BMJ Open

Effectiveness of a gamified digital intervention based on lifestyle modification (iGAME) in secondary prevention: a protocol for a randomised controlled trial

Antonio I Cuesta-Vargas ,[1,2] Attila Biró ,[1,2,3,4] Adrian Escriche-Escuder,[1,2] Manuel Trinidad-Fernández,[1,2] Celia García-Conejo ,[1,2] Cristina Roldan-Jimenez ,[1,2] Wen Tang,[5] Alfredo Salvatore,[6] Borjanka Nikolova,[7] Antonio Muro-Culebras,[1,2] Jaime Martín-Martín,[2,8] Manuel González-Sánchez,[1] María Ruiz-Muñoz,[9] Fermin Mayoral [2,10]

To cite: Cuesta-Vargas AI, Biró A, Escriche-Escuder A, *et al*. Effectiveness of a gamified digital intervention based on lifestyle modification (iGAME) in secondary prevention: a protocol for a randomised controlled trial. *BMJ Open* 2023;**13**:e066669. doi:10.1136/bmjopen-2022-066669

► 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-2022-066669).

Received 18 July 2022
Accepted 03 May 2023

For numbered affiliations see end of article.

Correspondence to
Attila Biró;
attila.biro@itware.hu and
Dr Antonio I Cuesta-Vargas;
acuesta@uma.es

ABSTRACT

Introduction Combating physical inactivity and reducing sitting time are one of the principal challenges proposed by public health systems. Gamification has been seen as an innovative, functional and motivating strategy to encourage patients to increase their physical activity (PA) and reduce sedentary lifestyles through behaviour change techniques (BCT). However, the effectiveness of these interventions is not usually studied before their use. The main objective of this study will be to analyse the effectiveness of a gamified mobile application (iGAME) developed in the context of promoting PA and reducing sitting time with the BCT approach, as an intervention of secondary prevention in sedentary patients.

Methods and analysis A randomised clinical trial will be conducted among sedentary patients with one of these conditions: non-specific low back pain, cancer survivors and mild depression. The experimental group will receive a 12-week intervention based on a gamified mobile health application using BCT to promote PA and reduce sedentarism. Participants in the control group will be educated about the benefits of PA. The International Physical Activity Questionnaire will be considered the primary outcome. International Sedentary Assessment Tool, EuroQoL-5D, MEDRISK Instruments and consumption of Health System resources will be evaluated as secondary outcomes. Specific questionnaires will be administered depending on the clinical population. Outcomes will be assessed at baseline, at 6 weeks, at the end of the intervention (12 weeks), at 26 weeks and at 52 weeks.

Ethics and dissemination The study has been approved by the Portal de Ética de la Investigación Biomédica de Andalucía Ethics Committee (RCT-iGAME 24092020). All participants will be informed about the purpose and content of the study and written informed consent will be completed. The results of this study will be published in a peer-reviewed journal and disseminated electronically and in print.

Trial registration number NCT04019119

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study protocol has been reported according to the 'Standard Protocol Items: Recommendations for Interventional Trials declaration'.
⇒ Gamification systems based on graphs, rewards, points and social support were included in the application to motivate the change to an active lifestyle.
⇒ The inclusion of behaviour changes techniques and factors influencing sedentary behaviour is a differentiating aspect with respect to other gamified interventions.
⇒ The lack of objective measures in the primary outcome have been controlled including the International Physical Activity Questionnaire as a validated and widely used tool in research and clinical settings.
⇒ Several assessment points with follow-up to check the use of the intervention after the main stage of the study.

BACKGROUND

In the period between 2010 and 2019, the rate of disability-adjusted life years increased in those under 50 years of age compared with the period 1990–2019 globally.[1] The main contributors to this growth are non-communicable diseases (NCDs), and major drivers within this category include musculoskeletal disorders, mental disorders and cancer.[2] Non-specific low back pain (NSLBP) is a musculoskeletal disorder and the most common disability in many countries where the lifetime prevalence is approximately between 60% and 70% in developed countries and the prevalence during the year is estimated between 15% and 45%.[3 4] Depression is a mental disorder that causes

premature mortality and disability around the world and is strong correlated to a poor physical activity (PA) level.[5 6] Finally, breast cancer leads the top of the diagnosed type of cancer in the female gender and the survivors have to struggle with a significant morbidity after the overcome of the cancer.[7] Due to the sequelae of the disease and the cardiotoxicity of the treatment, these patients tend to inactivity and sarcopenia, which is a risk factor for recurrence.[8]

A large part of the risk factors associated with these pathologies are modifiable and are related to self-care habits such as the consumption of tobacco, alcohol, physical inactivity or poor nutrition.[9] Addressable risk factors for NCDs include physical inactivity and sedentary lifestyles.[10] Physical inactivity is considered one of the prime causes of most chronic diseases.[11] 27.5% of adults from around the world do not meet PA recommendations and are therefore considered physically inactive.[11–15] This tendency towards physical inactivity leads to consequences that reduce functional systems capacities, leading to premature deterioration of general health status.[11 12 16 17] Sedentary behaviours are generally defined as 'any waking attitude characterised by energy expenditure equal to or less than 1.5 Metabolic Equivalents of Tasks (METs) while sitting or lying down'.[14 15] MET corresponds to a metabolic unit which quantifies oxygen consumption during a given activity. For instance, 1 MET corresponds to the resting metabolic rate, such as sitting quietly in a chair, which is approximately 3.5 mL O^2/kg/min.[18] The amount of energy consumed in other activities can be quantified in comparison with this value. Thus, an activity associated with 2 METs would require twice the energy consumed at rest.

While sedentary time is strongly associated with an increased risk of developing NCDs,[15 19] PA has been seen as a fundamental weapon of application for primary prevention against at least 35 chronic conditions.[11] Centres for Disease Control and Prevention (CDC) defines PA as 'any bodily movement produced by skeletal muscle contraction that raises energy expenditure above a reference level'.[20] Several organisations have published their Physical Activity Guidelines providing information and guidance on the types and amounts of PA that provide substantial health benefits.[21–23] The WHO recommends that adults engage in 150–300 min of moderate-intensity PA, 75–150 min of vigorous-intensity PA, or some equivalent blend of moderate-intensity and vigorous-intensity aerobic PA, per week.[23] Moderate-intensity refers to PA performed between 3 and 5.9 METs, while vigorous-intensity PA is performed at ≥6 METs.[23 24] For practical purposes, it is considered that all activities ≥3 MET can increase METs capacity and decrease the risk of future cardiac events.[25] A large body of evidence has been found on the benefits of PA and exercise in heterogeneous clinical populations, significantly improving function, physical and mental health, pain reduction and disability with increased activity.[13 21] Nevertheless, independently of this promotion of PA, it is necessary to also focus on breaking sedentary behaviour. Reducing sitting time and promoting active movement has been shown to reduce pain and disability in low back pain, improve anxiety, mental health, fatigue and cognitive function during the workday, and reduce risk factors of cardiovascular.[26–30]

Promoting PA and reducing sitting time in populations with NCDs is challenging for clinicians. As in other health contexts, the main challenges are associated with motivation and treatment adherence.[23 31 32] Thus, self-management strategies and behaviour change techniques (BCTs) are vital to managing chronic and NCDs.[33] BCTs are described as irreducible, observable and replicable elements of an intervention designed to redirect behaviour.[34] A recent meta-analysis from 2021[10] reported positive results on the effectiveness of multiple eHealth-based health behaviour change interventions to encourage PA in NCD patients. Likewise, in recent years, gamification has made its way among the tools for applying BCTs.[35] In gamification, game design elements are applied in non-game contexts to take advantage of its beneficial effects for purposes other than entertainment. Among other possible components, it has been suggested that these platforms for gamified intervention should include essential elements of a game such as points, badges, leaderboards, performance graphs, meaningful stories, avatars and teammates.[35] The effects of gamification promoting PA in several population against other interventions have been proved and should be integrated in more healthcare interventions.[36] In addition, it is potentially relevant to health behaviour change because it includes intrinsic motivation, broad appeal, broad applicability, cost-benefit efficiency, life adjustment and well-being support.[35]

Besides to the benefits of other e-health options, the use of smartphones can be an added value due to their ease of access, and they represent a great opportunity to incorporate gamification into people's routines. There are 6.6 billion smartphone users globally in 2022, and this figure is expected to grow in the coming years.[37] Smartphone games have been shown to be effective in providing a potentially cost-effective platform for gamification and health promotion, achieving a significant impact on public health.[38 39] Therefore, using gamification in mobile applications can be an exciting way to improve adherence and empower patients towards healthier lifestyle habits. In this context, thousands of health apps (many of them including gamification) are available in the market.[39] For these tools to be recommended by clinicians to their patients, previous studies should be carried out to prove that they work correctly, achieve their purpose and do not cause harm.[40–42] However, the much slower pace of academic research compared with commercial gamified tools development means that this usually does not happen.[39 43] Developing new gamification tools whose effectiveness is endorsed by a quality clinical trial in the target population is necessary. This study proposes using an intervention through a mobile application for the promotion of PA and the reduction of

sedentary behaviour, using BCTs, as part of a randomised clinical trial.

