MOVE-IT PILOT PROTOCOL

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STUDY PROTOCOL

Title

EXPLORATORY STUDY OF TWO NEW TOOLS TO IMPLEMENT PHYSICAL ACTIVITY THROUGH THE USE OF INFORMATION AND COMMUNICATION TECHNOLOGIES IN PERSONS WITH MILD-MODERATE INTELLECTUAL DISABILITY
(THE MOVE-IT PILOT)

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Abstract

Background: Persons with mild to moderate intellectual disability perform sub-standard physical activity. New information and communication technologies and gamification strategies can increase the uptake of physical activity habits. This pilot aims to evaluate the use of gamified mobile applications to improve physical activity performance in individuals with mild to moderate level of intellectual disability.

Methods: Pre-post evaluation of intervention on a group of 30 individuals with mild to moderate intellectual disability. The study duration is 4 weeks, in which the first 2 weeks consists on a programmed use of two mobile applications to perform physical activity twice a week in sessions of 20 minutes. During the second two 2 weeks participants can use the apps on voluntary basis and there are no programmed sessions. Data is collected at three time points: Baseline, after week 2 and after week 4. Primary outcome measurements are collected with the International Physical Activity Questionnaire Short Form (IPAQ-S), secondary outcome measures are collected with the Digital Competences Questionnaire and Learning Outcomes Questionnaire. Data will be analyzed using paired and grouped conventional nonparametric statistics for quantitative measures and qualitative analysis for open-ended questions

Discussion: This intervention aims to evaluate the acceptance of gamified mobile applications in the target population. Secondary aims are to explore the effect on physical activity habits and digital literacy.

Keywords

intellectual disability; physical activity; mobile health app; information and communication technology.

Administrative information

Title {1}	EXPLORATORY STUDY OF TWO NEW TOOLS TO IMPLEMENT PHYSICAL ACTIVITY THROUGH THE USE OF INFORMATION AND COMMUNICATION TECHNOLOGIES IN PERSONS WITH MILD-MODERATE INTELLECTUAL DISABILITY (THE MOVE-IT PILOT)
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Name and contact information for the trial sponsor {5b}	none
Role of sponsor {5c}	none

Introduction

Background and rationale {6a}

Intellectual Disability (ID), also known as cognitive impairment, is characterized by "significant limitations both in intellectual functioning and adaptive behavior as expressed in conceptual, social, and practical adaptive skills" (Schalock et al. 2010). ID differs from person to person and the age of the person, but it is always associated with an impaired cognitive ability. Disability depends not only on health conditions but also and crucially on the extent to which environmental factors supports the full participation and inclusion in the society ("Definition: intellectual disability" 2020) (World Health Organization Europe 2020)[1]. When compared to the general population, people with ID are on an increased risk of health problems (Balogh et al. 2008) (Olsen et al. 2021)[2],[3] worse coverage of health care needs, and difficulties to find appropriate health care (Hermans and Evenhuis 2014; Malt et al. 2013) (Olsen et al. 2023).

Specifically, people with ID have lower levels of physical activity than the general adult population (Stanish et al. 2019) and have a higher incidence of obesity (Folch et al. 2019; Kinnear et al. 2018). There are estimations that 50% of people with ID has a sedentary lifestyle, and 40% of them has low levels of physical activity (Haveman et al. 2011). A review by Dairo et al. (Dairo et al. 2016) found that 9% of the individuals with ID worldwide was able to make the World Health Organization (WHO) recommendation of physical activity. Sedentarism and low levels of physical activity lead to deconditioning, impaired function and reduced independence (Oviedo and Guerra-balic 2017).

We find several barriers for individuals with ID among the reasons of low activity levels: lack of resources for necessary support; reduced physical and behavioural skills; and lack of available programs (Kuijken et al. 2016). Studies for motivating physical activity to people with ID have shown that predictability with routine and familiarity, communication of purpose, and enjoyable and social activities promote motivation and participation (Mahy et al. 2010; Michalsen et al. 2020).The combination of physical activity routines and gamification has led to the theoretical framework of exergames, in which the exercising routines are ruled and supported by game-related resources (F. F. Mueller and Mandryk 2016). Videogames and virtual reality exergames are widely utilized by youth today and they offer particularly attractive features for individuals with IDs (Anderson-Hanley et al. 2011).

Exergames using video games, have been also investigated and found to be promising for individuals with ID (Rosly et al. 2017; Taylor et al. 2016). The use of touch screen devices such as smart-phones, tablets, and iPads has proven to have low cognitive demands and could be used to improve commitment to physical activity (Anzulewicz et al. 2016; Li et al. 2017) and to improve the overall quality of life (Ghahramani and Wang 2019). However, implementing these solutions in an effective manner requires meeting the user's needs by systematically analysing user preferences (Antypas and Wangberg 2014) (Michalsen et al. 2023)[4].

