in duration, energy expenditure [METs], moderate to vigorous PA [MVPA], step count, walking time, and active minutes) and change in time spent in SB (total time, leisure time, work, time spent in front of the computer, and time spent in front of television). These outcomes were continuous data either objectively measured (through accelerometers, pedometers, and smartphones) or subjectively measured by self-reported questionnaires. Data measured objectively were always prioritized in the analyses over self-reported questionnaires, which are more susceptible to bias with a potential overestimation of PA [37].

In addition, studies were excluded if they came from a review, commentary, or conference abstract; if they included data previously published in another study; if they were not

randomized and controlled; if they were not written in English; and if they were published before 2010.

Screening

In total, 2 authors (AM and AC) independently screened the titles and abstracts resulting from the search. Full texts of the potential included studies were checked before inclusion. Disagreements were resolved by discussion or by consulting a third author (MD), and agreement was measured using the κ statistic. A complete list of excluded studies is available on the OSF page of the project.

Data Extraction

In the data collection process, AM and AC extracted data independently and were blinded to each other using a predetermined and tested template. Disagreements were resolved by discussion or consultation with a third author (MD). Extracted data included the results of each study and three types of potential moderators:

1. Population-level moderators to assess the generalizability of the intervention (population characteristics, age, gender, and pathology).
2. Intervention-level moderators to better understand gamification mechanisms (theoretical model used to develop the intervention, gamification elements, and modality of the intervention [eg, internet-based, smartphone app, and presence of social incentives]).
3. Outcome-level moderators (outcomes, measure of PA or SB, and device).

Risk of Bias Assessment

For each eligible study, 2 reviewers (AM and AC) assessed the risk of bias using the purpose-built Cochrane risk of bias tool (Table 8.5 in the Cochrane Handbook for Systematic Reviews of Interventions [38]), which evaluates 7 domains (sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other risk of bias). A judgment of the potential risk of bias was made from the extracted information and rated as *high risk*, *low risk*, or *unclear* if the related information was not available. These evaluations of bias are reported in the review and included in the analysis, and a measure of agreement with the κ statistic was calculated. After the full assessment, we decided not to present the item *blinding of participants and personnel* in the review because it was similar for all studies, which were rated as *high risk*, blinding being unfeasible for this kind of intervention.

Data Synthesis and Statistical Analyses

First, data were synthesized in a qualitative review assessing the key elements of the studies and highlighting intervention differences. This qualitative review integrates all studies that met the eligibility criteria, including those for which we were unable to extract the data.

For the quantitative analysis, means and SDs of continuous PA or SB outcomes from individual studies were compiled when available or estimated using the method by Hozo et al [39] when median and IQR were reported. When the necessary data were not available in the original article, we first requested them from

the authors. If data could not be obtained, we extracted them from the graphs when available. If this was not possible, we excluded the study from the quantitative analysis.

A global meta-analysis was conducted to obtain a summary effect. In addition, when sufficient data were available (ie, 4 studies or more reporting an outcome), we conducted different meta-analyses for each specific outcome (steps, MVPA, and time in SB) and for the follow-up effect. To address the nonindependence of data caused by study effect, random-effects models [40] were preferred to the usual statistical tests. In addition, the Hartung–Knapp–Sidik–Jonkman method was used to reduce the production of false positives inherent to the DerSimonian–Laird method [41] and to obtain more robust estimates of variance. Continuous outcomes were analyzed using standardized mean difference (SMD) to account for different measurement instruments or mean difference (MD) when the measurements were close enough. We computed Hedges g [42] for effect sizes, which is similar to Cohen d but corrects for small sample bias, which are recurrent in the studies included. Thus, a Hedges g of 0.2 represents a small effect; 0.5, a moderate effect; and 0.8, a large effect [43]. We computed SMDs for outcome scores after the intervention (presented in the review) and change-from-baseline outcomes. Scores on postintervention effect sizes refer to treatment group results compared with the control group results after interventions. Change-from-baseline score effect sizes were calculated as a comparison between the treatment group pre–post effect size and control group pre–post effect size.

For studies that included multiple outcomes, we kept in the main analysis the primary outcome targeted in the initial article. If none of the PA outcomes reported by a study were the primary ones, we selected the one that was the most relevant from the perspective of the intervention and the original experiment. In designs with multiple time measurements, the assessment that was the most proximal to the end of the intervention was conserved. A time assessment had to be performed >2 weeks after the end of the intervention to be included in the follow-up analysis. When studies included multiple intervention groups with gamification features, they were combined into one group following the formulae recommended by the Cochrane Handbook [38]. Studies including multiple control groups could be integrated into different subgroup analyses if they compared their gamified intervention to both an active and an inactive control group.

Statistical heterogeneity was tested using forest plots and the I^2 statistic, which is the most common metric for measuring the magnitude of between-study heterogeneity and is easily interpretable (0%-40% might not be important, 30%-60% may represent moderate heterogeneity, 50%-90% may represent substantial heterogeneity, and 75%-100% may represent considerable heterogeneity) [44]. We conducted different influential analyses to address between-study heterogeneity. We first explored the presence of outliers, defined as studies with CIs that do not overlap with the CI of the summary effect.

We also performed leave-one-out analyses, which recalculated the summary effect several times, with 1 study omitted each time. Finally, we performed a Baujat plot [45], which is a diagnostic plot to detect sources of heterogeneity in the meta-analysis by comparing the contribution of each trial in the pooled effect with the overall Cochran Q test for heterogeneity.

We applied different methods to detect publication bias (funnel plot, Egger regression test [46], and Duval and Tweedie trim-and-fill procedure [47]). In addition, another approach to determine the evidential value of studies included in the analysis is to check the statistical power of individual studies. Therefore, we performed a sunset funnel plot [48], which is a funnel plot variant that visualizes the statistical power of each study included in the meta-analysis based on the summary effect size.

Thus, sensitivity analyses were conducted to address studies with a high risk of bias or a strong heterogeneity in the sample or studies identified as outliers. Subgroup analyses were conducted to explore possible sources of heterogeneity and test for population differences. Therefore, we conducted tests for subgroup differences using a random-effects model. In addition, moderation analyses were performed to explore the impact of potential explanatory variables and moderators on the effect size with meta-regressions when sufficient data were available (ie, at least 10 studies for each explanatory variable [38]). The results were expressed as regression coefficient estimates, 95% CIs, and P values.

For crossover trials, we first checked whether carry-over or period effects were problematic in the original texts of studies. For cluster randomized trials, we checked if the influence of the different clusters was not too important, analyzing the values of the intraclass correlation coefficient in the studies. Then, in the absence of sufficient information in the published articles, we addressed these studies as traditional parallel trials. Nevertheless, this procedure increased the probability of a unit of analysis error. Therefore, we performed sensitivity analyses without clusters and crossover trials to test the robustness of our results.

A summary of the analytical procedure is available in [Multimedia Appendix 1](#) (Figure S1). Analyses were performed on R (The R Project for Statistical Computing) using the *dmatar* package [49]. Risk of bias summary and risk of bias graphs were made via the *robvis* R package [50].

Results

Characteristics of Included Studies

We screened the titles and abstracts of 1626 articles, and 51 full-text articles were assessed for eligibility according to the inclusion criteria. Finally, 18 articles [21-36,51,52] were included in the qualitative analysis and 16 were included in the meta-analysis (Figure 1). The κ value of agreement for the screening phase was 0.64 between the 2 authors, reflecting good agreement [53].

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) flowchart of the literature search and screening process. PA: physical activity; RCT: randomized controlled trial.

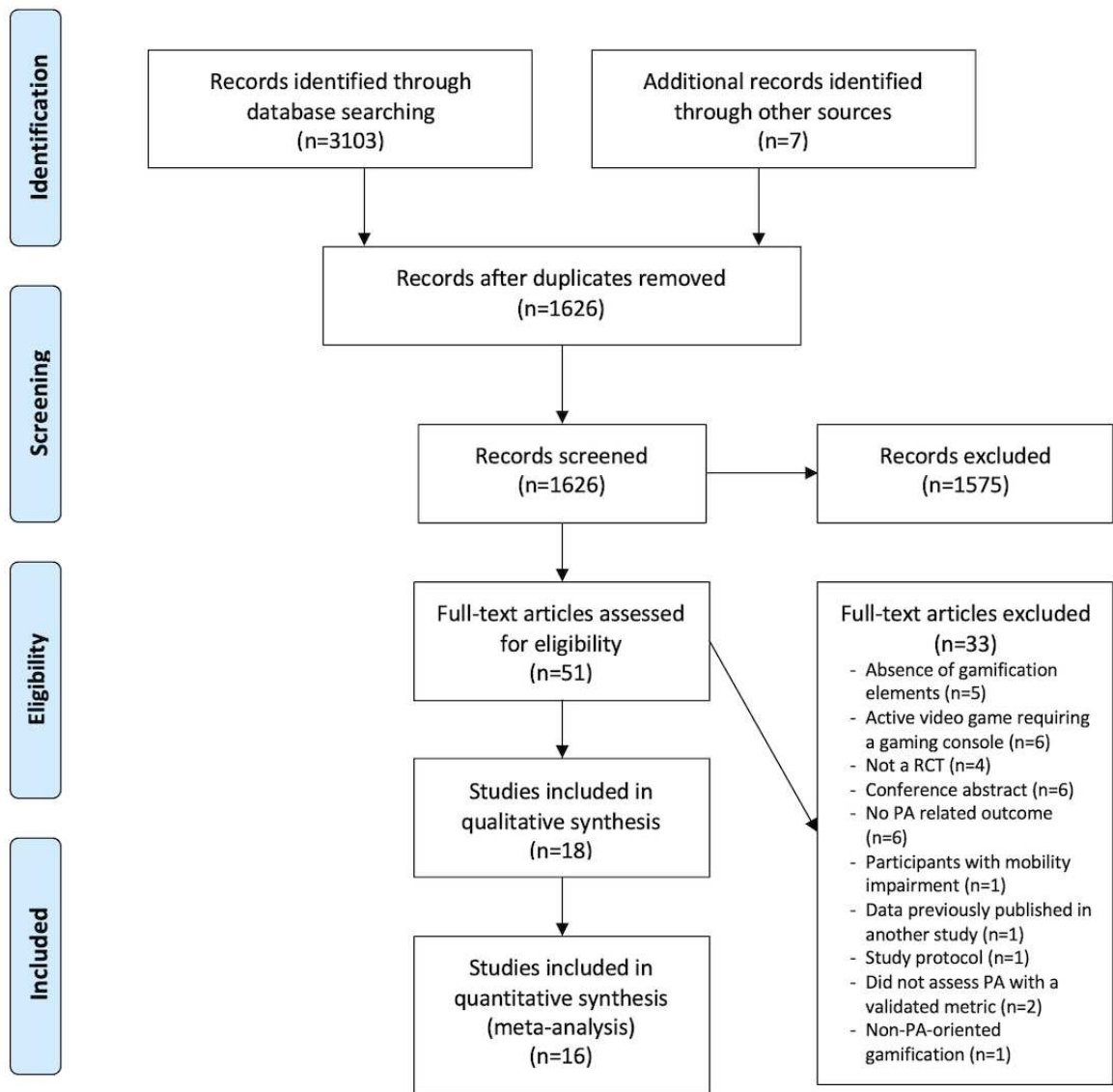


Table 1 provides an overview of the characteristics of the included studies. The 16 studies included in the quantitative analysis involved 2407 participants aged 9-73 years (mean 35.7 years, SD 17.2 years), with sample sizes ranging from 20 to 602. Overall, 67% (12/18) of studies included adult participants [22,24-30,32,34-36] and 33% (6/18) of studies included adolescents (ie, <18 years [21,23,31,33,51,52]). A total of 22% (4/18) of studies included patients with chronic diseases (ie, obesity [27,36], type 2 diabetes [35], and cardiovascular disease [28]).

A total of 6 trials were conducted in Europe; 4 in the United States; 3 in Australia and New Zealand; 3 in Canada; and 2 in Asia. Studies were published between 2014 and 2020, with 39% (7/18) published after 2018.

Most studies were based on a smartphone app (n=10; [23,28,30-35,51,52]), web-based (n=3; [21,24,29]), or both

(n=4; [22,26,27,36]). Nishiwaki et al [25] used a pedometer with computerized game functions. The duration of the intervention varied from 1 to 24 weeks, with a mean of 11.8 weeks, and the most common length was 24 weeks. The most used game mechanics were internet-based rewards, such as badges, medals, or trophies (13/18, 72%; [21,22,24,26-28,30,32,33,35,36,51,52]), teams or leagues (13/18, 72%; [21-24,26,27,29,32-34,36,51,52]), levels (9/18, 50%; [22,26,27,29,33,35,36,51,52]), points or scores (7/18, 39%; [22,26,27,29,30,35,36]), or the presence of a leaderboard (7/18, 39%; [22,29,30,33,34,51,52]). Almost all studies included social incentives such as team collaboration, social networking, and messaging facilities in their intervention (15/18, 83%; all except Nishiwaki et al [25], Direito et al [31], and Höchsmann et al [35]).

Table 1. Characteristics of included studies.

Study	Participants	Intervention	Theory	PA ^a outcomes
Corepal et al [21] ^b	Adolescents, n=224 (aged 12-14 years; 47% male participants)	The “StepSmart Challenge” was a web-based intervention that used gamification strategies to encourage and support PA behavior change; duration: 22 weeks	SDT ^c	Daily step count and MVPA ^d (min/day) objectively measured (Actigraph GT3x)
Dadaczynski et al [22] ^b	Adult workers in an automobile manufacture, n=144 (65% male participants)	“Healingo Fit” had the objective to promote low levels of PA using a tracking-based approach measuring PA with a Fitbit pedometer and a gamified intervention accessible by desktop and mobile devices; duration: 6 weeks	SCT ^e , TPB ^f , and health action process approach	Self-reported VPA ^g , MPA ^h , and minutes walked (min/week; IPAQ ⁱ)
Direito et al [31] ^b	Adolescents, n=35 (mean age 15.7 years, SD 1.2 years; 45% male participants; BMI 22.85)	“Zombies, run! 5K Training app” was a fully automated training program designed to improve fitness, combined with an immersing and fun story; duration: 8 weeks	SDT	MVPA, VPA, MPA, and LPA ^j and sedentary time (min/day) objectively measured (Actigraph GT3x) and self-reported PA (PAQ-A ^k)
Edney et al [32] ^b	Adults, n=284 (mean age 41.2 years, SD 11.2 years; 25% male participants; BMI 30.1)	“Active Team” was a mobile app designed to encourage inactive adults to meet PA guidelines. Gamification and social features were implemented to increase the social comparison, support, and influence among participants; duration: 12 weeks	SCT	MVPA (min/day) objectively measured (GENEActiv) and self-reported PA (Active Australia Survey)
Garde et al [51]	Adolescents, n=47 (mean age 10.3 years, SD 1.9 years; 34% male participants; BMI z-score 0.35)	“MobileKids Monster Manor” was a mobile exergame synchronized with an external activity monitor. The overall goal was to complete the story with PA and steps; duration: 1 week	SDT	Daily step count and active min/day objectively measured (Tractivity)
Garde et al [33] ^b	Adolescents, n=56 (mean age 11.3 years, SD 1.2 years; 62% male participants; BMI z-score 0.28)	“MobileKids Monster Manor” was a mobile exergame synchronized with an external activity monitor. The overall goal was to complete the story with PA and steps; duration: 1 week	SDT	Daily step count and active min/day objectively measured (Tractivity)
Garde et al [52]	Adolescents, n=37 (mean age 10.6 years, SD 0.5 years; 43% male participants; BMI z-score 0.21)	“MobileKids Monster Manor” was a mobile exergame synchronized with an external activity monitor. The overall goal was to complete the story with PA and steps; duration: 2 weeks	SDT	Daily step count and active min/day objectively measured (Tractivity)
Gremaud et al [34] ^b	Adult office workers, n=144 (mean age 40.5 years, SD 11.4 years; 76% male participants; BMI 29.7)	“MapTrek” was a mobile health platform that gamified Fitbit use for promoting PA by placing users in a series of internet-based walking races; duration: 10 weeks	SCT	Daily step count and daily active minutes count objectively measured (Fitbit Zip activity monitor)
Höchsmann et al [35] ^b	Patients with type 2 diabetes mellitus and obesity, n=35 (mean age 58.5 years; 53% male participants; BMI 32)	The intervention was a mobile app including a storyline, virtual rewards, individualized exercises, and daily PA promotion through a game; duration: 24 weeks	Taxonomy of behavior change techniques	Daily step count objectively measured (Garmin Vivofit 2)
Kurtzman et al [36] ^b	Adults with obesity, n=196 (mean age 41.4 years, SD 12.2 years; 13% male participants; BMI 36.2)	Participants were in teams of 2 and had to complete weekly goal targets to win points and badges; duration: 24 weeks	Behavioral economics	Mean step count objectively measured (Withings wrist-worn device)
Leinonen et al [23] ^b	Adolescents, n=496 (mean age 17.8 years, SD 0.6 years; 100% male participants; BMI 23.1)	The intervention was an app proposing a mixed-reality conquering game in which physical and social activities are rewarded; duration: 24 weeks	Transtheoretical model	Daily MVPA and daily sedentary time objectively measured (Polar Active)

Study	Participants	Intervention	Theory	PA ^a outcomes
Maheer et al [24] ^b	Adults, n=110 (mean age 35.6 years, SD 12.4 years; 42% male participants)	“Active Team” was a Facebook (Meta Platforms) app designed to encourage inactive adults to meet PA guidelines. Gamification and social features were implemented to increase the social comparison, support, and influence among participants; duration: 8 weeks	TPB	Self-reported MVPA, VPA, MPA, and minutes walked (min/week; Active Australia Survey)
Nishiwaki et al [25] ^b	Adults, n=20 (mean age 31 years, SD 3 years; 30% male participants; BMI 21.5)	Participants wore an activity monitor with computerized game functions, such as a story, a character, and objectives; duration: 6 weeks	— ¹	Daily step count and MVPA (metabolic equivalent of tasks hour/day) objectively measured (Lifecorder EX)
Patel et al [26] ^b	Adults, n=200 (mean age 55.9 years, SD 9.9 years; 44% male participants; BMI 27.1)	Participants were entered into a game with their family in teams and had to complete weekly goal targets to win points and badges; duration: 12 weeks	Behavioral economics	Daily step count objectively measured (Withings wrist-worn device)
Patel et al [27] ^b	Adults with overweight and obesity, n=602 (mean age 38.7 years, SD 10.4 years; 69% male participants; BMI 29.6)	Participants had to complete weekly goal targets to win points and levels. There were 3 versions of the intervention: support, collaboration, and competition; duration: 24 weeks	Behavioral economics	Daily step count objectively measured (Withings wrist-worn device)
Paul et al [28] ^b	Patients who survived stroke, n=23 (mean age 55.8 years, SD 10.7 years; 48% male participants; BMI 24.5)	In the “STARFISH” app, participants had to complete their PA objectives to improve their avatar; duration: 6 weeks	Control theory and Michie taxonomy of behavior change	Daily step count, sedentary time, and walking time (min/week) objectively measured (ActivPAL)
Thorsteinsen et al [29] ^b	Adults, n=21 (mean age 55.3 years, SD 11.2 years; 52% male participants)	The intervention “Lifestyle Tool” consisted of a rule-based website designed to help people plan and monitor their PA. The tool incorporated social and individual gaming components to increase motivation and engagement; duration: 12 weeks	—	Self-reported weekly activity minutes (daily report form)
Zuckerman and Gal-Oz [30] ^b	Students, n=59 (mean age 23.4 years, SD 1.4 years; 25% male participants)	“StepByStep” was an accelerometer-based mobile app with virtual rewards and social comparison intended to motivate people to incorporate more walking into their daily routine; duration: 1.5 week	SDT	Walking time (min/day) objectively measured (smart-phone accelerometer)

^aPA: physical activity.

^bThe studies included in the meta-analysis.

^cSDT: self-determination theory.

^dMVPA: moderate to vigorous physical activity.

^eSCT: sociocognitive theory.

^fTPB: theory of planned behavior.

^gVPA: vigorous physical activity.

^hMPA: moderate physical activity.

ⁱIPAQ: International Physical Activity Questionnaire.

^jLPA: light physical activity.

^kPAQ-A: Physical Activity Questionnaire for Adolescents.

^lNo theory mentioned.

Studies comparing gamified interventions with active control groups used a similar intervention without game elements (ie, an equivalent nongamified app [30–32] or a self-monitoring intervention with wearables or activity monitors [25–27,34,36]).

In most studies, the interventions were based on theoretical models. A total of 6 studies [21,30,31,33,51,52] were based on the self-determination theory [54]; 5 [22–24,32,34] on sociocognitive models (ie, the transtheoretical model [55], the

social cognitive theory [56], the theory of planned behavior [57], and the health action process approach [58]); and 3 [26,27,36] on behavioral economics models.

Outcomes measured in trials were diverse: they used either total PA duration or MVPA duration, SB duration, daily step count, walking duration, or active minute count. A total of 13 experiments measured PA objectively using devices such as triaxial accelerometers (n=7; [21,28,31–33,51,52]), wearable

devices for the general population (ie, Fitbit, Garmin, Polar, and Withings monitors; $n=6$; [23,26,27,34-36]), pedometers ($n=1$; [25]), or smartphones ($n=1$; [30]), and 5 assessed PA with self-reported measures (International Physical Activity Questionnaire [22], Physical Activity Questionnaire for Adolescents [31], Active Australian Survey [24,32], or other [29]). A total of 6 trials [21,24,26,27,32,36] completed a follow-up assessment from 12 to 30 weeks (mean 14.4 weeks) after the end of the intervention.

A total of 2 studies [51,52] were excluded from the meta-analysis and were only integrated in the qualitative review because we were unable to extract their results.

Risk of Bias

The 2 authors extracted the risk of bias data with a κ coefficient of 0.79, which is synonymous with excellent agreement [53]. Multimedia Appendices 2 [21-36] and 3 present the authors' judgments about each risk of bias item presented as percentages across all included studies in the meta-analysis and an overview of the different biases for each study. Overall, 1 study [28] was rated as high risk for sequence generation because assignments were based on recruitment order. Therefore, this study was also at a high risk for allocation concealment. A total of 3 studies [24,29,30] were at high risk of bias for the *blinding of outcome assessment* item because they measured PA using only

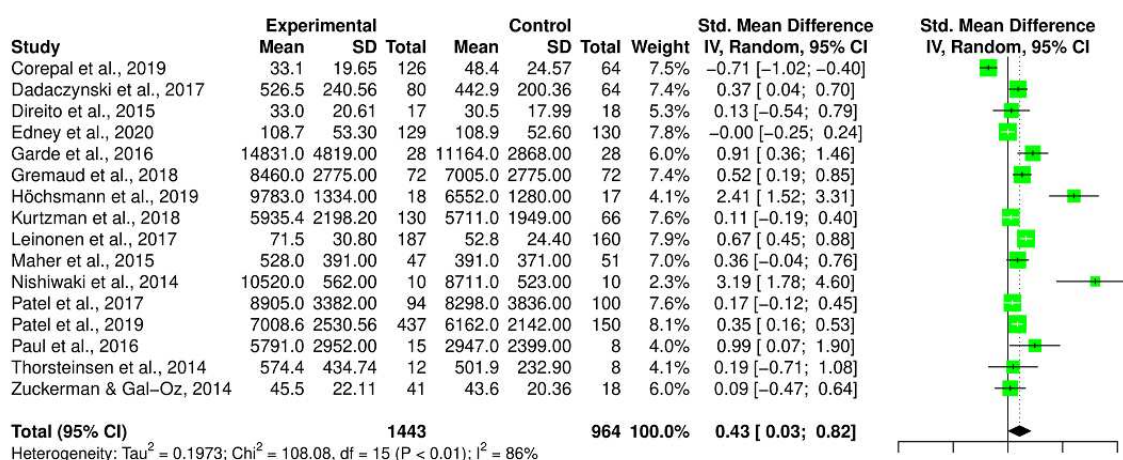
self-reports. In total, 5 studies [23,29,30,49,52] were at high risk of bias for the *incomplete outcome data* item because they reported high dropout rates and did not include intention-to-treat analyses and 5 studies [25,28,29,31,52] were rated at unclear risk for the *selective outcome reporting* item because they had not been preregistered or published in a protocol-study. Finally, 2 studies had other high risks of bias. The first one [25] was a crossover trial conducted without a washout condition, and the other one [21] was a cluster randomized trial with no control of clustering, no consideration of the clustering in the statistical analysis, and no test of baseline differences among groups.

Summary Effect

Overall, the SMD after the intervention for all PA outcomes (MVPA, daily step count, number of active minutes, and walking time) was a Hedges g of 0.43 (95% CI 0.03-0.82; $I^2=86\%$; Figure 2), representing a statistically significant small to medium effect. Similarly, we found a statistically significant SMD effect of a Hedges g of 0.38 (95% CI 0.07-0.69; $I^2=79\%$) for pre-post change scores.

Only 3 studies [23,28,31] assessed sedentary time as an outcome. Owing to this small sample size, the meta-analysis was not performed on this outcome.

Figure 2. Forest plot for the effect of gamification versus control on postintervention physical activity outcomes (moderate to vigorous physical activity, daily step count, number of active minutes, and walking time). Tau-square, chi-square, and I^2 measures of between-study heterogeneity [21-36]. IV: inverse variance.



Outliers and Influential Analyses

In the first analysis, substantial statistical heterogeneity was observed. To address between-study heterogeneity, we first looked for the presence of outliers. A total of 3 studies were considered as outliers [21,25,35], and after removing them, we still obtained a significant effect of a Hedges g of 0.34 (95% CI 0.17-0.51) with moderate heterogeneity ($I^2=58\%$).

Leave-one-out analyses showed that sequential removal of each study did not have an important impact on the general effect size, with effect sizes ranging from a Hedges g of 0.33 (95% CI 0.00-0.66; $I^2=84\%$) to a Hedges g of 0.48 (95% CI 0.13-0.83; $I^2=78\%$; Figure S2 in Multimedia Appendix 1).

The Baujat plot (Figure S3 in Multimedia Appendix 1) shows that 4 studies explained more heterogeneity than the others, more specifically, the study by Corepal et al [21] with a heterogeneity contribution of 40.13 and an effect size influence of 3.27.

Therefore, we excluded studies with a high or unclear risk of bias. After doing so, the effect was not significant (Hedges $g=0.33$, 95% CI -0.16 to 0.81; $I^2=78\%$).

The inclusion of crossover and cluster randomized trials in the meta-analysis may lead to biases. Thus, we excluded these designs from the analysis and obtained a statistically significant effect of $g=0.49$ (95% CI 0.05-0.92; $I^2=67\%$).

Finally, we decided to exclude articles by Corepal et al [21] and Nishiwaki et al [25] in the sensitivity analyses (which have been repeated afterward for each analysis) considering their influence on the pooled result, their contribution to overall heterogeneity, and their huge risk of bias (no control of clustering, no statistical consideration of clustering, and no test of baseline differences among groups in the study by Corepal et al [21] and no washout period and very low power for the study by Nishiwaki et al [25]). After doing so, we obtained a statistically significant effect of a Hedges g of 0.42 (95% CI 0.14-0.69; $I^2=74\%$).

Subgroup Analyses

We found no statistical differences in the effects between studies with participants with chronic diseases or healthy participants (Cochran $Q=0.73$; $P=.39$), between adults and adolescents (Cochran $Q=0.26$; $P=.61$), between studies with objective (devices) or self-reported PA outcomes (Cochran $Q=0.23$; $P=.63$), between active or inactive control groups (Cochran $Q=0.01$; $P=.92$), and between short- and long-term interventions (less or more than 12 weeks; Cochran $Q=0.60$; $P=.44$).

When performing the sensitivity analysis, there was a statistically significant effect of intervention on PA in adults (Hedges $g=0.36$, 95% CI 0.03-0.69; $I^2=71\%$; Figure S4 in Multimedia Appendix 1), on healthy people (Hedges $g=0.35$, 95% CI 0.15-0.55; $I^2=63\%$; Figure S5 in Multimedia Appendix 1), when the PA measure was objective (Hedges $g=0.45$, 95% CI 0.08-0.82; $I^2=80\%$; Figure S6 in Multimedia Appendix 1), when the PA measure was self-reported (Hedges $g=0.24$, 95% CI 0.08-0.39; $I^2=0\%$; Figure S6 in Multimedia Appendix 1), and for short interventions of <12 weeks (equivalent to a 3-month program; Hedges $g=0.44$, 95% CI 0.19-0.69; $I^2=16\%$; Figure S7 in Multimedia Appendix 1).

Moreover, subgroup analyses allowed us to examine the effect of gamified interventions when compared with inactive control groups and active control groups. After sensitivity analyses, we found a statistically significant effect of gamified interventions,

both when compared with inactive control groups (Hedges $g=0.58$, 95% CI 0.08-1.07; $I^2=81\%$; Figure S8 in Multimedia Appendix 1) and when compared with active control groups (Hedges $g=0.23$, 95% CI 0.05-0.41; $I^2=37\%$; Figure S8 in Multimedia Appendix 1).

Meta-Regressions

The age of participants ($\beta=.01$, 95% CI -0.02 to 0.04 ; $P=.39$), their gender ($\beta=.01$, 95% CI -0.01 to 0.02 ; $P=.47$), their BMI ($\beta=.04$, 95% CI -0.16 to 0.09 ; $P=.53$), the duration of the intervention ($\beta=-.01$, 95% CI -0.06 to 0.04 ; $P=.74$), or the number of game mechanics included in the intervention ($\beta=.01$, 95% CI -0.17 to 0.19 ; $P=.91$) were not statistically significantly associated with an increase in PA.

Lack of data precluded further meta-regressions, such as comparisons of leisure PA, or test of moderators, such as the impact of social incentives or the theoretical model used to develop the intervention.

Publication Bias

First, an inspection of the funnel plot showed that the effect sizes of individual studies were relatively symmetrically distributed around the pooled effect size. This observation was supported by the Egger test of the intercept, which indicated no asymmetry in the funnel plot ($b_0=1.38$, 95% CI -0.83 to 4.77 ; $P=.19$). We then applied a bias-correction technique, the trim-and-fill method, which indicated that 3 studies were missing at the bottom left of the funnel plot to obtain a full symmetry. After imputing the effect sizes corresponding of these missing studies to obtain a totally symmetrical funnel plot (Figure 3), the bias corrected summary effect was of a Hedges g of 0.24 (95% CI -0.24 to 0.73).

Finally, the sunset funnel plot (Figure 4) showed significant differences in power among studies, with some characterized by very low statistical power (7 studies under 45% power and 4 studies under 18%). The median power of all the tests was 63%.

Figure 3. Funnel plot after trim-and-fill bias correction. A filled circle represents an included study, and an empty circle represents a missing study.

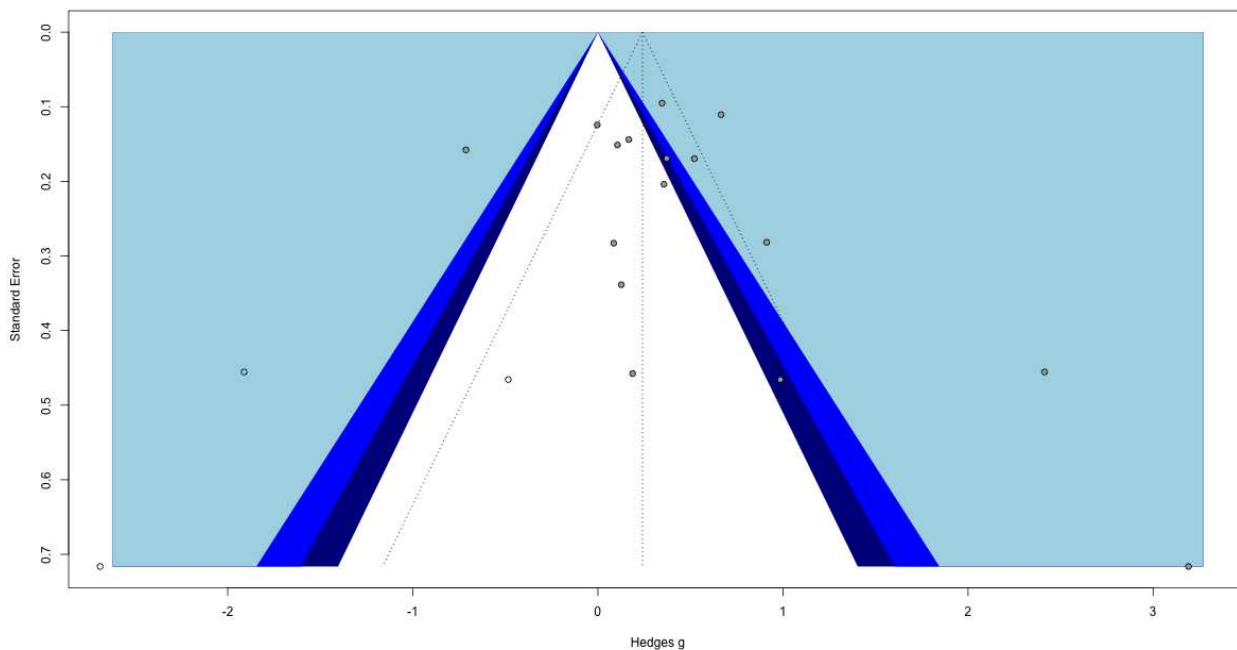
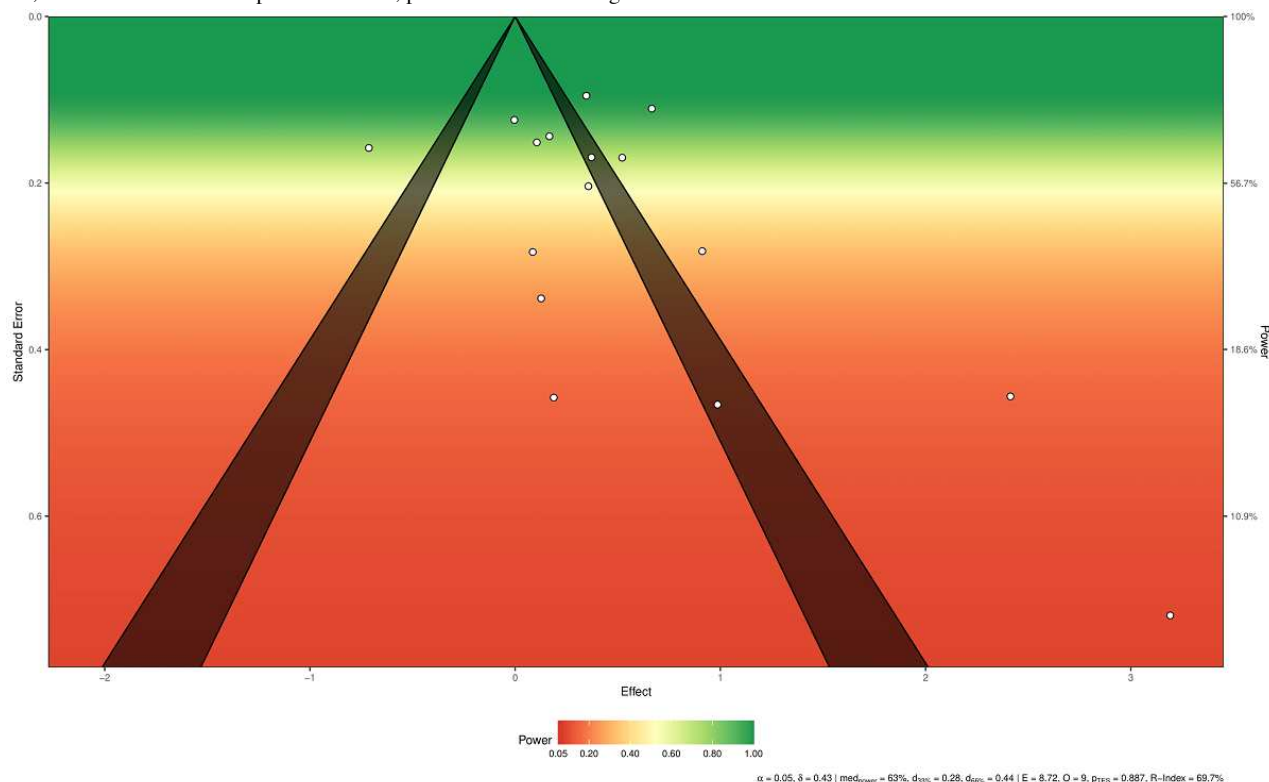


Figure 4. Power-enhanced funnel plot. White circles represent included studies. δ : true effect size; medpower: the median power of all tests; d33%: effect size needed for achieving 33% of median power; d66%: effect size needed for achieving 66% of median power; E: expected number of positive studies; O: observed number of positive studies; pTES: test of excess significance P value.



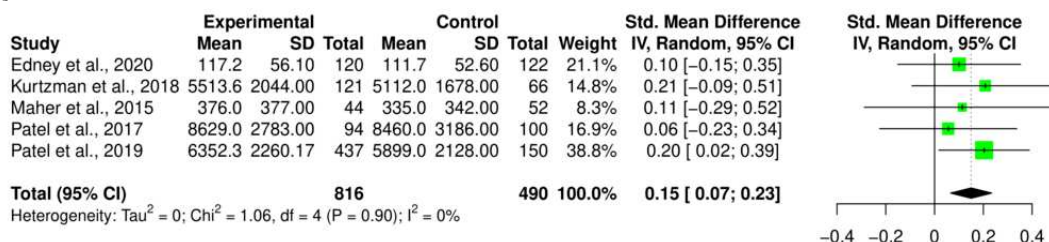
Secondary Analyses

Follow-up

There was no statistically significant effect of gamified interventions on total PA (MVPA and daily step count) after

follow-up periods with an SMD of a Hedges g of 0.09 (95% CI -0.07 to 0.26 ; $I^2=21\%$). When we performed the sensitivity analysis, gamification significantly increased PA (MVPA and daily step count) at follow-up (from 12 to 24 weeks after the end of the intervention; $g=0.15$, 95% CI 0.07 - 0.23 ; $I^2=0\%$; Figure 5).

Figure 5. Forest plot for the effect of gamification versus control on PA outcomes (moderate to vigorous physical activity and daily step count) after a follow-up period (from 12 to 24 weeks after the end of the intervention). Tau-square, chi-square, and I^2 measures of between-study heterogeneity [24,26,27,32,36]. IV: inverse variance.



Steps

We found no statistically significant effect of gamified interventions on step outcomes with an SMD of a Hedges g of 0.53 (95% CI -0.09 to 1.15; $I^2=89\%$), but a significant improvement in the number of daily steps with an MD of +1420.57 steps per day (95% CI 435.41-2405.73; $I^2=95\%$) was

observed. When excluding the 2 studies in the sensitivity analysis, we obtained a statistically significant effect of gamification on daily steps of a Hedges g of 0.49 (95% CI 0.05-0.93; $I^2=75\%$; Figure 6) and a statistically significant MD of +1609.56 steps per day (95% CI 372.39-2846.73; $I^2=86\%$; Figure 7).

Figure 6. Forest plot for the effect of gamification versus control on steps outcomes (daily step count and walking time). Tau-square, chi-square, and I^2 measures of between-study heterogeneity [22,26-28,30,33-36]. IV: inverse variance.

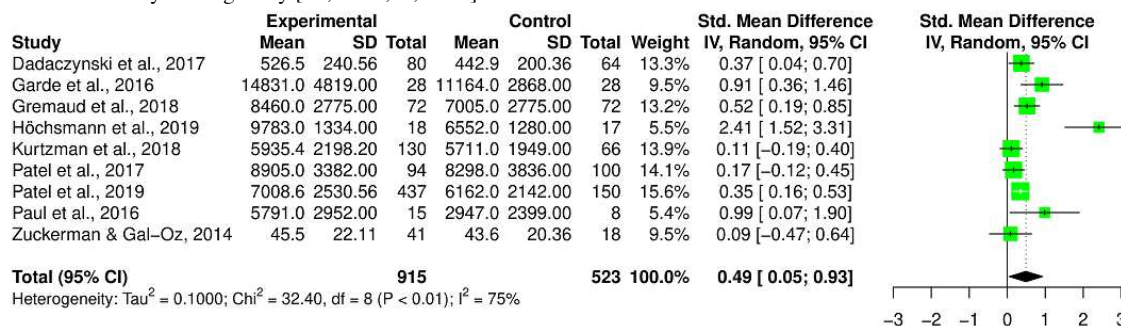
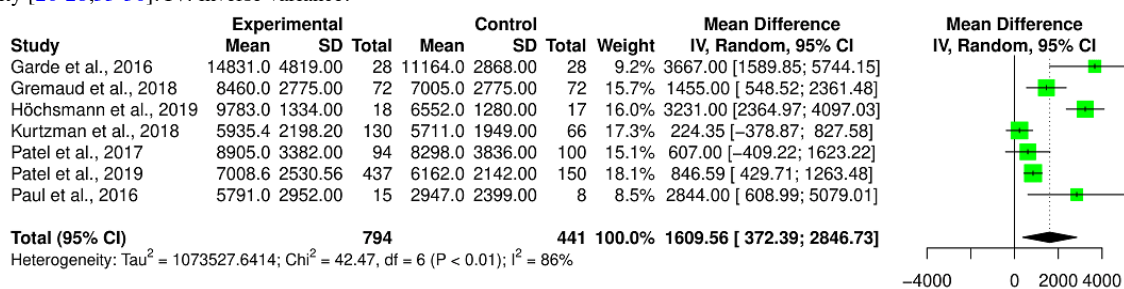


Figure 7. Forest plot for the mean difference of daily steps between gamification and control. Tau-square, chi-square, and I^2 measures of between-study heterogeneity [26-28,33-36]. IV: inverse variance.

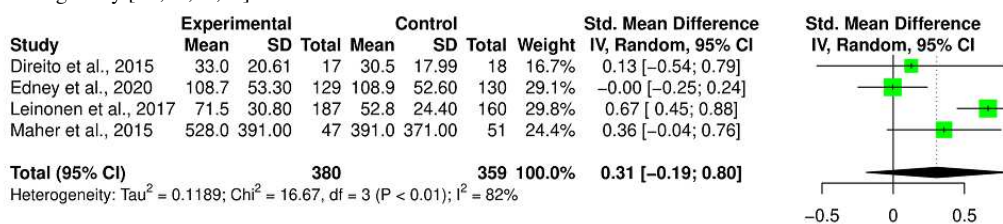


Moderate to Vigorous PA

There was no statistically significant effect of gamification on MVPA with an SMD of a Hedges g of 0.09 (95% CI -0.57 to

0.74; $I^2=93\%$). There was no statistically significant effect of a Hedges g of 0.31 (95% CI -0.19 to 0.80; $I^2=82\%$) in the sensitivity analysis (Figure 8).

Figure 8. Forest plot for the effect of gamification versus control on moderate to vigorous physical activity. Tau-square, chi-square, and I^2 measures of between-study heterogeneity [23,24,31,32]. IV: inverse variance.



