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Universidad del País Vasco
Euskal Herriko Unibertsitatea

CONTRIBUTIONS MADE BY PHYSIOTHERAPY TO THE DESIGN OF A GAME-BASED TECHNOLOGY SOLUTION AS THERAPY FOR IMPROVEMENT IN FRAILTY IN ELDERLY PERSONS

Iranzu Mugueta Aguinaga
2017

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“The important thing is not to stop asking questions”
A. Einstein

I see trees of green, red roses too
I see them bloom for me and you
And I think to myself what a wonderful world.

I see skies of blue and clouds of white
The bright blessed day, the dark sacred night
And I think to myself what a wonderful world.

The colors of the rainbow so pretty in the sky
Are also on the faces of people going by
I see friends shaking hands saying how do you do
But they're really saying I love you.

I hear baby's cry, and I watched them grow
They'll learn much more than I'll ever know
And I think to myself what a wonderful world.
Yes, I think to myself what a wonderful world.

Louis Armstrong.

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Iranzu Mugueta Aguinaga

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TABLE OF NOTATIONS

WHO	World Health Organization
FRADEA	Frailty y Dependence en Albacete
H-EPESE	Hispanic Stablished populations for Epidemiologic Studies of the Elderly
WHI-OS	Women´s Health Initiative Observational Study
SOF	Study of Osteoporotic Fractures
CSHA-CFS	Canadian Study of Health and Aging
FI	Frailty Index
BADL	Basic activities of daily living
ADL	Activities of daily living
IADL	Instrumental activities of daily living
PEP	recipitating Events Project
CGA-IF	Comprehensive Geriatric Assessment – Index of Frailty
WHAS	Women's Health and Aging Study
MSSA	MacArthur Study of Successful Aging
HDL	High Density Lipoprotein
IGF-1	Insulin-like growth factor 1
DHEA	Dehydroepiandrosterone
IL-6	Interleucina-6
CES-D	Center of Epidemiological Studies- Depression scale
BMI	Body mass index
TSHA	Toledo Study of Healthy Aging
GFST	Gérontopôle Frailty Screening Tool
FiND	Frail non-Disabled
SPPB	Short Physical Performance Battery
TUG	Timed Up and Go
FRAIL-NH	Frail-nursing home

ETUG	Expanded Timed Up-andGo
IEEE	Institute of Electrical and Electronics Engineers
EUGMS	European Union Geriatric Medicine Society
GFI	Groningen Frailty Indicator
WSN	Wireless sensor network
TAS	Threshold access sharing
PC	Personal computer
ICT	Information and communication technology
UPnP	Universal Plug and Play technology
ZWIP	Zorg- en Welzijns Info Portaal
ACRM	American Congress of Rehabilitation Medicine
ASNR	American Society of Neurorehabilitation
EVA	Ethylene vinyl acetate
SUS	System Usability Scale
HR	Heart Rate
HR MAX	` Heart Rate maximum
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
SpO2	Blood oxygen saturation
JIT	Just-in-Time
AOT	Ahead-of-Time
IDE	Integrated Development Environment
API	Application Programming Interface
EQ-5D-5L	European Quality of Life-5 Dimensions- 5 Levels
EQ-VAS	European Quality of Life-Visual analogue scale
FCT	Functional circuit training
RPE	Rating of Perceived Exertion

CHAFEA	Consumer, Health, Agriculture and Food Executive Agency
RCT	Randomized controlled trial

ABSTRACT

INTRODUCTION

According to the World Health Organization (WHO), it is estimated that there are more than 605 million people over 60 years of age in the world. The proportion of elderly persons will go on increasing over the coming decades – by the year 2025 it is estimated that there will be 1,200 million elderly persons throughout the world, and two out of every three will be living in developing countries.

The percentage of the population over 65 years old is projected to make up 18.2% of the total population in 2029 and 38.7% in 2064.

Spain is currently one of the countries in the world with the highest life expectancy, but when one speaks of life expectancy in terms of good health, the situation worsens in relation to other countries such as France, Sweden, Australia and Japan. For this reason, it is important to highlight the fact that living longer is not always a synonym for good quality of life and health.

Life expectancy at the time of birth in Spain is projected to reach 84.0 years in men and 88.7 in women by 2029, which is an increase of 4.0 and 3.0 years respectively. By 2064, if the current trend continues, the life expectancy of men would be over 91 years of age and nearly 95 in women.

Human ageing is a process that is characterized by the gradual loss of physical and cognitive capacities. Maintaining functional independence until the end of a person's life has been and remains the most ambitious goal pursued by geriatrics.

Despite accounting for a large sector of the population, there are gaps in our knowledge with regard to elderly persons. Specifically, there is a group of elderly persons who are on the edge of decline - what is referred to after 70 years of age as a frail elderly person.

The frailty in elderly persons has witnessed exponential growth in research and clinical practice in recent years, with there being consensus about the definition of frailty as a deregulated (potentially correctable or improvable) situation in many

biological systems, an accumulation of deficits, a reduction in physiological reserve and proneness to a range of adverse events.

Frailty is more related to biological age than to chronological age.

Frailty is currently defined as a biological clinical syndrome with a pathophysiological basis where multiple and interrelated body systems are affected. Such as process determines a decrease in the homeostatic reserve and the response to stressors, which causes an increase in vulnerability, being rehabilitated of disability and presentation of adverse health events.

Studying the phenomenon of frailty is also relevant because it is a powerful predictor of disability, hospitalization, falls, loss of mobility, cardiovascular disease and even mortality. Numerous studies have suggested that frailty is a detector of functional decline and mortality, and there are those that also show that the prevalence of frailty increases significantly as age increases, from 3.2% at 65 to 16.3% at 80 and 23.1% at 91 years of age.

As with the rest of the world, in Spain there are also a few studies on the prevalence of frailty in institutionalized settings, such as nursing homes. In the population of Cuenca, a 53.7% frailty rate, measured with the Fried's phenotype, was in their institutionalized settings.

Frailty is different from both comorbidity and disability, but they are all intimately interrelated. Both frailty and comorbidity predict disability. Disability can exacerbate frailty and comorbidity perfectly, and additionally the comorbidity of disease may favor the development of frailty. Fried et al. (2001) in the Canadian Health Study highlighted that the largest proportion of frail people are among those who are disabled.

Within the diagnosis of frailty, different evaluation tools may be described. On the one hand, there are numerous models of frailty in literature. An analysis of them has been made to conclude the model to be used in the present work. The model based on the appearance of functional impairment in the execution tests has been chosen because it presents more predictive capacity. Once the different indices and instruments for assessing and measuring frailty have been analyzed, the performance-based index Short Physical Performance Battery (SPPB) has been chosen because it is the instrument with

the highest predictive capacity. It allows the monitoring of the evolution of a subject over time. Additional technical material is not required.

In an ageing society it is necessary to establish new alternatives that may somehow try to meet the needs of elderly persons while increasing their perceived quality of life. In this respect, new technologies have become a basic tool in our society.

At present, many countries have a strong interest in having frail elderly people receive care in their own homes, trying to avoid unnecessary expense and institutionalization as much as possible and allowing them to live as independently as possible as long as possible.

Taking into account the above, it is necessary to create a technological solution. *In this way, this research intends to reduce the risk of frailty or, in the case where frailty already exists, decreasing the degree that is present.*

MATERIAL AND METHODS

After obtaining the approval of the Ethics Committee and permission from the management of the institutions where the study was to take place, informative talks and brochures were given to residents.

At the end of the diffusion period, 65 subjects showed interest. Of these, 46 subjects met the inclusion criteria.

Subjects who achieved the inclusion criteria (46) were cited to perform frailty screening tests with the Short Physical Performance Battery (SPPB) and to complete the EuroQol 5D-5L questionnaire. After frailty screening 40 subjects were classified according to age, sex, and Barthel Index, resulting in a study group (20) and a control group (20) of subjects respectively.

The sample proved to be homogeneous in terms of the age, sex, Barthel Index, frailty risk, EuroQol 5D-5L, and medical history of cardiovascular risk.

Two studies were proposed: ***Study 1: A pilot three-week randomized controlled trial (Phase 1)*** and ***Study 2: A pilot six-week randomized controlled trial with biofeedback (Phase 2)***

The following evaluation tests were used for both groups (study and control): the Short Physical Performance Battery (SPPB), Barthel Index, and EuroQol 5D-5L questionnaire. In addition, biofeedback has been recorded in the intervention group with the following physiological constants: systolic blood pressure, diastolic blood pressure, heart rate, and blood oxygen saturation. The study group also passed the scale of usability of the software to evaluate the game with another tool, in addition to the two simple questions that were daily asked.

RESULTS

Study 1: A pilot three-week randomized controlled trial (Phase 1)

- ***Results obtained from the short physical performance battery (SPPB) after 3 weeks***

By the third week, it was noted that the 19 (100%) subjects from the control group evidenced frailty risk, whereas the 20 subjects from the study group only evidenced 40% risk of frailty risk. The results confirmed the fact that 60% of subjects from the study group (12 of the 20 subjects) no longer evidenced frailty risk after the third week. Within the general framework, 85% (17 of the 20 subjects) of subjects from the study group showed some type of improvement in terms of their SPPB results.

On the other hand, in terms of game satisfaction, two questions were asked. As regards the first question, except on days 1 and 2 when there was a 10% percentage (2 subjects) and 5% (1 subject) respectively who gave a negative response, the 20 subjects from the study group responded YES on the other days. As regards the second question, except on days 1 and 2 when there was a 20% percentage (4 subjects) and 5% (1 subject) who gave a negative response, the 20 subjects from the study group responded YES on the other days.

Study 2: A pilot six-week randomized controlled trial with biofeedback (Phase 2)

- ***Results obtained from the short physical performance battery (SPPB) after 6 weeks***

By the sixth week, it was noted that 100% of subjects from the control group continued to evidence frailty risk, whereas only 5% of subjects from the study group evidenced this. No subject from the control group evidenced any improvement (increase

in score) in their SPPB results, whereas 100% of subjects from the study group evidenced improvements in their results after 6 weeks.

- ***Results obtained from the EuroQol 5D-5L after 6 weeks***

Analysing the difference in results in each group after 6 weeks, the mean EQ-5D-5L Index for the control group was less by 0.045, whereas in the study group the EQ-5D-5L Index produced a more stable mean (the mean of the differences was +0.012).

Analysing the difference in results in each group after 6 weeks, the mean EQ-VAS for the control group decreased (-12.63), whereas the EQ-VAS mean for the study group increased (12.05).

- ***Results obtained from the Barthel Index after 6 weeks***

The results obtained from the Barthel Index in the study group improved after 6 weeks with statistically significant evidence, with a value of $p < 0.003906$.

In contrast, the results obtained from the Barthel Index worsened in the control group after 6 weeks with statistically significant evidence, with a value of $p < 0.001952$.

- ***Results obtained from the compliance with suitable parameters to ensure that physical exercise is cardiac healthy and safe after 6 weeks***

1440 measurements were taken (4 physiological constants x 20 subjects x 18 days). Safety compliance of the exercise exceeded 87% in the 3 intervals and improved even more so as the days passed. Attention should be drawn to the fact that in no case was the activity abandoned due to physical discomfort.

- ***Results obtained from the Software usability scale (SUS) after 6 weeks***

The lowest score obtained was 70 while the highest was 100. The mean was 81.5. The results showed major acceptance in terms of usability of the FRED game among subjects from the study group.

- ***Results obtained from the game satisfaction after 6 weeks***

As regards the first question, except on days 1 and 2 when there was a 10% percentage (2 subjects) and 5% (1 subject) respectively who gave a negative response, the 20 subjects from the study group responded YES on the other days. As regards the second question, except on days 1 and 2 when there was a 20% percentage (4 subjects)

and 5% (1 subject) who gave a negative response, the 20 subjects from the study group responded YES on the other days.

DISCUSSION

The results, both in the 3-week feasibility study and in the 6-week follow-up support the hypothesis that FRED, exergame designed ad hoc, significantly reduced the presence and severity of risk for frailty in a sample of sedentary elders, thus potentially modifying their risk profile.

Authors like Cesari el al., Giné-Garriga et al., Clegg et al., Fairhall et al., Milte et al., Bieryla KA combine different types of physical activity which were performed over longer periods of time and at greater weekly frequency than the physical activity in our study using the FRED game. Although they manage to reduce frailty, they do so requiring far more time, and none of them contemplates exercise using an exergame. Only in the three previous ones is reference made to the EuroQol 5D-5L (EQ-5D-5L) questionnaire, in which no significant differences are shown, whereas with the FRED game, the study group remained stable after 6 weeks while the control group slightly worsened. Unlike the other two authors referred to above, the EuroQol-visual analogue scale (EQ-VAS) was recorded in the study, in which the control group worsened whereas the study group significantly improved. Furthermore, the degree of independence for activities of daily living also evidenced an improvement after 6 weeks carrying out physical activity using the FRED game. Therefore, the degree of frailty is able to be reduced in less time using the FRED game, while the perception of one's state of health and degree of independence in activities of daily living is much greater.

Regarding other studies such as the one made by Van Diest et al., used the exergame for unsupervised balance training at home - a virtual ice skater for 30 minutes, three times per week for six weeks. FRED game, highlights the ad hoc feature of FRED in terms of the design and putting together of exercises, placing importance on the types of scenario to ensure they are creative and intuitive and capture the subject's attention and interest.

As regards physiological constants such as heart rate, systolic blood pressure, diastolic blood pressure and blood oxygen saturation, there are no studies in the literature reviewed that have measured these constants in elderly people in order to

ascertain whether the physical exercise involved lies within certain safety parameters and whether it is in turn cardiac healthy.

CONCLUSIONS

The study undertaken confirms the fact that the FRED game proves to be a valid technological solution for reducing frailty risk.

Based on the study conducted, the exergame may be considered to be an effective, safe and entertaining alternative with which an improvement is made not only in terms of the physical and functional capacity of the individual, but also an improvement in psychological and social aspects which, in short, make the individual evidence a greater degree of independence over a longer time, i.e. “bring more life to the years”.

The present work brings to the scientific community a new approach in the use of games as therapy, since it stands out by the ad hoc design for a concrete profile of people, in this case frail elderly people.

This approach aims to direct the game as a therapy under the expert analysis of health professionals working within interdisciplinary groups can achieve really successful designs thus avoiding the use of standard games that are not designed specifically for health but for general leisure of the society.

This thesis has the first journal paper accepted which has been published in April 2017: Mugueta-Aguinaga I, Garcia-Zapirain B. Is Technology Present in Frailty? Technology a Back-up Tool for Dealing with Frailty in the Elderly: A Systematic Review[J]. A&D, 2017, 8(2): 176-195.

The game FRED is registered in the Copyright registry office of the Basque Government.

Collaboration in the SUNFRAIL European Project (Reference Site Network for Prevention and Care of Frailty and Chronic Conditions in community dwelling persons of EU countries). Project number: 664291. Funding Entity: CHAFEA Consumer, Health, Agriculture and Food Executive Agency.

The scale up of the English version of FRED in USA has already started. It presented the project Exercise Games with Biofeedback to Institutional Research Board and it has obtained the approval of the Ethical Committee from the University of

Louisville. Therefore, it will continue to be followed up until publishing the results in a journal paper. In addition, it has been necessary to pass the exams to obtain Human Subjects and HIPAA Research-Stage 1 - Basic Course which it was required from Collaborative Institutional Training Initiative (Citi Program) - Ethical Committee (University of Louisville).

Research Disclosure in USA: the research disclosure form is already under review and hopefully will be approved.

Attempt to present the project in every congress and day related to frailty in the elderly people, eg: Oral Communication in: XVI Congress of Zahartzaroa and IX Congress of the Navarre Society of Geriatric and Gerontology. Vitoria-Gasteiz, May 4-6, 2017.

The possibility of carrying out a study in the near future is under consideration, in which prevention of the onset of frailty could be studied.

RESUMEN

INTRODUCCION

Según la Organización mundial de la Salud (OMS), se estima que en el mundo hay unos 605 millones de personas de más de 60 años. La proporción de personas de edad seguirá aumentando durante las próximas décadas. Para el año 2025 se estima que habrá 1.200 millones de personas de edad en todo el mundo y dos de cada tres vivirán en países en desarrollo.

El porcentaje de población mayor de 65 años, que actualmente se sitúa en el 18,2% pasaría a ser el 24,9% en 2029 y del 38,7% en 2064.

Actualmente, España es uno de los países con mayor esperanza de vida en el mundo tras Japón, pero cuando se habla de esperanza de vida en buena salud, la situación empeora respecto a otros países como Francia, Suecia, Australia y Japón. Por esto, es importante señalar que añadir vida no siempre es sinónimo de buena calidad de vida y salud.

La esperanza de vida al nacer en España alcanzaría 84,0 años en hombres y 88,7 en mujeres en 2029, lo que significa un aumento de 4,0 y 3,0 años, respectivamente. Para el año 2064, si la tendencia actual continúa, la esperanza de vida en los hombres sería mayor de 91 años de edad y casi 95 en las mujeres.

El envejecimiento humano es un proceso que se caracteriza por la pérdida progresiva de las capacidades físicas y cognoscitivas, y el mantener la independencia funcional hasta el final de la vida, ha sido y continúa siendo la meta más ambiciosa de la geriatría.

A pesar de ser un gran sector de la población, existen lagunas de conocimiento en relación con los ancianos. En concreto hay un grupo de ancianos que se encuentran justo en el límite, al borde del deterioro, es lo que desde los años 70 se denomina anciano frágil.

La fragilidad en las personas mayores ha experimentado un crecimiento exponencial en la investigación y la práctica clínica en los últimos años, consensuándose la definición de fragilidad, como una situación (potencialmente

corregible o mejorable) de desregulación en múltiples sistemas biológicos, acumulación de déficits, disminución de la reserva fisiológica, y propensión a diversos eventos un adversos.

La fragilidad está más en relación con la edad biológica que con la cronológica.

Actualmente podemos definir la fragilidad como un síndrome clínico biológico a con base fisiopatológica donde se afecta múltiples e interrelacionados sistemas corporales un determinando disminución de la reserva homeostática y de la respuesta estresores, provocando un incremento de la vulnerabilidad, siendo rehabilitado de discapacidad y de presentación de episodios adversos de salud.

La fragilidad tiene una relevancia pronostica, anticipatoria, clínica, asistencial y epidemiológica. En gran medida, el interés generado por la fragilidad en los últimos años, estriba en que los sujetos frágiles tienen un riesgo elevado de eventos adversos sobre la salud a corto, medio y largo plazo.

La fragilidad es también relevante por ser un poderoso predictor de discapacidad, de hospitalización, de caídas, de pérdida de la movilidad, de enfermedad cardiovascular e incluso de mortalidad.

Hay diferentes estudios que demuestran que conforme aumenta la edad aumenta significativamente la prevalencia de fragilidad, desde 3,2% a los 65 años, 16,3% a los 80 años y 23,1% a los 90 años de edad.

Al igual que en el resto del mundo en España también hay pocos estudios realizados sobre la prevalencia de fragilidad en institucionalizados. Uno de ellos, en la población de Cuenca, se encontró un 53.7% de fragilidad en sus institucionalizados medido con el fenotipo de Fried.

Así pues la fragilidad es distinta tanto de comorbilidad como de discapacidad pero están íntimamente interrelacionadas. Tanto la fragilidad como la comorbilidad pronostican la discapacidad. La discapacidad puede exacerbar perfectamente la fragilidad y la comorbilidad, y la comorbilidad de las enfermedades puede favorecer, al menos de forma adicional, el desarrollo de la fragilidad. Fried et al. en 2001, ya apuntaban a esta distinción en su Canadian Health Study, resaltando que la mayor proporción de personas frágiles está entre las que se encuentran discapacitadas. Por

tanto, existe una alta probabilidad de encontrar una mayor proporción de personas frágiles entre las que están discapacitadas que entre las que no están discapacitadas.

Dentro del diagnóstico de fragilidad, se pueden encontrar descritas diferentes herramientas de evaluación. Por un lado, en la literatura existen numerosos modelos de fragilidad. Se ha realizado un análisis de los mismos para concluir el modelo a utilizar en el presente trabajo. El modelo basado en la aparición de deterioro funcional en las pruebas de ejecución ha sido el modelo elegido porque presenta más capacidad de predicción. Por otro lado, se encuentran también los índices e instrumentos de valoración y medida de la fragilidad. Una vez analizados los distintos índices e instrumentos de valoración y medida de la fragilidad, el índice basado en pruebas de ejecución: Short Physical Performance Battery (SPPB), ha sido el modelo elegido porque es el instrumento que presenta más capacidad de predicción, Permite monitorizar a lo largo del tiempo la evolución de un sujeto. No requiere material técnico adicional.

En una sociedad envejecida es necesario establecer nuevas alternativas que de alguna manera, traten de satisfacer las necesidades de las personas mayores, a la vez que incrementen su calidad de vida percibida. En este sentido, las nuevas tecnologías, se han convertido en una herramienta básica de nuestra sociedad.

Actualmente son muchos países los que tienen gran interés en que las personas mayores frágiles reciban atención en sus propios hogares, intentando evitar al máximo los ingresos e institucionalizaciones innecesarias y permitiendo vivir de la forma más independiente el máximo tiempo posible.

Teniendo en cuenta lo anterior, resulta necesario poder contribuir creando una solución tecnológica. De esta manera, se decide diseñar un juego cuyos contenidos sirvan para que las personas mayores puedan mejorar su capacidad física, mejorar su estado de salud e independencia en las actividades de la vida diaria, a través del juego en el que toman parte. De esta manera, se pretende reducir el riesgo de presentar fragilidad o en el caso de que la fragilidad ya existiera, mejorando el grado que se presente.

MATERIAL Y METODOS

Una vez obtenido el visto bueno del Comité de Ética y los permisos de la dirección de las residencies donde iba a tener lugar el estudio, se impartieron charlas informativas y folletos.

Al finalizar el periodo de difusión, 65 sujetos mostraron interés. De ellas, 46 sujetos cumplieron los criterios de inclusión.

Los sujetos que cumplieron los criterios de inclusión (46) fueron citados para realizar las pruebas de cribado de fragilidad con la Short Physical Performance Battery (SPPB) y para cumplimentar el cuestionario EuroQol 5D-5L. Los sujetos resultantes del cribado de fragilidad (40) fueron clasificados según rango de edad, sexo e Índice de Barthel. Resultando un grupo estudio (20) y un grupo control (20) de sujetos respectivamente.

La muestra ha resultado homogénea en cuanto al Índice de Barthel, edad, sexo e riesgo de fragilidad (Short Physical Performance Battery (SPPB), EuroQol 5D-5L y antecedentes cardiovasculares.

Se plantearon dos estudios: ***Estudio 1: Ensayo clínico controlado aleatorizado de 3 semanas (Fase 1)*** y ***Estudio 2: Ensayo clínico controlado aleatorizado de 6 semanas (Fase 2) con biofeedback***.

Se utilizaron los siguientes test de evaluación: la Short Physical Performance Battery (SPPB), Índice de Barthel y el cuestionario EuroQol 5D-5L para ambos grupos, estudio y control. En el grupo estudio además se registraron datos de biofeedback con las siguientes constantes fisiológicas: presión arterial sistólica, presión arterial diastólica, frecuencia cardiaca, saturación de oxigeno en sangre. Al grupo estudio también se le paso la escala de usabilidad del software para valorar el juego con otra herramienta, además de las dos sencillas preguntas que se les hacía a diario.

RESULTADOS

Estudio 1: Ensayo clínico controlado aleatorizado de 3 semanas (Fase 1)

Resultados de la Short Physical Performance Battery (SPPB) a las 3 semanas

A la tercera semana, se observó que los 19 (100%) sujetos del grupo control continuaron presentando riesgo de fragilidad, mientras que de los 20 sujetos del grupo

estudio, sólo presentaban riesgo de fragilidad el 40%. Los resultados confirmaron que el 60% de los sujetos del grupo estudio (12 de los 20 pacientes) ya no presentaba riesgo de fragilidad al finalizar la tercera semana. En el marco general, cabe destacar que, el 85% (17 de los 20 pacientes) de los sujetos del grupo estudio presentaron algún tipo de mejoría en sus resultados SPPB.

Por otro lado, en cuanto a satisfacción del juego, se realizaron dos preguntas. A la primera pregunta, excepto en los días 1 y 2 en los que hubo un porcentaje de 10% (2 sujetos) y 5% (1 sujeto) respectivamente que respondieron de forma negativa. El resto de los días, los 20 sujetos del grupo estudio respondieron SI. A la segunda pregunta, excepto en los días 1 y 2 en los que hubo un porcentaje de 20% (4 sujetos) y 5% (1 sujeto) respectivamente que respondieron de forma negativa. El resto de los días, los 20 sujetos del grupo estudio respondieron SI.

Estudio 2: Ensayo clínico controlado aleatorizado de 6 semanas (Fase 2) con biofeedback

- ***Resultados a las 6 semanas de la Short Physical Performance Battery (SPPB)***

A la sexta semana, se observó que el 100% de los pacientes del grupo control continuaron presentado riesgo de fragilidad, mientras que solo el 5% de los pacientes del grupo estudio presento riesgo de fragilidad. Ningún paciente del grupo control presento una mejora (aumento de puntuación) en sus resultados SPPB, mientras que el 100% de los pacientes del grupo estudio presento mejoras en sus resultados SPPB en el transcurso de 6 semanas.

- ***Resultados a las 6 semanas del EuroQol 5D-5L***

Analizando la diferencia de los resultados en cada grupo después de 6 semanas, en el grupo control en el EQ-5D-5L Index promedio es menor para 0.045, mientras en el grupo de estudio el EQ-5D-5L Index en promedio manchado más estable (La media de las diferencias es +0.012).

Analizando la diferencia de los resultados en cada grupo después de 6 semanas, se observó que la media del EQ-VAS del grupo control disminuyó (-12.63), mientras que la media del grupo estudio el EQ-VAS aumentó (12.05).

- ***Resultados a las 6 semanas del Índice Barthel***

Los resultados del Índice Barthel en el grupo estudio mejoraron después de 6 semanas con evidencia estadísticamente significativa, con un valor $p < 0.003906$.

En cambio, los resultados del Índice Barthel en el grupo control empeoraron después de 6 semanas con evidencia estadísticamente significativa, con un valor $p < 0.001952$.

- ***Resultados a las 6 semanas en relación al cumplimiento del ejerccio de forma segura y cardiosaluble***

Se realizaron 1440 mediciones (4 constantes fisiológicas x 20 sujetos x 18 días). En los tres intervalos el cumplimiento de seguridad del ejercicio físico superó el 87%, e incluso fue mejorando a medida que avanzaron los días. En ningún caso se abandonó la actividad por malestar físico.

- ***Resultados a las 6 semanas de la usabilidad del software [(Software usability scale (SUS)]***

La puntuación más baja fue de 70 mientras que la más alta fue 100. La media fue de 81.5. Este valor indica un buen resultado en el cuestionario SUS.

- ***Resultados a las 6 semanas de la satisfacción del juego***

A la primera pregunta, excepto en los días 1 y 2 en los que hubo un porcentaje de 10% (2 sujetos) y 5% (1 sujeto) respectivamente que respondieron de forma negativa. El resto de los días, los 20 sujetos del grupo estudio respondieron SI. A la segunda pregunta, excepto en los días 1 y 2 en los que hubo un porcentaje de 20% (4 sujetos) y 5% (1 sujeto) respectivamente que respondieron de forma negativa. El resto de los días, los 20 sujetos del grupo estudio respondieron SI.

DISCUSION

Los resultados, tanto en el estudio de factibilidad de 3 semanas como en el seguimiento realizado durante 6 semanas apoyan la hipótesis de que FRED, exergame diseñado ad hoc, reduce significativamente la presencia y gravedad del riesgo de fragilidad en una muestra de ancianos sedentarios, modificando potencialmente su perfil de riesgo.

Autores como Cesari el al., Giné-Garriga et al., Clegg et al., Fairhall et al., Milte et al., Bieryla KA han presentado trabajos en los que combinan distintos tipos de actividad física, realizada durante periodos de tiempo y frecuencia semanal superior a la actividad física realizada en nuestro estudio, a través del juego FRED. Aunque consiguen disminuir la fragilidad, lo consiguen precisando mucho más tiempo. Ninguno de ellos, contempla la realización de ejercicio físico utilizando exergame. Sólo en tres de los anteriores, se hace referencia al cuestionario EuroQol 5D-5L (EQ-5D-5L), donde no se muestran diferencias significativas mientras que con el juego FRED, al finalizar las 6 semanas, el grupo estudio permaneció estable mientras que el grupo control se deterioró ligeramente. Pudiendo añadir también en relación al EuroQol-Escala Visual Analógica (EQ-VAS), porque a diferencia de los otros autores anteriormente citados, si se registró en el estudio, que el grupo control empeoro mientras que el grupo estudio mejoro notablemente. Por otra parte, el grado de independencia para las actividades de la vida diaria, presento también una mejoría notable tras las 6 semanas realizando ejercicio físico con el juego FRED. Por tanto, con el juego FRED se consigue reducir el grado de fragilidad en menos tiempo y a su vez la percepción del estado de salud y grado de independencia en las actividades de la vida diaria es mucho mayor.

En relación con otros estudios como el dirigido por Van Diest et al., que utilizó como exergame para el entrenamiento sin supervisión del equilibrio en el hogar – con un patinador de hielo virtual, durante 30 minutos, tres veces por semana durante seis semanas. Esta conclusión, resalta sin duda la característica ad hoc de FRED en cuanto al diseño y elaboración de los ejercicios, dando importancia al tipo de escenarios para que sean creativos e intuitivos y capten la atención y el interés del sujeto.

En relación al biofeedback mediante el registro de los signos vitales tales como: frecuencia cardiaca, presión arterial sistólica, presión arterial diastólica y saturación de oxígeno en sangre, no hay en la literatura revisada, estudios que hayan recogido los signos vitales de personas mayores frágiles con el objetivo de comprobar que el ejercicio físico realizado se encuentra dentro de unos parámetros de seguridad y que a su vez es cardiosaludable. Los estudios que se han encontrado al respecto son muy diversos. En el juego FRED el control del biofeedback se realizó teniendo en cuenta 4 signos vitales, los cuales facilitaron información para asegurar que el ejercicio se realizaba dentro de parámetros seguros y cardiosaludables.

CONCLUSIONES

El estudio realizado confirma que el juego FRED es una solución tecnológica válida para disminuir el riesgo de fragilidad y prevenir su aparición.

En base al estudio realizado, se puede considerar el exergame como una herramienta alternativa segura, divertida con la que se logra mejorar no sólo la capacidad física y funcional del individuo, sino que también consigue mejorar los aspectos psicológicos y sociales, que en definitiva, hacen que el individuo presente mayor grado de independencia durante más tiempo. Esto es, "dar más vida a los años".

El presente trabajo aporta a la comunidad científica un nuevo enfoque en el uso de los juegos como terapia, puesto que destaca por el diseño ad hoc para un perfil concreto de personas, en este caso las personas mayores frágiles.

Este enfoque pretende dirigir el juego como terapia bajo el análisis experto de profesionales sanitarios que trabajando dentro de grupos interdisciplinares pueden lograr diseños realmente exitosos evitando de este modo, el uso de juegos estándar que no están diseñados específicamente para la salud, sino para el ocio general de la sociedad.

Con este trabajo se ha realizado la siguiente publicación y otras dos publicaciones enviadas en proceso de ser aceptadas: Mugueta-Aguinaga I, Garcia-Zapirain B. Is Technology Present in Frailty? Technology a Back-up Tool for Dealing with Frailty in the Elderly: A Systematic Review[J]. A&D, 2017, 8(2): 176-195.

El juego FRED está inscrito en el registro de la propiedad del Gobierno Vasco.

Colaboración en el Proyecto Europeo SUNFRAIL (Red de Referencia para la Prevención y Atención a la Fractura y Condiciones Crónicas en las personas que viven en la comunidad de los países de la UE). Número de proyecto: 664291. Entidad Financiadora: Agencia Ejecutiva CHAFEA, Consumo, Salud, Agricultura y Alimentación.

Actualmente, se ha comenzado la ampliación de la versión inglesa de FRED en USA. Se ha presentado el proyecto Exergames con Biofeedback a la Junta de Investigación Institucional y se ha obtenido la aprobación del Comité de Ética de la Universidad de Louisville. Por lo tanto, se continuará en el seguimiento hasta la

publicación de los resultados. Además, ha sido necesario aprobar los exámenes para obtener los certificados de Investigación Humana y la Investigación HIPAA-Etapa 1 - Curso Básico que fue requerido por el Comité de Ética (Universidad de Louisville) de Iniciativa Institucional de Formación Colaborativa (Programa Citi).

Patente en USA: el formulario de solicitud de patente en USA, se ha presentado, se encuentra en proceso de revisión, pendiente de aprobación.

Gran interés por presentar el proyecto en cada congreso relacionado con la fragilidad de las personas mayores, p.ej.: Comunicación Oral en: XVI Congreso de Zahartzaroa y el IX Congreso de la Sociedad Navarra de Geriatria y Gerontología. Vitoria-Gasteiz, 4-6 Mayo 2017.

La posibilidad de realizar un estudio en un futuro próximo, en el que se pueda estudiar la prevención de la aparición de la fragilidad.

PREFACE

The enclosed document is the result of many years work on my Ph.D in the Department of Neuroscience in the Faculty of Medicine and Nursing in the University of the Basque Country (UPV/EHU).

The development of software that has been created and designed in the PHD otherwise known as game FRED has been partly funded by Emakor through Beaz and has been carried out by a group in Deusto University called eVIDA.

The document presents the introduction, which is divided into two important areas, the medical history and technological history. To do this various bibliographic searches were carried out and the most relevant information has been taken and used. Following this a hypothesis has been formulated with investigative questions and their objectives. Then we have described the methods and materials that have been used, and explained the results found, comparing them to other authors. Finally the conclusion will be presented and discussed.

At the end of the document you will find the references used and the annex containing complimentary material that has been used in the thesis and in the investigative project.

"I believe in innovation and that the way you get innovation is you fund research and you learn the basic facts".
Bill Gates

1. *INTRODUCTION*

1 INTRODUCTION

Nowadays, frailty in our modern-day society, is a top-rated question. At the international level, it is considered a strategic line.

For this reason, in 2013, six major international (International Association of Gerontology and Geriatrics; Society on Sarcopenia, Cachexia, and Wasting Diseases; and the International Academy of Nutrition and Aging), European (European Union Geriatric Medicine Society), and US societies (American Medical Directors Association and American Federation for Aging Research) provided delegates to attend a consensus meeting. Based on this consensus, a preliminary manuscript was developed and whose title said: ”Frailty Consensus: a call to action” [1].

1.1 Medical background

Frailty represents an important challenge for aging populations. Pragmatically, at some point, the number of physical and psychological ailments people have becomes more important than the exact nature of those ailments, at least with respect to what they need and how their medical care is best administered. This is so even though, for subjects, it will always be important to know what exactly is wrong. Still, at some point, understanding the complexity of needs in frail people entails knowing exactly what is wrong, which is best achieved by allowing complexity to be embraced. This approach of embracing complexity by looking at measures of whole-system function (cognition, mobility, balance, independence in daily activities) is in contrast to the “problem list” method, a long and widely used approach in medicine.

1.1.1 Search keys

Taking into account the above, it is interested in establishing knowledge about the frailty: concept, definition, relevance, prevalence, risk factors, evaluation tools, relationship between frailty, function, disability and morbidity, among others.

It decided to conduct a search by way of a review from January 2005 to December 2015, in the course of which two databases were consulted:

- ***OVID Medline <1946 to December week 4 2015>***
- ***EMBASE via OVID < 1974 to 2015 week 53>***

The two previous databases include Pubmed Open Access

The search was undertaken in accordance with the following strategy, owing to the features of the databases selected:

(1) Medline and EMBASE: natural language and using the following keywords: frailty, elderly people, diagnosis, evaluation tool, risk factor, prevalence, functionality, disability, morbidity.

- Filters: date (2000-2015), language (English)

The following results were obtained from the review: (Figure 1)

- OVID Medline <1946 to December week 4 2015>: n=175
- EMBASE via OVID < 1974 to 2015 week 53>: n=152

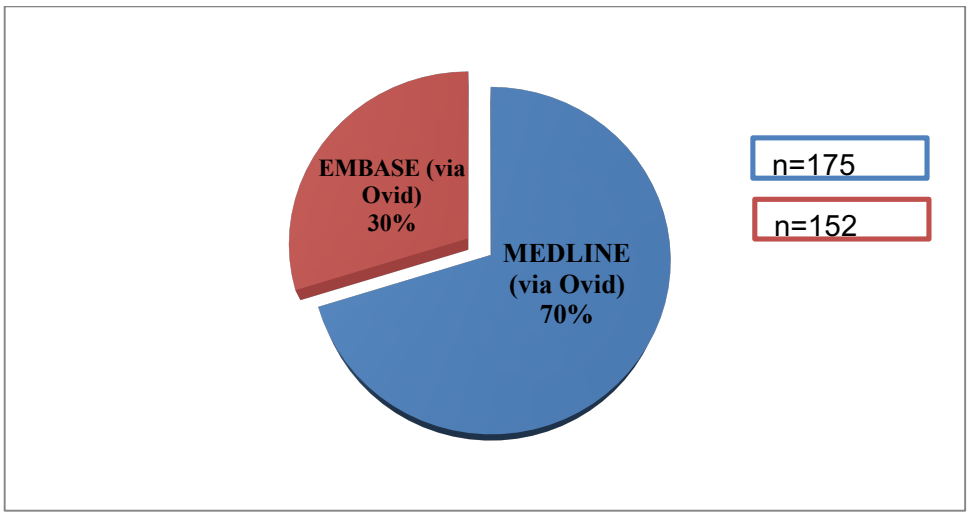

Figure 1. Percentage of results according to the data base reviewed.

Inclusion criteria: Articles that deal with information in relationship with frailty.

Exclusion criteria: Articles that do not deal with information in relationship with frailty.

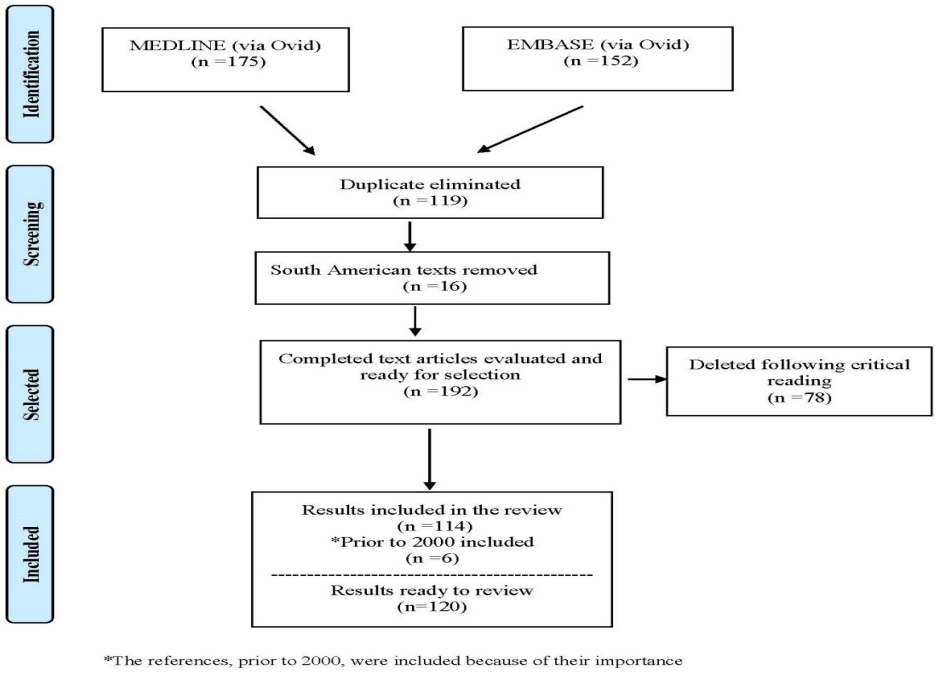

Figure 2. Flow Diagram. Strategy carried out in this review.

The 120 documents were analyzed meticulously so as to classify their content. Thus, the following terms related to frailty were the ones mainly observed: frailty, elderly people, diagnosis, evaluation tool, risk factor, prevalence, functionality, disability, morbidity.

Right after, the strategy and result of this search is shown.