Physical activity has shown to have positive effects on cardiovascular and psychosocial health of individuals with ID. Exergames links physical activity to a video game or entertainment

[1] Nations, U. "Convention on the Rights of Persons with Disabilities (CRPD), U. Nations." (2006).

[2] Monica Isabel Olsen, Erik Søndenaa, Ellen Melbye Langballe, Marianne Berg Halvorsen, Per Wilhelmsen, Erik Bautz-Holter & Audny Anke. Use of health and dental care services in adults with intellectual disability in relation to age and intellectual disability levels, Journal of Intellectual & Developmental Disability. 2023: 48:2, 172-183. DOI: 10.3109/13668250.2022.2109823

[3] Olsen MI, Halvorsen MB, Søndenaa E, Langballe EM, Bautz-Holter E, Stensland E, Tessem S, Anke A. How do multimorbidity and lifestyle factors impact the perceived health of adults with intellectual disabilities? J Intellect Disabil Res. 2021 Aug;65(8):772-783. doi: 10.1111/jir.12845. Epub 2021 May 11. PMID: 33977582.

[4] Michalsen H, Henriksen A, Pettersen G, Hartvigsen G, Wangberg S, Thrane G, Jahnsen R, Anke A. Using mobile health to encourage physical activity in individuals with intellectual disability: a pilot mixed methods feasibility study. Front Rehabil Sci. 2023 Aug 24;4:1225641. doi: 10.3389/fresc.2023.1225641. PMID: 37691911; PMCID: PMC10483399.

control and may yield better compliance with exercise. Moreover, rewards and being praised for performance in forms of feedback, medals, or awards - which is easily implementable in an exergame - has proven to be a promising way to add interest to physical activity for individuals with ID (Temple 2009), however, usually the persons assisting people with IDs (professionals or caregiver) frequently do not have the required knowledge and skills to promote its use. This project will design and develop prototypes of game-based eHealth solutions for behavior change and health promotion by influencing physical activity which have been explored and found to be promising in people with ID.

Objectives {7}

- To promote the healthy lifestyle and social inclusion of Persons with Intellectual Disabilities through their participation in ICT based exergames, in cooperation with other Persons with Intellectual Disabilities and relatives through the use of app based exergames.
- reduce disparities in access to and engagement with digital technologies by Persons with Intellectual Disabilities, relatives and professionals.
- Extend and develop the competences of Persons with mild-moderate levels of Intellectual Disabilities and personnel (relatives and professionals) who support Persons with intellectual Disabilities through the transference of knowledge and the use of tools related with the gamification of physical activity programs and exercises supported by Digital Tools.

Trial design {8}

A pre-post intervention trial to assess the impact of an intervention on a specific outcome in the target population. In this design, data is collected from the same group of individuals both before and after the intervention is implemented, and a follow-up 4 weeks after the intervention. The pre-intervention data serves as a baseline measurement, while the post-intervention and follow-up data will used to evaluate any changes or differences that result from the intervention. We aim to examine the effect of the intervention by comparing the outcome measures before and after its implementation, without the need for a control group. Potential confounding variables and limitations when interpreting the results of pre-post intervention trials will be dully considered. The intervention will be implemented in two different locations: CERCI OEIRAS (Portugal) and IVASS centers (Spain) in order to minimize external factors that may influence the observed changes.

Study setting {9}

The study will be done in CERCI OEIRAS (Lisbon, Portugal) and IVASS Day Care Centers (Valencia Region, Spain). CERCI OEIRAS is a social care cooperative working in the defence of the Rights of People with Disabilities, supporting their participation and integration in social and professional life, promoting the full exercise of their citizenship through an integrated set of actions and services. In their activities plan, the intervention on the field of exercise is very present, with a vast offer of physical activities perform indoor the organization and in the community. IVASS stands for "Instituto Valenciano de Atención Social y Sociosanitaria," which translates to the Valencian Institute of Social and Socio-Health Care. It is an agency within the Valencia Region of Spain that is responsible for managing and providing social and healthcare services. IVASS plays a key role in the region's healthcare and social care system, particularly in the administration and coordination of services for the elderly, dependent individuals, and individuals with disabilities. Its mission is to ensure the well-being and quality of life of these populations by offering various healthcare and social assistance programs and services.

Eligibility criteria {10}

In this study, the inclusion criteria consist of individuals who exhibit a low level of physical activity, possess basic knowledge of smartphone operation and mobile applications, and are willing to provide informed consent after receiving an information sheet about the research.

Exclusion criteria identify individuals who are not suitable for the study due to their inability to be aware of their surroundings when using the app, indicating a potential safety concern, as well as those with visual impairments, as the study may require visual interaction with the smartphone or app. These criteria are established to ensure the safety, comprehension, and suitability of participants in the research, allowing for a more targeted and informed investigation into the relationship between physical activity and smartphone app usage.