Summary of Findings (Grading of Recommendations Assessment, Development, and Evaluation)

The quality of evidence (grading of recommendations assessment, development, and evaluation, [GRADE]) in the included studies after sensitivity analyses for short-term PA, long-term PA, MVPA, steps, and daily steps was scored from

high to low (Table 2). The quality was downgraded for some outcomes because of high heterogeneity, high risk of bias, or imprecision owing to large CIs. Summaries of the various meta-analysis conducted in this review both on postintervention scores and pre–post intervention change scores are presented in Multimedia Appendix 1 (Figures S9-S11).

Table 2. Summary of findings.

Outcome	Number of participants (number of studies)	Standardized mean difference or mean difference (95% CI)	Quality of evidence (grading of recommendations assessment, development, and evaluation)
General PA ^a	2197 (14)	0.42 (0.14 to 0.69)	Low ^{b,c,d}
General PA (in comparison with active control groups)	1485 (7)	0.23 (0.05 to 0.41)	High
Long-term PA (follow-up)	1306 (5)	0.15 (0.07 to 0.23)	High
MVPA ^e	739 (4)	0.31 (–0.19 to 0.80)	Low ^{b,c,d}
Steps	1438 (9)	0.49 (0.05 to 0.93)	Low ^{b,c,d}
Daily steps	1235 (7)	1609.56 (372.39 to 2846.73)	Moderate ^{b,d}

^aPA: physical activity.
^bDowngraded because of high heterogeneity.
^cDowngraded because of risks of bias.
^dDowngraded because of imprecision (large CIs).
^eMVPA: moderate to vigorous physical activity.

Discussion

Principal Findings

Summary Effect

This meta-analysis of RCTs, including 16 studies and 2407 participants, revealed a statistically significant effect of gamified interventions, on average, of 12 weeks on total PA (Hedges $g=0.42$, 95% CI 0.14-0.69 after sensitivity analyses). This effect was small to medium, suggesting the effectiveness of gamified interventions in promoting PA in both healthy participants and participants with chronic diseases. This significant effect was robust, as it persisted even after the different influence analyses were performed. Moreover, the effect was statistically significant both for objective measures of PA (Hedges $g=0.45$, 95% CI 0.08-0.82) and self-reported measures (Hedges $g=0.24$, 95% CI 0.08-0.39) after sensitivity analyses. Unsurprisingly, subgroup analyses revealed after sensitivity analyses that the effect of gamified interventions is greater when compared with inactive control groups (such as waiting lists) than when compared with active control groups benefiting from a nongamified intervention (Hedges $g=0.58$, 95% CI 0.08-1.07 vs Hedges $g=0.23$, 95% CI 0.05-0.41). Nevertheless, these effects were both statistically significant. This suggests that gamified interventions are not only efficient in changing behavior but also, to a lesser extent, effective compared with equivalent nongamified PA interventions (such as smartphone apps or self-monitoring interventions). These results are important considering the assets of gamification, which has the advantages of (1) reorganizing existing activity rather than adding additional demands to people’s lives [13], (2) being easily implemented in natural contexts, and (3) having a broad

accessibility through technology and advancing sensors, permitting to address a large population.

Long-term Effect

When we analyzed the long-term effect of these interventions based on the follow-up measures of PA, carried out from 12 to 24 weeks (mean 14.4 weeks) after the end of the intervention, we found a statistically significant very small to small effect size of a Hedges g of 0.15 (95% CI 0.07-0.23) after sensitivity analyses. These results indicate that the effect of gamification persists after the end of the program, suggesting that it is not just a novelty effect due to the playful nature of gamification. However, this long-term effect was weaker and decreased with time after the end of the intervention.

Generalizability of Gamified Interventions

The absence of subgroup differences or effects of age, gender, and BMI on the pooled effect suggests a good generalizability of gamified interventions, which can be used for several types of populations. Thus, gamification may not only be efficient in young healthy individuals but can also target any kind of population regardless of their age or health status.

In sum, gamified interventions appear as an efficient tool to improve the PA of various populations, with moderate superiority over other similar interventions, such as mobile health monitoring apps, and a moderate sustainability of the effect after the intervention. Nevertheless, if many PA interventions increase PA levels in the short term, translating these temporary changes into long-term PA participation continues to be a challenge for PA research [59]. With that in mind, the potential of gamification for PA increases in the long

term, even minimal, is particularly important and promising in the area of PA interventions.

Additional Findings

Effect of Gamification on the Step Count

If the overall effect of gamified interventions on PA is positive, they increase the step count more than MVPA. Indeed, after sensitivity analyses, on the one hand, the meta-analyses revealed a statistically significant effect (Hedges $g=0.49$, 95% CI 0.05-0.93) of gamification for steps outcomes, with a statistically significant improvement of 1609.56 steps per day (95% CI 372.39-2846.73) for participants benefiting from gamified intervention versus those in the control group. On the other hand, no statistically significant effect of gamified interventions on MVPA was found (Hedges $g=0.31$, 95% CI -0.19 to 0.80). This can be explained by the game metrics and mechanics of the interventions included in the review, which are mainly focused on the step count of participants. Few interventions directly targeted MVPA. In the included studies, only 2 interventions [31,35] integrated multi-PA intensity goals and mechanics, notably with physical exercises or running sessions in the game. In other words, participants played most of the time with their number of steps and had to generally walk more to make points and play the game. This results in an increase in walking time but not necessarily in more intense PA.

These findings are interesting considering the potential health benefits of increasing the number of daily steps by 1600 because of gamification. Indeed, previous work showed that walking was statistically associated with decline in all-cause and cardiovascular mortality [60-63] and an improvement in body composition [64]. Moreover, Oja et al [62] suggested that any walking exposure is beneficial for cardiovascular health, endorsing the idea that the most important is more global PA regardless of the intensity [7,65] even when this activity only includes walking [60]. In comparison, a previous study evaluating the effectiveness of activity trackers with and without incentives to increase PA [66] showed a significant improvement of 1050 daily steps for the cash incentive intervention versus the control intervention (95% CI 600-1490) but no statistically significant difference for the Fitbit-only group (340 daily steps, 95% CI -100 to 790). In light of these results, gamified interventions appear as an added value compared with current interventions. Considering that 40% of the volunteers in this study abandoned their Fitbit monitor within 6 months, gamification is also a way to keep participants involved and motivated within the intervention.

Duration of Intervention

Our meta-regression analysis did not find an association between the observed effect of gamification on PA and intervention length. However, although no statistically significant effect of gamification for an intervention length of ≥ 12 weeks was found (Hedges $g=0.41$, 95% CI -0.19 to 1.01), the meta-analysis revealed a statistically significant effect of gamified interventions of <12 weeks on global PA (Hedges $g=0.44$, 95% CI 0.19-0.69). According to a previous meta-analysis that reported significant positive effects of smartphone apps on PA only when used over a short-term period of <3 months [67],

these results suggest that a condensed intervention could benefit more than a longer one, which could become redundant, boring, and exhausting for participants in the long run.

Statistical Heterogeneity

The meta-analysis also revealed considerable statistical heterogeneity. This heterogeneity may be explained by differences in study quality, diversity of designs, and variations in study populations. Despite several subgroup analyses, we cannot rule out that these subgroups and characteristics may not explain all the variance of the interventions. Indeed, demographic data often do not fully explain the differences in the effectiveness of interventions [68,69], and more precise sociopsychological variables such as personality traits or motivational factors could explain this poorly understood significant heterogeneity. Moreover, the risk of bias analysis and the sunset funnel plot showed substantial differences in the quality of the included studies that can influence the heterogeneity. Finally, various trial designs were used (ie, parallel RCT, cluster RCT, and crossover RCT) that can also contribute to the overall statistical heterogeneity.

Better Understanding Gamification Mechanisms

This meta-analysis is informative regarding the effectiveness of gamified interventions. In view of the observed heterogeneity, the next step will be to investigate its causes from an interventional and theoretical perspective. Gamified interventions involve multiple interacting elements, and it is crucial to estimate the weight of each element in the behavior change process and how they interact with each other. Is it game mechanics, the implementation of behavior change techniques, or the presence of social interactions that make gamification effective? Unfortunately, the small number of studies included in the meta-analysis impeded us from conducting in-depth moderation analyses to answer this question. To better understand these relations, it is essential that both the development and assessment of gamified interventions be central, transparent, evidence-based, context-aware, and research-oriented [70]. Moreover, if theoretical psychological models are often mentioned in the introduction of articles included in the review (Table 1), few have investigated the psychological mechanisms of their interventions in the field [22,31,71]. Future studies should explicitly discuss motivational theory and systematically test the effect of gamification on psychological outcomes known to be involved in behavior change (eg, self-efficacy, attitudes, and intention) to better understand its mechanisms. The consideration of personality traits and psychological variables to determine behavioral phenotypes [68] is a promising way to evaluate participant's responses to the interventions.

Perspectives for Future Research and Implications for Practice

The findings from this meta-analysis allow us to draw and discuss future work concerning the gamification of PA and SB. First, future trials should be conducted with more adequately powered sample sizes and should be strictly multiple arms-RCTs to isolate the effects of gamification elements and better understand gamification mechanisms. Second, the

long-term effects are currently the main challenge of health interventions. Thus, it is essential to investigate the evolution of the effects of gamified interventions over time. Therefore, there is a need for more long-term follow-up measurements. In addition, the potentialities of digital technologies and their capacity to collect a large amount of real-world data could be used to assess the evolution patterns of the effect, allowing the detailed identification of its sustainability and evolvement or even make forecasts via time series analyses. Third, to our knowledge, only 1 team of researchers worked on a gamified intervention targeting SB by introducing sedentary breaks as a gaming part [72]. Following this line of research, it could be interesting to develop gamified interventions affording participants to take more sedentary breaks. Finally, the cost-effectiveness ratio of gamified interventions may be better than that of many current interventions, considering the ease of implementation and generalizability of gamification. However, this assertion will have to be tested in future trials, including economic analyses.

In light of our results, gamified interventions appear to be a promising avenue to promote PA in different populations both in prevention in healthy people and in the treatment of chronic diseases. Gamified interventions have many benefits for participants with chronic diseases, such as empowerment of participants by improving their self-management skills, an effect across broad audiences enabling to target different types of pathologies, and an everyday life fit and easy implementation. Similar to other digital health processes, gamification makes it possible to address more patients, especially those who are isolated from health care facilities. Importantly, gamified interventions are especially pertinent during a health pandemic, such as the COVID-19 outbreak, in which PAs and social interactions are restricted because of lockdown or teleworking and where structured PA possibilities are limited both indoors and outdoors. Gamifying walking and daily activities is, in this context, a great way to improve PA and limit SB of individuals in addition to providing social interaction among players. In the meantime, the face-to-face management of chronic diseases is usually suspended during the pandemic, which underlines the importance of offering remote supervision of PA.

Nevertheless, in view of the weaker postintervention effect, this study suggests that a one-shot intervention is not sufficient. A more interesting design would be to address multiple *gamification doses* during or after the course of treatment to

obtain a sustainable implementation of the PA behavior. This configuration would also provide an ideal duration of intervention to avoid exhausting the participants with gamified interventions for >12 weeks.

Strengths and Limitations

To our knowledge, this is the first meta-analysis to quantitatively evaluate the effects of gamification on PA. This review has several other strengths. First, we conducted a comprehensive search strategy using multiple databases in collaboration with an academic librarian. Second, all stages of the review (screening and data extraction) were independently realized by 2 reviewers. Finally, various novel publication bias analyses and influence analyses were conducted in parallel with different subgroup analyses and meta-regressions.

However, some limitations of this work must be mentioned. Overall, the meta-analysis included a small number of studies, and some articles were feasibility or pilot trials. Therefore, several trials included small sample sizes and were highly underpowered. Some studies were conducted with a high risk of bias. One of the main limitations of this work is the impossibility of demonstrating that the effect of gamified interventions is led by gamification itself given the lack of research examining this question. Finally, in the main analysis, we included diverse PA outcomes evaluating similar constructs but which are slightly different in practice. Moreover, not all included outcomes were objectively measured. As the field matures and new trials are published, an update of this work will be important to confirm these preliminary results.

Conclusions

To conclude, gamified interventions appear to be a promising avenue for promoting PA in various populations. Influencing primarily the number of daily steps of the participants, gamification is an interesting way to improve daily PA and appears more efficient than equivalent nongamified interventions, such as mobile health apps. However, if the effect of gamification persists during follow-up, suggesting that gamified interventions are more than a novelty effect, this effect decreases with time with a smaller long-term effect. The integration of gamification in more global health care interventions could be a way to address this limited sustainability. Future rigorous trials are required to explore these perspectives.

Acknowledgments

The authors would like to thank the librarian at Clermont Auvergne University (Nathalie Pinol) for assistance in developing the search equations. The work of AM is supported by a grant from the French National Association for Research and Technology (Cifre PhD thesis) and by the company Kiplin. None of the sponsors were involved in any other aspect of the project, such as the design of the project's protocol and analysis plan, collection, and analyses. The funders had no input on the interpretation or publication of the study results. The authors also want to thank Challenge 3 I-SITE Clermont Auvergne Project 20-25 for their grant.

Authors' Contributions

AM designed the study protocol and search strategy in consultation with other authors. AM and AC conducted the screening, data extraction, and risk of bias assessment. AM and BP developed the meta-analytic procedure, and AM performed the statistical

analysis. The first draft of the manuscript was written by AM, and all authors commented on the previous versions of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplementary materials.

[[PDF File \(Adobe PDF File\), 999 KB-Multimedia Appendix 1](#)]

Multimedia Appendix 2

Risk of bias summary for studies included in the meta-analysis.

[[PDF File \(Adobe PDF File\), 301 KB-Multimedia Appendix 2](#)]

Multimedia Appendix 3

Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

[[PDF File \(Adobe PDF File\), 59 KB-Multimedia Appendix 3](#)]

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Abbreviations

GRADE: grading of recommendations assessment, development, and evaluation

MD: mean difference

MET: metabolic equivalent of task

MVPA: moderate to vigorous physical activity

OSF: Open Science Framework

PA: physical activity

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RCT: randomized controlled trial

SB: sedentary behavior

SMD: standardized mean difference

Edited by R Kukafka; submitted 25.12.20; peer-reviewed by C Maher, H Mehdizadeh, I Gupta, E Sadeghi-Demneh, H Pratomo, MDG Pimentel; comments to author 25.02.21; revised version received 31.03.21; accepted 19.10.21; published 04.01.22

Please cite as:

Mazeas A, Duclos M, Pereira B, Chalabaev A

Evaluating the Effectiveness of Gamification on Physical Activity: Systematic Review and Meta-analysis of Randomized Controlled Trials

J Med Internet Res 2022;24(1):e26779

URL: <https://www.jmir.org/2022/1/e26779>

doi: [10.2196/26779](https://doi.org/10.2196/26779)

PMID:

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9. Study 2: the impact of a gamified intervention on physical activity in real-life conditions: a retrospective analysis of 4800 individuals

Preprint available on medRxiv:

Mazeas, A., Forestier, C., Harel, G., Duclos, M., & Chalabaev, A. (2022). The Impact of a Gamified Intervention on Physical Activity in Real-Life Conditions: A Retrospective Analysis of 4800 Individuals. *medRxiv*.

The impact of a gamified intervention on physical activity in real-life conditions: a retrospective analysis of 4800 individuals

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Data, code & supplemental materials:

<https://osf.io/scnu7/>

Key words

behavior change; mHealth; gamification; intervention; physical activity.

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Abstract

Background. Digital interventions integrating gamification features hold promise to promote physical activity (PA). However, results regarding the effectiveness of this type of intervention are heterogeneous.

Objectives. This study aimed to examine the effectiveness of a gamified intervention and its potential moderators in a large sample using real-world data. Specifically, we tested (1) whether a gamified intervention enhanced daily steps during the intervention and follow-up periods compared to baseline, (2) whether this enhancement was higher in participants to the intervention than in nonparticipants, and (3) what participants' characteristics or intervention parameters moderated the effect of the program.

Methods. Data from 4819 individuals who registered for a mHealth Kiplin program between January 1st, 2019, and January 2nd, 2022 were retrospectively analyzed. In this intervention, participants could take part in one or several games where their daily step count was tracked, allowing individuals to play with their overall activity. Nonparticipants are people who registered to the program but did not take part in the intervention and were considered as a control group. PA was assessed via the daily step count of participants. Exposure to the intervention, the intervention content, and participants' characteristics were included in multilevel models to test the study objectives.

Results. Compared with nonparticipants, participants who benefited from the intervention had a significantly greater increase in mean daily steps from baseline during the same period ($p < .0001$). However, intervention effectiveness depended on participants' initial PA. Whereas the daily steps of participants with <7500 baseline daily steps significantly improved from baseline both during the Kiplin intervention (+3291 daily steps) and during follow-up periods (+945 daily steps), participants with a higher baseline had no improvement or significant decreases in daily steps after the intervention. Age ($p < .0001$) and exposure ($p < .0001$) positively moderated the intervention effect.

Discussion. In real-world settings and among a large sample, the Kiplin intervention was significantly effective to increase the daily steps of participants from baseline, during intervention and follow-up periods, and in comparison to nonparticipants. Interestingly, responses to the intervention differed as a function of individuals' initial PA with the existence of a plateau effect. Based on the insights of the self-determination theory, we can assume that the effect of gamification could depend of the initial motivation and activity of participants.

Introduction

Physically inactive individuals are at higher risk of developing non-communicable diseases – such as cardiovascular diseases, cancers, type 2 diabetes mellitus, or obesity – and mental health issues compared to the most active ones.¹ Yet, one-third of the world's population is insufficiently active^{2,3} and the trend is downward, with adults performing on average 1000 fewer steps than 2 decades ago⁴. Additionally, it has recently been reported that the global population step count did not return to pre-pandemic levels in the 2 years since the onset of the COVID-19 outbreak.⁵ In this context, there is an urgent need to increase physical activity (PA) of individuals in primary, secondary, and tertiary prevention.

Digital behavior change interventions and more particularly gamified services are promising avenues to promote PA. By their omnipresence in our lives, relatively low cost, ability to access content anywhere quickly, and capacity to collect real-time data in natural context, digital means allow for personalized, scalable, wide-reaching, and cost-effective interventions.⁶⁻⁸ However, there are concerns about the ability of digital programs to engage participants once the novelty wears off or to be effective on any type of audience regardless of their age, sociodemographic, or health status. In this context, gamification strategies introduce an exciting roadmap for addressing these challenges.

Gamification refers to the use of game elements in nongame contexts⁹ and allows to transform a routine activity into a more engaging one. The self-determination theory (SDT)¹⁰ is a commonly used theoretical framework for understanding the motivational impact of gamification on behavior. The SDT suggests the existence of different types of motivation that can be pictured on a continuum ranging from lack of motivation to intrinsic motivation (when the behavior is realized for the sake of the activity itself). Although different forms of motivation can initiate the action, people will be more likely to perform the behavior in the long term when their motivation is intrinsic, in other words, when the activity is performed for its inherent pleasure. From this perspective, a gamified intervention that provides fun and playful experiences would feed the intrinsic motivation of participants and would be more correlated with the long-term adherence to PA.

A recent meta-analysis¹¹ revealed that digital gamified interventions, lasting on average 12 weeks, improved PA by 1600 daily steps on average.

Importantly, the results showed that gamified interventions a) appear more effective than digital non-gamified interventions, b) seem appropriate for any type of user regardless of their age or health status, and c) the PA improvement persists in the long term. As a result, gamified interventions are emerging as high-potential behavior change tools to tackle the physical inactivity pandemic. However, these findings obtained from randomized controlled trials do not always reflect what happens in real-life settings.¹² In addition, the effect sizes reported in this meta-analysis were heterogeneous and the authors found high between-study heterogeneity (e.g., $I^2 = 82\%$).

If this heterogeneity may be explained by differences in study quality or diversity of designs in the included studies, the behavior change intervention ontology proposed by Michie et al.¹³ argues that heterogeneity in behavioral interventions could also be explained by different variables such as intervention characteristics (e.g., content, delivery), the context (e.g., characteristics of the population targeted such as demographics, setting such as the policy environment or physical location), exposure of participants with the program (e.g., engagement and reach), and the mechanisms of action (the processes by which interventions influence the target behavior). Considering these variables within gamification contexts could provide a useful means to better understand the conditions under which interventions are successful.

The present study investigated these questions based on a retrospective analysis of real-world data collected from a large sample of participants who were proposed a mHealth gamified intervention developed by the company Kiplin. In this one, participants could take part in one or several collective games where their daily step count was tracked, allowing individuals to play with their overall activity. In addition to offering the possibility of direct intervention on people's activity habits in natural context, the capacity of this mobile app to collect, in real-time, a large amount of objective real-world data can be useful to understand the processes and outcomes of behavioral health interventions.¹⁴ More specifically, these data can help make explicit when, where, for whom, and in what state for the participant, the intervention will produce the expected effect, notably thanks to continuous data collection over time. The within-person evolution in daily steps obtained via the app combined with between-person individual factors and intervention parameters is of great interest in this perspective.

Thus, the objectives of this study were to analyze the data collected in order (1) to examine within-individual evolutions of PA before, during, and after the intervention, (2) to test the effectiveness of a gamified program in real-life conditions on PA of participants versus nonparticipants, and (3) to explore the variables that could explain heterogeneity in response to the intervention. Based on previous results on gamification¹¹, we first hypothesized that PA would increase during and after the gamified program compared to baseline (H1). Second, we hypothesized that this improvement will be greater for participants than for non-participants (i.e., participants who registered on the app but did not complete any game, H2). Finally, we expected that the intervention's characteristics (i.e., type and number of games), the context within the intervention was performed (i.e., population and settings), and the exposure to the intervention (i.e., engagement of participants with the app) will moderate the intervention effect (H3).

Methods

Study design and participants

This study retrospectively analyzed data from adult participants who had registered for a Kiplin program and had given consent for their data to be collected. To be included, participants must be 18 years old or older, have registered on the app between January 1st, 2019, and January 2nd, 2022, and logged daily steps (measured via their smartphone or an activity monitor) on a time frame of at least 90 days with less than 20% of missing daily observations. Of the 134,040 individuals who registered on the Kiplin app on this timespan, 4819 met the eligibility criteria.

Non-wear days were defined as days with fewer than 1000 steps and considered as missing observations – as previous research suggested that daily step values less than 1000 may not represent full data capture.^{15,16} Days before the first day of the first game were considered as ‘baseline’ (14 days \pm 42.9, median \pm standard deviation), the period between the first day of the first game and the last day of the last game as ‘intervention period’ (19 days \pm 31.2), and the days after the last day of the last game as ‘follow-up’ (90 days \pm 22.8). We restricted the follow-up periods to 90 days post-intervention (i.e., 3 months).

Participants could receive the Kiplin intervention a) in the context of their work (i.e.,

primary prevention with employees), b) in a senior program (i.e., primary prevention with volunteer retirees), or c) as part of their chronic disease care (i.e., patients mainly treated for obesity or cancer). In all the aforementioned conditions, the program was paid not by the participant but by their employer or health care center.

Some participants registered for the program, created their account, but did not take part in the intervention (i.e., did not completed any game). These individuals were considered “nonparticipants” and were used as a control group (as proposed in previous research¹⁷). Similarly, the baseline period of these nonparticipants corresponds to the days prior to the date they were supposed to start the intervention period. See Figure 1 for the study flow chart.

The study was approved by local Ethics Committee (IRB00013412, CHU de Clermont Ferrand IRB #1, IRB number 2022-CF063) with compliance to the French policy of individual data protection.

The Kiplin intervention

Participants benefited from one or several PA games (depending on the program) lasting approximately 14 days each. If several games were proposed, these games followed each other in an interval of fewer than 60 days. Details on the games' content have been reported previously.¹⁸ In short, the Kiplin games are collective games where the daily step count performed by each participant is converted into points and allow each team to progress on a map (Fig. 2A), unlock clues in the context of an investigation (Fig. 2B), advance on a boardgame (Fig. 2C), or win a race (Fig. 2D). These games include a multitude of gamification mechanisms such as points, trophies, leaderboards, a chat, challenges, narratives – mechanics that are closely linked to proven behavior change techniques.¹⁹

Variables

The variables of interest were selected on the basis of the behavior change intervention ontology of Michie et al.¹³ and included (1) the longitudinal evolution of daily steps, (2) the exposure of each participant to the intervention, (3) the intervention parameters, and (4) the context (participants' characteristics and settings), as these variables are likely to influence the intervention effect. Table 1 specifies the measures of interest and their operationalization.

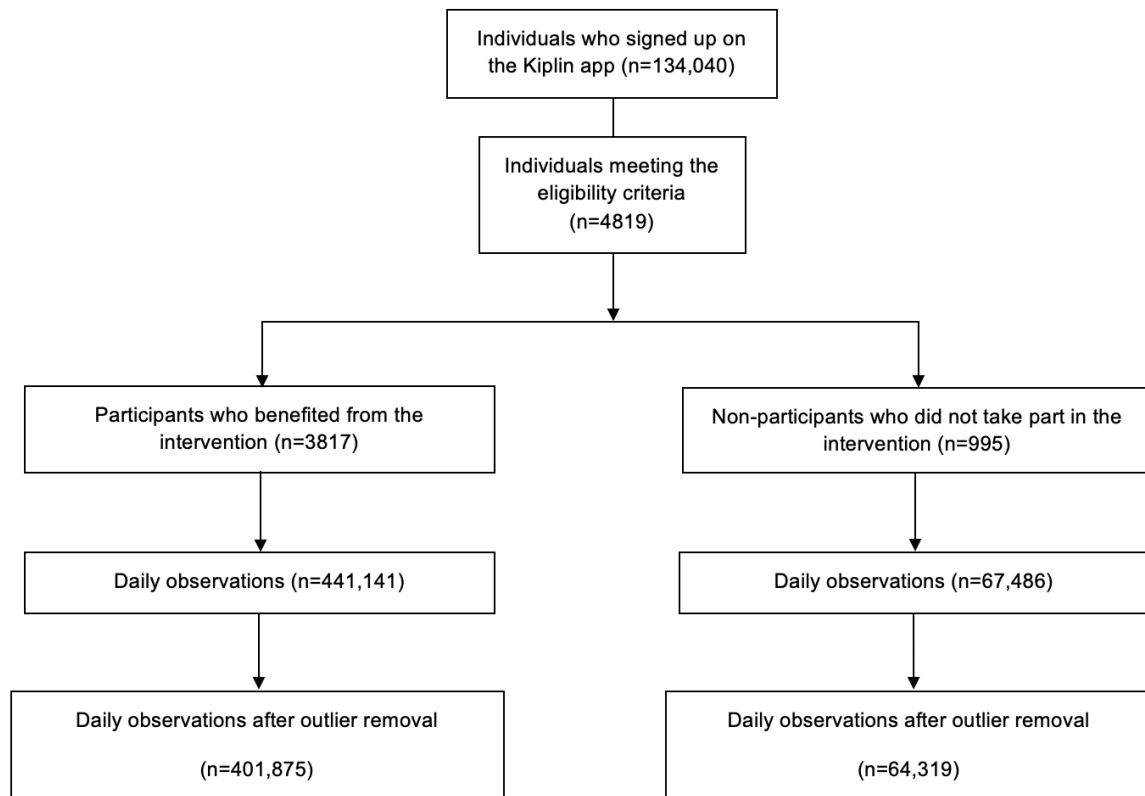


Figure 1. Study flow chart and screening of the databases.

Table 1. Operationalization of the variables

Outcome	Operationalization
Primary outcome – target behavior (dependent variable)	
Daily step count	PA was assessed via the daily step count, measured with the smartphone or activity monitor of the participant. The daily step count is a trusted proxy for PA. ²⁰ During onboarding, participants were asked to connect to their tracking device (e.g., Apple Health, Google Fit, Fitbit, Garmin) for synchronization of their step count data. In this way, the daily step count of the participants was automatically synchronized on the Kiplin app and the app could retrieve the daily step count for the previous 15 days.
Intervention (content and delivery) and mechanisms of action	
Type of game	Participants could play 4 types of games (i.e., challenge, adventure, boardgame, mission).
Exposure	
Compliance ratio	The engagement of participants with the app was computed as the compliance ratio representing the number of days with a login during the game period divided by the duration of the game periods. This variable allows measuring the frequency of the engagement with the service. ²¹
Number of games played	The total number of games played during the intervention period.
Context (population and setting)	
Self-reported age and gender	Filled out by participants when they registered on the app.
Population	Employees, seniors, or patients (treated for obesity, or cancer).
Cofounders	
Season	The season (winter, spring, summer, autumn) when the data step was logged, was controlled as the season can influence PA. ²²

Type of device	The type of device used to assess daily step count (i.e., Android or iOS smartphones, Garmin, Withings, Polar, Fitbit, or Tomtom wearables) was controlled as smartphone apps and wearable devices differ in accuracy and precision. ²³
Lockdown	The study period was characterized by the COVID-19 pandemic and 3 lockdowns were set up in France to limit the spread of the outbreak. As these periods had a strong influence on PA of individuals, ²⁴ we controlled the lockdown periods in our analyses.

Statistical analyses

We calculated the step count increase by subtracting the baseline average daily step count from the average daily step count during the intervention or follow-up periods for each participant and then computed the relative change in %. Mixed-effects models were used to 1) analyze within-person evolution across time (i.e., changes in daily steps between baseline, intervention, and follow-up periods), and across participants and nonparticipants, and 2) examine the associations between intervention parameters, exposure to the intervention, participants' characteristics and settings, and the daily steps evolution. This statistical approach controls for the nested structure of the data (i.e., multiple observations nested within participants), does not require an equal number of observations from all participants,²⁵ and separates between-person from within-person variance, providing unbiased estimates of the parameters.^{26,27}

First, an unconditional model (i.e., with no predictor) was estimated for each variable to calculate intra-class correlations (ICC) and estimate the amount of variance at the between and within-individual levels, which allowed us to determine whether conducting multilevel models was relevant or not. Then, a model that allowed random slope over time (i.e., model with random intercept and random slope) was compared to

the null model (i.e., with only random intercept) using an ANOVA, to evaluate whether the less parsimonious model explain a significantly higher portion of the variance of the outcome, compared to the unconditional model.^{28,29} Third, between-level predictors and confounding variables were added to another model (Model 1)*¹ and compared to the previous models. Finally, intervention characteristics as well as their interactions with the phases (i.e., baseline/intervention/follow-up) of the study were added in a final model excluding nonparticipants (Model 2)*².

Model fit was assessed via the Bayesian Information Criterion (BIC) and $-2 \times \log\text{-likelihood}$ ($-2LL$).³⁰ All models were performed using the *lmerTest* package in the R software.³¹ An estimate of the effect size was reported using the marginal and conditional pseudo R^2 . When the interaction terms turned significant, contrasts analyses were computed using the *emmeans* package.³² Models' reliability (estimated with residual analyses) and outliers detection were performed using the *Performance* package.³³ Sensitivity analyses were conducted using all data (including data before outlier imputation) and are available in supplementary materials.

The data and code for the statistical analyses used in the present study are available on Open Science Framework (<https://osf.io/scnu7/>).

*¹ The equation for the Model was the following: $Y_{ij} = (\beta_0 + \gamma_{0i} + \theta_{0j}) + (\beta_1 + \theta_{1j}) \text{Time}_j + \beta_2 \text{Phase}_j + \beta_3 \text{Age}_j + \beta_4 \text{Sex}_j + \beta_5 \text{Population}_j + \beta_6 \text{Season}_j + \beta_7 \text{Captor}_j + \beta_8 \text{Baseline PA}_j + \beta_9 \text{Lockdown}_j + \beta_{10} \text{Condition}_j \times \text{Phase}_j + \varepsilon_{ij}$ where β_0 to β_{10} are the fixed effect coefficients, θ_{0j} and θ_{1j} are the random effect for the participant j (one random intercept and one random slope), γ_{0i} is the random effect for the Time i (random intercept), and ε_{ij} is the error term.

*² The equation for the Model was the following: $Y_{ij} = (\beta_0 + \gamma_{0i} + \theta_{0j}) + (\beta_1 + \theta_{1j}) \text{Time}_j + \beta_2 \text{Phase}_j + \beta_3 \text{Age}_j \times \text{Phase}_j + \beta_4 \text{Sex}_j + \beta_5 \text{Population}_j \times \text{Phase}_j + \beta_6 \text{Season}_j + \beta_7 \text{Captor}_j + \beta_8 \text{Baseline PA}_j \times \text{Phase}_j + \beta_9 \text{Lockdown}_j + \beta_{10} \text{Compliance ratio}_j \times \text{Phase}_j + \beta_{11} \text{Number of games played}_j \times \text{Phase}_j + \beta_{12} \text{Type of Game}_j + \varepsilon_{ij}$ where β_0 to β_{12} are the fixed effect coefficients, θ_{0j} and θ_{1j} are the random effect for the participant j (one random intercept and one random slope), γ_{0i} is the random effect for the Time i (random intercept), and ε_{ij} is the error term.



Figure 2. Screenshots of the Kiplin games.

Results

Descriptive Results

Descriptive results are presented in Table 2. The final sample included 4812 adults (mean age = 42.7 ± 11.5 years; 60% women). Sociodemographic variables and baseline physical activity were not descriptively different between participants and nonparticipants. Participants wore an activity monitor measuring their daily step count for an average of 113 days (range = 90 – 686 days). 34,922 daily steps observations were missing on a total of 544,449, which is equivalent to 6.4% of missing data on the full dataset.

Is the gamified program effective to promote PA? (H1)

During the intervention period, participants increased their daily steps by 2619 steps per day on average (+55.6%), compared to the baseline period, and by 317 steps per day on average during the follow-up period (+13.8%), compared to the baseline. In comparison, the daily step count of the control group remained more or less stable throughout the same timeframe with a mean increase of 151 daily steps compared to baseline (+7.5%).

Overall, contrast analyses of the model for the intervention participants (Model 2, Table 3) revealed a negative effect of the intervention on the daily step count during the intervention phase compared to baseline activity ($b = -0.09$, 95 CI [-0.14; -0.05], $p < .0001$) and no significant effect ($b = 0.01$, 95 CI [-0.05; 0.06], $p = 0.79$) during follow-up periods compared to baseline. However, the patterns were

different when participants were stratified by baseline PA. Participants with lower baseline daily steps (<5000 steps per day or 5001-7500 steps per day) showed a significant increase of their daily steps during the intervention and the follow-up, both compared to the baseline (respectively $b = 0.25$, 95 CI [0.22; 0.28], $p < .0001$ and $b = 0.12$, 95 CI [0.09; 0.15], $p < .0001$). Participants with initial values between 7501 and 10000 steps did not have a significant increase in their daily steps during the intervention ($b = 0.00$, 95 CI [-0.05; 0.05], $p = 0.99$) nor during the follow-up period ($b = -0.01$, 95 CI [-0.04; 0.02], $p = 0.44$), compared to baseline. Participants who performed more than 10000 baseline steps had significant deteriorations during the intervention ($b = -0.13$, 95 CI [-0.19; -0.08], $p < .0001$) and follow-up ($b = -0.06$, 95 CI [-0.10; -0.03], $p = 0.0001$). These trends are depicted in Figure 3 and in Table 4. Results were similar in sensitivity analyses that used data without outlier imputation, except for participants with initial daily step count between 7501 and 10000 daily steps who observed significant improvements during and after the intervention (Table S1 and S2 in supplementary materials).

Is the intervention effect greater for participants compared to nonparticipants? (H2)

In Model 1 (Table 3), participants who received the intervention from Kiplin had a significantly greater increase in mean daily steps between baseline and the intervention period, compared with nonparticipants ($b = 0.54$, 95%CI [0.52; 0.58], $p < .0001$). The results were similar in sensitivity analyses (Table S2 in supplementary materials).

Table 2. Descriptive statistics.

	Participants	Nonparticipants
Participants	N=3817	N=995
<i>Sociodemographics</i>		
Age, mean (SD)	43.2 (11.08)	41.0 (12.81)
Female (%)	2313 (62)	510 (53)
Employees (%)	3,526 (92)	978 (98)
Patients (%)	194 (5)	17 (2)
Seniors (%)	97 (2)	-
<i>Exposure</i>		
Compliance ratio, mean (SD)	0.84 (0.23)	0
Games played, mean (SD)	1.28 (0.9)	0
In-game days, mean (SD)	22.06 (16.24)	0
<i>Observations in each type of game</i>		
Adventure (% of all days)	21,316 (33)	-
Boardgame (% of all days)	4,093 (6)	-
Challenge (% of all days)	32,801 (50)	-
Mission (% of all days)	6,915 (11)	-
<i>Type of device used</i>		
Android smartphone (%)	1076 (28)	286 (29)
iOS smartphone (%)	810 (21)	533 (54)
Fitbit (%)	750 (20)	52 (5)
Garmin (%)	1,071 (28)	109 (11)
Polar (%)	5 (0.1)	-
Tomtom (%)	3 (0.08)	-
Withings (%)	90 (2)	9 (1)
<i>Observations in each season</i>		
Winter (% of all days)	110,517 (24)	17,451(24)
Spring (% of all days)	94,961 (20)	21,162 (30)
Summer (% of all days)	129,039 (27)	8,804 (12)
Fall (% of all days)	138,429 (29)	24,086 (34)
<i>Observations in each lockdown</i>		
1 st lockdown – spring 2020 (% of all days)	10,872 (3)	925 (1)
2 nd lockdown – fall 2020 (% of all days)	32,298 (8)	4,110 (6)
3 rd lockdown – spring 2021 (% of all days)	23,435 (6)	1,757 (2)

Table 3. Mixed effect models' estimates.

	Unconditional Model			Model 1			Model 2		
	<i>b</i> [95 CI]	SE	<i>p</i>	<i>b</i> [95 CI]	SE	<i>p</i>	<i>b</i> [95 CI]	SE	<i>p</i>
Intercept	-0.04 [-0.06; -0.02]	0.01	<.001	-0.70 [-0.78; -0.62]	0.04	<.001	-0.34 [-0.39; -0.29]	0.03	<.001
Fixed Effects									
Time	-0.10 [-0.11; -0.09]	0.01	<.001	0.11 [0.05; 0.16]	0.03	<.001	-0.05 [-0.06; -0.04]	0.01	<.001
<i>Phases of the study</i>									
Baseline				Reference			Reference		
Intervention				0.01 [-0.02; 0.04]	0.01	0.441	0.31 [0.28; 0.34]	0.01	<.001
Follow-up				-			0.29 [0.27; 0.32]	0.01	<.001
<i>Participants' profile</i>									
Age				0.01 [-0.00; 0.02]	0.01	0.117	-0.00 [-0.02; 0.01]	0.01	0.523
Sex female				Reference			Reference		
Sex male				-0.01 [-0.03; 0.01]	0.01	0.397	0.02 [-0.00; 0.05]	0.01	0.104
<i>Condition</i>									
Control				Reference			-		
Kiplin				-0.03 [0.07; 0.09]	0.02	0.079	-		
<i>Population</i>									
Workers				Reference			Reference		
Seniors				-0.05 [-0.12; 0.03]	0.04	0.213	0.13 [0.05; 0.21]	0.04	0.002
Obese patients				-0.12 [-0.21; -0.02]	0.05	0.017	-0.01 [-0.14; 0.12]	0.06	0.864
T2DM patients				-0.37 [-0.62; -0.12]	0.13	0.003	-0.18 [-0.44; 0.09]	0.13	0.189
Cancer patients				0.02 [-0.05; 0.09]	0.04	0.532	0.07 [-0.01; 0.15]	0.04	0.076
Other patients				-0.11 [-0.21; -0.01]	0.05	0.031	0.08 [-0.05; 0.21]	0.07	0.241
<i>Type of game</i>									
Adventure							Reference		
Boardgame							-0.17 [-0.20; -0.14]	0.02	<.001
Challenge							-0.08 [-0.10; -0.06]	0.01	<.001
Mission							-0.17 [-0.20; -0.14]	0.01	<.001
<i>Exposure</i>									
Observance ratio							0.02 [0.00; 0.04]	0.01	0.021

Number of games					0.02 [-0.00; 0.04]	0.01	0.064
<i>Season</i>							
Winter		Reference			Reference		
Spring		0.04 [0.03; 0.06]	0.01	<.001	0.04 [0.02; 0.05]	0.01	<.001
Summer		0.11 [0.09; 0.13]	0.01	<.001	0.06 [0.05; 0.08]	0.01	<.001
Fall		0.07 [0.05; 0.09]	0.01	<.001	0.02 [0.01; 0.03]	0.01	<.001
<i>Type of device</i>							
Android		Reference			Reference		
iOS		-0.05 [-0.08; -0.03]	0.01	<.001	0.02 [-0.01; 0.05]	0.01	0.128
Fitbit		0.29 [0.26; 0.33]	0.02	<.001	0.50 [0.47; 0.53]	0.02	<.001
Garmin		0.17 [0.14; 0.20]	0.02	<.001	0.33 [0.30; 0.36]	0.01	<.001
Polar		-0.94 [-2.23; -0.35]	0.66	0.154	0.11 [-0.72; 0.95]	0.43	0.788
Tomtom		0.75 [0.35; 1.15]	0.21	<.001	0.81 [0.45; 1.18]	0.19	<.001
Withings		0.05 [-0.03; 0.12]	0.04	0.199	0.11 [0.05; 0.18]	0.03	0.001
<i>Lockdown</i>							
Periods without restrictions		Reference			Reference		
1 st lockdown		-0.09 [-0.21; -0.01]	0.02	<.001	0.18 [-0.20; -0.15]	0.01	<.001
2 nd lockdown		0.00 [-0.02; 0.03]	0.01	0.795	0.00 [-0.02; 0.02]	0.01	0.989
3 rd lockdown		0.01 [-0.01; 0.03]	0.01	0.502	0.02 [0.00; 0.03]	0.01	0.034
Random Effects							
Level 1 intercept variance	0.70	0.67			0.67		
Level 2 intercept variance	0.32	1.88			0.13		
-2*log (lh)	-515610.3	-236638.1			-449086		
Akaike Information Criteria	1031232.6	473334.3			898288.4		
Marginal R ² / Conditional R ²	0.01 / 0.38	0.071 / 0.86			0.225 / 0.39		

What are the moderators of the intervention effect? (H3)

The Model 2 estimates are displayed in Table 2. The variables under consideration explained 39% of the variance in daily steps. In this model, we tested the hypothesized interactions, to investigate predictors associated with the efficiency of the intervention (Table S4 in supplementary materials). Contrast analyses were conducted on significant interactions and revealed that the age ($b = 0.05$, $p < .0001$) and the compliance ratio ($b = 0.37$, $p < .0001$) were positively associated with the change in daily steps between baseline and intervention. Specifically, the older the age, the more regularly the individuals played and the more effective the intervention was. On the other hand,

the number of games played by participants was negatively associated with this change ($b = -0.02$, $p = 0.02$). In other words, the longer the intervention and the higher the number of games, the less effective the intervention. For categorical outcomes, contrast analyses revealed differences in the intervention effect between the different populations. Compared to employees, cancer patients ($b = -0.18$, $p < .0001$), and seniors ($b = -0.19$, $p < .0001$) observed a significantly weaker effect of the intervention in comparison to baseline PA. There was no significant difference between employees and obese patients ($b = -0.07$, $p = 0.13$). All the results of these analyses are available in supplementary materials.