Thus, the aim of the project is to analyse the clinical effectiveness of a gamified mHealth application (iGAME) developed in the context of lifestyle modification and a BCT approach, through a randomised clinical trial which includes sedentary participants with three clinical subtypes of NCDs where lifestyle modification is the centre of its best practice: (1) people with NSLBP; (2) breast cancer survivors (BCS); (3) people with mild depression (MD). The initial hypothesis is that after 12 weeks of participation in the original iGAME mobile application, the participants of the three intervention subgroups will increase the amount and distribution of energy consumption and reduce the sedentary behaviour.

METHODS AND ANALYSIS

Trial design

It is presented a single-blind, parallel, randomised controlled trial protocol that it will be conducted in sedentary patients with NSLBP of a mechanical and degenerative nature, BCS and patients with MD. This study is expected to start during the year 2023. This project has been approved by the Portal de Ética de la Investigación Biomédica de Andalucía Ethics Committee (RCT-iGAME 24092020). The Standard Protocol Items: Recommendations for Interventional Trials declaration[44] was followed during the elaboration of this protocol. According to ensure transparent and standardised reporting of the trial, the study will be in accordance with the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and OnLine TeleHealth[45 46] and the principles of the Declaration of Helsinki. Before the inclusion, all the participants will be informed about the purpose and methodology of the study using a written informed consent that must be signed (online supplemental file 1).

Patient and public involvement

It will be necessary for the involvement of the path group they will be assigneients to perform the study. During the early stages, different insights were received from patients about their conditions and use of the smartphone, which helped in the elaboration of this protocol.

Participants will be always reminded that they can choose not to do some suggested tasks or even withdraw from the research without any consequence to them. They are also reminded that their participation in the study is completely voluntary. Additionally, participants will be able to tell a friend and family member about the application and invite them to use it to help do activities together and increase the social factor. Plus, they will know their specialist will be able to see their scores for follow-up.

After the publication of the study, the participants will receive an inform with their results through an email and the researcher will prepare a study newsletter with the main outputs for a non-specialist audience.

Participants

Recruitment details

Patients will be recruited from the Spanish Health System in the Malaga Health Section, specifically from the Hospital Regional de Málaga (Hospital Civil) of Malaga, Spain.

The study population will consist of 48 subjects, composed of sedentary subjects from three types of clinical subpopulations (secondary prevention): NSLBP, BCS and MD. The recruiters will be two medical specialists from each medical field who will identify potential subjects according to the selection criteria.

Eligibility criteria

General and specific eligibility criteria according to the condition will be established.

General inclusion criteria

1. Age between 18 and 65 years.
2. Sedentary behaviour self-recognised by the subject using the International Sedentary Assessment Tool (ISAT): sitting or lying activities related to values <1.5 METs[19] held for more than >4 hours per day.[47]
3. Contemplation stage in the Prochaska Stages of Change model in order to express the intention to remove sedentary behaviours.

General exclusion criteria

1. Severe mental disorders.
2. Severe diseases that limit the physical capacity.
3. More than 7 points in the TECH-PH scale for technophobia or fear of new technologies.[48]
4. Declared difficulty in attending for required measurements/focus groups.

Specific eligibility criteria for NSLBP

Inclusion criteria

NSLBP with symptoms of a mechanical or degenerate nature using Waddell's classification for acute and chronic presentations.[49]

Exclusion criteria

LBP due to specific spinal disease, infection, presence of a tumour, osteoporosis, fracture, structural deformity, inflammatory disorder, radicular symptoms or cauda equina syndrome.[50]

Specific eligibility criteria for BCS

Inclusion criteria

Women with a clinical history of diagnosis of primary breast cancer, having completed surgical, radiotherapy or chemotherapy treatment with no evidence of recurrence, presence of tumour or metastatic disease at the time of recruitment.[51]

Exclusion criteria

Cardiovascular event defined as stable or unstable angina, acute pulmonary oedema, cardiac rhythm disorders

or syncope of unrelated aetiology in the year prior to inclusion.

Specific eligibility criteria for MD

Inclusion criteria

Patient Health Questionnaire-9 (PHQ-9) score between 5 and 9 points.[52]

Exclusion criteria

Other severe mental disorders identified by the Mini International Neuropsychiatric Interview.[53]

Concealed allocation

Participants will be assigned randomly to one of the two groups using an external software after the compliance of selection criteria. The experimental and control group will be available for each subtype of participants (NSLBP, BCS and MD) and participants will not know which group they will be assigned at this moment.

It will be used sealed opaque envelopes methods to conceal the allocation. An external assistant outside of the study will prepare sealed and numbered consecutively opaque envelopes. A randomiser software will create a number list to assign each envelope. These envelopes will be locked in a folder only accessible to the external assistant.

Interventions

Experimental group

Participants will receive a 4-week trial intervention based on gamification using built-in BCTs to promote PA and reduce sedentary behaviour. The intervention will be carried out using a new mobile application (iGAME) that proposes to perform daily tasks to increase PA and reduce sedentary behaviour. The application is a Progressive Web App that can be used in any smartphone and developers can update continuously. These proposals are based on a system of challenges and rewards. Through gamification, the application builds a series of individualised pathways to feedback and challenge based on their individual actions. According to the participant's individual level of PA at baseline, as measured with the International Physical Activity Questionnaire (IPAQ),[54] they will be classified into one of nine levels. These levels denote the type and minimum number of activities, along with the METs per week target provided as part of iGAME to the participant. On successful completion of those goals and targets, participants progress to the next level.

Regarding behaviour changes, several modification strategies proposed in the taxonomy of Michie *et al*[34] and the most used techniques in digital health[55] are applied, including but not limited to the establishment of personalised goals, feedback and monitoring, social support and education. Figure 1 shows the active components that the app will have in order to implement BCT. These strategies have been included in several gamified features: graphs about the total weekly METs and comparisons between other weeks, an achievements system to reward specific performed goals with medals and a point system based

Figure 1 Behaviour changes techniques (BCT) included in the iGAME mobile app based on the study, Martín-Martín *et al*.[55]

in coins to spend in the app shop to get new personification items for the profile.[35] In addition, the application has been specifically designed to act on two important components: social support and sedentary factors. Social support can be useful by enabling the user to perform activities with other individuals, including patients, relatives or health professionals and share their achievements as been adapted to Spin an internal network or commonly used social networks. These actions will give more points and feedback to produce more motivation. On the other hand, the format and content of the application is based on a previous analysis that proposes six clusters that factors influencing sedentary behaviour.[56] The physical health activity considering social context and home or natural environments, psychology and free-cost activities were taken into account to propose the application tasks.[56] The development of the application is being carried out by the European Consortium 'iGAME', financed by the European Programme Marie Skłodowska-Curie Actions RISE H2020. The open source of this application will be published together with the completed study. Examples of the application design of the first prototype is available in online supplemental file 2.