Who will take informed consent? {26a}

Informed consent will be obtained by the legal tutor or representative of the participant, who can be the subject him/herself in some cases.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable

Interventions

Explanation for the choice of comparators {6b}

In this pre-post interventional study designed to investigate the acceptability of the tools, as well as to explore increase in physical activity habits, the primary outcome will be measured with the International Physical Activity Questionnaire Short Form (IPAQ-S)[5]. The main comparator will be the Self-Comparison, where each participant serves as their own control or reference to estimate the effect. The study will compare each participant's pre-intervention physical activity levels with their post-intervention levels. This analysis will be also aggregated, to compare the grouped effects of the intervention (mean/median and standard deviation) to minimize factors affecting to single subjects. Acceptance will be investigated…
Secondary outcomes for Digital Competences and Learning Outcomes of the training framework will be evaluated with two separate questionnaires. The main comparator will be a quantitatitative score based on the answers provided in the questionnaires. Questionnaire

Intervention description {11a}

The intervention will consist on four phases:

1) Training to physiotherapists and monitors of the institutions participating in the study on the use of Exergaming and ICTs to motivate physical activity. This training will also include a description of the intervention protocol.
2) In the baseline, the recruited participants (those who meet the inclusion criteria) and monitors will be instructed on the use of the apps and baseline data will be collected by means of three questionnaires: IPAQ and Digital Literacy. IPAQ will be only done in participants with intellectual disability who met the inclusion criteria. After the baseline data collection and during 2 weeks, the participants will implement 3 sessions per week of physical activity supported with the two mobile apps: Sorterious and AGA.
3) After these 2 weeks, the post-intervention data will be collected by means of the same questionnaires: IPAQ and Digital Literacy. IPAQ will be only done in participants with intellectual disability who met the inclusion criteria and completed 5 out of the 6 programmed sessions.
4) After 2 weeks from the post-intervention sampling, the follow-up data will be collected by means of the same questionnaires: IPAQ, Digital Literacy and Learning Ouctomes. IPAQ will be only done in participants with intellectual disability.

[5] Lee, Paul H., et al. "Validity of the international physical activity questionnaire short form (IPAQ-SF): A systematic review." *International journal of behavioral nutrition and physical activity* 8.1 (2011): 1-11.

The intervention sessions will consist of the following structure:

1. Introduction (5 minutes):
    - Briefly introduce the session and its goals.
    - Welcome participants and create a positive and inclusive atmosphere.
    - Briefly explain the benefits of physical activity.
2. (Only in the first session) App Introduction and Instructions (10 minutes):
    - Introduce the Sortreius or AGA app and explain its features.
        - Demonstrate how to navigate the app, emphasizing simplicity and user-friendliness.
        - Provide step-by-step instructions on how to use the app for the exercises.
        - Encourage questions and ensure everyone is comfortable using the app.
3. Warm-Up (5 minutes):
    - Lead a group warm-up to prepare participants for the exercises.
    - Incorporate simple and engaging warm-up activities suitable for all fitness levels.
4. Independent App Use (20 minutes):
    - Guide participants through the first set of exercises, demonstrating proper form and technique.
    - Transition to independent app use by participants.
    - Emphasize inclusivity and offer modifications for varying abilities.
    - Encourage participants to ask questions or seek assistance if needed.
    - Circulate around the room, providing individual assistance and encouragement.
    - Ensure everyone is comfortable using the app independently.
6. Cool Down and Stretching (5 minutes):
    - Lead a cool-down routine to help participants gradually lower their heart rate.
    - Include gentle stretches focusing on major muscle groups.
    - Talk about the session

Criteria for discontinuing or modifying allocated interventions {11b}

The criteria for discontinuing or modifying allocated interventions plays a crucial role in ensuring the safety, well-being, and feasibility of the research. The criteria is to monitor the intervention's impact and to safeguard the participants' best interests. Discontinuation or modification includes situations where participants experience adverse effects or discomfort related to the app usage or if there are any significant challenges in the app's usability specific to condition or circumstance of the participant. Additionally, the discontinuation criteria encompasses any unforeseen ethical, logistical, or practical issue that emerge during the study, which may necessitate intervention adjustments or even discontinuation if the safety or ethical integrity of the research is compromised. Discontinuation will be registered as part of the study.

Strategies to improve adherence to interventions {11c}

The research team will perform weekly virtual meetings before and after de intervention, and during the follow-up phase. Associations will provide smartphones or tablets to implement the session with the apps whenever the participant has not its own device.