1.1.2 Frailty concept

According to the World Health Organization (WHO), it is estimated that there are more than 605 million people over 60 years of age in the world. The proportion of elderly persons will go on increasing over the coming decades – by the year 2025 it is estimated that there will be 1,200 million elderly persons throughout the world and two out of every three will be living in developing countries [2].

The percentage of the population over 65 years old, which currently stands at 18.2% in 2029 and 38.7% in 2064 [2].

Spain is currently one of the countries in the world with the highest life expectancy after Japan, but when one speaks of life expectancy in terms of good health, the situation worsens in relation to other countries such as France, Sweden, Australia and

Japan. For this reason, it is important to highlight the fact that living longer is not always a synonym for good quality of life and health [3].

Life expectancy at the time of birth in Spain would reach 84.0 years in men and 88.7 in women by 2029, which means an increase of 4.0 and 3.0 years respectively. By 2064, if the current trend continues, life expectancy in men would be over 91 years of age and nearly 95 in women [2].

Human ageing is a process that is characterized by the gradual loss of physical and cognitive capacities, and maintaining functional independence until the end of one's life has been and remains the most ambitious goal pursued by geriatrics [4].

Despite accounting for a large sector of the population, there are gaps in our knowledge with regard to elderly persons. Specifically, there is a group of elderly persons who are just on the limit, on the edge of decline - what is referred to after 70 years of age as a frail elderly person.

There is no consensus as to the definition of "frail"; it is sometimes referred to as "vulnerable," "incapable," "weak," "at-risk elderly." However, the importance of reaching a consensus is fundamental since it is impossible to pose a solution to problems without knowing exactly what health professionals understand by "frail," "elder" or "frailty." Obtaining consensus on the concept of frailty could help to propose preventive measures and actions to prevent frail populations' deterioration and to promote their independence.

There has been little evaluation of management strategies, diagnostic tools, frailty assessment scales, etc. Without properly investigating the current protocol for frailty diagnosis and subsequent management practices, it cannot be known whether the current methods are as effective as possible.

Authors such as Ho, Williams and Hardwick [5] estimate that primary prevention of age-related impairment can occur in up to 50% of the elderly, if diagnostic tools or risk indicators are obtained.

Therefore, the identification of risk factors, causes, markers and / or predictors of frailty could be useful in the diagnosis of frailty in the elderly and, as a consequence,

this would mean an improvement in their quality of care and creation of preventive measures suitable.

1.1.3 Frailty definition

Since the 1990s many concepts of frailty have been proposed.

According to the classic Brocklehurst frailty model[6,7], this was understood as a cause or risk of losing the ability to continue living in the community. In other words, frailty was understood as the precarious balance between the state of health and the health and social resources that are needed to keep the individual at home. The breakdown of this delicate balance can lead to dependency, institutionalization and, later, death.

In the 1990s, the Barber questionnaire was important because it directed the development of clinical studies in our environment towards social vulnerability [8,9].

The frailty in elderly persons has witnessed exponential growth in research and clinical practice in recent years, with there being consensus about the definition of frailty as a deregulated (potentially correctable or improvable) situation in many biological systems, accumulation of deficits, a reduction in physiological reserve and proneness to a range of adverse events[10,11].

Frailty is more related to biological age than to chronological age [12-14].

At present frailty can be defined as a biological clinical syndrome with a pathophysiological basis where multiple and interrelated body systems are affected, determining a decrease in the homeostatic reserve and the response to stressors, causing an increase in vulnerability and presentation of adverse health events [15].

Recent international consensus defines physical frailty as a major «medical syndrome with many causes and contributors that is characterised by a reduction in strength, resistance and biological function that increases individual vulnerability leading in turn to greater dependency and/or death»[1].

Numerous studies have suggested that frailty is a detector of functional decline and mortality [8-10], and there are those that also show that the prevalence of frailty increases significantly as age increases, from 3.2% at 65 to 16.3% at 80 and 23.1% at 91 years of age [16-18].

Until very recently, the research on frailty has been a slow process due to the absence of a valid definition. Two great references in this field arose: first, Linda P. Fried's model in 2001 [19], the model in which the phenotype developed as a risk situation for developing disability. Second, Kenneth Rockwood's model [20-22], a multidomain model, states that frailty consists of several health conditions including geriatric syndromes and disability measures, with 70 items, later grouped on a hierarchical scale.

The most used and validated definition is the application of the phenotype described by Linda Fried in the Cardiovascular Health Study [19,21]. It holds that a subject is frail if it meets three or more criteria, pre frail if it meets one or two criteria and non frail if it does not fulfill any criteria. The criteria have shown good validity in different cohorts of the elderly. In decreasing order of frequency, the most permanent aspects of frailty in the community are weakness, slowness, low activity, exhaustion, and weight loss. The criterion that was most strongly associated with the development of frailty in non-frail subjects was weight loss, followed by exhaustion, weakness, low activity and slowness [23].

1.1.4 Relevance of frailty

Frailty has a prognostic, anticipatory, clinical, care and epidemiological relevance [24]. To a large extent, the interest generated by frailty in recent years is that frail subjects have a high risk of adverse health events in the short, medium and long term. It is also verified that frailty is a predictor of mortality as demonstrated in the FRADEA study [25]. In the Hispanic Established Populations for Epidemiologic Studies of the Elderly (H-EPESE) study, 84% of the subjects labeled as frail died during the 10 years of follow-up, whereas during the same period, only 33% of the non frail people died. [26]. This relationship with mortality was also made objective by Fried, [19] in the Women's Health Initiative Observational Study (WHI-OS)[27] and by Ensrud in the Study of Osteoporotic Fractures (SOF) [28].

Frailty is also relevant because it is a powerful predictor of disability [19,28-30], hospitalization [19,29], falls [19,28], loss of mobility [19,31] and cardiovascular disease[32].

It should be noted that only a small minority of subjects with "multimorbidity" and multiple chronic diseases are frail. In the Canadian Health Study [19], only 9.7% of the

adults with "multimorbidity" were frail while 67.7% of the frail had "multimorbidity" among the 9 pathologies considered [19], which were: acute myocardial infarction, angina pectoris, heart failure, peripheral artery disease, arthritis, cancer, diabetes, hypertension and chronic obstructive pulmonary disease. The average number of pathologies that a frail subject suffers from is 2.1, compared to 1.4 among non-frail adults [33]. These findings suggest that the mechanisms that lead to frailty are not the same as those that lead to chronic diseases, unless they are in a severe-advanced stage or through interrelations between the different pathophysiological mechanisms of the pathologies interacting with each other. One of these mechanisms would not be a "precipitator" of frailty, except in very advanced stages [34]. Table 1 lists the chronic diseases associated with frailty published in different cohort studies [19,27,35,36].

PREVALENCE				
	WOMEN		TOTAL	
Chronic diseases	FRAIL	NON FRAIL	FRAIL	NON FRAIL
Hipertension	60.8	43.4	50.8-53.1	34.0-38.8
Chronic renal failure	54.3	42.5	--	--
Osteoarthritis	78.2	48.1	25.9-70.8	9.7-44.8
Depressive symptoms	46.3	13.3	--	--
Coronary heart disease	17.2-41.5	5.8-20.8	--	--
Diabetes mellitus	9.9-21.3	2.6-12.1	13.6-25.0	10.0-12.1
Chronic obstructive pulmonary disease	9.8-15.5	2.5-4.3	12.3-14.1	7.4-5.8
Acute myocardial infarction	--	--	8.6-13.3	4.4-7.3
Rheumatoid arthritis	6.4	1.6	--	--
Ictus	4.4	1.1	12.3	3.8
Peripheral arterial disease	--	--	3.8-14.8	1.5-5.6
Congestive Heart Failure	3.5	0.6	12.3-13.6	2.0-3.6

Table 1. Association of chronic disease with frailty in women and in general. Source: [34]

1.1.5 Prevalence of frailty in elderly people

Numerous studies have suggested that frailty is a detector of functional decline and mortality [8-10], and there are those that also show that the prevalence of frailty increases significantly as age increases, from 3.2% at 65years to 16.3% at 80 years and 23.1% at 91 years of age [37].

Different studies with a population of 61,000 elderly people over 65 years show results of 10.7% prevalence of frailty, that is higher in women while they age, which become greater than 25% when the women are over 85 years. Another no less important fact is the prevalence of pre-frailty, that is, the risk of becoming frail in the next two years, which is around 40-50% in the elderly. The importance of these striking figures on frailty does not lie in their high prevalence (800,000 frail elderly people in Spain and

more than three million pre-frail ones), but rather in their role as independent risk factors for adverse events. [11,25,38,39].

The frailty and dependence study in Albacete (FRADEA) has shown that, in comparison to the average-aged population, the frailty factor in populations of people over 70 years of age: implies an adjusted risk of mortality 5.5 times higher, a risk of new disability 2.5 times greater, and a risk of loss of mobility 2.7 times greater. In this same study it was objectified that frailty is associated with older age, female gender, higher disease burden, disability and cognitive function, among other factors. It must be taken into account that being frail is a state of pre-disability, which begins at an advanced age and closer to the end of life. This state of pre-disability can be prevented and treated, helping individuals to age with a better quality of life [11]. In the case of the studies conducted in Spain, six longitudinal cohorts pinpoint the prevalence of frailty in different proportions according to age groups and the criteria used to measure it. (Figure 3)

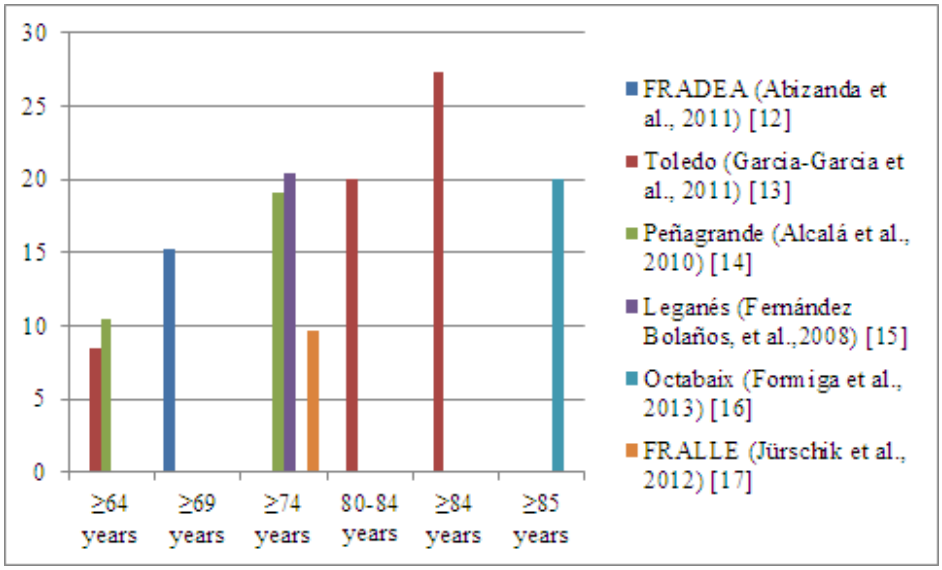

Figure 3. Prevalence of frailty in Spain. Data from cohorts of longitudinal aging studies in Spain.

Only two studies in Spain [39,40], two in Canada [41,42], and one in Poland [43], have included the institutionalized, with a prevalence between frailty of 29.2 and 53.7%. The number of institutionalized older adults in Spain is 212,475 [44], 4.7% of the Spanish population. The elderly population of the institutions is quite heterogeneous, with variable rates of disability, multi-morbidity and quality of life [45]. The detection of frailty could be useful for the better management of institutionalized subjects and to try to reverse that frailty. A number of studies have investigated similar institutionalized populations. One of the first that analyzed the frailty of the institutionalized residents

was carried out in Canada. This cohort consisted of older adults (87.7 +/- 6.7 years), 83% of whom were disabled and 83% of whom exhibited a high level of deterioration of mobility. For their study cardiovasculary health study, Rockwood et al.[42] describe frailty using the clinical scale of frailty (CSHA-CFS and Frailty Index (FI)), which characterizes frailty as an increased risk of mortality, disability and cognitive impairment. In Alberta, another study conducted in Canada, researchers using Fried's frailty criteria, identified the prevalence of frailty at 48% [41].

In Poland the prevalence of frailty was 34.9% according to the frailty clinical scale (CSHA-CFS).

As in the rest of the world in Spain there are also few studies on the prevalence of frailty among the institutionalized. One of them found a 53.7% frailty measured with Fried's phenotype in the institutionalized population of Cuenca [40]. Another study carried out in Albacete population in 2 residential settings with a sample of 332 subjects whose median age was 84 observed a prevalence of frailty of 68.8% and of 28.4% pre-frail and 2.8% non-frail [45]. In the different national and international studies, a high prevalence of frailty in relation to non-institutionalized people is seen, so it would be interesting for more studies to investigate a better intervention in this population.

Institutionalized older adults are a heterogeneous population in the rates of disability, multi-morbidity, quality of life, and vulnerability. Interventions in this population should be individualized. Detection and treatment of frailty could be useful in preventing disability, decreased mobility, falls, and mortality [41]. However, due to the scant studies on frailty specially designed for institutionalized older adults, many questions remain unresolved [46-48].

1.1.6 Factors in risk of frailty

There are publications that review the diseases and risk factors that condition frailty [49], however they do not clearly differenciate between predictors of frailty and its consequences.

In the CHSA-CFS [19], the predictors could be classified according to the damages in different organs and systems as well as in the pathologies that could be risk factors. The damages in different organs and systems include: cognitive impairment (with or without dementia), alteration of sense organs and language, sphincter incontinence, inability to perform the basic activities (instrumental or not) of daily living (BADL), poor balance and mobility problems which may be in relation to falls and fractures,

pathologies derived from cardiovascular problems (acute or chronic myocardial infarction, arrhythmias, peripheral vasculopathies, congestive heart failure, hypertension, angina), gastrointestinal diseases, renal diseases, musculoskeletal system diseases (arthritis, musculoskeletal problems, bursitis, rheumatism), respiratory system or malignant diseases, social isolation associated with or without psychological problems and memory problems, changes in behavior and sleep alterations, and nutrition and dental problems. Among the pathologies predictive of frailty, Fried pointed out the following: arterial hypertension, congestive heart failure, angina, arthritis, cancer, diabetes, peripheral vascular disease, and myocardial infarction.

Using the GSS91 scale a predictor index was developed by McDowell in 2001 in the context of a prospective cohort study tracking 8,949 elderly people for 7 years. The index included the following conditions: high blood pressure, heart problems, diabetes, arthritis, bursitis or rheumatism, respiratory problems, skin problems or allergies, digestive problems or stomach ulcers, migraine, elevated cholesterol, emotional problems, vision, hearing, and language comprehension [50].

After thar, Fried with other authors, developed a classification of possible risk factors for frailty, including: physiological factors, activated inflammation, immune system dysfunction, anemia, endocrine system abnormality, being overweight or underweight, age, comorbidity or medical condition, cardiovascular disease, diabetes, stroke, arthritis, chronic obstructive pulmonary disease, cognitive impairment, cerebral changes, socio demographic and psychological aspects, female gender, low socioeconomic status, race, depression, and disability in activities of daily living (ADL) [51].

Using the Rockwood frailty index, the CHSA-CFS [22] obtained as results, that it is more frequent to present high score in their frailty scale the women who have cognitive alteration and incontinence, mobility problems, impairment in the functionality for ADL, and associated comorbidity. They added that high levels of frailty were associated with fewer falls, probably because a high proportion were bedded.

Baztán Cortés in 2006, collects criteria of frailty used by other authors such as Hammerman, Ferrucci and Rockwood to use as risk factors of frailty. These were: advanced age (> 80/85 years), female sex, atypical presentation of diseases, dependence on others for Activities of daily living (ADL), high risk of dependence, and other

adverse health outcomes, reduction of physiological reserve, presence of chronic diseases, comorbidity and polypharmacy, presence of complex medical and psychosocial problems, presence of geriatric syndromes (falls, incontinence, delirium, malnutrition)[52].

1.1.7 Relationship between frailty, function, disability and morbidity

The terms frailty, comorbidity, function (and the consequence of their loss, disability) are often used interchangeably to identify the physically vulnerable subset of older adults requiring specialized health care. However, from the point of view of geriatrics they are different clinical entities, although interrelated ones. Each one has a great clinical significance and clinical treatment because they have their own contents and challenges. Therefore, each one presents itself individually.

Disability is defined as a difficulty or dependency in performing the essential activities of an independent life, including basic activities of daily living (BADL) and Instrumental activities of daily living (IADL). The World Health Organization recommends measuring the health of the elderly in terms of function, and more specifically in terms of loss of function. The degree of health of the elderly will be better or worse depending on their functional situation--that is, in relation to the greater or lesser degree of disability or dependence [53]. The Council of Europe's recommendation adopted in September 1998 defines dependency as "the need for assistance or important assistance for activities of daily living"--or, more precisely, "a state in which people need assistance and/or important assistance in order to carry out the ordinary acts of daily life, and in particular, those related to personal care" because of reasons related to lack or loss of physical, mental or intellectual autonomy. It is an adverse result in health and it is an important predictor of dependence, mortality, hospitalization, and need for social care as well as frailty, without being the same as frailty. The Spanish population over 65 years old in 2050 will be around 32% of the total population [2]. This segment of the population has a high rate of disability and dependence, which is around 30%, with different degrees of severity[54]. Disability in Spain is more prevalent among those over 80 and among women [55].

Functionality includes two major domains, functional limitations as the difficulty to perform motor tasks by themselves, and the disability as limitations in performing defined social roles and tasks within a physical and socio-cultural environment [56,57].

Functional limitations act as "bricks of activities"[58], because they are the basic motor and non-motor elements that allow the complex functions of the human being to be performed (mobility, learning, memories, vision, hearing and communication), although they are not enough by themselves to explain all the functionality since they do not take into account the interaction between individual and environment [59]. The evaluation of both domains in functional assessment has been demonstrated to identify elderly at risk, to characterize the progression towards dependence and to understand the appropriate moments to establish effective interventions [58]. Most of the indices used to assess frailty include functional items or elements that assess disability [19,22].

Finally, comorbidity is defined as the presence of two or more diseases diagnosed from the medical point of view in the same individual, with the diagnosis of each disease based on pre-established and known criteria, this has been associated with frailty, although they are not the same, since between 32% and 72% of frail elderly in the community do not present comorbidity [19,39] (Figure 4).

The frailty is different from both comorbidity and disability but they are intimately interrelated. Both frailty and comorbidity predict disability. Disability can exacerbate frailty and comorbidity perfectly, and the comorbidity of disease may favor, at least in an additional way, the development of frailty. Fried et al. in 2001, in the Canadian Health Study, highlighted that the largest proportion of frail people are among those who are disabled [19].

The CHS indicates that the presence of disability or frailty could favor the development or progression of chronic diseases, possibly through the lower levels of activity associated with the two previous conditions or through other pathways that affect some fundamental biological mechanisms essential for the maintenance of homeostasis, such as inflammation or balance between sympathetic and parasympathetic [60,61].

This causal relationship justifies the frequent presence of these conditions and indicates the clinical importance of differentiating them in order to identify the appropriate interventions that could avoid a condition, since its precursor is present.

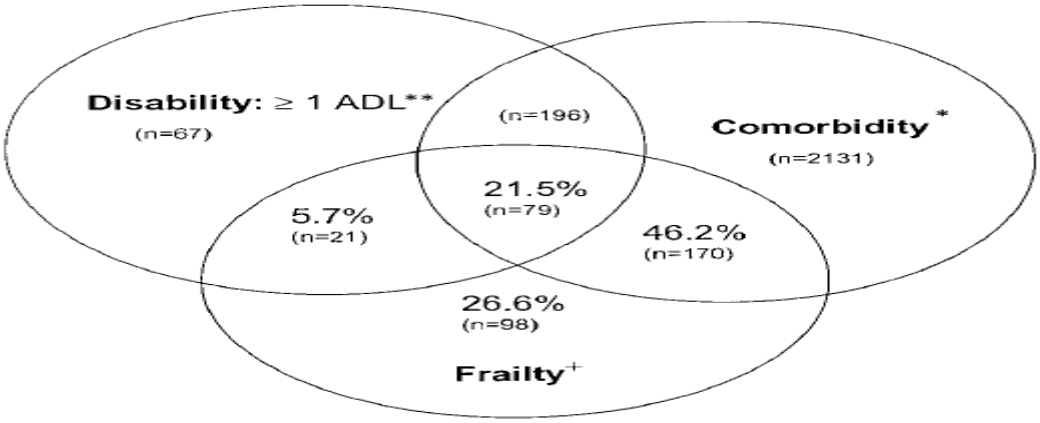

*Figure 4. Venn diagram showing degree of overlap of frailty with disability in ADL and comorbidity (≥ 2 diseases). Total represented: 2,762 subjects who had comorbidity and / or disability and / or frailty. The n of each subgroup is indicated in parentheses. + Frail: general n = 368 frail subjects (both cohorts). * Comorbidity: general n = 2,576 with 2 or more of the following 9 diseases: myocardial infarction, angina pectoris, congestive heart failure, claudication, arthritis, cancer, diabetes, hypertension, COPD. Of these, 249 were also frail. ** Disabled: total n = 363 with a disability in ADL; of these, 100 were frail. Source: Graphic and footer* [19].

Given the above, there is a high probability of finding a greater proportion of frail people among those who are disabled than among those who are not disabled.

1.1.8 Evaluation tools

1.1.8.1 Frailty models

It is difficult to find a general consensus for putting together criteria about frailty in a unified manner, although it is true that over the last 20 years, several models have been developed with a view to achieving this. The first of these is the one proposed in the Canadian Health Study by Fried [19], which is a model that focuses mainly on physical frailty by assessing the decline of the physical function in different domains (weight loss, tiredness, limited physical activity, muscular weakness and mobility), as will be described later. The second model is the one based on deficit accumulation theory, the purpose of which is to assess the burden of deficits that are present in the ageing process (illness, disability, physical performance, psychic performance and social assessment), with the data being constructed in the form of different frailty indexes such as that used in the National Population Health Survey of Canada [62], the Yale Precipitating Events Project (PEP)[63], the one used in the CSHA,[22] or the one put together from a subsample of the CSHA known as Comprehensive Geriatric Assessment - Index of Frailty (CGA-IF)[64]. In the last few years, there has been a unifying model of domains of both physical function and psychological domains (cognition and humour) and of the social role [65]. The models outlined here that attempt to conceptualise uniform criteria to detect and assess frailty will be developed in

the following sections. Likewise, an attempt has been made to put together different frailty models based on biological criteria [66], defined as a geriatric syndrome [67] or by assessing deterioration in different functional tests [68].

In 2012 a "last" attempt was made to develop a standardised-general model for the screening and diagnosis of frailty using a Delphi model known as the Frailty Operative Definition-Consensus Conference Project [69]. In this study it was agreed that the definition of frailty should involve an assessment of physical performance, gait speed, mobility, nutritional status, mental health and cognition. Although agreement was reached as to the areas to be assessed, consensus was not reached as to the diagnostic methods needed to carry it out. There was also agreement as to the fact that there should be no single biomarker that by itself would "diagnose" frailty and that a combination of biomarkers would be necessary without remembering what the right combination was.

Experts agreed that this is a multi-dimensional syndrome characterised by decreased reserve and decreased resistance to stressors and with an agreement percentage of 85-95%, insofar as frailty and disability are two distinct entities. A single operational definition of frailty was not agreed. There was also agreement on the need to assess the severity of frailty but not on the identification of specific markers for that task. There was agreement on the relationship between frailty and age but no age limit was established to assess it. Lastly, there was major disagreement when establishing a time to perform clinical evaluation and biomarkers in the diagnostic process.

1.1.8.1.1 Frailty phenotype model

The frailty phenotype arises within some large population-based studies about ageing. With the Canadian Study of Health and Aging (CSHA) the concept of frailty arises as an accumulation of deficits. Secondly, with CHS, a new model of frailty was developed, based on sarcopenia and energy imbalance, with a feedback relationship being established known as the "frailty cycle"[19].

Fried and Walston's model [19] meets the criteria for the definition of frailty: it is a biological phenomenon that affects multiple systems and confers vulnerability on the individual. This model is able to determine vulnerability, predict adverse events and relate to the alteration of multiple biological systems that define the frailty syndrome. This was later confirmed in a cohort of women over 65 at the WHAS (Women's Health and Ageing Study) [67]. The study lends support to the fact that it is treated as a

different syndrome of the disability, and can be deemed to be a precursor to this one owing to its key features of weakness, decrease in resistance and slowness in terms of performance. The presence of at least three of the five criteria was diagnosed as meaning frail, while the presence of one or two of them was considered as meaning pre-frail.

1.1.8.1.2 Model of deficit accumulation

Authors such as Rockwood and Mitnisky [22], within the context of the CSH, have developed the frailty model based on an accumulation of deficits at different levels. Physiological processes and systems accumulate deficits with ageing, just like cells. Over the years, humans have experienced an increase in the number of diseases and situations that condition their relationship with the environment and their response to internal and external stressors. The scale that emerges from this model is a predictor of mortality[62] and from the clinical point of view may be useful within comprehensive geriatric assessment for the purpose of identifying subjects at risk of adverse health events in the short and medium term, as well as contributing towards decision making in the allocation of resources. Among the disadvantages is the inclusion of disability parameters, if one starts from the premise that frailty is a pre-disability state[22].

1.1.8.1.3 Model based on biological criteria

Starting with biological criteria-markers, an attempt is made to detect the pre-clinical state of frailty. The most commonly-used markers are the musculoskeletal system (sarcopenia and dysfunction of muscle fibres), the endocrine e system (testosterone, growth hormone / IGF-1, cortisol, dehydroepiandrosterone (DHEA) or vitamin D), inflammation and immunity mediators and even chromosomes. Of these, the most studied is the inflammatory component since it has been suggested that frailty is a low-grade inflammatory state[70].

In the MacArthur Study of Successful Aging (MSSA) [71], a series of biomarkers were collected, with which the allostatic load was found to be related to frailty, meaning that the possibility of frailty increased by 10% for each point that the allostatic load increased[72]. Other studies such as WHAS I and II also related the allostatic load to increased frailty by putting together 10 items in its model: blood pressure (systolic and diastolic), body mass index, total cholesterol / HDL, low creatinine clearance, IGF-1 decrease, high glycosylated hemoglobin, high IL-6, increased triglycerides and a low amount of dehydroepiandrosterone[73].

Immuno-endocrine biomarkers were used in the Hertfordshire Ageing Study . In this study, an increase in the number of leukocytes and the decrease in the cortisol / dehydroepiandrosterone ratio were related to the increased risk of frailty and mortality at 10 years. It was concluded that both measures could be used in programmes for early detection of the population at risk of frailty [74]. However, in spite of advances made in recent years, none of the clinical markers linked to frailty has shown clinical effectiveness in terms of their screening-diagnosis.

1.1.8.1.4 Model based on geriatric syndromes

The concept of geriatric syndrome is a relatively recent one, as this terminology started being used towards the end of the 1960s. At the beginning, within the term geriatric syndromes reference was made to the characteristics evidenced more often by the elderly who had received geriatric services than those receiving other services. This terms is currently used to refer to a set of pictures resulting from the combination of a series of diseases that are highly prevalent among the elderly, and that often lead to functional or social disability. The major geriatric syndromes, also known as the 4 giants of geriatrics, include: immobility, instability-falls, urinary incontinence, and cognitive impairment. Up to 50% of those over 65 suffer from one or more of these syndromes[75].

To assess the extent to which the frailty phenotype conforms to the definition of a geriatric syndrome, the WHAS I and II study [67] analysed patterns which evidenced the 5 criteria that define this phenotype. By dividing the study population into three subgroups with similar profiles in terms of the frailty criteria provided, it was ascertained that the prevalence of each criterion increased progressively in each subgroup, thus indicating an increase in the severity of the frailty. These findings confirm the internal validity of frailty by matching frailty criteria with the geriatric syndrome, thus justifying the current division of these subgroups into non-frail, pre-frail and frail[76].

1.1.8.1.5 Model based on the appearance of deterioration in the Performance-Based tests

These models are being used relatively often to detect frailty tests that assess gait, balance and mobility, and would appear to be in line with other functionality tests. Up to 17.7% of studies use such functional tests to screen frailty [68]. Among the most used are walking speed and the “timed get up and go” test. Gait velocity is an independent

predictor of short-term functional loss [16] and is part of the frailty phenotype, being the most important criterion according to the most recent publications [77].

1.1.8.2 Indices and instruments for valuation and measurement of frailty

1.1.8.2.1 Fried's frailty phenotype

The frailty phenotype is a tool developed by the L. Fried group deriving from analysis of subjects from the Cardiovascular Health Study (CHS) [19]. It contains five sections: (Table 2)

- Unintentional weight loss of >10 lbs (≥4.5 kg) or ≥5% of body mass in the last year (obtained from subject, caregiver or medical records).
- Exhaustion (audited information based on two questions from the Center for Epidemiological Studies Depression (CES-D) scale [78]; a score from 1 [fatigue or exhaustion felt rarely or not at all] to 4 [fatigue or exhaustion felt most of the time]. 3 or 4 points means that the test is positive for decreased physical activity).
- Low physical activity (energy expenditure weekly rate calculated on the basis of the modified Minnesota Leisure Time Activity Questionnaire) [79].
- Weakness (assessment based on measurement of handgrip strength; interpretation of results takes into account sex and body mass index [BMI]). A Kern digital dynamometer was used for grip strength measurement.
- Slow gait (walking time over a distance of 15 ft [4.57 m]; interpretation of results takes into account sex and height).

Subjects who fulfilled none of the criteria were considered non-frail, subjects who fulfilled 1 and 2 criteria were classified as pre-frail, and subjects who fulfilled ≥3 criteria were classified as frail.

FRIED FRAILTY PHENOTYPE CRITERIA	
UNINTENTIONAL WEIGHT LOSS	5 kg or ≥5% of body mass in the last year
WEAKNESS	Assessment based on the handgrip strength measurement adjusted by sex and body mass index [BMI]
EXHAUSTION	Audited information based on two questions from Center for Epidemiological Studies Depression (CES-D) scale
SLOW GAIT	Walking time over a distance of 15 ft [4.57 m] adjusted by sex and height
LOW PHYSICAL ACTIVITY	Energy expenditure weekly rate calculated on the basis of the modified questionnaire Minnesota Leisure Time Activity Questionnaire adjusted by sex.

Table 2. Fried frailty criteria. Source:[19]

1.1.8.2.2 Rockwood's Frailty index or index of deficit accumulation

The frailty index proposed by Rockwood et al in 2001, based on a sub-analysis of the Canadian Study of Health and Aging (CSHA), was a prospective five-year study designed to study the epidemiology of dementia in Canada [22,80]. This is calculated based on the presence or absence of symptoms (such as sadness), signs (such as tremor), laboratory index abnormalities, illness or disability. Originally 92 variables were included, with the presence of frailty being more likely than the highest index of frailty. Later versions have been drafted to make it more manageable, reducing the number of variables without reducing the predictive value. The most recent version is based on 37 variables [62,81].

The following table describes the classification of subjects according to Rockwood's Frailty index or index of deficit accumulation. (Table 3)

GROUPS	CHARACTERISTICS
Group 1	Robust: people who make patience on a regular basis.
Group 2	Healthy without active pathology, but somewhat less energetic than group 1.
Group 3	Healthy with treatment: Symptoms or controlled with treatment.
Group 4	Apparently vulnerable: not dependent, but with symptoms associated with comorbidities.
Group 5	Mild frailty: with some degree of dependence on the instrumental activities of daily life.
Group 6	Moderate frailty: they need help for the basic instrumental activities of daily life.
Group 7	Severe frailty: completely dependent on the basic activities of daily life or with terminal illness.

Table 3. Classification of subjects according to Rockwood's Frailty index or index of deficit accumulation.

1.1.8.2.3 Physiological index or Sanders' index

Recently, a tool has been defined consisting of analytical or biological parameters to decrease the functional reserve of the renal, respiratory, vascular, cerebral and glucose metabolism systems, evidencing very good correlation with the frailty phenotype [66]. The accumulation of anomalous biological markers would have a non-linear effect on the pathogenesis of frailty, being more relevant for the purpose of identifying the number of body systems with the functional reserve diminished than the system itself.

1.1.8.2.4 Groningen indicator frailty

Self-administered questionnaire comprising 15 items and 8 frailty factors: mobility, physical exercise, vision, hearing, food, morbidity, cognition and psychosocial aspects [13].

1.1.8.2.5 Frailty trait scale

Developed within the framework of the TSHA (Toledo Study of Healthy Ageing) [82]. In this study, it is argued that the health condition with which we reach old age is built throughout life, and so when the involutive changes inherent in ageing become relevant, or disorders appear in the different systems deriving from the presence of diseases, each subject will be at greater or lesser risk of adverse health events depending on their biological reserve: it is this biological trait that is called a "trait of frailty", which is a continuous phenomenon where more decline in the biological reserve is apparent, the closer the threshold is to evidencing adverse effects deriving from it,

without this being a qualitative leap, but rather, a continuous intensification in terms of the risk. It was developed by collecting data regarding ADL, social support, co-morbidity, physical activity, quality of life, depressive symptoms, cognitive function, anthropometric data, walking speed, strength in both upper and lower extremities and time to get up and sit in a chair. Under this premise, from this data, which was collected and based on the Fried model, the so-called "frailty trait" scale was developed with 12 items that rate 8 frailty dimensions. The global score refers to the sum of the points of each item, and is normalised from 0 to 100 points, with 0 being the best score and 100 being the worst. The score range was from 0 to 92.

1.1.8.2.6 Instruments used in primary care

Two frailty screening questionnaires were developed and validated between 2013 and 2014 at the Gérontopôle Institute of Research of the Ageing in Toulouse (France). The two tools were designed to screen frailty in persons aged 65 years or older, without disability (Kartz test of basic activities of daily living greater than or equal to 5/6) and without acute pathology.

The first tool, GFST (Gérontopôle Frailty Screening Tool) is divided into two parts [83]. The first part consists of six questions whose main objective is to draw the primary care physician's attention to the signs and symptoms that are potentially associated with frailty. The second part is passed if there is an affirmative answer, in which the doctor expresses his personal view of the subject. If that is the case, the possibility of consulting a specialist centre to rule out the presence of frailty is then rated. The benefits of this assessment of a collaborative decision mean that, as in the case of Toulouse, primary care physicians can especially count on at least a specialist structure for the detailed diagnosis of frailty and other geriatric syndromes, such as the Gérontopôle. 1108 people were rated after the first year this tool was implemented [84]. Full assessment has shown that nearly 94% of primary-age-elders were either frail or pre-frail according to the criteria used by L. Fried et al., demonstrating good sensitivity and specificity.

It should be emphasized that GFST is a secondary prevention tool in frail subjects at an early stage of dependence.

The second tool developed by the same group is the FiND questionnaire (Frail non-Disabled), which is also divided into two parts [85].

The first part assesses the presence of alterations in mobility at an early stage with two questions. The second part assesses the components of frailty with three questions.

An affirmative answer to one of the questions implies presence of disability, while to one of the last three means the presence of frailty.

1.1.8.2.7 Performance-Based test or index

On the one hand, the "TUG " Timed Up and Go test was designed specifically to quantify mobility [86], and it has demonstrated its value for predicting deterioration in health status and activities of daily living as well as falls, similar to walking speed, although evidence of its success as a predictive tool for incident disability is more scarce [87]. Failure in this test seems to be the best predictor in the short term (at one year) and therefore more useful if associated with consequent interventions, as opposed to the lack of physical activity and physical exercise that it predicts in the longer term (to three years)[16]. There is experience of its use and it has been validated in our environment [88,89], and has also been validated for the purpose of assessing the risk of falls, having also recently been validated as a diagnostic tool for frailty [90].

On the another hand, the main clinical usefulness of the performance-based model is the detection of subjects at risk of functional impairment. The most validated and commonly-used test in our environment is the "Short Physical Performance Battery" (SPPB) or Guralnik test, the use of which is both widespread and validated. It is the only test specifically designed to predict disability [91], and has demonstrated its ability to predict adverse events, dependence, institutionalisation, and mortality[92-94]. In addition to predicting institutionalisation and death, it was shown as early as the 1990s that the SPPB was a tool that allows the subject's evolution to be monitored over time (1 point changes are clinically significant), and significantly predicts the development of dependence, both in activities of daily living and in 4-year mobility [95]. This predictive capacity was demonstrated in different populations, always according to age, sex and co-morbidity [93].

For all the aforementioned reasons, the SPPB is one of the most validated and reliable tests for detecting frailty and predicting disability [96], and has been recommended as an objective measure of mobility limitations [97,98]. In a significant sample of non-dependent 74-year-olds who were attended to within a primary care

setting, 30.5% (36.6% women, 21% men) evidenced functional limitation based on this test.

The SPPB consists of three very easy to perform parts that do not require that any specific instrument be used. (Figure 5)

In the first part – ***the balance test*** - the participant tries to maintain 3 positions: side-by-side stand, semi-tandem and tandem stand for 10 seconds each.

In the ***gait speed test***, the participant walks a distance of 4 metres at their normal pace, this test is performed twice and the shortest time is recorded. Gait velocity is the objective test for assessing functional limitation that is most commonly-found in literature. In longitudinal studies, it has demonstrated its capacity to predict adverse events such as hospitalisation, frailty, falls, dependence and mortality [99-101]; it is also one of the components of the Fried frailty phenotype [19]. In a Spanish cohort of 70-year-olds the P50 was 0.91 m/s for men and 0.67 m/s for women, while the P25 was 0.69 m/s and 0.43 m/s respectively [39]. In the Toledo Study of Healthy Ageing, designed specifically to study frailty, Percentile 20 (which is the one used in the Cardiovascular Health Study to establish the cut-off point in the item "gait speed" of the frailty criteria) was placed between 0.37 and 0.5 m/sec[102,103], adjusted for sex and height. A recent Spanish study found that the cut-off point with the best predictive value of frailty would be between 0.8 and 0.9m / s, ultimately proposing a figure of 0.8 m / s for more general use. The most-used tests are those that calculate speed in distances of 2.4 metres, 4 metres or 6 metres, calculated at the speed of usual step. The tests last between 2 and 3 minutes, and are tests that perform very well in terms of predictive validity and reliability test-retest (with coefficients between 0.8 and 0.9). Professionals who carry out the test must have undergone a minimum pre-training, and the test itself is widely-accepted among professionals and subjects because it is easy to conduct [104]. It is therefore a simple measure that could also be used clinically as a predictor of incident disability.

Lastly, in the case of ***the chair stand test***, the participant stands up from and sits down on a chair 5 times as quickly as possible, and the total time taken is recorded. Timing begins when the subject initiates the first survey. It counts up every time the participant gets up and finishes timing when the subject is standing upright the last time.

The stopwatch is stopped if the subject's hands are helped, if after 1 minute the participant has not completed the test or if there is concern about their safety.