Control group

The control group will receive the usual indications about the harms of a sedentary lifestyle and the benefits of PA, not receiving any specific intervention. If the use of the experimental intervention proves to be more beneficial

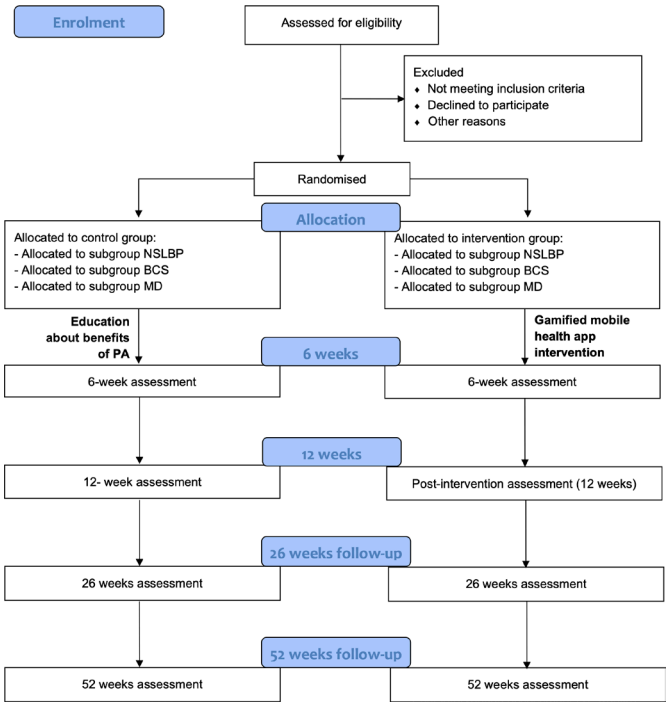


Figure 2 Flowchart of the study. BCS, breast cancer survivors; MD, mild depression; NSLBP, non- specific low back pain; PA, physical activity.

than the usual information, the participants assigned to the control group will be offered the opportunity to receive the intervention outside the framework of the study. The flow chart of the study is shown in figure 2.

Outcome measures

Both groups will be evaluated at the beginning, in the middle of the intervention (6 weeks), at the end of the intervention (12 weeks) and after intervention in two follow-ups: 26 weeks and 52 weeks. The development of the evaluations, as well as the control and resolution of possible events that may occur, will be under the supervision of the researcher. Participants must complete different questionnaires that will be completed at each of the measurement times. Anthropometric and demographic variables will be collected for descriptive analysis, only in the first evaluation, including age, gender, weight, height and body mass index.

Primary outcome measures

The analysis of psychometric variables offers the possibility of performing a self-reported evaluation with questionnaires that are sensitive to changes. The analysis of the volume of PA evaluated by the IPAQ[54] will be considered the primary outcome variable. The main outcome will explore intergroup differences between the experimental and control group in the different timepoints and the intragroup follow-up to check if the behaviour change has been kept after the application use in three follow-up timepoints.

The IPAQ integrates a set of four sections. Long (five separately requested activity domains) and short (four generic items) versions are available for use by phone or self-administered methods. The purpose of the questionnaire is to establish an instrument for the comparison of common and internationally comparable data on a person's health-related PA. To do this, questions related to PA performed in the previous 7 days are completed. The IPAQ constitutes an alternative way to the use of accelerometers for the calculation of energy consumption.

Secondary outcome measures

The ISAT[57] aims to establish an instrument for the assessment of sedentary behaviour (in all its forms: sitting, lying, etc). The ISAT constitutes, together with the IPAQ, an alternative way to the use of accelerometers for the calculation of energy consumption. The ISAT[57] aims to establish an instrument for the assessment of sedentary behaviour (in all its forms: sitting, lying, etc). The ISAT constitutes, together with the IPAQ, an alternative way to the use of accelerometers for the calculation of energy consumption.

The 5-dimension EuroQol scale (EQ-5D)[58] was created with the intention of obtaining a health index that related the quantity and quality of life, while serving as an instrument to measure the effectiveness in the economic evaluation of health technologies. The scale includes the five dimensions considered most relevant to health-related quality of life: mobility, self-care, usual activities, pain/discomfort and anxiety/depression; with three levels of gravity in each dimension.

The MEDRISK Instrument[59] is a tool designed to assess patient satisfaction with physical therapy care through intrinsic and extrinsic factors.

The consumption of Health System resources will be quantified through the DIRAYA Health Information Recording System, software used by the Andalusian Health System. The consumption of drugs or healthcare consumption will be assessed, among other data that may be of interest in quantifying the expenditure of resources.

Specific questionnaires for the breast cancer subgroup

The Piper Fatigue Scale[60] is a tool designed to assess cancer-related fatigue in BCS. This scale has been validated in Spanish.[61]

The Fear-Avoidance Components Scale[62] is a widely used method for quantifying existing fear-avoidance components in patients with pain-related medical conditions. This scale has been validated in Spanish in BCS.[63]

Specific questionnaires for the subgroup of non-specific mechanical low back pain

The Roland-Morris Questionnaire or Rolland-Morris Questionnaire[64] was designed to provide reliably evaluation of the degree of NSLBP-related physical disability, understanding physical disability as the limitation in carrying out activities of daily living. This questionnaire has been validated in Spanish.[65]

The Spine Functional Index[66] was designed to evaluate the spine's functionality as a whole, unlike previous

indices designed for specific segments such as the neck or other spinal segments. This index has been validated in Spanish.[67]

Specific questionnaires for the sample of the MD subgroup in primary care

The Mini International Neuropsychiatric Interview consists of a brief structured diagnostic interview designed to generate Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) and International Classification of Diseases (ICD-10) diagnoses.[53] This tool has been adapted to Spanish.[68]

The PHQ-9 questionnaire is one of the most used instruments to assess the presence and severity of depressive symptoms.[69] The participants describe their state of mind according the last 2weeks before the evaluation. The ranges from 0 to 3 indicate 'none', 'several days', 'more than half of the days' and 'almost every day', respectively. The total scores vary from 0 to 27. There exists a validated version in Spanish.[52] This version has been shown to have good psychometric properties (for diagnosing any disorder, k=0.74; overall accuracy, 88%; sensitivity, 87%; specificity, 88%).

Other measures

Not per protocol treatments

At the beginning of the intervention, participants will be informed of the importance of carrying out the project according to the established methodology and researchers will try to motivate the patients to continue with the assigned intervention. They will be asked to record any deviation from the protocol in a diary.

Data management

The score of the primary and secondary outcomes will be registered and safe in database files in a flash drive with password. The members of the study only can know the password to access the cyphered data. The mean differences from both groups between the baseline evaluation and the following measurements (6 weeks, 12 weeks, 26 weeks and 52 weeks) will determine the success of the intervention.

Sample size

The sample size has been calculated using the G Power V.3.1.9.2 software (University of Düsseldorf, Germany). An a priori calculation was used in order to test the alternative hypothesis and obtaining a larger effect size with the use of the experimental application. The calculation was based on the effect size of a similar study,[31] about the minutes of total PA (measured with IPAQ), considering a level of significance of 0.05 (error α<5%), and a statistical power of 0.8 (80%), for an effect size of 0.98. Consequently, a total sample consisting of 56 sedentary patients would be needed. Assuming a dropout rate of 20%, an approximate sample of 68 subjects will be needed. The three conditions will be represented equally inside of the total sample.

Blinding

A single blind system will be established. The evaluators will not be aware in any case of the origin of the subjects to whom the measurement is carried out. Due to the type of intervention, it is not possible to blind the subjects; they will be blinded as to whether they belong to the intervention or control group.

Statistical analysis

Statistical analyses will be conducted based on an intention-to-treat analysis. There will be five measurements in the study (baseline, 4 weeks, 12 weeks, 26 weeks and 52 weeks). The total sample will be compared with the control group, and a subanalysis will be performed comparing the three different group of patients. Variables will be presented as the mean and SD if the data follow a normal distribution, or as the maximum, minimum and three quartiles if the data do not follow such a distribution. The effect sizes will be calculated according to Cohen's d.[70] The Shapiro-Wilk test will be used to analyse the normal distribution of the data (p>0.05). Depending on the parametric test, the Student's t-test or Mann-Whitney U test was used to compare the scores between the two groups at each assessment timepoint. Repeated measures of analysis of variance will be applied to analyse the intervention on the different evaluation timepoints with a Group by Time interaction.