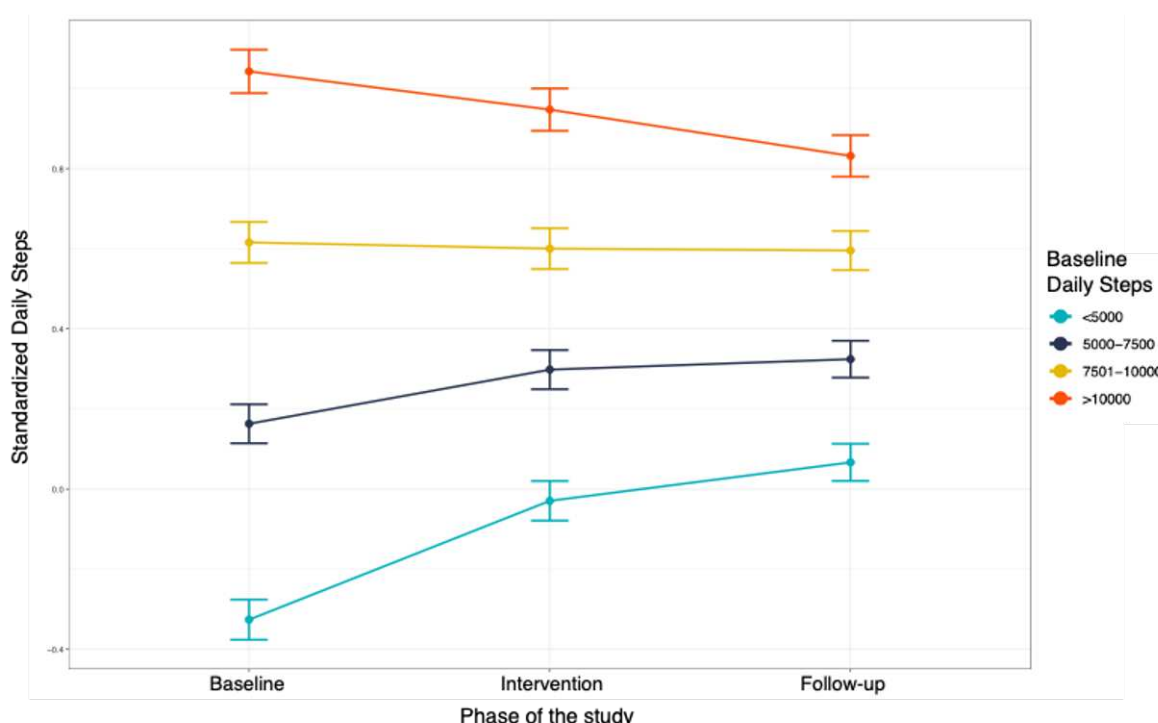


Figure 3. Changes in daily steps throughout the study phases for participants who received a Kiplin program, stratified by baseline daily steps

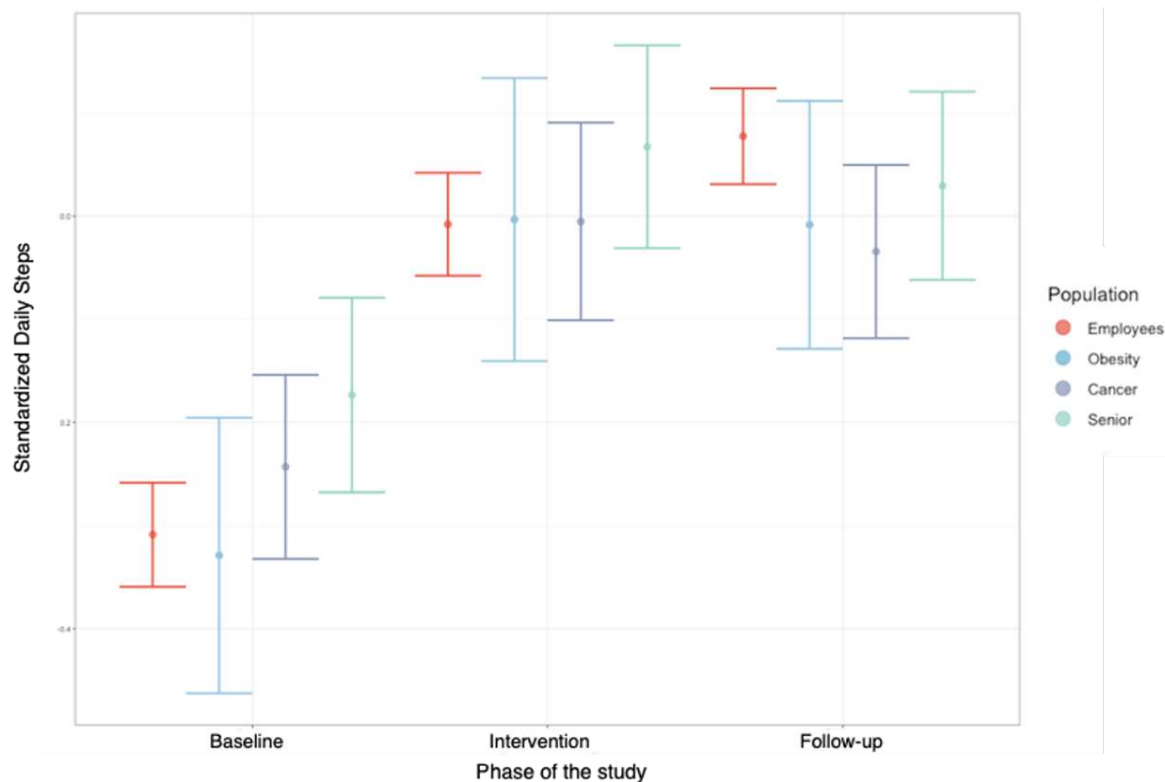


Figure 4. Changes in daily steps across the study phases for the different populations who received a Kiplin program.

Table 4. Description of the mean daily step count during baseline, intervention, and follow-up periods, changes, and relative changes from baseline in function of participants' baseline daily step count.

	<5000	5000-7500	7501-10000	>10000
Baseline daily step count	3671	6096	8818	10111
Intervention daily step count	7490	8855	10301	11388
Follow-up daily step count	5119	6534	7971	9424
Change from baseline during the intervention	3820	2762	2187	1309
Change from baseline during follow-up	1459	431	-156	-697
Relative change during intervention	+118.8 %	+47.2 %	+28.8 %	+16.9 %
Relative change during follow-up	+49.5 %	+8.2 %	-1 %	-4.3 %

Discussion

This study revealed that participants benefiting from the Kiplin games significantly increased PA compared with nonparticipants during the same period. Interestingly, the intervention effect depended on the baseline PA of individuals. Participants with lower baseline steps (<7500 steps per day) significantly improved their PA both during the intervention (between +34% and +76%) and follow-up periods (between +10% and +33%) whereas participants with more than 7500 steps had no significant change or significant decreases. These results suggest that a gamified program is more efficient among inactive individuals than active ones, with the existence of a plateau effect. They also confirm recent findings^{11,34}

and the ability of gamified interventions to improve PA both during and after the end of the program and in real-life settings³⁵ – at least for the more inactive individuals. This effectiveness is particularly interesting considering that current behavioral interventions struggle to change PA in the long haul.³⁶

The SDT can be a useful framework to explain these contrasting results between initially active and inactive participants. Whereas gamification strategies could enhance the intrinsic motivation of inactive participants as suggested by a previous study,³⁷ the use of rewards on already motivated people could undermine their intrinsic motivation. Known as the overjustification effect,³⁸ this phenomenon suggests that if people receive rewards for doing an activity that

they used to enjoy, they are likely to discount the internal reason, and thus become less intrinsically motivated than before getting the rewards. This could explain why the same intervention had positive effects on inactive participants who performed more daily steps after the end of the intervention (i.e., during follow-up periods) compared to already active ones who observed significant decreases after the intervention compared to their baseline PA.

The results of this study also stressed that older age may not be incompatible with gamified interventions. Indeed, the intervention effectiveness was moderated by the age of the individual and gamification was more efficient among older individuals, compared to younger ones. These findings are in line with a previous study³⁹ which found that older users had a greater degree of use of the gamification features. The authors proposed the explanation that older adults pay generally more attention to their health and thus have a stronger intention to engage in a health program. From another perspective and in light of the gamification strategies embedded in the Kiplin intervention, these results could also be explained by the fact that these strategies are accessible – inspired by traditional board game rules and mechanics widely known in the general population – and thus may be more attractive for older populations. Indeed, the most engaging game mechanics may diverge between youth and other populations,⁴⁰ and we can expect that younger populations may prefer more complex game mechanics and need more novelty during the intervention to stay interested by the service.

Regarding the effects of the gamified intervention according to the characteristics of the population, a stronger effect was found for programs among employees and obese patients. If these results must be taken with caution considering the high variability observed in patients or senior participants, these findings suggest that gamified interventions are suitable for both primary and tertiary prevention, as suggested by previous work.¹¹

The findings also revealed several insights that could help to improve future intervention design. First, exposure to the content is essential for the gamified intervention to be effective. It is interesting as gamification has often been assimilated into a self-fulfilling process permitting automatic engagement of participants. These results are consistent with previous findings demonstrating that higher use of gamification features was associated with greater intervention

effectiveness.^{39,41} If gamification can ultimately increase program engagement, developers need first to design their apps to be as attractive as possible and optimize retention.

Second, the total number of games played was negatively associated with the intervention effect, suggesting that a shorter intervention could be more beneficial for behavior change. These results are in line with previous research^{11,42} suggesting that users benefit more from digital interventions shorter than 3 months. It also suggests a « dose-response » relationship in inverted U shape, with an optimal “middle” to find. Nevertheless, it is necessary to take into consideration the fact that Kiplin programs of more than one game are built in such a way as to decimate several doses at regular intervals. Periods without games were therefore considered in the intervention phases and could explain why, overall, the shorter games were more efficient. More refined analyses of the intervention effect over time will be necessary in the future.

Third, the daily step count of participants was significantly higher in the adventure and the challenge. These two games share the characteristic of being more competitive with a stronger emphasis on leaderboards than the two other games more focused on collaboration. In this vein, Patel et al.⁴³ observed that the competitive version of their gamified intervention outperformed the collaborative and supportive arms. Moreover, various studies demonstrated that leaderboards are a particularly successful gamification mechanic.^{39,44}

Strengths and limitations

This study has several strengths, including the large number of participants included, the intensive objective PA measurement in real-life conditions, and the longer baseline and follow-up duration compared with most trials on gamification that typically incorporate measurement bursts dispersed across time.¹¹

However, several limitations should be considered. First, this study was observational and not a randomized controlled trial. Thus, we cannot establish the causality of the intervention's effect on outcome improvement. The nonparticipants are not a true control group. If they did not receive the intervention, it may be for underlying motivational reasons that could impact their PA.

Second, intervention lengths differed between participants. Third, if multilevel models are useful for describing trends in PA behavior change over time,

they are limited in their capacity to assess precise fluctuations patterns of non-stationarity behavior such as PA⁴⁵ across time and time series analyses could be used in future longitudinal studies to precisely describe patterns of change.

Finally, the compliance ratio used in this study as a proxy for engagement tends to oversimplify the exposure of participants to the service. Complementary measures of engagement (e.g., using the number of logins, time spent per login, and the number of components accessed) will need to be conducted to draw the longitudinal impact of the engagement of the participants on the intervention effect.

Conclusion

In this study in which we retrospectively analyzed the daily step count of 4800 individuals in real-life conditions, participants who benefited from the Kiplin gamified intervention had a significantly greater increase in mean daily steps from baseline than nonparticipants. Responses to the intervention were significantly different as a function of individuals' initial PA. Whereas participants with less than 7500 baseline daily steps had significant improvements both during the intervention and follow-up periods with +3291 daily steps during the program and +945 after the intervention on average, the intervention had no effect on participants with initial values >7500. The motivational effect of gamification could therefore depend on the initial PA and motivational profile of the participants. The age of participants and their engagement with the app were positively and significantly associated with the intervention effect while the number of games played was negatively associated with it. The results of this study suggest that gamification is effective to promote PA in inactive populations with short and medium-term effects. To our knowledge, this study is the first to examine the longitudinal effect of a gamified program outside the context of a trial, with real-world data. The results of this study are therefore highly generalizable and confirm the interest of gamification in both primary and tertiary prevention, and in a broad spectrum of ages.

Additional Information

Contributions

Conceptualization of the study: AM; data curation: AM, GH; investigation: AM; methodology and statistics: AM,

CF; software: AM; writing – original draft: AM; writing – review & editing: all the authors.

Declaration of interests

AC, CF, 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. GH is employed by Kiplin.

Funding

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 study and no influence on the interpretation or publication of the study results.

Data & Code Accessibility

The anonymized data used in this study and the R code are available on the Open Science Framework (<https://osf.io/scnu7/>).

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Summary Chapter 3

Gamification refers to the use of game elements in nongame contexts and holds great promise for physical activity promotion. However, there is no evidence of the effectiveness of gamified interventions, with the existence of mixed results in the literature. Study 1 revealed through a systematic review and meta-analysis of randomized controlled trials that digital gamified interventions, lasting on average 12 weeks, had a statistically significant effect on physical activity in comparison to control groups. More specifically, these interventions improved daily physical activity by 1600 daily steps on average. Importantly, the results showed that a) gamified interventions appear more effective than digital non-gamified interventions, b) seem appropriate for any type of user regardless of their age or health status, and c) the physical activity improvements, albeit weak, persist after follow-up periods. These findings have been confirmed in study 2, which evaluated the effect of a gamified intervention in real-life conditions on a sample of 4800 individuals. Indeed, participants benefiting from this intervention also improved their physical activity but the results revealed the existence of a plateau effect: the gamified intervention significantly improved the physical activity of participants with lower baseline steps (<7500 steps per day) whereas participants with more than 7500 initial steps had no change or significant decreases. These results suggest that gamified interventions are effective only among inactive individuals. Interestingly, the improvement observed in initially inactive participants lasted during follow-up periods (up to 12 weeks post-intervention). Once again, participants' age did not appear to be a barrier to the effectiveness of the intervention. Instead, the results indicate a positive moderating effect of age on the intervention effect. Engagement with the app also positively moderated the effect of the program.

Chapter 4

The contribution of technology to physical activity programs

Some authors argued that “the healthcare system is not well designed for the management of chronic conditions” (Steinhubl et al., 2013) with the presence of logistic and cost limitations for both patients and the healthcare system. These constraints have multiple consequences such as low engagement of patients in their care, and high costs for healthcare. The COVID-19 pandemic that plagued the world during the years of this thesis has exacerbated these limitations, as most of the in-person or physical healthcare was unfeasible with the risk of contagion. Therefore, researchers and clinicians had to innovate to be able to continue providing adapted physical activity programs. This period has been a real accelerator for the world of digital health, with increased use and consideration of eHealth and mHealth tools (Scott et al., 2020). Indeed, digital health services are promising to tackle patients' inconveniences and healthcare difficulties, as digital tools are potentially powerful means to alleviate pressure on existing health and social care systems (Fagherazzi et al., 2020; Gunasekaran et al., 2021).

This doctoral work has been impacted in the same way, which motivated us to imagine, implement, and evaluate new ways of delivering the content of physical activity programs but at a distance. This chapter presents two studies that evaluated the validity, effectiveness, and reliability of eHealth and mHealth tools to propose remote supervised physical activity sessions and physical condition tests.

10. Study 3: comparison of a hybrid program including telecoaching with face-to-face supervised physical activity in chronic disease rehabilitation: a pilot study

Preprint available on medRxiv:

Mazeas, A., Rausch, F., Pereira, B., Penando, S., Roland, M., Chalabaev, A., & Duclos, M. (2022). Comparison of a hybrid program including telecoaching with face-to-face supervised physical activity in chronic disease rehabilitation: a pilot study. *medRxiv*

Comparison of a hybrid program including telecoaching with face-to-face supervised physical activity in chronic disease rehabilitation: a pilot study

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Data & supplemental materials:

<https://osf.io/a89zw/>

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Key words

chronic disease, exercise, telemedicine, eHealth, telehealth, videoconferencing

Abstract

Background. If adapted physical activity (PA) is an undiscussable part of the rehabilitation of patients with noncommunicable diseases (NCDs), current programs face many constraints that limit their impact. Hybrid programs combining on-site rehabilitation visits and telecoaching may optimize the benefits of such intervention and allow efficient use of resources.

Objectives: The first aim of this pilot study was to test the effectiveness of a 3-month hybrid program combining face-to-face sessions, exercise in autonomy at home, and telecoaching sessions on PA level and health parameters of patients treated for various NCDs. This study also compared the effects of this program to the usual care i.e., 3-month face-to-face supervised adapted PA program.

Methods. 20 patients treated at the University Hospital of Clermont-Ferrand on the verge of the 1st lockdown due to the COVID-19 outbreak were proposed a hybrid program. To compare this program to the usual care, we randomly selected 100 patients from a database of 500 previous patients who benefited from a face-to-face program, in the same hospital and in the same conditions. This selection was performed by matching baseline characteristics of patients in order to obtain comparable groups. Changes in self-reported PA, physical capacities, anthropometrics, and body composition of patients from both programs were evaluated using random-effect models.

Results. Participants who benefited from the hybrid program significantly improved their cardiorespiratory capacity as revealed by their performance on the 6MWT and the 10MWT. They also reported performing significantly more PA at the end of the program compared to baseline. The change in the 6MWT performance was significantly higher in the hybrid program compared to the usual care. Adherence in the hybrid group was heterogeneous.

Discussion. A hybrid program including telecoaching appears 1) effective in improving PA and cardiorespiratory of participants, and 2) a riveting alternative to traditional face-to-face rehabilitation programs from a behavior change perspective. Future rigorous trials are needed to confirm the perspectives of this pilot study.

Introduction

Noncommunicable diseases (NCDs, e.g., cardiovascular diseases, cancers, type 2 diabetes mellitus (T2DM), chronic obstructive pulmonary diseases (COPD) are responsible for 70% of all deaths worldwide¹ and are today a priority public health issue. If the roots of these pathologies are complex and multifactorial, physical inactivity and sedentary behaviors are considered major factors in the appearance and development of NCDs.² As physical activity (PA) significantly reduces the risk of developing complications related to chronic diseases³⁻⁶ and limits the progression of these pathologies,^{7,8} PA is an essential component in the treatment of NCDs.

In consequence, patients with NCDs can usually benefit from supervised PA programs suited to their disease (i.e., adapted PA, APA), which aim to improve functional capacity and muscle strength without having detrimental effects or complications on disease progression.⁹ However, while these programs are considered the gold standard, they face several limitations for both patients and the healthcare system. On the one hand, APA programs can be difficult to access for patients, due to lack of availability on the scheduled sessions, lack of economic means, or geographical distance from the care center.¹⁰ These concerns are exacerbated in rural and low-income areas and during the COVID-19 outbreak,¹¹ which had a direct impact on the rehabilitation of patients with NCDs.¹² On the other hand, as these face-to-face sessions require qualified professionals, are provided at specific times and within clinics or hospitals, partitioners, hospitals, and clinics are overloaded, waiting lists for care appear, and the current system cannot handle the rising number of patients with NCDs who need APA.

Therefore, in a context of decreasing financial resources for patient care and increased constraints,¹³ there is an urgent need to develop and test more effective and cost-effective therapies. In this vein, the use of technologies and e-health facilities are promising avenues to optimize access to care. Telerehabilitation and telecoaching are methods of delivering services that use technology to serve patients and clinicians by minimizing the barriers related to distance, time, and costs.^{14,15} Several devices and approaches have been used to provide APA at patients' homes. First, unsupervised home training with or without video content (e.g., on VHS, DVD, or Internet) or semi-supervised training with phone calls to monitor compliance and participants'

progression have been proposed. More recently, remote supervised APA programs have been developed using videoconference software.

If these different forms of intervention have been studied separately, few studies have yet evaluated the effect of a program combining these approaches, whereas programs combining on-site rehabilitation visits and real-time telecoaching may optimize the benefits of the intervention and allow efficient use of resources.¹³ The present pilot study – conducted in the context of the first lockdown due to the COVID-19 pandemic in France (Spring 2020) – aimed to evaluate the effectiveness of a hybrid program combining face-to-face sessions in the first instance, and then telecoaching, on self-reported PA, cardiorespiratory fitness, and muscular capacities. The second objective of this pilot study was to compare the efficacy of this program in comparison to the usual care of the same hospital (i.e., face-to-face supervised PA) using a database of previous patients.

Methods

This study followed STROBE guidelines for the reporting of observational studies¹⁶ and the TIDieR checklist for strengthening intervention description and replication.¹⁷

Participants and study design

In March 2020, we proposed to the last 20 patients (mean age = 54.3 ± 13.4 years; 65% women; BMI = 30.6 ± 7.7 kg/m²) involved in a supervised APA program at the University Hospital of Clermont-Ferrand (France), to finish their program remotely with telecoaching sessions. To be included in the present study, participants must have had at least 30% of the planned sessions remaining. In this sample, participants were treated for obesity ($n = 9$), cancer ($n = 5$), COPD ($n = 3$), and T2DM ($n = 3$).

To test the effectiveness of this program in comparison to the usual care, we selected 100 patients (mean age = 54.8 ± 13.8 years; 65% women; BMI = 31.8 ± 7.6 kg/m²) in a database of 500 individuals who had already completed a 3-month face-to-face program in the same conditions (i.e., same coaches, same evaluators, and the same planned number of sessions) at the University Hospital of Clermont-Ferrand. To make this comparison relevant, we randomly selected the participants in the database on the basis of matching age, sex, baseline PA, and baseline BMI between both the hybrid group and the face-to-face group. The selected participants were treated

for obesity (n = 49), cancer (n = 8), COPD (n = 20), and T2DM (n = 23).

Patients of both groups had stable conditions and a prescription from their referring physician or specialist. They were tested at baseline (T0) and at the end of the program (T1). Participants of the hybrid program must have attended at least one face-to-face and one videoconference session to be included in the analyses. The study was conducted in the University Hospital of Clermont-Ferrand in accordance with the protocol of Helsinki. All data were obtained during the patient care path. Written informed consent was obtained from all participants and all the used and analyzed information was obtained exclusively from anonymous data (CNIL n°0164).

Variables

The usual care of the University Hospital of Clermont-Ferrand consisted of 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 were composed of a warm-up, followed by 50 min of endurance exercises, muscle strengthening exercises, and stretching - all supervised by an APA coach. Aerobic and resistance exercises were performed in a circuit organized as a row of six exercise stations (three aerobic and three resistance exercises). Aerobic exercises were performed at 50% of VO₂max the first week and the intensity was gradually increased by 10% every 2 weeks to target at least 80% of VO₂max over the last 9 weeks. For resistance exercises, patients performed a single set of 8–12 repetitions of unloaded exercises the first week and the number of sets was gradually increased to 3. These exercises were performed at 50% of 1RM during the first week. Then the load was gradually increased by 10% every 2 weeks, and remained at 80% of 1RM over the last 5 weeks. The patients from the database group benefited from this program.

In the hybrid program, participants started with the same content described above (i.e., supervised face-to-face PA). These sessions were then substituted by a telecoaching program combining exercises in autonomy and live videoconferencing sessions. In the telecoaching part, patients were proposed each week a) paper or video content with exercises to be done in autonomy comprising each time three levels of difficulty for a duration of 40 to 50 min, and b) collective live sessions by videoconferencing lasting 45 minutes to 1 hour. More specifically, these sessions were similarly constructed to those conducted usually in face-to-face using patients'

available material, were proposed several times a week by an APA coach. These videoconference sessions were open access for patients, meaning they could participate in more than 36 sessions in total. Compliance and progression to the exercises performed in autonomy were monitored by the coaches each weekend via phone calls. This hybrid program lasted 3 months and comported on average 50% of telecoaching sessions (range = 40 to 70%).

Measures

The baseline (T0) and post-intervention (T1) tests were conducted in the same conditions for both groups (i.e., at the hospital) and measured physical characteristics, body composition, self-reported PA, and physical capacities of patients. All measures were performed at the same time of the day to control for circadian variations.

Anthropometric measurements and body composition.

Body mass was measured to the nearest 0.1 kg using a calibrated digital scale, and height was measured to the nearest 0.1 cm using a wall-mounted stadiometer. BMI was calculated as body mass (kg) divided by height squared (m²). Body composition was assessed by bioelectrical impedance analysis (BODYSCAN QuadScan 4000, Belgium).

Self-reported PA. PA and sedentary behaviors during transportation time, leisure time, and work time were assessed using the Global Physical Activity Questionnaire (GPAQ).¹⁸

Physical capacities. Muscular strength of the upper limbs was 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 dynamometer (Takei Grip-D, Takei, Japan) was conserved.¹⁹ Aerobic endurance was estimated via the 10 Meter Walk Test (10MWT) which measures the shortest time to walk 10 meters in a standardized corridor.²⁰ Two measurements were conducted and only the best performance was conserved. Functional capacity at sub-maximum intensity was assessed via the 6-minute walk test (6MWT), which measures the distance covered in meters in a standardized 30-meter-long corridor.²¹

Statistical analyses

Sample size and power analysis. This pilot study is a control case. Therefore, the sample size was influenced by the recruitment capacity at the time of the inclusions. We were able to propose to 20 participants the hybrid program. Based on the closest programs we found in the

literature,^{22,23} we conducted a sample size estimation to determine the number of participants needed to be selected in the database. In order to demonstrate a difference equivalent to an effect size of 0.7 for 80% power and a two-sided type I error at 0.05, we required a sample size of 20 participants in the experimental group and 100 participants in the database. Selecting more participants from the database was not associated with an increase in power, so we considered using a 1:5 ratio.

Data analyses. Continuous data were expressed as means and standard deviations (SD). The normality of the distribution was checked with a Shapiro-Wilk test. We conducted random-effect models with the following fixed effects: time, group (hybrid program vs. usual care), and their interaction. Participant effect was considered as random (effect) in order to model between and within-subject variability. The normality of residuals was checked for all models. When appropriate, a logarithmic transformation of the dependent variable was performed. Thus, random-effect models were conducted to assess 1) the effect of time in hybrid program group, 2) the effect of time in the usual care group, and 3) the interaction group \times time. An additional model was performed to control the number of videoconferencing sessions attended in the hybrid group. For non-repeated data, the two groups were compared for quantitative variables using Student t-test or Mann-Whitney test when the assumptions of t-test were not met. The study of homoscedasticity was studied using equality of variance Fisher-Snedecor test. For categorical variables, Chi-squared and Fisher's exact test were applied. Differences were considered statistically significant at $p < 0.05$. As analyses were exploratory, the individual p -values have been reported without applying systematically mathematical correction according to several works reported in the literature,^{24,25} but with a specific attention paid on the magnitude of differences and to the clinical relevance expressed using effect-size and 95% confidence interval.²⁶ Statistical analyses were performed using Stata software (version 15, StataCorp, College Station, USA). The data and code for the statistical analyses used in the present study are available on Open Science Framework (<https://osf.io/a89zw/>).

Results

Effect of the programs on pre/post evolution of clinical outcomes

Table 1 displays patients' baseline characteristics stratified by group. Participants who benefited from the hybrid program significantly improved their performance at the 6MWT (+166.75 meters, $p < 0.001$) and the 10MWT (+0.11 m/s, $p = 0.027$). They also reported performing significantly more PA at the end of the program (+21.47 MET.h/week, $p = 0.002$) compared to before. The other variables were not significantly impacted by the program (Table 2). The results followed the same trends when the number of telecoaching sessions performed was controlled – with significant improvements on self-reported PA ($p < 0.001$), 6MWT ($p = 0.019$), and 10MWT ($p = 0.007$) performances whereas there was no significant improvement on other outcomes.

On the other hand, participants who benefited from the usual care improved their performance at the 6MWT (+39.53 meters, $p < 0.001$), the 10MWT (+0.09 m/s, $p < 0.001$), and the handgrip test (+1.13 kg, $p < 0.001$ on the right hand and + 1.54 kg, $p < 0.001$ on the left hand). Weight (-0.42 kg, $p = 0.023$), fat mass (-0.56%, $p < 0.001$), and self-reported physical activity (+10.81 MET.h/week, $p = 0.002$) were also improved at the end of the program compared to baseline (Table 2).

Table 1. Baseline demographic and clinical characteristics (mean \pm standard deviation).

Variables	Hybrid program (n=20)	Usual care (n=100)	p value
Men/Women	7/13	35/65	1.000
Age (years)	54.30 \pm 13.37	53.82 \pm 13.78	0.949
Anthropometrics			
Weight (kg)	83.98 \pm 24.01	86.91 \pm 22.02	0.617
BMI (kg/m ²)	30.56 \pm 7.71	31.80 \pm 7.64	0.517
Body composition			
Fat mass (%)	37.60 \pm 8.97	37.74 \pm 9.25	0.948
Lean mass (kg)	51.98 \pm 15.42	53.57 \pm 13.35	0.670
Physical capacities			
Right hand grip (kg)	32.01 \pm 11.57	35.16 \pm 11.39	0.276
Left hand grip (kg)	32.09 \pm 10.52	33.25 \pm 11.01	0.658
6MWT (m)	536.05 \pm 103.62	528.14 \pm 81.80	0.822
10MWT (m/s)	1.30 \pm 0.19	1.26 \pm 0.19	0.373
Physical activity			
GPAQ (MET.h/week)	38.82 \pm 26.17	48.70 \pm 48.62	0.932

Table 2. Changes in parameters before and after the hybrid program and the usual care (mean \pm standard deviation).

Hybrid program (n=20)				Usual care (n=100)			
Variables	T0	T1	p value	Variables	T0	T1	p value
Anthropometrics				Anthropometrics			
Weight (kg)	83.98 \pm 24.01	84.18 \pm 24.01	0.784	Weight (kg)	86.91 \pm 22.02	86.49 \pm 22.06	0.023
BMI (kg/m ²)	30.56 \pm 7.71	30.63 \pm 7.57	0.748	BMI (kg/m ²)	31.80 \pm 7.64	31.66 \pm 7.54	0.014
Body composition				Body composition			
Fat mass (%)	37.60 \pm 8.97	37.16 \pm 9.31	0.335	Fat mass (%)	37.74 \pm 9.25	37.18 \pm 9.27	<0.001
Lean mass (kg)	51.98 \pm 15.42	52.54 \pm 15.70	0.119	Lean mass (kg)	53.57 \pm 13.35	53.18 \pm 13.94	0.725
Physical capacities				Physical capacities			
Right hand grip (kg)	32.01 \pm 11.57	34.10 \pm 11.90	0.201	Right hand grip (kg)	35.16 \pm 11.39	36.29 \pm 11.25	<0.001
Left hand grip (kg)	32.09 \pm 10.52	32.53 \pm 11.82	0.506	Left hand grip (kg)	33.25 \pm 11.01	34.79 \pm 10.81	<0.001
6MWT (m)	536.05 \pm 103.62	602.80 \pm 121.60	<0.001	6MWT (m)	528.14 \pm 81.80	567.67 \pm 81.49	<0.001
10MWT (m/s)	1.30 \pm 0.19	1.41 \pm 0.28	0.027	10MWT (m/s)	1.26 \pm 0.19	1.35 \pm 0.22	<0.001
Physical activity				Physical activity			
GPAQ (MET.h/week)	38.82 \pm 26.17	60.29 \pm 37.45	0.002	GPAQ (MET.h/week)	48.70 \pm 48.62	59.51 \pm 53.51	0.002

When looking at participation rates, the two programs showed different patterns. Whereas the 100 participants included in the usual care group have all completed their 36 sessions, compliance rates are more heterogeneous in the hybrid program. Indeed, if on average these participants have completed as many sessions as the usual care group ($M_{sessions} = 37$, $SD = 15.65$), some patients completed more sessions (i.e., telecoaching sessions were in self-service) while other showed poor participation. In the hybrid group, 11 patients performed more than 36 sessions ($M = 49$, $range = 39-60$), 5 patients performed between 18 and 36 sessions ($M = 30$, $range = 25-35$), and 4 patients performed less than 18 sessions ($M = 14$, $range = 10-17$).

Comparison between the hybrid program and the usual care

Random-effects models revealed a significant interaction group \times time on the 6MWT ($d = 0.24$, 95%CI [0.04; 0.43], $p = 0.019$). In other words, the pre/post change in the 6MWT performance was significantly higher in the hybrid program compared to the usual care. Other group \times time interactions on weight ($d = 0.11$, 95%CI [-0.07; 0.31], $p = 0.235$), fat mass ($d = 0.10$, 95%CI [-0.10; 0.29], $p = 0.338$), lean mass ($d = 0.06$, 95%CI [-0.13; 0.26], $p = 0.527$), hand grip right ($d = 0.10$, 95%CI [-0.10; 0.30], $p = 0.313$) and left ($d = -0.16$, 95%CI [-0.36; 0.02], $p = 0.093$), 10MWT ($d = 0.02$, 95%CI [-0.17; 0.21], $p = 0.840$), and self-reported PA ($d = 0.14$, 95%CI [-0.06; 0.37], $p = 0.161$) outcomes were not significant.

Discussion

The objective of this pilot study was to examine the effectiveness of a hybrid APA program – integrating 50% of telecoaching sessions in average and physical exercises in autonomy at home – on PA, body mass, body composition, and physical capacities among patients with NCDs. The results revealed that progressively substituting supervised face-to-face PA sessions with telecoaching, was effective to increase total PA and improve cardiorespiratory fitness. Moreover, this improvement in cardiorespiratory fitness was significantly more efficient compared to patients who had completed the supervised 3-month APA program exclusively in face-to-face.

These results are important considering the health benefits of such physical improvements. Indeed, any gain in cardiorespiratory capacities of 1 MET is accompanied by a 12% reduction in mortality both in healthy individuals and in subjects with NCDs,²⁷ whether they are between 20 and 65 years old or over 65.²⁸ In addition, PA plays an essential role in improving physical and mental health and overall quality of life.^{29,30} These findings are especially positive considering that this study was conducted during the first lockdown due to the COVID-19 pandemic which caused a global decrease in PA levels of various populations.^{31,32} In the present study, the hybrid intervention not only counteracted the negative effects of lockdown on PA but also participated to increase

physical capacities, as reflected by performances in the 6MWT and 10MWT.

Interestingly, participants of the hybrid program had a significantly higher improvement in cardiorespiratory fitness than participants who benefited from the usual care and there were no other differences in effectiveness. When seeing the big picture, we can observe that the hybrid program had better benefits on cardiorespiratory fitness and global PA, when the results of the usual care were better balanced across health outcomes with improvements in weight, body composition, and physical strength. Through a detailed analysis of the GPAQ, we observed that PA was better distributed across the week in the hybrid program group and we can assume that it is due to the non-supervised training and the collective settings of telecoaching sessions. First, where APA interventions are subject to a compensatory decrease of global PA (i.e., decreased usual and leisure PA in compensation for increased supervised PA),³³ the telecoaching program could counteract this phenomenon by promoting exercise outside the sessions. In a different idea, the collective setting of telecoaching sessions could act as a motivational catalyst as exercising in group settings has been shown to increase motivation for PA.³⁴ In short, telecoaching sessions could be interesting to improve global PA from a behavior change perspective whereas face-to-face programs could be more useful to improve general strength and body composition.

Overall, these findings are consistent with previous studies suggesting that telerehabilitation and telecoaching are associated with positive clinical results, even comparable to conventional face-to-face approaches.^{22,35} Another study conducted during the COVID-19 pandemic period also revealed statistically significant improvements in all parameters of physical fitness and in the quality of life of overweight and obese patients who benefited from a telerehabilitation program.²³

Even if the magnitude of the effect sizes observed in this pilot study is moderated, these results are promising from an interventional point of view, opening new perspectives of care. Indeed, even smaller improvements or equivalence in the effectiveness of e-health interventions in comparison to usual care are important, given the potential reach of these interventions. Because of its digital nature and its

associated assets as the opportunity to practice easily from home, telecoaching interventions can answer the time, cost, and geographical limits of current programs. Moreover, telecoaching is an interesting way to provide APA when face-to-face management is impossible (e.g., patients with cystic fibrosis).^{36,37} Lastly, a remote program has proved to be efficient in a period of health pandemic and could be useful in future crises.

These findings are an interesting basis for future investigations aimed to test the effectiveness of telecoaching programs integrating telecoaching sessions versus face-to-face hospital programs in a rigorous way with randomized controlled trials. Considering the strong disparities in the number of sessions attended by patients in the hybrid group, it will be capital to examine the determinants explaining optimal engagement in a remote program.

Nevertheless, it is essential to keep in mind that this is a pilot study with many limitations. First, the present study was observational without a proper control group or objective measure of PA. Yet self-reported measures of PA are likely to be overestimated.³⁸ Second, the number of participants was small as this study was a pilot test. Moreover, a selection-history effect could play here since the patients did not complete their program at the same period. Finally, this study was conducted in the COVID-19 context, a period of significant change in PA habits.³⁹ In light of these elements, future studies are needed to confirm these results.

Conclusion

This study suggests that a hybrid APA program with telecoaching and face-to-face sessions is efficient to increase PA and improve cardiorespiratory fitness of patients with NCDs. Such program could be an interesting alternative to face-to-face programs allowing to remove logistical barriers, while keeping some face-to-face sessions that allow coaches and patients to get to know each other and to teach the exercises to participants. Rigorous trials are needed to confirm these perspectives.

Additional Information

Contributions

Conceptualization of the study: AM, FR, MD; data collection: FR, SP, MR, data curation: FR; methodology and statistics: AM, BP; software: BP; writing – original draft: AM; writing – review & editing: all the authors

Declaration of interests

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Funding

The work of AM is supported by a grant from the French National Association for Research and Technology (Cifre PhD Thesis) and by the company Kiplin. None of the sponsors were involved in any other aspect of the project, such as the design of the project's protocol and analysis plan, the collection, and analyses. The funders had no input on the interpretation or publication of the study results. The authors wanted also to thank the challenge 3 I-SITE Clermont Auvergne Project 20-25 for their grant.

Data availability statement

The anonymized datasets presented in this study can be found on the OSF page of the project (<https://osf.io/a89zw/>).

Acknowledgments

The authors wish to thank the participants of the University Hospital Clermont-Ferrand for their time and dedication.

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11. Study 4: validity and reliability of an app-based medical device to empower patients in evaluating their physical capacities

Preprint available on medRxiv:

Mazeas, A., Blond, M., Chalabaev, A., & Duclos, M. (2022). Validity and reliability of an app-based medical device to empower patients in evaluating their physical capacities. *medRxiv*

Validity and reliability of an app-based medical device to empower patients in evaluating their physical capacities

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Data, code & supplemental materials:

<https://osf.io/4hzke/>

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Key words

6-minute walk test; sit-to-stand chair test; objective functional impairment; smartphone app; mHealth; medical device; cardiorespiratory fitness

Abstract

Background. Cardiorespiratory fitness and muscle strength are valid markers of health and strong predictors of mortality and morbidity. The tests used to measure these variables require in-person visits with specialized equipment and trained personnel – leading to organizational constraints both for patients and hospitals, and making them difficult to implement at a large scale. In this context, technologies embedded in smartphones offer new opportunities to develop remote tests.

Objectives: This study aimed to test the validity and reliability of *MediEval*, a newly developed app-based medical device that allows individuals to perform the 6-minute walk test (6MWT) and the 30-second sit-to-stand (30s-STs) test on their own using GPS signal and camera detection with a skeleton extraction algorithm.

Methods. A total of 53 healthy adults performed the two tests in three different sessions to determine the intra- and inter-day reproducibility. Test validity was assessed by comparing the results obtained from the app to gold standard measures. Spearman correlation coefficients, the relative measurement error, intraclass correlation coefficients, and the standard error of measure were computed for each test.

Results. The results revealed high to excellent validity of the app in comparison to gold standards ($\rho=0.79$ for the 6MWT and $\rho=0.98$ for the 30-second STS test) with low relative measurement error. The mean differences between the app and the gold standard measures were 8.96m for the 6MWT and 0.28 repetition for the 30s-STs test. Both tests had good test-retest reliability (ICCs = 0.77).

Discussion. The *MediEval* medical device proposes valid and reproducible measures of the 6MWT and the 30s-STs test. This device holds promise for improving patient experience, performing physical capacity tests more frequently, and improving the scalability of the healthcare system. Ultimately, the medical-economic impact of this device could be high. Future studies in clinical context are needed to evaluate the responsiveness and the smallest detectable changes of the device for specific populations with chronic disease

Introduction

Cardiorespiratory fitness and muscle strength are important predictors of the overall health of individuals – being strongly associated with reduced morbidity and mortality, reduced risk of developing chronic diseases, and improvement in the functional capacities and autonomy of patients.^{1–5} The evaluation of these two dimensions is essential as physical activity is part of patients' non-drug therapy.⁶ This evaluation allows monitoring the functional capacities at the level of an individual or a population, tailoring supervised physical activity programs, measuring the effectiveness of these programs, informing the patients on their health, and ultimately empowering them.

The 6-minute walk test (6MWT) is a commonly used self-paced test for the objective assessment of functional exercise and cardiorespiratory capacity. This test measures the distance patients walk on a flat and hard surface over a six-minute period. The reliability, validity, and responsiveness of the 6MWT have been extensively tested and validated across various clinical settings.^{7–9} The popularity of the 6MWT can be explained by its many assets. This submaximal test is safer, easier to administer, better tolerated, and better reflects daily life activities than high-intensity or incremental tests.^{10,11} Moreover, it is simple to analyze and interpret, inexpensive, and takes less than 10 minutes to conduct.