Each test is given a score from 0 (worst performance) to 4 (best performance): for the balance test and according to a hierarchical combination of performance in the 3 component subtests and the other 2 tests, a 0 score is assigned to those who do not complete or try out the test, and scores from 1 to 4 according to the time taken. A total score is obtained for the whole battery, which is the sum of that obtained from the 3 tests, and ranges between 0 and 12. Scores below 10 evidence frailty [96,105]

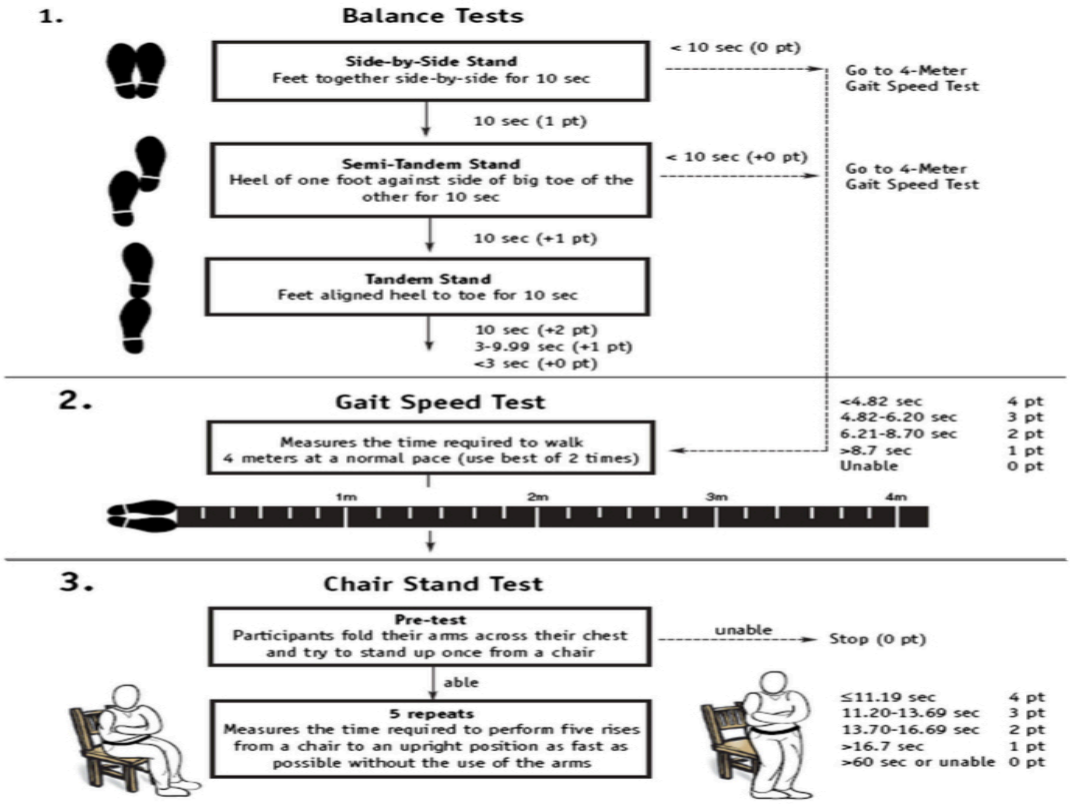

Figure 5. Short Physical Performance Battery (SPPB) flowchart. Source: [106].

1.1.8.2.8 Instrument for use in nursing homes

The first specific scale for the diagnosis of frailty in subjects in residence was developed in 2014.

The FRAIL-NH scale is a tool used to diagnose frailty in people in residence who evidence a reversible condition which, with appropriate treatment, could result in an improvement in results [107]. This scale assesses physical and psychological abilities, such as abilities, nutritional aspects and dependence in some basic activities of daily life, and consists of seven variables with a score between 0 and 2 (possible score

between 0 and 14, the higher the score, the greater the frailty), so that subjects are considered frail if the score is higher than 7 (Table 4). If residents evidence both criteria, they are given the highest score.

FRAIL-NH		0	1
Fatigue	No	Yes	PHQ-9≥10
Resistence	Independent transfer	Set up	Physical help
Ambulation	Independient	Assistive device	Not able
Incontinence	None	Bladder	Bowel
Illness	≤5	5-9	≥10
Loss of weight	None	≤5% in 3 months	≥10 in 6 months
Nutritional approach	Regular Diet	Mechanically altered	Feeding tube
Help with dressing	Independient	Set up	Physical help

Table 4. FRAIL-NH scale for the diagnosis of frailty in residence.Source:[107].

1.1.9 Analysis of evaluation tools

An analysis of the assessment tools needs to be carried out in order to draw conclusions so as to be able to choose the most appropriate ones for use in the studies that they intend to address in this project.

Regarding frailty models, Table 5 analyses the advantages and disadvantages of the different models that have been developed regarding frailty. The conclusion is drawn that the model based on the appearance of functional impairment in the implementation tests will be the model that evidences the most predictive capacity and, therefore, the most complete one, with no drawbacks.

	Advantages	Disadvantages
Frailty phenotype model Fried et al.	-Achieve definition criteria -Detect: *vulnerability * predict adverse events * in relation to multiple biological systems -If there is evidence of clinical efficacy in screening-diagnosis -Is the oldest -Reference model	-additional technical material requiered
Model of deficit accumulation Roockwood et al.	-Predicting Mortality -Useful in integrative geriatric assessment * Adverse events: short / medium term * Decision making for resources	- Including disability parameters
Model based on biological criteria	-Detection of the preclinical state of frailty through the alteration of biological markers	-There is no evidence of clinical efficacy in screening-diagnosis
Model based on geriatric syndromes	- The groups are justified: non-frail, pre-frail and frail	-There is no evidence of clinical efficacy in screening-diagnosis
Model based on the appearance of deterioration in the Performance-based tests	-Show agreement with other tests of functionality -Correlation with the Fried Phenotype -If there is evidence of clinical efficacy in screening-diagnosis - Predict: *adverse events *dependence *institutionalization *mortality	

Table 5. Frailty models: advantages and disadvantages.

Table 6 analyses the advantages and disadvantages of the different instruments that have been developed according to the indexes and instruments used to assess and measure frailty. The conclusion is drawn that the Performance Testing Index: Short Physical Performance Battery (SPPB) is the most predictive instrument, as it allows a subject's evolution to be monitored over time. Additional technical material is not required and it has no drawbacks.

		Advantages	Disadvantages
Fried's frailty phenotype		-Validated and used in numerous studies -Reference model	-Additional technical material requiered
Rockwood's Frailty index or index of deficit accumulation		-Collect a lot of information	-Not easy to use -Does not include physical tests
Physiological index or Sanders' index		-Good correlation with the Fried Phenotype	-Non lineal effect -Not easy to use -Does not include physical tests
Groningen indicator frailty		-Collect a lot of information	-Very long -Self administered -Does not include physical tests
Frailty trait scale		-Good correlation with the Fried Phenotype	-Very long -A little bir used
Instruments used in primary care	GFST	-Secondary prevention in frail subjects at an early stage of dependence	-Does not include physical tests
	FiND	-Assess if there is a disability -Assess if there is a frailty	-Does not include physical tests
Performance-based test or index: Short Physical Performance Battery (SPPB)		-Very validated and used -Easy to use -Very reliable for detecting frailty and predicting disability -It allows to monitor over time the evolution of a subject -Predicts significantly the development of dependence in ADL and 4-year mobility -Additional technical material not requiered -Correlation with the Fried Phenotype	
Instrument for use in nursing homes		-Unique for diagnosis of frailty in residence -Validated	-Recent appearance -A little bir used -Does not include physical tests

Table 6. Evaluation toools/frailty instruments: advantages and disadvantages.

1.1.10 Summary

Frailty is a status of extreme vulnerability to endogenous and exogenous stressors exposing the individual to a higher risk of negative health-related outcomes. Frailty may represent a transition phase between successful aging and disability, and a condition to target for restoring robustness in the individual at risk. Given its syndromic nature, targeting frailty requires a comprehensive approach. The identification of frailty as a target for implementing preventive interventions against age-related conditions is pivotal. Every effort should be made by health care authorities to maximize efforts in this field, balancing priorities, needs, and resources. Raising awareness about frailty and age-related conditions in the population is important for effective prevention, and should lead to the promotion of lifelong healthy behaviors and lifestyle.

After this analysis of the evaluation tools, **the decision is taken to use for the research project** of this doctoral thesis the **model based on the appearance of deterioration in the Performance-Based tests**, which in turn presents as a tool the Performance-Based test or index: **Short Physical Performance Battery (SPPB).**

1.2 Technological background

In an ageing society it is necessary to establish new alternatives that may somehow try to meet the needs of elderly persons while increasing their perceived quality of life. In this respect, new technologies have become a basic tool in our society.

At present, many countries have a strong interest in having frail elderly people receive care in their own homes, trying to avoid unnecessary income and institutionalization as much as possible and allowing them to live as independently as possible as long as possible [108-111].

At the same time, there is also a growing interest in the adoption of assistive technologies both to support and to improve the system of services and work of health professionals [112-116].

Specialist literature contains many reviews of studies that include technology as support and tools that can be used to provide benefits to medical practice, thus taking into consideration new future challenges [117,118].

1.2.1 Search keys

By observing the major role played by technology in our modern-day society, it may ask the following question: to what extent is technology present in its relationship with frailty or, put another way, what technological resources are used to deal with frailty? There is interest in establishing which devices and programmes have been developed thus far to help deal with the issue of frailty that are related to prevention, diagnosis, care and treatment, among other areas.

- ***OVID Medline <1946 to December week 4 2015>***
- ***EMBASE via OVID < 1974 to 2015 week 53>***
- ***Web of Science (2005-2015):*** gathering together all the databases included: ***main Web of Science™ collection, Current Contents Connect®, Derwent Innovation Index℠, Inspec® , KCI-Korean Journal Database, MEDLINE® and SciELO Citation Index***
- IEEE Xplore (2005-2015)

It decided to conduct a search by way of a review from January 2005 to December 2015, in the course of which four databases were consulted:

The search was undertaken in accordance with the following two strategies, owing to the features of the databases selected:

(1) Medline and EMBASE: these databases permit the use of descriptors and even expand on them, combining them always with natural language and using the following keywords:

- As expanded descriptors: frail elderly, software, computers (hardware term was included), telecommunications, videogames.

- As natural language: frailty, software, telecommunications, kinect, videogames, wii, exergame, exergaming, sensors, serious games, robots, virtual reality.

- Filters: date (2005-2015), language (English).

(2) Web of Science and IEEE Xplore: conversely, these databases do not permit the use of descriptors, whereby exclusively natural language must be used using the following keywords:

- As natural language: frailty, software, hardware, telecommunications, kinect, videogames, wii, exergame, exergaming, sensors, serious games, robots, virtual reality.

- Filters: date (2005-2015), language (English).

The following results were obtained from the review:

- OVID Medline <1946 to December week 4 2015>: n=130

- EMBASE via OVID < 1974 to 2015 week 53>: n=304

- Web of Science (2005-2015) : n=271

- IEEE Xplore (2005-2015) : n=136

Inclusion criteria: Articles that deal with programmes and devices developed in relationship with frailty.

Exclusion criteria: Articles that do not deal with programmes and devices developed in relationship with frailty.

The results were reviewed to control duplicates by noting that most papers in these databases could also be found in the Web of Science. (Figure 6)

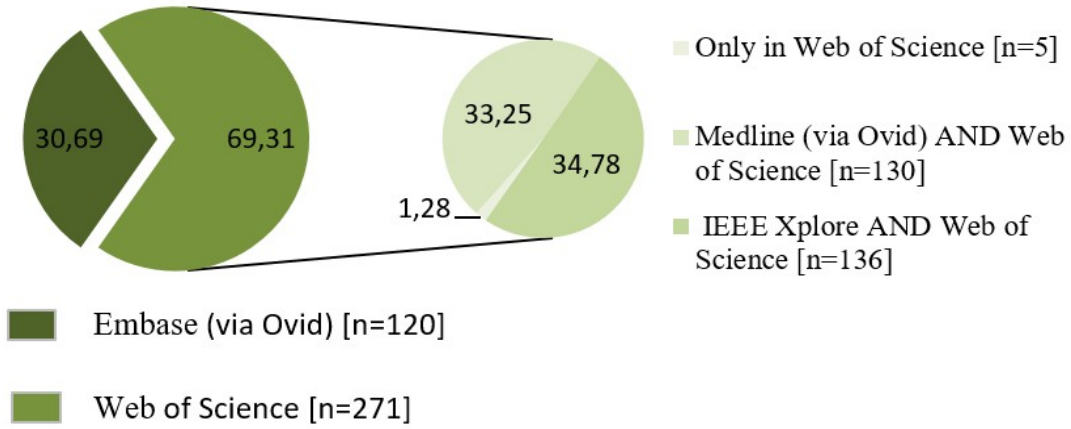

Figure 6. Percentage of results according to the data base that was reviewed.

For this reason, the decision was made to work with the results obtained from the Web of Science alongside those from EMBASE, as in this last-mentioned database can be found some European publications not found in the Web of Science. Following critical reading of the documents, the total number included in the review amounted to 104 documents. (Figure 7)

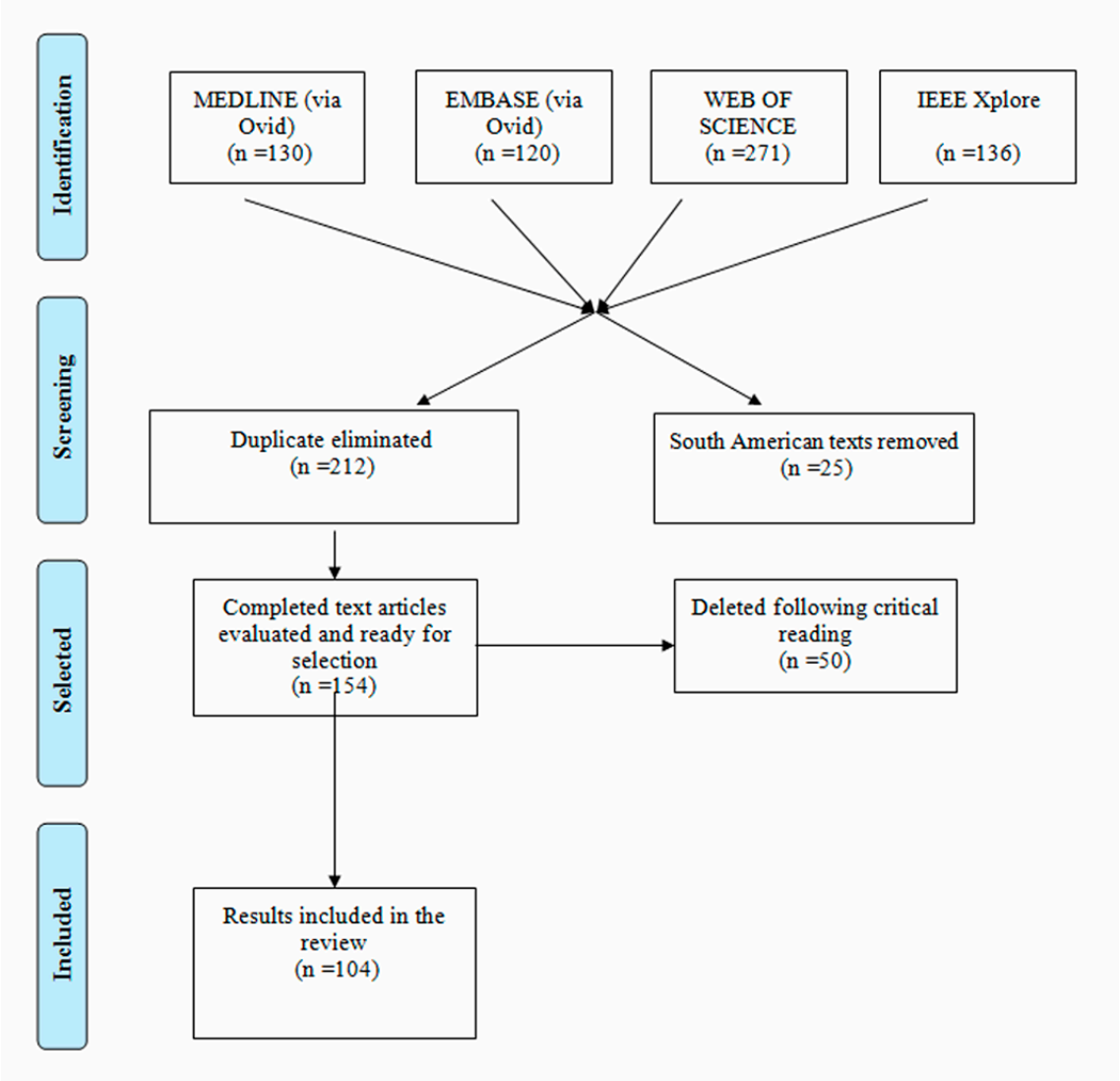

Figure 7. Flow Diagram. Strategy carried out in this review

The 104 documents were analyzed meticulously so as to classify their content. Thus, the following areas of work related to frailty were the ones mainly observed: prevention, diagnosis, care and treatment. These in turn require some type of hardware or software and in fact both in most cases. Studies exist in which the research covers one or more areas of care (Figure 8), although this review has tended to focus on those papers that deal with a single area of activity.

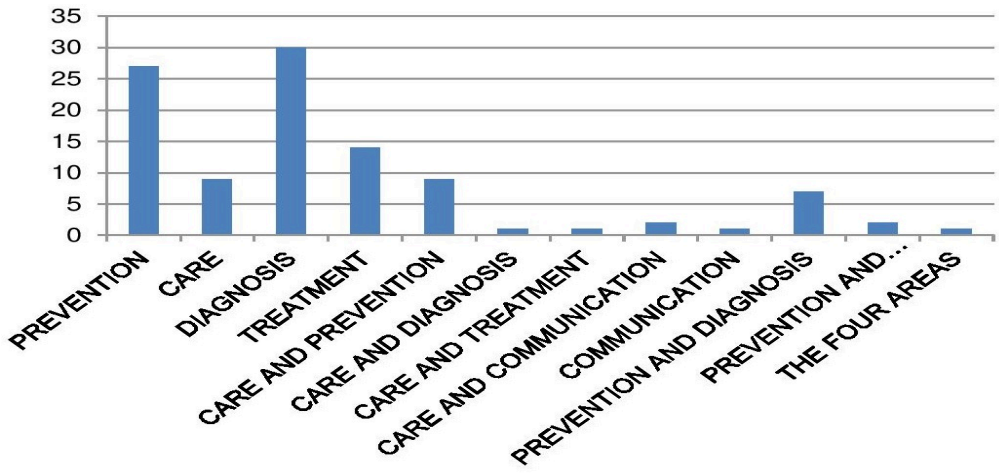

Figure 8. Results found between 2005-2015 for specific areas

Eighty documents devoted their research to the validation and/or ascertaining of different types of hardware, software or both, in the following areas: prevention, care, diagnosis and treatment.

Of the documents reviewed, most were geared to researching and developing hardware and/or software related to diagnosis and prevention of frailty. To a lesser extent, they focused on treatment and care. (Figure 9)

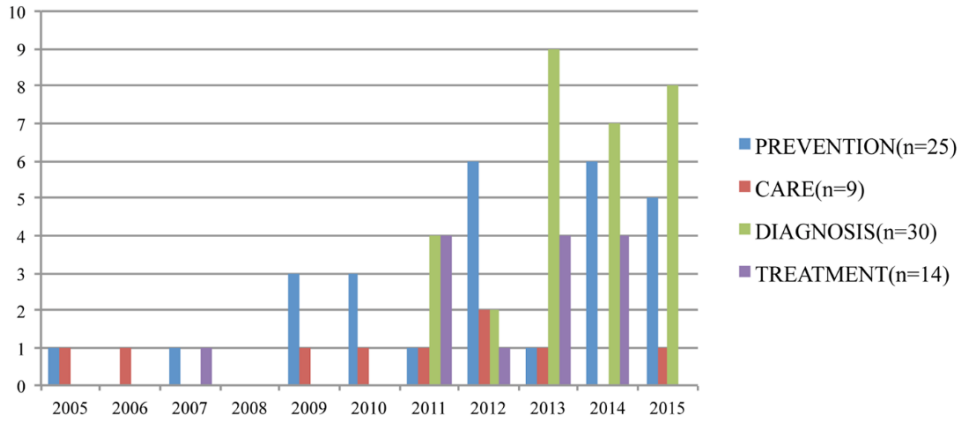

Figure 9. Results found for selected areas when reviewing 2005-2015 and yearly results and selected areas found for the review.

Despite taking into account results that date back to 2005, it was really between 2011 and 2015 during which the greatest number was concentrated. (Figure 9)

1.2.2 Technological solutions

1.2.2.1 Area: Diagnosis

The first studies aimed at researching into some tool or device that might help to diagnose frailty did not appear until 2011. (Figure 10)

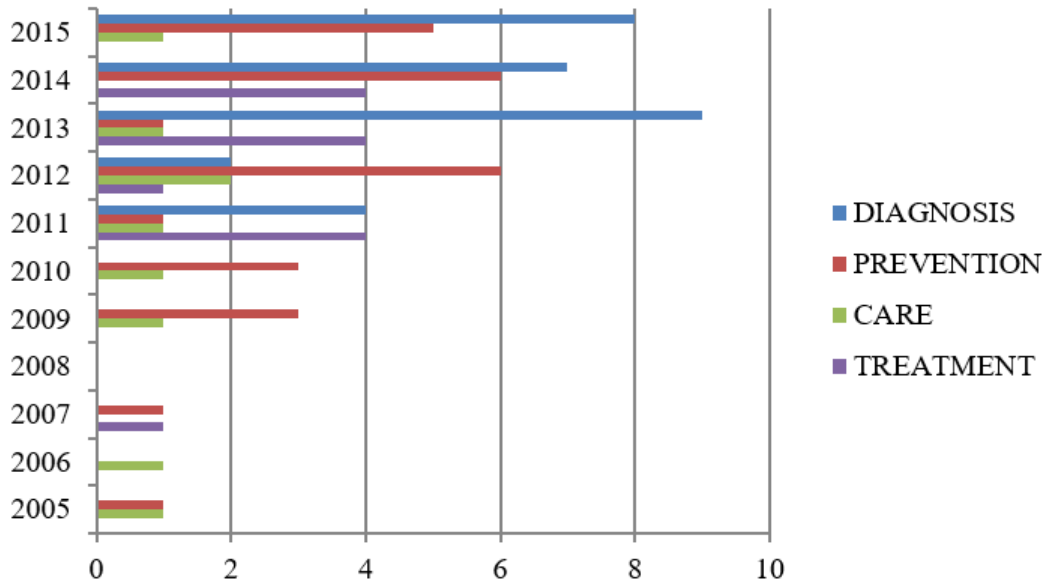

Figure 10. Results found by year and by area: Diagnosis, Prevention, Care, Treatment.

On the one hand, papers were found that focused on an assessment of frailty taking into account the trial-based model.

Ganea et al., 2011[119] conducted a study showing the parameters obtained via a small inertial sensor and portable data recorder (Physilog®, BioAGM, CH) fitted to the waist, to distinguish between elderly subjects with differing states of health and functional states.

Martínez-Ramirez et al., 2011 [120] carried out a study, the purpose of which was to examine the orientation and acceleration of signals deriving from a triaxial inertial magnetic sensor during balancing trials conducted while the subject was standing up, among a frail, pre-frail and healthy population. The wavelet transform was used in data analysis [121]. The authors concluded by stating that the absolute sum of the wavelet coefficients of the details corresponding to orientation signals and acceleration were associated with the frailty syndrome.

Chang et al., 2013 [122] conducted research, the purpose of which was to integrate wireless sensors and artificial neural networks in order to develop a system capable of gathering data and administering the information required to assess frailty as automatically as possible. To do so, they used a measuring device based on household goods in daily use, with a view to providing home-based means of measurement and thus ensuring that health controls would not be confined to healthcare establishments. The system consisted of five parts: (1) eScale: a scale for measuring the subject's

reaction time; (2) eChair: a chair used to detect slowness of movement, weakness and weight loss; (3) ePad: to measure the subject's capacity for balance; (4) eReach: to measure functional scope; (5) electronic questionnaire: to measure tiredness when performing an activity; (6) information base portal: a system based on information obtained from the gateway, so as to gather together all the data and predict the subject's frailty. The analytical model proposed using an artificial neural network might effectively and easily estimate the level of functional decline. In the long-term, the variation in indicators monitored might permit early detection of frailty and, hence, its early treatment.

Fontecha et al., 2013 [123] took advantage of the features and capacities of the mobile phone (accelerometer sensors, capacity for wireless communication and processing capacities, among others) to develop a new method that achieved an objective assessment of frailty in an elderly population – a model with several mobile tools for assessing frailty, that would permit mobility in clinical environments and obtain assessments at any time.

Galan-Mercant et al., 2013; Galan-Mercant et al., 2014 and Galan-Mercant et al., 2015 [124-126] managed to identify a series of cinematic variables that demonstrated greater accuracy in discrimination in terms of functional capacity among two groups of elderly persons (frail and non-frail) in phases of the expanded trial involving standing up and leaving (ETUG), using inertial sensors integrated into the iPhone 4®. They reached the conclusion that the cinematic parameters obtained from the internal inertial sensors in the iPhone 4® proved promising for the purpose of carrying out the ETUG analysis and that there were encouraging signs insofar as these parameters in separate phases of the ETUG procedure might offer the chance to improve discrimination between frail and non-frail people. However, a further in-depth study was still needed to verify the findings.

Zaffarana et al., 2014 [127] presented their work at the 10th International Congress of the European Union Geriatric Medicine Society - Geriatric Medicine Crossing Borders, in which they implemented a specific algorithm in the ETUG trial that helped to identify frailty more accurately using inertial sensors integrated into a Samsung Galaxy SII/III.

Castro et al., 2015 [128] designed an application known as InCense in which different technologies were found to be involved and integrated into smartphones such as an accelerometer, gyroscope, digital compass, camera, bluetooth, proximity sensors, GPS, microphones and WIFI. The application gathered together the physical activity carried out by subjects and transferred the resulting information in order to identify frailty.

Papers were also found that focused on the assessment of frailty by taking into account one or more of Fried's criteria [19].

Gallego et al., 2011 [129] presented a study at the 2011 Annual Scientific Meeting of the American Geriatrics Society, the purpose of which was to assess the strength of manual pressure as a predictor of mortality within 6 months in elderly persons following hospitalization as a result of serious illness. A hand-grip electronic dynamometer was used, and the aim was to ascertain whether pressing strength is linked to frailty insofar as it increases mortality. 387 elderly persons over 80 years of age took part. The conclusion was drawn that frailty was linked to a greater vulnerability towards factors involving stress, functional decline and inaccurate health diagnosis. It was shown that a frailty marker such as grip strength (pressing strength) was closely associated with mortality 6 months following hospitalization as a result of serious illness.

Chang et al., 2011 [130] designed research using wireless sensors, the purpose of which was to develop a system to detect and assess frailty via interactive multimedia games that would enable users to gather and administer personal information automatically at home. The interactive games incorporated an electronic pressing strength sensor and an electronic pressure sensor that gathered information. They were compared to traditional methods used to measure frailty so as to put their validity and reliability to the test, and they concluded that the device accurately measures grip strength to help detect frailty.

Zavala et al., 2012 [131] conducted a study, the purpose of which was to design and assess video games that would enable muscle strength to be measured in order to help detect the first signs of dynapenia (age-related loss of muscle strength). To do so, they created a device that could be incorporated into the remote control of the Wii™ or Xbox 360 console that would measure grip strength. They designed two games with which to

measure grip strength and compared this to the traditional measuring method for grip strength using a dynamometer. They concluded that the device accurately measures grip strength and thus helps to detect the first signs of dynapenia – a criterion included in the assessment of frailty.

Chkeir et al., 2013 [132] developed a device based on the Grip Ball dynamometer patented in 2008 by Hogrel & Duchêne et al., 2008 [133], whereby they more accurately measured grip strength and were able to transmit the data obtained via bluetooth to a PC or tablet. The results obtained helped to assess the degree of frailty, and they drew the conclusion that the device needed to be improved by carrying out studies on the relevant population in order to obtain a range of strength between sexes.

Hewson et al., 2013 [134] proposed the design of an innovative system in order to objectively quantify the level of frailty based on a series of remote tests, each of which use objects similar to those found in homes. A modified ball was used to assess maximum grip strength, while a smartphone equipped with triaxial accelerometer was used to estimate walking speed and the level of physical activity. Lastly, they used a set of bathroom scales to asses involuntary weight loss. All the data generated was then transferred via smartphone to a remote service provider in which the user, their environment and any authorized healthcare professional could access them.

Jaber et al., 2013 [135] submitted the ARPEGE at the 2013 IEEE 15th International Conference on e-Health Networking, Applications & Services-Healthcom. This project consisted of a set of technological tools referred to as the ARPEGE package to assess frailty in elderly persons within their habitual environment, i.e. in their home, with reference to Fried's physical frailty scale [19]. The ARPEGE package comprised different measuring devices connected wirelessly to a tablet-PC that would enable non-professionals to handle them easily. Frailty assessment was of a maximum 8 minute duration, and an initial experiment involving 150 subjects was set in motion at the time the project was submitted. The aim was to demonstrate the acceptability and usefulness of the set of tools.

Dapp et al., 2013 [136] presented a study at the 9th International Congress of the European Union Geriatric Medicine Society (EUGMS) that was carried out using the GAITRIte® system for analyzing walking speed that incorporates some wireless sensors attached to the body, whereby objective data about participants' walking speed was

obtained. This objective data was added to other information obtained regarding leisure activities, health-related events, socio-economic, medical and professional aspects, lifestyle habits, limitations in terms of day-to-day activities, mobility problems and risk of falling. The results obtained were then assessed according to Fried's frailty phenotype [19], and the results showed that the system had sufficient functional competence for the purpose of detecting pre-clinical signs of functional decline.

Drubbel et al., 2013 [137] carried out a study to assess frailty in a cohort of 1580 subjects over 60 years of age in primary care, to compare the results obtained between the Groningen Frailty Indicator (GFI) questionnaire and the FI score calculated previously by researchers, and using software designed by the authors in a prior study [49]. The FI and GFI results were moderately superimposed in identifying frailty in elderly community results. Based on the results, the authors suggested estimating an initial FI with recorded routine health data as a means of improving the identification and optimization of resources in primary care. Only subjects with a high FI score – i.e. with a high risk of frailty – completed the GFI questionnaire.

Toosizadeh et al., 2014; Toosizadeh et al., 2015 and Toosizadeh et al., 2015 [138-140] implemented a new method to objectively assess frailty using a wireless sensor connection and movement of the upper extremities. Subjects bent their elbow repeatedly for 20 seconds on each side. It was shown that frailty and pre-frailty can be predicted to 94% sensitivity and 98% specificity if compared to Fried's criteria. The physical assessment is easily made in less than 1 minute.

1.2.2.1.1 Conclusions Area: Diagnosis

A general frailty rate using technology is still to be created. However, we have been able to ascertain that a great deal of research has been carried out since 2011 and is still being carried out to establish the most suitable tool. In the papers reviewed, it has been ascertained that despite isolated developments to measure a variable such as pressing strength or walking speed, the integration of different measuring devices into a single tool is essential for establishing a comprehensive assessment method in which the 5 criteria described by Fried are taken into consideration. From the studies analyzed in this area, the one that gets closest is the ARPEGE project presented by Jaber et al., 2013 [135], at the IEEE 15th International Conference on e-Health Networking, Applications & Services-Healthcom. Table 7 contains the studies analyzed.

Results in area: Diagnosis

AUTHOR	YmEAR	COUNTRY	CLINIC GROUP	CONTROL GROUP	AGE	DIAGNOSIS	AREA	METHOD	CLASSIFICATION
Ganea et al., 2011[119]	2011	Switzerland	79	27	≥65	Frailty	Diagnosis	Portable inertial sensor	Hardware
Martinez-Ramirez et al.,[120]	2011	Spain	32	24	75-83	Frailty	Diagnosis	Triaxial inertial guidance sensor Analysis: Wavelet	Hardware
Chang et al., 2013[122]	2013	Taiwan	160	149	≥65	Frailty	Diagnosis	Integration of wireless sensors and artificial neural networks	Hardware Software
Fontecha et al., 2013[123]	2013	Spain	20	--	78-86	Frailty	Diagnosis	Accelerometer sensor integrated into smartphone	Hardware Software
Galan-Mercant et al.,2013;2014 y 2015 [124-126]	2013	Spain	30	--	≥65	Frailty	Diagnosis	Inertial sensor Location:iPhone4®	Hardware
Zaffarana et al., 2014[127]	2014	Italy	94	--	65–90	Frailty	Diagnosis	Inertial sensors in Samsung Galaxy SII/III	Hardware
Castro et al., 2015[128]	2015	Mexico	15	--	73-79	Frailty	Diagnosis	Incense application in smartphone	Hardware Software
Gallego et al., 2011[129]	2011	Spain	387	--	≥80	Frailty	Diagnosis	Hand grip	Hardware Software

Results in area: Diagnosis									
AUTHOR	**YmEAR**	**COUNTRY**	**CLINIC GROUP**	**CONTROL GROUP**	**AGE**	**DIAGNOSIS**	**AREA**	**METHOD**	**CLASSIFICATION**
Chang et al.,2011[130]	2011	Taiwan	160	149	≥65	Frailty	Diagnosis	Electronic measurement of pressure grip force and distance	Hardware Software
Zavala et al., 2012[131]	2012	Mexico	11	--	65-85	Frailty	Diagnosis	Wii console using remote sensor	Hardware Software
Chkeir et al., 2013[132]	2013	France	360	--	Senior	Frailty	Diagnosis	Grip-ball Dynamometer	Hardware Software
Hewson et al., 2013[134]	2013	France	--	--	Senior	Frailty	Diagnosis	Grip-ball Dynamometer Digital bathroom scale Acelerometer	Hardware Software
Jaber et al., 2013[135]	2013	France	150	--	≥75	Frailty	Diagnosis	ARPEGE Project	Hardware Software
Dapp et al., 2013[136]	2013	Switzerland	3326	--	≥60	Frailty	Diagnosis	GAITRite®-System	Hardware Software
Drubbel et al., 2013[137]	2013	Netherlands	1580	--	≥60	Frailty	Diagnosis	Software GFI data	Software
Toosizadeh et al., 2014 y 2015[138-140]	2014	USA	117	--	≥65	Frailty	Diagnosis	Wireless sensors	Hardware Software

Table 7. Results in area: Diagnosis

1.2.2.2 Area: Prevention

Most results in this area focused on the design of devices and tools aimed at detecting situations of risk and/or falling.

The increase in results was significantly greater after 2012. (Figure 10)

Lee et al., 2005 [141] conducted research that involved placing some cameras on the ceiling of a room fitted out for the study with bedroom furniture such as a bed and chair, among others. The researchers asked the study group to adopt five positions and repeat them three times, and the results of the behavioural pattern were then compared to previous recordings that simulated falls. The system detected 77% of falls and lost 23%. There were only false alarms on 5% of occasions.

Reeves et al., 2007 [142] carried out a study in which they used 20 environmental sensors fitted in a home that detected participants' daily activity with a view to designing algorithms to establish normal behavioural patterns among users – and thus be able to identify any deviations from these normal patterns in real time. When they detected deviations, an alarm went off to alert carers of a possible situation involving risk.

Jun et al., 2009 [143], used the 3D Vicon movement capturing system and six markers, and to this system they added accelerometers and gyroscopes. The purpose of the study was to obtain detailed parameters in the laboratory that could then be used to detect falls. They studied walking patterns based on silhouettes taken from sequences of images. Three features of the walking patterns were researched from three different image capturing perspectives: shoulder height, spine tilt and centre of the silhouette. By assessing fourteen sequences of images that represented a range of healthy walking styles in frail people, features were extracted and compared to the results obtained when capturing movement using the 3D Vicon system.

Zouba et al., 2009 [144] used cameras and sensors but incorporated them in a laboratory environment known as GERHOME comprising four rooms: kitchen, living room, bedroom and bathroom. The aim was to conduct a more exhaustive analysis of movement-related patterns in daily life in the search for changes in behaviour that might predict risky situations. The data obtained from 2 volunteers was analyzed (of 64 and 85 years of age), and the accuracy in recognizing postures and events ranged from between 62 and 94%, while sensitivity was within the 62-87% range.

Tolkiehn et al., 2011 [145] included an ADXL330 triaxial accelerometer, a barometric pressure sensor (VTI SCP 1000-D01) and a wireless sensor network (WSN) in their research, located in a device attached to the waist. The experimental results showed not only a reliable fall detector but also managed to ascertain the direction of fall, thus being able to predict the location of the affected joint.

Menelas et al., 2012 [146] designed a game that would enable users to keep their balance on five different types of flooring (broken stone, stone powder, sand, concrete and wood). The proposed game combined elements from the real world with an interactive virtual one provided by a Kinect™ sensor. When exposing the user to various destabilizing events (disturbances) provided by an interactive shoe, the purpose of the game was to strengthen the lower extremities and prevent falls. On the other hand, as a result of using interactive footwear, it was possible to record users' dynamics and their capacity to maintain postural stability following a disturbance in real time.

Nakajima et al., 2012 [147] carried out a study with the aid of some manipulated inner soles in which the results revealed that capturing walking pattern features may identify elderly persons with a high risk of falling.

Tchalla et al., 2012[148] simply ascertained that a system for switching a light on around the bed significantly reduced falls in the home when the subject placed their foot on the floor when getting in or out of bed, alongside an intercommunication system based on a medal-shaped switch used for assistance in the event of emergency.

Sadasivam et al., 2014 [149] proposed the development of a remote-controlled robot (Spykee) equipped with video camera and different sensors that passed over all types of flooring, including carpets. The purpose of the study was to see whether the robot was able to make an assessment of risks in the home by detecting potential hazards and preventing falls.

Ando et al., 2015 [150] carried out a laboratory study in which they used all possible capacities of a smartphone to not only detect the risk of falling but also to discriminate between the different types of fall in frail people. The fall detection methodology was based on an acceleration and orientation analysis, and the information gathered by the smartphone sensors was processed via threshold algorithms (TAS). The authors showed that the methodology developed was able to detect and classify three

types of possible fall (forwards, backwards, seated, on stairs and sideways). This work could be used both for indoors and outdoors in places such as museums, hospitals and public spaces, but also in the home (e.g. for monitoring subjects who have recently been discharged from hospital).

Chaccour et al., 2015 [151] developed a Zimmer® frame equipped with acoustic signals, infrared sensors, an ultrasound sound, optic sensors and inertial accelerometers. The Zimmer® frame was validated in the laboratory with 5 students, and the results obtained showed the ability of the Zimmer® frame to detect obstacles by giving off an acoustic signal – very useful for preventing knocks and falls.

Dubois et al., 2015 [152] proposed a system for preventing falls in the home. This system was based on an in-depth analysis of images provided by the Microsoft Kinect™ sensor, and was designed to detect whether the person being monitored has fallen or is performing a risky activity such as getting on a chair. The results obtained from previous research by Dubois et al., 2013 and Dubois et al., 2014 [153,154] showed that it was possible to identify a person's activity and to analyze measurements of the walking parameters from in-depth images, although there was a problem with identifying the person being monitored. To recognize the person being monitored, the walking parameters of that person were used rather than facial recognition and algorithms were developed to enable the sensor to detect this, thus managing to personalized prevention of falling in the home without the need for them to carry any other type of device.

1.2.2.2.1 Conclusions Area: Prevention

Preventing risky situations and preventing falls in elderly persons is of the utmost importance so as to thus in turn prevent any increase in their degree of frailty and ensure they remain independent for as long as possible.

With this aim in mind, we found devices in most of the studies reviewed – specifically wireless sensors of different types (motion, optic and pressure, etc.) that determine the risk of falling in elderly persons according to the data recorded and compared to normal behavioural patterns.

In terms of new features, we found on the one hand the inclusion within the research analyzed of something as common in our day-to-day lives as smartphones and, on the other, recognition of the person being monitored from among others who may

share the household as obtained using the Microsoft Kinect™ sensor. Lastly, the use of robots constitutes a challenge that is already starting to bear fruit. Table 8 contains the studies analyzed.

Results in area: Prevention

AUTHOR	YEAR	COUNTRY	CLINIC GROUP	CONTROL GROUP	AGE	DIAGNOSIS	AREA	METHOD	CLASSIFICATION
Lee et al., 2005[141]	2005	Canada	21	--	20-40	Frailty	Prevention	Videocameras	Hardware Software
Reeves et al., 2007[142]	2007	United Kingdom	-- 21 municipios	--	Senior	Frailty	Prevention	20 Wireless environmental sensors	Hardware Software
Jun et al., 2009[143]	2009	USA	--	--	Healthy Young Adults	Frailty	Prevention	Vicon 3D system 6 markers	Hardware Software
Zouba et al., 2009[144]	2009	France	2	--	64-85	Frailty	Prevention	GERHOME: Cameras and sensors	Hardware Software
Tolkiehn et al., 2011[145]	2011	United Kingdom	12	--	$\bar{x}$ 26	Frailty	Prevention	Acelerometer Barometric pressure sensor	Hardware Software
Menelas et al., 2012[146]	2012	Canada	--	--	Only laboratory tests	Frailty	Prevention	Kinect™ Interactive shoe	Hadware Software
Nakajima et al., 2012[147]	2012	Japan	498	--	$\bar{x}$ 74	Frailty	Prevention	Manipulated inner soles	Hadware Software
Tchalla et al., 2012[148]	2012	France	96	98	≥65	Frailty	Prevention	Telecare	Hardware Software

Results in area: Prevention									
AUTHOR	**YEAR**	**COUNTRY**	**CLINIC GROUP**	**CONTROL GROUP**	**AGE**	**DIAGNOSIS**	**AREA**	**METHOD**	**CLASSIFICATION**
Sadasivam et al., 2014[149]	2014	USA	9	--	71-90	Frailty	Prevention	Robot with videocamera	Hardware Software
Ando et al., 2015[150]	2015	Italy	10	--	25-44	Frailty	Prevention	Smartphone	Hardware Software
Chaccour et al., 2015[151]	2015	France	--	--	Young adults in laboratory	Frailty	Prevention	Optical sensors Inertial acelerometer Audio notification module Location module Infrared sensors Ultrasonic sensor	Hardware Software
Dubois et al., 2015[152]	2015	Switzerland	12	--	21-54	Frailty	Prevention	Sensor Kinect	Hardware Software

Table 8. Results in area: Prevention

1.2.2.3 Area: Care

The number of results in this area has been very stable over most years since 2005, with there being a significant upswing in 2012. (Figure 10)

Savenstedt et al., 2005 [155] established an internet protocol with broadband together with a conference system, the purpose of which was to set in motion a telecare service. In the results they found technical limitation in transferring communication, and they thought it necessary to carry out further studies in which the technical conditions could improve so as to quantitatively and qualitatively assess the results obtained.