In addition, a control subanalysis will be performed to check the overestimation of the IPAQ for the calculation of the PA. A criterion validity test will be conducted to compare IPAQ and the Lis2DH12 inertial sensor with accelerometers as objective gold standard.[71 72] One experimental group will be chosen randomly, and they will receive the inertial sensor during the 4-week intervention.

The statistical analysis will be carried out using SPSS V.25.0 software.

ETHICS AND DISSEMINATION

Research ethics approval

This proposal entails conducting studies in humans. The Portal de Ética de la Investigación Biomédica de Andalucía Ethics Committee gave the approval to this research protocol (RCT-iGAME 24092020). The rights of confidentiality, integrity and intimacy of the participants will be guaranteed, as well as their freedom to participate or not in the study, for which it will be necessary that they previously give their express and written consent once they have received the appropriate information. In addition, the recommendations of the Declaration of Helsinki will be followed.

All participants will be previously informed of the objectives of the research, as well as its voluntary, anonymous and confidential nature. They will be provided with written informed consent, which was previously approved by the Ethics Committee. The informed consent will be signed by the participant and the researcher. Informed consent will provide the opportunity to make a conscious

and deliberate decision whether to participate in the study. Informed consent document is available in its original language (Spanish) as online supplemental file 1 (SF1). Participants will be informed that participation will be voluntary and that they may withdraw from it at any time.

Safety considerations

The research will be carried out in accordance with the precautionary principle to prevent and avoid risks to life and health. In any case, the coverage of the possible risks derived from the study will be guaranteed. Furthermore, any unexpected adverse effect during the intervention and the follow-up will be reported to the Ethics Committee by the participants and researchers. The researcher team will give an appropriate treatment for the adverse effect if it appears.

Protocol amendments

Any significant changes in the protocol will be mentioned in the following publications.

Confidentiality

To ensure accurate, complete and reliable data, all study-related information will be securely stored at the study site. All participant information will be stored in locked file cabinets in areas with limited access. A coded identification number will identify the reports, data collection, process and administrative forms to maintain participant confidentiality.

Dissemination

The main results of this study will be published as a scientific paper in an international journal about e-health or digital interventions in clinical populations. Other specific results will be disseminated in international congresses as lectures or communications.

DISCUSSION AND PERSPECTIVES

This protocol shows the methodology of a randomised controlled trial designed to assess the clinical effectiveness of a gamified mobile application developed in the context of lifestyle modification and a BCT approach in people with NSLBP, BCS and people with MD.

This study will provide clinicians with directly applicable evidence about strategies to promote PA and break sedentary behaviour framed in a change in lifestyle, promoted through mobile gamification and BCTs. Unfortunately, the current programmes against sedentarism in these population groups have little importance in the system and the patient is became the most responsible without any strong support during this process of change. Thus, if the effectiveness are demonstrated, this application can be widely used as a health instrument in these populations. Likewise, it should be studied other comparisons for further generalisation in other populations.

Author affiliations
[1]Departamento de Fisioterapia, Universidad de Malaga, Andalucia Tech, Malaga, España
[2]Instituto de Investigacion Biomédica de Málaga (IBIMA), Malaga, España
[3]ITware, Budapest, Hungary
[4]Department of Electrical Engineering and Information Technology, George Emil Palade University of Medicine, Pharmacy, Science, and Technology of Targu Mures, Targu Mures, Romania
[5]Bournemouth University, Poole, UK
[6]Sensor ID Snc, Boiano, Italy
[7]Arthaus, Skopje, North Macedonia
[8]Departamento de Medicina Legal, Universidad de Malaga, Málaga, España
[9]Departamento de Enfermeria, Universidad de Malaga, Malaga, España
[10]Salud Mental, Hospital Regional Universitario de Malaga, Malaga, Spain

Correction notice This article has been corrected since it was published online. The sixth author name has been updated from “Cristina Roldán Roldán Jiménez” to “Cristina Roldan-Jimenez”.

Twitter Antonio I Cuesta-Vargas @aicuesta, Attila Biró @biroattila, Celia García-Conejo @CeliaConejo and Cristina Roldan-Jimenez @cristinaroldanj

Contributors All authors met the criteria recommended by the International Committee of Medical Journal Editors. AIC-V, FM, WT, AS, AB and BN formulated the conception, design and methods for the study. AIC-V, MG-S, AM-C, JM-M, MG-S and MR-M drafted the manuscript. AIC-V, AE-E, MT-F, CG-C and CRRJ adapted the manuscript to the journal. All authors agreed on the definitive version.

Funding This study is framed within the European Project 'Multi-dimensional Intervention Support Architecture for Gamified eHealth and mHealth Products (iGAME)' (ID 823871). This project, made up of a consortium of three companies (Arthaus, ITware and SensorID from Macedonia, Hungary and Italy, respectively), two academic partners (Bournemouth University in the UK and the Universidad de Málaga in Spain) and the Andalusian Health System, is funded by the Marie Skłodowska-Curie Research and Innovation Staff Exchange (Call H2020-MSCA-RISE-2018) grants from the European Union with a total amount of €837 200.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Antonio I Cuesta-Vargas http://orcid.org/0000-0002-8880-4315
Attila Biró http://orcid.org/0000-0002-0430-9932
Celia García-Conejo http://orcid.org/0000-0002-4570-4330
Cristina Roldan-Jimenez http://orcid.org/0000-0002-7355-9740
Fermin Mayoral http://orcid.org/0000-0002-9710-9672

REFERENCES

1 Vos T, Lim SS, Abbafati C. Diseases and injuries collaborators. global burden of 369 diseases and injuries in 204 countries and territories,