Relevant concomitant care permitted or prohibited during the trial {11d}

Not applicable

Provisions for post-trial care {30}

Not applicable

Outcomes {12}

Type of outcome	Measurement and instrument	Analysis metric	Method	Timepoints
Primary	Metabolic Equivalent (MET) in minutes per week (IPAQ-S)	Change from the baseline	Paired analysis and aggregated analysis (mean/median +- sd)	Baseline 2 weeks 4 weeks
Secondary	Digital Literacy (Questionnaire)	Change from the baseline	Paired analysis	Baseline 4 weeks
Secondary	Learning Outcomes (Questionnaire)	Change from the baseline	Paired analysis	Baseline 4 weeks

The IPAQ-S is, more acceptable than an activity tracker, and thereby more suitable for individuals with severe and profound ID [6]. METs, or Metabolic Equivalents, are a measure used in exercise physiology and clinical research to quantify the energy expenditure associated with various physical activities. They provide a standard for comparing the energy costs of different activities and can be clinically relevant

[6] Michalsen H, Henriksen A, Pettersen G, Hartvigsen G, Wangberg S, Thrane G, Jahnsen R and Anke A (2023) Using mobile health to encourage physical activity in individuals with intellectual disability: a pilot mixed methods feasibility study. Front. Rehabil. Sci. 4:1225641. doi: 10.3389/fresc.2023.1225641

Participant timeline {13}

- Baseline (Week 0): Enrollment, data collection and Training. Start the physical activity program with the use of apps.
- Post intervention (Week 2). Intervention finishes. Data collection.
- Follow-up (Week 4). Data collection

Sample size {14}

Sample size is calculated on the anticipated mean and standard deviation of the energy cost of walking at 3.0 km/h. Energy expenditure data is highly heterogeneous and scarce for the target population, therefore reference values were derived from data from similar studies ([7],[8]). Standard formulas for sample size determination were used in order to obtain the desired sample size for a two-tailed single-sample t-test with the following requirements: power = .90, α = .05, d = 0.5 (medium effect). The desired sample size was calculated to be 36. A similar figure was obtained for an a priori power analysis for the mixed ANOVA with two repetitions and two groups (i.e., one between-subjects and another between two groups) with the following parameters: power = .9, f = 0.25 (medium), α = .05. Accounting for a 15% drop-out ratio the final sample size estimation is 43 participants with intellectual disabilities.

Recruitment {15}

Achieving adequate participant enrollment to meet the target sample size in this pilot is essential for the validity of the results. The first measure to ensure participation is a clear and compelling communication of the study's purpose, benefits, and potential contributions to the participants. Engaging with professionals in the two study settings is crucial to build trust and credibility. Regular follow-up and communication with the local managers of the study may maintain their interest and commitment throughout the study. Adapting recruitment strategies based on ongoing feedback and tracking the progress of enrollment can ensure that the target sample size is met in a timely and effective manner. At the end of the study, participants should receive a report on the study achievements and results.

Assignment of interventions: allocation

Not applicable

Sequence generation {16a}

Numerical identifiers will be randomly generated and assigned to each participant upon registration for registering into the Sorterious app. Participants will be not allocated into groups.

Concealment mechanism {16b}

Not applicable

Implementation {16c}

Not applicable

[7] Agiovlasitis, S., Choi, P., Allred, A. T., Xu, J., & Motl, R. W. (2020). Systematic review of sedentary behaviour in people with Down syndrome across the lifespan: A clarion call. Journal of Applied Research in Intellectual Disabilities, 33(2), 146-159

[8] Reece, Jeff Walkley, Energy expended by adults with and without intellectual disabilities during activities of daily living, Research in Developmental Disabilities, Volume 31, Issue 6, 2010, Pages 1380-1389, ISSN 0891-4222, https://doi.org/10.1016/j.ridd.2010.06.022

Assignment of interventions: Blinding

Who will be blinded {17a}
Not applicable

Procedure for unblinding if needed {17b}

Not applicable

Data collection and management

Plans for assessment and collection of outcomes {18a}

Baseline data will be collected through comprehensive participant assessments, capturing relevant information. Outcome data, central to the study's objectives, will be meticulously gathered using validated measurement tool IPAQ directly and indirectly. Data collection from the questionnaires processes will include a structured interview conducted by trained personnel to maintain consistency and accuracy. Additionally, electronic data capture systems will be employed, ensuring secure and real-time data entry on the use of the apps (duration and number of interactions). To minimize missing data, reminders and follow-up procedures will be implemented, and data will be regularly monitored for completeness and accuracy. All collected data will be subjected to rigorous validation and verification procedures, and any inconsistencies will be promptly addressed.

Data from questionnaires will be centralized in the two study settings and once anonymized, digitalized for secure storage in the UPV centers.

Study instruments

- IPAQ-S (Annex I)
- Digital literacy (Annex I)
- Learning Outcomes (Annex I)

Plans to promote participant retention and complete follow-up {18b}
Data of discontinued participants will no be used for the analysis.