Finkelstein et al., 2006 [156] developed the VALUE programme in which they introduced the use of an internet portal that required a PC and video conferencing. The results obtained from this study successfully showed messages being sent and requests for product and care.

Vincent et al., 2006 [157] ascertained that the telecare system proved to be far more effective and efficient when the service included healthcare professionals.

Savolainen et al., 2008 and Magnusson et al., 2012 [158,159] presented the ACTION project in which they introduced information and communication technology (ICT) by developing a study with internet- and video conferencing-based education programmes. This programme successfully obtained the telecare service and communication among frail elderly persons.

Lin et al., 2008 [160] carried out a study in which they used a physiological wireless sensor system. These biosensors were monitored remotely via WiFi, radio frequency and Universal Plug and Play (UPnP) technology. The results showed early detection of signs of decline, thus improving the quality of care and satisfaction of frail elderly persons.

Mahoney et al., 2009 [161] developed the implementation of wireless sensors based on the ZigBee system in the home via the AT EASE programme, to promote care and environmental monitoring and responding to the demand for safety and wellbeing of elderly persons, family members and carers at residential care homes without violating privacy. The results pointed to a perception of the need and usefulness for residents of the system in order to retain their independence and avoid being transferred to a more

restrictive environment such as a hospital, this being the key to the programme's success.

Vacher et al., 2011 and Vacher et al., 2013 [162,163] presented the SWEET-HOME audio technology-based smart home project. The results showed the detection of sound, movement and speech in real time – very promising for frail elderly persons with mobility difficulties.

Robben et al., 2012 [164] implemented an innovative portal that encompassed e-health technologies – an information portal about health and wellbeing (ZWIP). The results showed a very important medium for overcoming fragmentation of health care and for facilitating the participation of frail elderly persons. However, it was found to be limited insofar as it has so far been adopted very little in daily practice.

Pigini et al., 2012 [165] implemented an SRS Mobile platform in the SHADOW multi-mission robot, whereby they managed to get the robot to accompany the frail elderly person in performing a range of daily tasks. The results concluded that robot care was positive in the scenarios involving daily life that had been experimented with, except for in the kitchen. Having said this, participants pointed out that interaction with professionals and/or carers offers greater independence.

Clarke et al., 2013 [166] developed an expandable modular platform comprising integrated sensors: four physiological sensors and three environmental sensors. They did not submit any results because the study was still underway. They revealed the fact that initial data was encouraging for the purpose of providing care and detecting possible hazardous events in frail elderly persons.

De Folter et al., 2014 [167] presented the InCasa project that was defined as an integrated network for care/independence of frail elderly persons. The system comprised a sensor for use in bed and two motion sensors, and the results demonstrated the system's capacity for monitoring daily mobility – very useful for detecting hazardous events and signs of decline.

Man et al., 2015 [168] presented an application platform via interactive software with eleven functions that can be used from any PC, tablet or smartphone. The results showed it to be a very useful and suitable platform for any device, and participants

highlighted the fact that it was easy to use as well as being useful as support for their independence and self-sufficiency.

1.2.2.3.1 Conclusions Area: Care

Technology is able to supervise indicators referring to state of health, provide warnings about events such as falls, and give early warning of potential problems and signs of decline in frail elderly persons.

There is also broad recognition of technology's potential for improving the safety and independence of frail elderly persons. This technology enables quality services to be accessed and the ability for such subjects to remain in their own homes to be extended, thus improving their quality of life by improving their independence.

Technology complements the care work carried out by carers and healthcare professionals but does not yet replace it, because from the previously-described results we can deduce that interaction with professionals and/or carers offers still greater independence. Table 9 contains the studies analyzed.

Results in area: Care									
AUTHOR	**YEAR**	**COUNTRY**	**CLINIC GROUP**	**CONTROL GROUP**	**AGE**	**DIAGNOSIS**	**AREA**	**METHOD**	**CLASSIFICATION**
Savenstedt et al., 2005[155]	2005	Sweden	18	..	Senior	Frailty	Care	Telecare	Hardware Software
Finkelstein et al., 2006[156]	2006	USA	40	40	≥60	Frailty	Care	Telecare: VALUE program	Hardware Software
Vincent et al., 2006[157]	2006	Canadá	38	--	≥65	Frailty	Care	Telecare	Hardware
Savolainen et al., 2008 y Magnusson et al., 2012[158,159]	2008	Sweden	--	--	Senior	Frailty	Care	Technology of the information and communication. (TICs)	Hardware Software
Lin et al., 2008[160]	2008	Taiwan	--	--	≥60	Frailty	Care	Wireless physiological sensors	Hardware Software
Mahoney et al., 2009[161]	2009	USA	13	--	$\bar{x}$ 79	Frailty	Care	AT EASE Project	Hardware Software
Vacher et al., 2011 y 2013[162,163]	2011	France	13	--	$\bar{x}$ 35	Frailty	Care	SWEET-HOME Project	Hardware Software
Robben et al., 2012[164]	2012	Netherlands	290	--	≥70	Frailty	Care	e-salud web site	Software

Results in area: Care									
AUTHOR	**YEAR**	**COUNTRY**	**CLINIC GROUP**	**CONTROL GROUP**	**AGE**	**DIAGNOSIS**	**AREA**	**METHOD**	**CLASSIFICATION**
Pigini et al., 2012[165]	2012	Italy	63	--	75-91	Frailty	Care	Robot Shadow	Hardware Software
Clarke et al., 2013[166]	2013	United Kingdom	11	--	45-82	Frailty	Care	Integrated sensor platform	Hardware Software
De Folter et al., 2014[167]	2014	United Kingdom	--	--	Senior	Frailty	Care	inCASA (integrated network)	Hardware Software
Man et al., 2015[168]	2015	Netherlands	73	--	≥65	Frailty	Care	Interactive Software with 11 functions	Software

Table 9. Results in area: Care

1.2.2.4 Area: Treatment

This is the area in which the least number of results were found in the course of the present review.

The years in which the greatest number of results were concentrated were as in the case of the Diagnosis area, i.e. between 2011 and 2015. (Figure 10)

Ganea et al., 2007 [169] carried out a study using a system of inertial sensors attached to a trunk with a data recorder to monitor the activity. The results indicated that the tool was simple yet accurate for the purpose of monitoring frail elderly persons and objectively assessing the effectiveness of a rehabilitation programme.

Bondoc et al., 2011 [170] presented the study they had embarked on at the American Congress of Rehabilitation Medicine (ACRM)–American Society of Neurorehabilitation Annual Conference (ASNR), Progress in Rehabilitation Research. The purpose of this study was to determine the effect of the Nintendo® Wii™ console based on functional interventions regarding the participation and physical condition of frail elderly persons within an institutional environment. No results were obtained because the study was still underway.

Conversely, Kwok et al., 2011 [171] did provide results in the study in which they made a comparison between the active Nintendo® Wii™ programme and gymnasium-based standard rehabilitation in frail elderly persons so as to ensure a reduction in falls and also fear of falling. The study was the first randomized test conducted using the Nintendo® Wii™ as a tool for reducing falls and the fear of falling in frail elderly persons, and the results showed that use of Nintendo® Wii™ proved to be more effective than the traditional model as it successfully reduced the number of falls. The programme is suitably cost-effective.

Szturm et al., 2011 [172] conducted a study in which they used pressure and motion sensors together with a biofeedback screen that included three types of video game. The purpose of the study was to ascertain whether balance training via interactive games would result in better control of dynamic balance compared to a standard physical strength and balance programme. The results indicated that (1) the biofeedback screen helped to improve balance; (2) improvement in response when tried out on different surfaces; (3) the movements required to complete the experimental tasks were selected randomly whereby new research is required that would take into account a detailed

design of the movements to be made; (4) the experimental tasks had levels of difficulty that could be manipulated so as to ascertain and challenge the performance of each individual. The authors plan to carry out future home-based studies.

Daniel et al., 2011 [173] presented a study using the Nintendo® Wii™ at the 2011 Annual Scientific Meeting of the American Geriatrics Society, in which they compared the activity carried out by the Geri-Fit® exercise programme to that done with the Nintendo® Wii™ and to a control group. The results indicated an improvement in the physical and muscular state of pre-frail participants both in terms of treatment using Geri-Fit® and the Nintendo® Wii™.

Daniel et al., 2012 [174] conducted a study in pre-frail elderly persons in which the Nintendo® Wii™ console was combined with exercises performed in the seated position and a control group. The purpose of the study was to ascertain the effectiveness of a new rehabilitation programme using some popular games while the participant was wearing a waistcoat laden with weight, thus enabling the degree of frailty of pre-frail participants to be reduced. The results pointed to the fact that there was no difference between intervention groups, and the authors concluded by stating that the exercise programme using Nintendo® Wii™ was as effective as the exercise programme performed in the seated position. They also stressed that use of the console could prove to be very useful in rehabilitation at home following discharge from hospital and/or to perform the exercise in a group.

Tsai et al., 2013 [175] carried out a study, the purpose of which was to assess the acceptability of an aptitude test application (iFit) in a game environment for installation in an assisted community. The games are based on trials that also serve as the following tests: grip strength; balance and reaction time. It was ascertained that the platform could be used to promote health and prevent the appearance of frailty, and the application could be installed both on PCs and tablets and smartphones.

Jorgensen et al., 2013 [176] conducted a study to examine postural balance and muscle strength in elderly persons from the community. In the course of the study they compared the intervention group to another control group that were wearing ethylene vinyl acetate (EVA) inner soles for daily use. The results indicated significant improvements in maximum muscle strength of the leg and in overall functional performance. Bilateral static postural balance remained unaltered.

Kim et al., 2013 [177] carried out an unsupervised virtual reality study that consisted of a muscle strength exercise programme for the hip and balance control. The clinical group evidenced significant improvement in the trials conducted in relation to the control group. The authors insisted that a virtual reality-based exercise programme might prove to be a useful tool for improving the reduction in physical function in elderly persons as a home-based exercise, provided that this is supervised.

Lauritzen et al., 2013 [178] took part in the GameUp: Game-Based Mobility Training and Motivation of Senior Citizens project with a work in which they researched into the use of the FitBit Ultra application as opposed to the Samsung Galaxy S3 pedometer smartphone application and some video cameras. The results showed that the FitBit Ultra application was advisable for carrying out physical activity such as walking in young adults and in more elderly persons who need a little technical assistance with walking (stick). However, this application was not considered advisable if a Zimmer® frame is used for walking.

Padala et al., 2014 [179] presented a study at the 2014 Annual Scientific Meeting - American Geriatrics Society in which they conducted a retrospective review of 400 subjects ≥ 60 years of age who had undergone rehabilitation in a specialist nursing home. Of these, 63 subjects had the documentation for use of Wii Fit at their disposal during rehabilitation, while a further 63 subjects made up the control group and had no documentation for use of Wii Fit, but only underwent physical therapy. By comparing differences between the groups in terms of the change experienced since the time of admittance in daily activities, balance and the distance covered, the authors concluded that the use of Wii Fit improves these three points, namely balance, the distance covered and daily activities.

Kubicki et al., 2014 [180] carried out a study with a view to researching into the effects of a 2D virtual reality-based programme on postural control associated with a swift movement of the arm in frail elderly persons for rehabilitation purposes, by re-learning to use the upper extremities. They used the virtual reality system, Fovea Interactive®, and a marker on the arm and forearm. The results suggested that a certain level of motor skill re-learning was retained in frail subjects and concluded by saying they thought more training would be necessary to be able to automate the movement.

Geraedts et al., 2014 [181] conducted an assessment study to ascertain compliance with and the effectiveness of an individually-adapted physical activity programme undertaken at home for frail elderly persons. This was done using a physical activity sensor in the form of a pendant to ensure it would be portable and would provide remote feedback using a PC tablet on which videos of the exercises were displayed. The results showed that the programme constituted an innovative method for stimulating physical activity in frail elderly persons. The authors considered that the insight gained in this study could be used to develop and streamline the application of innovative technology in exercise programmes in the home. As a following step, they proposed conducting an effectiveness assessment via a randomized controlled trial.

Geraedts et al., 2015 [182] conducted a randomized controlled trial in which they validated the research carried out in 2014, as described above. In this validation, the authors confirmed that the study group obtained better results in terms of leg mobility than the control group. Therefore, they considered the sensor to be a valuable tool for assessing physical activity in the home based on leg mobility time in frail elderly persons. The authors also thought that further studies would be necessary to specify more specific aspects of walking and postures involved within the daily activity pursued by frail elderly persons.

Fairhall et al., 2015 [183] conducted a randomized controlled trial, the purpose of which was to assess a multi-factor intervention in the development of frailty in pre-frail elderly persons compared to a control group. The results showed mobility improvement, and the multi-factor intervention provided major potential benefits in terms of preventing transition towards frailty.

1.2.2.4.1 Conclusions Area: Treatment

Most research activity was concentrated between 2011 and 2015 in the case of this area. Regular physical activity is essential for elderly adults in general, as this is considered to be the way to remain healthy and independent.

The studies mainly used the Nintendo® Wii™ console to promote physical activity. The putting into practice of this type of console has thus far been tried out in the area of rehabilitation, although its use is confined to games designed for the console and these games do not always meet the full requirements of certain types of treatment.

A further step forward is offered by the introduction of virtual reality using the Fovea Interactive® system as a re-learning method.

Different mobile applications such as FitBit, iFit or some other type of motion sensor or activity gauge both promote and improve physical activity such as walking. This might be used to assist other technologies so as to form part of a more integral method.

The multi-factor intervention programme is very complete, but requires the intervention of many healthcare professionals that means its accessibility is limited. Table 10 contains the studies analyzed.

Results in area: Treatment

AUTHOR	YEAR	COUNTRY	CLINIC GROUP	CONTROL GROUP	AGE	DIAGNOSIS	AREA	METHOD	CLASSIFICATION
Ganea et al., 2007[169]	2007	Switzerland	30	--	74-86	Frailty	Treatment	Inertial sensor system	Hardware Software
Bondoc et al., 2011[170]	2011	USA	20	20	Senior	Frailty	Treatment	Wii sports and Wii Fit program	Hardware
Kwok et al., 2011[171]	2011	Singapore	40	40	≥60	Frailty	Treatment	Nintendo Wii console	Hardware
Szturm et al., 2011[172]	2011	Canada	14	16	65-85	Frailty	Treatment	Pressure and motion sensors	Hardware Software
Daniel et al., 2011[173]	2011	USA	12	11	≥65	Frailty	Treatment	Geri-Fit® program Wii console	Hardware Software
Daniel et al., 2012[174]	2012	USA	16	7	≥70	Frailty	Treatment	Wii®-fit Nintendo Wii console	Hardware
Tsai et al., 2013[175]	2013	Taiwan	101	--	≥60	Frailty	Treatment	iFit fitness testing platform	Hardware Software
Jorgensen et al., 2013[176]	2013	Denmark	28	30	≥65	Frailty	Treatment	Nintendo Wii console	Hardware
Kim et al., 2013[177]	2013	South Korea	18	14	65-72	Frailty	Treatment	Virtual reality	Hardware Software

Results in area: Treatment									
AUTHOR	**YEAR**	**COUNTRY**	**CLINIC GROUP**	**CONTROL GROUP**	**AGE**	**DIAGNOSIS**	**AREA**	**METHOD**	**CLASSIFICATION**
Lauritzen et al., 2013[178]	2013	Sapin	18	--	81-90 25-45	Frailty	Treatment	Fitbit Ultra (activity tracker). Samsung Galaxy S3 (pedometer application)	Hardware
Padala et al., 2014[179]	2014	USA	63	63	≥70	Frailty	Treatment	Wii-Fit	Hardware
Kubicki et al., 2014[180]	2014	France	23	23	≥70	Frailty	Treatment	Based on 2D virtual reality Fovea Interactive® and marker	Hardware
Geraedts et al., 2014[181]	2014	Netherlands	50	--	70-85	Frailty	Treatment	Wireless motion sensor	Hardware Software
Geraedts et al., 2015[182]	2015	USA	20	--	≥70	Frailty	Treatment	Hybrid sensor: acelerometer and barometric pressure sensor	Hardware
Fairhall et al., 2015[183]	2015	Australia	115	115	≥70	Frailty	Treatment	Multifactorial intervention program with online exercises	Interactive computer software

Table 10. Results in area: Treatment

1.2.3 Summary

This paper provides a review of the most relevant devices and technologies that were developed between 2005 and 2015 in the different areas covered by frailty, namely prevention, care, diagnosis and treatment. In most of the results, classified according to areas, the objective that had been set out for each study was met, and all studies show that technologies make it possible to work in different areas linked to frailty.

However, what is the most suitable technology for each area? May we conclude by stating that these technologies are genuinely useful in each area?

After having analyzed each study one by one, it is important to focus attention on the set of these technologies classified according to areas and to compare them, so as to find a satisfactory response to these questions.

In the area of diagnosis, the scales on which the authors based the design of the devices are: Fried's phenotype model of frailty and the trial-based model. 15 studies stand out among those that assess frailty, taking into account the different models described.

This review shows how research provides very similar results in terms of the development of technologies based on one scale or another. (Figure 11)

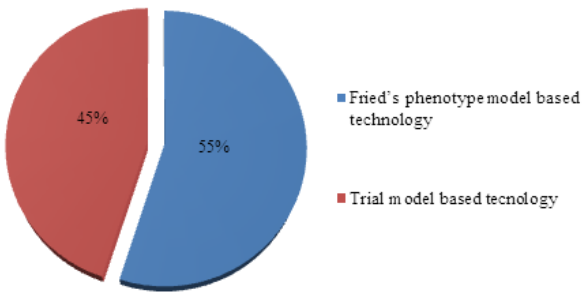

Figure 11. Percentage of results according to the scales on which the authors base for the design of technology in the area: Diagnosis.

Irrespective of the scale used for the design, advances made in wireless technology can be noted, as can the integration of smartphones, within the interactive multimedia game world – and even in smart clothes that may facilitate more standardized assessment in daily physical activity [184].

Thus, when assessing the functional capacity of elderly persons, healthcare professionals may have objective information at their disposal for assessment purposes, as the information provided is often based on self-reports by the interested parties themselves, and this may vary a great deal from one individual to the next.

The results show that there is a correlation between the frailty results obtained via the interactive game system and the results obtained from traditional measuring methods. They also show that the interactive game-based system is a predictive tool of great specificity that can be used to assess frailty.

The most recent finding related to sensors attached to the arm and forearm features, in addition to its simplicity, a unique characteristic that is its applicability in individual health clinics. To ascertain test-retest reliability and the viability of a new method, the authors envisage assessing the tool in a larger sample, in different groups of subjects and in different areas of health care.

These parameters might in the future prove to be of great interest in the clinical sphere of activity to help with methods used to identify the elderly population with frailty syndrome.

In the area of prevention, frailty is also recognized as a factor involving risk of falling. The negative consequences related to falls include fear of falling, loss of confidence, anxiety, depressive symptoms and reduction in self-sufficiency, which may lead to social isolation and/or avoidance of physical activity. However, it is also known that up to 40% of falls can potentially be prevented, according to Kojima et al., 2015 [185].

This review shows how research provides very similar results in terms of the development of devices that use both wireless sensors with cameras and Kinect™ sensors to analyze movements and postures that may indicate a risk of falling. (Figure 12)

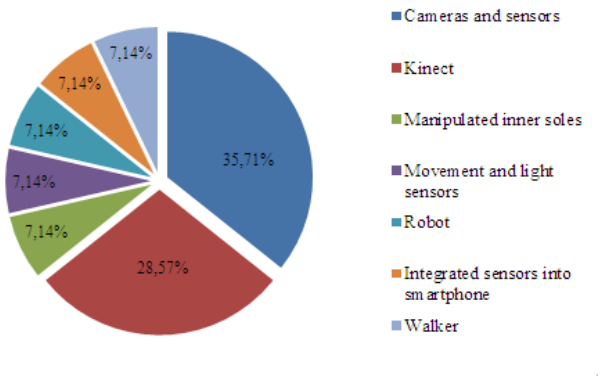

Figure 12. Percentage of devices used in studies for fall prevention.

Promising results have been obtained for future studies that may increase the accuracy both of extracting features of risky patterns and postures such as the monitoring of elderly persons thought to be at risk.

Using a robot to identify possible risks in the home is a new feature, although the study itself pinpoints to several research questions about how best to use remote-controlled robots in another sense that may for instance help to reduce the number of home visits by staff and therefore improve efficiency owing to cost reduction.

In the area of care, the highest percentage was found in the use of different wireless sensors - motion, physiological and environmental in particular – that constitute what are known as smart homes based on different back-up technologies in terms of software needed to develop them. They can prove very interesting in the area of care for frail elderly persons in order to encourage their independence and also improve their quality of life. According to what the authors have been able to ascertain, telecare would seem to be very effective and efficient when the service involves professionals. The application platform is a new system that uses an interactive software that can be operated via any device such as a tablet or smartphone – a feature that encourages independence of frail elderly persons, thus increasing their quality of life. Conversely, the use of robots in care has not yet gained popularity, with contact with other subjects such as carers still being preferred. (Figure 13)

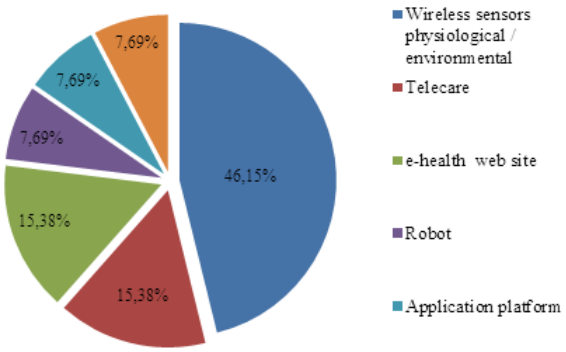

Figure 13. Percentage of tools used in the study for care.

In the area of treatment, the Nintendo® Wii™ console is the most-used tool in the studies analyzed for treatment of frailty in elderly persons. The results show better effectiveness over the traditional method or other tools used in each case, but the disadvantage is that when performing the games that are habitually used in studies, only one or two extremities are involved. These are not activities that envisage more complete ones in which both the trunk and the extremities take part in the game.

Although the physical activity programme that is adapted individually via remote feedback using a tablet-PC that shows exercise videos proved to be very effective, it is limited by the motion sensor used to record only activity involving the legs. The authors consider that future research could include extending the activity programmes at home.

In using pressure and motion sensors with interactive games, the introduction of automatic adaptation of the game being played based on the signals received from the sensors in order to balance the difficulty faced with perceived skills or the physical condition in order to offer better incentives in terms of the player's participation, is considered to be an interesting improvement that could be taken into account when using systems with such interactive games.

Virtual reality is currently in the developmental phase in terms of treatment of frailty. Only one study provides us with insight about this complex system, albeit one replete with possibilities (Figure 14).

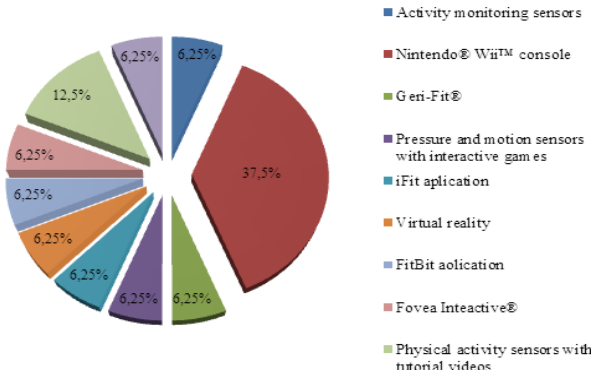

Figure 14. Percentage of devices used in the studies for treatment.

The studies shows that all technologies are suitable for use as tools for treating frail elderly persons.

The serious games appear in 3 of the 4 revised areas. According to the following relation regarding the total: number of articles with use serious games/ number of total articles. The relation is: Diagnosis (1/16), Prevention (2/12), Care (0/12) and Treatment (7/15).

The application of technological solutions in health care is a field that is constantly expanding and about which there are great expectations both on the part of users and healthcare professionals and carers, despite the existing reticence in this area known as a technology gap.

Worldwide, the number of elderly members of the population and the need to be able to assist them properly is on the increase. This need requires major material and human resources that in turn increase costs.

It is of the utmost importance to continue working to reduce the gap existing between technology, frail elderly persons, healthcare professionals and carers by bringing together the different views about technology and thus stimulate dialogue, an increased awareness and knowledge about the respective fields in order to engage in collaboration on projects that may reduce costs and improve health and quality of life.

The researchers should think not only in searching new tools that include active participation of the subjects, but also that involve amusement in order to obtain considerable implication so that success in participation, adherence and activity compliance is achieved regardless the frailty area in which it is developed. In this way, serious games are very interesting.

At present, the serious games are a tool with many possibilities that are being slowly implemented in frailty researches and from which good results are expected in a near future.

"Research is formalized curiosity. It is poking and prying with a purpose".
Zora Neale Hurston

2. *JUSTIFICATION, HYPOTHESIS AND OBJECTIVES*

2 JUSTIFICATION, HYPOTHESIS AND OBJECTIVES

2.1 Justification

Frailty is an important predictor of adverse outcomes in elderly people, such as death (up to 45% a year), institutionalisation, falls, mobility decline, increased disability in basic (BADL) and instrumental activities of daily living (IADL) and hospitalisation, and those with pre-frailty have an increased risk of becoming frail within 3 years [45].

Institutionalised older adults are a heterogeneous population in disability rates, multi-morbidity, quality of life and vulnerability. Interventions in this population should be individualised, and detection and treatment of frailty could be of use in preventing disability, mobility decline, falls and mortality [45].

The last decade has seen a rapid increase in research into the use of technology in the elderly population [186,187]. Exercise via interactive video games – known as exergames – is being increasingly used to increase physical activity, thus improving health and the physical function in elderly persons [186,188-190].

The concept of exergame may be defined as the use of a video game that incorporates physical activity into the game, leading to an improvement in motivation and adherence to participation in that physical activity [191].

Exergames may have basic advantages over traditional exercise, as they easily enable specific tasks to be performed via a range of levels of difficulty. This in turn enables the user to start at a suitably challenging level and then to gradually progress in terms of level of difficulty that can be based on individual performance in real time[186]. However, commercial games that are easily available are mainly designed for entertainment and recreational purposes for younger users with more complex interaction and interface. Exergaming technology is therefore now less of a feasible option for many elderly people [192-194], and furthermore, games available on the market are mainly designed for enjoyment and are not based on basic exercising principles. For games to be effective, users need to make movements with specific features during the game that may be deemed relevant for the function being trained.

Taking into account the above, a contribution needs to be made by creating a technological solution. Thus, it has been decided that a game should be designed whose

contents enable elderly persons to improve their physical capacity and their state of health and independence in the activities they carry out in their daily life via the game in which they take part. The aim is therefore to reduce frailty risk or, if frailty already existed, to improve the extent to which it is in evidence.

In addition to overcoming the technological barrier existing between elderly persons and the use of technological devices, the aim is also to ensure that the game has extra appeal over those already existing such as WII sport (bowling, tennis, boxing) and Wii fit[174,195], in which the scenarios and movements are unique. The extra appeal offered by FRED is that the user passes through different scenarios in which they carry out a range of activities with a specific objective in mind or within a main activity.

The ultimate goal is for the user to be the protagonist, to like the game, and for them to find it appealing so as to become more involved in and further pursue the exercise [196].

2.2 Hypothesis

The exergame as a technological solution can help reduce the risk of frailty in elderly persons by improving their functional capacity, as well as motivating them to perform physical exercise. Physical exercise should be clinically safe and cardiac healthy.

2.2.1 Research questions

It will attempt to answer the following research questions in order to check the previous hypothesis:

- Would the game (FRED) be able to reduce the risk of frailty?
  - Reducing the risk of frailty by performing physical exercise with the FRED game is deemed possible. For this reason, the implementation of a study that seeks to answer the question being asked is proposed.

- Would the game (FRED) be able to motivate subjects to do exercise?
  - Motivating frail elderly persons to do exercise is deemed possible. The aim is to achieve the above via the design of a game that they like and that motivates them.
- Could the exercise performed with the game (FRED) be clinically safe and cardiovascular for frail elderly persons?

- Daily physiological parameters will be collected in order to ensure that the physical exercise to be performed with the game (FRED) is clinically safe and cardiovascular.

2.3 OBJECTIVES

This section describes the general and specific objectives that it is hoped will be achieved by this project.

2.3.1 General objective

The general objective of this project is to design and implement a game for decreasing the risk of frailty and improving functional capacity of elderly persons to enable them to remain independent as long as possible.

2.3.2 Specific objectives

2.3.2.1 Physical objectives

- Improve physical and functional capacity
- Encourage exercise in elderly persons to avoid a sedentary lifestyle.
- Improve the balance in elderly persons to ensure they are safer and more independent.
- Avoid falls in elderly persons to prevent hospitalization.
- Ensure that elderly persons remain independent in terms of the basic activities of daily living (BADL).
- Adherence to and compliance with exercise.

2.3.2.2 Physiological objectives

- Perform an exercise which ensures basic safety parameters of heart rate, blood pressure and blood oxygen saturation.
- Perform a cardiovascular exercise.

2.3.2.3 Technological objectives

- Design and implementation of the serious game, including:
  - Creative and intuitive scenarios
  - Specific exercises created respecting biomechanics and neuromotor activity.
- Different activities with a goal or within a main activity.
- Achieve usability of the game.

2.3.2.4 Social objetives

- Improve the perception of quality of life.
- Encourage participation and integration.
- Improve mood state.
- Avoid isolation in elderly persons.

“In much of society, research means to investigate something you do not know or understand”.
Neil Armstrong

3. *MATERIAL AND METHODS*

3 MATERIAL AND METHODS

3.1 Experimental design

3.1.1 Ethics committee approval

Approval was requested and obtained from the Ethics Committee in Research of the Deusto Foundation (University of Deusto), reference number Ref: ETK-17/15-16, in order to proceed with the study.

3.1.2 Participant Recruitment

Contact was established with two residential homes, and the necessary permits were requested and obtained from the management at the home.

Recruitment at both residential homes was undertaken via informative talks that were given. These talks were open to all interested residents and were advertised via informative posters and pamphlets.

Interested subjects signed the duly-informed consent form. Screening was arranged for 65 subjects in total in accordance with the the inclusion and exclusion criteria.

3.1.3 Study type

The following studies have been carried out

- ***A pilot three-week randomized controlled trial (Phase 1):*** A feasibility pilot study to verify that the game designed, achieves to reach the objective set: reduce the risk of presenting frailty of the subjects. For this purpose, the Short Physical Performance Battery (SPPB) has been used.
- ***A pilot six-week randomized controlled trial (Phase 2) with biofeedback***: Pilot study to verify that the game designed, over 6 weeks has continued to achieve the objective set: reduce the risk of presenting frailty of the subjects. For this purpose, the Short Physical Performance Battery (SPPB) has been used. In addition, the Barthel Index and the EuroQol 5D-5L questionnaire have been included. Biofeedback has been recorded with the following physiological constants: systolic blood pressure, diastolic blood pressure, heart rate and blood oxygen saturation, in the intervention group, with which it has been verified that the physical exercise posed in the FRED game is inside of heart-healthy and safe parameters.

3.1.4 Participants

3.1.4.1 Inclusion criteria

Inclusion criteria: persons over 65 years of age with a Barthel Index equal to or above 90 points who carry out no scheduled physical activity

3.1.4.2 Exclusion criteria

Exclusion criteria: persons over 65 years of age with a Barthel Index less than 90 points or with a Barthel Index equal to or above 90 points who carry out scheduled physical activity.

3.1.4.3 Description of the sample

Of the 65 subjects who showed interest in taking part in the study, 46 met the inclusion criteria, and these subjects were again asked to carry out some specific tests in order to evidence their degree of frailty

Of the 46 subjects, 40 obtained scores below 10, i.e. 40 subjects evidence frailty risk according to the SPPB test.

40 subjects started the study, although only 39 completed it. One subject from the control group passed away before the study was completed.

The following table summarises the major features of both groups. (Table 11)

	Control G. (n=20)	Study G. (n=20)
Inclusion Barthel	Slight Dependence 60% Independence 40%	Slight Dependence 60% Independence 40%
Age	83.32±8.82 años	85.47±6.45 años
Sex	Man 40% Woman 60%	Man 40% Woman 60%
Frailty Risk	100%	100%
SPPB	7.16±1.07	7.28±1.86
Diabetes Mellitus(DM)	No 80% Yes 20%	No 80% Yes 20%
Hypertension(HT)	No 45% Yes 55%	No 45% Yes 55%
Dyslipidaemia (DL)	No 75% Yes 25%	No 75% Yes 25%
DM and HT	No 85% Yes 15%	No 85% Yes 15%
DL and HT	No 85% Yes 15%	No 85% Yes 15%
Medical history of cardiovascular risk	No 70% Yes 30%	No 70% Yes 30%
EQ-5D-5L	85.19±14.59	86.79±10.52
EQ-VAS	71.5±17.85	74.7±17.58

Table 11. Description of sample features. Measurement of quality of life in terms of health. DM:Diabetes Mellitus; HT:Hipertensión; DL:Dyslipidaemia; EQ 5D-5L y EQVAS.

The sample proved to be homogeneous in terms of the Barthel Index, age, gender and frailty risk, EuroQol 5D-5L, Medical History of Cardiovascular Risk.

3.1.5 List and description of evaluation tools: indices, questionnaries and tests

The following evaluation tools were used in this study, and these were authorised for use by different authors following prior request for permission by email. With the intention of respecting the privacy of the contents, these e-mails have not been attached as attachments.

The evaluation tools have been:

- **Barthel Index**: a scale with which a quantitative estimate is obtained of the degree of independence a subject has to pursue activities of daily living. The score ranges from 0 to 100. [197,198]
  The interpretation of this score is described below. (Table 12)

BARTHEL INDEX	INTERPRETATION
0-20	Total dependence
21-60	Severe dependence
61-90	Moderate dependence
91-99	Slight dependence
100	Independence

Table 12. Barthel Index: score and interpretation

- **EuroQol 5D-5L:** a standardised measure for state of health developed by the EuroQol Group in order to provide a single, general measurement applicable to a wide range of health conditions and treatments, which in turn provides a single descriptive profile and a unique state of health rate that may be used in clinical assessment. The individual themselves assesses their state of health – first in terms of seriousness via dimensions (descriptive system) and then via a visual analogue scale (VAS) for more general assessment purposes. This last scale ranges from 0 to 100. [199-201].

- **Short Physical Performance Battery (SPPB)**: This Battery includes 3 tests: balance test, gait speed and standing up from/sitting down on a chair 5 times. These tests follow a hierarchical sequence.

  In the first test, the balance test, the participant tries to maintain 3 positions: side-by-side stand, semi-tandem and tandem stand for 10 seconds each. In the second test, the gait speed test, the participant walks a distance of 4 metres at their normal pace, this test is performed twice and the shortest time is recorded. Lastly, in the case of the chair stand test, the participant stands up from and sits down on a chair 5 times as quickly as possible, and the total time taken is recorded. Each test is given a score from 0 (worst performance) to 4 (best performance): for the balance test and according to a hierarchical combination of performance in the 3 component subtests and the other 2 tests, a 0 score is assigned to those that do not complete or try out the test, and scores from 1 to 4 according to the time taken. A total score is obtained for the whole battery, which is the sum of that obtained from the 3 tests and ranges between 0 and 12. Scores below 10 evince frailty[105,202].(Figure 15)

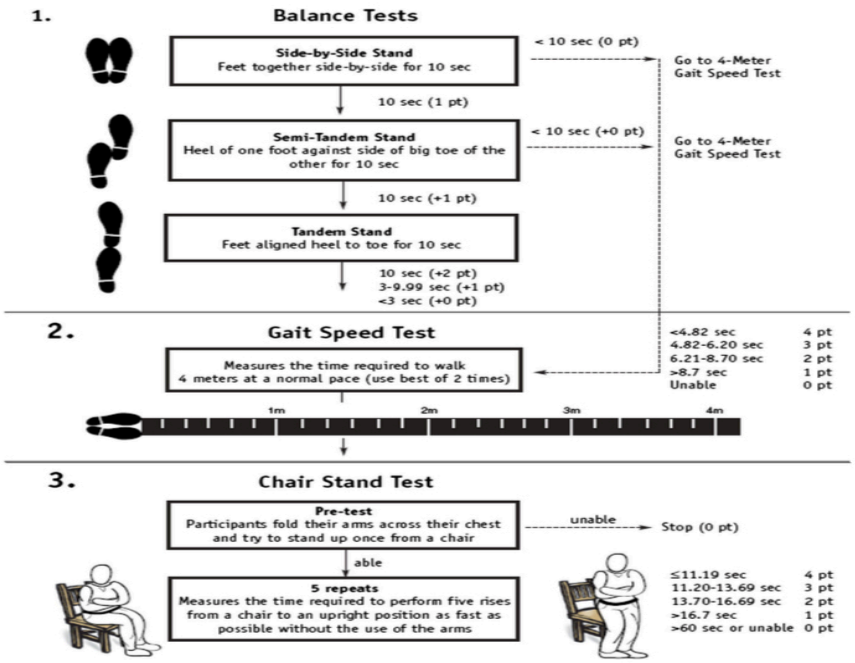

Figure 15. Short Physical Performance Battery (SPPB) flowchart. Source:[106].

- **The System Usability Scale (SUS):** This is a questionnaire based on the Likert scale to rate the capacity for using systems. The score may be between 0 and 100, in which 100 represents the best usability and a score of ≥68 is considered positive [203].

3.1.6 Evaluation test

Frailty screening was undertaken using the Short Physical Performance Battery (SPPB), validated and normalised within our milieu, which combines balance testing, gait speed and chair stand. This prioritization was based on its successful validation in detecting frailty and great reliability in predicting disability[105,202].

Of the 46 subjects, 30 obtained scores below 10, i.e. 40 subjects may be considered frail.

In addition to the Barthel Index, the 40 subjects filled in the following questionnaire: EuroQol 5D-5L. Medical records related to risk of heart failure were also gathered.

3.1.7 Radomization and procedure

The groups were randomized as follows.

To undertake randomization, these 40 subjects were classified according to range of age, gender and Barthel Index, obtaining a study group and a control group of subjects respectively.

With the resulting groups, the procedure described below has taken place.

The subjects belonging to the study group carried out three sessions per week over a 3 and 6 week period. Each session involved 20 minutes of activity divided into three parts.

The first targeted both the upper and lower extremities, while the second and third targeted specifically the upper and lower extremities respectively. On completion of each part, the subject has the chance to rate the exertion made using the simplified Borg scale [18]. Depending on their rating, they will either be able to continue immediately, or after doing some abdominal-diaphragmatic breathing exercises that will be of a duration that depends on the rating of the exertion made. After completing these breathing exercises, they may choose to continue or otherwise abandon the activity.

In the 6-week study group, the physiological constants – blood pressure, heart rate and blood oxygen saturation – were recorded prior to commencing the FRED game, immediately after completing it and after 5 minutes had elapsed, according to the publications reviewed.[204-206].