1990-2019: A systematic analysis for the global burden of disease study 2019. *Lancet* 2020;396:1204–22.
2 GBD. Diseases and injuries collaborators. global health Metrics-non-Communicable diseases-level 1 cause. 2019. Available: https://www.thelancet.com/pb-assets/Lancet/gbd/summaries/diseases/non-communicable-diseases.pdf [Accessed 17 Oct 2020].
3 Duthey B. *Priority medicines for Europe and the World-2013 update. background paper 6-priority diseases and reasons for inclusion. BP 6.24-low back pain*. WHO Collaborating Centre for Pharmaceutical Policy and Regulation, 2013.
4 Vlaeyen JWS, Maher CG, Wiech K, *et al*. Low back pain. *Nat Rev Dis Primers* 2018;4:52.
5 World Health Organization (WHO). *Depression and other common mental disorders: global health estimates*. Geneva: World Health Organization, 2017. Available: https://apps.who.int/iris/handle/10665/254610
6 Huang Y, Li L, Gan Y, *et al*. Sedentary behaviors and risk of depression: A meta-analysis of prospective studies. *Transl Psychiatry* 2020;10:26.
7 Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. *CA Cancer J Clin* 2019;69:7–34. 10.3322/caac.21551 Available: https://onlinelibrary.wiley.com/toc/15424863/69/1
8 Lahart IM, Metsios GS, Nevill AM, *et al*. Physical activity, risk of death and recurrence in breast cancer survivors: A systematic review and meta-analysis of Epidemiological studies. *Acta Oncol* 2015;54:635–54.
9 Budreviciute A, Damiati S, Sabir DK, *et al*. Management and prevention strategies for non-Communicable diseases (Ncds) and their risk factors. *Front Public Health* 2020;8.
10 Duan Y, Shang B, Liang W, *et al*. Effects of eHealth-based multiple health behavior change interventions on physical activity, healthy diet, and weight in people with Noncommunicable diseases. *J Med Internet Res* 2021;23.
11 Booth FW, Roberts CK, Laye MJ. Lack of exercise is a major cause of chronic diseases. *Compr Physiol* 2012;2:1143–211.
12 Hallal PC, Andersen LB, Bull FC, *et al*. Global physical activity levels: Surveillance progress, pitfalls, and prospects. *The Lancet* 2012;380:247–57.
13 Guthold R, Stevens GA, Riley LM, *et al*. Global trends in insufficient physical activity among adolescents: A pooled analysis of 298 population-based surveys with 1·6 million participants. *Lancet Child Adolesc Health* 2020;4:23–35.
14 Arocha Rodulfo JI. Sedentary lifestyle a disease from Xxi century. *Clin Investig Arterioscler* 2019;31:233–40.
15 Memon AR, Stanton R, To Q, *et al*. Sedentary behaviour research in adults: A Scoping review of systematic reviews and meta-analyses. *J Sports Sci* 2021;39:2219–31.
16 Bauman A, Ainsworth BE, Sallis JF, *et al*. The descriptive epidemiology of sitting. A 20-country comparison using the International physical activity questionnaire (IPAQ). *Am J Prev Med* 2011;41:228–35.
17 Cunningham C, O' Sullivan R, Caserotti P, *et al*. Consequences of physical inactivity in older adults: A systematic review of reviews and meta-analyses. *Scand J Med Sci Sports* 2020;30:816–27. 10.1111/sms.13616 Available: https://onlinelibrary.wiley.com/toc/16000838/30/5
18 Jetté M, Sidney K, Blümchen G. Metabolic equivalents (METS) in exercise testing, exercise prescription, and evaluation of functional capacity. *Clin Cardiol* 1990;13:555–65.
19 Tremblay MS, Aubert S, Barnes JD, *et al*. Sedentary behavior research network (SBRN) – terminology consensus project process and outcome. *Int J Behav Nutr Phys Act* 2017;14:75.
20 Centers for Disease Control and Prevention (CDC). Physical health status of world trade center rescue and recovery workers and Volunteers- New York City,2002-August 2004. *MMWR Morb Mortal Wkly Rep* 2004;53:807–12.
21 Posadzki P, Pieper D, Bajpai R, *et al*. Exercise/physical activity and health outcomes: An overview of Cochrane systematic reviews. *BMC Public Health* 2020;20:1724.
22 Piercy KL, Troiano RP, Ballard RM, *et al*. The physical activity guidelines for Americans. *JAMA* 2018;320:2020–8.
23 Bull FC, Al-Ansari SS, Biddle S, *et al*. World health organization 2020 guidelines on physical activity and sedentary behaviour. *Br J Sports Med* 2020;54:1451–62.
24 Mendes M de A, da Silva I, Ramires V, *et al*. Metabolic equivalent of task (Mets) thresholds as an indicator of physical activity intensity. *PLoS ONE* 2018;13.
25 Franklin BA, Brinks J, Berra K, *et al*. Using metabolic equivalents in clinical practice. *Am J Cardiol* 2018;121:382–7.
26 Gray CM. Reducing sedentary behaviour in the workplace. *BMJ* 2018;363.
27 Edwardson CL, Yates T, Biddle SJH, *et al*. Effectiveness of the stand more AT (smart) work intervention: Cluster randomised controlled trial. *BMJ* 2018;363.
28 Barone Gibbs B, Hergenroeder AL, Perdomo SJ, *et al*. Reducing sedentary behaviour to decrease chronic low back pain: The stand back randomised trial. *Occup Environ Med* 2018;75:321–7.
29 Chevance G, Foucaut AM, Bernard P. State of knowledge on sedentary behaviors. *Presse Med* 2016;45:313–8.
30 Nooijen CFJ, Blom V, Ekblom Ö, *et al*. Improving office workers' mental health and cognition: A 3-arm cluster randomized controlled trial targeting physical activity and sedentary behavior in multi-component interventions. *BMC Public Health* 2019;19:266.
31 Degroote L, Plaete J, De Bourdeaudhuij I, *et al*. The effect of the eHealth intervention 'Myplan 1.0' on physical activity in adults who visit general practice: A quasi-experimental trial. *Int J Environ Res Public Health* 2018;15:228.
32 Guthold R, Stevens GA, Riley LM, *et al*. Worldwide trends in insufficient physical activity from 2001 to 2016: A pooled analysis of 358 population-based surveys with 1·9 million participants. *Lancet Glob Health* 2018;6:e1077–86.
33 Lyubomirsky S, Layous K. How do simple positive activities increase well-being *Curr Dir Psychol Sci* 2013;22:57–62.
34 Michie S, Richardson M, Johnston M, *et al*. The behavior change technique Taxonomy (V1) of 93 Hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46:81–95.
35 Sailer M, Hense JU, Mayr SK, *et al*. How Gamification motivates: An experimental study of the effects of specific game design elements on psychological need satisfaction. *Computers in Human Behavior* 2017;69:371–80.
36 Mazeas A, Duclos M, Pereira B, *et al*. Evaluating the effectiveness of Gamification on physical activity: Systematic review and meta-analysis of randomized controlled trials. *J Med Internet Res* 2022;24.
37 Oberlo. How many people have Smartphones? 2022. Available: https://www.oberlo.com/statistics/how-many-people-have-smartphones [Accessed 30 Jun 2022].
38 Johnson D, Deterding S, Kuhn K-A, *et al*. Gamification for health and wellbeing: A systematic review of the literature. *Internet Interv* 2016;6:89–106.
39 Edwards EA, Lumsden J, Rivas C, *et al*. Gamification for health promotion: Systematic review of behaviour change techniques in Smartphone Apps. *BMJ Open* 2016;6.
40 Kumar S, Nilsen WJ, Abernethy A, *et al*. Mobile health technology evaluation: The mHealth evidence workshop. *Am J Prev Med* 2013;45:228–36.
41 O'Neil A, Cocker F, Rarau P, *et al*. Using Digital interventions to improve the Cardiometabolic health of populations: A meta-review of reporting quality. *J Am Med Inform Assoc* 2017;24:867–79.
42 Muro-Culebras A, Escriche-Escuder A, Martin-Martin J, *et al*. Tools for evaluating the content, efficacy, and usability of mobile health Apps according to the consensus-based standards for the selection of health measurement instruments: Systematic review. *JMIR Mhealth Uhealth* 2021;9:e15433.
43 Riley WT, Glasgow RE, Etheredge L, *et al*. Rapid, responsive, relevant (R3) research: A call for a rapid learning health research enterprise. *Clin Transl Med* 2013;2.
44 Chan A-W, Tetzlaff JM, Altman DG, *et al*. SPIRIT 2013 statement: Defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
45 Altman DG. Better reporting of randomised controlled trials: The CONSORT statement. *BMJ* 1996;313:570–1.
46 Eysenbach G, Group C-E. CONSORT-EHEALTH: Improving and standardizing evaluation reports of web-based and mobile health interventions. *J Med Internet Res* 2011;13:e126.
47 Ekelund U, Steene-Johannessen J, Brown WJ, *et al*. Does physical activity attenuate, or even eliminate, the detrimental Association of sitting time with mortality? A Harmonised meta-analysis of data from more than 1 million men and women. *Lancet* 2016;388:1302–10.
48 Anderberg P, Eivazzadeh S, Berglund JS. A novel instrument for measuring older people's attitudes toward technology (Techph): Development and validation. *J Med Internet Res* 2019;21.
49 Muñiz J, Elosua P, Hambleton RK, *et al*. International test Commission guidelines for test translation and adaptation: Second edition. *Psicothema* 2013;25:151–7.
50 van Tulder M, Becker A, Bekkering T, *et al*. Chapter 3. European guidelines for the management of acute nonspecific low back pain in primary care. *Eur Spine J* 2006;15 Suppl 2:S169–91.
51 Sanft T, Denlinger CS, Armenian S, *et al*. NCCN guidelines insights: Survivorship, version 2.2019. *J Natl Compr Canc Netw* 2019;17:784–94.