The chair sit-to-stand (STS) test involves the functional movement of rising from a seated position and is frequently used to assess lower-limb muscular strength. Several variations of the STS test have been described in the literature including the 30-second STS test, which measures the number of stands achieved in 30 seconds. This test has acceptable test-retest reliability (for a review see⁸) and moderate-to-high correlations with lower limb strength.^{12,13} In addition, this test is often used to assess the functional capacity of older adults to predict and prevent falls.¹⁴ Similar to the 6MWT, the 30-second STS is easy to administer, analyze, and interpret. It requires little equipment, can be performed in any environment, and takes no more than 3 minutes to complete.^{8,15,16}

Despite their many apparent benefits, these tests involve, in practice, high costs and limitations for both patients and healthcare institutions. On the one hand, these tests entail travel costs and additional stress for patients, who have to come specifically to the

hospital/platform to perform the tests. On the other hand, implementing these tests leads to organizational constraints for the healthcare center that must set up a dedicated corridor, and involve significant human resource costs with the presence of a specialized professional to conduct the tests, analyze, and interpret the results. More recently, the in-person requirement for these tests also made them difficult to implement during the COVID-19 pandemic. For all these reasons, these two tests cannot be performed on a regular basis whereas they could be conducted in the absence of trained professionals if the patient has the appropriate tools to easily and accurately measure performance.¹⁰

To address these challenges, m-health tools represent a promising perspective. With the widespread availability of affordable smartphones and internet access (14 billion mobile devices and 4.9 billion internet users in the world in 2021)¹⁷ the majority of the population now owns a smartphone, which enables the remote completion of the tests near or at the patient's home. As early as 2011, Wevers et al.¹⁸ demonstrated that the 6MWT could be performed outdoors using a global positioning system (GPS) or a measuring wheel (reproducible, responsive, and valid test), suggesting that this test could be performed from patients' homes. Matthew et al.¹⁹ suggested the feasibility of using a single-depth camera to assess STS movements, opening new assessment perspectives. In addition, the feasibility of remote 30-second STS tests appears good as a recent study suggested that a video-guided STS test is suitable for participants of varying ages body sizes, and activity levels.²⁰ In consequence, it would be conceivable to estimate the distance walked or the number of repetitions performed during the tests using the smartphone's GPS or smartphone camera of the user.

In this perspective, the Kiplin company developed in collaboration with the present authors and the CEA tech Nantes a medical device to empower patients in conducting the 6MWT and the 30-second STS test. *MediEval* is a stand-alone software module integrated within a mobile app and certified class 1 medical device under the European Medical Device Regulation. The aims of the present study are to test the validity and reliability of this app-based medical device to evaluate the cardiorespiratory fitness and lower limb muscle strength of healthy individuals in a natural environment.

Methods

System design/app development

MediEval is a class 1 medical device (Unique Device Identifier 3770024180008) allowing individuals to perform the 6MWT and the 30s-STS test, in autonomy. This app module is incorporated within the Kiplin app (available on iOS and Android smartphones, with iOS version 13 and Android version 7 as minimum configurations). Subjects need to have a physical activity prescription to access the content of MediEval.

Technical functioning of the 6MWT. The distance traveled by the user during the 6MWT is computed on the basis of the phone's location by GPS position, recorded every 5 seconds.²¹ The triangulation of the GPS points is then used to calculate the distance traveled and the associated speed in a straight line over each 5-second interval. The total distance walked is computed by summing the distances obtained for each interval. The distance measured on the outlier intervals (i.e., intervals where anormal speed is detected), is then corrected on the basis of our algorithm.

Technical functioning of the 30s-STS test. The number of STS movements performed by the user is determined by an algorithm applied to the video stream transmitted by the phone. The first step is to apply a skeleton extraction carried out by a state-of-the-art algorithm²² on each image obtained through the video stream, which provides angle values for the whole skeleton and allows analysis of the user's biomechanical movements. Specific angle values are then used to classify the user's posture using a binary decision tree. Likewise, a binary decision tree is used to qualify the detected posture as correct or incorrect (especially to check the position of the arms, which need to be crossed at the wrists and held against the chest). The number of correct STS sequences is used to calculate the test result.

User experience. Through written and video tutorials, as well as the validation of a checklist before each test (Fig. 1B), the user is invited to respect the following instructions:

- the 6MWT must be performed outdoors, on a flat surface, with no curves and no risk of GPS obstruction (no tall buildings or trees), where the user will be able to go back and forth for 100 meters;
- the STS test must be performed in a bright room, using a traditional chair (i.e., at about knee height

when standing $\approx 43\text{cm}$) without armrests, and the user needs to position his phone on another chair at a sufficient distance so that he can be filmed by the phone's camera.

For the 6MWT, the user cannot start the test if the GPS accuracy of his phone does not stabilize under 15m for at least 5 seconds as the start button is not available. If the accuracy is acceptable, a clickable Play button allows the user to start the test, and a timer displaying the time remaining until the end appears (Fig. 1D). The app also emits a vibration every minute to indicate the remaining time. The end of the 6-minute test is indicated to the user on the screen and by means of vibrations of the phone. A long vibration and a display on the screen indicate the end of the test.

For the STS test, in order to ensure that the camera has been positioned properly, the user is invited to take a photo to check that the camera captures the user's body from head to toe when he or she is standing (Fig. 1C). Then, a clickable Play button allows starting the test with a 15-second countdown for the user to take place. During the test, the time remaining over is displayed on the screen, with a beep sounding for each STS movement detected as correct. Similarly, when an incorrect STS sequence is detected, a different beep sounds. The end of the test is indicated to the user on the screen and by a long beep.

At the end of the tests, the user is asked to evaluate his level of muscular fatigue and dyspnea using Borg's scale. The app then displays the result of the test, including the distance achieved in meters and the comparison with the theoretical distance that the user should perform (i.e., calculated according to Enright and Sherrill's equations, 1998) for the 6MWT, and the number of correct repetitions (i.e., 30s-STS test score), and incorrect movements detected for the STS test (Fig. 1E).

Usability tests with participants of various ages conducted prior to this study did not raise any problems of ergonomics, usability, or comprehension.

Participants

A total of 53 healthy adults aged 21 to 63 years old (mean age = 33 ± 10.9 years; Body Mass Index (BMI) = $22.8 \pm 3.0 \text{ kg/m}^2$; 57% women) volunteered to participate in the current study. Participants must be aged >18 years and answer 'no' to all items of the Physical Activity Readiness Questionnaire for Everyone (PAR-Q+)²⁴ to be included. They were

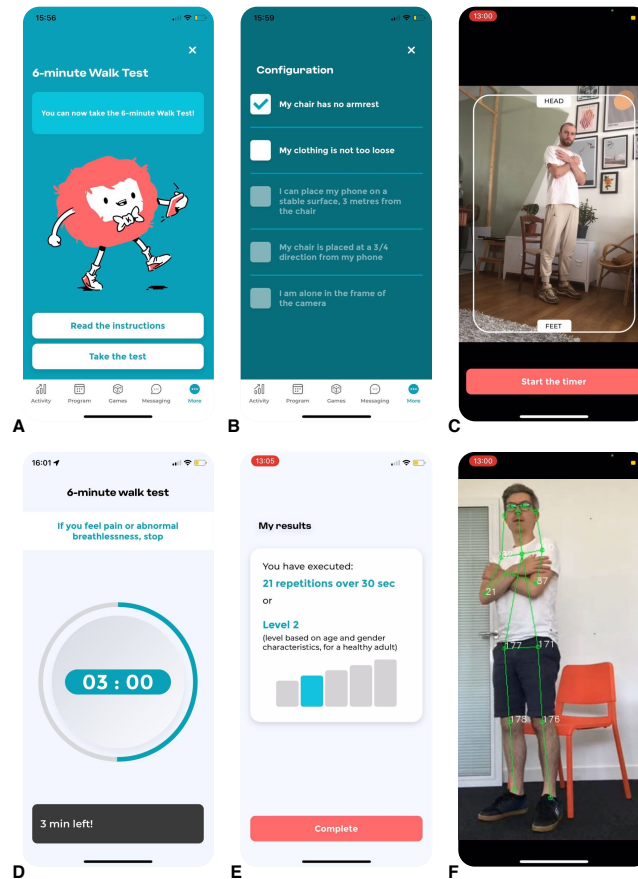


Figure 1. Screenshots of the MediEval medical device. (A) Welcome screen for the 6MWT. (B) Checklist for the 30s-STS test. (C) Photo taken to check that the camera captures the user’s body from head to toe for the 30s-STS. (D) Screen during the 6MWT. (E) Results for the 30s-STS test. (F) Detection of the skeleton algorithm (this view is not available for the user).

excluded in case of injury, surgery, or any disease pathology which could affect their physical aptitude or their gait. Participants were enrolled between May and October 2022. The study protocol was approved by the local ethics committee (IRB00012476-2022-26-04-177). Written informed consent was obtained from all participants and all analyzed information was obtained exclusively from anonymous data.

Procedure and measures

Criterion validity refers to the extent to which scores obtained from the app are related to a gold standard.²⁵ For the 6MWT, we compared the distance computed by the app to the distance measured via a distance wheel accurate to 0,1 m (M20, GEO FENNEL, Germany), which is a commonly accepted gold standard of distance measurement.^{18,26,27} For the STS test, the video stream generated during the test was recorded and analyzed a posteriori by two observers instructed to the guidelines of the STS. A third observer was consulted in case of discrepancy between the first

observers. This video analysis was considered the gold standard²⁰ and compared to the app’s result.

Reproducibility concerns the degree to which repeated measurements in stable persons during a test-retest procedure provide similar answers.²⁵ In this context, the time period between the repeated administrations should be long enough to ensure recuperation, though short enough to ensure that clinical change has not occurred. The test-retest should therefore not be conducted more than 2 weeks apart. Within-day reproducibility is also of interest to assess the potential effect of time of day or circadian cycles on test reliability. In the present study, each participant was invited to perform a 6MWT and a 30s-STS test during three independent sessions. The first two sessions were conducted on the same day in order to measure the intra-day reproducibility of the device. These sessions were conducted in the morning and in the afternoon, at a minimal 6-hour interval (maximum 12 hours), in order to ensure the participants' recovery. The last session was scheduled several days later (minimum 1 week; maximum 2 weeks) in the morning

at the same time as the first session in order to evaluate the inter-day reproducibility of the tests.

Full procedure. In the first session, participants answered the PAR-Q+ and signed the consent form. Each participant performed the tests with their own phone in order to approach real-life measurements and to control the smartphone brand in the analyses. To do so, participants downloaded the Kiplin app on their phones and entered their demographic information on *MediEval*. This included age, gender, height, and body weight to calculate BMI (kg/m^2). Previous research showed that adult self-report of weight and height is strongly correlated with objectively measured values.²⁸ Then, they watched the video tutorial explaining the tests. After the experimenter has verified the correct understanding of the instructions, the participants performed the 6MWT on an athletics track. The test consisted of round trips on a 100m straight line, delimited by two marks (which the participants had to turn around). At the end of the 6 minutes, the participant stopped and the total distance covered was measured with the distance wheel. In a second time, participants had to perform the 30s-STST test, after having done a few warm-ups and set up their phones in the appropriate conditions. The number of repetitions was noted by the experimenter and the video of the test was recorded for later verification. The other two sessions followed the same procedure. Participants did not receive monetary compensation.

Statistical analyses

Sample size and power analysis. We conducted an a priori sample size estimation based on 1) preliminary results of the device in internal tests and the available scientific literature that allow us to expect a reliability (intraclass correlation coefficient, ICC) of 0.85 ($p=1$), and 2) the recommendations of Terwee et al.,²⁵ which proposed a minimal acceptable reliability (ICC) of 0.70 ($p=0$). This power analysis revealed that 53 participants were needed to reach 80% power and a two-sided type I error at 0.05.

Data analysis. Criterion validity was assessed by calculating the correlation between the scores given by the app and the score measured via the gold standard. The scoring system for correlation coefficients as described by McCall²⁹ was used: 0.0-0.2 very low or negligible; 0.2-0.4 low; 0.4-0.7 moderate, 0.7-0.9 high; and > 0.9 very high. Validity was considered convincing when the correlation with the gold standard was at least 0.70.²⁵ The difference between the app-based and gold standard-based

measures was transformed into the relative measurement error (*rME*), which provides the ratio of the absolute error to the measurement in comparison to the gold standard. Systematic differences between the two measures were investigated with Bland & Altman plots.³⁰ Reproducibility can be divided into two different constructs: the *reliability* concerns the degree to which patients can be distinguished from each other despite measurement error³¹ whereas the *agreement* concerns the absolute measurement error (i.e., how close the scores on repeated measures are). ICC was used to assess reliability, as it is the most appropriate and commonly used reliability parameter for continuous measurements.²⁵ Usually, 0.70 is recommended as the minimum standard for reliability.³² Between-person and within-period variances were estimated with a linear mixed effects model for absolute agreement, adjusted for age, BMI, and type of smartphone. The agreement was computed as the standard error of measurement (SEM)³³ which represents the standard deviation of repeated measures in one patient, and was calculated from the square root of the error variance of the ICC ($\sqrt{\text{VarError}}$). Bland-Altman plots were performed to visualize agreement.

All analyses were conducted using R (R Foundation for Statistical Computing). The data and code for the statistical analyses used in the present study are available on Open Science Framework (<https://osf.io/4hzke/>).

Results

A total of 158 measurements for both tests were obtained. Participants' demographics are reported in Table 1.

Criterion validity

Results indicated a high correlation between the 6MWT distance measured by the Medieval app and the distance measured via the distance wheel ($\rho=0.79$, $p<0.001$) and a very high correlation between the STS test scores obtained with the app and observed scores ($\rho=0.98$, $p<0.001$). Figure 2 shows Bland-Altman plots comparing the app scores with the gold standard measure for both tests. For the 6MWT, the plot illustrates a mean difference of 8.96 m and a 95% limit of agreement of -76.96 to 94.88 m whereas the plot relative to the STS test reveals a mean difference of -0.28 repetition and a 95% limit of agreement of -2.16 to 1.70 repetitions. Examination of the plots suggests the existence of outliers for both tests. The mean $|rME|$ for the 6MWT was 4.40% and 1.73% for the STS test. For the 6MWT, mean $|rME|$ stratified by

phone brands ranged as the following: OnePlus (1.14%), Huawei (2.22%), Realme (2.44%), iPhone (3.14%), Samsung Galaxy (4.67%), Google Pixel (5.06%), and Xiaomi (20.1%). The |rME| of Xiaomi phones was significantly higher than the other brands ($p<0.001$) and corresponds to the outliers visible on the Brand-Altman plot. Thus, when excluding Xiaomi phones in sensitivity analyses, the correlation between the scores app and the distance measured via the distance wheel was $\rho=0.83$, with a mean |rME| of 3.78%.

Reproducibility

Test-retest reliability estimates of the MediEval indicated acceptable intra-day stability for the 6MWT (ICC = 0.83) and the STS test (ICC = 0.79) and inter-day reproducibility for the 6MWT (ICC = 0.72) and the STS test (ICC = 0.68). The adjusted ICCs considering the 3 measurement points were 0.67 for 6MWT and 0.70 for the STS test. ICC values were higher without adjustment for age, BMI, and type of smartphone (ICC = 0.77 for both tests). As a comparison, the ICC for the gold standard measures of the 6MWT and the STS test were respectively ICC = 0.78 and ICC = 0.75. The SEM for the 6MWT was 35.20 and 2.66 for the STS test. Finally, Bland-Altman plots comparing the test-retest app scores for both tests reveal intra-day mean differences of respectively -7.19m (95% limit agreement [-19.01; 4.63])

for the 6MWT and -1.32 repetition (95% limit agreement [-2.30; -0.34]) for the STS test. Inter-day mean differences were -27.35m (95% limit agreement [-42.72; -11.97]) for the 6MWT and -2.04 repetitions (95% limit agreement [-3.25; -0.83]) for the STS test (Fig. 3).

Table 1. Descriptive statistics.

Descriptive statistics	
<i>Demographics</i>	
Age, mean (SD)	33.18 (11.00)
Female/male	30/23
BMI kg/m², mean (SD)	22.64 (2.84)
<i>Type of smartphone used</i>	
iPhone (% of all tests)	24 (44%)
Google Pixel (% of all tests)	8 (14%)
Samsung Galaxy (% of all tests)	14 (26%)
Huawei (% of all tests)	3 (6%)
Xiaomi (% of all tests)	3 (6%)
OnePlus (% of all tests)	1 (2%)
Realme (% of all tests)	1 (2%)
<i>Test scores</i>	
6MWT meters, mean (SD)	704.55 (79.13)
30s-STs repetitions, mean (SD)	21.87 (5.89)

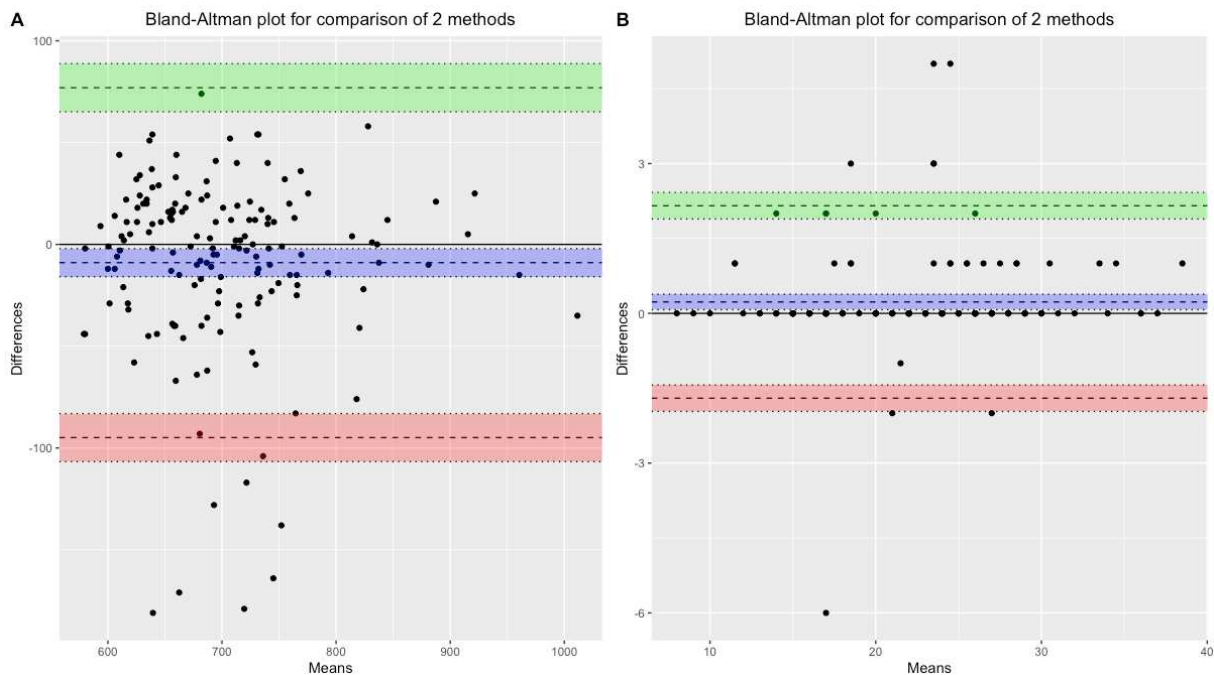


Figure 2. Bland-Altman plots for validity. (A) Comparison of the app-based and distance wheel measure of the 6MWT distance. (B) Comparison of the app-based and observed performance at the 30s-STs test. The upper and lower lines represent the 95% limits of agreement, and the center line indicates the mean difference.

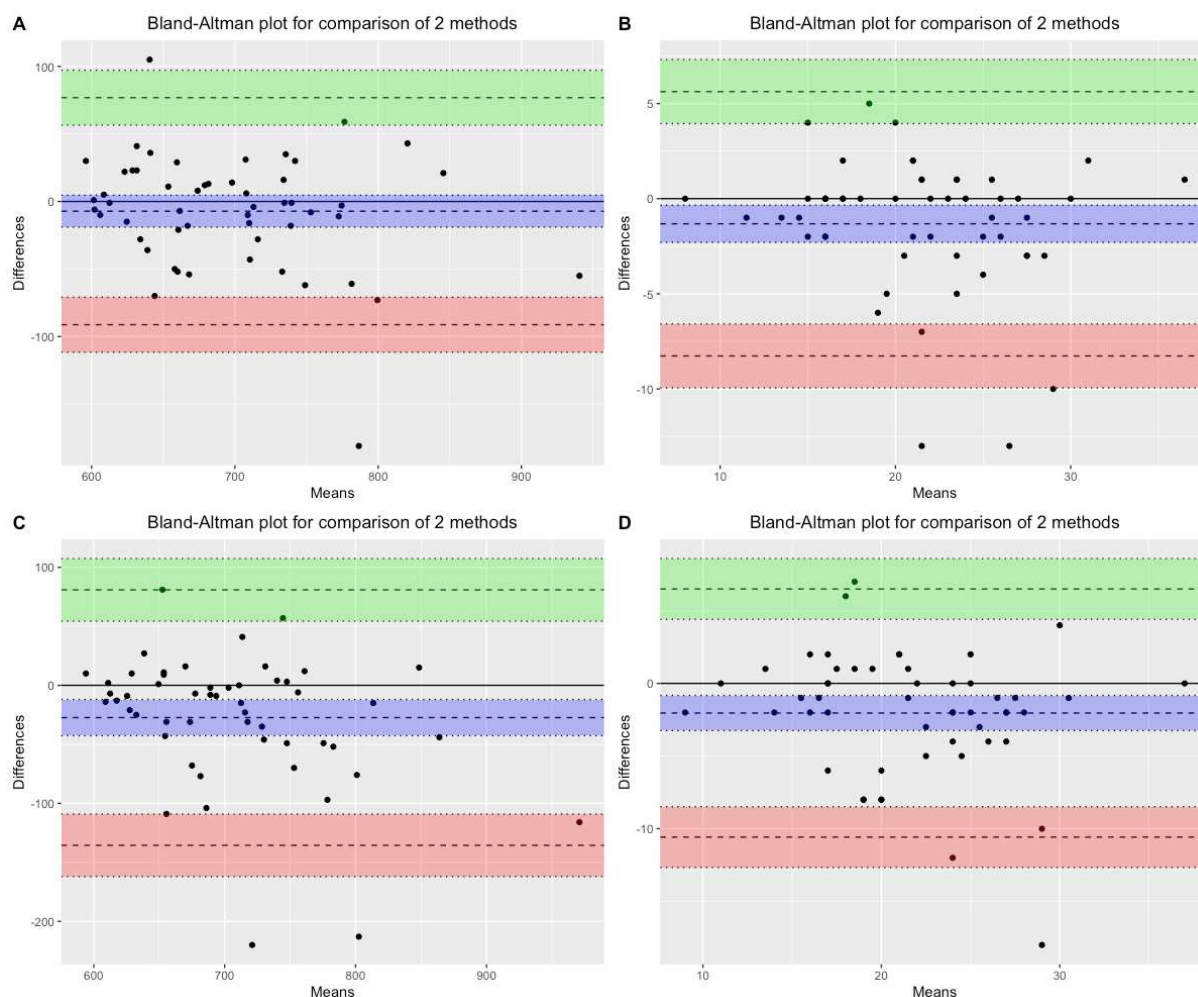


Figure 3. Bland-Altman plots for reproducibility. (A) Intra-day test-retest for the 6MWT. (B) Intra-day test-retest for the 30s-STST test. (C) Inter-day test-retest for the 6MWT. (D) Inter-day test-retest for the 30s-STST test. The upper and lower lines represent the 95% limits of agreement, and the center line indicates the mean difference.

Table 2. Summary of the results.

Variables	6MWT	30s-STST test
Validity (correlation)	0.79	0.98
Relative measurement error (%)	4.40	1.73
Reliability (ICC)	0.77	0.77
Intra-day reliability (ICC)	0.83	0.79
Inter-day reliability (ICC)	0.72	0.68
Standard error measurement	35.20	2.66
Smallest detectable change	97.56	7.37

Discussion

Principal findings

The main contribution of the current study was to develop and evaluate the validity and reproducibility of an app-based medical device aimed to empower individuals in conducting physical condition tests on their own. The results revealed high to excellent validity of the app in comparison to gold standards – with high correlations and low rME – which suggests

that the *MediEval* device was precisely able to measure the physical performance. Indeed, the mean differences between the app and the gold standard measures were 8.96m for the 6MWT and 0.28 repetition for the 30s-STST test. Moreover, the reliability and agreement of the device during the test-retest were good and similar to the reliability of scores obtained with gold standard measures.

Comparison with previous research

Our results for the 6MWT are comparable with previous studies that showed good acceptability, validity, and reliability of devices that used the GPS coordinates of the smartphone to calculate the 6MWT distance outdoors.^{21,27} For the 30s-STS test, this study is the first to design and test the innovative way of assessing STS movements by camera detection using a skeleton extraction algorithm. Other options for physical functioning remote assessment are to conduct the tests via videoconferencing technology³⁴ or using video-guided self-administered tests.²⁰ If these two options showed positive validity estimates, these methods require personnel to administer or evaluate the test where the present device allows patients to perform the test independently.

Strengths and limitations

The major strength of this study is the validation of an innovative medical device in real-life conditions among a population of various ages who used their own smartphone to perform the tests. Indeed, these tests have been conducted in everyday-life reproducible conditions, whereas previous studies evaluating GPS-based 6MWT assessment apps have been conducted in a lab environment and settings that do not seem practically feasible for the patient (e.g., performing the 6MWT on a straight course of 500–700m). The generalization of the *Medieval* medical device on a large scale will also be facilitated by the fact that the app is available on both iOS and Android smartphones (covering the vast majority of the global mobile operating system market share with cumulatively >99%).³⁵

Despite these positive assets, the 6MWT that needs to be performed outdoors to get an accurate GPS signal can still be complicated to implement for patients, especially in winter or in the midst of big cities with buildings. Moreover, several factors can limit the accuracy of the GPS such as atmospheric fluctuations, ephemeris error, satellite clock drift, hardware error, and unfavorable satellite geometry that may lead to an overestimation of distance³⁶ Finally, in this study participants followed the instructions of the examiners to perform the tests. We can question whether the tests will be performed correctly in a real-life setting when the patients are alone.

This study also revealed that a GPS-based remote 6MWT is not as accurate on all smartphones. The statistical analyses showed that Xiaomi

smartphones had a significantly higher rME than the other brands tested. This could be explained by a poorer-quality GPS embedded in these phones. Large longitudinal data collection in the post-market surveillance process will allow adapting the algorithms according to the GPS accuracy and the type of smartphone. In the meantime, the results of 6MWT tests performed with Xiaomi smartphones should be interpreted with caution.

Perspectives for future research and implications for practice

The first step in developing and evaluating *MediEval* was to ensure that the device would validly and reproducibly measure performance on fitness tests under supervised conditions in healthy individuals. The next step is to test this medical device in clinical settings among patients with chronic diseases. Such study will be important to determine the interpretability of the device. This construct refers to the extent to which scores obtained from the app can be interpreted by providing reference data from the target population.³⁷ In other words, interpretability is capital regarding change scores to be able to affirm if a change in the measured performance should be considered part of the measurement error or as a real change.^{25,37} In addition, this next experiment conducted in the context of a supervised physical activity program will allow determining the responsiveness of the device (i.e., the ability to detect clinically important changes over time). Since this device could generate important money savings and facilitate the onboarding of patients in physical activity programs, it will also be essential to evaluate the economic impact of the use of a such device for the healthcare system. As mentioned earlier, it will also be capital in future studies to test that the remote tests are performed properly in accordance with the instructions given in the tutorials with the collection of real-world data.

From a practical point of view, as physical capacities are important markers of health both in young and in adults, healthy or with chronic diseases, the development of a cost-effective measure of physical capacities that could be implemented in medical offices, in hospital settings but also at home can help to determine subjects at high risks.³⁸ Moreover, *MediEval* offers a new opportunity to monitor patients' physical health status and symptoms over time due to the faculty of performing more tests

independently.¹⁰ Using this medical device, practitioners may encourage patients self-monitor their health condition, which can contribute to the empowerment of the individual and promote behavior change as self-monitoring is a key behavior change technique and an appreciated feature in mobile apps.^{39,40} On other aspects, these remote tests could reduce medical test anxiety and the associated stress for patients. Finally, *MediEval* opens new perspectives for measuring the strength, mobility, and physical function of large epidemiologic cohorts. Such device could therefore be a complement to physical activity measurements performed on representative samples of the general population at the country level – allowing ultimately to determine and monitor the physical condition of the populations of a country.

Conclusion

Traditional physical fitness and muscular strength tests require in-person visits with specialized equipment and trained personnel, leading to organizational constraints both for patients and hospitals and making them difficult to implement on a large scale. *MediEval*, an app-based medical device, allows participants to conduct the 6MWT and the 30s-STST test remotely and in autonomy. The present validating study revealed that this device conveniently measures participants' performances with good validity and reproducibility estimates on healthy participants. Future studies will evaluate the responsiveness and validity of this device in clinical settings among patients with chronic diseases.

Additional Information

Contributions

Conceptualization: AM, MB, MD; Data curation: AM; Investigation: AM; Methodology and statistics: AM; Software: AM; Writing – original draft: AM; Writing – review & editing: all the authors.

Declaration of interests

AC 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.

Funding

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 study and no influence on the interpretation or publication of the study results.

Data sharing

The anonymized data used in this study and the R code are available on the Open Science Framework (<https://osf.io/4hzke/>).

Acknowledgments

The authors want to thank Charlotte Herbrecht (research assistant) for helping out with the measurements and all the participants for their time and involvement.

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Summary Chapter 4

Current physical activity programs involve logistical and financial limitations for both patients and the healthcare system. eHealth and mHealth services are promising tools to propose remote programs at a distance and allow patients to follow remote telecoaching sessions or perform physical condition tests from home. Study 3 was a pilot experiment conducted during the first lockdown due to the COVID-19 pandemic evaluating the effectiveness of a hybrid program combining in-person and telecoaching sessions, on 20 patients with various chronic diseases. The results suggested that such program was effective to increase total physical activity and improve cardiorespiratory fitness. Moreover, this improvement was significantly more efficient compared to 100 similar patients who had completed the same 3-month program but exclusively in face-to-face settings. Study 4 aimed to evaluate the validity and reliability of an app-based medical device to allow remote physical condition tests. 53 healthy adults performed the 6-minute walking test and the 30-second sit-to-stand test during three different sessions to measure test-retest reliability and correlation with gold-standard measures. Results revealed high to excellent validity of the app in comparison to gold standards with low relative measurement error, and both tests had good test-retest reliability. The tools tested in these two studies appear promising to improve the reach and evaluation of adapted physical activity programs.

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Chapter 5

The DIPPAO randomized controlled trial

No rigorous trial has yet demonstrated the effectiveness or cost-effectiveness of digital physical activity interventions over the usual care (i.e., supervised physical activity programs). In addition, gamified and digital intervention mechanisms have been seldom evaluated in previous studies. The DIPPAO (for Digital Intervention Promoting Physical Activity among Obese people) randomized controlled trial conducted as part of this thesis investigated these research gaps.

In order to answer the different theoretical and methodological limits introduced in Part I of this thesis, this trial included a) a 6-month follow-up to evaluate the mid-term effect of the intervention, b) intensive longitudinal assessment of daily steps over the whole study in order to accurately capture physical activity behavior, c) both between-group differences in benefit and within-person evolutions in an idiographic approach, d) several measures of psychological constructs informed by the self-determination theory and the social identity approach with the consideration of stereotypes-related variables, and e) cost-effectiveness analyses.

Study 5 introduces the theoretical background, hypotheses, and protocol of this two-arm parallel randomized controlled trial testing the effectiveness of the Kiplin digital intervention among obese type 2 diabetes patients, in comparison to the usual supervised PA program of the University Hospital of Clermont-Ferrand. A total of 50 patients were randomized to one of the two interventions and followed a 3-month program with a 6-month follow-up. Changes in daily steps, body composition, physical capacities, motivation, or perceived weight stigma across the study were evaluated. Study 6 reveals the preliminary results of this trial.


Note: as the protocol of this trial was elaborated in 2020, it does not include all the theoretical, methodological, or technological advances of this thesis. For instance, the MediEval medical device was not used in this trial.

12. Study 5: digital intervention promoting physical activity among obese people (DIPPAO) randomized controlled trial: study protocol

Published in BMJ Open:

Mazéas, A., Chalabaev, A., Blond, M., Pereira, B., & Duclos, M. (2022). Digital intervention promoting physical activity among obese people (DIPPAO) randomised controlled trial: study protocol. *BMJ open*, 12(6), e058015.

BMJ Open Digital intervention promoting physical activity among obese people (DIPPAO) randomised controlled trial: study protocol

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To cite: Mazéas A, Chalabaev A, Blond M, *et al.* Digital intervention promoting physical activity among obese people (DIPPAO) randomised controlled trial: study protocol. *BMJ Open* 2022;**12**:e058015. doi:10.1136/bmjopen-2021-058015

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-058015>).

Received 05 October 2021

Accepted 17 May 2022



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ABSTRACT

Introduction Physical inactivity and excessive sedentary behaviours are major preventable causes in both the development and the treatment of obesity and type 2 diabetes mellitus (T2DM). Nevertheless, current programmes struggle to engage and sustain physical activity (PA) of patients over long periods of time. To overcome these limitations, the Digital Intervention Promoting Physical Activity among Obese people randomised 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 patients with T2DM in comparison to the usual supervised PA programme of the University Hospital of Clermont-Ferrand, France. A total of 50 patients will be randomised to one of the two interventions and will follow a 3-month programme with a 6-month follow-up postintervention. 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 with the current treatment, we will conduct a cost-utility analysis between the two conditions. A mixed-model approach will be used to analyse 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, No 21 004-65219). Results will inform the Kiplin app development, be published in scientific journals and disseminated in international conferences.

Trial registration number NCT04887077.

INTRODUCTION

Overweight and obesity, which concern one in two adults in western countries,¹ are among the most important health risk factors, and is

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Randomised controlled trial comparing a digital gamified intervention targeting physical activity to another existing non-drug treatment.
- ⇒ Between-person and within-person level analyses of daily steps will provide insight on group differences and individual trajectories of behaviour change.
- ⇒ A 6-month follow-up will inform on the sustainability of the 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.

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 behaviours (SB) are both major factors in the development of these diseases.^{2–7}

Positive effects of physical activity (PA) for these patients are recognised both at the scientific and institutional levels. Indeed, they can benefit from supervised PA programmes suited to their disease (ie, adapted PA, APA), which allow to improve functional capacity and muscle strength without having detrimental effects or complications on disease progression.⁸ However, these programmes 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 programmes is generally observed.¹⁰

Given that PA of obese and patients with T2DM 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 programmes, 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 individualised 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 with current programmes, 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-analysis²¹ revealed that gamified interventions improved PA with an increase of more than 1600 daily steps. Importantly, additional analyses indicated that (1) gamified interventions appear more effective than equivalent non-gamified interventions and (2) 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 behaviour change in obese people

Another key driver to enhance the effectiveness of e-health interventions is the use of behaviour change theories and techniques (BCTs), as they allow to target the active ingredients of behaviour 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 programmes 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 Consolidated Standards of Reporting Trials (CONSORT) statement²⁶ or the WHO²⁷ have emphasised 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 behaviour change theories (eg, theory of planned behaviour,²⁸ transtheoretical model,²⁹ self-determination theory (SDT)³⁰) and BCTs.³¹

In addition, recent research has emphasised the importance of precision medicine which focuses on individual variability and social and societal factors of behaviour 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 internalised negative stereotypes into their self-perceptions, leading them to avoid activities in which they feel being stigmatised, 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 optimise their effectiveness.

Theoretical framework

To address these challenges, the present intervention was built based on the tenets of the SDT³⁶ and the social identity approach (SIA).³⁷

SDT: The SDT is an empirically validated framework which focuses on factors that promote sustained motivation and well-being.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 behaviour comes from the individual's will. Research has revealed that an autonomous motivation has positive emotional, cognitive and behavioural 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.

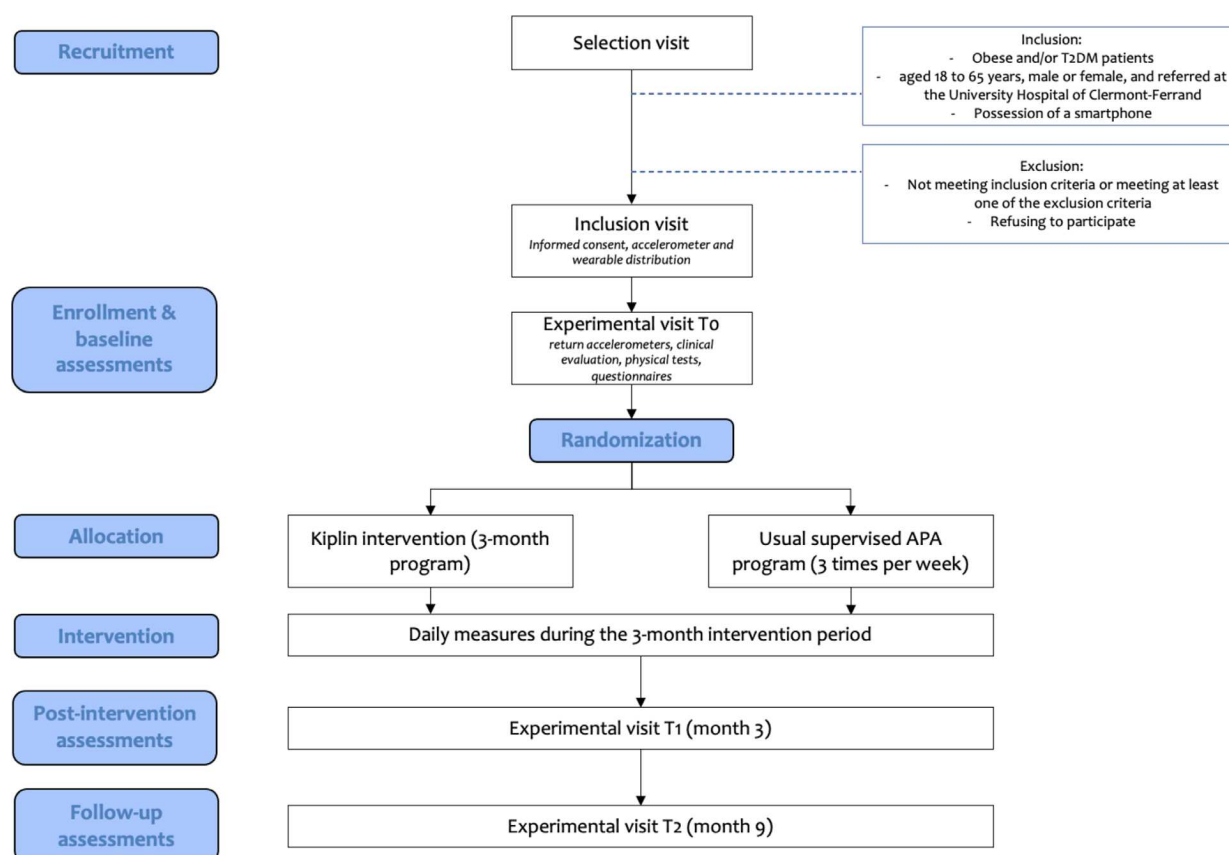


Figure 1 Study flow chart. APA, adapted physical activity; T2DM, type 2 diabetes mellitus.

In parallel, SDT postulates that autonomous motivation increases when three basic psychological needs are satisfied³⁰: the need for autonomy (ie, need to feel responsible of one's own actions), for competence (ie, need to feel effective in one's interactions with the environment), and for relatedness (ie, 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 First, gamification strategies such as points scores, badges, levels and competitions, sustain the need for competence by providing feedbacks on the user's behaviour. Second, customisable environments of the games or user choices may support autonomy. Finally, leaderboards, teams, groups or communication functions may support the need for relatedness.²⁰

SIA: 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 behaviours 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 theory⁴⁷ and the self-categorisation theory.⁴⁸ As social identity

theory introduces the capacity for groups to be internalised into our sense of self (ie, speaking and living situations in the name of 'we' and 'us' rather than just 'I' and 'me'), the self-categorisation 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 categorisation process. Individuals categorise 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 catalyse the effects of groups with shared social identities.

A recent body of work investigates the links between self-categorisation theory and long-term adherence of PA programmes. 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 programme 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



Figure 2 Screenshots of the Kiplin app. (A) The telecoaching sessions reservation. (B) The adventure. (C) The investigation. (D) The boardgame. (E) The chat. (F) The activity monitoring tool.

confronted with stigmatisation. Thus, the shared identities forged during a group-based intervention regrouping individuals with the same stigma (eg, 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 Digital Intervention Promoting Physical Activity Among Obese (DIPPAO) randomised controlled trial (RCT) is to evaluate the effectiveness of the Kiplin intervention—a group-based digital programme centred 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: (1) a gamification of PA through multiple games, (2) a remote APA programme with videoconferencing sessions, (3) an interface for exchange and conversation and, (4) an activity monitoring tool. This 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 (ie, 3 months face-to-face supervised APA programme). Additional objectives of this RCT will be to better understand the mechanisms underlying this digital intervention and to test its cost-utility compared with the usual care. More specific hypotheses on the expected effects of the intervention are proposed in online 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 programme of the University Hospital of Clermont-Ferrand, on patients with obesity and/or T2DM. Both arms will benefit from a 3-month programme and assessments will be carried at baseline, 3 and 9 months. The conduct and reporting of the trial will follow the CONSORT guidelines.^{26 54} For an overview of the study design, see figure 1.

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 18–65 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 online 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. They will sign a written consent form before being included in the study (see online 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

Table 1 Implementation of BCTs within the app following Michie *et al*'s taxonomy⁷⁵

BCT	Related app feature or game mechanic
Goal setting behaviour (1.1)	Set daily step goals.
Action planning (1.4)	Choose the goal according to several suggestions. Time-limited challenges encourage participants to maximise 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.

BCTs, behaviour change techniques; PA, physical activity.

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 1 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 programme, the T1 experimental visit will be carried, and the T2 experimental visit will be placed 6 months after the end of the programme 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.

Randomisation, allocation and blinding

Following the first experimental visit, patients will be randomised in one of the two conditions with a 1:1 allocation. The associate biostatistician will carry out a permuted block randomisation in advance by computer with randomly varying block sizes. The randomisation 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 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 anonymised 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 catalyser promoting good habits' by the participants. Afterward, the full intervention including telecoaching APA sessions in a 12-week programme has been pilot tested on different patient pathways (unpublished data), including obese and patients with T2DM.

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 2 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: personalised and evolving daily step goal +general PA guidelines; at the end of the programme: video capsules to continue exercising in autonomy +assistance to plan an activity and find a club)	PA recommendations (at the start of the intervention: general PA guidelines; at the end of the programme: assistance to plan an activity and find a club)
Gamification of PA (3 games of 14 days each 2 weeks apart)	
Chat and messenger	
Activity monitoring tool (mobile app +Garmin Vivofit 3)	
APA, adapted PA; PA, physical activity.	

Patients' feedbacks were all positive and enthusiastic and no organisational issues have been identified, suggesting that the intervention was ready to be tested in an RCT.

Intervention overview

To promote behaviour change, we implemented within the Kiplin app 16 BCTs. Previous meta-analyses have shown these techniques to be effective in increasing walking behaviour,⁵⁶ to encourage behaviour 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 programme. Videoconferencing is an interesting perspective to reduce the organisational limitations of face-to-face programmes. With this telemedicine approach, professionals can offer tailored interventions from a distance and propose a remote home-based APA programme to patients in addition of providing monitoring, social support and therapeutic education.⁶¹ Thus, this programme 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 2 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 min 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 email 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 (ie, endurance 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 recommendations²¹ 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 (ie, the adventure (figure 2B), the mission (figure 2C) and the board game (figure 2D); more details about the games in online 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 programme (figure 2E). During the games, this messenger will be animated every day by 'Pilot Kiplin' (ie, 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 mobilise and inform participants about the games or to remind them to participate to the telecoaching session they are registered.