- **Heart Rate (HR): <76% Heart Rate Maximum (%FCMAX)(*)**
- **Systolic Blood Pressure (SBP): <150mmHg**
- **Diastolic Blood Pressure (DBP): <90mmHg**
- **Blood Oxygen Saturation (SpO2): Variations <5%SpO2.**

(*)Modified Borg scale: a 5 score on the Borg scale is included together with the maximum heart rate percentage [<76% Heart Rate Maximum (%FCMAX)] in order to ascertain that the perceived exertion is correctly related to heart rate.

The following parameters were established taking into account these publications [204-206] (Table 13), above all to assess the fact that under no circumstances may the pursuit of physical exercise using the FRED game put the subject at any risk, thus ensuring that the activity is safe and, in turn, to assess whether it may also be beneficial to cardiovascular health:

ABSOLUTE INTENSITY			RELATIVE INTENSITY			
Intensity	MET	EXAMPLES	%HRmax	RPE(Borg Sacale)*	RPE(Bcrg Scale)**Modificada	Talk Test
Light	1.1-2.9	Walkirg<4.7km/h, light household work	50-63	10-11	0-3	
Moderate	3-5.9	Walkirg briskly(4.8-6.5 km/h, slow cycling(15 km/h), painting/decorating, vacuuming, gardening(mowing lawn), golf(pulling clubs in trolley),tennis(doubles),ballroom dancing, water aerobics	64-76	12-13	4-5	Breathing is faster but compatible with speaking full sentences
Vigorous	≥6	Race-walking,jogging or running,bicycling >15km/h,heavy gardening(continuous digging or hoeing),swimming laps,tennis(single)	77-93	14-16	6-10	Breathing very hard, incompatible with carrying on a conversation comfortably

*Table 13. Classification of intensity of physical activity. Examples of absolute and relative levels of intensity. MET (metabolic equivalent). RPE (Rating of perceived exertion) (*20 value Borg score) (**10 value Borg score). % HRmax, percentaje of measured or estimated maximum heart rate (220-age). Source: Modified from Howley*[207]

After completing the FRED game session each day, each participant from the study group was asked 2 simple questions, with just a YES or NO answer.

The subjects belonging to the control group continued to lead their daily lives in the course of which they had no physical activity scheduled.

On one hand, after 3 weeks and having taken part in 9 physical activity sessions with the FRED game, the Short Physical Performance Battery (SPPB) test was once again carried out to ascertain whether the degree of frailty had been reduced.

And on other hand, after 6 weeks and having taken part in 18 physical activity sessions with the FRED game, the Short Physical Performance Battery (SPPB) test was once again carried out to ascertain whether the degree of frailty had been reduced. The Barthel Index and the EuroQol 5D-5L questionnaire were in turn run passed the subjects and lastly, the System Usability Scale (SUS) was applied exclusively to subjects from the intervention group.

3.1.8 Stadistical analysis

The R open code statistical programme version 3.2 for Windows is used to carry out the statistical tests and create the graphs.

The Wilcoxon Exact Test is carried out in order to compare the means obtained from the study group before the test and after 3 and 6 weeks.

The relationship between an improvement in their results and belonging to the study group was measured using the Pearson and Fisher-Exact tests.

An adjusted Cochran-Mantel-Haenszel estimate was used to compare the relative risks involved when stratifying the data in terms of age and gender.

3.2 System design

3.2.1 FRED game creation basis

The FRED game was designed as a type of exergame [191], in which the author of this thesis, in their capacity as physiotherapist, designed the contents of the game while at the same time taking into account both specific movements for developing physical exercise and the devising of different scenarios in which these movements could be developed. These scenarios are developed in a logical order to ensure that the subjects who perform them find a meaning to the activity. Each movement is designed by taking

into account both biomechanical and neuromotor parameters and evidence features of sufficient extent to be recognised by the Kinect™ sensor.

3.2.2 Materials used for the development and start up of the FRED game

FRED is a game that has been developed using a 3D unity motor, and needs a Kinect™ game controller connected to a computer and a screen or TV.

Unity is a game engine based in native C^{++}. Despite Unity allows for implementing code in C#, JavaScrip (UnityScript) or less frequently in Boo, FRED is 90% implemented in C# and some simple scripts for handle objects were developed in JavaScript. The code from Unity is executed in Mono or Microsoft.NET framework, compiled just-in-time (JIT) (except for iOS, which does not allow JIT code, and Mono is native compiled Ahead-of-Time (AOT).

Unity allows for try the game in an IDE without having to realize any sort of compilation or export. When the code is executed in Unity, Mono version 3.5 was employed, this version is compatible with the API.

The minimum technical characteristics required for the computer are: 7th Generation Intel® Core™ processor which supports up to 16GB of RAM Memory, integrated graphics Geforce GTX970. USB 3.0, Windows 10 – 64 bits Operating System.

3.2.3 FRED game description

The author of this thesis, in their capacity as physiotherapist has designed the FRED game presenting the structure in its design to be described in this section. (Figure 16)

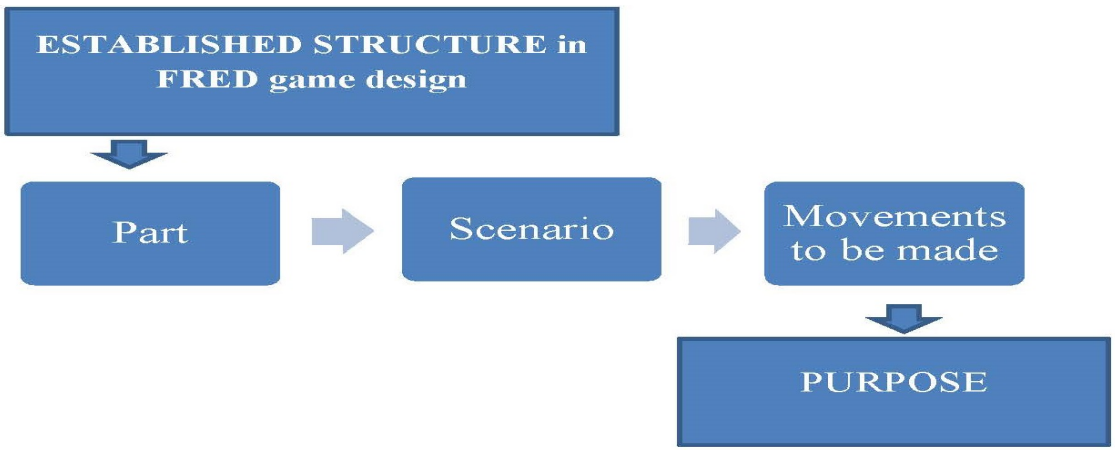

Figure 16. Established structure in Fred game design.

The FRED game consists of three parts. Each part presents creative and intuitive scenarios to capture the attention and interest of the subject.

In each scenario specific movements are carried out to exercise large muscle groups comprising several joints. Specific movements also have to have the characteristic of being functional movements, ie, set of movements that serve to perform a specific activity such as: the set of movements made during the action of picking up an apple, rolling up a hose, etc.

The repeated functional movements of the upper limbs and upper trunk such as reaching, leading to the side an object, carrying an object backwards and bending [208,209] facilitate independence in the basic activities of daily life (BADL) such as transfers, dressing, feeding and toilet [210]. While repeated functional movements of the lower limbs and lower trunk can provide functionally relevant improvements, such as cardiovascular fitness [211], walking distance, speed, transfers as well as, independence in activities of daily living [208,209].

Of course, and although it is not the main objective of this research as a health professional, the author of this work, considered it fundamental that the exercise performed in the game designed (FRED), meets the criteria of being cardio healthy and safe.

The FRED game unfolds on an estate where there is a road lined with trees that leads to a hamlet with a vegetable garden and vineyards. The game consists of various scenarios. Each scenario represents one or more steps in a simplified process to produce txakoli [24]. The user starts to carry out the different activities which are remote controlled and in order, and each activity corresponds to a specific movement of the upper and/or lower extremity. Apart from the physical activity, the game requires attention, coordination of movement, balance, accuracy and spatial orientation.

The Kinect™ sensor detects and records the ranges of movement and time that have been previously defined, giving a positive score to successfully-completed exercises and showing the final score at the end of each part.

Each session involved 20 minutes of activity divided into three parts. The first targeted both the upper and lower extremities, while the second and third targeted specifically the upper and lower extremities respectively.

On completion of each phase, the subject has the chance to rate the exertion made using the simplified Borg scale [212]. Depending on their rating, they will either be able to continue immediately, or after doing some abdominal-diaphragmatic breathing exercises that will be of a duration that depends on the rating of the exertion made. After completing these breathing exercises, they may choose to continue or otherwise abandon the activity. (Figure 17)

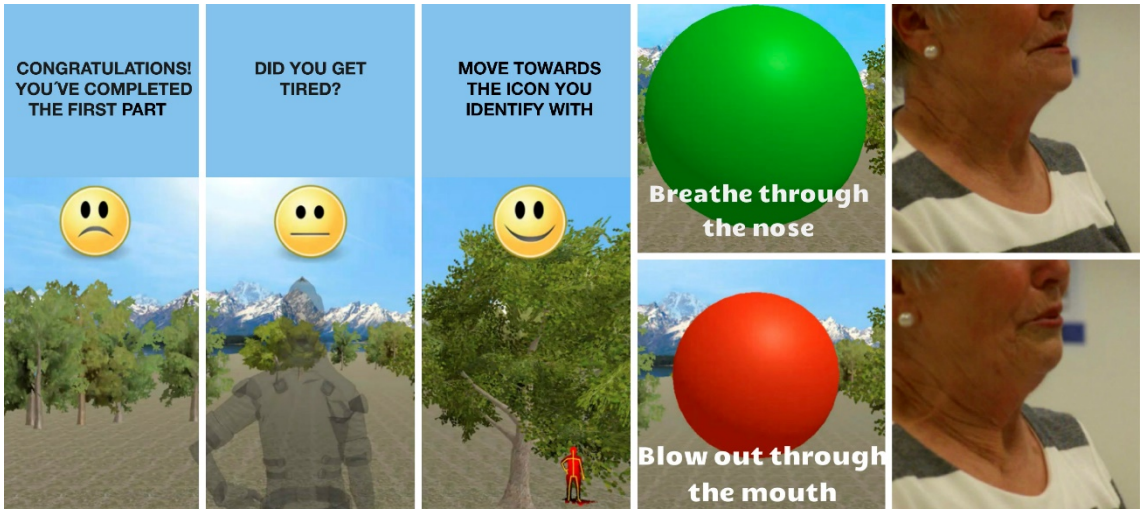

Figure 17. Images of the game at the moment when the effort made is rated, together with images of the moment when the breathing exercises are carried out.

As the image shows, the subject should be placed on the emoticon that expresses how it feels. If the subject feels good, will continue to play without breathing. In case of neutral sensation, the subject has to perform 5 diaphragmatic breathing before continue playing. If on the contrary, the subject fells wrong, the breaths that have to be performed are doubled (10 diaphragmatic breathing). The balloon that appears in the image facilitates the realization of the breaths. The balloon swells and is green when the subject breathes, while on the contrary, it decreases in size and changes to red when the subject blows out the air.

Below the different scenarios of the game with be considered and in sequential order. It is described every single movement that is necessary to carry out, what is their objective and why they have been used. (Figure 18)

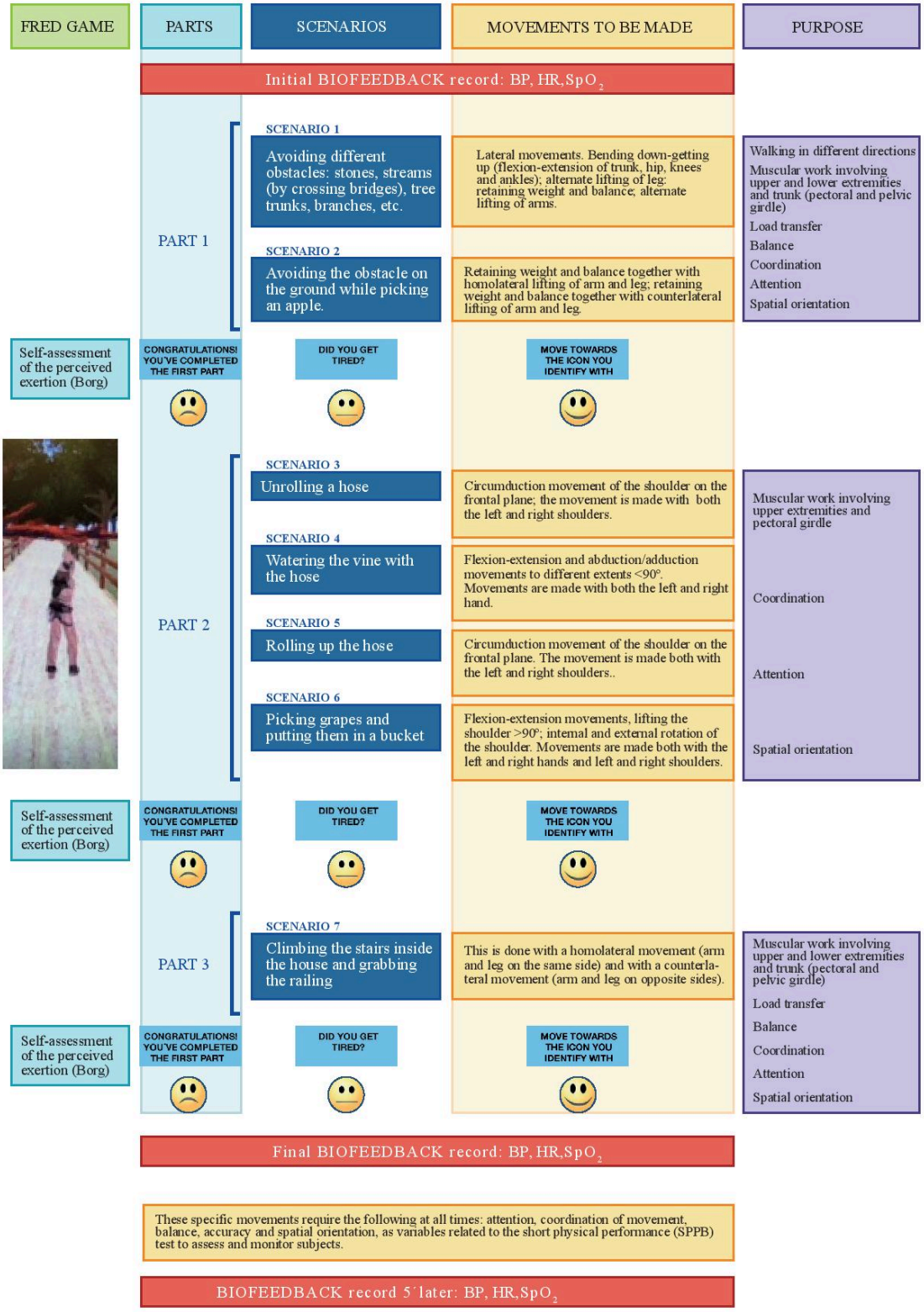

Figure 18. FRED Game overview: structure and contents.

The game FRED presents three levels of difficulty. These levels of difficulty depend on the time and situation of the different obstacles to overcome and the situation of the fruits to pick up. (Table 14)

FRED LEVELS	TOTAL TIME
LEVEL 1 (LOW DIFFICULTY)	10 MINUTES
LEVEL 2 (MEDIUM DIFFICULTY)	20 MINUTES
LEVEL 3 (HIGH DIFFICULTY)	30 MINUTES

Table 14. Difficulty levels of FRED game.

In this research project has been used the level 2 (medium difficulty), therefore, 20 minutes of total duration.

Below is a general summary as a **synopsis** of the main activity chosen for the **FRED game**.

The player begins his adventure of elaborating txakoli, heading towards the hamlet by a road in which he finds different obstacles that must surpass to add points. Once in the hamlet, the player have to water the vineyard. To do this, unroll the hose, observes how the vineyards grow while watering, while adding points. After finishing watering, he goes to roll up the hose. Once collected, the player begins to pick the grape up and puts it in a bucket. All the collected grapes will be found in the wine press located at the top floor, which the player will have to access by going up stairs.

Part 1

Scenario 1: Avoiding different obstacles

In which the player walks on a path towards a hamlet along which they have to avoid different obstacles: stones, streams (by crossing bridges, tree trunks and branches).

Specific movements *to be made in* ***Scenario 1***: Lateral movements: bending down-getting up (flexion-extension of trunk, hip, knees and ankles); alternate lifting of leg: retaining weight and balance; alternate lifting of arms. (Figure 19)

These specific movements require the following at all times: attention, coordination of movement, balance, accuracy and spatial orientation, as variables related to the Short Physical Performance Battery (SPPB) to assess and monitor subjects.

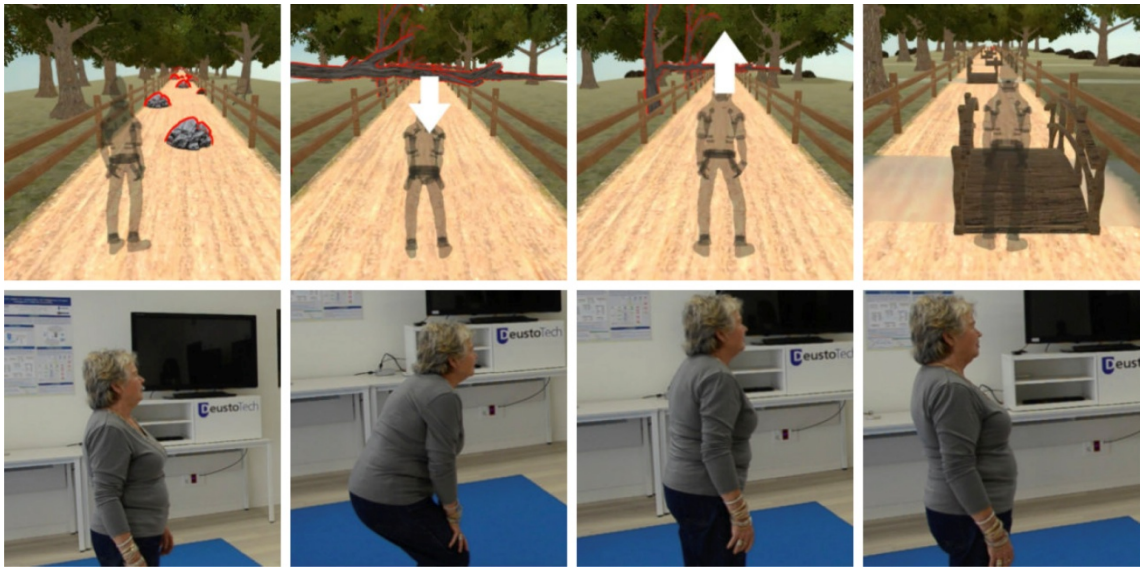

Figure 19. Images of the game in scenario 1.

The **purposes** of the movements used in the ***scenario 1*** are:

- Walking in different directions
- Muscular work involving upper and lower extremities and trunk (pectoral and pelvic girdle)
- Load transfer
- Balance
- Coordination
- Attention
- Spatial orientation

Scenario 2: Avoiding the obstacle on the ground while picking an apple.

At the end of the path, over the last few metres before reaching the hamlet, the player has to avoid an obstacle while at the same time picking an apple. These movements will be alternately shown in homolateral and contralateral form.

Specific movements *to be made* ***in Scenario 2***: Retaining weight and balance together with homolateral lifting of arm and leg; retaining weight and balance together with contralateral lifting of arm and leg. (Figure 20)

These specific movements require the following at all times: attention, coordination of movement, balance, accuracy and spatial orientation, as variables related to the Short Physical Performance Battery (SPPB) to assess and monitor subjects.

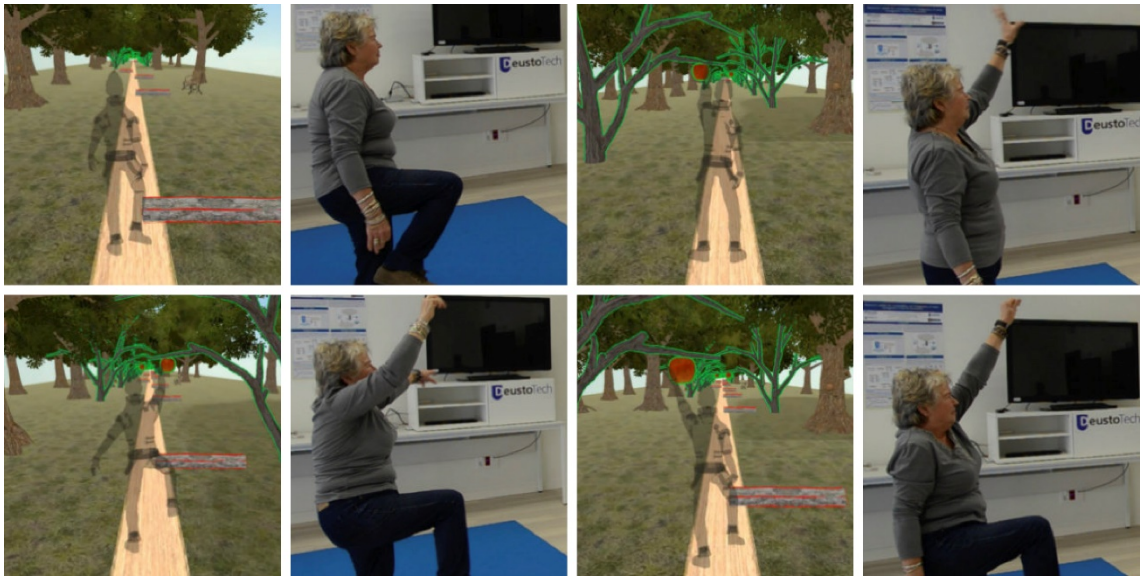

Figure 20. Images of the game in scenario 2.

The **purposes** of the movements used in the **scenario 2** are:

- Walking in different directions
- Muscular work involving upper and lower extremities and trunk (pectoral and pelvic girdle)
- Load transfer
- Balance
- Coordination
- Attention
- Spatial orientation

Part 2

<u>Scenario 3: Unrolling a hose.</u>

The player reaches the hamlet, picks up a hose outside and unrolls it.

Specific movements *to be made* ***in Scenario 3***: Circumduction movement of the shoulder on the frontal plane; the movement is made with both the left and right shoulders. (Figure 21)

These specific movements require the following at all times: attention, coordination of movement, balance, accuracy and spatial orientation, as variables related to the Short Physical Performance Battery (SPPB) to assess and monitor subjects.

Figure 21. Images of the game in scenario 3.

The **purposes** of the movements used in the **scenario 3** are:

- Muscular work involving upper extremities and pectoral girdle
- Coordination
- Attention
- Spatial orientation

Scenario 4: Watering the vine with the hose.

The user observes how the vines grow while they are watering them.

Specific movements *to be made* ***in Scenario 4***: Flexion-extension and abduction/adduction movements to different extents <90º. Movements are made with both the left and right hand. (Figure 22)

These specific movements require the following at all times: attention, coordination of movement, balance, accuracy and spatial orientation, as variables related to the Short Physical Performance Battery (SPPB) to assess and monitor subjects.

Figure 22. Images of the game in scenario 4.

The **purposes** of the movements used in the **scenario 4** are:

- Muscular work involving upper extremities and pectoral girdle
- Coordination
- Attention
- Spatial orientation

Scenario 5: Rolling up the hose.

After finish watering, the player goes to pick up the hose used.

Specific movements *to be made* ***in Scenario 5***: circumduction of the shoulder on the frontal plane. The movement is made both with the left and right shoulders. (Figure 23)

These specific movements require the following at all times: attention, coordination of movement, balance, accuracy and spatial orientation, as variables related to the Short Physical Performance Battery (SPPB) to assess and monitor subjects.

Figure 23. Images of the game in scenario 5.

The **purposes** of the movements used in the **scenario 5** are:

- Muscular work involving upper extremities and pectoral girdle
- Coordination
- Attention
- Spatial orientation

Scenario 6: Picking grapes and putting them in a bucket.

Specific movements *to be made* ***in Scenario 6***: Flexion-extension movements, lifting the shoulder >90º; internal and external rotation of the shoulder. Movements are made both with the left and right hands and left and right shoulders. (Figure 24)

These specific movements require the following at all times: attention, coordination of movement, balance, accuracy and spatial orientation, as variables related to the Short Physical Performance Battery (SPPB) to assess and monitor subjects.

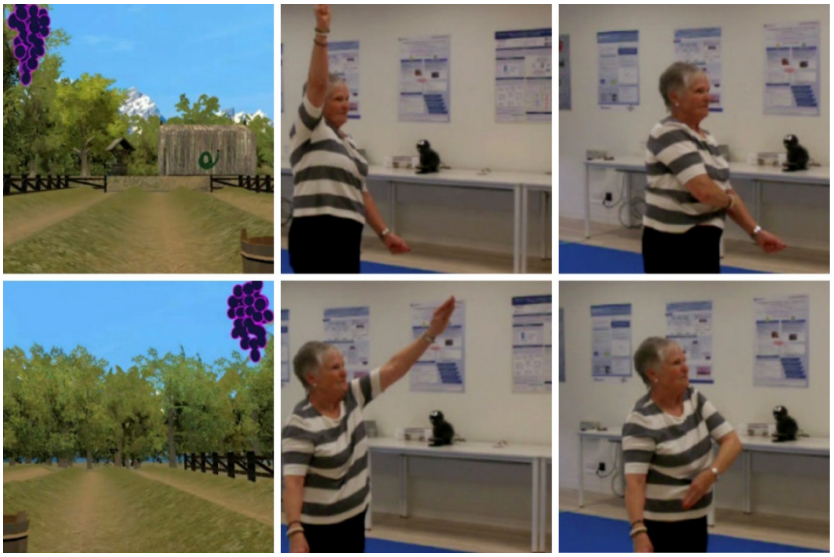

Figure 24. Images of the game in scenario 6.

The **purposes** of the movements used in the **scenario 6** are:

- Muscular work involving upper extremities and pectoral girdle
- Coordination
- Attention
- Spatial orientation

Part 3

<u>Scenario 7: Climbing the stairs inside the house and grabbing the railing.</u>

Specific movements *to be made* ***in Scenario*** *7*: This is done with a homolateral movement (arm and leg on the same side) and with a contralateral movement (arm and leg on opposite sides). (Figure 25)

These specific movements require the following at all times: attention, coordination of movement, balance, accuracy and spatial orientation, as variables related to the Short Physical Performance Battery (SPPB) to assess and monitor subjects.

Figure 25. Images of the game in scenario 7.

The **purposes** of the movements used in the **scenario 7** are:

- Muscular work involving upper and lower extremities and trunk (pectoral and pelvic girdle)
- Load transfer
- Balance
- Coordination
- Attention
- Spatial orientation

3.2.4 Devices used to take physiological constants for biofeedback

3.2.4.1 Blood pressure and heart rate measuring device

The device used to take the blood pressure and heart rate has been OMRON® 10 series Blood Pressure Monitor. Model BP786N. (Figure 26)

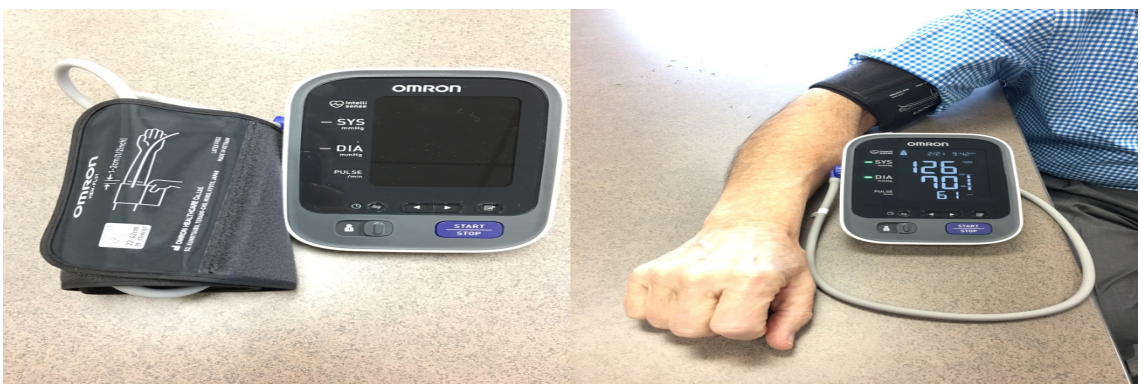

Figure 26. Device used to measure the blood pressure and heart rate.

This device has the following technical characteristics: (Table 15)

Model	BP785N IREFI HEM-7321-Z
Display	LCDdigital display
Measurement range	Pressure: O to 299 mmHg
	Pulse: 40 to 180 beats/mln
Accuracy	Pressure:±3 mmHg or 2% of reading
	Pulse:± 5% of display reading
Inflation	Fuzzy-logic controlled by electric pump
Deflation	Automatic pressure release valve
Measurement Method	Oscillometric method
IP classification	IP 20
Power source	4 "AA" batteries 1.5V or AC adapter (INPUT AC100-240V 50/60Hz 0.12A)
Battery life	Approximately 1000 meaaurements (uaing new alkaline batteries)
Operating temperatura / humidity	50ºF to 104"F (10 ºC to 40 ºC) / 15 to 90% RH
storage temperature / humldity / air preuure	-4ºF to 140ºF (-20ºC to 60ºC) / 10 to 95% RH / 7OO to 1060 hPa
Weight	Monitor :Approximately(400 g) not including batteries
	Arm cuff :Approximately 5 3/4 oz.(183 g)
Dimensions	Monitor :Approximately(124 mm x 90 mm x 161 mm)
	Arm culf :Approximately[(145 mm x 532 mm (air tube: 750 mm)]
Cuff circumference	9" to 17" (220 to 420 mm)
Memory	Up to 100 per user
Applied part	Type BF
Protection against electric shock	lntemally powered ME equipment (When using only lhe batteries)
	Class II ME equipment (AC adapter)
Notes	•These specifications are subject to change without notice. •In the clinical validation study, the 5th phase was used on 85 subjects for determination of diastolic blood pressure. •This device has not been validated for use in pregnancy.

Table 15. Technical specifications of the device used to measure blood pressure and heart rate.

The device used has been tested and validated for use in clinical practice.

It has an online application called **Omron Healthcare** that allows recording the blood pressure and heart rate taken.

3.2.4.2 Blood oxygen saturation level measuring device

The device used to take the blood oxygen saturation level has been iHealth® Wireless Pulse Oximeter. Model PO3. (Figure 27)

Figure 27. Device used to measure the blood oxygen saturation level.

This device has the following technical characteristics: (Table 16)

Specifications	**Model: PO3**
	Classification: Internally powered, type BF
	Wireless communication: Bluetooth 4.0 BLE
	Display system: LED
	Machine size: 62mm x 33mm x 28mm
Range & Battery	SpO2 measuring range: 70-99%
	SpO2 accuracy: 70-99%,±2%; <70%, no definition
	Pulse rate measuring range: 30-250bpm
	Pulse rate accuracy: ±2bpm or ±2% larger one
	Power: Battery, 3.7V li-ion, 300 mAh
Operation & Storage	Operating temperature: 5°C-40°C
	Operating humidity: <80%
	Storage and transport temperature: -20°C-55°C
	Storage and transport humidity: <95%

Table 16. Technical specifications of the device used to measure the blood oxygen saturation level.

The device used has been tested and validated for use in clinical practice.

It has an online application called **iHealth MyVitals** that allows recording the blood oxygen saturation level taken.

3.2.5 Record of activity performed and biofeedback

The biofeedback is recorded daily 3 times in each session: before, immediately after and 5 min after finish the physical exercise with FRED game.

The following is the record sheet that is used during the pilot six-week randomized controlled trial (Phase 2) with biofeedback. (Table 17)

<table>
<tr><td colspan="10">ID</td></tr>
<tr><td colspan="3">LEVEL 2
FRED GAME</td><td>DATE</td><td>MINUTE</td><td>BORG</td><td colspan="2">PHYSIOLOGICAL CONSTANTS AFTER</td><td colspan="3">PHYSIOLOGICAL CONSTANTS 5’ AFTER FINISH</td></tr>
<tr><td colspan="3">DAY</td><td rowspan="2">FULL ACTIVITY</td><td rowspan="2"></td><td>END PART 1</td><td>BP</td><td>HR</td><td>%SpO2</td><td>BP</td><td>HR</td><td>%SpO2</td></tr>
<tr><td colspan="3">PHYSIOLOGICAL CONSTANTS BEFORE</td><td>END PART 2</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>BP</td><td>HR</td><td>%SpO2</td><td rowspan="2">NOT FULL ACTIVITY</td><td rowspan="2"></td><td rowspan="2">END PART 3 (AT THE END OF ACTIVITY)</td><td colspan="2">DO YOU LIKE IT?</td><td>YES
NO</td><td colspan="3" rowspan="2">NOTES:</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td rowspan="2"></td><td colspan="2">Do you find it motivating for the purpose of improving your physical condition?</td><td>YES

NO</td></tr>
</table>

Table 17. Record sheet used for daily data collection.

Before starting the session, blood pressure, heart rate and blood oxygen saturation have been taken. Once the physiological constants have been registered, the subject has performed the physical activity with the FRED game. In case of not completing the game, it is necessary to note the minute in which the subject leaves. Physiological constants are taken immediately at the end and five minutes after finishing. The registration was done daily and for each subject.

“What we find changes who we become”.
Peter Morville

4. RESULTS

4 RESULTS

4.1 *Study 1: A pilot three-week randomized controlled trial (Phase 1)*

4.1.1 Description of the process

The following CONSORT flow chart outlines the complete procedure that took place in the course of the study 1. (Figure 28)

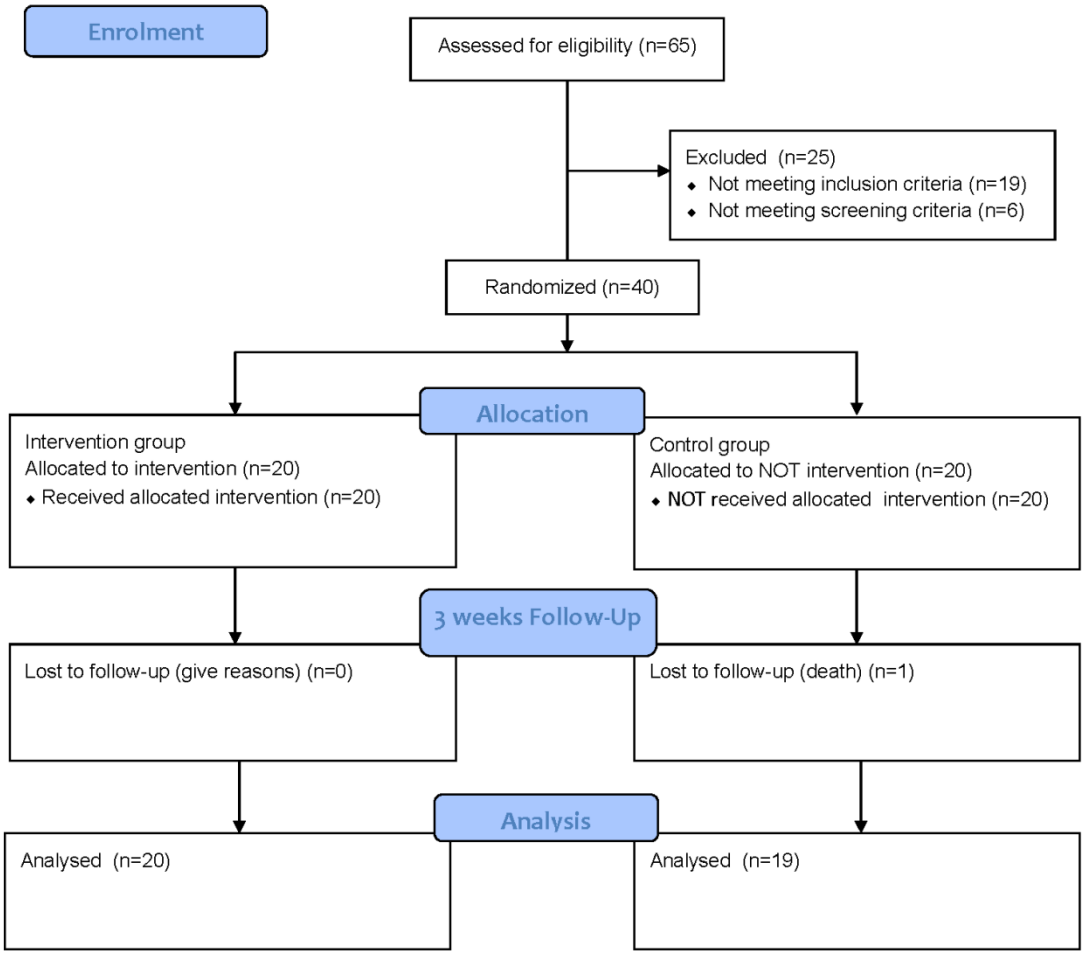

Figure 28. CONSORT Flow diagram of the progress through the phases of a parallel randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis). Source: [213].

Therefore, of the 40 subjects who commenced the study, 39 completed it. One subject from the control group passed away before the study was completed.

4.1.2 Description of the sample in week 1

In the first week of the study it was noted that both groups were at 100% risk of evidencing frailty and it could also be observed that although the control group evidence a greater minimum and maximum range than the study group, both means were similar. (Table 18)

4.1.3 Results obtained from the short physical performance battery (SPPB) after 3 weeks

After analysing the results obtained in the tests carried out using the SPPB, after 3 weeks and after having conducted 9 physical activity sessions using the FRED game, it was noted that the results from the study group increased whereas those from the control group decreased, as can be seen in Table 18.

	SPPB – 1st WEEK		SPPB – 3rd WEEK	
Stadistics	**Control G.**	**Study G.**	**Control G.**	**Study G.**
Mínimum	3.00	6.00	3.00	7.00
1st Qu.	6.00	6.00	5.00	8.00
Median	8.00	7.00	7.00	10.00
Mean	7.16	7.25	6.42	9.40
3rd Qu.	8.50	8.00	8.00	10.25
Maximum	9.00	9.00	9.00	11.00
Std. Dev.	1.86	1.07	1.74	1.39

Table 18. Statistical description of SPPB results in the first and third weeks of the study.

On the one hand, 25% of subjects from the control group obtained scores between 5 and 7, whereas at the start of the study (week 1) they obtained scores between 6 and 8. Conversely, it was also noted a substantial improvement in scores obtained by subjects from the study group – the minimum increase from 6 to 7 and 50% of subjects obtained scores of 10 or over, which means that these subjects are no longer considered to be exposed to frailty risk according to the SPPB tests. (Table 18, Figure 29).

The Wilcoxon test was carried out to determine that the results from the study group obtained improved after 3 weeks. This test enabled the initial hypothesis to be rejected that the results obtained by the study group before and after would be the same, with a value of $p < 0{,}001$.

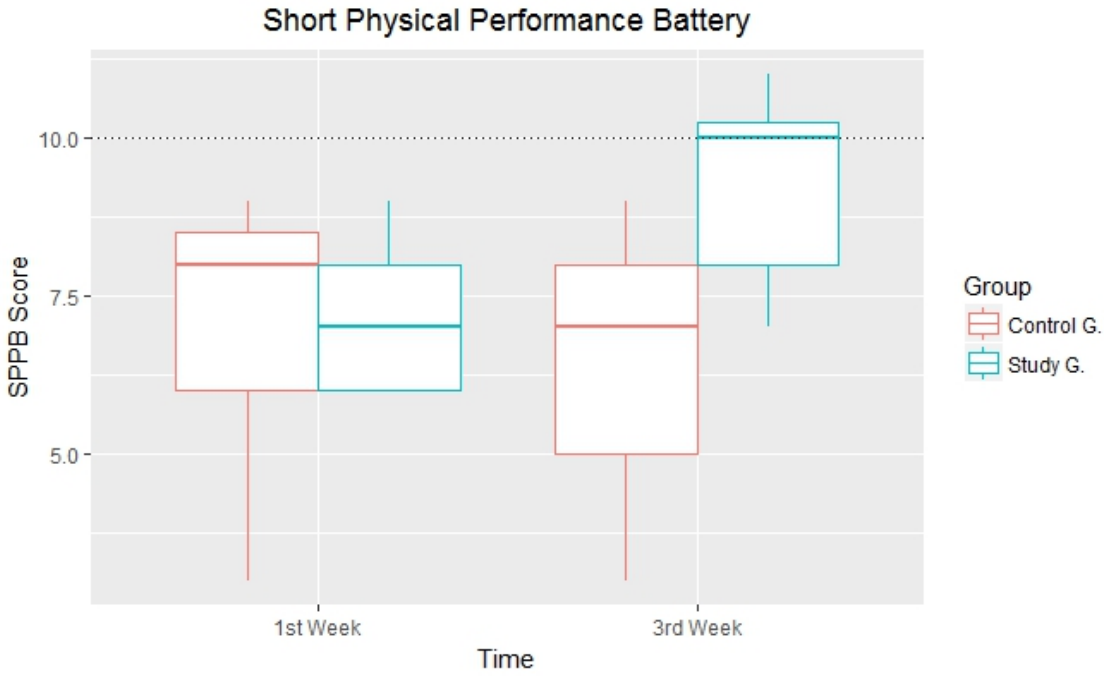

Figure 29. Score obtained using the Short physical performance battery (SPPB) in weeks 1 and 3.