52 Diez-Quevedo C, Rangil T, Sanchez-Planell L, *et al*. Validation and utility of the patient health questionnaire in diagnosing mental disorders in 1003 general hospital Spanish Inpatients. *Psychosom Med* 2001;63:679–86.
53 Sheehan DV, Lecrubier Y, Sheehan KH, *et al*. The mini-International neuropsychiatric interview (M.I.N.I.): The development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry* 1998;59 Suppl 20:22–33.
54 Craig CL, Marshall AL, Sjöström M, *et al*. International physical activity questionnaire: 12-Country Reliability and validity. *Med Sci Sports Exerc* 2003;35:1381–95.
55 Martín-Martín J, Roldán-Jiménez C, De-Torres I, *et al*. Behavior change techniques and the effects associated with Digital behavior change interventions in sedentary behavior in the clinical population: A systematic review. *Front Digit Health* 2021;3.
56 Buck C, Loyen A, Foraita R, *et al*. Factors influencing sedentary behaviour: A system based analysis using Bayesian networks within DEDIPAC. *PLoS One* 2019;14.
57 Prince SA, LeBlanc AG, Colley RC, *et al*. Measurement of sedentary behaviour in population health surveys: A review and recommendations. *PeerJ* 2017;5:e4130.
58 Balestroni G, Bertolotti G. Euroqol-5D (EQ-5D): An instrument for measuring quality of life. *Monaldi Arch Chest Dis* 2012;78:155–9.
59 Beattie P, Turner C, Dowda M, *et al*. The Medrisk instrument for measuring patient satisfaction with physical therapy care: A Psychometric analysis. *J Orthop Sports Phys Ther* 2005;35:24–32.
60 Piper BF, Dibble SL, Dodd MJ, *et al*. The revised Piper fatigue scale: Psychometric evaluation in women with breast cancer. *Oncol Nurs Forum* 1998;25:677–84.
61 Cantarero-Villanueva I, Fernández-Lao C, Díaz-Rodríguez L, *et al*. The Piper fatigue scale-revised: Translation and Psychometric evaluation in Spanish-speaking breast cancer survivors. *Qual Life Res* 2014;23:271–6.
62 Neblett R, Mayer TG, Hartzell MM, *et al*. The fear-avoidance components scale (FACS): Development and Psychometric evaluation of a new measure of pain-related fear avoidance. *Pain Pract* 2016;16:435–50. 10.1111/papr.12333 Available: http://doi.wiley.com/10.1111/papr.2016.16.issue-4
63 Gutiérrez-Sánchez D, Roldán-Jiménez C, Pajares B, *et al*. Validity and reliability of the Spanish fear-avoidance components scale in breast cancer survivors. *Eur J Cancer Care (Engl)* 2021;30.
64 Roland M, Fairbank J. The Roland-Morris disability questionnaire and the Oswestry disability questionnaire. *Spine (Phila Pa 1976)* 2000;25:3115–24.
65 Kovacs FM, Llobera J, Gil Del Real MT, *et al*. Validation of the Spanish version of the Roland-Morris questionnaire. *Spine (Phila Pa 1976)* 2002;27:538–42.
66 Gabel CP, Cuesta-Vargas A, Qian M, *et al*. The Oswestry disability index, Confirmatory factor analysis in a sample of 35,263 Verifies a one-factor structure but practicality issues remain. *Eur Spine J* 2017;26:2007–13.
67 Cuesta-Vargas AI, Gabel CP. Validation of a Spanish version of the spine functional index. *Health Qual Life Outcomes* 2014;12.
68 Ferrando L. *MINI International Neuropsychiatric Interview*. Madrid: IAP, 1998. Available: www.academia.cat/files/425-7297.../MinientrevistaNeuropsiquatribaInternacional.pdf
69 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606–13.
70 Diener MJ. *Cohen's D In: The Corsini Encyclopedia of Psychology*. John Wiley & Sons, Ltd, 2010: 1.
71 Martín-Martín J, Wang L, De-Torres I, *et al*. The validity of the energy expenditure criteria based on open source code through two inertial sensors. *Sensors (Basel)* 2022;22.
72 Martín-Martín J, Jiménez-Partinen A, De-Torres I, *et al*. Reliability study of inertial sensors Lis2Dh12 compared to Actigraph Gt9X: Based on free code. *J Pers Med* 2022;12:749.

Consentimiento informado – Información al paciente

Título del protocolo: **Efectividad de una intervención digital basada en modificación de estilos de vida en prevención secundaria: iGAME ensayo clínico aleatorizado controlado**

Investigadores principales: Dr. Antonio I. Cuesta Vargas y Dr. Fermín Mayoral Cleries

Sede donde se recoge los datos del estudio:
Facultad de Ciencias de la Salud,
Universidad de Málaga
Arquitecto Francisco Peñalosa, 3, 29071 Málaga

Nombre y edad del paciente:

Antes de proceder a la firma de este consentimiento informado, lea atentamente la información que a continuación se le facilita y realice las preguntas que considere oportunas. Una vez comprendido todos los apartados del estudio, y si desea participar, se le pedirá que firme el presente consentimiento, del cual, se le entregará una copia firmada y fechada.

Justificación del estudio

Usted ha sido invitado a participar en un estudio de investigación. En este documento se le explicará por qué va a realizar el estudio y que implicará. Por favor, antes de tomar una decisión es importante que entienda todo y lea este documento de forma cuidadosa.

El presente estudio está organizado por los Grupos de Investigación Clinimetría en Fisioterapia y Salud Mental, grupos perteneciente al Instituto de Investigación Biomédica de Málaga (IBIMA). La presente investigación forma parte de un proyecto financiado por la Comisión Europea a través del programa Horizon 2020.

Objetivos del estudio:

- Estudiar la efectividad sobre la conducta sedentaria de un programa de intervención basado en la utilización de las nuevas tecnologías de gamificación y los juegos formativos.

Importancia:

- Aunque existen numerosas estrategias de intervención sobre la conducta sedentaria, en un alto porcentaje de éstas no se ha comprobado la efectividad de las herramientas utilizadas.

Los resultados de esta investigación serán más fiables y mejores si todas las personas a las que invitamos a participar deciden tomar parte en el estudio y por ello esperamos que usted lo haga.

De usted depende decidir si quiere formar parte del estudio o no. Este estudio no sería capaz de hacerse sin la participación voluntaria de los entrevistados. Como no puede ser de otra manera, usted es libre de retirarse en cualquier momento sin necesidad de dar ninguna razón.

Implicaciones para el paciente

- La participación es totalmente voluntaria.
- El participante puede retirarse del estudio cuando así lo manifieste, sin ser su decisión cuestionada y sin que esto repercuta en sus cuidados médicos.
- Todos los datos carácter personal, obtenidos en este estudio son confidenciales y se tratarán conforme a la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos y Garantía de los Derechos Digitales.
- La información obtenida se utilizará exclusivamente para los fines específicos de este estudio.

Criterios de selección

Usted fue seleccionado principalmente por tener entre 18 y 65 años, tener una conducta sedentaria reconocida y mantener una intención de cambio de esta conducta.

Cuesta-Vargas AI, *et al. BMJ Open* 2023; 13:e066669. doi: 10.1136/bmjopen-2022-066669

Procedimiento de recogida de datos y programa de intervención

Si decide aceptar participar en el estudio, se le realizarán algunas preguntas sobre usted, sus hábitos y sus antecedentes médicos. Se realizarán en la primera sesión evaluaciones a través de cuestionarios. Estos cuestionarios se volverán a cumplimentar a las 6, 12, 27 y 52 semanas.

Una vez realizada la evaluación inicial, se iniciará una intervención de 12 semanas. En el caso de ser asignado al grupo intervención, su participación estará basada en el uso de una aplicación móvil orientada en la modificación de la conducta sedentaria. En el caso de ser asignado al grupo control, recibirá pautas generales acerca del sedentarismo y la actividad física.

Contraindicaciones

Las contraindicaciones aquí descritas han sido consideradas previamente a la realización del presente estudio para incluirle a usted dentro del mismo, pero le informamos de las mismas por si se hubiera presentado alguna de ellas y usted no nos lo hubiese comunicado anteriormente:

- Enfermedades psiquiátricas graves.
- Deterioro cognitivo severo.
- Incapacidad psíquica para comprender los test.
- Patologías sistémicas agudas.
- Tumor.
- Infarto de miocardio reciente.
- Enfermedades infecciosas.
- Embarazo.

Al firmar este documento, usted desvincula de toda responsabilidad a todos los investigadores de este estudio, además de afirmar que se encuentra en perfectas condiciones para la ejecución de todos los ejercicios propuestos. Usted antes de comenzar el estudio e incluso antes de firmar el presente documento, puede formular cuantas preguntas estime oportunas.