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	
<i>Anthropometric measurements and body composition</i>	
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 multifrequency 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 PA ⁷⁶ as well as in overweight and obese children and adolescents. ⁷⁷
<i>PA and SB</i>	
Objective PA	Accelerometer-based PA (Actigraph GT3X+; ActiGraph LLC, Pensacola, Florida, USA) to measure the time spent in light-intensity, moderate-intensity 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 behaviours will be collected using the Recent Physical Activity Questionnaire ⁷⁸ 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
<i>Physical capacities</i>	
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. ⁷⁹ 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 min walking test (6MWT). The 6MWT is a simple and convenient test that measures the distance in metres a patient can walk in 6 min in a standardised 30 m long corridor. This test will be performed following the American Thoracic Society guidelines ⁸⁰ and has been validated in the past. ⁸¹
<i>Quality of life</i>	
Quality of life	Via the EQ-5D-5L questionnaire ⁸² assessing five dimensions: mobility, autonomy of the person, current activity, pain/discomfort, anxiety/depression.
<i>Psychological mediators</i>	
Perceived enjoyment	Perceived enjoyment of PA during the intervention will be evaluated using the Physical Activity Enjoyment Scale. ⁸³ 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 ⁸⁴ will be used to measure perceived competence (eg, I feel that I am able to complete exercises that are personally challenging), autonomy (eg, I feel free to exercise in my own way), and relatedness (eg, 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 PA will be assessed using a short version of the Motivation Scale Towards Health-oriented Physical Activity. ⁸⁵ 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 ⁸⁶ 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.

Continued

Table 3 Continued

Outcome	Assessment method
Weight stigma	Three forms of weight stigma will be evaluated. A modified version of the Everyday Discrimination Scale ⁸⁷ will assess perceived discrimination. This questionnaire consists of 5 items (eg, 'In the last month, 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, ⁸⁷ composed of 3 items (eg, '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 Internalisation Scale ⁸⁸ will be used to assess weight bias internalisation. This questionnaire is composed of 11 items (eg, '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).
<i>Programme adherence</i>	
APA sessions attendance and perceived exertion	The no 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. ⁸⁹
App engagement	For the Kiplin group only, the app engagement and utilisation 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.
<i>Economic evaluation</i>	
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 healthcare 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, 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.
<i>Control variables</i>	
Perceived vulnerability against COVID-19	An adapted version of the perceived vulnerability questionnaire ⁹⁰ will be used. This questionnaire is composed of 6 items (eg, '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 digitalisation	Via one item (ie, 'I feel comfortable with the use of smartphones and digital objects') rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree).
APA, adapted physical activity; BMI, body mass index; DIPPAO, Digital Intervention Promoting Physical Activity Among Obese; QALY, Quality-adjusted life year; RCT, randomised controlled trial; SB, sedentary behaviours; T2DM, type 2 diabetes mellitus.	

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 behaviour and promote self-monitoring of PA. Self-monitoring and goal setting strategies have been pointed as major predictors of PA at short term 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 programme 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 programme. 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 personalise 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 favours homogeneous groups in terms of gender and age. In addition, participants will complete a short and fun personality questionnaire on entering their programme.

Table 4 Schedule of enrolment, interventions and assessments

Study period								
	Selection visit	Inclusion visit	T0	Intervention			T1	T2
Time point	M-1	M-1	0	M1	M2	M3	M3	M9
Enrolment:								
Eligibility screen	X							
Informed consent		X						
Randomisation			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
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
Programme adherence								
Control variables			X				X	X
Adverse events	At any time							
6MWT, 6 min walk test; PA, physical activity.								

6MWT, 6 min walk test; PA, physical activity.

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 generalisability of the results outside the scope of this trial.

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 programme 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 min 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 organised as a row of six exercise stations (three aerobic and three resistance exercises). Aerobic exercises will be performed at 50% of VO₂max the first week and the intensity will be gradually increased by 10% every 2 weeks to target at least 80% of VO₂max over the last 9 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 2 weeks and remain at 80% of 1RM over the last 5 weeks.

The content of both groups is summarised in [table 2](#).

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, Olathe, Kansas, 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.⁶⁹ The temporal zone of evaluation will extend from 7 days before the start of the intervention (ie, baseline assessment), through the 3 months of intervention (ie, evolution during the interventional phase), to 7 days after the end of the intervention (ie, 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^{70 71}) and will be removed from the analysis. As using pedometers positively influence daily PA,⁷² 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 (ie, display of the daily number of steps, calories burned, distance travelled and minutes of activity performed) following the randomisation. The wearables of the usual supervised PA programme 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) physical capacities and (4) quality of life. Psychological mediators and programme 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 schedule template⁷³).

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-analysis⁷⁴ that have reported an effect size of $d=0.51$, (95% CI 0.12 to 0.91, $I^2=90\%$) for PA interventions comprising wearables and smartphone apps compared with 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 to 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 intraclass correlation coefficient of 0.5 (in order to take into account the interindividual and intraindividual variability), 2002 individual-days are necessary per group (ie, 22 participants per group). We propose to include 25 participants per group in order to foresee potential drop-outs, 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 (V.15; StataCorp).

Analyses of primary outcome

Longitudinal data will be assessed using linear mixed models in order to account for intraindividual 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 \times 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% CIs.

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 (eg, gender, age, BMI and engagement). Particular attention, primarily descriptive, will be paid to participants' adherence to different intervention programmes. 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 stigmatisations or in-group identification, Bayesian inferences could be applied in an exploratory perspective.

Continuous secondary outcomes will be analysed 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 χ^2 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-centred 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.

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, No 21 004-65219). 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 authorisation 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 programme aim to promote behaviour change and long-term PA among patients with obesity and/or T2DM. Backed by scientific knowledge, this intervention may change patient's behaviour by improving their self-determined motivation towards PA, reducing weight stigma that usually act as PA barriers, and ultimately

participating to improve programme adherence. More globally, this intervention is the opportunity to address a wider audience though one unique programme by responding to the limits and constraints of face-to-face programmes. Findings will be of interest to researchers, practitioners and policy-makers in future discussions on the relevance of digital interventions in the treatment of chronic diseases.

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Acknowledgements 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 conceptualised the project and obtained the funding. All authors 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. Trial sponsor: University Hospital CHU G. Montpied, Clermont-Ferrand.

Disclaimer 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.

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.

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

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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13. Study 6: preliminary results of the DIPPAO randomized controlled trial

Preliminary results of the DIPPAO randomized controlled trial

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Key words

behavior change; mHealth; gamification; intervention; physical activity; sports and exercise medicine.

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Abstract

Background. If physical inactivity and excessive sedentary behavior are major preventable causes in both the development and the treatment of obesity and type 2 diabetes mellitus (T2DM), current programs struggle to promote long-term physical activity (PA) in obese persons and T2DM patients. The DIPPAO trial aimed to answer this issue by testing the effectiveness of the Kiplin program, a group-based gamified digital intervention incorporating supervised PA sessions in telecoaching, in comparison to the usual face-to-face supervised PA program.

Methods. In this two-arm parallel randomized controlled trial, 50 obese and T2DM patients were randomized to one of the two interventions and followed a 3-month program with evaluations before, after the program, and after a 6-month follow-up. In the present study, data from 39 patients who had already finished their program were analyzed. The primary outcome was the evolution in daily steps through the trial and follow-up. Secondary outcomes included body composition, physical capacities, motivation, quality of life, and perceived weight stigma. A mixed-model approach was used to analyze the change in outcomes over time. In addition, through an idiographic approach, generative additive models were conducted to explore the evolution of the effect of the Kiplin intervention across time.

Results. Compared with the usual care, patients who benefited from the Kiplin intervention had a significantly greater increase in mean daily steps from baseline during the intervention ($b = 0.22$, 95%CI [0.08; 0.36], $p = 0.002$) and during follow-up periods ($b = 0.43$, 95%CI [0.23; 0.62], $p < .0001$). For secondary outcomes, mixed-effect models indicated no significant difference in change between the two groups, except a quadratic effect of time between the end of the program and the end of the follow-up, suggesting a difference in the evolution of the cardiorespiratory fitness between the two groups post-intervention. The feeling of solidarity within the Kiplin condition positively moderated the intervention effect. Generative additive models revealed the existence of different patterns of responses among patients of the Kiplin group.

Discussion. The Kiplin digital intervention effectively improved PA during the intervention and follow-up periods compared to a traditional supervised face-to-face PA program. Interestingly, the effect size observed during the intervention persisted over the follow-up period, suggesting good sustainability of the intervention effect. If the final results of the trial follow the same trends, the practical implementation of such digital intervention for the treatment of obesity and T2DM will be strongly considered.

Introduction

The DIPPAO randomized controlled trial aims to compare the effectiveness, cost-effectiveness, and psychological mechanisms of the Kiplin program (i.e., a group-based digital intervention integrating gamification and supervised physical activity (PA) by telecoaching) in comparison to the usual care (i.e., face-to-face supervised PA sessions) among patients treated for obesity and/or type 2 diabetes Mellitus (T2DM). To answer these objectives, different outcomes have been evaluated at

inclusion, after the 3-month programs, and after a 6-month follow-up. In November 2022, inclusions were completed (i.e., 50 patients recruited), 39 patients completed two measurement times, and 12 patients completed the whole study. In this paper, we propose preliminary results of the primary and some secondary outcomes of this trial, based on data available to date.

Based on previous results on the effectiveness of gamification to promote physical activity,^{1,2} we

hypothesized that patients of the Kiplin group would have a greater increase in PA levels compared to baseline than the usual care. We also hypothesized that this improvement in PA would sustain after the follow-up period. In parallel, informed by the self-determination theory³ and the social identity approach,⁴ we hypothesized that the effect of the Kiplin intervention would be explained by its ability to promote a self-determined motivation toward PA or to develop a strong social identity within the intervention group (i.e., being the basis for mutual and social support). The latter aspect should allow individuals to overcome their fear of being discriminated, and more generally remove barriers related to the negative stereotypes that target them.^{5,6}

Methods

Procedure

The DIPPAO study is a two-arm parallel prospective randomized controlled trial conducted at the University Hospital of Clermont-Ferrand, France. The protocol of this trial has been reviewed and approved by the Local Human Protection Committee (CPP Ile de France XI, N° 21 004-65219) and registered on ClinicalTrials.gov (NCT04887077). All participants provided informed consent. Full details of the study methods and intervention content have been reported previously.⁷ There were no deviations from the prespecified protocol during the trial. The elements that may be different between the protocol and the final analysis will be specified in the following methods section.

Outcomes

Among the variables reported previously in the protocol study, this preliminary analysis will focus on the primary outcome (i.e., change in daily steps over 3 months – from the baseline, through the 3 months of intervention, to 7 days after the end of the intervention), the evolution of daily step count over 9 months considering the follow-up period, and the evolution of the body mass index (BMI), body composition (i.e., lean and fat mass), muscle strength (i.e., handgrip and isokinetic dynamometer), cardiorespiratory fitness (i.e., 6-minute walking test, 6MWT), quality of life (EQ-5D), perceived motivation (i.e., autonomous and controlled motivation), and perceived weight stigma (i.e., perceived discrimination, weight stigma concerns, and weight bias internalization) over 9 months. In-group identification, psychological

needs satisfaction, and perceived enjoyment will be included as moderators of the primary outcome.

The analyses conducted to control the psychometric qualities of the questionnaires revealed good reliability of the scales, except the quality of life questionnaire (i.e., EQ-5D, Cronbach's $\alpha = 0.52$), which was therefore excluded from this preliminary analysis. These analyses are available in supplemental materials.

Statistical analyses

General points. All analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria). In this paper, the statistical analyses followed per-protocol principles. Whereas intention-to-treat (ITT) analysis includes all randomized patients, per-protocol analysis includes only patients who completed the treatment originally allocated and performed at least two measurement times. ITT analyses will be available in the final version of the study results. Baseline variables were reported as numbers and percentages for categorical variables and means with standard deviations (SDs) for continuous variables. According to the CONSORT 2010 statement,⁸ group differences in baseline variables were not compared using significance testing.

Primary analysis. The change in daily steps was evaluated between baseline and the intervention period, between baseline and one week after the end of the intervention, and between baseline and the follow-up period using linear mixed-effect models. This statistical approach controls for the nested structure of the data (i.e., multiple observations nested within participants), does not require an equal number of observations from all participants,⁹ and separates between-person from within-person variance, providing unbiased estimates of the parameters.^{10,11} The models included the following fixed effects: group, period (i.e., baseline, intervention, or follow-up), and group \times period interaction. We computed the difference between baseline and one week after the end of the intervention in one model and baseline and the whole follow-up duration in another. We considered random intercepts for participants and random linear slopes for repeated measures at the participant level. In addition to this model, we conducted an adjusted model with the following fixed effects: group, period, group \times period interaction, age, baseline physical activity, BMI, and season, as these factors were significantly associated with the intervention effect in a previous study.² Non-wear days were defined as days with fewer than 1000 steps and considered as missing data.

First, an unconditional model (i.e., with no predictor) was estimated for each variable to calculate intra-class correlations (ICC) and estimate the amount of variance at the between and within-individual levels. Then, a model that allowed random slope over time (i.e., model with random intercept and random slope) was compared to the null model (i.e., with only random intercept) using an ANOVA, to evaluate whether the less parsimonious model explain a significantly higher portion of the variance of the outcome, compared to the unconditional model.^{12,13} Third, between-level predictors were added to the final model (and confounding variables in the adjusted model).

Model fit was assessed via the Bayesian Information Criterion (BIC) and $-2\log\text{-likelihood}$ ($-2LL$).¹⁴ All models were performed using the *lmerTest* package in the R software.¹⁵ An estimate of the effect size was reported using the marginal and conditional pseudo R^2 . Contrast analyses were computed using the *emmeans* package.¹⁶

Unlike what was announced in the protocol study, we decided to not perform group x time interactions for this primary outcome considering the possibility of a nonlinear effect of the intervention across time. In consequence, we fitted complementary models to assess the dynamic effect of intervention across time (see the exploratory section below).

Secondary analyses. Continuous secondary outcomes were analyzed using mixed-effect models (including the group, time, and group x time interaction terms as fixed effects) to assess changes in body composition, physical condition, self-reported motivation, and weight stigma across 9 months (i.e., considering the three measurement points). In addition, a growth curve model was tested to investigate whether there was a nonlinear change in outcomes over time and both linear and quadratic components were included in the model. Because of the limited number of parameters that could be estimated with three time points, only the linear slope was allowed to vary across individuals.

Exploratory analyses. In addition, specific mixed-effect models were conducted on Kiplin participants to assess potential moderator effects (i.e., app use, number of messages exchanged, participation in the game, and psychological variables during the intervention).

In a complementary analysis of the primary outcome, we reanalyzed the daily steps data of patients of the Kiplin group following an idiographic approach, meaning that each participant was analyzed separately from the others.¹⁷ To this end, we conducted Generative

Additive Models (GAMs).¹⁸ GAMs are an extension of generalized linear mixed models that allow the estimation of smoothy varying trends where the relationship between the covariates and the response is modeled using smooth functions. The use of these functions is advantageous as it does not restrict the model to a linear relationship.¹⁹ GAMs are particularly well-suited to the modeling of time series data with one level of measurement (i.e., repeated measurements nested within one individual), as they can accommodate the inclusion of autocorrelated error terms.²⁰ For these specific analyses, participants must have less than 50% of missing data on the baseline/intervention/one week-post intervention period to be included and missing days were imputed using the Kalman Filter method as this method is recommended for univariate time series imputation.²¹ Data were imputed separately for each dataset (i.e., each participant). Nonlinearity was estimated using the effective degrees of freedom (edf) of the GAMs' smoothing terms with $\text{edf} \geq 3$ indicating some form of nonlinearity.²⁰ GAMs were computed using the *mgcv* package²² and the *visreg* package²³ was used for model visualization.

Results

Descriptive Results

Between July 2021 and November 2022, 50 participants were recruited and enrolled in the study. In November 2022, 39 patients had completed 2 measurement points (T0, T1) and data collection was complete for 12 patients (T0, T1, T2). Details of participant flow through the trial are pictured in Figure 1.

The sample analyzed in this paper included 39 patients (mean age = 47.45 ± 13.74 years; 77% women, mean BMI = 40.17 ± 7.42 kg/m²). A total of 11 patients had T2DM. Descriptive results are presented in Table 1. At baseline, participants completed an average of 6229 (SD=3789) daily steps per day. Table S1 in supplementary materials presents the descriptive statistics for the clinical secondary outcomes.

Table 1. Descriptive statistics.

	Kiplin	Usual care
Patients	21	18
Sociodemographics		
Age, mean (SD)	47.5 (11.6)	47.89 (16.13)
Female, n (%)	16 (76)	14 (78)
BMI kg/m ² , mean (SD)	40.03 (7.95)	40.32 (7.02)
Obese, n (%)	18 (90)	17 (94)
T2DM, n (%)	5 (25)	6 (33)
Highest education level		
Less than high school, n (%)	5 (26)	8 (44)
High school, n (%)	4 (21)	2 (12)
University degree (%)	10 (53)	8 (44)
Physical activity (daily steps)		
Baseline, mean (SD)	5,633 (3,303)	6,994 (4,249)
Missing daily step values, n (%)	429 (9.5)	243 (11.1)

Primary outcome

Contrast analyses revealed that participants of the Kiplin group had a significantly greater increase in mean daily steps between baseline and the intervention period, compared with the usual care ($b = 0.22$, 95%CI [0.08; 0.36], $p = 0.002$). The difference between the two groups turned non-significant for the baseline/one-week post-intervention change comparison ($b = 0.17$, 95%CI [-0.22; 0.58], $p = 0.39$). However, when considering the full follow-up period, the daily step count change from baseline of patients in the Kiplin group remained significantly greater than that in the control arm ($b = 0.43$, 95%CI [0.23; 0.62], $p < .0001$).

The baseline/intervention period change for the Kiplin group corresponds to an effect size of $d = 0.35$ (95%CI [0.22; 0.49]). Interestingly, the effect size of the baseline/follow-up change in the Kiplin group is almost identical ($d = 0.34$, 95%CI [0.17; 0.51]). In the meantime, participants of the control group showed no significant improvement in daily steps in baseline/intervention change ($d = 0.03$, 95%CI [-0.14; 0.20]) but a baseline/follow-up improvement ($d = 0.28$, 95%CI [0.17; 0.51]). The latter results are consistent with our hypothesis of a potential compensatory effect between leisure PA time and supervised PA time (see supplementary online material 1 of the study protocol).⁷

Results of the adjusted models follow the same trends and are available in supplementary materials (Table S2).

Secondary outcomes

Results of the mixed-effect models revealed significant effects of time for the 6MWT and the isokinetic dynamometer performances. In addition, these models revealed no significant group x time interactions for secondary outcomes, except a significant interaction between condition and the quadratic effect of the 6MWT ($b = 2.19$, $p = 0.007$), suggesting a difference in evolution between the two groups between the end of the intervention and the end of the follow-up (T1 and T2).

Exploratory analyses

In an exploratory perspective, several interactions between the phase of the study and potential moderators were tested in different models among patients of the Kiplin group. Results revealed a significant interaction between the intervention period and the perceived solidarity dimension of the in-group identification questionnaire ($b = 0.21$, $p = 0.04$). Other interactions were statistically non-significant.

Results of the GAMs models investigating the evolution of the daily step count across time for each participant of the Kiplin group are displayed in Table 2.

Table 2. Results of the Generative Additive Models evaluating the evolution of daily steps across time between baseline and one week after the end of the intervention for the Kiplin group.

	Estimate	edf	<i>p</i>
Patient #1	1.28	1.87	0.01
Patient #2	4.10	1.87	0.01
Patient #3	5.00	8.39	<.001
Patient #4	0.87	1.00	0.35
Patient #5	0.52	1.00	0.47
Patient #6	1.11	1.14	0.25
Patient #7	0.44	1.53	0.57
Patient #8	3.06	8.10	<.001
Patient #9	0.02	1.00	0.88
Patient #10	2.01	4.01	0.09
Patient #11	2.07	2.07	0.09
Patient #12	9.94	1.46	<.001
Patient #13	2.13	4.72	0.06
Patient #14	2.36	1.00	0.13
Patient #15	7.50	5.40	<.001
Patient #16	0.03	1.00	0.86
Patient #17	1.45	6.84	0.21
Patient #18	1.64	5.93	0.15
Patient #19	7.00	1.35	<.001
Patient #20	1.85	5.40	0.11
Patient #21	3.24	7.83	<.001

Notes. edf = effective degrees of freedom.

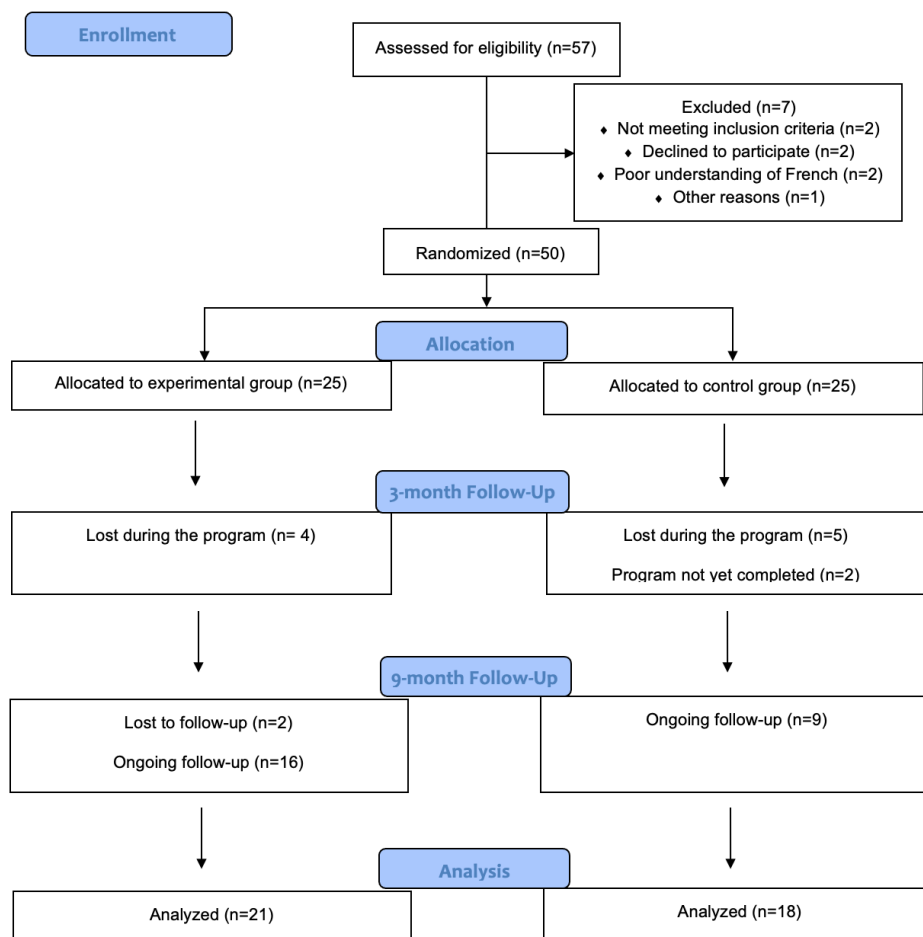


Figure 1. Study flow diagram (updated in November 2022).

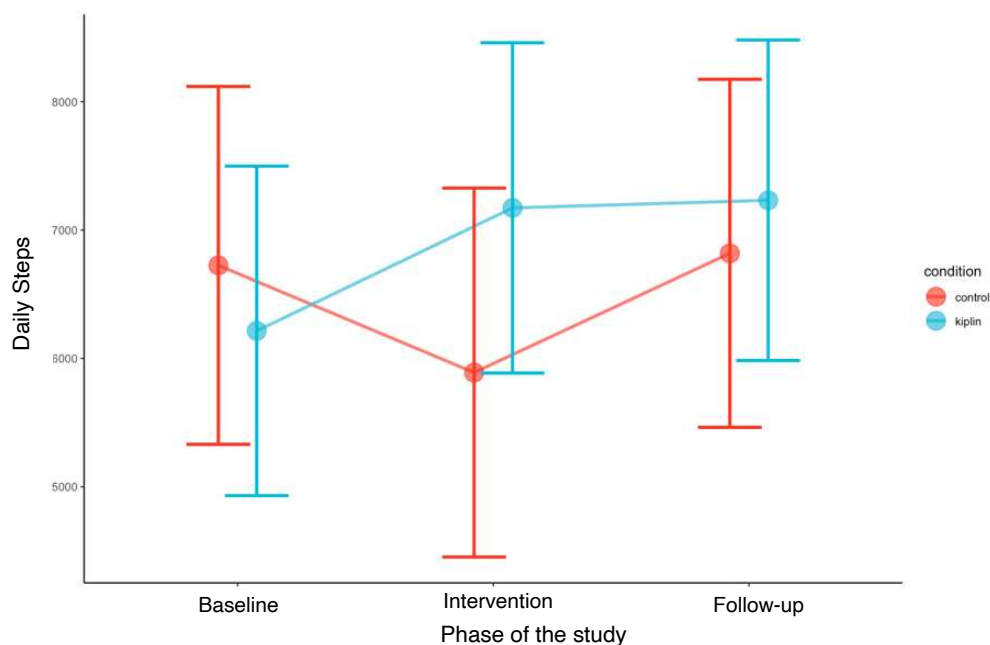


Figure 2. Changes in daily steps throughout the study phases for the Kiplin and control groups

The edf of the smoothing term ranged from 1.0 to 8.39. A total of 9 participants had $\text{edf} > 3$, indicating non-linear patterns across time. Globally, 8 patients had significant changes in daily steps across time ($p < 0.05$). Plots of the evolution of daily steps across time for 8 patients are presented in Figure 3 and all the plots are available in the supplemental materials.

Discussion

Main results

The results of this controlled randomized trial revealed that a group-based gamified digital intervention significantly increased daily PA compared to a traditional PA program. Interestingly, this significant difference was observed both during the program and during follow-up period (i.e., 6-month post-intervention). No statistical differences were found on the secondary outcomes evaluated in this paper, except for the performance at the 6MWT where the evolution between the end of the study and the end of the follow-up was also significantly greater for patients of the Kiplin group.

These results are particularly promising for several reasons. Where current usual PA programs struggle to change the PA of individuals in the long haul,^{24,25} the Kiplin intervention meets this limitation. Perhaps the most exciting element is that the effect size observed during the intervention persisted over the follow-up time, suggesting a good sustainability of the intervention effect both in daily PA and physical capacities. It will be interesting to investigate the long-term evolution of PA with longer follow-ups in order to determine the precise durability of the intervention effect.

The benefits of improving daily physical activity are now well-recognized.²⁶ A recent meta-analysis revealed that taking more steps per day was associated with a progressively lower risk of all-cause mortality, regardless of age, health status, or intensity.²⁷ Therefore, we can imagine that this PA behavior change will have long-term benefits for the health of the Kiplin group patients. This greater improvement is already visible in the evolution of the performance of the 6MWT between the end of the intervention and the end of the follow-up. This result is important as low cardiorespiratory fitness is associated with a high risk of cardiovascular disease, all-cause mortality, and mortality rates.²⁸ In consequence, any gain in cardiorespiratory capacities of 1 MET is accompanied by a 12% reduction in mortality both in healthy individuals and in subjects with chronic

diseases,²⁹ whether they are between 20 and 65 years old or over 65.³⁰

The absence of differences between the two groups on other cardio-metabolic parameters is also promising from a medical-economical point of view, since the Kiplin intervention would have the same efficiency than the current treatment (i.e., effect on cardiorespiratory fitness and muscle strength of the lower limbs) but with fewer sessions. However, these results need to be confirmed with equivalence tests³¹ and with the cost-utility analysis of this trial.

Additional results

Other results revealed that the feeling of solidarity (i.e., a proxy for social identity)³² with the Kiplin group moderated the effect of the intervention. In other words, participants of the Kiplin group who developed a social identity within their intervention group had better results. This confirms that one of the potent ingredients of this gamified digital intervention could be its ability to induce collaborative behavior, even among complete strangers.³³

In addition, the idiographic approach conducted in this study highlighted the existence of various response patterns within the Kiplin group. More especially, GAMs models revealed a) between- and within-person variability during the intervention considering that some participants had high edf (synonym of non-linearity relationships) while others had linear trends, and b) heterogeneous responses to the intervention with several patients who observed no significant changes across the intervention. These results suggest that the digital intervention would not be adapted to every individual, highlighting the need to effectively screen patients who would benefit from such intervention. Indeed, we can assume that depending on the motivational profile,³⁴ the acceptability of the technologies,³⁵ or the physiological profile³⁶ of the participants, some would require in-person program. This emphasizes the importance of 5P medicine: preventive, personalized, participative, predictive, and evidence-based.

Finally, the variability observed within the intervention leads us to believe that the transition between the games and non-games periods needs to be optimized and that continuous tuning interventional designs such as just-in-time interventions may be appropriate to better account for rapidly changing behavioral states due to the dynamic nature of PA and gamified interventions.^{33,37}

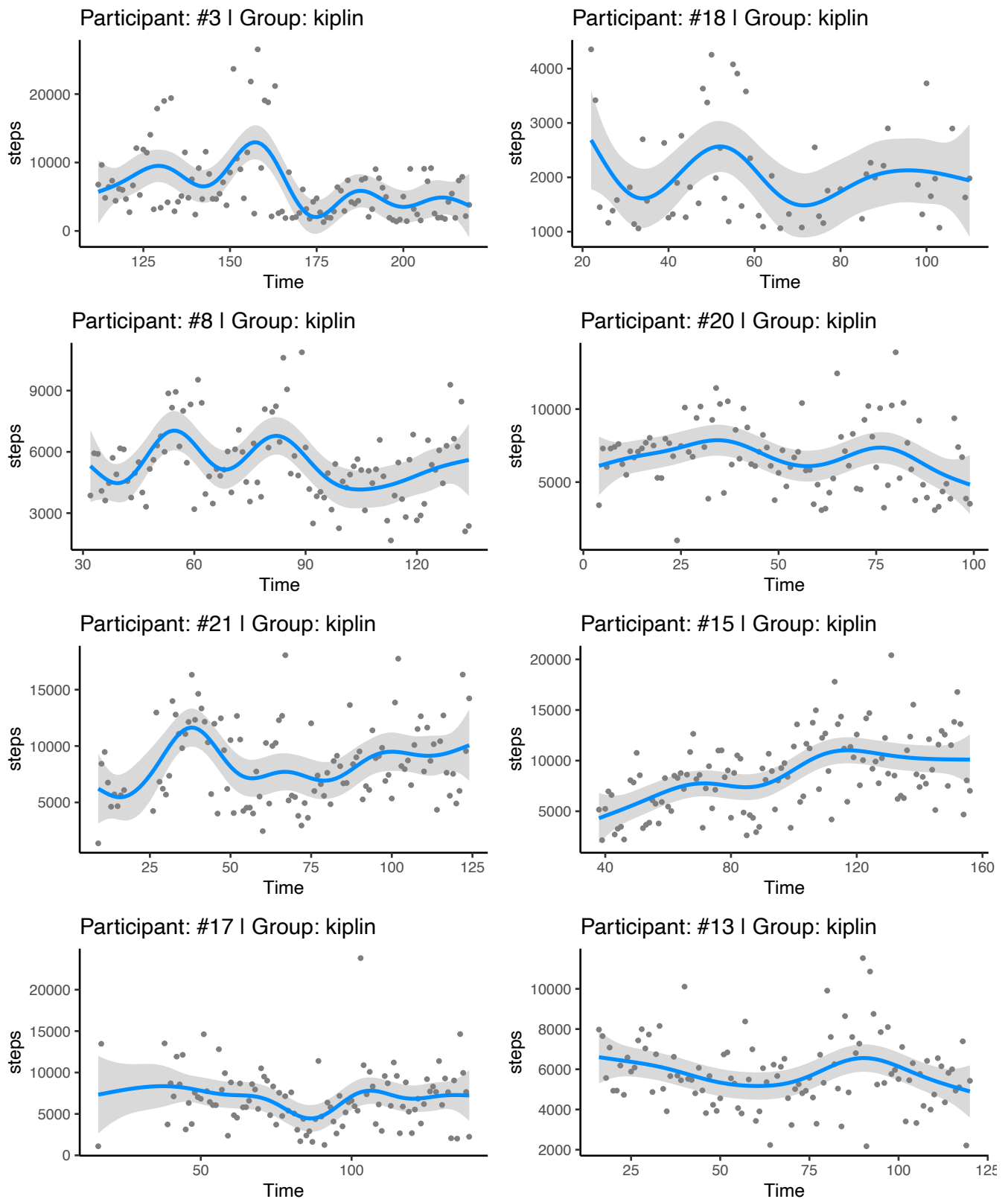


Figure 3. Plots of the Generalized Additive Models for the evolution of daily steps from baseline to one-week post-intervention for 8 patients of the Kiplin group that showed various intervention responses patterns. Time in days.

Strengths and limitations

This study has several strengths, including the intensive objective PA measurement in real-life conditions, the 6-month follow-up measures, the battery of multidisciplinary variables (i.e., psychological and physiological). However, several limitations need to be mentioned.

First, the results are preliminary analyses conducted on a restricted sample, with therefore lower statistical power than planned. Even in the case of positive or negative findings, we cannot rule out the possibility of false positives or negatives.³⁸

Second, this trial has been conducted during COVID-19 times, and this unprecedented situation may have influenced physical activity and participants' response to the intervention.^{39,40}

Third, if the use of wearables (i.e., Garmin Vivofit 2) was an interesting opportunity to measure longitudinal daily steps in natural settings and at high intensity, we cannot rule out that the two groups did not wear it in the same way (as participants of the Kiplin group were more rewarded for wearing the object through gamification). While qualitative interviews (unpublished) with patients revealed that wearing the object was not cumbersome and that they wore it continuously in both groups, there is no objective data to support these claims. In this context, the use of wearables able to detect continuous heart rate signals is a promising way to assess and control wear time. In the same idea, these devices did not provide insights into the influence of both interventions on moderate-to-vigorous PA nor time spent sedentary and the analysis of accelerometer data will be interesting in this sense.

Finally, such as many psychological constructs, perceived pleasure and affective responses to a program can be modeled and operationalized in different ways. In this study, we asked participants at the end of the program (T1) if they have felt pleasure during the intervention. This measure refers to remembered affects, which are the retrospective global evaluation of the pleasure or displeasure associated with past experiences.⁴¹ These global evaluations of past affective experiences are not merely perceived or felt as they are cognitively constructed and involve both memory (recalling how we felt) and judgement processes (the meaning attached to those feelings).^{42,43} Thus, remembered pleasure can be influenced by different processes and be different than the pleasure that is perceived during the program. It would therefore be

interesting to measure the pleasure perceived during *in situ* the program with Ecological Momentary Assessment.⁴⁴

Conclusion

In the light of data available to date, the Kiplin intervention significantly increased daily PA compared to a traditional PA program. This higher efficiency was observed both during the intervention and follow-up periods, introducing interesting interventional perspectives and associated health benefits. If the final results of the DIPPAO trial follow the same trends, the practical implementation of such group-based gamified digital intervention for the treatment of obesity and T2DM will be strongly considered. These findings will have to be confirmed in a phase III trial.

Additional Information

Contributions

Conceptualization of the study: AM, AC, MD; data collection: AM, MD; data curation: AM, BP, GH; investigation: AM; methodology and statistics: AM, BP; software: AM; writing – original draft: AM; writing – review & editing: all the authors

Declaration of 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.

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. Trial sponsor: University Hospital CHU G. Montpied, Clermont-Ferrand.

Acknowledgments

The authors wanted to thank the challenge 3 I-SITE Clermont Auvergne Project 20-25 for their grant. They also wanted to thank Stéphane Penando and Aliette Wauthier for their involvement in the measurement assignments, and all the included patient for their time.

Ethics committee approval

The protocol of this trial has been reviewed and approved by the Local Human Protection Committee (CPP Ile de France XI, No 21 004-65219).

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Summary Chapter 5

The DIPPAO trial aimed to evaluate the effectiveness of the Kiplin program, a group-based gamified digital intervention incorporating supervised physical sessions in telecoaching, in comparison to the usual face-to-face supervised PA program. In study 6, preliminary analyzes were conducted with data from 39 patients who had already finished their program. The results revealed that patients who benefited from the Kiplin intervention had a significantly greater increase in mean daily steps from baseline during the intervention and during follow-up periods, in comparison to the usual program. Interestingly, the durability of the intervention effect for the Kiplin group was high. The results also showed that the feeling of solidarity within the Kiplin condition positively moderated the intervention effect. Finally, additional analyses conducted following an idiographic approach revealed strong heterogeneity among patients of the Kiplin group, with the existence of different patterns of responses across time. These results hold good promise for the use of digital intervention for the treatment of obesity and T2DM but that will need to be confirmed in the complete analysis of the trial.

PART III

General Discussion

General Discussion

With the increasing prevalence of chronic diseases, physical inactivity, and sedentary behavior, it is of paramount importance to develop interventions that can help individuals to be more active in the long haul. While current programs struggle to engage participants and change physical activity over the long term and are associated with strong organizational and budgetary constraints, digital interventions and gamification appear as promising avenues. Nevertheless, to date, there is no clear evidence of the effectiveness of such interventions.

Through a close academic/industrial collaboration, this thesis aimed to develop and evaluate a digital intervention integrating gamification to promote the physical activity of patients with chronic diseases. More specifically, the thesis aims were to test the effectiveness of gamification in promoting physical activity among several populations and settings, develop and assess innovative ways of proposing supervised physical activity care at a distance, and evaluate the effectiveness of a multi-component digital intervention on the physical activity of obese and diabetic patients in comparison to usual care. Chapters 3 to 5 of this thesis reported results from one meta-analysis, one randomized controlled trial, and three empirical studies that used a range of experimental methodologies to address the aforementioned research objectives.

In this final part, the key findings obtained in relation to the research objectives are first discussed. The following sections discuss the overall strengths and limitations of the research process, propose suggestions for future research, and outline the implications for policy and practice.

14. Empirical results and answers to the thesis objectives

14.1. Is gamification effective to promote physical activity?

As mentioned earlier, there are a number of concerns in the scientific literature about the effectiveness, long-term efficacy, and generalizability of gamified interventions to

different user populations. The results of this doctoral work suggest the efficacy of gamified interventions to promote physical activity at both short term (during or just after the intervention period) and at mid-term (after follow-up periods). The quality of evidence is high as three different studies, conducted with three different designs, and in three different contexts provide support to this conclusion (Table 1). Interestingly, the gain from intervention was maintained approximately at the same level during follow-up periods in study 2 among initially inactive individuals and in study 6 among obese and diabetic patients, suggesting an interesting durability of the behavior change after the intervention.

Table 1. Designs, contexts, and populations of studies 1, 2, and 6 on gamification.

	Study 1	Study 2	Study 6
Design	Meta-analysis of RCTs	Large-scale retrospective analysis	Phase II RCT
Context	Comparison of gamified interventions to inactive and active control groups within RCTs	Comparison of participants benefiting from a gamified intervention to nonparticipants in real-life settings	Comparison of a gamified intervention to the current gold standard of physical activity programs
Population	Large sample of healthy adults and patients with chronic diseases	Large sample of healthy adults and patients with chronic diseases	Patients treated for obesity and type 2 diabetes
Effect sizes	$g = 0.42$ at the end of the intervention and $g = 0.15$ after follow-up (in average 14 weeks post-intervention)	$d = 0.84$ during the intervention (33 days in average).	$d = 0.50$ during the intervention (3 months) and $d = 0.76$ during follow-up (6months after intervention)

Note: RCT, Randomized Controlled Trial.

These three studies also reported that these results were generalizable to different populations of participants regardless of their age, health status, or body mass index, and in different settings (in primary or tertiary prevention in chronic disease management).

These findings are particularly meaningful in several aspects. Regarding effectiveness, they suggest that gamification is not just a novelty effect and that the benefits are sustained over time. This is particularly important considering the difficulties of current programs in effectively promoting patients' physical activity over the long term. These results are also particularly important because it was not clear that such programs would influence long-term physical activity and activity of patients with chronic diseases or older people (Koivisto & Hamari, 2019a; Sardi et al., 2017).

Nevertheless, the findings of these three studies ranged from small to large effects, suggesting that greater efforts may be needed to understand in which conditions these interventions are successful and optimize intervention effectiveness. In the same idea, study 6 revealed high inter-individual heterogeneity in the intervention responses, highlighting the need to better understand the determinants of the success of gamified intervention. In addition, if the results of study 1 suggested that gamified interventions were more effective than other digital interventions to increase physical activity – gamification acting as a catalyst of digital interventions – these results need to be confirmed in further studies. Finally, the potential impacts of gamification on moderate-to-vigorous physical activity have not been demonstrated and this may also be the focus of future studies.

14.2. Can eHealth and mHealth provide effective and reliable adapted physical activity care at a distance?

Adapted physical activity programs are associated with high costs and limitations for both patients and healthcare institutions. Results of studies 3, 4, and 6 suggest that eHealth and mHealth solutions can be efficient and reliable tools to provide remote supervised physical activity sessions and allow patients to perform their physical fitness test battery from home. The results are valuable considering the potential direct benefits of such remote programs, such as the possibility to offer care to more patients, especially those who are far from healthcare centers, reducing healthcare costs, and preventing patients from too many travels. Beyond these direct effects, they could also

bring other indirect benefits such as improving patient empowerment, reducing stress, and ultimately enhancing program adherence and efficacy.

From another perspective, these tools open new perspectives of totally remote programs with a multi-component digital therapeutic integrating gamification, telecoaching, and physical condition assessments. In addition, the MediEval medical device could also be useful in research to assess large epidemiologic cohorts or participants included in decentralized trials.

An important aspect of these tools is their ability to enhance the reach of action and interventional possibilities of health professionals. In the telecoaching sessions, adapted physical activity coaches can effectively provide physical activity sessions and care to several patients at the same time via videoconferencing software. With the use of the MediEval medical device, they can better and more regularly monitor the health status and training progression of their patients by asking them to perform tests from home. It is not necessarily needed to reinvent the wheel to improve programs and the use of digital technology may augment existing programs by addressing some of their limitations.

Nevertheless, if the present results highlight the validity and reliability of these digital means, their operationalization and use on a larger scale remain to be demonstrated. Therefore, future studies are needed to evaluate the medico-economic impact of these tools and their effects in real-life settings. Considering the engagement crisis usually observed within digital interventions (see chapter 2), we can naturally question whether patients will use these devices autonomously. It is also certain that the contribution of these tools will depend on their adoption by the various actors of the health sector (i.e., medical doctors and physical activity coaches). In this perspective, it could be judicious to strengthen the onboarding of patients (e.g., with a clear user experience, tutorials, and starter kit) to ensure their understanding and facilitate the use of these tools. The use of gamification features could also be interesting to improve session observance or the realization of the tests. On the side of healthcare professionals, it appears important to train and sensitize the health professionals on the interest of these tools.