By the third week, it was noted that the 19 (100%) subjects from the control group evidenced frailty risk, whereas the 20 subjects from the study group only evidenced 40% risk of frailty risk. The results confirmed the fact that 60% of subjects from the study group (12 of the 20 subjects) no longer evidenced frailty risk after the third week. Within the general framework, 85% (17 of the 20 subjects) of subjects from the study group showed some type of improvement in terms of their SPPB results. (Figure 30).

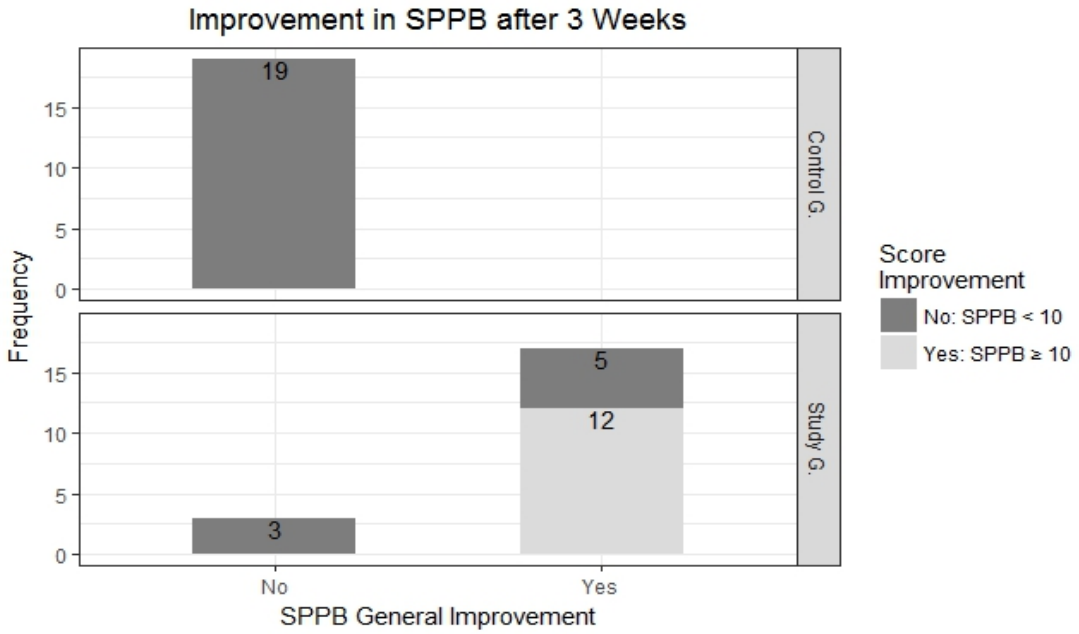

Figure 30. Percentage frailty and number of subjects in control group and study group at the end of week 3.

Figure 30 shows the evolution of results obtained from both groups, broken down using a bar chart that shows whether subjects improved or otherwise, and whether subjects ended up exceeding the frailty limit (SPPB ≥ 10).

Dependence between an improvement in their results and belonging to the study group was measured via Pearson and Fisher-Exact tests. These tests show that the SPPB results depend on the group to which the subject belongs, with a value of $p < 0{,}001$.

Below are described the scores obtained by the subjects in the SPPB tests conducted in the first week and after 3 weeks, according to categories (Figure 31).

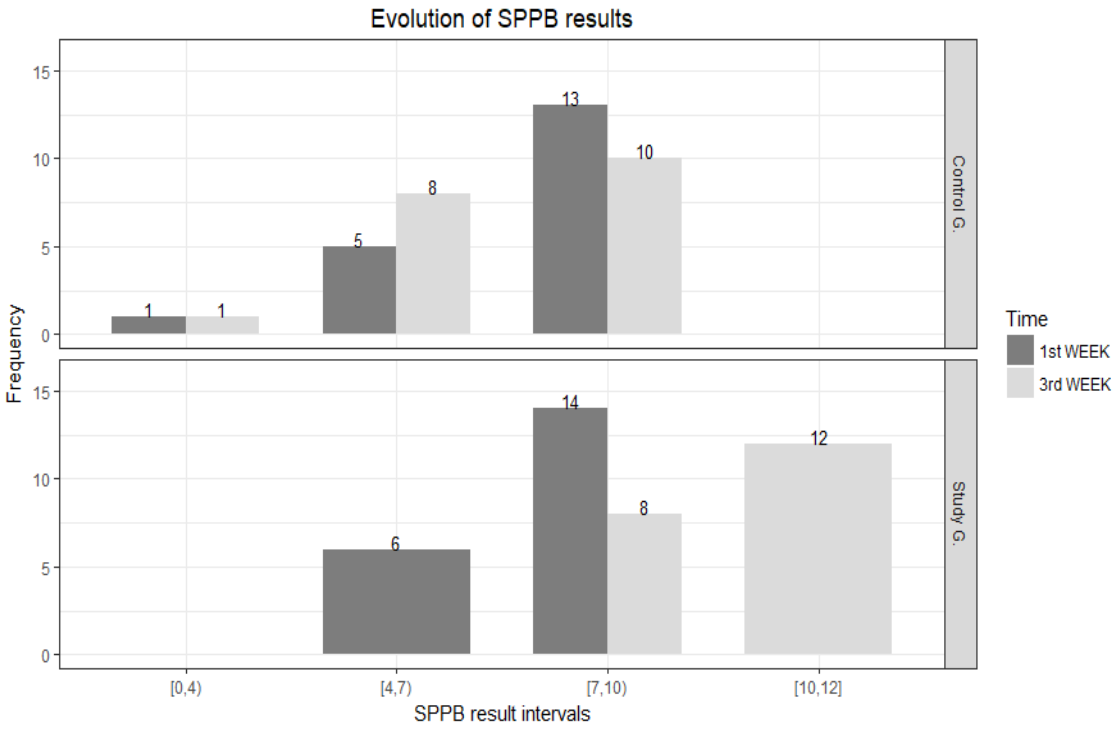

Figure 31. The Short physical performance battery (SPPB) score evolution.

In terms of evolution of SPPB results and taking into account the intervals marked, it was also noted that 3 subjects from the control group dropped from the interval [7,10] to the one immediately below, whereas all the subjects from the interval [4,6] in the study group moved up to higher intervals (3 subjects to the interval [7,10] and 3 subjects to the interval [10,12]). Additionally, 9 subjects from the interval [7,10] moved up to the interval [10,12].

It was not necessary to compare SPPB results with regard to age or gender as the effect of these variables was minimised by the fact of having a homogenous sample of subjects in the control and study groups.

After 3 weeks, the relative risk for all subjects from the control group of obtaining an SPPB results below 10 is 2.5 times greater than that for all the subjects from the study group (Figure 13). The relative risk according to age of the control group (Cochran-Mantel-Haenszel estimate) for 2 strata (< 85 and ≥ 85 years) is 2.53 greater than for the study group under the same conditions, while the relative risk according to gender of the control group is 2.52 times greater than for the study group, also under the same conditions.

It was noted that the relative risk of all subjects from the control group in comparison to the study group was nearly identical to the relative risks according to age and gender, whereby these variables were excluded from being considered distortion factors (what are known as confusion variables in statistics). This was due to the homogenous nature evidenced by the control and study groups in terms of age and gender.

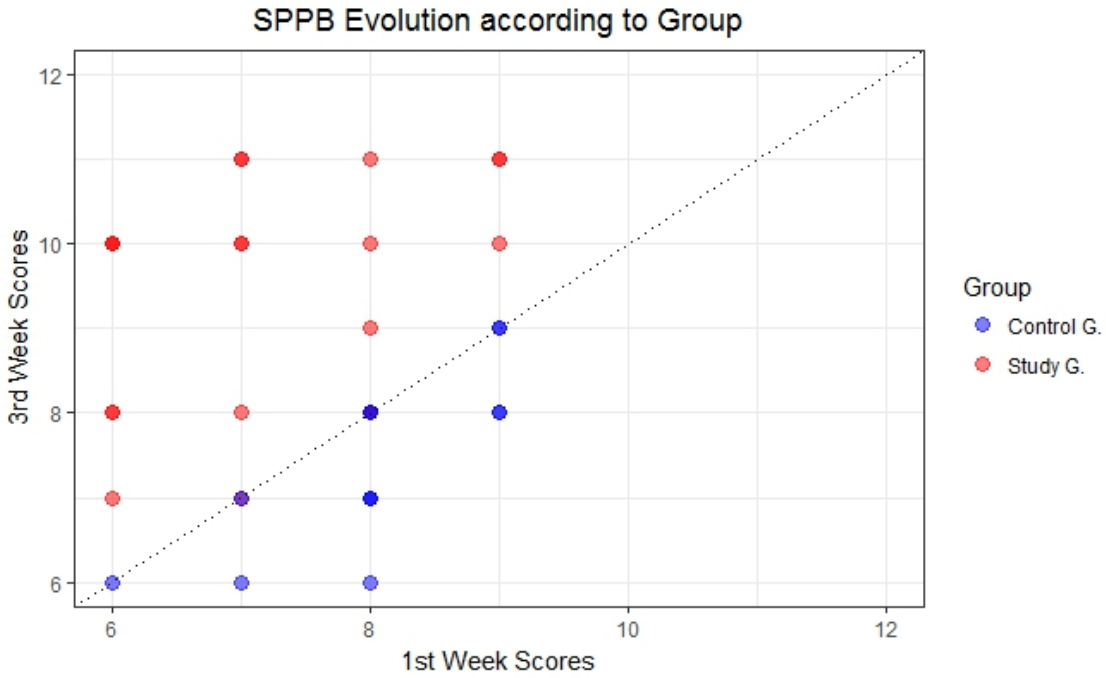

Figure 32. Distribution of the Short physical performance battery (SPPB) score obtained according to age and gender.

4.1.4 Game satisfaction:

After completing the game each day, each participant was asked 2 questions, with the possible responses being YES or NO:

1. Do you like the game?

2. Do you find it motivating for the purpose of improving your physical condition?

As regards the first question, except on days 1 and 2 when there was a 10% (2 subjects) and 5% (1 subject) respectively who gave a negative response, the 20 subjects from the study group responded YES on the other days. (Figure 33)

As regards the second question, except on days 1 and 2 when there was a 20% (4 subjects) and 5% (1 subject) who gave a negative response, the 20 subjects from the study group responded YES on the other days. (Figure 33).

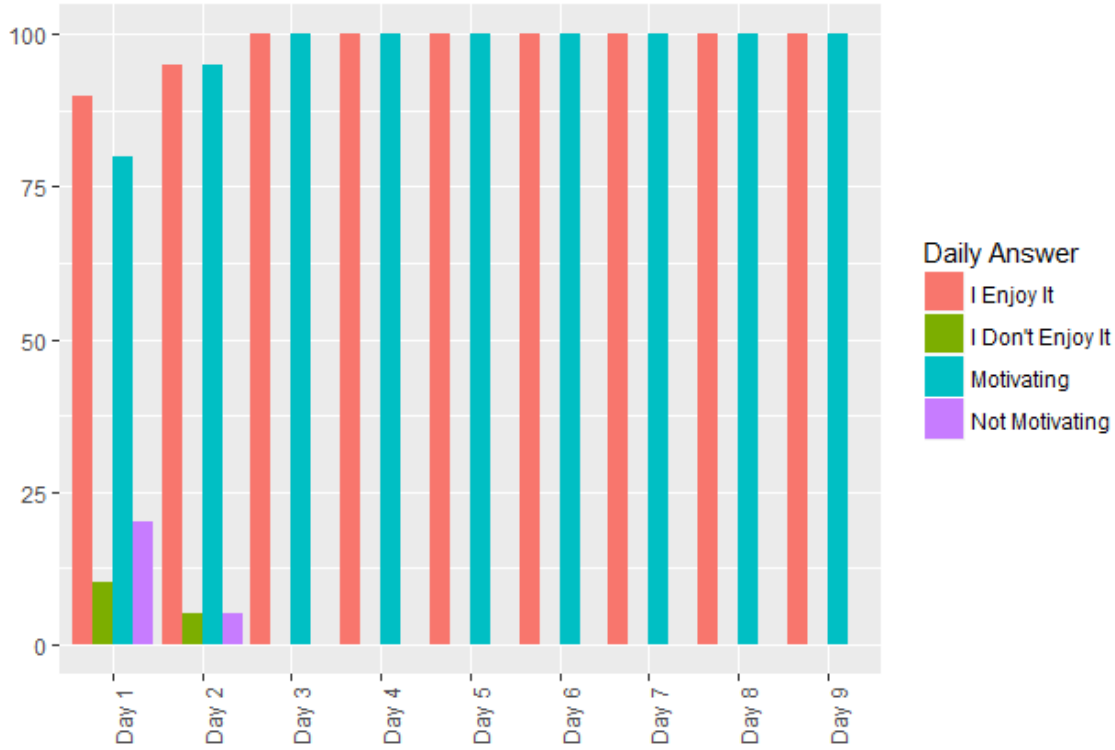

Figure 33. Daily response percentages by the study group to the questions: "Do you like the game?" and "Do you find it motivating for the purpose of improving your physical condition?".

4.2 *Study 2: A pilot six-week randomized controlled trial (Phase 2) with biofeedback*

4.2.1 Description of the process

The following CONSORT flow chart outlines the complete procedure that took place in the course of the study 2. (Figure 34)

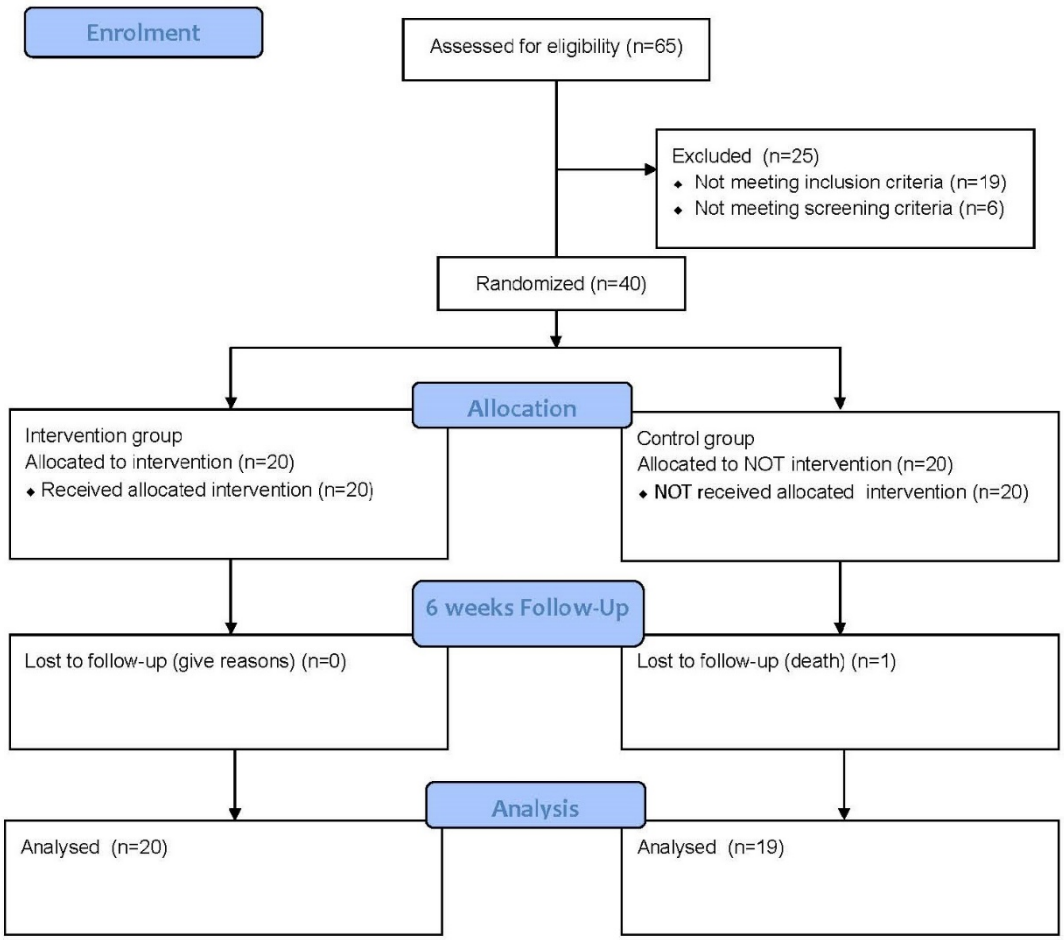

Figure 34. CONSORT Flow diagram of the progress through the phases of a parallel randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis). Source: [213].

Therefore, of the 40 subjects who commenced the study, 39 completed it. One subject from the control group passed away before the study was completed.

4.2.2 Description of the sample in week 1

In the first week of the study it was noted that both groups were at 100% risk of evidencing frailty and it could also be observed that although the control group evidenced a greater minimum and maximum range than the study group, both means were similar. (Table 19)

	SPPB – 1st WEEK		SPPB – 6th WEEK	
Stadistics	**Control G.**	**Study G.**	**Control G.**	**Study G.**
Mínimum	3.00	6.00	3.00	7.00
1st Qu.	6.00	6.00	5.00	11.00
Median	8.00	7.00	6.00	11.00
Mean	7.16	7.25	5.95	11.00
3rd Qu.	8.50	8.00	6.50	12.00
Maximum	9.00	9.00	9.00	12.00
Std. Dev.	1.86	1.07	1.62	1.17

Table 19. Statistical description of SPPB results in the first and sixth weeks of the study.

4.2.3 Results obtained from the short physical performance battery (SPPB) after 6 weeks

After analysing the results obtained in the tests carried out using the SPPB, after 6 weeks and after having conducted 18 physical activity sessions using the FRED game, it was noted that the results from the study group substantially improved whereas those from the control group worsened, as can be seen in Table 19.

After 6 weeks, all subjects from the study group except for 1 obtained a score over 10, i.e. they were no longer considered to be exposed to frailty risk in accordance with the SPPB tests (Figure 35). Conversely, all subjects from the control group remained exposed to frailty risk (with a score below 10) after 6 weeks.

The Wilcoxon test was carried out to determine whether results from the study group improved after 6 weeks, and the initial hypothesis that the before and after results obtained by the study group would be the same, with a value of $p < 0{,}001$, was rejected with this test.

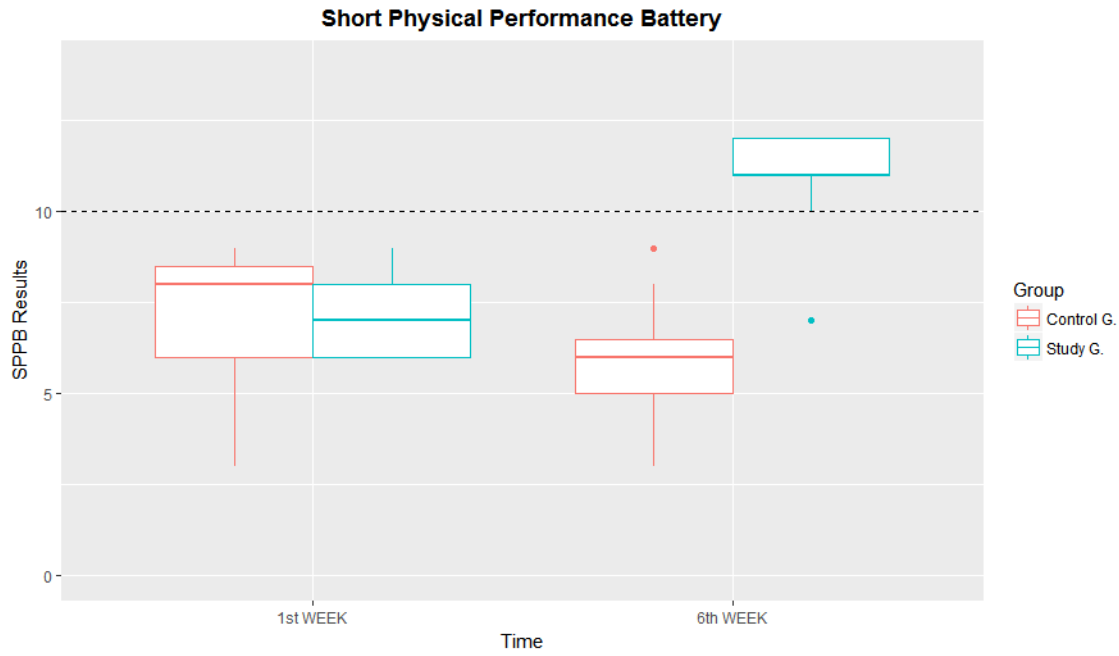

Figure 35. Score obtained in the SPPB in week 1 and week 6.

By the sixth week, it was noted that 100% of subjects from the control group continued to evidence frailty risk, whereas only 5% of subjects from the study group evidenced this. No subject from the control group evidenced any improvement (increase in score) in their SPPB results, whereas 100% of subjects from the study group evidenced improvements in their results after 6 weeks (Figure 36). By carrying out the Fisher-Exact test on this information, strong evidence was obtained to suggest that there was a difference in the proportion of subjects who improved their SPPB in general between the two groups (study and control), with statistical significance of $p < 0.001$.

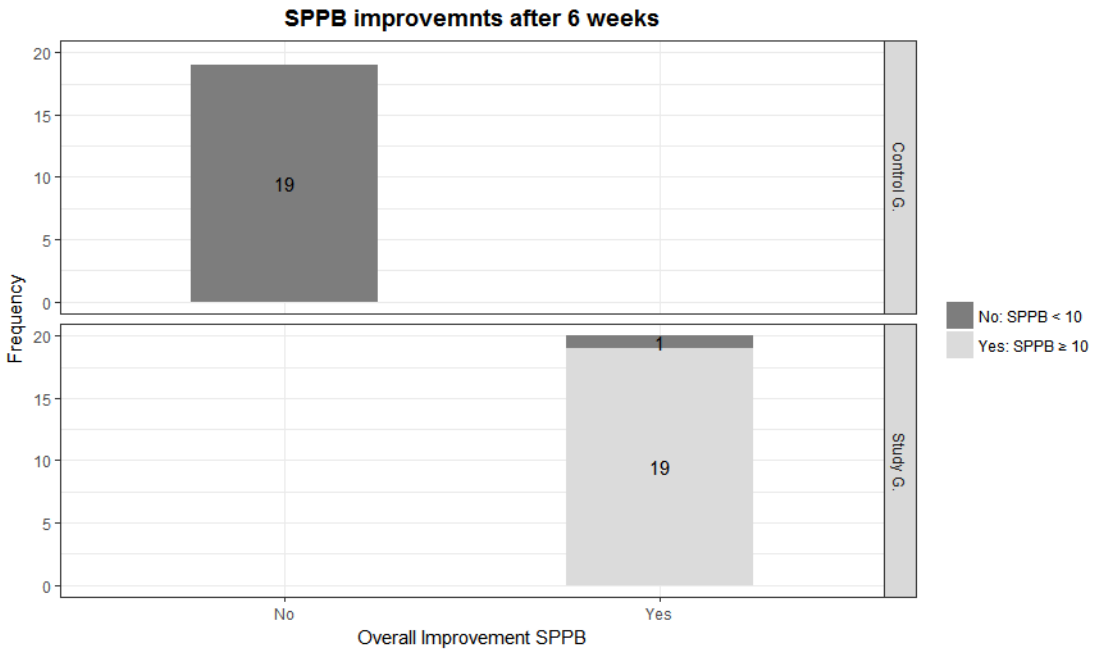

Figure 36. Percentage frailty and number of subjects in control group and study group at the end of week 6. Details provided of the evolution of results obtained from both groups, broken down using a bar chart that shows whether subjects improved or otherwise, and whether subjects ended up exceeding the frailty limit (SPPB ≥ 10).

Below are described the scores obtained by subjects in the SPPB tests carried out in the first week and after 6 weeks, according to category. (Figure 37)

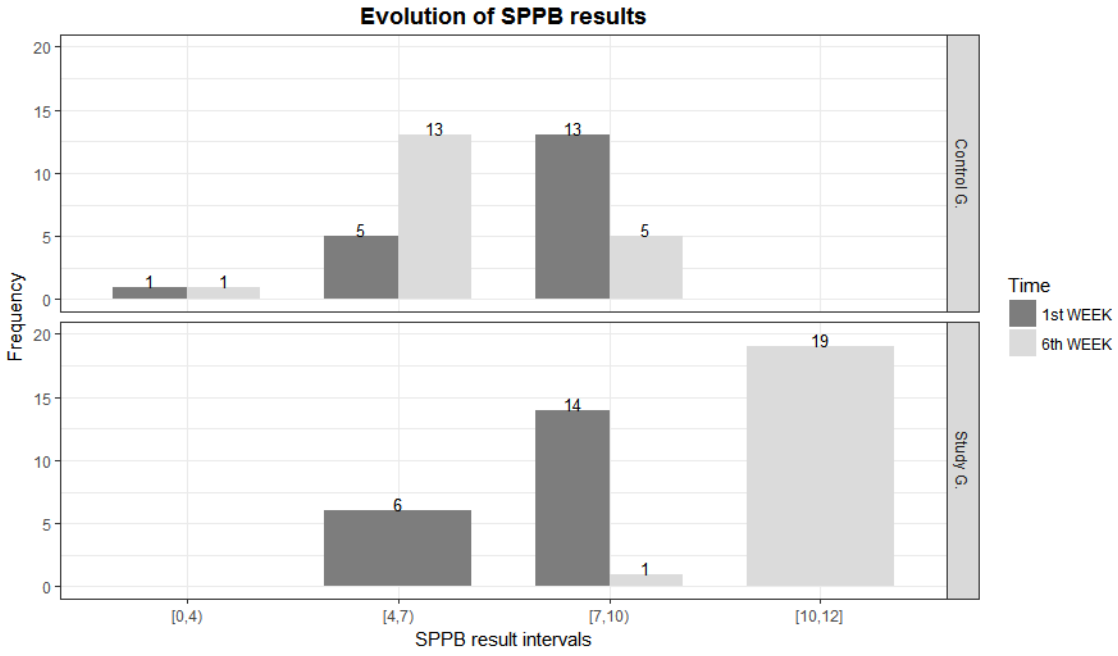

Figure 37. SPPB score evolution.

In terms of evolution of SPPB results and taking into account the intervals marked, it was noted that 8 subjects from the control group dropped from the interval [7,10] to the one immediately below, whereas all the subjects from the interval [4,7] in the study

group moved up to intervals [10,12]. Additionally, 13 subjects moved up from the interval [7,10] to the interval [10,12], and 1 subject remained at the interval [7,10], as their SPPB result of 9 subjects did not change after 6 weeks. (Figure 37)

It was not necessary to compare SPPB results with regard to age or gender as the effect of these variables was minimised by the fact of having a homogenous sample of subjects in the control and study groups. (Figure 38)

On the one hand, by using the Fisher-Exact test strong evidence was found to suggest that there was no difference in the proportion of male and female subjects without risk of being exposed to frailty (SPPB $\geq$ 10) after 6 weeks, with statistical significance of $p < 0.001$.

And on the other, the Fisher-Exact test was adjusted according to age (85 years and over). Once again, strong evidence was found to suggest that there was no difference in the proportion of subjects of 85 years and over and those under 85 years of age without risk of being exposed to frailty (SPPB $\geq$ 10) after 6 weeks, with statistical significance of $p < 0.001$.

Both results were obtained as of the homogeneity existing between the control group and the study group in terms of age and gender. (Figure 38)

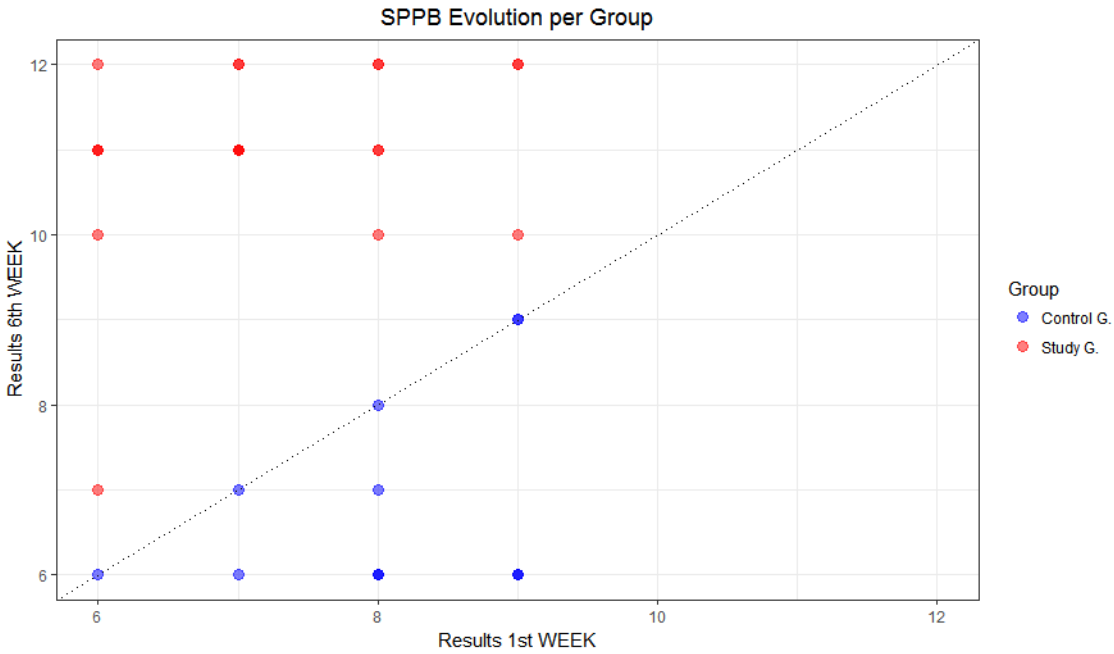

Figure 38. Distribution of SPPB score obtained according to age and gender.

4.2.4 EuroQol 5D-5L

4.2.4.1 EQ-5D-5L Index

It was noted that the general scores obtained from the EQ-5D-5L Index for the control group decreased by the end of the 6 weeks (Table 20).

EQ-5D-5L INDEX	Control G.		Study G.	
Stadistics	**1st WEEK**	**6th WEEK**	**1st WEEK**	**6th WEEK**
Mínimum	0.64	0.59	0.61	0.72
1st Qu.	0.84	0.75	0.84	0.84
Median	0.92	0.87	0.92	0.92
Mean	0.89	0.85	0.89	0.90
3rd Qu.	1.00	0.92	0.95	0.93
Maximum	1.00	1.00	1.00	1.00
Std. Dev.	0.11	0.12	0.10	0.08

Table 20. Statistical description of the EQ-5D-5L Index for control and study groups.

From the control group only 37% (7 subjects) improved or maintained the EQ-5D-5L Index after 6 weeks. In contrast, from the study group, 68 % (14 subjects) improved or maintained the EQ-5D-5L Index after 6 weeks.

In figure 39, it can see that the EQ-5D-5L Index for the study group remained relatively stable with the median remaining at 0.92, whereas it decreased from 092 to 9.87 in the case of the control group. (Figure 39)

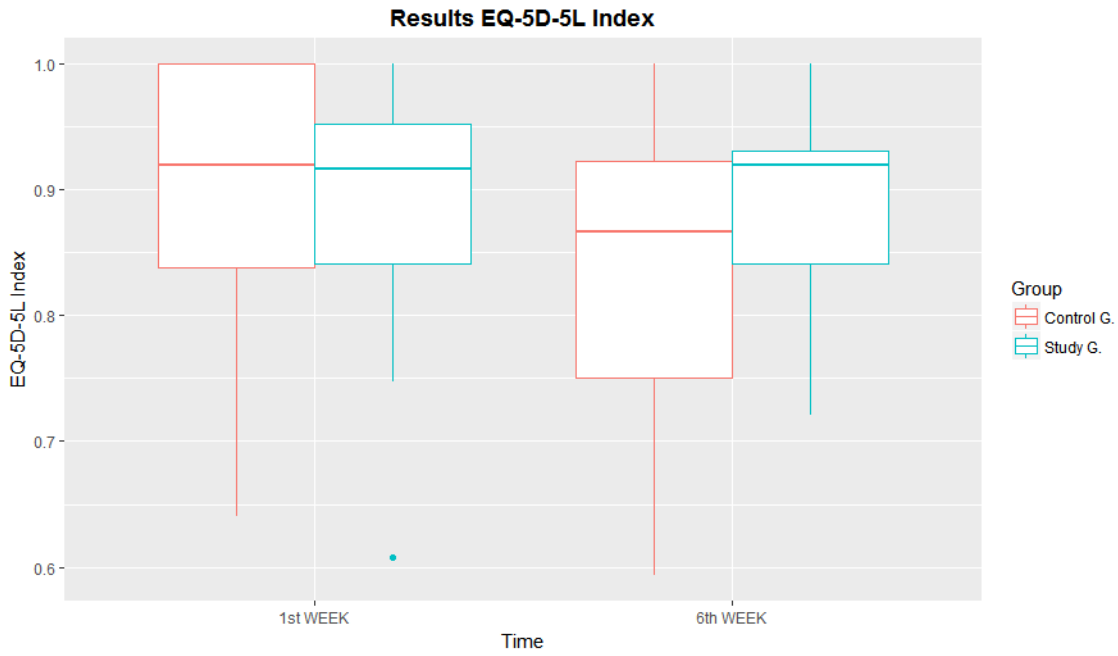

Figure 39. Results obtained from the EQ-5D-5L Index in week 1 and week 6 for control and study groups.

When analysing the difference in results in each group after 6 weeks, the mean EQ-5D-5L Index for the control group was less by 0.045, whereas in the study group the EQ-5D-5L Index produced a more stable mean (the mean of the differences was +0.012). (Table 21).

EQ-5D-5L Index Difference		
Stadistics	**Control G.**	**Study G.**
Mínimum	-0.0212	-0.128
1st Qu.	-0.082	-0.043
Median	-0.078	0.0
Mean	-0.045	0.012
3rd Qu.	0.0	0.071
Maximum	0.178	0.159
Std. Dev.	0.092	0.078

Table 21. Statistical description of the EQ-5D-5L Index differences for control and study groups.

When comparing these changes using the t-test, the following null hypothesis was rejected: the treatment does not affect changes in EQ-5D-5L Index, with a 95% confidence level and value of p= 0.046. (Figure 40).

In accordance with the Wilcoxon test, the following null hypothesis was also rejected: there was no difference in improvement in health between the two groups being treated, with p value = 0.0391. (Figure 40)

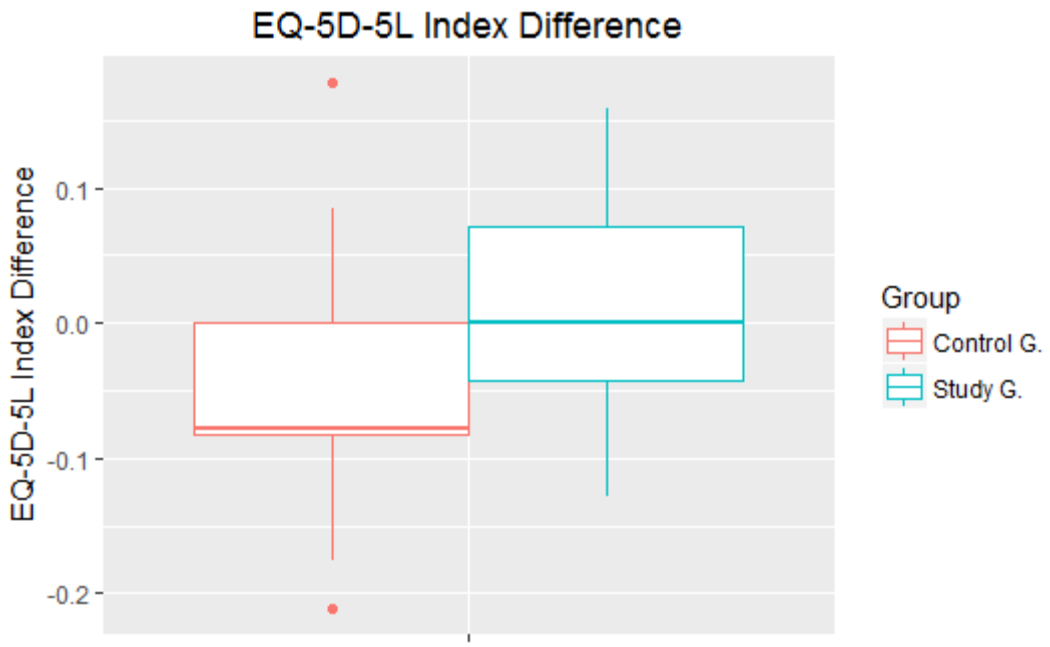

Figure 40. Results of EQ-5D-5L Index differences in week 1 and week 6 for control and study groups.

In conclusion, in terms of the EQ-5D-5L Index, the study group remained stable whereas the control group slightly worsened.

4.2.4.2 EQ-VAS

Descriptively, an improvement was quickly able to be noted in EQ-VAS results for the study group. The mean increased from 74.7 to 86.8 and the range between the first and second quartile increased after 6 weeks from 60 and 86.25 to 78.75 and 100 respectively. Conversely, the mean for the control group decreased from 72.63 to 60 points, while the range between the first and second quartile also decreased after 6 weeks from 60 and 85 to 47.50 and 70 respectively. (Table 22)

EQ-VAS	Control G.		Study G.	
Stadistics	**1st WEEK**	**6th WEEK**	**1st WEEK**	**6th WEEK**
Mínimum	50.00	30.00	50.00	50.00
1st Qu.	60.00	47.50	60.00	78.75
Median	70.00	60.00	77.50	95.00
Mean	72.63	60.00	74.70	86.75
3rd Qu.	85.00	70.00	86.25	100.0
Maximum	100.0	100.0	100.0	100.0
Std. Dev.	17.59	18.18	17.58	16.41

Table 22. Statistical description of the EQ-VAS for control and study groups.

Visually, in Figure 41, the improvement of the study group compared with the control group was verified. The median of the study group went from 77.5 to 95, whereas in the control group it decreased from 70 to 60 from week 1 to week 6.

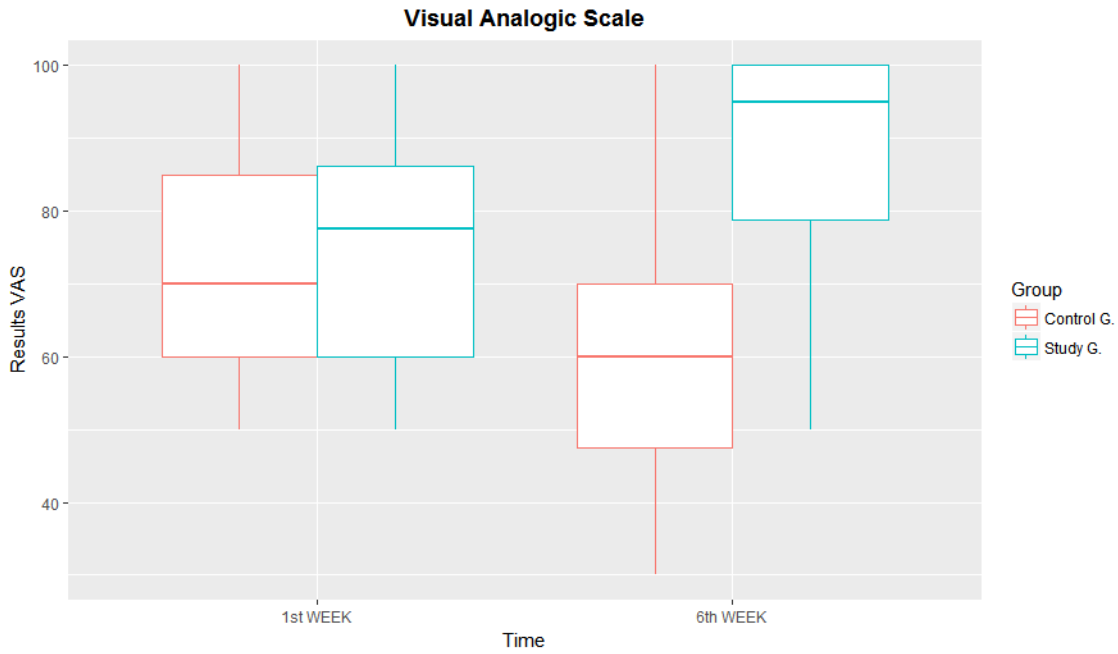

Figure 41. Results of EQ-VAS in week 1 and week 6 for control and study groups.