Data management {19}

Data entry will be conducted using secure electronic systems, ensuring accurate recording of participant responses and assessments. To promote data quality, double-entry verification and validation checks will be implemented, reducing the risk of errors and enhancing reliability. Each data point will be assigned a unique identifier and stored without personally identifiable information to protect participant privacy. Access to the data will be strictly controlled and limited to authorized personnel. Data security measures, including encryption and password protection, will safeguard against unauthorized access. Weekly backups, both on-site (MOVEIT server) and off-site (external server), will prevent data loss, and disaster recovery protocols will be in place to ensure the preservation of valuable research data.

Confidentiality {27}
The protection of personal information and confidentiality of potential and enrolled participants is of utmost importance throughout all phases of the pilot. Prior to the trial, personal information will be collected through secure and confidential means, ensuring that only essential data is gathered, and participants are informed about the purposes of data collection. During the trial, any shared information will be de-identified, with data points assigned unique numerical identifiers, preventing any linkage to specific individuals. Access to personal information will be

strictly limited to authorized personnel, and robust data security measures, including encryption and password protection, will be in place to safeguard this information. After the trial, all personal data will be securely archived and retained in compliance with relevant data protection regulations. Any published results or reports will only contain aggregated and anonymized data, further preserving confidentiality.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The first part of the statistical analysis will involve a comprehensive descriptive statistical analysis, including quality assessment (missing data, outliers, normality and balance). The primary outcome measure of interest is the level of physical activity, which was quantified in METs (Metabolic Equivalents), treated as a continuous variable. METs are a reliable measure of energy expenditure during physical activities and provide valuable insights into individuals' activity levels during a period of time.

Additionally, we investigate two secondary outcomes: digital literacy and participants' learning outcomes as assessed through the questionnaires in Annex I. The preferred statistical test for a pre-post study in which a comparison between measurements is done before and after an intervention within the same group are the paired t-test and the Wilcoxon signed-rank test. The choice between the two depends on the underlying assumptions of the data as resulting from the descriptive analysis. Data normality for continuous variables will be assessed by visual inspection (normal probability plot), and skewness (k><2) and by conducting a normality test, such as the Shapiro-Wilk test.

The paired T-Test will be applied upon appropriate for normally distributed data or data that approximates a normal distribution in which it is assumed that the differences between pre and post measurements are normally distributed, and variances are roughly equal. This test is applied to continuous data, and the differences between pre and post measurements are close to being normally distributed.

A Wilcoxon Signed-Rank Test will be applied if the data is not normally distributed or when the variables are dealing with ordinal or ranked data. This test will be applied if the descriptive analysis results in an un-specific distribution for the differences between pre and post measurements.

Interim analyses {21b}

No interim analyses will be performed

Methods for additional analyses (e.g. subgroup analyses) {20b}

In the probable case of sub-group analysis, a paired one-way ANOVA test will be implemented to assess the inter group differences in the primary and secondary outcomes.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

To mitigate the potential impact of protocol non-adherence, clear and comprehensive instructions will be provided to both participants and instructors, as well as regular monitoring and follow-up to promote adherence to the study protocol. Reasons and circumstances for protocol non-adherence cases will be documented and sensitivity analyses will be performed to assess the robustness of the results to potential deviations from the protocol.

Missing data will be handled on stablished statistical methods to minimize bias and optimize the use of available information. Pattern and mechanism for missing data management, such as whether if it will be missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR) will be considered. Depending on the nature of the missing data, suitable techniques such as multiple imputation, maximum likelihood estimation, or appropriate model-based approaches to impute missing values will be used. The goal is to ensure that conducted analyses accounted for the uncertainty introduced by missing data, thus providing more accurate and reliable results.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

All the tools, analyses and results will be publicly available

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

The study committee will be the following:

- Coordination: Antonio Martinez (UPV)
- Pilot setting coordination: Maria Sorzano (IVASS) and Duarte Correia (CERCI OEIRAS)
- Statistical analysis: Andrea García Montaner (UPV)
- ICT tools: André Hendriksen (UiT)

Composition of the data monitoring committee, its role and reporting structure {21a}

Same as above.

Adverse event reporting and harms {22}

Adverse event reporting and monitoring for potential harms is established through a system for collecting, documenting, and analyzing any adverse events that may occur during the study. Pilot setting coordinators will be responsible for promptly identifying, recording, and evaluating adverse events, whether they are directly related to the study interventions or occur as a result of other factors. The protocol adheres to ethical guidelines and regulatory requirements in reporting any serious adverse events to the relevant authorities and institutional review boards as necessary. Additionally, the research protocol includes provisions for monitoring potential harms to participants, and will implement measures to mitigate risks and protect the rights and safety of all involved individuals.

Frequency and plans for auditing trial conduct {23}

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

No amendments are foreseen.