Cuesta-Vargas AI, *et al. BMJ Open* 2023; 13:e066669. doi: 10.1136/bmjopen-2022-066669

Aclaraciones

- Su decisión de participar en el estudio es completamente voluntaria.
- No habrá ninguna consecuencia desfavorable para usted, en caso de no aceptar la invitación.
- Si decide participar en el estudio puede retirarse en el momento que lo desee, aun cuando el investigador responsable no se lo solicite, informando las razones de su decisión la cual será respetada en su integridad.
- No tendrá que hacer gasto alguno durante el estudio.
- No recibirá pago por su participación.
- En el transcurso del estudio usted podrá solicitar información actualizada sobre el mismo, al investigador responsable.
- Todos los datos y resultados obtenidos y emanados del presente estudio estarán destinados sólo y exclusivamente a la presente investigación.
- La información obtenida en este estudio, utilizada para la identificación de cada paciente, será mantenida con estricta confidencialidad por el grupo de investigadores.
- Si considera que no hay dudas ni preguntas acerca de su participación, puede, si así lo desea, firmar la Carta de Consentimiento Informado anexa a este documento.

Sus datos serán tratados de acuerdo a la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos y Garantía de los Derechos Digitales.

Declaración del consentimiento informado

Yo,

he leído y comprendido la información previamente descrita y mis preguntas han sido respondidas. He sido informado y entiendo que los datos e imágenes obtenidas en el estudio pueden ser publicados o difundidos con fines científicos, manteniendo mi anonimato en todo momento. Por ello, acepto participar en el presente estudio de investigación.

Recibiré una copia firmada y fechada del presente consentimiento.

Firma del participante:	Fecha:
Nombre y firma del testigo (sólo si corresponde):	Fecha:

D. Antonio I. Cuesta Vargas, como investigador principal de este estudio, o alguno de sus colaboradores, declara que:

Yo, , con cargo de en el presente estudio, he explicado al Sr(a) arriba firmante, la naturaleza y los propósitos de la investigación, así como le he expuesto los riesgos y beneficios que implica la participación. He respondido las preguntas del paciente y he solicitado si tiene alguna duda. Acepto que he leído y conozco la normativa correspondiente para realizar investigación con seres humanos y me acojo a ella.

Una vez concluidas y aclaradas todas las dudas y consultas, se procede a firmar el presente documento:

Fecha:

Firma del investigador:

Carta de revocación del consentimiento

Título del protocolo: **Efectividad de una intervención digital basada en modificación de estilos de vida en prevención secundaria: iGAME ensayo clínico aleatorizado controlado**.

Investigadores principales: Antonio I. Cuesta Vargas y Fermín Mayoral Cleries

Sede donde se recoge los datos del estudio: Hospital Civil
Pza. Hospital Civil s/n 29009 Málaga

Nombre y edad del paciente:

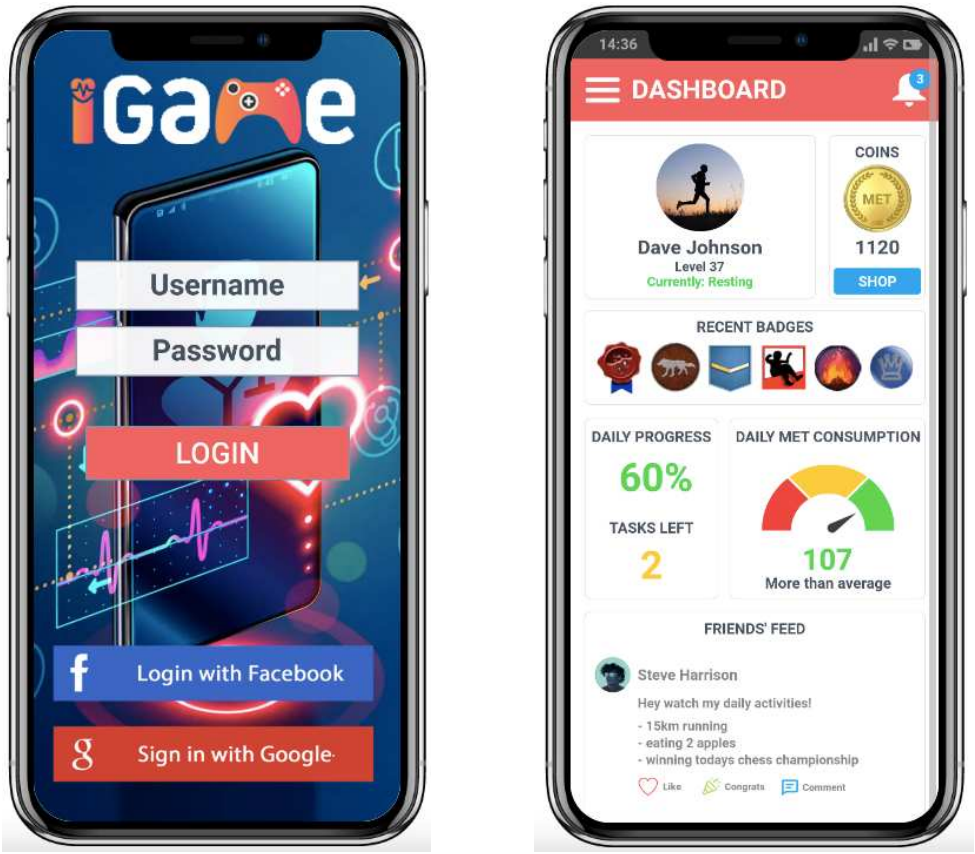
Por este conducto deseo informar mi decisión de retirarme de este protocolo de investigación por las siguientes razones:

Firma del participante:

Fecha:

Nombre y firma del testigo (sólo si corresponde):

Fecha:



Supplementary file 2. Screenshots of first application prototype, not final version. All rights of the screenshot and the application belong to their respective owners: the iGame project consortium.

Consentimiento informado – Información al paciente

Título del protocolo: **Efectividad de una intervención digital basada en modificación de estilos de vida en prevención secundaria: iGAME ensayo clínico aleatorizado controlado**

Investigadores principales: Dr. Antonio I. Cuesta Vargas y Dr. Fermín Mayoral Cleries

Sede donde se recoge los datos del estudio:
Facultad de Ciencias de la Salud,
Universidad de Málaga
Arquitecto Francisco Peñalosa, 3, 29071 Málaga

Nombre y edad del paciente:

Antes de proceder a la firma de este consentimiento informado, lea atentamente la información que a continuación se le facilita y realice las preguntas que considere oportunas. Una vez comprendido todos los apartados del estudio, y si desea participar, se le pedirá que firme el presente consentimiento, del cual, se le entregará una copia firmada y fechada.

Justificación del estudio

Usted ha sido invitado a participar en un estudio de investigación. En este documento se le explicará por qué va a realizar el estudio y que implicará. Por favor, antes de tomar una decisión es importante que entienda todo y lea este documento de forma cuidadosa.

El presente estudio está organizado por los Grupos de Investigación Clinimetría en Fisioterapia y Salud Mental, grupos perteneciente al Instituto de Investigación Biomédica de Málaga (IBIMA). La presente investigación forma parte de un proyecto financiado por la Comisión Europea a través del programa Horizon 2020.

Objetivos del estudio:

- Estudiar la efectividad sobre la conducta sedentaria de un programa de intervención basado en la utilización de las nuevas tecnologías de gamificación y los juegos formativos.

Importancia:

- Aunque existen numerosas estrategias de intervención sobre la conducta sedentaria, en un alto porcentaje de éstas no se ha comprobado la efectividad de las herramientas utilizadas.

Los resultados de esta investigación serán más fiables y mejores si todas las personas a las que invitamos a participar deciden tomar parte en el estudio y por ello esperamos que usted lo haga.

De usted depende decidir si quiere formar parte del estudio o no. Este estudio no sería capaz de hacerse sin la participación voluntaria de los entrevistados. Como no puede ser de otra manera, usted es libre de retirarse en cualquier momento sin necesidad de dar ninguna razón.