When analysing the difference in results in each group after 6 weeks, the mean EQ-VAS for the control group decreased (-12.63), whereas the EQ-VAS mean for the study group increased (12.05). (Table 23).

EQ-VAS Difference		
Stadistics	**Control G.**	**Study G.**
Mínimum	-40.00	0.00
1st Qu.	-20.00	0.00
Median	-10.OO	10.00
Mean	-12.63	12.05
3rd Qu.	-5.00	20.00
Maximum	0.00	45.00
Std. Dev.	10.85	12.13

Table 23. Statistical description of the EQ-VAS differencces for control and study groups.

In accordance with the Wilcoxon test, it is rejecting the null hypothesis with a value $p < 0.001$ in favour of an alternative hypothesis that there is a difference in improvement in EQ-VAS results between the two groups being treated. (Figure 42).

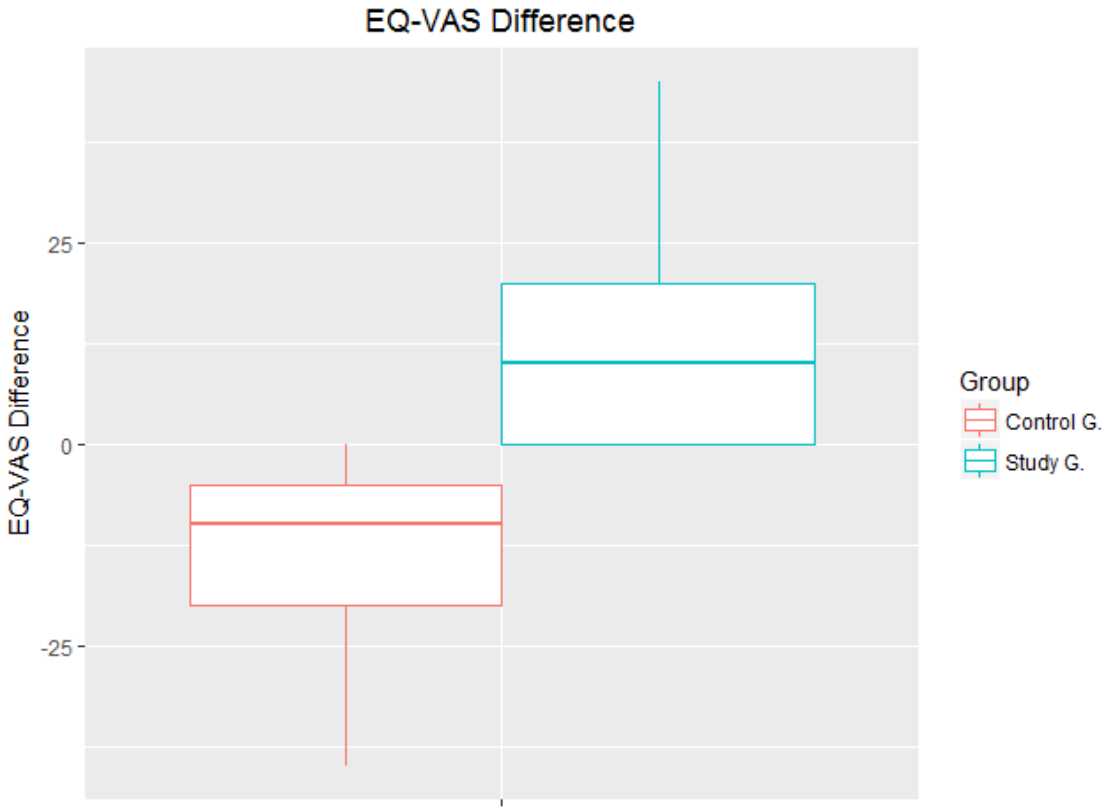

Figure 42. Results of EQ-VAS differences in week 1 and week 6 for control and study groups.

In conclusion, in terms of the EQ-VAS, the control group worsened whereas the study group significantly improved.

4.2.5 Barthel Index

Both control and study groups commenced the physical activity with homogenous features (minimum, maximum, mean and median). (Table 24)

Barthel Index	Control G.		Study G.	
Stadistics	**1st WEEK**	**6th WEEK**	**1st WEEK**	**6th WEEK**
Mínimum	90	85	90	90
1st Qu.	90	90	90	98.75
Median	95	90	95	100
Mean	95.26	91.84	95	98
3rd Qu.	100	95	100	100
Maximum	100	100	100	100
Std. Dev.	4.56	5.06	4.59	3.77

Table 24. Statistical description of the Barthel Index for control and study groups.

After 6 weeks, the Barthel Index significantly improved in subjects belonging to the study group. 50% attained the maximum score of 100 points whereas, conversely, the results obtained by subjects from the control group substantially worsened.

The results obtained from the Barthel Index in the study group improved after 6 weeks with statistically significant evidence, with a value of $p < 0.003906$.

In contrast, the results obtained from the Barthel Index worsened in the control group after 6 weeks with statistically significant evidence, with a value of $p < 0.001952$. (Figure 43)

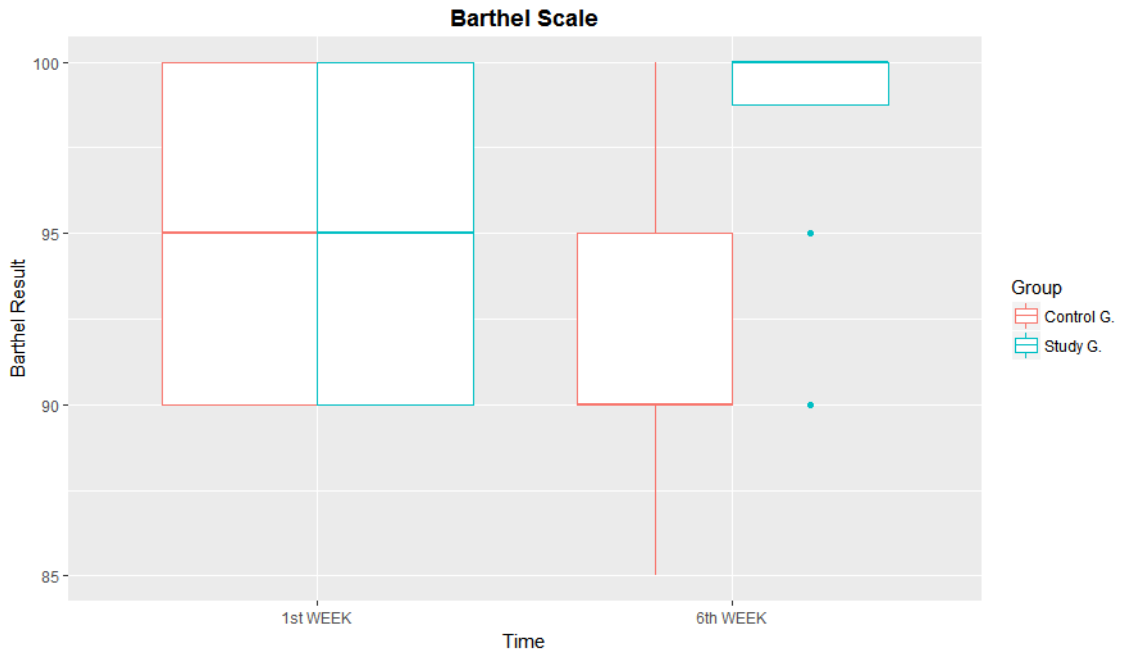

Figure 43. Results of Barthel Index In week 1 and week 6 for control and study groups.

4.2.6 Biofeedback: Physiological constants

4.2.6.1 Heart Rate (HR)

Below is the graph showing interquartile ranges of work intensity attained by subjects from the study group during exercise, grouped together in 6-day intervals and expressed as a percentage of maximum heart rate (%HRMax). Values below the broken line (76%) represented moderate and light levels of exercise intensity, meaning that subjects below this line remained within suitable parameters of cardiac healthy and safe physical exercise. (Figure 44)

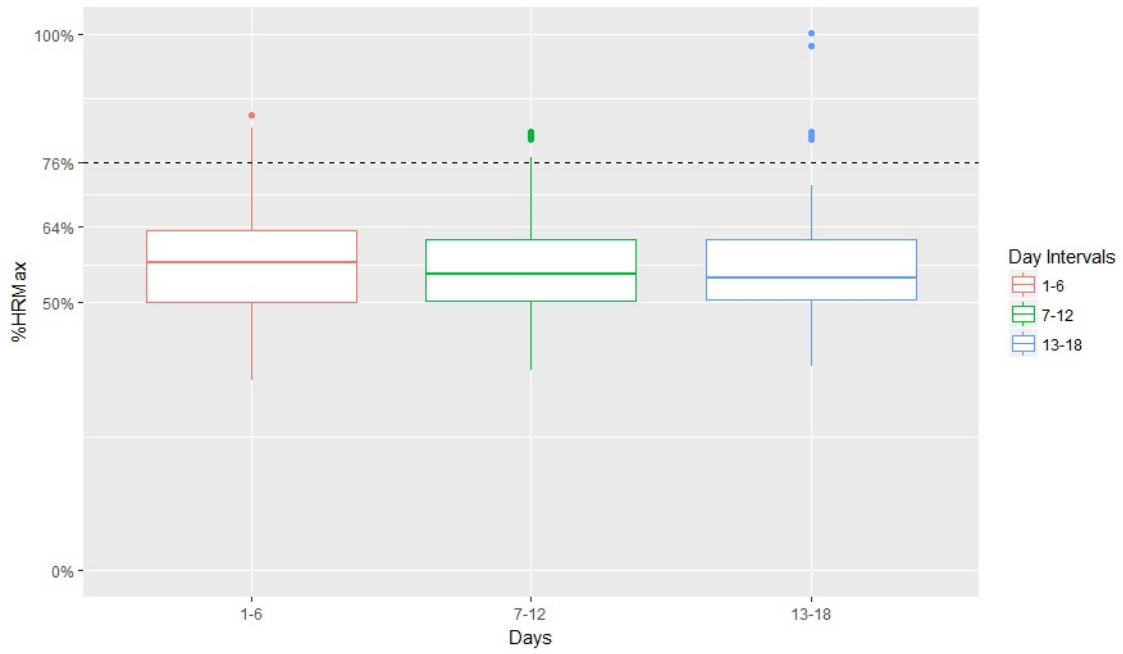

Figure 44. Results of the maximum heart rate percentage (%HR Max) for the study group during exercise, grouped together into 6-day intervals.

Of the 360 heart rate measurements (20 subjects x 18 days' measurement) taken over the 18 days of exercise, 20 measurements failed to reach the cut-off point, i.e. only 5.55% of measurements were not below the 76% intensity cut-off point and the 94.5% of measurements remained below the cut-off point. (Figure 45)

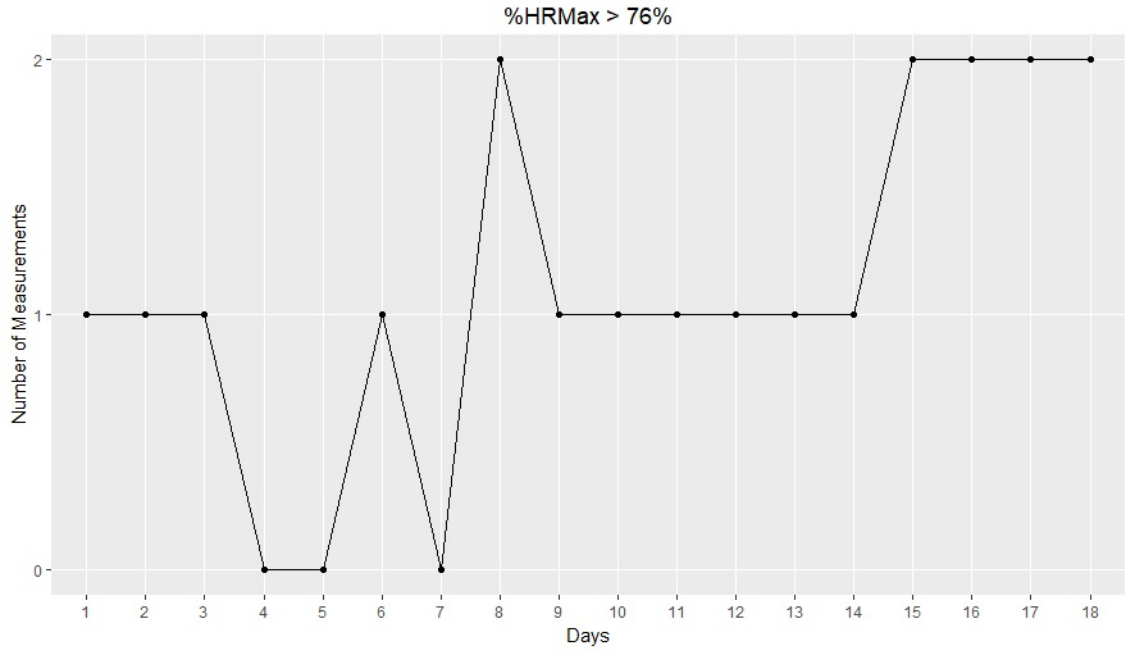

Figure 45. Number of % heart rate measurements (% FCmaximun) which were above the cut-off point per day.

4.2.6.2 Modified Borg Scale

Below is the graph showing interquartile ranges of perceived exertion intensity attained by subjects from the study group during exercise, grouped together in 6-day intervals and expressed according to the modified Borg scale. Values below the broken line (5 = <76% Heart Rate Maximum) represented moderate and light levels of exercise intensity, meaning that subjects below this line remained within suitable parameters of cardiac healthy and safe physical exercise. (Figure 46)

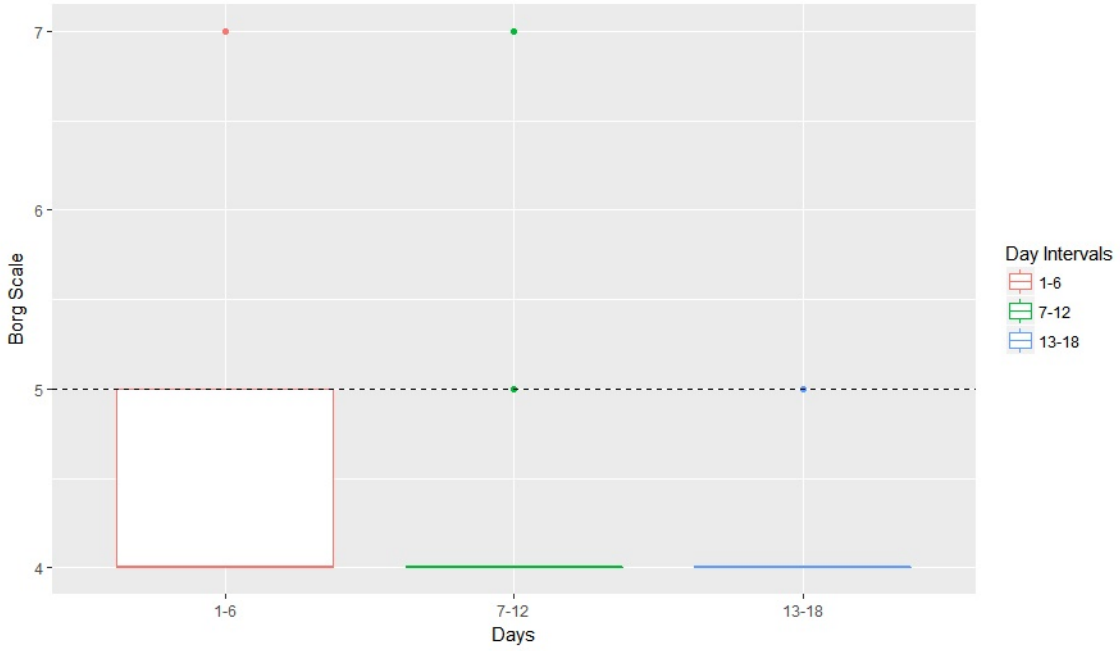

Figure 46. Results of the intensity of perceived exertion according to the Borg scale for the study group during exercise, grouped together into 6-day intervals.

Of the 360 Borg scale measurements (20 subjects x 18 days' measurement) taken over the 18 days of exercise, 7 measurements failed to reach cut-off point 5. In other words, 98.1% of measurements remained below the cut-off point. Subjects remained below the cut-off point except for 2 subjects. (Figure 47)

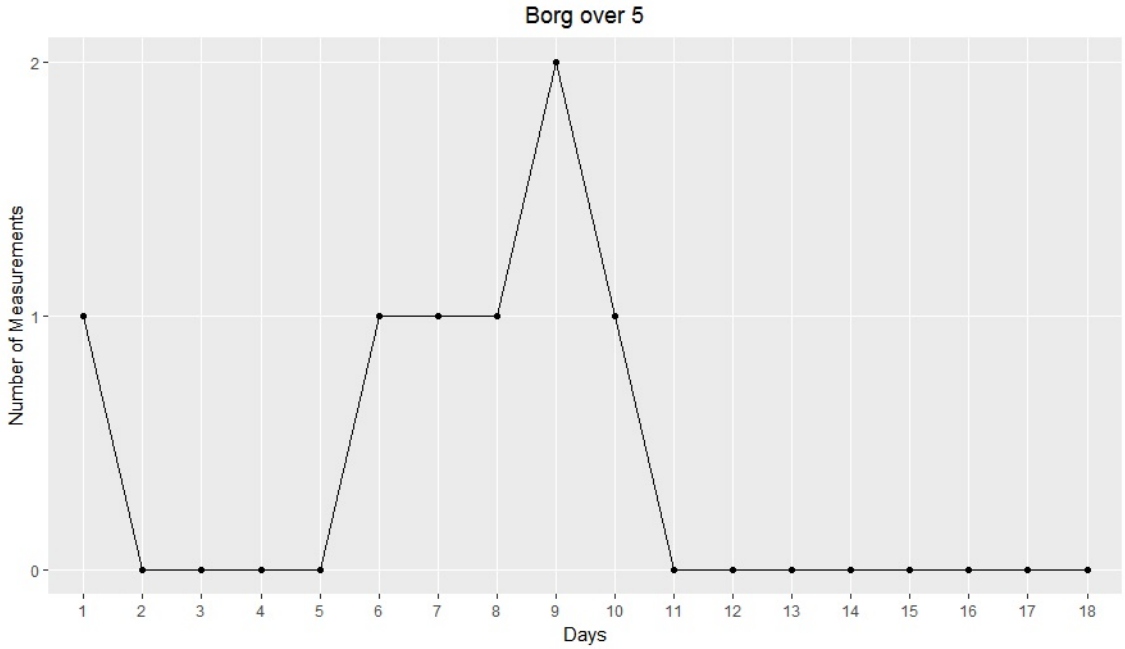

Figure 47. Number of perceived exertion measurements (Borg) which were above the cut-off point per day.

Attention should be drawn to the fact that in no case was the activity abandoned due to physical discomfort.

4.2.6.3 Systolic blood pressure (SBP)

Below is the graph showing interquartile ranges of systolic blood pressure (SBP) attained by subjects from the study group during exercise, grouped together in 6-day intervals and expressed in millimetres of mercury (mmHg). Values below the broken line (150mmHg) represented suitable levels of systolic blood pressure, meaning that subjects below this line remained within suitable parameters of cardiac healthy and safe physical exercise. 75% of subjects remained below the 150 line in the 3 intervals. (Figure 48)

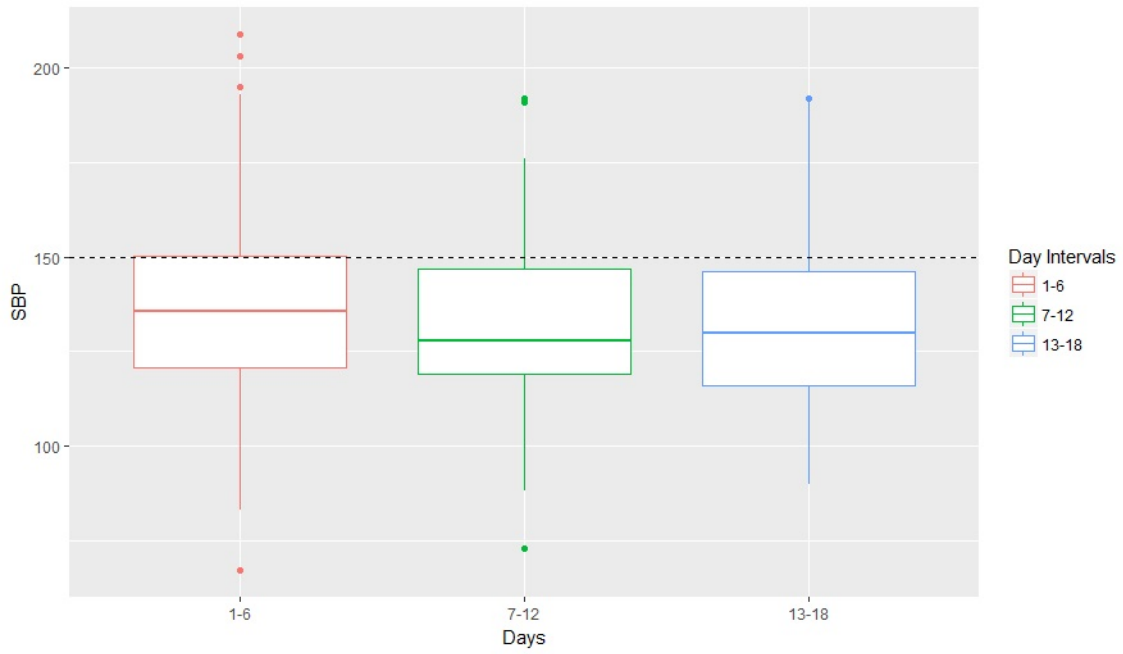

Figure 48. Results of systolic blood pressure (SBP) for the study group during exercise, grouped together into 6-day intervals.

Of the 360 SBP measurements (20 subjects x 18 days' measurement) taken over the 18 days of exercise, 69 measurements (19.2%) exceeded the cut-off point, whereas 80% remained below the 150 cut-off point. (Figure 49)

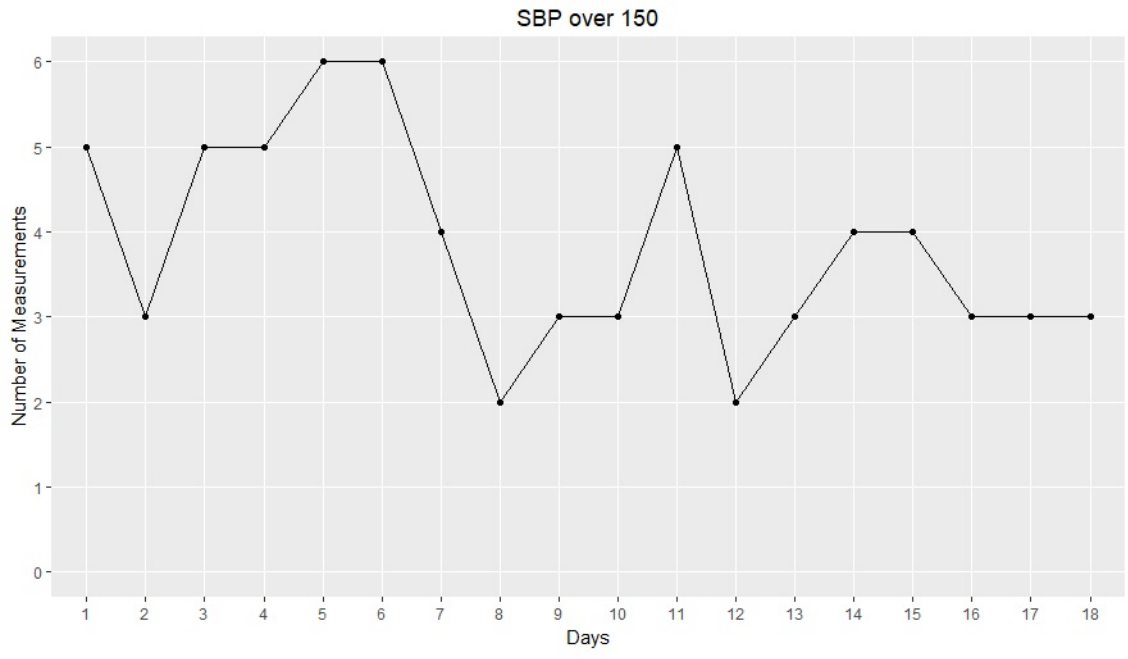

Figure 49. Number of systolic blood pressure (SBP) measurements which were above the cut-off point per day.

It was noted that the 5 subjects who exceeded the cut-off point on the first day decreased to 3 subjects by day 18. (Figure 49)

4.2.6.4 Diastolic blood pressure (DBP)

Below is the graph showing interquartile ranges of diastolic blood pressure (DBP) attained by subjects from the study group during exercise, grouped together in 6-day intervals and expressed in millimetres of mercury (mmHg). Values below the broken line (90mmHg) represented suitable levels of diastolic blood pressure, meaning that subjects below this line remained within suitable parameters of cardiac healthy and safe physical exercise. 75% of subjects remained below the 90 line in the 3 intervals. (Figure 50)

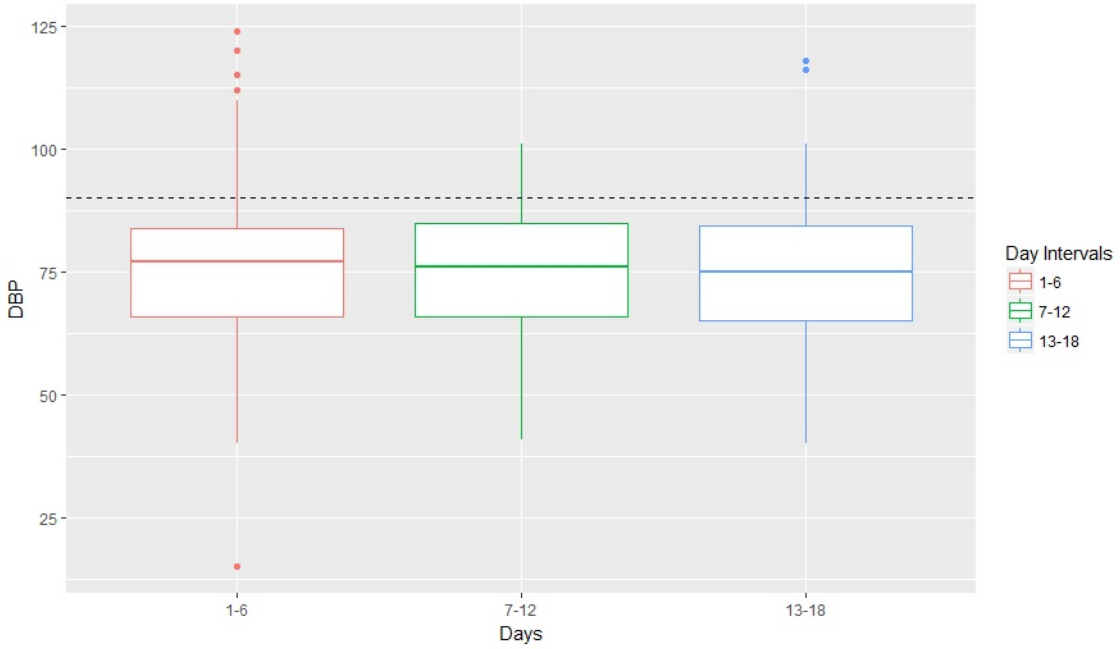

Figure 50. Results of diastolic blood pressure (DBP) for the study group during exercise, grouped together into 6-day intervals.

Of the 360 DBP measurements (20 subjects x 18 days' measurement) taken over the 18 days of exercise, 63 measurements (17.25%) exceeded the cut-off point, whereas 82.5% remained below the 90 cut-off point. (Figure 51)

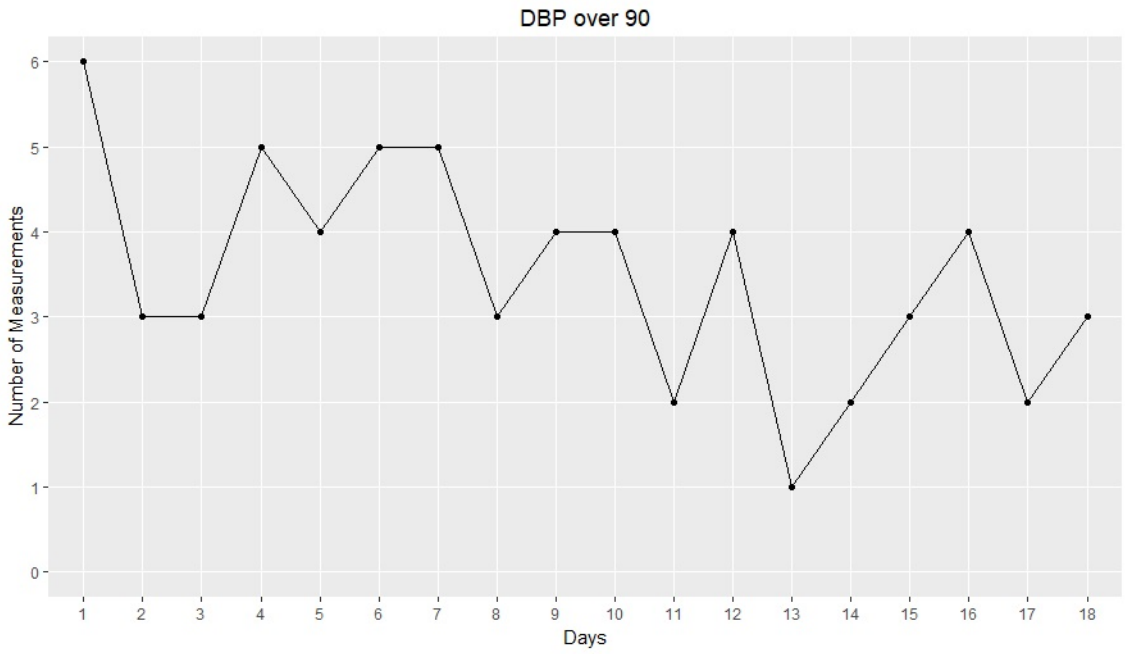

Figure 51. Number of diastolic blood pressure (DBP) measurements which were above the cut-off point per day.

It was noted that the 6 subjects who exceeded the cut-off point on the first day decreased to 3 subjects by day 18. (Figure 51)

4.2.6.5 Blood oxygen saturation (Sp02)

Below is the graph showing interquartile ranges of daily variations in blood oxygen saturation (SpO2) attained by subjects from the study group during exercise, grouped together in 6-day intervals and expressed as a percentage. Values below the broken line (5% SpO2) represented suitable levels of blood oxygen saturation, meaning that subjects below this line remained within suitable parameters of cardiac healthy and safe physical exercise. In the last interval of the study, all subjects were found to be with an SpO2 variation below 5%. (Figure 52)

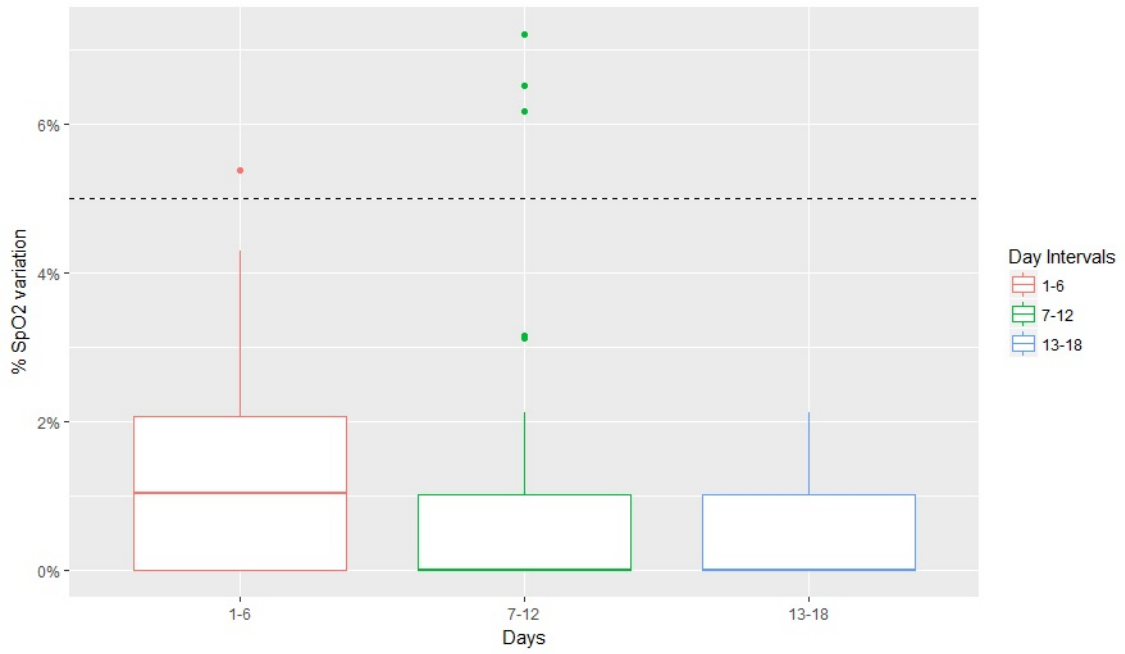

Figure 52. Results of daily variations in blood oxygen saturation (SpO2) for the study group during exercise, grouped together into 6-day intervals.

Of the 360 SpO2 measurements (20 subjects x 18 days' measurement) taken over the 18 days of exercise, 5 measurements failed to reach the cut-off line (variation <5% SpO2). (Figure 53)

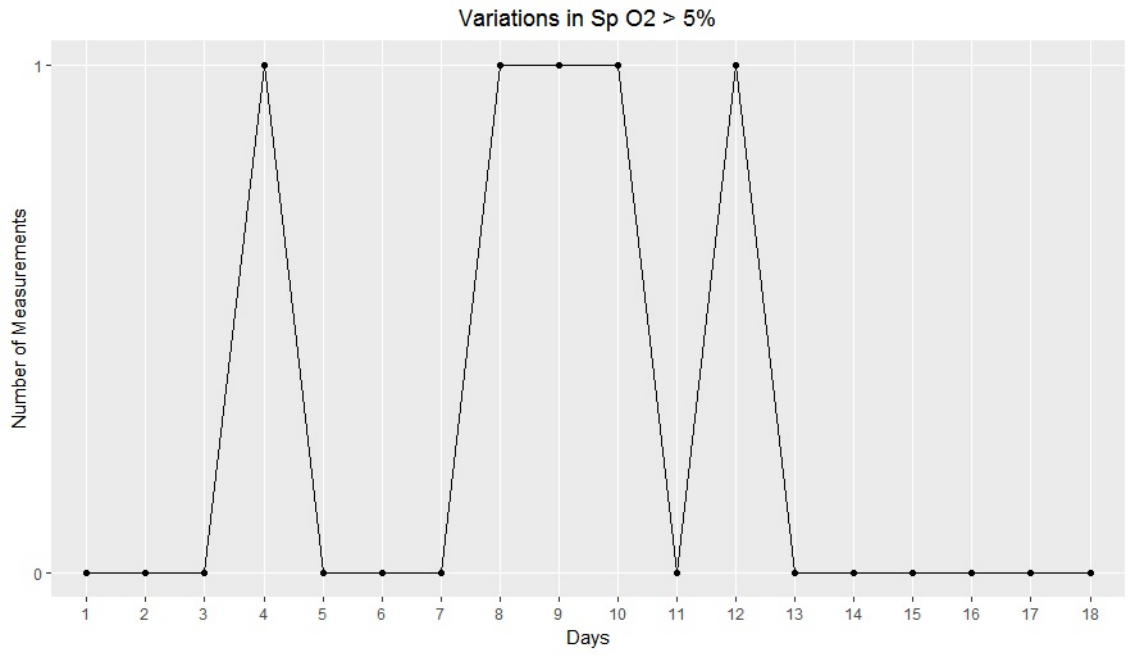

Figure 53. Number of blood oxygen saturation measurements which were above the cut-off point per day.

Therefore, only 1.4% of measurements were below the 5% cut-off point, whereas 98.6% of measurements remained at variation levels of <5% SpO2. (Figure 53)

4.2.6.6 *Compliance with suitable parameters to ensure that physical exercise is cardiac healthy and safe*

As was described in the system's design, the aim was for the proposed activity with the FRED game was not to entail any risk to the subject who carries it out. To this end and taking into account the parameters described in table 13 together with the maximum published scores for systolic and diastolic blood pressure and blood oxygen saturation [204-206], the percentage resulting from the sum of all physiological constant measurements was ascertained, namely: maximum heart rate, systolic blood pressure, diastolic blood pressure and blood oxygen saturation, taken from subjects belonging to the study group during exercise, grouped together into 6-day intervals and expressed as a percentage. Thus, compliance with suitable parameters may ensure that physical exercise be both cardiac healthy and safe.

1440 measurements were taken (4 physiological constants x 20 subjects x 18 days).

Safety compliance of the exercise exceeded 87% in the 3 intervals and improved even more so as the days passed. (Figure 54)

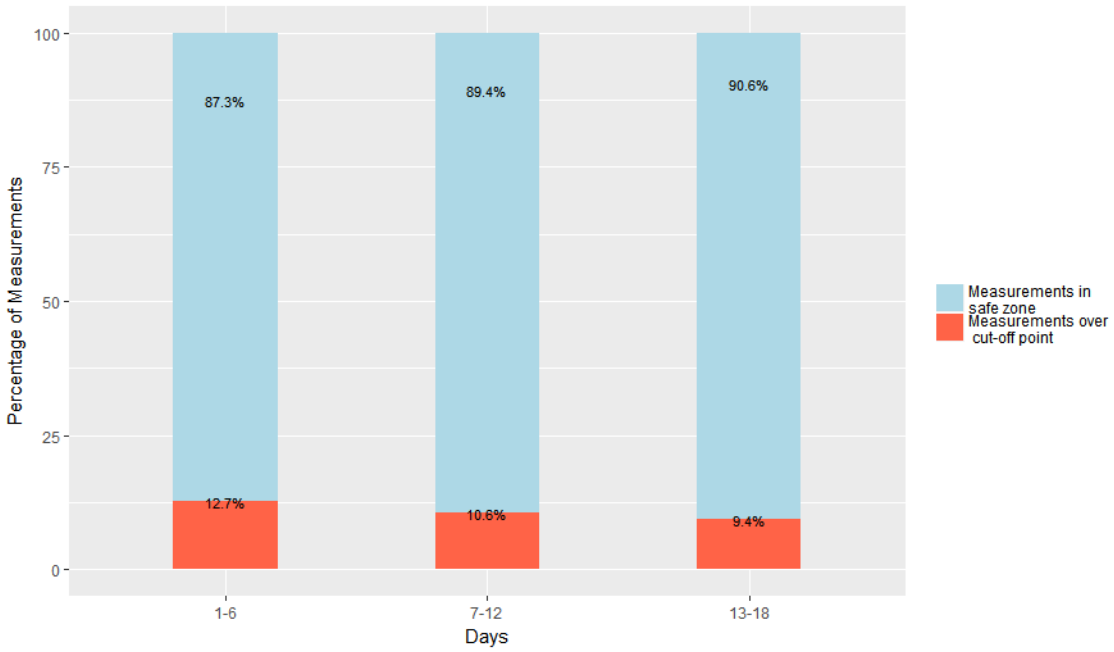

Figure 54. Measurement percentage within the parameters established as being safe for the following physiological constants - maximum heart rate, systolic blood pressure, diastolic blood pressure and blood oxygen saturation (HR, SBP, DBP, SpO2) – for subjects from the study group during exercise, grouped together into 6-day intervals.