Dissemination plans {31a}

This study is committed to effective dissemination of its findings to maximize the impact of the training framework and to contribute to the broader knowledge of accessible ICTs for persons with intellectual disabilities and the promotion of physical activity habits. Dissemination plans encompass a multi-faceted approach that includes peer-reviewed publications in indexed scientific journals, relevant conferences and symposia, as well as engagement with key stakeholders in multiplier events.
All the information related to the study will be accessible through the project web site (https://moveit.webs.upv.es/) and social media channels.

Declarations

Acknowledgements

Authors' contributions {31b}

Funding {4}
Erasmus + Program. KA2 . SEPIE under 2021-1-ES01 KA220-ADU-000026343 grant

Availability of data and materials {29}
Materials and resources are available in EN, SP, PT, IT and NO in the project website. Data will be available upon request through the project website.

Ethics approval and consent to participate {24}
Ethics approval has been obtained from the UPV Ethical Committee ensuring that the study adheres to the highest ethical standards and safeguards the rights, safety, and welfare of all participants. Informed consent is an essential component of the research process, and every individual involved in the study, including participants and their legal guardians if applicable, will be provided with clear and comprehensible information about the study's purpose, procedures, potential risks, and benefits. They will be given the opportunity to ask questions and are encouraged to make a fully informed decision regarding their participation. Their voluntary, written consent should be obtained before any study-related activities commence. The research team is dedicated to upholding ethical principles, respecting the autonomy and dignity of all participants, and ensuring that the study will be conducted with the utmost integrity and transparency.

Consent for publication {32}
Not applicable

Competing interests {28}

Participating entities declare no competing interests in the execution of this study. Any partner is economically benefiting from this action.

ANNEX I. Study Questionnaires

IPAQ Short Form

We are interested in finding out about the kinds of physical activities that the participants do as part of their everyday lives. The questions will ask about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the vigorous activities that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time. 1.

During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

___ days per week

☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

___ hours per day
___ minutes per day

☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

___ days per week

☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

___ hours per day
___ minutes per day

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

___ days per week

☐ No moderate physical activities → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

___ hours per day
___ minutes per day

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

___ hours per day
___ minutes per day

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating

Digital Literacy

This is a 10-item questionnaire to evaluate the digital literacy on the use of mobile apps for people with intellectual disabilities.

1. How often do you use a mobile device or tablet?
   - [ ] Every day
   - [ ] A few times a week
   - [ ] A few times a month
   - [ ] Rarely or never

2. Which mobile apps do you use most often? (List specific apps, if known)
   - [ ] Social media apps (e.g., Facebook, Instagram)
   - [ ] Communication apps (e.g., WhatsApp, Messenger)
   - [ ] Entertainment & Music apps (e.g., YouTube, Netflix, Spotify)
   - [ ] Educational apps & Photos (e.g., learning games)
   - [ ] Other (please specify): _____

3. How confident are you in navigating through your mobile device's home screen and opening apps?
   - [ ] Very confident
   - [ ] Somewhat confident
   - [ ] A little confident
   - [ ] Not confident at all

4. Can you send a message or a text using an app like WhatsApp or Messenger?
   - [ ] Yes
   - [ ] No
   - [ ] I'm not sure

5. Can you take a photo or video using the camera on your mobile device?
   - [ ] Yes
   - [ ] No
   - [ ] I'm not sure

6. Do you know how to adjust the volume or brightness settings on your mobile device?
   - [ ] Yes
   - [ ] No
   - [ ] I'm not sure

7. Have you ever used voice commands (e.g., "Hey Siri" or "OK Google") on your mobile device to perform tasks?
   - [ ] Yes
   - [ ] No
   - [ ] I'm not sure

8. How comfortable are you with using apps to access information, like looking up a website or searching for information?
   - [ ] Very comfortable
   - [ ] Somewhat comfortable
   - [ ] A little comfortable
   - [ ] Not comfortable at all

9. Are you aware of privacy and safety settings in mobile apps, like setting passwords or controlling who can see your information?
   - [ ] Yes

- [ ] No
- [ ] I'm not sure

10. What assistance or support do you need to use mobile apps more comfortably? (Select all that apply)
- [ ] I need someone to show me how to use apps.
- [ ] I need apps to have simpler and clearer instructions.
- [ ] I need help setting up accessibility features.
- [ ] I don't need any assistance.

Learning Outcomes

The MOVEIT pilots are organized with the objective of improving knowledge about Physical Activity, knowing how to develop a physical activity program, improving ICT skills and promoting the use of exergaming in people with intellectual disabilities.

Next, you will be asked a series of questions related to the training you have just received to evaluate the learning obtained with the MOVEIT materials.