14.3. Is a digital intervention more effective and cost-effective than usual care in promoting physical activity among patients with NCDs?

Although digital interventions have been extensively tested in comparison to passive or active control groups, no rigorous trial has yet demonstrated the superiority of gamified digital physical activity interventions over existing ones. The main objective of the DIPPAO randomized controlled trial (studies 5 and 6) was to compare the effectiveness of such intervention on physical activity change and clinical settings, among patients treated for obesity and with type 2 diabetes, and in comparison to a 3-month face-to-face supervised physical activity program of 36 sessions. The results revealed that the digital intervention was more effective than the traditional program to promote daily walking, which is generally the main physical activity in the general population. These results are particularly promising as a significant difference was also observed during follow-up periods. By being effective in changing long-term behavior, the Kiplin digital intervention may have a significant impact on the health of patients, particularly through the benefits of regular physical activity on cardiorespiratory fitness (study 6).

While it is imperative to take these preliminary results with caution (notably because this study was conducted during COVID-19 times and because of the low sample size), they are particularly promising from a clinical practice point of view. Indeed, the economic and practical benefits will be substantial if the digital program achieves better outcomes with 30% fewer sessions. In this sense, the medico-economic analysis will be particularly important to quantify these potential benefits for the healthcare system.

It should be emphasized that the Kiplin intervention is not fully digitalized, as telecoaching sessions are conducted by adapted physical activity coaches and because the games are animated by a virtual assistant which is operated by a human. While we may consider that the social part of the Kiplin program is one of its potent ingredients considering the influence of the in-group identification on the intervention effect observed in study 6, it would be interesting to compare this type of hybrid program to total digitalized interventions (e.g., using pre-recorded physical activity sessions and chatbots).

If the results of the full analysis of the DIPPAO trial follow the same trend, the next steps would be to conduct a phase III trial among the same clinical population, with more patients and longer follow-up. It could be interesting to include additional clinical variables, such as blood glucose variability monitoring for diabetic patients, which is an important longitudinal biomarker. In addition, phase IV trials will be needed to establish real-world effectiveness, which is “evaluated in an observational, non-interventional trial in a naturalistic setting” (Suvarna, 2010). Such trials must involve a diversity of settings, participants, and deliverers (Hill, 2012). Therefore, to conduct such studies, the use of decentralized trials presented in chapter 2 of this thesis could be particularly interesting in order to include a large panel of patients in the context of daily life.

14.4. What are the moderating variables of gamified digital interventions?

Understanding how, when, where, and for whom an intervention works is capital to optimize its efficacy and contributing to the accumulation of knowledge (Araújo-Soares et al., 2018; Hekler et al., 2016; Leviton et al., 2010; Ogilvie et al., 2011). In this PhD work, we investigated the potential moderators of the effect of gamification and digital programs on physical activity.

Studies 1 and 2 indicated that the duration of the intervention is a key parameter influencing its effect. In both studies, our results suggested that a longer intervention would not be more beneficial than a shorter one. In parallel, study 2 suggested that engagement with the service was necessary for the intervention to be effective. These two results considered jointly suggest a minimum effective dose with an inverted u-shaped relationship with time. Thus, disseminating multiple doses of gamification at frequent times could be useful to maximize engagement without tiring and boring the participants in the long term.

Study 2 also revealed the potential existence of plateau effect in the effectiveness of gamified interventions to promote physical activity. As a matter of fact, the examined intervention significantly improved the physical activity of participants with lower baseline steps (<7500 steps per day) whereas participants with more than 7500 initial steps had no change or significant decreases. Thus, gamified interventions could be effective only among inactive individuals. Among other factors, this

characteristic could explain the strong statistical heterogeneity observed in the meta-analyses of study 1.

If the identification of these moderators is of great help for the optimization of interventions and can be the basis for future intervention-design recommendations, the understanding of the underlying psychological mechanisms is still in progress. Through our literature review and meta-analysis (study 1), we observed that few studies have investigated the psychological constructs and determinants involved in gamified interventions. On our side, we do not have solid results either despite our willingness to move forward in the DIPPAO trial. The reasons for these limited results will be further explored in the next section of this discussion.

However, the moderating effect of solidarity within the in-group on the Kiplin intervention represents an avenue for further investigation about the influence of social identity on group-based digital interventions. Hypothetically, these results could suggest that one of the main mechanics of gamification is its ability to stimulate the collective and that when a social identity is created in the group, then the intervention is more effective.

15. Limits, unanswered questions, and avenues for future research

This thesis has tried to provide answers to the above-mentioned objectives using different experimental designs with both gold standard methods (e.g., meta-analysis, randomized controlled trial) and innovative methods in the domain of physical activity (e.g., intensive longitudinal assessment of the daily step count, idiographic approach). Using an interdisciplinary scope – drawing on theoretical frameworks and methods from health and social psychology, behavioral and sports medicine, complexity science, and medical economics – we considered a broad range of factors in controlled environments such as clinical trials but also in real-life conditions. Nevertheless, it should be pointed out that there are several limitations to be considered when interpreting the various results presented in this doctoral work. The recognition of these limits offers new research perspectives that are discussed in this section.

15.1. Understanding of the mechanisms underlying the gamification effect

As stated in the last section, if this thesis has provided a certain degree of evidence on the effectiveness of gamified digital interventions, the present results had a lower contribution to the understanding of the underlying psychological processes that may explain the efficacy of gamified interventions on physical activity. This may be due to the complexity of evaluating the different intervention modules in isolation. Indeed, gamified digital interventions involve a multitude of interconnected components whose influence is difficult to distinguish from others if the intervention is evaluated globally. The proper way to answer this issue seems to decompose the intervention and conduct multiple arms–randomized controlled trials to isolate the effects of gamification elements. Without such rigorous research design, we face the difficulty of demonstrating that the effect of gamified interventions is led by gamification itself.

Unfortunately, conducting such experimental studies was not compatible with the objectives of this PhD because they require high statistical power and ultimately the enrolment of many participants, which is not compatible with a clinical trial testing the efficacy of an intervention compared to the usual care. The investigation of the psychological mediators in the DIPPAO trial is therefore merely underpowered in secondary exploratory analyses. In order to advance our understanding of these interventions, future studies with the exclusive objective of investigating the effect of the intervention components in isolation and the underlying mechanisms through multi-arms designs will be capital.

In this perspective, innovative research frameworks such as the Multiphase Optimization Strategy (MOST; Collins et al., 2007) are promising. MOST design is an engineering-inspired framework for optimizing behavioral interventions that includes three key phases: preparation, optimization, and evaluation. Through factorial experiments, the objective of such design is to improve the intervention by evaluating the effectiveness and cost-effectiveness of each element. Once filtered, the modules can be evaluated in the optimization phase using an optimization trial, such as sequential multiple assignment randomized trial (SMART, Almirall et al., 2014) or micro-randomized trials (Klasnja et al., 2015). Thus, different optimized intervention packages can be specified to clearly test differential impact (Hekler et al., 2020).

Ultimately, these experiments can help researchers to fine-tune intervention components (Ntoumanis, 2022) and better understand their mechanisms.

It is also noteworthy that some psychological constructs assessed in the DIPPAO trial were potentially measured with a too-low sampling frequency. If we can expect changes in self-determined motivation or perceived stigma and discrimination to change slowly on a multi-month scale, enjoyment, psychological needs satisfaction or group identification are certainly more dynamic constructs that need to be measured at higher frequency in order to assess variability/instability of these processes (Chevance et al., 2021; Heino et al., 2021). Ecological momentary assessment is an interesting methodological perspective to better capture time- and spatially-varying explanatory factors (Dunton, 2017; Perski et al., 2022).

Finally, conceptual frameworks that informed this PhD work (i.e., the self-determination theory and the social identity approach) had a heavy cognitive valence. As detailed in the first chapter of this thesis, dual models have the particularity to both consider automatic and reflective systems in the adoption and maintenance of physical activity. It is recognized that the consideration of these two systems is required to optimize behavior change (Michie et al., 2011). Thus, interrogating the mechanisms of gamification under the prism of dual approaches (e.g., the role of affective responses, emotions, or self-control in the gamified intervention effect) is another perspective to move forward.

15.2. Interindividual heterogeneity

While the results of this thesis indicated that gamification could be addressed to any audience regardless of age or health status, we also observed a constant heterogeneity in the participants' responses. For example, the idiographic approach considered in the DIPPAO trial (study 6) revealed various individual patterns and no effect of the digital intervention on some patients. Heterogeneous adherence rates observed in study 3 and the high statistical heterogeneity revealed in study 1 also support this point. In view of these elements, it seems important to specify that, in spite of the efficiency and generalizability of gamification and digital inventions, these programs will not necessarily be adapted to all patients and individuals.

In this regard, it should be pointed out that significantly less attention has been paid to issues and aspects which precede the effects of gamification (Koivisto & Hamari, 2019b). Future research should therefore pay more attention to the pre-

determinants and requirements of gamification and digital intervention success. Advances in this knowledge could allow implementing advanced screening features, with the aim to propose digital intervention to individuals who might benefit of it. To this end, a promising perspective could be the determination of individuals phenotypes on the basis of a battery of variables such as the acceptability of technologies (e.g., individuals who perceive usefulness in the digital intervention, Venkatesh & Davis, 1996), the motivational profile (e.g., participants with impersonal causal orientations, Hagger & Hamilton, 2020; Hayotte et al., 2021) or stage of change (e.g., participants who have the intention to change and are in contemplation or preparation phases, Prochaska & DiClemente, 1983), the physiological profile (e.g., based on meaningful biomarkers, Roberts et al., 2018), or personality traits (e.g., evaluation of grit, a measure of perseverance and passion for long-term goals, Duckworth et al., 2007).

Finally, as introduced in Chapter 2, digital interventions can provide individually tailored resources through just-in-time adaptive interventions (JITAI), aiming to propose interventions that continuously “tune” to each user’s evolving needs (Hekler et al., 2020). This type of intervention could be a solution to adapt the content to non-responding participants and optimize intervention generalizability. Proposing just-in-time adaptative gamified strategies, that are personalized as a function of the participant's situation and needs, would be a particularly promising direction.

15.3. Operationalization and measure of engagement

Study 2 revealed that some forms of engagement are needed for gamified intervention to be effective. This result is important as gamification has often been assimilated into a self-fulfilling process permitting automatic engagement of participants into an eHealth service, with the misconception that any technology that employs game strategies will be more engaging (Cugelman, 2013; Mazeas et al., 2022). Previous research has revealed such relationships between exposure and digital intervention effectiveness (see Chapter 2).

One limit of this PhD work is that we only operationalized engagement based on the number of logins and the number of messages exchanged. Although such quantitative engagement measures are interesting because they are objective and can be captured easily and noninvasively (Maher et al., 2022), they do not provide insights into the more qualitative aspects of engagement such as affect, attention, or interest

(Perski et al., 2017). Alternative quantitative measures based on system usage data, such as real-time analytics could be fruitful in future studies. In this sense, tools such as Mixpanel (Mixpanel, 2018) are interesting to assess indicators such as the intersession period, the duration of the sessions, time spent in the app, or the screen flow (i.e., the path that users take and which functionalities or interfaces they use).

In addition, it seems necessary to investigate more precisely the links between user experience and engagement. In this perspective, models such as METUX (for Motivation, Engagement and Thriving in User Experience, Peters et al., 2018) could be used in future studies. The METUX model proposes a framework grounded in psychological research that provides actionable insights with respect to how technology designs support or undermine basic psychological needs and their impact on motivation and engagement. Future work could be conducted through a mixed methods approach, associating quantitative and qualitative data, in longitudinal research to understand user experiences and their relations with intervention effectiveness across time (Dures et al., 2010; Tuthill et al., 2020).

15.4. Intervening on sedentary behavior

The preliminary results of the DIPPAO randomized controlled trials proposed in this thesis did not include insights the impact of the Kiplin intervention on sedentary time. These results will be of interest to test if the promotion of daily light physical activity through gamification can have an indirect effect on sedentary behavior.

However, we can imagine that this will not be enough to counteract the growing prevalence of sedentary behavior among the general population. For instance, a previous rehabilitation program focused on exercise, resulted in only a slight reduction of prolonged sitting time in cardiac patients (ten Broeke et al., 2022). Until now, the Kiplin intervention is mainly focused on the promotion of daily physical activity. It is therefore essential to develop complementary intervention modules or gamification strategies that specifically target sedentary behavior change. Our systematic review and meta-analysis pointed out that few studies had been conducted to develop this type of intervention. Yet, building gamified interventions that target sedentary breaks as a gamified part could be interesting considering the positive effects of these breaks on health.

Research has indeed revealed that interrupting prolonged sitting every 30 min with standing or walking is associated with positive effects on metabolic function –

resulting in lower insulin and lower glucose levels (Belcher et al., 2015; Henson et al., 2016). To be effective, recent research suggested that such interventions should notably focus on high-risk moments, such as sitting time in the evenings and after higher-than-usual physical activity (ten Broeke et al., 2022). In the same idea, the investigation within the DIPPAO randomized controlled trial of potential compensation mechanisms between supervised physical activity sessions and the daily-light physical activity during the same day or the following days, will be interesting to test whether gamified interventions can counteract these “isotemporal displacements” (Gomersall et al., 2015) by boosting daily physical activity.

15.5. The use of ‘high-tech’ interventions in health

Finally, another limitation of this thesis is that the intervention developed can be defined as ‘high-tech’, given that its components and modules require a smartphone, an internet connection, the smartphone’s camera, or a GPS signal. Using such technologies can be problematic for several reasons. First, if smartphones and internet access have a high penetration rate in western countries, the implementation of digital programs in white spots (i.e., areas that are not covered by a cell phone network or the Internet) could be limited. This situation is comparable in some developing countries with low connectivity. It is therefore important to think about other programs that can be disseminated with low-tech means (e.g., intervention using text messages instead of the internet) less dependent on technology and hybrid solutions (i.e., involving both in-person and remote care). Future research should aim to also develop and investigate such interventions until we can expand the digital interventions for everyone, in order to ensure health equity.

Second, the environmental impact of digital interventions needs also to be considered. Information and communication technologies (ICTs) and more particularly the multiplication of smartphone production and use, or data traffic and storage are associated with high environmental consequences, which are not sustainable with respect to required energy and systems-wide action needed as part of the energy objectives of the 2015 Paris Agreement (Chevance et al., 2020; Ferreboeuf et al., 2019). Especially, digital means require a greater proportion of worldwide electricity, which ultimately increases greenhouse gas emission.

One may argue that because of its laudable goals, digital health might deserve prioritization of energy over other sectors if effective (Chevance et al., 2020).

Moreover, the Kiplin programs seem to limit the environmental consequences by not producing specific hardware and using smartphones that people already own. However, the reflection of these usages must still be questioned, especially because rebound effects can happen (e.g., a situation in which improvements in the technical efficiency of energy use ultimately lead to greater direct or indirect energy consumption, Chevance et al., 2020). For example, on the one hand digital health technologies and their ability to provide remote programs could reduce carbon emissions due to the travel saved but increase internet and energy consumption on the other hand. In this context, future research investigating digital health interventions should systematically consider both the short-term and long-term effects on health but also the environmental implications of particular digital health technologies before promoting such solutions to larger audiences (Chevance et al., 2020).

Finally, while gamification research commonly focused on the positive impacts of technology on human motivation and behavior (Deterding, 2015; Seaborn & Fels, 2015), the potential negative, adverse, non-preferable effects of gamification have been seldom evaluated (Koivisto & Hamari, 2019b) and raise a number of questions. In a world increasingly quantified where a multitude of our behaviors are measured and monitored, we can question the consequences of adding extra monitoring of daily behavior. We also may ask if the paradox of adding screen time to promote movement cannot ultimately increase the amount of sedentary behavior by rebound effect. Finally, it appears also essential to consider all the possible, positive or adverse, effects of gamification strategies such as leaderboards and competitive features. Such questions should be investigated in future studies.

16. Implications for policy and clinical practice

It is generally assumed that behavioral interventions that provided evidence of efficacy in lab and field experiments, and have been shown to be effective both in randomized controlled trials and in real-world contexts, can be implemented in clinical practice (Hagger & Weed, 2019; King, 2015; Sheeran et al., 2017). While further clinical trials are needed (i.e., especially phase III and IV trials) to confirm the findings of this thesis, these ones fulfill all the aforementioned requirements and it appears appropriate to recommend the use of the Kiplin intervention in adapted physical activity programs. Indeed, such interventions are interesting in practice for several reasons.

First, gamified interventions have many benefits for participants with chronic diseases, such as a long-term enhancement of their physical activity, empowerment by improving their self-management skills, an everyday life fit, and easy implementation. Also, they are a unique opportunity for patients who are isolated from healthcare facilities to benefit from a complete program. These interventions have a broad reach thanks to their digital nature, which enable to increase the care capacity, and the large deployment of physical activity actions. These digital programs were also pertinent during COVID-19 times and could be helpful in future crises. Finally, as gamified interventions seem to be also effective on healthy inactive participants, these programs could be utilized in primary care among employees and in prevention initiatives among local communities.

To go further, it is essential to ask what is needed to ensure the implementation of these findings in practice. It is well documented that the results of most behavioral and health promotion studies have not been translated into practice or that the resulting interventions are relatively short-lived, under-funded, or not effective due to poor implementation, up-scaling, or translation (Glasgow et al., 2004; Marteau et al., 2006). Among these factors, funding is perhaps the most influential as interventions need sufficient financial support to ensure the necessary networks and providers required to implement the intervention in practice (Hagger & Weed, 2019). If many behavioral interventions receive initial investment, this one is pale compared to the funds allocated to other treatments (especially pharmacological ones) and funding is generally not sustained in the long haul (Russell et al., 2008). The funding of digital interventions by governments and health agencies is thus a key issue in order to transform the promising intervention perspectives into results on the field.

In France, things are moving in the right direction. While the *Strategic Council for the Health Industries* has recognized digital therapeutics as strategic for the future of French and European healthcare, act 58 of the 2022 *Social Security Financing Law* envisages the early reimbursement of digital services and interventions that have demonstrated innovative value. This new law establishes a framework for recognizing and transferring original digital interventions between research and the regulatory, administrative, and operational worlds. This is a first move to address the funding issues and the gap between research experimentations and sustainable implementation on the market but that will need to be reinforced and

sustained in order to maximize the dissemination of innovative digital interventions on the field.

Finally, it is unrealistic to expect governments, stakeholders, policymakers, or health care providers to identify, assimilate, and implement research findings reported in scientific publications and the responsibility is on those producing the evidence to outline the human and economic advantages of innovative interventions (Hagger & Weed, 2019; Marteau, 2018). To ensure optimal implementation of the work of this thesis, the ball will also be in our court with the need to disseminate the results of this research and conduct phase III and IV trials, less frequent in the behavioral literature because they are time-consuming but needed for advocating investment and implementation of these interventions among stakeholders (Hagger & Weed, 2019; Michie & West, 2013).

17. Conclusion

The present PhD work investigated the effect of gamification and digital interventions to promote physical activity through a close academia/industry collaboration and 6 studies with various methodologies. The results showed that gamification is an effective interventional perspective to promote short and mid-term physical activity of various users, regardless of their age or health status. Gamification could therefore act as a catalyst, allowing to improve the impact of digital interventions. In the meantime, other results demonstrated the validity and reliability of a hybrid program including telecoaching and an innovative app-based medical device to propose remote adapted physical activity programs. Combined together, these findings open the door to new digital therapeutics that involve these different components for the treatment of chronic diseases. The DIPPAO randomized controlled trial evaluating the effectiveness of such intervention among obese and type 2 diabetes patients already showed promise for the implementation of such interventions in real-life.

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Appendices

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Appendix 1: supplementary materials of study 1

1. Supplemental figures referred in the manuscript
2. Search equations for databases
3. Table 2. Risk of bias summary for studies included in the meta-analysis
4. Table 3. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies
5. List and reasons for excluded studies

1. Supplemental figures referred in the manuscript

Table S1 Keywords used for database searches

Physical activity and sedentary behaviors	Gamification	e-health	Trial
exercise		telemedicine	iOS
sport	gamification	telehealth	android
“active living”	exergaming	e-health	website
“active transport”	game	m-health	digital*
“exercise therapy”	gamified	mobile	electronic*
fitness	gaming	internet	device
sedent*	gameful*	applications	framework*
“sitting time”	multiplayer	smartphone	wearable
inactive	player	cellphone	“social
inactivity	playing	Iphone	network”
walk*		facebook	Technolog*
			“randomized controlled trial” RCT randomized trial “clinical trial” “controlled trial”

N.B. Some additional terms and synonyms could be used for some database. For more information, see search strings for each database.

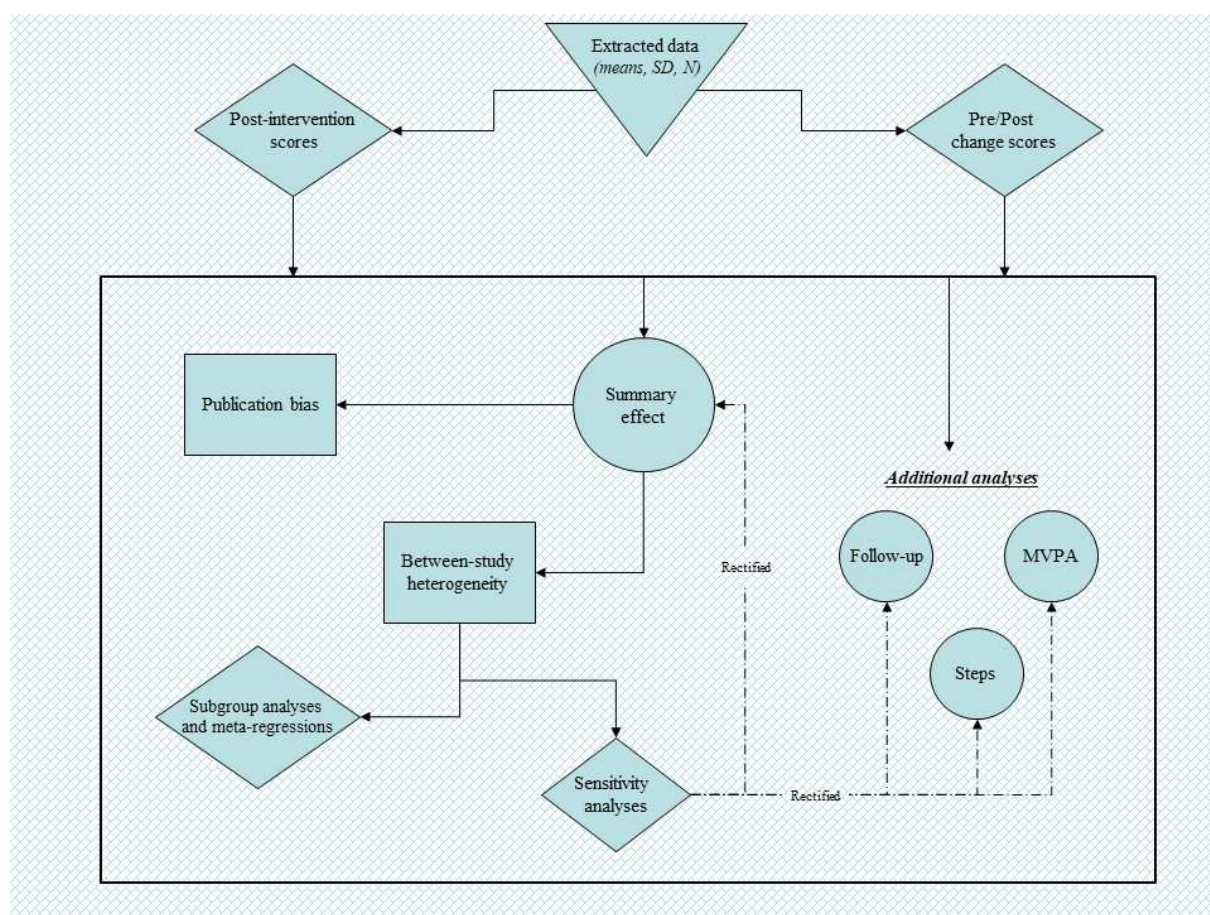


Fig. S1 Statistical analyses summary. All analyses were conducted two times, both for post-intervention scores and for pre/post intervention change scores

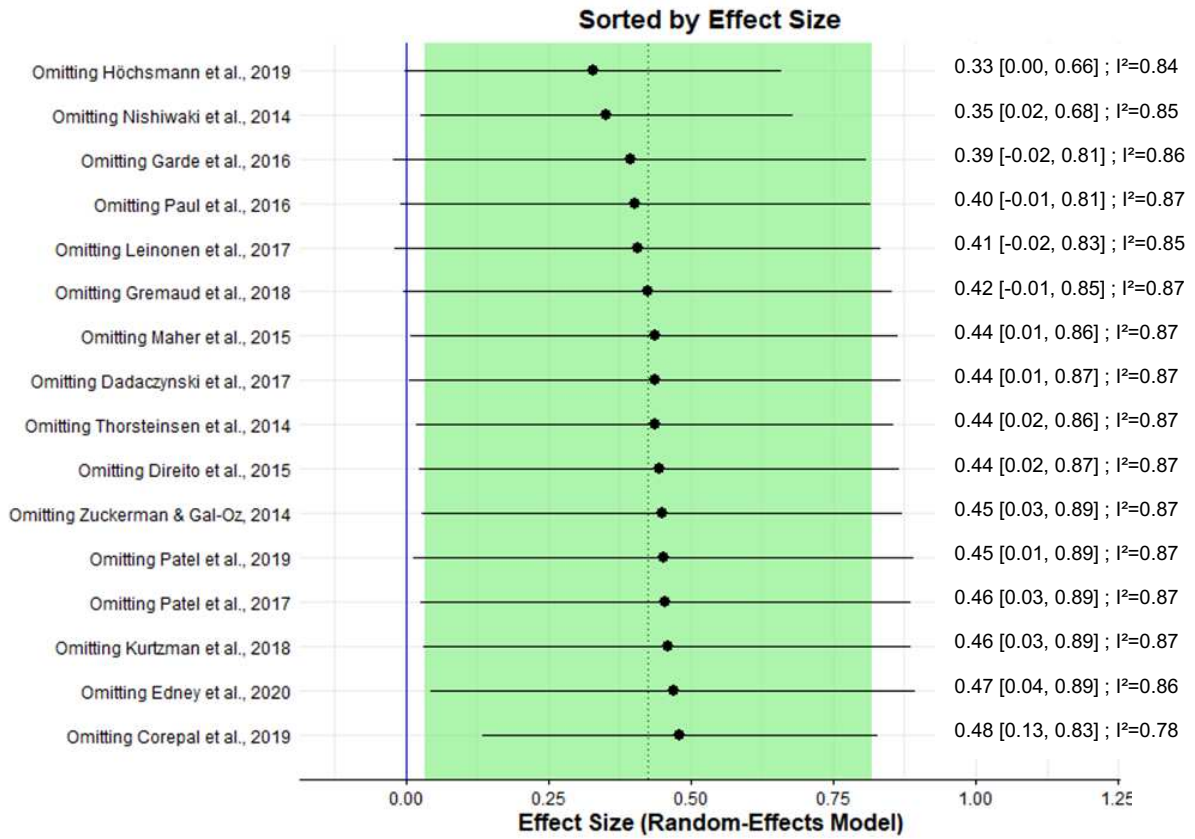


Fig. S2 Forest plots representing Leave-one-out analyses ordered by effect size (Hedge's g ; low to high)

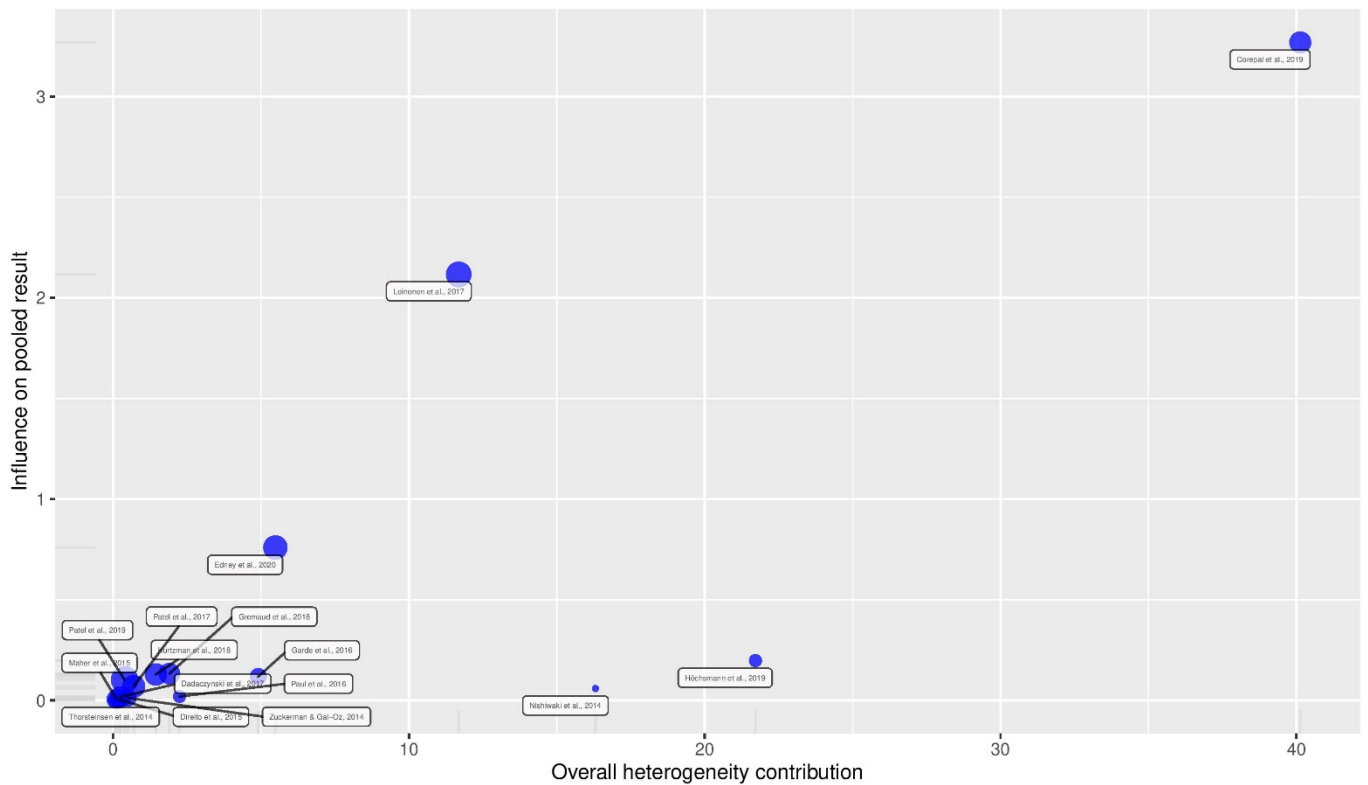


Fig. S3 Baujat plot representing the contribution of each study to the overall heterogeneity (measured by Cochran's Q) in function of its influence on the pooled effect size

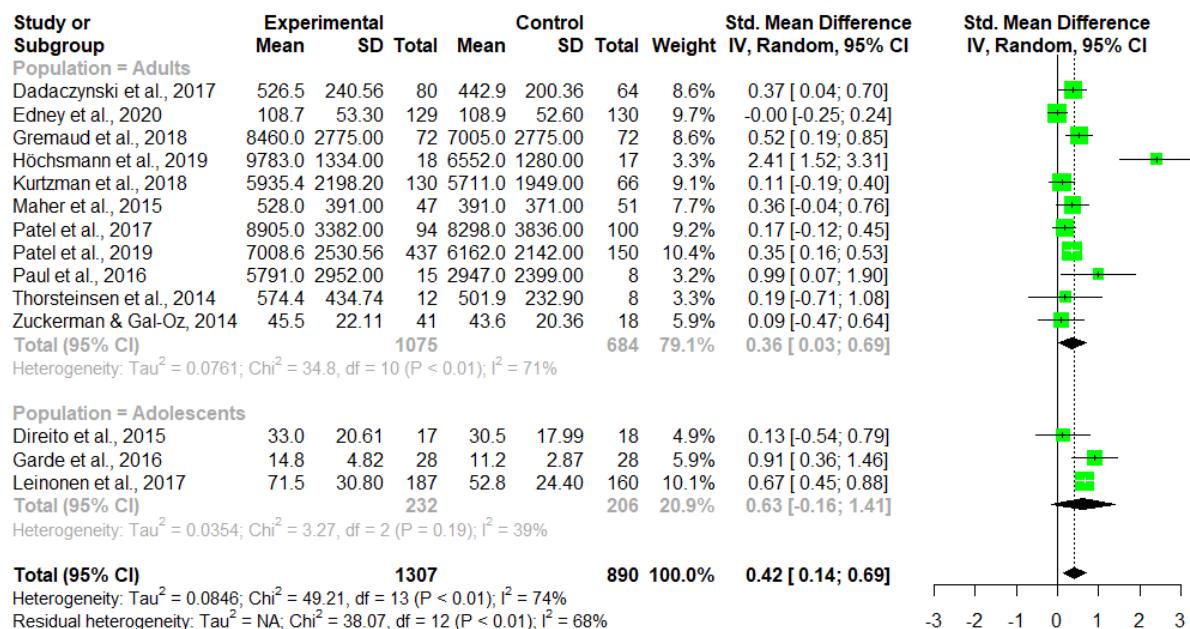


Fig. S4 Forest plot with age subgroups (adults versus adolescents) for the effect of gamification versus control on post-intervention PA outcomes (moderate-to-vigorous physical activity (MVPA), daily step count, number of active minutes, and walking

time). *SD* standard deviation, *Std* standardized, *IV* inverse variance, *CI* confidence interval, *Tau*², *Chi*², and *I*² measures of between-study heterogeneity

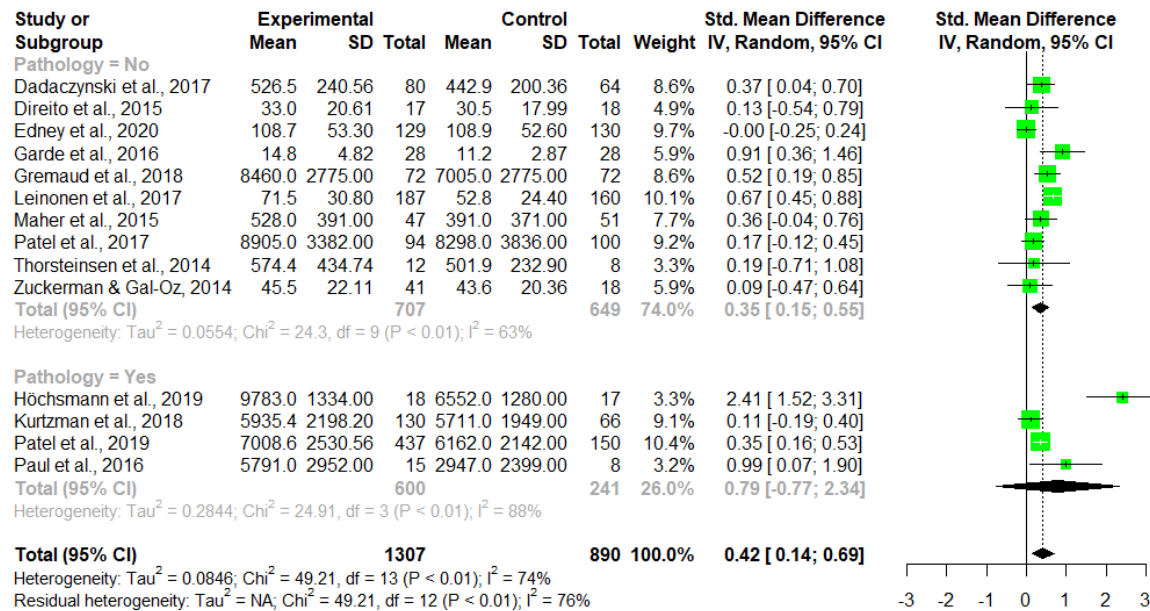


Fig. S5 Forest plot with health condition subgroups (healthy people versus patients with chronic diseases) for the effect of gamification versus control on post-intervention PA outcomes (moderate-to-vigorous physical activity (MVPA), daily step count, number of active minutes, and walking time). *SD* standard deviation, *Std* standardized, *IV* inverse variance, *CI* confidence interval, *Tau*², *Chi*², and *I*² measures of between-study heterogeneity

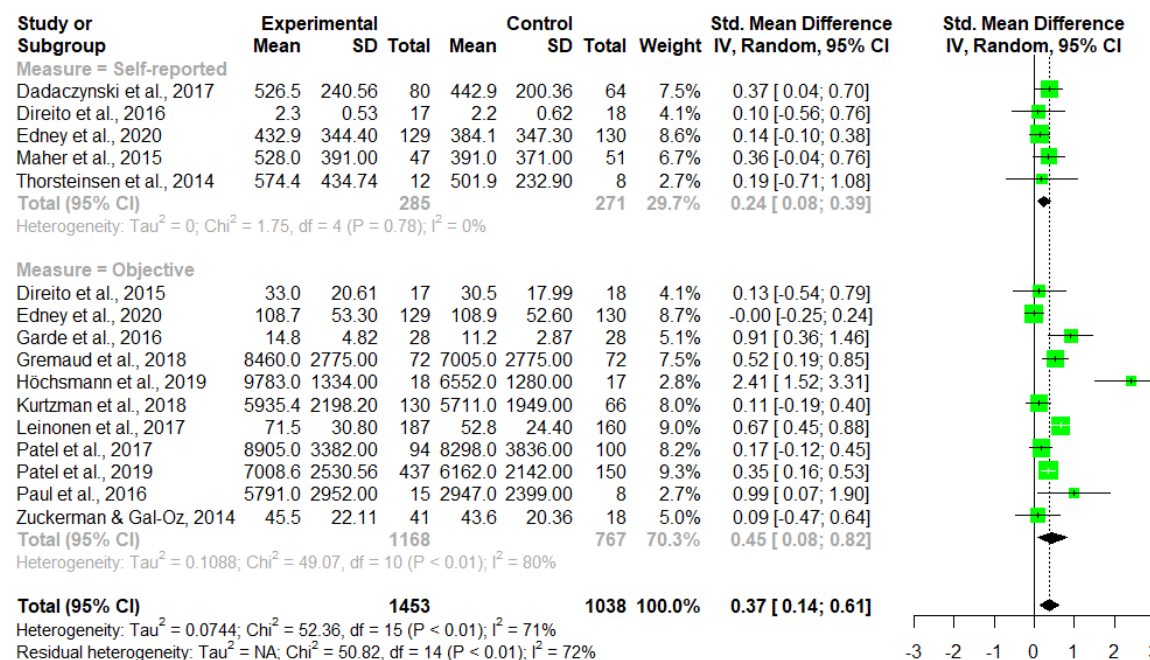


Fig. S6 Forest plot with type of measure subgroups (self-reported versus objective measures) for the effect of gamification versus control on post-intervention PA outcomes (moderate-to-vigorous physical activity (MVPA), daily step count, number of active minutes, and walking time). *SD* standard deviation, *Std* standardized, *IV* inverse variance, *CI* confidence interval, *Tau*², *Chi*², and *I*² measures of between-study heterogeneity

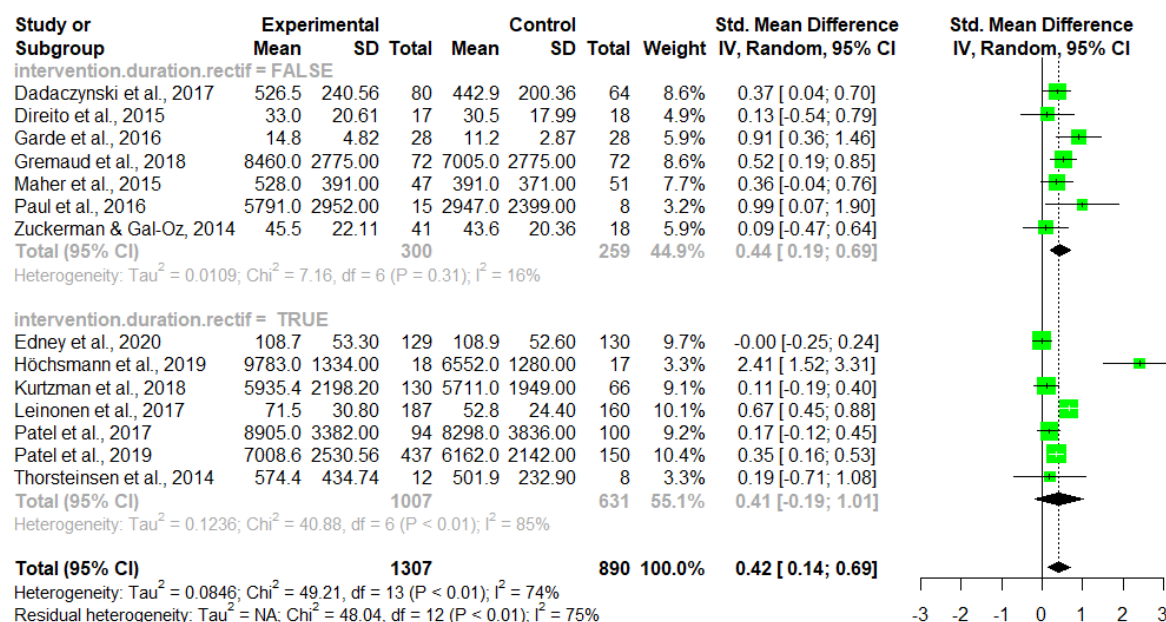


Fig. S7 Forest plot with subgroups in function of intervention duration (less than 12 weeks versus 12 weeks or more) for the effect of gamification versus control on post-intervention PA outcomes (moderate-to-vigorous physical activity (MVPA), daily step count, number of active minutes, and walking time). *SD* standard deviation, *Std* standardized, *IV* inverse variance, *CI* confidence interval, *Tau*², *Chi*², and *I*² measures of between-study heterogeneity