Implicaciones para el paciente

- La participación es totalmente voluntaria.
- El participante puede retirarse del estudio cuando así lo manifieste, sin ser su decisión cuestionada y sin que esto repercuta en sus cuidados médicos.
- Todos los datos carácter personal, obtenidos en este estudio son confidenciales y se tratarán conforme a la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos y Garantía de los Derechos Digitales.
- La información obtenida se utilizará exclusivamente para los fines específicos de este estudio.

Criterios de selección

Usted fue seleccionado principalmente por tener entre 18 y 65 años, tener una conducta sedentaria reconocida y mantener una intención de cambio de esta conducta.

Cuesta-Vargas AI, *et al. BMJ Open* 2023; 13:e066669. doi: 10.1136/bmjopen-2022-066669

Procedimiento de recogida de datos y programa de intervención

Si decide aceptar participar en el estudio, se le realizarán algunas preguntas sobre usted, sus hábitos y sus antecedentes médicos. Se realizarán en la primera sesión evaluaciones a través de cuestionarios. Estos cuestionarios se volverán a cumplimentar a las 6, 12, 27 y 52 semanas.

Una vez realizada la evaluación inicial, se iniciará una intervención de 12 semanas. En el caso de ser asignado al grupo intervención, su participación estará basada en el uso de una aplicación móvil orientada en la modificación de la conducta sedentaria. En el caso de ser asignado al grupo control, recibirá pautas generales acerca del sedentarismo y la actividad física.

Contraindicaciones

Las contraindicaciones aquí descritas han sido consideradas previamente a la realización del presente estudio para incluirle a usted dentro del mismo, pero le informamos de las mismas por si se hubiera presentado alguna de ellas y usted no nos lo hubiese comunicado anteriormente:

- Enfermedades psiquiátricas graves.
- Deterioro cognitivo severo.
- Incapacidad psíquica para comprender los test.
- Patologías sistémicas agudas.
- Tumor.
- Infarto de miocardio reciente.
- Enfermedades infecciosas.
- Embarazo.

Al firmar este documento, usted desvincula de toda responsabilidad a todos los investigadores de este estudio, además de afirmar que se encuentra en perfectas condiciones para la ejecución de todos los ejercicios propuestos. Usted antes de comenzar el estudio e incluso antes de firmar el presente documento, puede formular cuantas preguntas estime oportunas.

Cuesta-Vargas AI, *et al. BMJ Open* 2023; 13:e066669. doi: 10.1136/bmjopen-2022-066669

Aclaraciones

- Su decisión de participar en el estudio es completamente voluntaria.
- No habrá ninguna consecuencia desfavorable para usted, en caso de no aceptar la invitación.
- Si decide participar en el estudio puede retirarse en el momento que lo desee, aun cuando el investigador responsable no se lo solicite, informando las razones de su decisión la cual será respetada en su integridad.
- No tendrá que hacer gasto alguno durante el estudio.
- No recibirá pago por su participación.
- En el transcurso del estudio usted podrá solicitar información actualizada sobre el mismo, al investigador responsable.
- Todos los datos y resultados obtenidos y emanados del presente estudio estarán destinados sólo y exclusivamente a la presente investigación.
- La información obtenida en este estudio, utilizada para la identificación de cada paciente, será mantenida con estricta confidencialidad por el grupo de investigadores.
- Si considera que no hay dudas ni preguntas acerca de su participación, puede, si así lo desea, firmar la Carta de Consentimiento Informado anexa a este documento.

Sus datos serán tratados de acuerdo a la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos y Garantía de los Derechos Digitales.

Declaración del consentimiento informado

Yo,

he leído y comprendido la información previamente descrita y mis preguntas han sido respondidas. He sido informado y entiendo que los datos e imágenes obtenidas en el estudio pueden ser publicados o difundidos con fines científicos, manteniendo mi anonimato en todo momento. Por ello, acepto participar en el presente estudio de investigación.

Recibiré una copia firmada y fechada del presente consentimiento.

Firma del participante:	Fecha:
Nombre y firma del testigo (sólo si corresponde):	Fecha:

D. Antonio I. Cuesta Vargas, como investigador principal de este estudio, o alguno de sus colaboradores, declara que:

Yo, , con cargo de en el presente estudio, he explicado al Sr(a) arriba firmante, la naturaleza y los propósitos de la investigación, así como le he expuesto los riesgos y beneficios que implica la participación. He respondido las preguntas del paciente y he solicitado si tiene alguna duda. Acepto que he leído y conozco la normativa correspondiente para realizar investigación con seres humanos y me acojo a ella.

Una vez concluidas y aclaradas todas las dudas y consultas, se procede a firmar el presente documento:

Fecha:

Firma del investigador:

Carta de revocación del consentimiento

Título del protocolo: **Efectividad de una intervención digital basada en modificación de estilos de vida en prevención secundaria: iGAME ensayo clínico aleatorizado controlado**.

Investigadores principales: Antonio I. Cuesta Vargas y Fermín Mayoral Cleries

Sede donde se recoge los datos del estudio: Hospital Civil
Pza. Hospital Civil s/n 29009 Málaga

Nombre y edad del paciente:

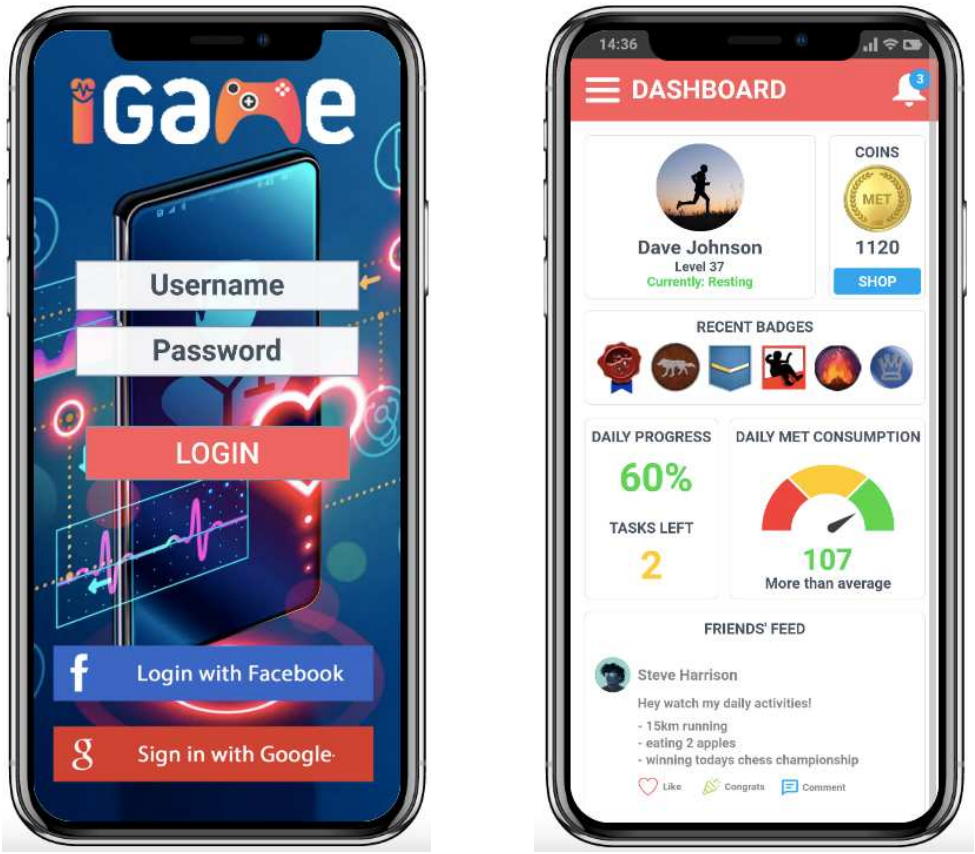
Por este conducto deseo informar mi decisión de retirarme de este protocolo de investigación por las siguientes razones:

Firma del participante:

Fecha:

Nombre y firma del testigo (sólo si corresponde):

Fecha:



Supplementary file 2. Screenshots of first application prototype, not final version. All rights of the screenshot and the application belong to their respective owners: the iGame project consortium.