Questionnaire

1. **How do the theoretical systems below define intellectual disability? Connect each one with the corresponding definition.**

ICD-10	A condition of arrested or incomplete mental development, characterized especially by the deterioration of skills manifested during the period of development, skills that contribute to the general level of intelligence, that is, cognitive, linguistic, motor and social skills.
DSM-5	The notion of IQ has been adopted as a significant statistical factor for an adequate diagnosis at the level of cognitive functioning.
ICF	In the recent version, the notion of mental retardation has been changed to the notion of 'Intellectual Development Disorder'.
WHO	Defines intellectual disability according to the interaction between the notion of activity limitation and deficiencies.

2. **How do the following models or theories define "Motivation?" Connect each one with the corresponding definition.**

Behavioral Theory of Behavior	The concept of self-efficacy plays a central role. People would have specific beliefs about themselves and their abilities to do something: these ideas would represent the background of each action and regulate motivation levels.
Bandura's motivation model	Motivation can be classified as not present, present thanks to intrinsic motivation (interesting, achievable in itself), present thanks to extrinsic and external motivation factors (e.g., specific rewards, positive feedback).
Self-Determination Theory	The concept of self-efficacy plays a central role. People would have specific beliefs about themselves and their abilities to do something: these ideas would represent the background of each action and regulate motivation levels.

3. Regarding DOMS (Delayed Onset Muscle Pain), indicate True (T) or False (F).

Regardless of the physical activity performed, it is not possible to prevent DOMS	T	F
Stop if you feel extreme pain	T	F
There are specific remedies for DOMS	T	F
One week is enough to increase the intensity level when we introduce a new exercise into the routine.	T	F
It is important to make soft progressions and alternate it with rest	T	F

4. Indicate whether the following images represent aerobic or anaerobic exercise.

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5. The following definitions of intellectual disability, what classification do they correspond to?

Mild	People with intellectual disabilities are slower in all areas of conceptual development, social skills and daily living. These people can learn practical life skills, allowing them to live independently with minimal levels of need for
Moderate	People with this intellectual disability usually have congenital syndromes with significant delays in all areas, cannot live independently and require close supervision and help in self-care activities. They have very limited ability to communicate and often have physical limitations.
profound	People with this intellectual disability have notable developmental delays and may have physical signs of impairment. Your self-care requires moderate support. They have good communication skills, but usually cannot communicate on complex topics. These people can take care of themselves, but they may need more instruction and support than the typical person.
Severe	People with this intellectual disability have the ability to understand speech, but otherwise have limited communication skills and can only communicate at the most basic levels. They cannot successfully live an independent life and will need to live in an occupational center.

6. In a muscle strengthening session, rank the following parts from 1 to 5 in order.

Return to calm and stretch _____

Cardiovascular exercise _____

Balance and coordination exercises _____

Warm-up_____

Muscle strengthening _____

7. **In the following situations when performing physical exercise, indicate whether it is more advisable to continue or stop the activity?**






ACTIVITIES

To find out if you have knowledge and are aware of the risks associated with technology and the use of exergames, complete the following activities.

Activity 1: Rate each item on a scale of 1 to 5, with 1 being strongly disagree and 5 being strongly agree.

Assistive technologies	
	I have basic knowledge of assistive technologies designed for people with intellectual disabilities.
	I can install and configure assistive devices or software.
	I know resources to learn more about assistive technologies.
Online security	
	I can identify common online threats, such as spam emails or suspicious websites.
	I know how to create strong and unique passwords.
	I am cautious about sharing personal information online.
Privacy	
	I know the privacy settings on social media platforms and adjust them as necessary.
	I understand the importance of obtaining consent before sharing photographs or personal information of people with disabilities online.
	I can explain the concept of digital footprint and its implications.
Ethical considerations	
	I can describe ethical considerations related to the use of technology in the context of people with disabilities.
	I am aware of the importance of respecting the autonomy and preferences of people with disabilities when using technology.

Activity 2: ICT Integration

Select a type of exercise	
	Fine motor skills
	Gross motor skills
	Aerobic capacity/endurance
Choose 2 or 3 types of technologies	
	Wearable sensors
	Apps
	Augmented reality
	Guided exercise
	Telemetry
	Serious Games
Identify business elements	
Item #1	
Item #2	
Item #3	
Develop a routine	

ANNEX II. Information Sheet

Title of the project: Development of a training program to improve the levels of activity and physical exercise of people with intellectual disabilities through exergames and technology (MOVE-IT).

Project information

With this document we give you information and invite you to participate in these pilot activities. Before deciding on your participation, read this document carefully and request any additional information you deem appropriate. It is important that you know and understand all aspects of the project.

You can withdraw your consent whenever you wish.

Tell us if you have questions or need more information. Feel free to ask questions about any aspect that will help you clarify your doubts about it.

PROJECT

People with intellectual disabilities tend to have lower levels of physical activity compared to the general adult population and have a higher incidence of obesity. Some estimates establish that 50% of people with intellectual disabilities follow a sedentary lifestyle, presenting a low level of physical activity in 40% of cases. Sedentary lifestyle and these low levels of physical activity lead to problems that affect Their independence.