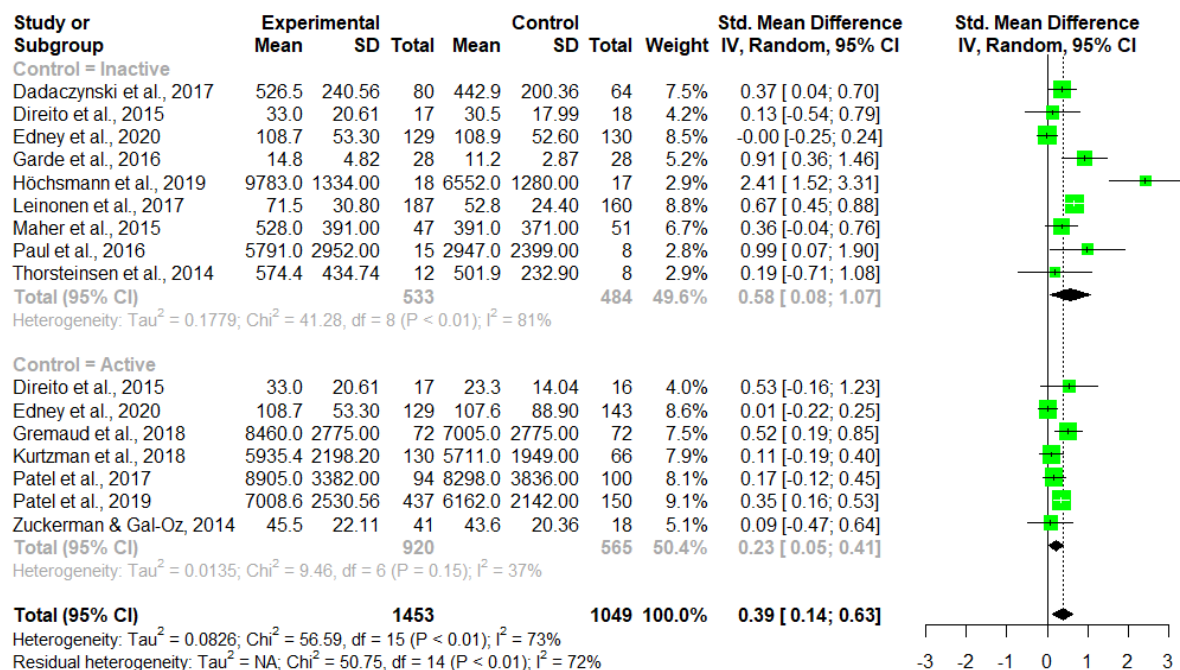


Fig. S8 Forest plot with control groups subgroups (inactive control group versus active control group) for the effect of gamification versus control on post-intervention PA outcomes (moderate-to-vigorous physical activity (MVPA), daily step count, number of active minutes, and walking time). *SD* standard deviation, *Std* standardized, *IV* inverse variance, *CI* confidence interval, τ^2 , χ^2 , and I^2 measures of between-study heterogeneity

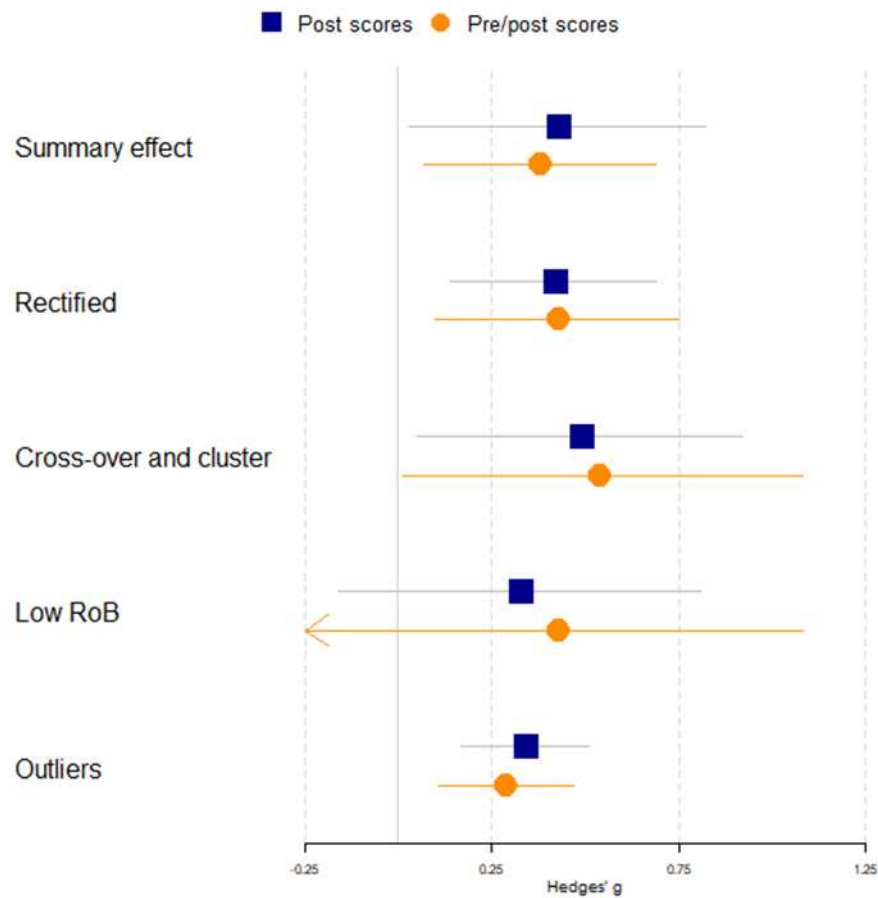


Fig. S9 Summary of the meta-analyses conducted on global PA (i.e., summary effect of gamification versus control, rectified effect after ‘sensitivity analysis’, effect after removing cross-over and cluster trials, effect after removing studies with a high Risk of Bias (RoB), and effect after removing outliers) both for post-intervention scores and pre/post intervention change scores

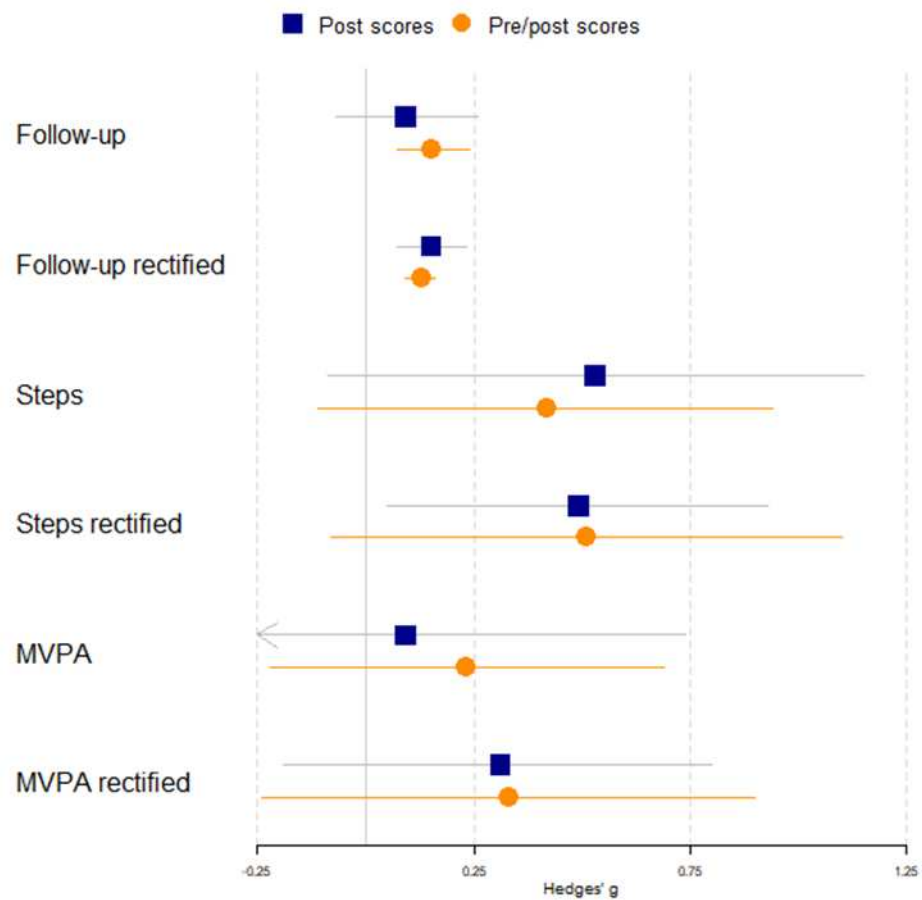


Fig. S10 Summary of the meta-analyses conducted on other outcomes (i.e., effect of gamification versus control after a follow-up period (from 12 to 24 weeks after the end of the intervention), effect on steps outcomes, effect on moderate-to-vigorous physical activity (MVPA), and rectified effects after ‘sensitivity analyses’) both for post-intervention scores and pre/post intervention change scores

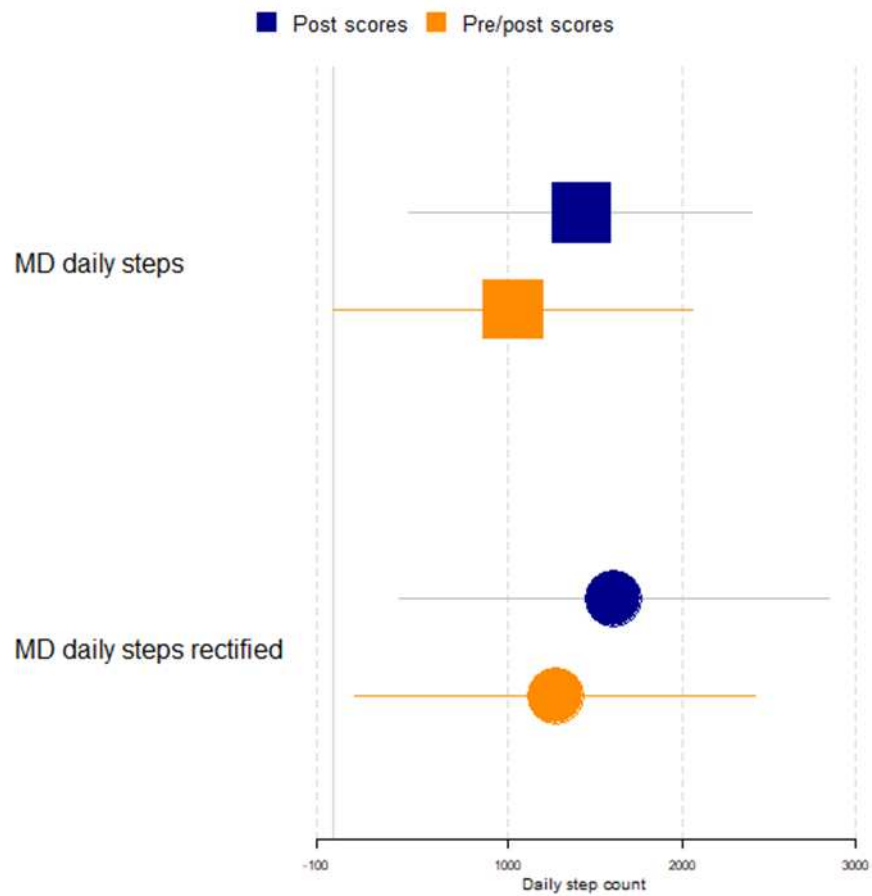


Fig. S11 Summary of the meta-analyses conducted on daily steps (i.e., mean difference of daily steps between gamification and control) both for post-intervention scores and pre/post intervention change scores

2. Search equations for databases

Search String PubMed (615)

- #1. ("exercise"[MH] OR "exercise"[TW] OR "exercises"[TW] OR "active living"[TW] OR "active transport"[TW] OR "activities, physical"[TW] OR "activity, physical"[TW] OR "physical activities"[TW] OR "physical activity"[TW] OR "exercise therapy"[MH] OR "physical fitness"[MH] OR fitness[TW] OR sedent*[TW] OR "sitting time"[TW] OR inactive[TW] OR inactivity[TW] OR walk*[TW])
 - #2. (gamification[TW] OR exergaming[TW] OR "exer-gaming"[TW])
 - #3. (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR clinical trials as topic[mesh:noexp] OR randomly[tiab] OR trial[ti])
 - #4. #1 AND #2 AND #3
 - #5. (game[TW] OR games[TW] OR gamified[TW] OR gaming[TW] OR gameful*[TW] OR multiplayer[TW] OR player[TW] OR players[TW] OR playing[TW])
 - #6. ("telemedicine"[MH] OR "telemedicine"[TW] OR "telehealth"[TW] OR e-health[TW] OR m-Health[TW] OR eHealth[TW] OR mHealth[TW] OR "mobile applications"[MH] OR "applications"[TW] OR "application"[TW] OR app[TW] OR apps[TW] OR "online"[TW] OR "mobile"[TW] OR "internet"[TW] OR "web based"[TW] OR "Smartphone"[MH] OR "phone, smart"[TW] OR "smart phones"[TW] OR "smartphones"[TW] OR "smart phone"[TW] OR "phones, smart"[TW] OR "Smartphone"[TW] OR "cell phone"[TW] OR Iphone[TW] OR android[TW] OR iOS[TW] OR "Wearable Electronic Devices"[MH] OR website[TW] OR digital*[TW] OR system*[TW] OR electronic*[TW] OR technolog*[TW] OR device[TW] OR framework*[TW] OR "social support"[Mesh:NoExp] OR "facebook"[TW] OR "networks, social"[TW])
 - #7. #1 AND #3 AND #5 AND #6
 - #8. #4 OR #7
- Filters: English, from 2010-2020

Search String EMBASE (491)

('sport'/exp OR 'exercise'/exp OR 'physical activity' OR 'climbing'/exp OR 'walking'/exp OR 'sitting'/exp) AND ('exergame'/exp OR 'exergaming'/exp OR 'active video game'/exp OR exergam*:ti,ab,kw OR 'active video gam*:ti,ab,kw OR 'active videogam*:ti,ab,kw OR 'active computer gam*:ti,ab,kw OR 'gamification'/exp OR 'gamifi*:ti,ab,kw OR (('recreational game'/exp OR 'game-based':ti,ab,kw OR 'gam*:ti,ab,kw) AND ('telehealth'/exp OR 'mobile application'/exp OR 'smartphone'/exp OR 'wearable computer'/exp OR 'social network'/exp OR 'virtual reality'/exp))) AND ('clinical trial'/de OR 'controlled clinical trial'/de OR 'randomized controlled trial'/de OR 'randomized controlled trial topic'/de) AND [embase]/lim NOT ([embase]/lim AND [medline]/lim)

Search String CENTRAL (1602)

- #1. ("exercise":ti,ab,kw OR "exercises":ti,ab,kw OR "active living":ti,ab,kw OR "active transport":ti,ab,kw OR "activities, physical":ti,ab,kw OR "activity, physical":ti,ab,kw OR "physical activities":ti,ab,kw OR "physical activity":ti,ab,kw OR fitness:ti,ab,kw OR sedent*:ti,ab,kw OR "sitting time":ti,ab,kw OR inactive:ti,ab,kw OR inactivity:ti,ab,kw OR walk*:ti,ab,kw)

- #2. (gamification:ti,ab,kw OR exergaming:ti,ab,kw OR “exer-gaming”:ti,ab,kw)
- #3. #1 AND #2
- #4. (game:ti,ab,kw OR games:ti,ab,kw OR gamified:ti,ab,kw OR gaming:ti,ab,kw OR gameful*:ti,ab,kw OR multiplayer:ti,ab,kw OR player:ti,ab,kw OR players:ti,ab,kw OR playing:ti,ab,kw)
- #5. ("telemedicine":ti,ab,kw OR "telehealth":ti,ab,kw OR "e-health":ti,ab,kw OR "m-Health":ti,ab,kw OR "eHealth":ti,ab,kw OR "mHealth":ti,ab,kw OR "applications":ti,ab,kw OR "application":ti,ab,kw OR app:ti,ab,kw OR apps:ti,ab,kw OR "online":ti,ab,kw OR "mobile":ti,ab,kw OR "internet":ti,ab,kw OR “web based”:ti,ab,kw OR "phone, smart":ti,ab,kw OR "smart phones":ti,ab,kw OR "smartphones":ti,ab,kw OR "smart phone":ti,ab,kw OR "phones, smart":ti,ab,kw OR "Smartphone":ti,ab,kw OR “cell phone”:ti,ab,kw OR Iphone:ti,ab,kw OR android:ti,ab,kw OR iOS:ti,ab,kw OR website:ti,ab,kw OR digital*:ti,ab,kw OR system*:ti,ab,kw OR electronic*:ti,ab,kw OR technolog*:ti,ab,kw OR device:ti,ab,kw OR framework*:ti,ab,kw OR "facebook":ti,ab,kw OR "networks, social":ti,ab,kw OR "social network":ti,ab,kw OR "network, social":ti,ab,kw OR "social support":ti,ab,kw OR "support, social":ti,ab,kw OR "social networking":ti,ab,kw OR virtual*:ti,ab,kw)
- #6. #1 AND #4 AND #5
- #7. #3 OR #6

Limit: Publication Year from 2010 to 2020 in Trials.

Search String Scopus (306)

((TITLE ("physical activity" OR sport OR exercise? OR walking OR fitness OR "active living" OR "active transport" OR sedent* OR "sitting time" OR inactiv* OR (physical AND near/1 AND activit*))) AND (TITLE-ABS-KEY ("randomi?ed controlled trial" OR "randomi?ed clinical trial" OR "controlled clinical trial" OR randomi?ed OR rct)) AND (TITLE-ABS-KEY (gamifi* OR exergam* OR "exer-gam*"))) OR ((TITLE ("physical activity" OR sport OR exercise? OR walking OR fitness OR "active living" OR "active transport" OR sedent* OR "sitting time" OR inactiv* OR (physical AND near/1 AND activit*))) AND (TITLE-ABS-KEY ("randomi?ed controlled trial" OR "randomi?ed clinical trial" OR "controlled clinical trial" OR randomi?ed OR rct)) AND (TITLE-ABS-KEY (game? OR multiplayer OR player? OR playing OR play)) AND (TITLE-ABS-KEY (telemedicine OR telehealth OR "e-health" OR "m-Health" OR ehealth OR "mHealth" OR application? OR app? OR online OR mobile OR internet OR "web based" OR "phone, smart" OR "smart phones" OR "smartphones" OR "smart phone" OR "phones, smart" OR "Smartphone" OR "cell phone" OR iphone OR android OR "iOS" OR website OR digital* OR system* OR electronic* OR technolog* OR device OR framework* OR "facebook" OR "networks, social" OR "social network" OR "network, social" OR "social support" OR "support, social" OR "social networking" OR virtual*))) AND (LIMIT-TO (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR , 2014) OR LIMIT-TO (PUBYEAR , 2013) OR LIMIT-TO (PUBYEAR , 2012) OR LIMIT-TO (PUBYEAR , 2011) OR LIMIT-TO (PUBYEAR , 2010)) AND (LIMIT-TO (LANGUAGE , "English")))

Search String Web of Science (89)

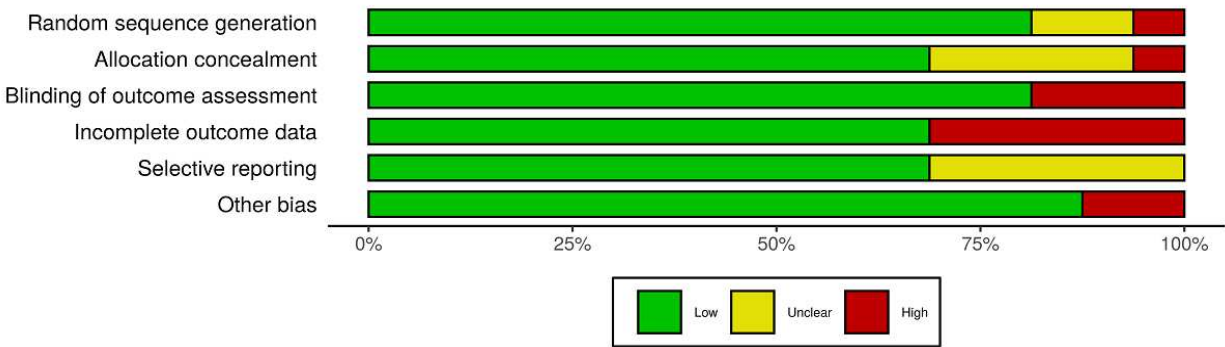
- #1. TI = ("physical activity" OR sport OR exercise? OR walking OR fitness OR "active living" OR "active transport" OR sedent* OR "sitting time" OR inactive OR inactivity OR (physical NEAR/1 activit*))

- #2. TI = (gamifi* OR exergam* OR exer-gam*)
- #3. TS= ("clinical trial*" OR "controlled trial*" OR "follow-up stud*" OR "prospective stud*" OR "random*" OR "single blind*" OR "double blind*" OR rct)
- #4. #1 AND #2 AND #3
- #5. TS= (telemedicine OR telehealth OR e-health OR m-Health OR eHealth OR mHealth OR application? OR app? OR online OR mobile OR internet OR "web based" OR "phone, smart" OR "smart phones" OR "smartphones" OR "smart phone" OR "phones, smart" OR "Smartphone" OR "cell phone" OR Iphone OR android OR "iOS" OR website OR digital* OR system* OR electronic* OR technolog* OR device OR framework* OR facebook OR "networks, social" OR "social network" OR "network, social" OR "social support" OR "support, social" OR "social networking" OR virtual*)
- #6. TI = (game? OR multiplayer OR player? OR playing OR play)
- #7. #1 AND #3 AND #5 AND #6
- #8. #4 OR #7

3. **Table 2.** Risk of bias summary for studies included in the meta-analysis

Study	Judgement						
	Random sequence generation	Allocation concealment	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias	Overall
Corepal et al., 2019	+	+	+	×	+	×	×
Dadaczynski et al., 2017	+	-	×	×	+	+	×
Direito et al., 2015	+	+	+	+	+	+	+
Edney et al., 2020	+	+	+	+	+	+	+
Garde et al., 2016	+	+	+	×	-	+	×
Gremaud et al., 2018	+	+	+	+	+	+	+
Höchsmann et al., 2019	+	+	+	+	+	+	+
Kurtzman et al., 2018	+	+	+	+	+	+	+
Leinonen et al., 2017	+	+	+	×	+	+	×
Maher et al., 2015	+	+	×	+	+	+	×
Nishiwaki et al., 2014	-	-	+	+	-	×	×
Patel et al., 2017	+	+	+	+	+	+	+
Patel et al., 2019	+	+	+	+	+	+	+
Paul et al., 2016	×	×	+	+	-	+	×
Thorsteinsen et al., 2014	+	-	×	×	-	+	×
Zuckerman & Gal-Oz, 2014	-	-	+	+	-	+	+

4. **Table 3.** Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies



5. List and reasons for excluded studies

Source	Study ID	Study authors	Year	Title	Recommendation	Comment
Databases	1	Aalbers et al.	2016	<i>Changing Behavioral Lifestyle Risk Factors Related to Cognitive Decline in Later Life Using a Self-Motivated eHealth Intervention in Dutch Adults</i>	Exclude	Absence of gamification elements in the intervention
Databases	2	Allam et al.	2015	<i>The effect of social support features and gamification on a Web-based intervention for rheumatoid arthritis patients: randomized controlled trial</i>	Include	
Databases	3	Behm-Morawitz et al.	2016	<i>A Second Chance at Health: how a 3D Virtual World Can Improve Health Self-Efficacy for Weight Loss Management Among Adults</i>	Exclude	More a game than gamification
Databases	4	Chang et al.	2018	<i>Efficacy of a game-based mobile application intervention in physical activity promotion and health management</i>	Exclude	Conference abstract
Databases	5	Coknaz et al.	2019	<i>A digital movement in the world of inactive children: favourable outcomes of playing active video games in a pilot randomized trial</i>	Exclude	Active video game
Databases	6	Coombes et al.	2016	<i>Gamification of active travel to school: a pilot evaluation of the Beat the Street physical activity intervention</i>	Exclude	Not randomized
Databases	7	Corepal et al.	2019	<i>A feasibility study of 'The StepSmart Challenge' to promote physical activity in adolescents</i>	Include	
Databases	8	Dadaczynski et al.	2017	<i>Promoting physical activity in worksite settings: results of a German pilot study of the online intervention Healingo fit</i>	Include	
Databases	9	De Ferranti et al.	2011	<i>Increasing physical activity in inner city youth using novel interactive gaming</i>	Exclude	No gamification
Databases	10	Deliva et al.	2014	<i>The World Transplant Games: an incentive to improve physical fitness and habitual activity in pediatric solid organ transplant recipients</i>	Exclude	No gamification
Databases	11	Direito et al.	2015	<i>Apps for IMproving FITness and Increasing Physical Activity Among Young People: the AIMFIT Pragmatic Randomized Controlled Trial</i>	Include	
Databases	12	Edney et al.	2019	<i>User Engagement and Attrition in an App-Based Physical Activity Intervention: secondary Analysis of a Randomized Controlled Trial</i>	Exclude	Comparison between regular and super users of the app
Databases	13	Edney et al.	2020	<i>A Social Networking and Gamified App to Increase Physical Activity: Cluster RCT</i>	Include	
Databases	14	Foley et al.	2014	<i>The effect of active video games by ethnicity, sex and fitness: Subgroup analysis from a randomised controlled trial</i>	Exclude	Active video game

Databases	15	Garde et al.	2018	<i>A Multi-Week Assessment of a Mobile Exergame Intervention in an Elementary School</i>	Include	
Databases	16	Garde et al.	2016	<i>Evaluation of a Novel Mobile Exergame in a School-Based Environment</i>	Include	
Databases	17	Garde et al.	2015	<i>Assessment of a Mobile Game ("MobileKids Monster Manor") to Promote Physical Activity Among Children</i>	Include	
Databases	18	Givon et al.	2016	<i>Video-games used in a group setting is feasible and effective to improve indicators of physical activity in individuals with chronic stroke: a randomized controlled trial</i>	Exclude	Active video game
Databases	19	Gotsis et al.	2013	<i>Wellness partners: design and evaluation of a web-based physical activity diary with social gaming features for adults</i>	Include	Outcome?
Databases	20	Gremaud et al.	2018	<i>Gamifying Accelerometer Use Increases Physical Activity Levels of Sedentary Office Workers</i>	Include	
Databases	21	Haque et al.	2020	<i>A Persuasive mHealth Behavioral Change Intervention for Promoting Physical Activity in the Workplace: Feasibility Randomized Controlled Trial</i>	Include	Outcome?
Databases	22	Hassett et al.	2020	<i>Digitally enabled aged care and neurological rehabilitation to enhance outcomes with Activity and Mobility UsiNg Technology (AMOUNT) in Australia: a randomised controlled trial</i>	Exclude	Not all the participants were expected to be able to walk independently
Databases	23	Heldt et al.	2018	<i>Telemedicine Therapy for Overweight Adolescents: First Results of a Novel Smartphone App Intervention using a Behavioural Health Platform</i>	Exclude	Conference abstract
Databases	24	Höchsmann et al.	2019	<i>Novel Smartphone Game Improves Physical Activity Behavior in Type 2 Diabetes</i>	Include	
Databases	25	Höchsmann et al.	2019	<i>Effectiveness of a Behavior Change Technique-Based Smartphone Game to Improve Intrinsic Motivation and Physical Activity Adherence in Patients With Type 2 Diabetes: Randomized Controlled Trial</i>	Exclude	No PA outcome
Databases	26	Johnston et al.	2012	<i>Using an alternate reality game to increase physical activity and decrease obesity risk of college students</i>	Include	Not randomized
Databases	27	Kauhanen et al.	2014	<i>Active video games to promote physical activity in children with cancer: A randomized clinical trial with follow-up</i>	Exclude	Study protocol
Databases	28	Kurtzman et al.	2018	<i>Social Incentives and Gamification to Promote Weight Loss: The LOSE IT Randomized, Controlled Trial</i>	Include	
Databases	29	L'Allemand et al.	2018	<i>Design and interim evaluation of a smartphone app for overweight adolescents using a behavioural health intervention platform</i>	Exclude	Conference abstract

Databases	30	Leinonen et al.	2017	<i>Feasibility of Gamified Mobile Service Aimed at Physical Activation in Young Men: Population-Based Randomized Controlled Study (MOPO)</i>	Include	
Databases	31	Lwin et al.	2016	<i>Effects of Exergaming and Message Framing in School Environments on Physical Activity Attitudes and Intentions of Children and Adolescents</i>	Exclude	Active video game
Databases	32	Mancioppi et al.	2019	<i>Good-day: Efficacy of gamification of an educational training to mediterranean diet on weight and metabolic control in paediatric obesity. preliminary data at 6 months</i>	Exclude	Conference abstract
Databases	33	Mo et al.	2019	<i>Using Gamification and Social Incentives to Increase Physical Activity and Related Social Cognition among Undergraduate Students in Shanghai, China</i>	Exclude	Not randomized
Databases	34	Nishiwaki et al.	2014	<i>A pilot crossover study: effects of an intervention using an activity monitor with computerized game functions on physical activity and body composition</i>	Include	
Databases	35	Patel et al.	2017	<i>Effect of a Social Incentive-Based Gamification Intervention Using Wearable Devices and Smartphones on Physical Activity: The Be Fit Randomized Clinical Trial</i>	Exclude	Conference abstract
Databases	36	Patel et al.	2017	<i>Effect of a Game-Based Intervention Designed to Enhance Social Incentives to Increase Physical Activity Among Families: The BE FIT Randomized Clinical Trial</i>	Include	
Databases	37	Patel et al.	2019	<i>Effectiveness of Behaviorally Designed Gamification Interventions With Social Incentives for Increasing Physical Activity Among Overweight and Obese Adults Across the United States: The STEP UP Randomized Clinical Trial</i>	Include	
Databases	38	Pope et al.	2018	<i>Lessons Learned Through the Implementation of an eHealth Physical Activity Gaming Intervention with High School Youth</i>	Exclude	No results
Databases	39	Ryan et al.	2017	<i>Engagement compliance and retention with a gamified online social networking physical activity intervention</i>	Exclude	No PA outcome
Databases	40	Shake et al.	2018	<i>Efficacy of Bingocize®: a Game-Centered Mobile Application to Improve Physical and Cognitive Performance in Older Adults</i>	Exclude	No PA outcome
Databases	41	Sun et al.	2016	<i>Impact of an active educational video game on children's motivation</i>	Exclude	Active video game
Databases	42	Sun et al.	2013	<i>Impact of exergames on physical activity and motivation in elementary school students: A follow-up study</i>	Exclude	Active video game
Databases	43	Thorsteinsen et al.	2014	<i>Increasing physical activity efficiently: an experimental pilot study of a website and mobile phone intervention</i>	Include	

Databases	44	Wyke et al.	2019	<i>The effect of a programme to improve men's sedentary time and physical activity: The European Fans in Training (EuroFIT) randomised controlled trial</i>	Exclude	Absence of game elements
Other sources	45	Dombrowski et al.	2020	<i>Game of Stones: Feasibility randomised controlled trial of how to engage men with obesity in text message and incentive interventions for weight loss</i>	Exclude	No gamification, no PA outcome
Other sources	46	Maher et al.	2015	<i>A Web-Based, Social Networking Physical Activity Intervention for Insufficiently Active Adults Delivered via Facebook App: Randomized Controlled Trial</i>	Include	
Other sources	47	Paul et al.	2016	<i>Increasing physical activity in stroke survivors using STARFISH, an interactive mobile phone application: a pilot study</i>	Include	
Other sources	48	Pyky et al.	2017	<i>Effect of tailored, gamified, mobile physical activity intervention on life satisfaction and self-rated health in young adolescent men: A population-based, randomized controlled trial (MOPO study)</i>	Exclude	Data previously published in another study
Other sources	49	Zuckerman and Gal-Oz	2014	<i>Deconstructing gamification: evaluating the effectiveness of continuous measurement, virtual rewards, and social comparison for promoting physical activity</i>	Include	
Other sources	50	Chen et al.	2014	<i>HealthyTogether: Exploring Social Incentives for Mobile Fitness Applications</i>	Include	
Other sources	51	Douglas et al.	2018	<i>Individual differences in regulatory mode moderate the effectiveness of a pilot mHealth trial for diabetes management among older veterans</i>	Exclude	No PA outcome

Appendix 2: supplementary materials of study 2

1. Analyses with outliers included

Table S1. Description of the mean daily step count during baseline, intervention, and follow-up periods, changes and relative changes from baseline in function of participants' baseline daily step count.

	<5000	5000-7500	7501-10000	>10000
Baseline daily step count	3681	6228	8666	12177
Intervention daily step count	8562	10402	12737	15670
Follow-up daily step count	5373	6928	8755	11058
Change from baseline during the intervention	4871	4134	4071	3493
Change from baseline during follow-up	1693	659	89	-1119
Relative change during intervention	+149.0 %	+66.9 %	+47.5 %	+29.8 %
Relative change during follow-up	+56.1 %	+10.9 %	1.1 %	-8.7 %

Table S2. Results of the contrast analyses performed on the mixed-effects models for each hypothesis.

	<i>b</i> [95 CI]	SE	<i>P</i>
Is the gamified program effective to promote PA? (H1)			
<i>Overall</i>			
Intervention baseline	-0.16 [-0.20; -0.11]	0.02	<.001
Follow-up baseline	-0.10 [-0.15; -0.05]	0.03	0.0001
<5000			
Intervention baseline	0.20 [0.17; 0.22]	0.01	<.001
Follow-up baseline	0.17 [0.15; 0.19]	0.01	<.001
5000-7500			
Intervention baseline	0.13 [0.10; 0.16]	0.01	<.001
Follow-up baseline	0.10 [0.08; 0.11]	0.01	<.001
7501-10000			
Intervention baseline	0.08 [0.04; 0.12]	0.02	<.001
Follow-up baseline	0.02 [0.00; 0.05]	0.03	<.05
>10000			
Intervention baseline	-0.13 [-0.18; -0.07]	0.03	<.001
Follow-up baseline	-0.13 [-0.16; -0.10]	0.02	<.001
Is the intervention effect greater for participants compared to nonparticipants? (H2)			
Intervention baseline	0.64 [0.61; 0.66]	0.01	<.001
What are the moderators of the intervention effect? (H3)			
Intervention × Age	0.07 [0.06; 0.08]	0.01	<.001
Intervention × Compliance ratio	0.49 [0.46; 0.54]	0.01	<.001
Intervention × Nb of games	-0.04 [-0.07; -0.01]	0.01	<.001

Table S3. Description of the mean daily step count during baseline, intervention, and follow-up periods, changes and relative changes from baseline for participants and nonparticipants.

	Participants	Nonparticipants
Baseline daily step count	7421	6574
Intervention daily step count	11559	6581
Change from baseline during the intervention	4138.4	199.3
Relative change during intervention	+75.6 %	+9.1%

2. Interaction analyses for moderators of the intervention

Table S4. Interactions tested between the intervention phase, participants' characteristics, and intervention parameters in Model 2.

	<i>b</i> [95 CI]	SE	<i>P</i>
Model 1			
Intervention × Control	Reference		
Intervention × Kiplin	0.55 [0.52; 0.58]	0.02	<.001
Model 2			
Intervention × Age	0.05 [0.04; 0.06]	0.01	<.001
Intervention × Compliance ratio	0.37 [0.35; 0.38]	0.01	<.001
Intervention × Nb of games	-0.02 [-0.03; -0.00]	0.01	0.021
Intervention × Workers	Reference		
Intervention × Cancer	-0.18 [-0.24; -0.12]	0.03	<.001
Intervention × Obese	-0.07 [-0.16; 0.02]	0.04	0.133
Intervention × Senior	-0.19 [-0.25; -0.13]	0.03	<.001
Intervention × base <5000	Reference		
Intervention × base 5000 - 7500	-0.23 [-0.26; -0.20]	0.01	<.001
Intervention × base 7501 - 10000	-0.41 [-0.44; -0.38]	0.02	<.001
Intervention × >10000	-0.60 [-0.64; -0.57]	0.02	<.001

Notes base = baseline daily steps; control = nonparticipants

3. Results of contrast analyses on baseline/intervention changes between population settings:

Obese patients vs **Employees** ($b = -0.07$, 95 CI [-0.155; 0.02], $p = 0.133$)

Cancer patients vs **Employees** ($b = -0.18$, 95 CI [-0.24; -0.12], $p < .0001$)

Seniors vs **Employees** ($b = -0.19$, 95 CI [-0.25; -0.13], $p < .0001$)

—

Cancer patients vs **Obese patients** ($b = -0.11$, 95 CI [-0.21; -0.02], $p = 0.02$)

Seniors vs **Obese patients** ($b = -0.12$, 95 CI [-0.22; -0.02], $p = 0.02$)

—

Cancer patients vs **Seniors** ($b = 0.00$, 95 CI [-0.07; 0.08], $p = 0.90$)

Appendix 3: supplementary materials of study 5

1. supplementary online material 1
2. supplementary online material 2
3. supplementary online material 3
4. supplementary online material 4

1. 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 through 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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2. 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.

3. supplementary online material 3

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



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 l'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.

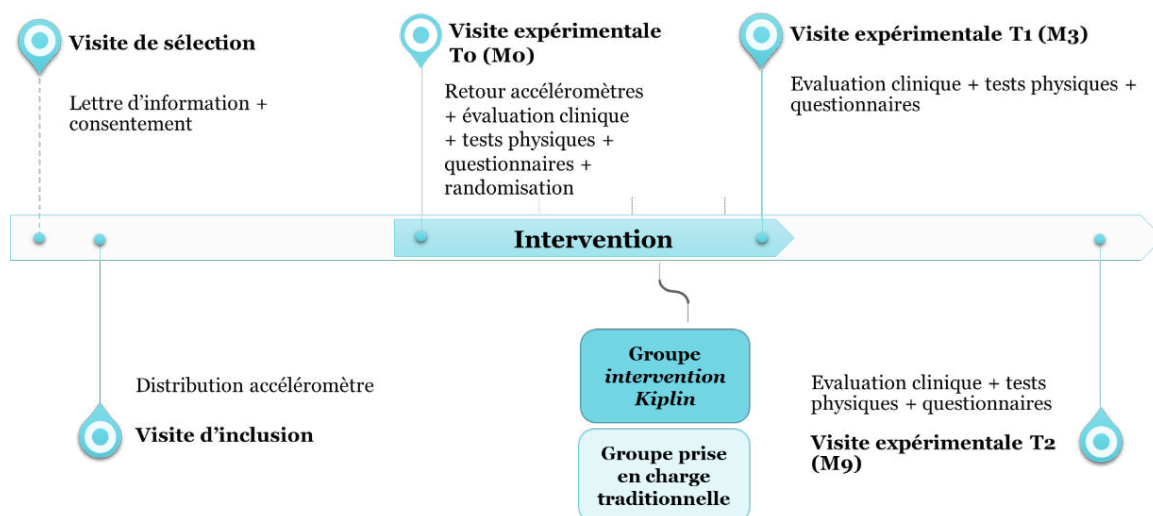


Schéma récapitulatif du protocole expérimental

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 minimales 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.

4. 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.



Appendix 4: supplementary materials of study 6

1. Psychometric qualities of the questionnaires at To
2. Descriptive statistics on clinical secondary outcomes
3. Adjusted mixed effect model for the primary outcome
4. Plots of the Generalized Additive Models for the evolution of daily steps from baseline to one-week post-intervention for the 21 patients of the Kiplin group

1. Psychometric qualities of the questionnaires at To

- **Everyday discriminations scale**

Estimate	McDonald's ω	Cronbach's α
Point estimate	0.952	0.949
95% CI lower bound	0.924	0.923
95% CI upper bound	0.975	0.967

Note. Of the observations, pairwise complete cases were used.

- **EQ-5D**

Estimate	McDonald's ω	Cronbach's α
Point estimate	0.582	0.522
95% CI lower bound	0.406	0.279
95% CI upper bound	0.713	0.695

Note. The following item correlated negatively with the scale: eq5_to.

- **Weigh stigma concerns**

Estimate	McDonald's ω	Cronbach's α
Point estimate	0.922	0.912
95% CI lower bound	0.877	0.861
95% CI upper bound	0.956	0.946

- **Modified Weight Bias Internalization**

Estimate	McDonald's ω	Cronbach's α
Point estimate	0.857	0.837
95% CI lower bound	0.804	0.769
95% CI upper bound	0.900	0.888

- **Motivation Scale Towards Health-oriented Physical Activity**

Estimate	McDonald's ω	Cronbach's α
Point estimate	0.777	0.799

Estimate	McDonald's ω	Cronbach's α
95% CI lower bound	0.690	0.702
95% CI upper bound	0.863	0.869

- **In-group identification questionnaire**

Estimate	McDonald's ω	Cronbach's α
Point estimate	0.974	0.973
95% CI lower bound	0.952	0.960
95% CI upper bound	0.986	0.982

Note. Of the observations, pairwise complete cases were used.

- **Physical Activity Enjoyment Scale**

Estimate	McDonald's ω	Cronbach's α
Point estimate	0.844	0.840
95% CI lower bound	0.533	0.769
95% CI upper bound	0.921	0.893

Note. Of the observations, pairwise complete cases were used. The following items correlated negatively with the scale: pleasure7_rever, pleasure13_rever.

- **Psychological need satisfaction in exercise scale**

Estimate	McDonald's ω	Cronbach's α
Point estimate	0.894	0.886
95% CI lower bound	0.693	0.835
95% CI upper bound	0.952	0.924

Note. Of the observations, pairwise complete cases were used.

2. Descriptive statistics on clinical secondary outcomes

Table S1. Descriptive statistics on clinical secondary outcomes

Kiplin program (n=21 at To/T1 and n=4 at T2)			
Variables	To	T1	T2
Anthropometrics			
BMI (kg/m ²)	40.09 ± 7.75	39.63 ± 7.98	42.91± 3.52
Body composition			
Fat mass (%)	45.60 ± 10.00	44.87 ± 9.31	53.50± 1.25
Lean mass (kg)	57.25 ± 12.44	56.72 ± 13.12	53.30 ± 7.00
Physical capacities			
Hand grip (kg)	33.48 ± 8.87	33.97 ± 9.34	30.90 ± 4.80
Dynatrack (kg)	53.68 ± 17.82	57.14 ± 16.50	53.13 ± 12.56
6MWT (m)	517.95 ± 69.67	524.04 ± 70.90	502.50 ± 59.57
Usual care (n=9 at To/T1 and n=9 at T2)			
Variables	To	T1	T2
Anthropometrics			
BMI (kg/m ²)	40.06 ± 6.91	40.15± 6.86	42.40± 7.06
Body composition			
Fat mass (%)	45.19 ± 9.66	45.08± 9.66	47.00± 9.08
Lean mass (kg)	57.36 ± 10.52	57.72 ± 13.12	58.27± 7.12
Physical capacities			
Hand grip (kg)	32.05 ± 8.07	32.54 ± 9.07	30.82 ± 7.48
Dynatrack (kg)	50.13 ± 16.07	59.06 ± 19.90	53.14 ± 13.89
6MWT (m)	479.11 ± 76.10	514.39 ± 88.62	522.25 ± 502.50

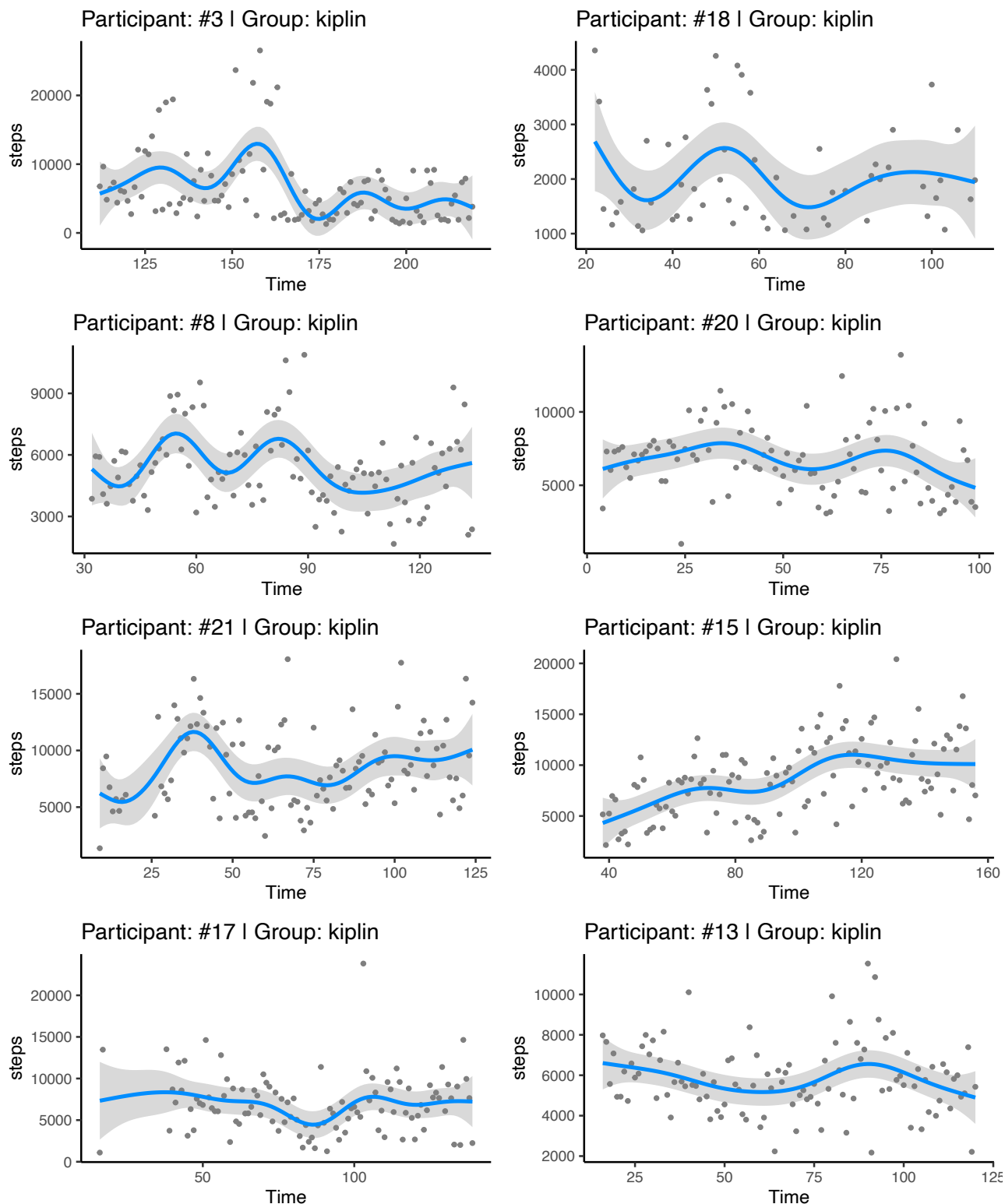
3. Adjusted mixed effect models the primary outcome

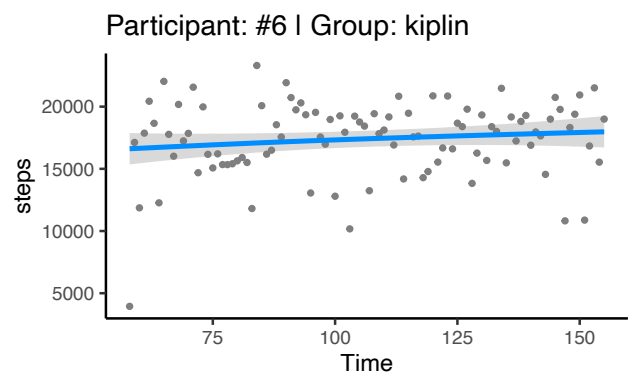
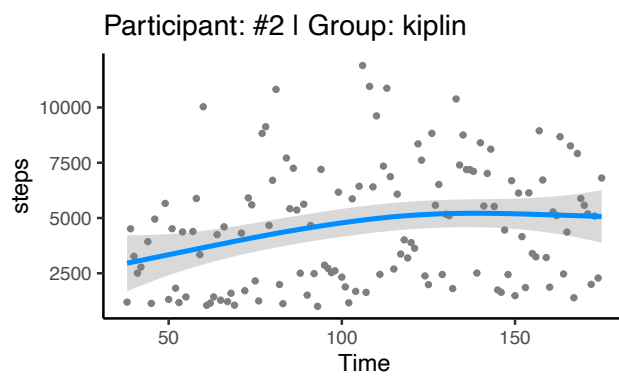
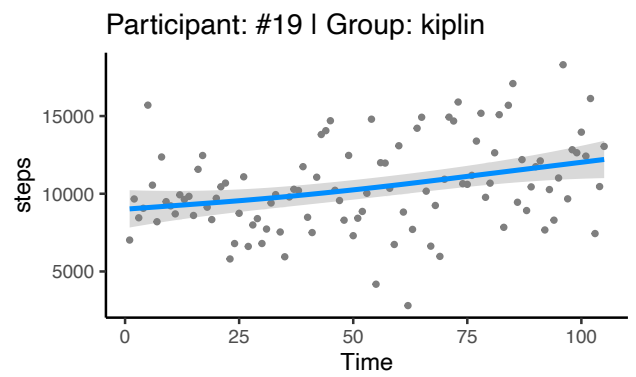
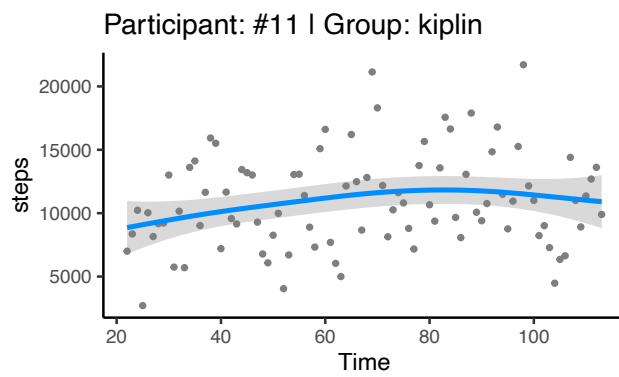
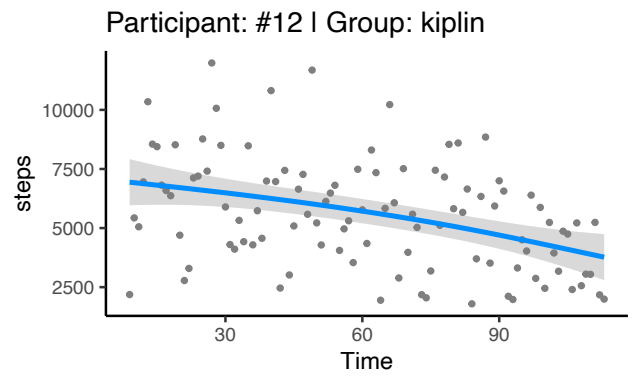
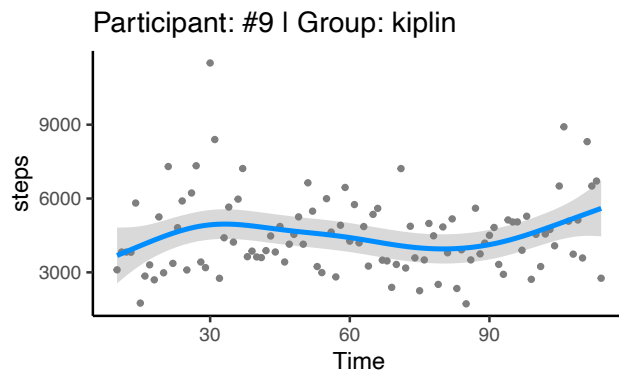
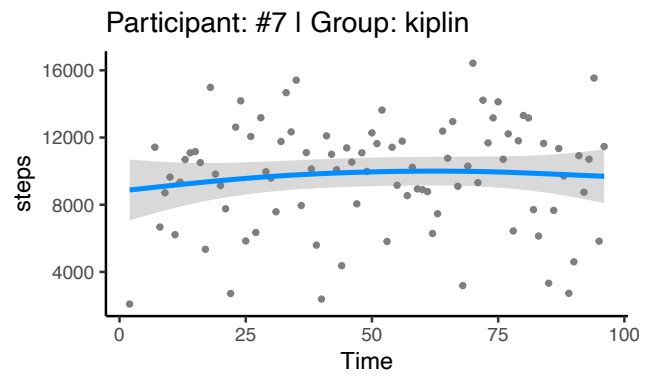
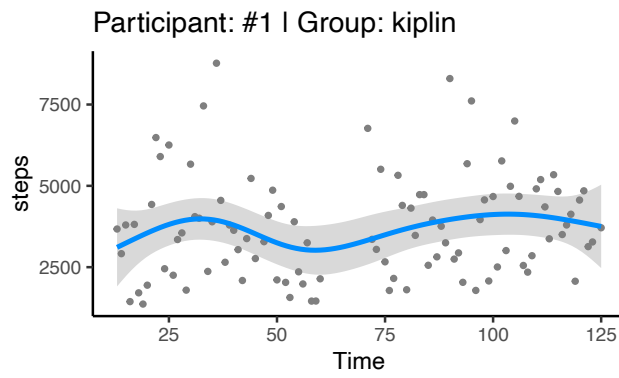
Table S2. Mixed-effect model for the evolution of daily steps across the trial and follow-up periods adjusted for age, season, BMI, and baseline physical activity.

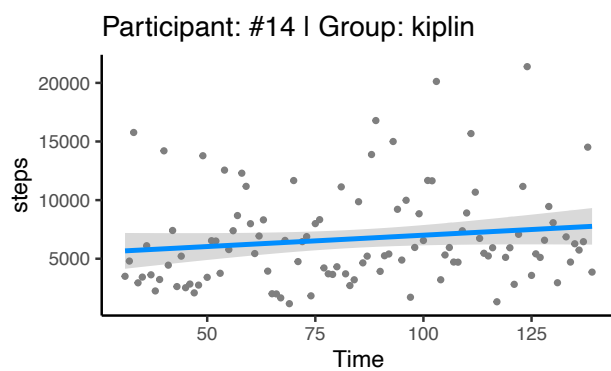
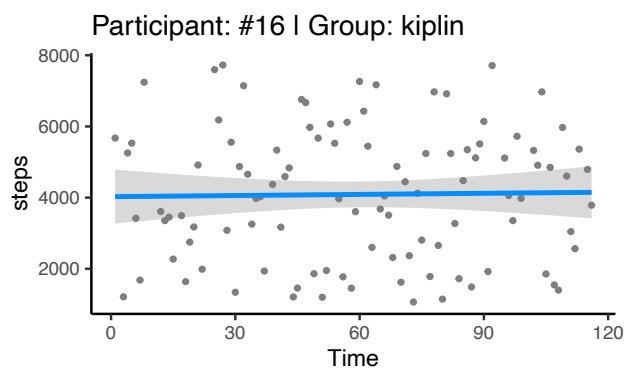
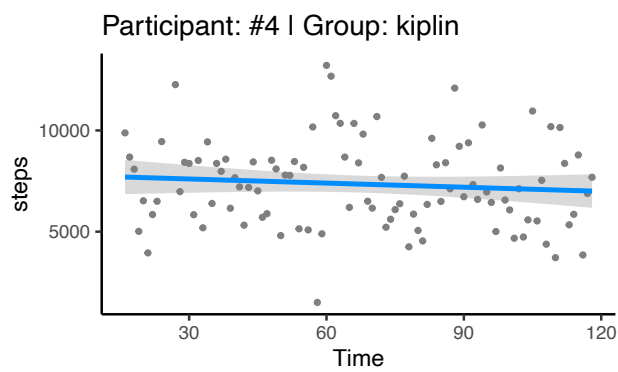
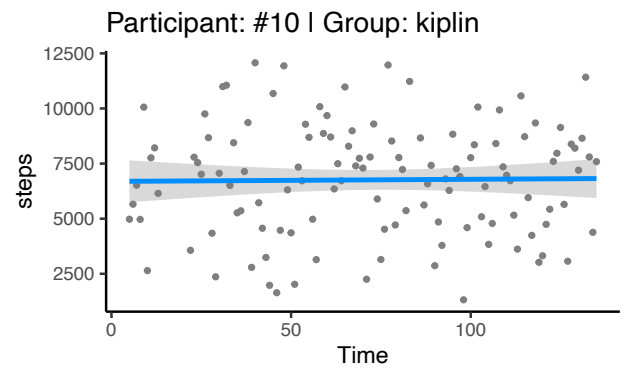
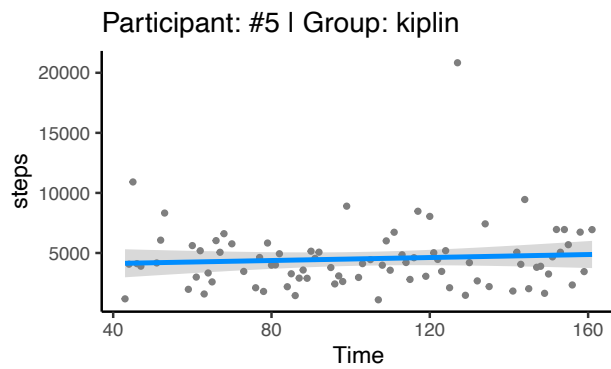
<i>Predictors</i>	steps			
	<i>Estimates</i>	<i>std. Error</i>	<i>CI</i>	<i>p</i>
(Intercept)	-0.66	0.11	-0.88 – -0.43	<0.001
phase [follow-up]	-0.19	0.08	-0.35 – -0.04	0.015
phase [intervention]	0.03	0.05	-0.08 – 0.13	0.623
condition [kiplin]	0.09	0.13	-0.15 – 0.34	0.458
age	-0.06	0.06	-0.17 – 0.05	0.268
season	0.02	0.01	-0.00 – 0.05	0.092
base5000-7500	0.49	0.14	0.21 – 0.77	0.001
base7501-10000	0.93	0.15	0.63 – 1.22	<0.001
base [>10000]	1.52	0.20	1.13 – 1.90	<0.001
bmi	-0.16	0.06	-0.28 – -0.04	0.009
phase [follow-up] * condition [kiplin]	0.44	0.10	0.25 – 0.64	<0.001
phase [intervention] * condition [kiplin]	0.22	0.07	0.08 – 0.37	0.002
Random Effects				
σ^2	0.48			
$\tau_{00 \text{ id}}$	0.15			
$\tau_{11 \text{ id.time}}$	0.02			
$\theta_{01 \text{ id}}$	0.66			
ICC	0.24			
N_{id}	35			
Observations	6026			
Marginal R^2 / Conditional R^2	0.347 / 0.503			
log-Likelihood	-6407.380			

Note. Base = baseline physical activity.

4. Plots of the Generalized Additive Models for the evolution of daily steps from baseline to one-week post-intervention for the 21 patients of the Kiplin group







Long résumé en Français

Le dernier rapport de l'Organisation Mondiale de la Santé (2022) estime qu'environ 500 millions de personnes vont développer une maladie cardiovasculaire, une obésité, un diabète, ou tout autre maladie chronique attribuable à l'inactivité physique entre 2020 et 2030. Ces pathologies représentent aujourd'hui la première cause de décès à travers le monde (Forouzanfar et al., 2016) et coûtent 27 milliards de dollars annuels. Plus particulièrement en France, le coût social de l'inactivité physique peut être estimé à 140 milliards d'euros par an, tandis l'excès de comportements sédentaires quotidien coûterait 494 millions d'euros à l'assurance maladie (Commission Évaluation Économique et Santé Publique, 2022 ; Noël Racine et al., 2022).

Dans ce contexte, la promotion de l'activité physique et la réduction des comportements sédentaires constituent un enjeu majeur. En effet, ces dernières années ont vu s'accumuler un certain nombre de preuves scientifiques venant étayer les bénéfices de l'activité physique pour la santé et les effets délétères des comportements sédentaires prolongés. Une activité physique régulière permet non seulement de prévenir le risque de développer des maladies chroniques (e.g., Manson et al., 2002 ; Wolin et al., 2009), mais aussi de limiter leur progression (e.g., Duclos et al., 2013 ; Pedersen & Saltin, 2015) et de réduire la mortalité précoce associée à ces pathologies (e.g., Ekelund et al., 2019). Il existe également des preuves scientifiques d'une relation dose-réponse entre la mortalité et le temps total passé en comportement sédentaire (Ekelund et al., 2019, 2020 ; Li et al., 2022).

Cependant, malgré cette reconnaissance scientifique, force est de constater que la population générale reste insuffisamment active et particulièrement sédentaire. On estime aujourd'hui qu'un tiers de la population mondiale ne respecte pas les recommandations d'activité physique (Guthold et al., 2018 ; Hallal et al., 2012), et la tendance est à la baisse, les individus effectuant en moyenne 1000 pas quotidiens de moins qu'il y a deux décennies (Conger et al., 2022). Les résultats de l'étude *Nutrinet* ont révélé que le temps moyen passé en position assise des Français était de près de 12 heures lors d'une journée de travail et de 9 heures un jour de congé (Saidj et al., 2015). Par ailleurs, si la population générale est insuffisamment active, la situation est encore

plus alarmante chez certains publics comme les patients atteints de maladies chroniques, les femmes et les personnes obèses ; ces populations présentant des niveaux d'activité physique inférieurs à ceux de la population générale (Barker et al., 2019 ; Hallal et al., 2012).

Pour toutes ces raisons, aider les personnes inactives et sédentaires à adopter un style de vie plus actif apparaît comme un défi impératif de santé publique. En France, une série d'actions a été initiée afin de promouvoir l'activité physique des patients atteints de maladies chroniques. Ces derniers peuvent notamment bénéficier de séances d'activité physique adaptée, qui comprennent des activités physiques et sportives ajustées aux capacités et à la maladie de la personne à des fins de prévention, de réhabilitation, de réinsertion, d'éducation à la santé ou d'inclusion sociale.

Néanmoins si ces programmes semblent efficaces pour aider les individus à effectuer des changements initiaux dans leurs comportements de santé, ces interventions peinent à engager les participants et à promouvoir l'activité physique sur le long terme, avec le constat que seul un faible pourcentage de patients maintient une activité physique lors du retour à leur domicile, une fois le programme terminé (Boiché et al., 2019). De plus, ces programmes conduits en présentiel sont associés à de multiples contraintes organisationnelles et budgétaires qui limitent leur impact et leur dissémination à grande échelle. Pour les hôpitaux et les centres de soin, les créneaux sont difficiles à multiplier en raison de capacités d'accueil limitées et de financements restreints (Charles et al., 2019). Pour les patients, ces programmes peuvent être difficiles d'accès en raison du manque de disponibilité aux séances prévues, du coût de ces séances ou de l'éloignement géographique du centre de soin (Jerant et al., 2005). Ces problématiques ont été exacerbées durant la pandémie de la COVID-19, qui a rendu impossible la prise en charge en présentiel des maladies chroniques à cause du risque de contamination liée au virus.

Afin de répondre à ces différents enjeux, le recours aux interventions digitales est particulièrement prometteur. Communément appelé "e-santé" et défini comme « l'utilisation des technologies de l'information et de la communication pour toutes les activités liées à la santé, et/ou la prestation de soins à distance », ces nouvelles formes d'intervention permettent de proposer des programmes qui tirent profit des nouvelles technologies pour soutenir le changement de comportement d'activité physique en contexte écologique (Arigo et al., 2019 ; Walsh & Groarke, 2019). En outre, de par leur

accessibilité et leur omniprésence dans nos vies, leur coût relativement faible, leur capacité à accéder rapidement à du contenu de n'importe où, et leur capacité à collecter des données en temps réel, les smartphones, objets connectés et autres outils digitaux ont la capacité d'étendre la portée des interventions comportementales à moindre coût, tout en réduisant les contraintes des patients.

Néanmoins, en dépit de ces perspectives sans précédent pour améliorer la prise en charge des patients atteints de maladies chroniques et optimiser le changement de comportement des individus, de nombreux défis sont encore à surmonter afin d'implémenter ces outils de manière pérenne dans le système de santé. En effet, il n'existe à ce jour aucune preuve scientifique suffisante pour justifier leur efficacité sur le long terme. En particulier, nous pouvons nous interroger sur la capacité des programmes numériques à susciter l'intérêt des participants une fois le temps de la nouveauté passé. L'engagement des utilisateurs est généralement limité dans le temps, avec en moyenne 80% des participants ne s'engageant qu'à un niveau minimum et ne se connectant pas plus d'une fois aux applications de santé (Meyerowitz-Katz et al., 2020).

La question de la scalabilité de ces interventions peut également être soulevée. Nous pouvons notamment nous interroger sur le fait que ces outils soient réellement adaptés à tout type de public, quel que soit leur âge ou état de santé. Plus largement, nous pouvons également nous demander si la réduction du présentiel ne pourrait pas entraîner un effet négatif sur la motivation des patients.

De plus, si les interventions numériques semblent avantageuses par rapport aux programmes actuels, aucune preuve d'une meilleure efficacité ou d'un meilleur rapport coût-efficacité n'a été démontrée pour l'instant (Brown et al., 2021 ; Muellmann et al., 2018).

Enfin, plusieurs auteurs ont fait l'observation que la conception des interventions digitales n'est que rarement fondée sur les connaissances scientifiques relatives aux changements de comportements (Conroy et al., 2014 ; Nikolaou & Lean, 2017). Or il existe tout un pan de recherche en psychologie de la santé et de l'activité physique sur les déterminants du changement de comportement. Le recours à ces cadres théoriques est essentiel car ils créent un contexte pour comprendre, expliquer et finalement intervenir sur l'activité physique.

Les perspectives interventionnelles offertes par la démocratisation des outils numériques sont multiples. Parmi elles, nous pouvons citer le concept de gamification. La gamification est l'utilisation d'éléments de jeu dans des activités qui en sont au départ dépourvues afin de favoriser le changement de comportement par une augmentation de l'engagement et de la motivation. En intégrant des mécanismes de jeu tels que les points, les niveaux, les classements, les badges, les défis ou des éléments de personnalisation dans des activités de routine telle que l'activité physique du quotidien, la gamification vise à intégrer à ces activités les ingrédients qui rendent les jeux agréables afin de motiver les participants à pratiquer d'avantage (Cugelman, 2013). La gamification promet donc une double amélioration en rendant les activités plus agréables et en assurant l'engagement à long terme des personnes dans des tâches initialement perçues comme peu motivantes (Sardi et al., 2017).

En outre, la gamification apparaît comme une solution prometteuse pour surmonter les défis associés à l'utilisation des interventions digitales en renforçant l'engagement, en facilitant l'implémentation de techniques de changement de comportement reconnues et en favorisant l'adoption d'interventions numériques par des populations ayant une faible littéracie numérique en plus de potentiellement favoriser le changement de comportement à long terme. Cependant, à l'instar des interventions digitales, l'efficacité de la gamification reste encore à démontrer. Les premières revues de la littérature sur ce sujet ont en effet révélé l'existence de résultats mixtes (Johnson et al., 2016 ; Koivisto & Hamari, 2019 ; Seaborn & Fels, 2015) et, plus alarmant encore, certains auteurs ont observé que les effets étaient d'autant plus nuancés lorsque les études étaient plus rigoureuses d'un point de vue méthodologique (Koivisto & Hamari, 2019). Ainsi, l'efficacité des interventions gamifiées pour promouvoir l'activité physique doit être évaluée par le biais de nouvelles études scientifiques rigoureuses.

Par conséquent, l'objectif de ce travail doctoral est d'apporter des éléments de réponse à ces questions importantes, notamment en développant et en évaluant l'efficacité d'une intervention digitale basée sur la gamification pour promouvoir l'activité physique de patients atteints de maladies chroniques. Pour cela, le programme de recherche proposé s'est articulé autour d'une étroite collaboration avec l'entreprise Kiplin, éditrice de jeux de santé numériques, et visait à répondre aux questions suivantes non encore explorées dans la littérature :

- 1) La gamification est-elle efficace pour promouvoir l'activité physique des individus ? (Objectif 1)
- 2) Les outils digitaux permettent-ils de proposer des programmes d'activité physique fiables et efficaces à distance ? (Objectif 2)
- 3) Un programme digital est-il plus efficace et plus rentable d'un point de vue médico-économique qu'un programme d'activité physique adaptée traditionnel ? (Objectif 3)
- 4) Quelles sont les variables modératrices de ces interventions digitales gamifiées ? (Objectif 4)

Cette thèse tente de répondre à ces questions par l'intermédiaire de 6 études aux méthodologies complémentaires. Plus précisément, les études 1 et 2 visent à répondre aux objectifs 1 et 4, les études 3 et 4 à l'objectif 2 et enfin les études 5 et 6 aux objectifs 1, 3 et 4.

La première étude reportée dans cette thèse est une revue systématique et une méta-analyse dont l'objectif est d'évaluer et de quantifier l'efficacité à court et long terme des interventions gamifiées précédemment testées dans la littérature et d'investiguer leur généralisation à différentes populations. Dans cette optique, 5 bases de données ont été passées au crible afin de recenser les essais randomisés contrôlés publiés en anglais entre 2010 et 2020 qui ont testé l'impact d'une intervention digitale gamifiée sur l'activité physique en comparaison à un groupe contrôle actif (i.e., groupe témoin bénéficiant d'une autre intervention dépourvue d'éléments de jeu) ou inactif (i.e., groupe témoin non exposé, tel qu'une liste d'attente). La taille d'effet pour chaque variable d'activité physique a été calculée par l'intermédiaire de méta-analyses utilisant des modèles à effets aléatoires. 16 études et 2407 participants ont été inclus dans ces différentes analyses. Les résultats principaux démontrent un effet global faible à modéré de $g = 0,42$ (95%CI [0,14 ; 0,69]) concernant l'efficacité des interventions gamifiées en comparaison à des groupes contrôle pour promouvoir l'activité physique. Plus précisément, ces interventions ont amélioré l'activité physique quotidienne des individus de 1600 pas en moyenne. Aucun effet d'interaction avec des modérateurs tel que l'âge, le sexe ou le statut pondéral n'a été détecté, suggérant une

bonne généralisabilité de la gamification à différents publics. Les analyses mesurant l'effet à la suite de période de suivi (i.e., en moyenne 14 semaines post-intervention) ont révélé un effet plus faible mais significatif de $g = 0,15$ (95%CI [0,07 ; 0,23]). Enfin, les résultats révèlent un effet significativement positif à la fois lorsque les interventions gamifiées sont comparées à des groupes contrôle inactifs ($g=0,58$, 95% CI [0,08 ; 1.07]), et à des groupes contrôle actifs comprenant une intervention digitale non gamifiée ($g=0,23$, 95% CI [0,05 ; 0,41]). Ceci suggère que les interventions gamifiées sont plus efficaces que d'autres interventions digitales plus classiques et permettraient de catalyser le changement de comportement. Il est également important de noter que cette méta-analyse a révélé une hétérogénéité statistique considérable.

Les études incluses dans cette revue étant des essais contrôlés, qui peuvent parfois ne pas être représentatif des conditions de vie réelle, l'étude 2 vise à confirmer l'efficacité à court et moyen terme ainsi que la généralisabilité des interventions gamifiées en contexte écologique sur la base de données de vie réelle. En prime, nous avons également exploré l'existence de potentiels modérateurs de l'effet de ces interventions pouvant être à l'origine de la forte hétérogénéité statistique observée dans l'étude 1. Plus précisément, dans cette étude rétrospective de données longitudinales d'activité physique de plus de 4800 participants, nous avons testé (1) si l'intervention gamifiée Kiplin améliorait le nombre de pas quotidiens pendant les périodes d'intervention et de suivi par rapport à l'activité initiale, (2) si cette amélioration était plus élevée chez les individus ayant bénéficié de l'intervention en comparaison aux non-participants (i.e., individus s'étant enregistrés pour le programme mais n'ayant participé à aucun jeu), et (3) si certaines caractéristiques des participants ou paramètres de l'intervention modéraient l'effet du programme.

Les résultats ont révélé que les participants ayant bénéficié de l'intervention ont observé un changement de comportement significativement plus important en comparaison aux non-participants, sur la même période de temps ($b = 0,55$, $p < 0,0001$). Néanmoins, tous les participants ayant bénéficié de cette intervention n'ont pas eu les mêmes bénéfices. Tandis que les participants ayant un nombre de pas initial inférieur à 7500 ont vu leur activité être significativement améliorée, à la fois pendant la période d'intervention et pendant la période de suivi (jusqu'à 3 mois post-intervention), les participants avec une activité initiale supérieure à 7500 pas quotidien n'ont quant à eux pas observé d'améliorations. Ce résultat suggère que

l'intervention gamifiée Kiplin est efficace pour promouvoir l'activité physique des participants inactifs seulement. Les résultats indiquent également que l'âge ($b = 0,05$, $p < 0,0001$) et l'exposition à l'intervention ($b = 0,37$, $p < 0,0001$) ont modéré positivement l'effet du programme. En d'autres termes, plus les participants étaient âgés et plus ils ont interagi avec l'application, meilleure était l'efficacité de l'intervention sur le changement de comportement.

Si à la vue de ces premiers résultats les interventions gamifiées apparaissent efficaces dans leur capacité à promouvoir l'activité physique légère des participants, nous avons postulé que son association avec de séances d'activité physique adaptée au sein d'un programme pouvait être pertinente afin d'optimiser les effets et bénéfices pour le patient. Néanmoins, comme introduit précédemment, ces programmes en présentiel sont associés à une série de limites organisationnelles et budgétaires. Afin de répondre à ces dernières, les études 3 et 4 évaluent la validité, l'efficacité et la fiabilité d'outils de e-santé pour proposer des séances d'activité physique à distance.

L'étude 3 est une étude pilote visant à évaluer l'efficacité d'un programme hybride associant séances d'activité physique adaptée en présentiel et telecoaching auprès de patients atteints de maladies chroniques. Le second objectif de cette étude est de comparer les résultats de cette prise en charge à un programme classique exclusivement réalisé en présentiel. Dans cette optique, le programme hybride a été proposé à 20 patients au printemps 2020 et l'impact de ce programme a été mesuré sur le changement du niveau d'activité physique, la condition physique et la composition corporelle entre avant et après le programme. Ces évolutions ont ensuite été comparées aux résultats de 100 patients similaires sélectionnés dans une base de données de 500 patients ayant bénéficié précédemment du même programme, avec les mêmes coachs, dans le même établissement de santé, avec les mêmes évaluateurs mais avec des séances réalisées uniquement en présentiel. Ces patients ont été sélectionnés aléatoirement sur la base d'un appariement entre les variables initiales des patients des deux groupes.

Les résultats de cette étude indiquent que les participants ayant bénéficié du programme hybride ont amélioré de manière significative leur capacité cardiorespiratoire, comme le révèlent leurs performances sur le test de marche de six minutes (TM6) et le test de marche de 10 mètres. Ils ont également déclaré avoir pratiqué significativement plus d'activité à la fin du programme par rapport à leur

activité initiale. Enfin, l'amélioration de la performance au TM6 était significativement plus élevée dans le programme hybride par rapport à la prise en charge traditionnelle. Les résultats de cette étude pilote suggèrent la faisabilité et l'efficacité d'un programme hybride incluant des séances de telecoaching pour augmenter l'activité physique et la capacité cardiorespiratoire de patients atteints de diverses maladies chroniques. Néanmoins, ces résultats seront à confirmer dans des essais plus larges et contrôlés.

L'objectif de l'étude 4 est d'évaluer la validité et la fiabilité d'un dispositif médical innovant permettant d'autonomiser les individus dans la conduite de tests de condition physique. Nous avons dans cette étude testé les qualités de *MediEval*, un dispositif médical développé par l'entreprise Kiplin basé sur une application mobile permettant aux individus d'effectuer eux-mêmes le TM6 et le test assis-debout de 30 secondes. Afin de mesurer la validité et la fiabilité de ce dispositif, 53 adultes sains ont été recrutés afin de réaliser les deux tests au cours de trois sessions différentes, afin de déterminer la reproductibilité intra- et inter-jours. La validité du test a été évaluée en comparant les résultats mesurés par le logiciel à des mesures de référence (i.e., distance mesurée en mètre par l'intermédiaire d'un odomètre pour le TM6 et évaluation visuelle d'un examinateur pour le test assis-debout).

Les résultats ont révélé une corrélation élevée à excellente des mesures fournies par l'application par rapport aux gold standards ($\rho=0,79$ pour le 6MWT et $\rho=0,98$ pour le test assis-debout de 30 secondes), avec une faible erreur de mesure relative, ce qui suggère une bonne validité du dispositif. Les deux tests avaient également une bonne fiabilité test-retest (ICC = 0,77). Ainsi le dispositif *MediEval* apparaît comme un dispositif valide et reproductible pour mesurer la performance réalisée par les participants aux TM6 et test assis-debout et son utilisation pourrait être associé à des bénéfices à la fois directs (e.g., réduction des frais liés au déplacement des patients) et indirects (e.g., amélioration des capacités d'auto-gestion des patients). Ces résultats restent à confirmer en contexte clinique.

Dans un troisième et dernier temps, nous avons conduit un essai randomisé contrôlé nommé DIPPAO (pour *Digital Intervention Promoting Physical Activity among Obese people*) dans le but d'évaluer rigoureusement l'efficacité et le ratio coût-efficacité d'une intervention digitale intégrant des mécaniques de gamification et des séances d'activité physique adaptée en telecoaching (i.e., intervention complète Kiplin) auprès de patients atteints d'obésité et de diabète de type 2. DIPPAO a pour

objectif principal de comparer cette intervention digitale à l'actuel gold standard de la prise en charge en activité physique adaptée (i.e., un programme en présentiel de 36 séances sur 12 semaines).

L'étude 5 rapporte le cadre théorique, les objectifs, les hypothèses, le protocole et les mesures de cet essai. En bref, DIPPAO est un essai prospectif contrôlé randomisé à deux bras parallèles, évaluant et comparant l'efficacité de deux programmes de 3 mois sur l'évolution du nombre de pas quotidien, de la composition corporelle, de la qualité de vie et de la condition physique au cours de l'étude. Ces variables ont été mesurées avant le début du programme, à la fin de ce dernier et après un temps de suivi de 6 mois post-intervention. En outre une batterie de variables psychologiques a également été évaluée afin d'investiguer les potentiels mécanismes psychologiques pouvant expliquer l'effet de l'intervention. Enfin, afin d'évaluer une potentielle rentabilité économique supérieure du programme digital, cette étude inclut une analyse cout-utilité.

L'étude 6 présente les résultats préliminaires de cet essai, en valorisant les données accessibles au mois de novembre 2022. A cette date, 39 patients avaient terminé leur programme et 12 patients l'étude entière (i.e., 3 temps de mesure). Les résultats ont été à la fois analysés par l'intermédiaire de modèles multiniveaux et de modèles additif généralisés selon une approche idiographique. Les résultats suggèrent que, en comparaison de la prise en charge traditionnelle, les patients qui ont bénéficié de l'intervention Kiplin ont eu une augmentation significativement plus importante du nombre moyen de pas quotidiens par rapport à leur activité initiale pendant l'intervention ($b = 0,22$, $p = 0,002$) et pendant les périodes de suivi ($b = 0,43$, $p < 0,0001$). Les modèles multiniveaux n'ont indiqué aucune différence significative de changement entre les deux groupes sur les résultats secondaires, à l'exception d'un effet quadratique du temps entre la fin du programme et la fin du suivi. Ce résultat suggère une différence dans l'évolution de la capacité cardiorespiratoire entre les deux groupes à la suite de l'intervention qui pourrait être liée à l'augmentation d'activité physique sur le long terme. Nous avons également observé que le sentiment de solidarité au sein de la condition Kiplin a modéré positivement l'effet de l'intervention. Les modèles additifs génératifs ont révélé l'existence de différents patterns de réponses parmi les patients du groupe Kiplin. Ces résultats suggèrent que l'intervention Kiplin serait plus efficace pour promouvoir l'activité légère à court et moyen terme qu'un

programme classique. De manière intéressante, la taille d'effet observée pendant la période d'intervention a persisté pendant la période de suivi, ce qui suggère une bonne durabilité de l'effet au cours du temps. Néanmoins il est essentiel de souligner que ces résultats sont des analyses préliminaires qui seront à confirmer dans l'analyse finale de l'essai.

En conclusion, les résultats de ce travail doctoral soulignent au travers de 6 études les perspectives prometteuses de la gamification pour promouvoir l'activité physique de différentes populations, quel que soit leur âge ou état de santé, à la fois sur le court et le moyen terme. Les résultats de cette thèse suggèrent également qu'un programme digital intégrant de la gamification et du telecoaching pourrait être une plus-value intéressante dans la prise en charge de l'obésité et du diabète de type 2. Ces résultats devront être confirmés dans les analyses finales de l'essai DIPPAO.

Les prochaines étapes seront de mener un essai de phase III au sein de la même population clinique, avec un plus grand nombre de patients et un suivi plus long. En outre, des essais de phase IV seront également nécessaires pour établir l'efficacité en contexte de vie réelle (Suvarna, 2010) et nécessiteront d'impliquer une diversité de milieux, de participants et de prestataires afin de tester la scalabilité de ce type d'intervention (Hill, 2012).

Les interventions testées au cours de ce travail doctoral sont intéressantes en pratique pour plusieurs raisons. Tout d'abord, elles présentent de nombreux avantages pour les participants atteints de maladies chroniques, tels qu'une amélioration à moyen terme de leur activité physique, une amélioration de leurs compétences d'autogestion, une utilisation facile et adaptée au quotidien des patients (e.g., les interventions digitales gamifiées ne demandent pas de matériel spécifique en dehors du smartphone ou de dédier des créneaux de temps spécifiques à leur utilisation). De plus, ces outils apparaissent comme une stratégie prometteuse pour atteindre les patients isolés des établissements de santé, leur permettant de bénéficier d'un programme complet. Ces interventions ont en effet une large portée grâce à leur nature numérique, qui permet d'augmenter la capacité de prise en charge et disséminer à plus large échelle les bénéfices de programmes d'activité physique.

Enfin, il est aussi important de noter que ce travail doctoral n'est pas exempt de certaines limites. Certaines questions restent encore sans réponses et cette thèse propose des perspectives de recherches qui pourront être développées dans de futur

travaux. Par exemple, si cette thèse a fourni un certain degré de preuves sur l'efficacité des interventions numériques gamifiées, les résultats actuels ont eu une contribution plus faible concernant la compréhension des processus psychologiques sous-jacents pouvant expliquer l'efficacité des interventions gamifiées sur l'activité physique. Il pourrait par exemple être intéressant d'interroger les mécanismes de ces interventions au travers du prisme des approches duales, en investiguant par exemple le rôle des réponses affectives, des émotions ou des ressources de contrôle de soi dans l'effet de l'intervention gamifiée.

De plus une certaine hétérogénéité interindividuelle avec des patterns relativement contrastés entre les patients a pu être observée dans les différents travaux de cette thèse. Cette limite nous invite à penser de nouvelles méthodes afin de 1) mieux dépister et sélectionner les participants en fonction d'une batterie de variables psychologiques et physiologiques qui nous permettrait de ne proposer un programme digital qu'aux patients qui pourraient en bénéficier et 2) développer des interventions gamifiées adaptatives en temps réel qui s'adaptent aux besoins et à l'état des participants afin d'optimiser l'effet de l'intervention.

Titre : Développement et évaluation d'une intervention digitale fondée sur la gamification pour promouvoir l'activité physique de personnes atteintes de maladie chronique

Face à la prévalence grandissante de l'inactivité physique et des comportements sédentaires, il n'a jamais été aussi important de développer des interventions permettant de promouvoir efficacement et durablement un style de vie actif chez les patients atteints de maladies chroniques. Si un certain nombre d'initiatives existent dans ce sens, les programmes actuels se heurtent généralement à la difficulté d'engager les patients et de changer le comportement sur le long terme. De plus, ces programmes dispensés en présentiel sont associés à une série d'enjeux logistiques et économiques qui limitent leur impact et dissémination à grande échelle. Dans cette optique, la gamification et les nouvelles technologies apparaissent comme des outils prometteurs pour favoriser le changement de comportement en contexte écologique et proposer des interventions efficaces et fiables à distance. Néanmoins, à ce jour la littérature scientifique n'avait pas démontré l'efficacité de tels outils pour la prise en charge de l'activité physique. Ainsi, la question centrale de ce travail doctoral était de savoir si et dans quelles conditions l'utilisation d'intervention digitales et de la gamification pouvait être pertinente pour promouvoir l'activité physique de patients atteints de maladies chroniques. Au travers de 6 études, les résultats de ce travail doctoral soulignent les perspectives prometteuses de la gamification pour promouvoir l'activité physique de différentes populations, quel que soit leur âge ou état de santé, à la fois sur le court et le moyen terme. Les résultats de cette thèse suggèrent également qu'un programme digital intégrant de la gamification et du telecoaching pourrait être une plus-value intéressante dans la prise en charge de l'obésité et du diabète de type 2. Ces conclusions viennent enrichir la littérature dans le domaine et mettent en évidence un certain nombre d'implications cliniques, d'enjeux de développement et de perspectives de recherche afin de comprendre plus finement ces interventions et d'en optimiser leur efficacité.

Mots-clés : activité physique, changement de comportement, e-santé, gamification, intervention, m-santé

Title: Development and Evaluation of a Digital Intervention Based on Gamification to Promote the Physical Activity of Patients with Chronic Diseases

Considering the growing prevalence of physical inactivity and sedentary behavior, it is of paramount importance to develop interventions that effectively and durably promote active lifestyles in patients with chronic diseases. While a number of initiatives already exist, current physical activity programs struggle to engage participants and change behavior over the long haul. In addition, these face-to-face programs are associated with a series of logistical and economic issues that limit their impact and widespread dissemination. In this context, the use of gamification and digital technologies appear to be promising tools for promoting behavior change in an ecological context and for providing effective and reliable interventions at a distance. Nevertheless, to date, the scientific literature has not demonstrated the effectiveness of such interventions. Therefore, the main objective of this doctoral work was to know if and under which conditions the use of digital interventions and gamification could be relevant to promote physical activity in patients with chronic diseases. Through 6 studies, the results of this doctoral work highlight the promising perspectives of gamification to improve both short and mid-term daily physical activity levels of various populations, regardless of their age or health status. The findings of this thesis also indicate that physical activity digital programs integrating gamification and telecoaching could be an interesting added value for the treatment of obesity and type 2 diabetes. This doctoral work presents new knowledge about the effectiveness of digital interventions and discusses the resulting clinical implications, design insights, and research perspectives to better understand these interventions and optimize their effectiveness.

Keywords: behavior change, eHealth, gamification, intervention, mHealth, physical activity