MOVE-IT proposes an innovative methodology based on the implementation of applications and the development of a training program to improve the skills of staff and caregivers of people with intellectual disabilities, giving them the necessary skills to guide physical activity programs and use ICT to through exergames.

The objective of the project **MOVE-IT** is "*design and develop a combined education and intervention program to promote physical activity in people with intellectual disabilities both at home, in institutions or in the community through the use of technological exergames*".

Within the MOVE-IT project, these specific pilots have the objective of "*use the materials produced involving real end users (staff and people with intellectual disabilities) to evaluate the feasibility of the training course and provide recommendations for future exploitation*".

The MOVE-IT project is being developed within the ERASMUS+ 2021 PROGRAM. It started in November 2021 and will end in February 2024 (28 months).

The consortium that carries it out is made up of: Universitat Politècnica de València (coordinator), Institut Valencià de Serveis Socials (IVASS) (Spain), Cercioeiras (Portugal), ORAS Rehabilitation Center (Italy) and University of Tromso (Norway).

SELECTION OF PARTICIPANTS

We are inviting both people with intellectual disabilities and their professionals and caregivers to the pilots.

VOLUNTARY PARTICIPATION

Your participation in this research is completely voluntary. You can decide to participate or not.

COSTS AND FINANCING

The development of the pilot activities will not entail any financial cost to the participants. All costs will be covered by the project **MOVE-IT**, funded by the European Commission through the competitive call for ERASMUS + projects.

RISKS ASSOCIATED WITH RESEARCH

There are no physical or psychological risks during participation in this research.

RIGHT TO REFUSE OR WITHDRAW

You do not have to participate in that activity.

ANNEX III. Informed Consent

This activity in which you participate is operated by UPV SABIEN and whose registered address is Camino de Vera s/n, Edificio 8G. Access B, 1st floor, 46022 Valencia we are committed to protecting and preserving the privacy of participants when carrying out pilot activities within the framework of the MOVEIT project.

This policy sets out how we process personal data that we collect from you or that you provide to us through electronic means. We confirm that we will keep your information secure and fully comply with all applicable EU laws and regulations. Please read the following carefully to understand what happens to the personal data you choose to provide to us or that we collect from you when you visit this site. By participating or registering in project activities (our website) you are accepting and consenting to the practices described in this policy.

Types of personal information we may collect from you

We may collect, store and use the following types of personal information about people participating in project activities:

Information you provide to us. You can provide us with information about yourself by filling out forms on our website or on paper. This includes information you provide when you submit a contact/inquiry form. The information you provide to us may include your name, address, email address and telephone number and other personal information relating to your situation.

How may we use the information we collect?

We use information in the following ways:

Information you provide to us. We will use this information:

- To provide you with information and/or services that you request from us;
- To validate the activities that we have developed and are testing in these pilots.
- To report on the progress of the project activities to the consortium partners, the financing entity, and in dissemination and dissemination activities. No personally identifiable data will be included in the reports
- We may take photographs/videos of the activity for dissemination and reporting purposes. Any personal and sensitive information, such as faces, will be blurred.

Disclosure of your information

Any information you provide to us will be sent directly to us by email or stored on a secure server located in the EU. We use a trusted corporate website and hosting provider to facilitate project operation and management.

We do not rent, sell, or share personal information about you with other people or unaffiliated companies. We will use reasonable efforts to ensure that your personal data is not disclosed to regional/national institutions and authorities, unless required by law or other regulations.

Unfortunately, the transmission of information over the Internet is not completely secure. Although we will do our best to protect your personal data, we cannot guarantee the security of your data transmitted to our site; Any transmission is at your own risk. Once we have received your information, we will use strict procedures and security features to try to prevent unauthorized access.

Your rights: access to your personal data

You have the right to ensure that your personal data is processed lawfully ("Right of Access"). Your right of access can be exercised in accordance with data protection laws and regulations. Any request for access to a topic must be made in writing to anmarmil@itaca.upv.es. We will provide you with your personal data within the legal deadlines. To enable us to track any of your personal data we may have, we may need to request more information from you. If you have a complaint about how we have used your information, you have the right to lodge a complaint with the Information Commissioner's Office (ICO).

Changes to our privacy policy

Any changes we may make to our privacy policy in the future will be posted on this page and, where appropriate, notified to you by email. Please check back frequently for any updates or changes to our privacy policy.

Contact

Questions, comments and requests regarding this privacy policy are welcome and should be directed to Antonio Martínez Millana, anmarmil@itaca.upv.es.

Consent

Hereby, being informed about the activity and being aware about the use of my personal information, I voluntarily agree to participate and provide the requested information

Signature: _____

Date: _____