Attention should be drawn to the fact that in no case was the activity abandoned due to physical discomfort.

4.2.7 Software Usability Scale (SUS)

With the range being considered from 0-100 for software usability scale (SUS) results, in which scores above 68 were deemed to be positive. It was noted that all subjects who carried out the activity over 6 weeks using the FRED game scored above the cut-off point (68). The lowest score obtained was 70 while the highest was 100. (Figure 55)

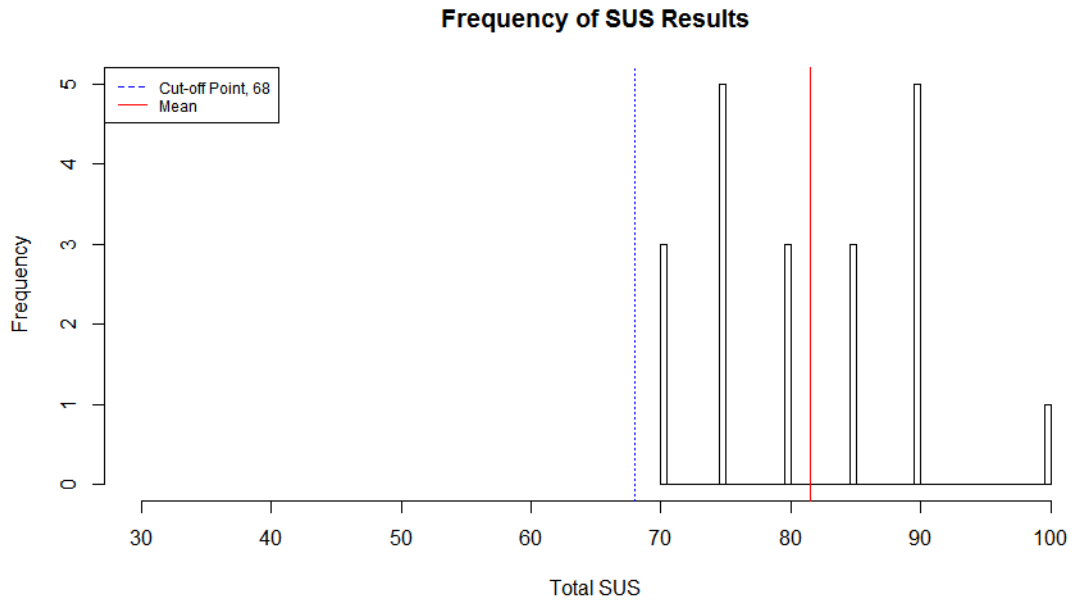

Figure 55. Histogram of results obtained using the software usability scale (SUS); red line: mean; blue line represents cut-off point.

The mean was 81.5. This score indicates a good result in the SUS questionnaire. (Table 25)

Total SUS Scale- Stadistics	
Mínimum	70.0
1st Qu.	75.0
Median	80.0
Mean	81.5
3rd Qu.	90.0
Maximum	100.0
Std. Dev.	4.56

Table 25. Statistical description of the software usability scale (SUS) for study group.

The results showed major acceptance in terms of usability of the FRED game among subjects from the study group.

4.2.8 Satisfaction with, adherence to and compliance with the FRED game

After completing the game each day, each participant from the study group was asked 2 questions, with the possible responses being YES or NO:

1. Do you like the game?

2. Do you find it motivating for the purpose of improving your physical condition?

As regards the first question, except on days 1 and 2 when there was a 10% (2 subjects) and 5% (1 subject) respectively who gave a negative response, the 20 subjects from the study group responded YES on the other days. (Figure 56)

As regards the second question, except on days 1 and 2 when there was a 20% (4 subjects) and 5% (1 subject) who gave a negative response, the 20 subjects from the study group responded YES on the other days. (Figure 56)

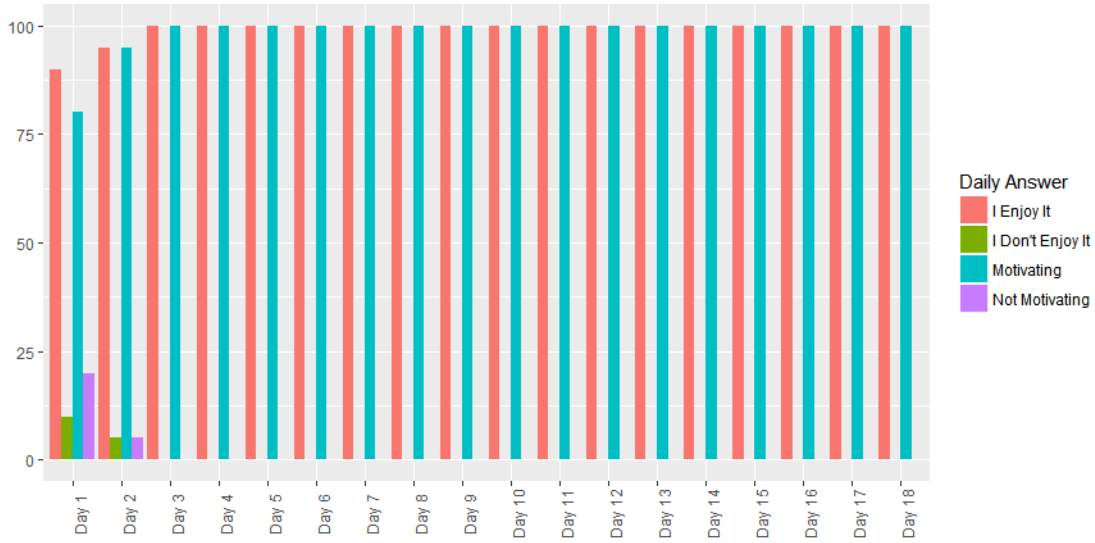

Figure 56. Daily response percentages by the study group to the questions: "Do you like the game?" and Do you find it motivating for the purpose of improving your physical condition?".

"Discussion is imposible with someone who claims not to seek the truth, but already to possess it".
Romain Rolland

5. DISCUSSION

5 DISCUSSION

In this section it is collected ***the discussion of the results obtained, contrasting them with those of other authors*** who have worked on related topics

The results, both in the 3-week feasibility study and in the 6-week follow-up ***support the hypothesis*** that FRED, exergame diseñado ad hoc, ***significantly reduced the presence and severity of risk for frailty*** in a sample of sedentary elders, thus potentially modifying their risk profile.

The results, consistent with previous evidence, suggest that elders with higher risk profiles may still benefit from preventive strategies and should not be excluded a priori from interventions to prevent disability.

Cesari el al.[214] conducted a study in which the physical activity programme included aerobics (walking), strength, flexibility and balance training which were undertaken in three phases over a 12-month period: adoption (weeks,1-8), transition (weeks 9-24) and maintenance (week 25 to month12). The results indicated that the regular physical activity may reduce frailty, especially in subjects at higher risk of disability. Future studies should be aimed at testing the possible benefits produced by multidomain interventions on frailty.

Giné-Garriga et al.[215] conducted a study with a combination of functional balance and lower-body strength-based exercises over a 12-week period, referred to as the functional circuit training program (FCT). This involved setting aside 1 day a week for balance training and another day for lower-body strength-based exercises of 15 minutes each. The obtained results showed that functional circuit training program (FCT) is effective in improving self-reported measures of fear of falling and health status in a group of physically frail people.

Clegg et al.[216] compared the effectiveness of the HOPE programme with usual care via a blind pilot randomised controlled trial (RCT) over a 12-month period, completing 15 minutes, 3 times a day over 5 days of the week. The results indicated that the HOPE program trial has provided preliminary evidence that the deterioration in mobility experienced by elderly people with frailty may be reduced through a 12 week exercise intervention. Apart from mobility, independence in activities of daily living was also assessed via the Barthel Index, in which no significant differences between

both groups was evidenced. As regards self-assessment of one's state of health and quality of life via the EuroQol 5D-5L (EQ-5D-5L) questionnaire, the results showed a slight worsening. No data was provided about self-assessment of one's state of health via the EuroQol-visual analogue scale (EQ-VAS).

Fairhall et al.[77] made a comparison between study group and control group with frail elderly people by setting in motion a multi-factor intervention programme with online exercises over a 12-month period. The results showed that the prevalence of frailty was 14.7% less in the intervention group than in the control group after 12 months. There were no significant differences between groups in terms of scores regarding the usefulness of the EuroQol 5D-5L (EQ-5D-5L) questionnaire. There was not any data about self-assessment of one's state of health via the EuroQol-visual analogue scale (EQ-VAS).

Milte et al.[217] conducted a study over 2 weeks in order to explore the relative importance given to health and quality of life by elderly people who performed therapeutic gymnastics and undertook hydrotherapy sessions. Only results for the EuroQol 5D-5L (EQ-5D-5L) questionnaire were shown in this study, and no data was provided about the EuroQol-visual analogue scale (EQ-VAS).

Bieryla KA[218] used the Xbox Kinect™ to improve balance in elderly people. The results showed an improvement in terms of the balance tests carried out. However, no improvements were evidenced in the Timed Up and Go (TUG) test, which the author did not expect given that use of the Kinect™ compels participants to move more than other game systems.

The above studies[77,215-218] combine different types of physical activity which were performed over longer periods of time and at greater weekly frequency than the physical activity in our study using the FRED game. Although they manage to reduce frailty, they do so requiring far more time, and ***none of them contemplates exercise using an exergame***. Only in the thee previous ones is reference made to the EuroQol 5D-5L (EQ-5D-5L) questionnaire, in which no significant differences are shown, whereas with the FRED game, the study group remained stable after 6 weeks while the control group slightly worsened. Unlike the other two authors referred to above, the EuroQol-visual analogue scale (EQ-VAS) was recorded in the study, in which the control group worsened whereas the study group significantly improved. Furthermore,

the degree of independence for activities of daily living also evidenced an improvement after 6 weeks carrying out physical activity using the FRED game. Therefore, ***the degree of frailty is able to be reduced in less time using the FRED game, while the perception of one's state of health and degree of independence in activities of daily living is much greater.***

The study conducted by Daniel et al. [174], uses the exergame as physical activity to be carried out in order to reduce frailty. In this case, they use the Nintendo® and Wii™ console with general games designed for all types of public such as bowling, tennis and boxing, and compare them to seated exercise and control. They carried out exercise sessions for 45 minutes three times per week for 15 weeks. The results suggested that all the differences reflected improved physical functional status in the seated exercise or Wii-fit groups compared to the control group. **The FRED game** differs from the above study because it **managed to reduce the degree of frailty to a fifth of the time** (3 weeks as opposed to 15), **including sessions of less than half the duration** (20 min as opposed to 45 min). **In addition**, the FRED game **continued to reduce the degree of frailty over the 6-week period** and consequently, it would seem to be more effective.

The study conducted by Van Diest et al.[195] used the exergame for unsupervised balance training at home - a virtual ice skater for 30 minutes, three times per week for six weeks. The pilot study showed that unsupervised home-based exergaming is feasible in community-dwelling older adults, but also that participants do not benefit equally from the programme, thereby emphasizing the need for more personalized exergame training programmes. This conclusion without doubt highlights the ad hoc feature of FRED in terms of the design and putting together of exercises, placing importance on the types of scenario to ensure they are creative and intuitive and capture the subject's attention and interest. The specific movements that were carefully chosen for each scenario, respecting biomechanics, neuromotor functions and participation both of upper and lower extremities and the trunk, were able to facilitate independence in terms of basic activities of daily living (ADLs) such as transferring, dressing, eating, toileting and walking.

As regards physiological constants such as heart rate, systolic blood pressure, diastolic blood pressure and blood oxygen saturation, ***there are no studies in the literature***

reviewed that have measured these constants in elderly people in order to ascertain whether the physical exercise involved lies within certain safety parameters and whether it is in turn cardiac healthy. Studies found in this regard are very diverse, among which attention should be drawn to the following.

Scheer et al.[219] assessed the effects caused in heart rate, ventilation, oxygen consumption and energy expenditure using Nintendo Wii, Sony Move and Microsoft Kinect™ when competing against a computer or human opponent in young adults. The resulting data for oxygen consumption was used to compare the Nintendo Wii, Sony Move and Microsoft Kinect™ games using moderate health guidelines to promote physical activity.

O'Donovan et al.[220] considered comparing energy expenditure when playing in individual and multi-player mode using Xbox Kinect™ and Wii™ consoles. They concluded that energy expenditure and heart rate increased when playing with the Xbox Kinect™ console in multi-player mode.

Holmes et al.[221] sought to determine training exercise intensity using the Xbox Kinect™ in adults over the age of 18 who had been diagnosed as having cystic fibrosis (CF), an illness in which physical exercise forms a very important part of therapy. They concluded that training with the Xbox Kinect ™ represents a high-intensity exercise for adults with CF and may be considered a suitable alternative to conventional types of exercise.

There is a recent publication by Barry el al.[222], in which they describe the study conducted to compare the effects of exergaming with traditional gymnastics-based exercises in which patterns of movement, intensity and physiological demand were similar for postural control. All participants (young adults) completed three exercise sessions of 30 minutes' duration a week over a 4-week period. Heart rate was compared between groups and no differences were found. Ratings for perceived exertion (RPE) or the Borg scale were significantly lower in the Kinect ™ group. The Kinect ™ group perceived less physical exertion than the group which carried out traditional gymnastics-based exercises. There were also significant differences in terms of acceptance of the technology between groups and in considering it to be a positive exercise experience, with higher scores in the case of the Kinect exercise group. They concluded that exergaming with Kinect ™ may attain moderate levels of physical

exercise intensity with positive feelings about the reduction in perceived exertion in comparison to traditional types of exercise. In this sense, the results obtained using the FRED game are very similar in terms of the fact that a moderate level of physical activity intensity may be obtained, accompanied by a low rating of perceived exertion. This was also accepted positively and proved a motivating force in improving the individual's physical condition.

In spite of reaching similar conclusions, it is necessary to emphasize that ***in the game FRED the control of the biofeedback was realized of more complete form. That is, taking into account the physiological constants, which provided more information to talk about safety and cardiac healthy.***

Karahan et al.[223] conducted a study to compare the effects between exergames using the Xbox Kinect™ device and exercise at home involving balance training, functional mobility and quality of life among subjects over 65 years of age. Each subject played for 30 minutes 5 days per week over a 6-week period (30 sessions in total) in the company of an experienced nurse, who was able to carry out cardiopulmonary monitoring in order to ensure there were no events and, thus, ensure the safety of the exercise being undertaken. The extent to which participants enjoyed it was in turn assessed using a 5-point Likert scale (0-5). Results were positive and both groups improved in terms of balance, functional mobility and quality of life, although the authors pointed out that the group which did the exercise using the Xbox Kinect™ device obtained better results. In this sense, ***the FRED game differs because*** it resulted in a major difference in terms of physical condition ***after just 3 sessions a week and for less duration, as the risk of frailty evidenced in the study group was significantly reduced*** whereas it considerably worsened in the control group. Similarly, it did so ***in terms of independence in activities of daily living, with the study group obtaining better results in the Barthel Index than the control group, which obtained a worse result after 6 weeks***. As regards compliance with safety with a view to preventing any event from taking place that might put the participants at risk, physiological constants were measured in the FRED game such as heart rate, rating for perceived exertion, systolic blood pressure, diastolic blood pressure and blood oxygen saturation. These measurements were taken before commencing, immediately afterwards and 5 minutes after having completed in order to make an assessment taking into account the safety parameters established and published by European guides, resulting in a cardiac healthy

and safe exercise because safety compliance of the physical exercise ***exceeded 87% and even improved as the days went by. Moreover, in no case was the activity abandoned due to physical discomfort.***

A recent publication by Meneghini et al.[224] involves a qualitative study about the perception of elderly people with regard to participation in exergaming-based exercise. Fourteen subjects (55-77 years of age) carried out 12 weeks of exercise (50 min, 3 days / week) using Xbox 360 Kinect™ Sports. Participants reported psychological benefits (self-esteem, concentration, mood, reasoning, memory and wellbeing), physical benefits (agility and physical conditions) and social interaction (exchange of experiences, friendship and competitiveness). As regards group experiences, innovation, the game itself and visual stimulation were cited as features of the games, and the perception of benefits from participation in exergames fostered the pursuit of exercise and increases motivation among participants. In this sense, in the case of the ***FRED game, it managed to reduce the frailty risk that benefit from physical exercise entails by half the time (weeks) and in sessions of less than half the duration. It also managed to improve the degree of independence in activities of daily living and in the perception of participants' state of health***. The study group awarded the game very high scores, meaning that the game was accepted and rated very positively in terms of its usability. ***The game was also adhered to and complied with by the study group, as all and every one of the participants completed the same number of sessions and responded 100% to the daily questions to ascertain whether they liked the game and whether they found it motivating for the purpose of improving their physical condition.***

All the benefits obtained that have been described above are due to the added appeal provided by the FRED game over other existing types of video game. This added appeal is based on its being a game designed ad hoc in which the aim is for the user to be the protagonist. Thus, greater involvement, adherence to and compliance with physical exercise is achieved.

“Research is creating new knowledge”.
Neil Armstrong

6. CONCLUSIONS

6 CONCLUSIONS

The conclusions reached at the end of the work are the following:

6.1 Review of the general and specific objetives

6.1.1 General objective

The general objective of this project is to design and implement a game which decreases the risk of frailty and improves the functional capacity of elderly people allowing them to remain independent as long as possible.

6.1.1.1 Accomplishment of the general objective

The FRED game developed ad hoc has contributed in reducing the degree of frailty improving the functional capacity of the frail elderly people continuing to be independent for as long as possible.

6.1.2 Specific objectives

Right after, the conclusions in relation to the specific objectives.

6.1.2.1 Physical objectives

- ***Improve the physical and functional capacity***
- ***Encourage exercise in elderly people avoiding the sedentary lifestyle***

The FRED game designed ad hoc game has been able to improve the physical and functional capacity because it has managed to encourage them to carry out exercise avoiding the sedentary lifestyle presented by elderly people in general and to a greater extent frail elderly people.

- ***Improve the balance in elderly people being safer and more independent***
- ***Avoid falls in elderly people preventing hospitalization***

Frail elderly people can improve balance by exercising with FRED game. By doing this falls can be avoided and so hospitalization. Thus they can have greater security in carrying out their activities of daily life and consequently have greater independence.

- ***Remain independent in the basic activities of daily living (BADL)***

The FRED game contributes to remain independent in the activities of daily living avoiding the institutionalization of frail elderly people.

- ***Adherence and exercise compliance***

Having been designed ad hoc the feature proved very appealing among frail elderly people, who felt themselves to be the protagonists and thus achieved better involvement in, adherence to and compliance with physical exercise.

6.1.2.2 Physiological objectives

- ***Perform exercise which achieves basic safety parameters of heart rate, blood pressure and blood oxygen saturation***
- ***Perform a cardiovascular exercise***

The activity proposed with the FRED game has not posed any risk for the frail elderly people who have done it because they have worked on cardiac healthy and within safe parameters.

6.1.2.3 Technological objetives

- ***Design and implementation of the serious game, including: Creative and intuitive scenarios, specific exercises created respecting biomechanics and neuromotricity***

The exercises performed in the different scenarios are very intuitive and comprise several articulations respecting biomechanics and neuromotricity. The habitual practice of these exercises facilitates independence in the basic activities of daily life.

- ***Different activities with a goal or within a main activity***

The game presents several activities to perform within the main activity. The person who performs the game goes through different scenarios in which he performs different activities during the performance of his exercises in the context of the elaboration of txakoli.

- ***Achieve the usability of the game***

The game has proved usability since the people who have used it have positively valued.

6.1.2.4 Social objectives

- ***Improve the perception of quality of life***
- ***Motivating participation and integration***
- ***Improve mood state***
- ***Avoid the isolation in elderly people***

Frail elderly people improved the perception of their state of health and quality of life while in turn their mood was improved. They became motivated towards participation and integration thus able to prevent a sense of isolation, which they would otherwise easily tend towards.

6.2 Review of the research questions and hypothesis

The ad hoc developed FRED game helped to reduce the degree of frailty by improving the functional capacity of frail elderly people, thus enabling them to remain independent as long as possible.

The FRED game showed that it is able to motivate frail elderly people in doing exercise, because it involved a game that they liked and proved motivating for the purpose of improving their physical condition.

The activity proposed with the FRED game did not entail any risk to the frail elderly people who took part in it, given that they worked within safe and cardiac healthy parameters.

6.3 Study conclusions

The study undertaken confirms the fact that the FRED game proves to be a valid technological solution for reducing frailty risk.

Based on the study conducted, the exergame may be considered to be an effective, safe and entertaining alternative with which an improvement is made not only in terms of the physical and functional capacity of the individual, but also an improvement in psychological and social aspects which, in short, make the individual evidence a greater degree of independence over a longer time, i.e. “bring more life to the years”.

The possibility of carrying out a study in the near future is under consideration, in which prevention of the onset of frailty could be studied.

6.4 Scientific impact

The present work ***brings to the scientific community a new approach in the use of games as therapy***, since it stands out by the ad hoc design for a concrete profile of people, in this case the frail elderly people.

This approach aims to direct the ***game as a therapy under the expert analysis of health professionals working within interdisciplinary groups can achieve really successful designs thus avoiding the use of standard games*** that are not designed specifically for health but for general leisure of the society.

This thesis has the ***first journal paper accepted which has been published*** in April 2017: Mugueta-Aguinaga I, Garcia-Zapirain B. Is Technology Present in Frailty? Technology a Back-up Tool for Dealing with Frailty in the Elderly: A Systematic Review. A&D, 2017, 8(2): 176-195.

Moreover, another ***two articles are already under review*** and hopefully will be published.

The ***game FRED is registered in the Copyright registry office of the Basque Government***.

Collaboration in the SUNFRAIL European Project (Reference Site Network for Prevention and Care of Frailty and Chronic Conditions in community dwelling persons of EU countries). Project number: 664291. Funding Entity: CHAFEA Consumer, Health, Agriculture and Food Executive Agency.

The scale up of the English version of FRED in USA has already started. It presented the project Exercise Games with Biofeedback to Institutional Research Board and it has obtained the ***approval of the Ethical Committee from the University of Louisville***. Therefore, it will continue to be followed up until publishing the results in a journal paper. In addition, it has been necessary to pass the exams to obtain Human Subjects and HIPAA Research-Stage 1 - Basic Course which it was required from COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM) - Ethical Committee (University of Louisville).

Research Disclosure in USA: the research disclosure form is already under review and hopefully will be approved.

Attempt to present the project in every congress and day related to frailty in the elderly people, eg: *Oral Communication in:* ***XVI Congress of Zahartzaroa and IX Congress of the Navarre Society of Geriatric and Gerontology****. Vitoria-Gasteiz, May 4-6, 2017.*

The possibility of carrying out a study in the near future is under consideration, in which prevention of the onset of frailty could be studied.

“I respect my limitations, but I don't use them as an excuse.”

Stephen R. Donaldson

7. LIMITATIONS

7 LIMITATIONS

The study has limitations in that, for budgetary reasons, development of the game has only been able to reach a level of difficulty of the three levels anticipated at the moment of its conception.

These levels would provide different starting points according to the physical conditions of the elderly at the start and would enable a higher level of difficulty to be reached as the days go by.

Assistance is currently being requested to continue developing the different levels of difficulty of the game and to be able to carry out a study in the short / medium term.

“Things are as they are because they were as they were.”

Thomas Gold

8. REFERENCES

8 REFERENCES

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“Evolution tell us where came from, not where we can go.”

Jerry A. Coyne

9. APPENDIX

9 APPENDIX

9.1 APPENDIX: Ethical Committee approval

Deusto
Comité de Ética en Investigación

DICTAMEN DEL COMITÉ DE ÉTICA EN LA INVESTIGACIÓN DE LA UNIVERSIDAD DE DEUSTO

Ref: ETK-17/15-16

Tras la evaluación del proyecto "Exergames y fragilidad" que presenta Dña. **Begoña García Zapirain**, Investigadora del grupo eVida (DeustoTech-Life), el Comité de Ética en Investigación de la Universidad de Deusto, tal y como se hace constar en el acta de la reunión del 20 de Mayo de 2016 en la que se tomó el acuerdo, no encuentra objeción alguna, y califica el proyecto de **APTO**.

Tras el estudio de la información aportada (descripción del proyecto, modelos de consentimiento informado, cronograma, etc.), se considera que el procedimiento en la fase de captación de participantes, su tratamiento durante el tiempo que dura el proyecto, la utilización y protección que se otorga a los datos obtenidos y a los resultados finales del proyecto, es adecuado y se ajusta a los principios metodológicos, éticos y jurídicos que debe tener este tipo de investigación. No se observan riesgos de ningún tipo para los participantes.

No obstante, se podrían hacer alguna matización que mejoraría el contenido de la solicitud:

1. Como en todo proyecto de investigación sería oportuno que a los participantes del proyecto, y una vez finalizado el mismo, se explicara o bien se pusiera a su disposición los resultados generales que se han alcanzado con dicho proyecto.

Y para que así conste,

Dña. Cristina de la Cruz Ayuso
Coordinadora de la Comisión de Ética en Investigación
Universidad de Deusto

En Bilbao a 23 de Mayo de 2016

9.2 APPENDIX : Nursing-homes approvals

9.2.1 Residencia Txurdinagabarri

En Bilbao, a 7 de enero de 2016.

REUNIDOS

DE UNA PARTE.- D. Jesús Vázquez Aguado provisto de D.N.I número 14.584.320-C, actuando en nombre y representación de la asociación Emankor, provista de C.I.F. número G-48421747, con domicilio en Bilbao (Bizkaia), dirección Fernando Jiménez, miembro de la DYA 14 (Lonja).

Y, DE OTRA PARTE,- D. MIKEL TELLAECHE REPARAZ provisto de D.N.I. número 15963857V en nombre y representación de la SERVICIOS SOCIALES AITA MENNI SL provista de C.I.F. número B95370011, con domicilio social en Bilbao (Bizkaia), dirección Egaña, 10.

EXPONEN

I.- Que la asociación Emankor es una entidad sin ánimo de lucro que nace hace 25 años con el objeto de atender a las cambiantes necesidades sociales de la sociedad de Bilbao. Dentro de su actividad. La asociación Emankor ha desarrollado diferentes servicios para el colectivo de personas mayores participando activamente como miembro del grupo de Envejecimiento Activo de la Asociación Vasca de Geriatría y Gerontología, Zahartzaroa.

En el desarrollo de estos proyectos, la asociación Emankor ha detectado unas necesidades que pretenden cubrir buscando soluciones tecnológicas que favorezcan la vida activa y la interacción social y que, mediante el empleo de nuevas tecnologías, contribuyen en procesos rehabilitadores.

En el ámbito de dicha actividad, la asociación Emankor se dispone a desarrollar un proyecto de Innovación

II.- Que SERVICIOS SOCIALES AITA MENNI SL es una entidad mercantil que desarrolla en la CAPV como actividades enmarcadas dentro de su objeto social las siguientes: atención a personas mayores en instituciones sociales.

Los medios y soportes utilizados por Asociación Emankor, y, en su caso, por sus encargados de tratamiento, incluyendo los ordenadores, discos duros y cualquier otro soporte informático, así como los soportes no automatizados, en ningún momento podrán quedar almacenados ni ser custodiados en las instalaciones de Txurdinagabarri.

Al finalizar la vigencia del Acuerdo pactado en el presente documento, puesto que Txurdinagabarri no habrá tratado en forma alguna datos de carácter personal vinculados a la investigación, la responsabilidad sobre los mismos será exclusiva de asociación Emankor.

SÉPTIMA. RESOLUCIÓN DEL ACUERDO

El acuerdo de colaboración podrá ser resuelto por las siguientes causas:

. a) por incumplimiento de cualquiera de las cláusulas del acuerdo.

. b) Por mutuo acuerdo de las partes.

De conformidad con todo lo expuesto y acordado, en el ejercicio de las atribuciones de que son titulares los firmantes, suscriben por duplicado el presente Acuerdo en el lugar y fecha al principio indicados.

emankor sarea
C.I.F.: G-08121747
Fernando Jiménez, 14 - Lonja • 48004 BILBAO

Servicios Sociales AITA MENNI Gizarte Zerbitzuak
RESIDENCIA TXURDINAGABARRI EGOITZA

ASOCIACIÓN EMANKOR

Fdo. Jesús Vázquez Aguado

RESIDENCIA TXURDINAGABERRI

Fdo. Mikel Tellaeche Reparaz

9.2.2 Residencia Vitalitas-Sarriko

En Bilbao, a 7 de enero de 2016.

REUNIDOS

DE UNA PARTE.- D. Jesús Vázquez Aguado provisto de D.N.I número 14.584.320-C, actuando en nombre y representación de la asociación Emankor, provista de C.I.F. número G-48421747, con domicilio en Bilbao (Bizkaia), dirección Fernando JImenez, miembro de la DYA 14 (Lonja).

Y, DE OTRA PARTE.- D./Dña Nagore Elorrieta Muruaga, Directora de la residencia Vitalitas Sarriko, provisto de D.N.I número 78.906.502-B, en nombre y representación de Vitalitas Sarriko, S.L. provista de C.I.F. número B-95705950, con domicilio social en Avda. de La Libertad, Nº 65-3º B- 48900-Barakaldo, Bizkaia

EXPONEN

I.- Que la asociación Emankor es una entidad sin ánimo de lucro que nace hace 25 años con el objeto de atender a las cambiantes necesidades sociales de la sociedad de Bilbao. Dentro de su actividad. La asociación Emankor ha desarrollado diferentes servicios para el colectivo de personas mayores participando activamente como miembro del grupo de Envejecimiento Activo de la Asociación Vasca de Geriatría y Gerontología, Zahartzaroa.

En el desarrollo de estos proyectos, la asociación Emankor ha detectado unas necesidades que pretenden cubrir buscando soluciones tecnológicas que favorezcan la vida activa y la interacción social y que, mediante el empleo de nuevas tecnologías, contribuyen en procesos rehabilitadores.

En el ámbito de dicha actividad, la asociación Emankor se dispone a desarrollar un proyecto de Innovación

II.- Que Vitalitas Sarriko, S.L. es una entidad mercantil que desarrolla en la CAPV como actividades enmarcadas dentro de su objeto social las siguientes:

- La prestación de todo tipo de servicios de asistencia social, sanitaria, gerontológica, asistencial, psicológica y social.
- Gestión de Residencias, pisos tutelados, Centros de Día.
- Prestación de Servicios de Ayuda Domiciliaria.

será exclusiva responsabilidad de Emnakor y, en su caso, de sus encargados de tratamiento, para lo cual utilizarán en todo momento recursos propios. Asociación Emankor y, en su caso, sus encargados de tratamiento, establecerán las medidas de seguridad necesarias para que el personal de Vitalitas Sarriko que colabore en la investigación en ningún momento tenga acceso a los datos personales de las personas usuarias del centro vinculados a la misma.

Los medios y soportes utilizados por Asociación Emankor, y, en su caso, por sus encargados de tratamiento, incluyendo los ordenadores, discos duros y cualquier otro soporte informático, así como los soportes no automatizados, en ningún momento podrán quedar almacenados ni ser custodiados en las instalaciones de Vitalitas Sarriko.

Al finalizar la vigencia del Acuerdo pactado en el presente documento, puesto que Vialitas Sarriko no habrá tratado en forma alguna datos de carácter personal vinculados a la investigación, la responsabilidad sobre los mismos será exclusiva de asociación Emankor.

SÉPTIMA. RESOLUCIÓN DEL ACUERDO

El acuerdo de colaboración podrá ser resuelto por las siguientes causas:

. a) por incumplimiento de cualquiera de las cláusulas del acuerdo.

. b) Por mutuo acuerdo de las partes.

De conformidad con todo lo expuesto y acordado, en el ejercicio de las atribuciones de que son titulares los firmantes, suscriben por duplicado el presente Acuerdo en el lugar y fecha al principio indicados.

emankor sa
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Fernando Jiménez, 14 - Lonja - 48004 BILBAO

ASOCIACIÓN EMANKOR

Fdo. Jesús Vázquez Aguado

RESIDENCIA VITALITAS SARRIKO
Avd. Lehendakari Aguirre, nº 138
48015 - BILBAO

RESIDENCIA VITALITAS SARRIKO

Fdo. Nagore Elorrieta Muruaga

9.3 APPENDIX: Information sheet and informed consent for the studies

HOJA DE INFORMACIÓN A LOS PARTICIPANTES EN LA INVESTIGACIÓN

Estimado/a _____,

Nos dirigimos a usted como equipo que desarrolla el trabajo **"Exergames y fragilidad"** en la Residencia "_____". Con esta carta, nos gustaría informarle de dicho proyecto de investigación y solicitar su participación en el mismo. Usted ha sido elegido, gracias a la colaboración del equipo asistencial de la Residencia _____, para participar en el desarrollo del estudio. Entendemos que su participación es vital para el desarrollo del mismo.

El equipo de investigación está formado por la asociación Emankor, que cuenta con la colaboración de una fisioterapeuta de Osakidetza-Servicio Vasco de Salud e ingenieros informáticos pertenecientes a DeustoTech Life de la Universidad de Deusto con el objetivo de abordar un Proyecto de Innovación en el que se pretende crear una herramienta eficaz para realizar ejercicio a través del juego.

La herramienta desarrollada se validara con este estudio de investigación del que le ofrecemos forme parte. Queremos informarle además que este estudio forma parte del Proyecto de Investigación de Tesis Doctoral de la Universidad del País Vasco en codirección con la Universidad de Deusto, cuya investigadora principal es Iranzu Mugueta Aguinaga, Fisioterapeuta de Osakidetza-Servicio Vasco de Salud con quien usted puede contactar directamente, llamando al teléfono 656779915.

¿Qué significa la palabra **exergame?** Es el uso del videojuego que integra el juego con la actividad física, con lo que se consigue mejorar la motivación y adhesión a la participación de la actividad física.
Se trata de un programa de actividades físicas de bajo impacto, de actividades moderadas, guiadas por el propio juego, que permite aumentar el tiempo de actividad física al centrarse en la diversión de los juegos, sin dejar de ofrecer beneficios de la actividad física, en lugar de centrarse en el esfuerzo.

¿Qué es fragilidad? Es la situación de salud en la que se tienen disminuídas las reservas fisiológicas, de manera que se encuentra en una situación de mayor vulnerabilidad y por tanto, de mayor probabilidad de presenter episodios adversos (caídas, hospitalización…). Es un concepto dinámico, por lo que no todos los individuos son frágiles de la misma manera y además puede ser diferente en la misma persona según el periodo de tiempo.

El **objetivo** de este estudio es realizar ejercicio a través de juegos para mejorar su capacidad funcional disminuyendo así el grado de fragilidad presente.

Puesta en marcha del estudio: Para llevar a cabo este estudio se realizarán unas pruebas previas de valoración para conocer su capacidad funcional al inicio.

Una vez realizadas estas pruebas, el número total de participantes se dividirá aleatoriamente(al azar) en 2 grupos, uno de estudio y otro de control.

- Si usted es de las personas que está en el grupo estudio: realizará 3

veces en semana ejercicio durante 30 minutos con los juegos que hemos diseñado para el estudio durante 6 semanas, en un espacio que se habilitara de forma expresa en la Residencia. Se le indicara como hacerlo y se realizaran ensayos previos para garantizar su correcta ejecución.

- Si usted, en cambio, es de la personas que se encuentra en el grupo control, no realizara los ejercicios y continuara con su vida diaria con normalidad.

Al finalizar las 6 semanas, se realizaran las pruebas de valoración para comprobar el efecto de la investigación a ambos grupos. Esto es a todos los participantes.

Los **beneficios** esperados de esta investigación para usted es

- Si pertenece al grupo de estudio: que mejore su capacidad funcional.
- Si pertenece al grupo control: bienestar por colaborar en la demostración de la utilidad de un herramienta para la mejora de la capacidad funcional como es el ejercicio a través del juego, para que más adelante se pueda utilizar en residencies como la suya.
- No recibirá ningún beneficio económico por participar en el estudio.

No consideramos que haya **riesgos** para su salud derivados de la participación en el estudio salvo el tiempo que usted nos vaya a dedicar.

La participación en este estudio es **voluntaria**. Usted es libre de retirarse en cualquier momento sin que ello tenga consecuencia de ningún tipo en la Residencia. Usted tiene el derecho de negarse a participar, sin que ello pueda ocasionarle ningún perjuicio.

Para cualquier duda o comentario que usted pueda tener al respecto de este proyecto y de su participación en él, no dude, por favor en contactar con la investigadora principal, Iranzu Mugueta Aguinaga. Tfno xxx-xx-xx-xx (tfno.Personal-se elimina para impresión como anexo de tesis).

Para ello, se le entregara esta hoja informativa del mismo y un consentimiento de que está de acuerdo en la participación en el mismo, la cual deberá firmar.

Este estudio se adhiere a la normativa establecida por la Ley Orgánica 15/1999 de 13 de diciembre sobre **protección de datos de carácter personal** y a la Ley 41/2002 básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Así, la confidencialidad de la información provista por usted en el estudio está asegurada. Ningún nombre o referencia personal será utilizado en los materiales de trabajo ni presentado en el informe, ya que el equipo utilizará códigos asignados a cada paciente, eliminando toda referencia personal de todos los materiales. Serán exclusivamente los miembros del equipo investigador quienes, en caso necesario, podrán acceder a la identidad de quienes participen, y tengan acceso a la información personalizada que se facilite. Los archivos donde se guarde la relación código-participante será destruida tan pronto finalice el estudio.

CONSENTIMIENTO INFORMADO

a) **Datos del estudio para el que se otorga el consentimiento**:

Iranzu Mugueta Aguinaga, investigadora principal del estudio " Exergames y fragilidad en la Residencia _____

a) **Datos del participante**

Nombre del participante:_____

b) **Persona que proporciona la información y hoja de consentimiento:**

Nombre: _____

1.- Declaro que he leído la Hoja de Información al Participante sobre el estudio citado.
2.- Se me ha entregado una copia de la Hoja de Información al Participante y una copia de este Consentimiento Informado, fechado y firmado. Se me ha explicado las características y el objetivo del estudio, así como los posibles beneficios y riesgos del mismo.
3.- He contado con el tiempo y la oportunidad para realizar preguntas y plantear las dudas que poseía. Todas las preguntas fueron respondidas a mi entera satisfacción.
4.- Se me ha asegurado que se mantendrá la confidencialidad de mis datos.
5.- El consentimiento lo otorgo de manera voluntaria y sé que soy libre de retirarme del estudio en cualquier momento del mismo, por cualquier razón, sin tener que dar explicaciones y sin que tenga ningún efecto sobre mi tratamiento o mi atención en la Residencia _____
en el futuro.

DOY **NO DOY**

Mi consentimiento para la participación en el estudio propuesto. (táchese lo que no proceda)

Firmo por duplicado, quedándome una copia

Firma del participante:	Firma de la investigadora:	Fecha:

9.4 APPENDIX: Photograph and Publicity Release Form

Autorización de reproducción de imagen fotográfica, audio y/o video

Por la presente yo, _____ Identificado/a con el documento de identidad _____autorizo al equipo de investigación formado por la investigadora principal, Emankor y a DeustoTech Life de la Universidad de Deusto, para que use, edite, publique, reproduzca, distribuya y/o licencie la imagen titulada de cuyos derechos de autor soy titular.

Reconozco que esta autorización no supone pago, ni retribución, ni compensación resultante de su uso.

Tengo conocimiento de que esta imagen puede editarse, copiarse, exhibirse, publicarse o distribuirse, por varios medios incluyendo el electrónico, sin que tenga derecho a examinar o autorizar la reproducción del producto final en que ella aparezca.

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Por medio de la firma de esta Autorización reconozco que he leído íntegramente y entendido plenamente la autorización anterior y consciente de las repercusiones legales acepto atenerme a ella.

Nombre y apellido_____

Firma _____

Fecha _____

1

Autorización de uso de imagen fotográfica, audio y/o video

(A ser firmada por la ***persona o personas claramente identificables en las fotografías, audios y/o videos)***.

Por la presente cedo los derechos de reproducción de mi imagen, al equipo de investigación formado por la investigadora principal, Emankor y a DeustoTech Life de la Universidad de Deusto. Reconozco que cedo estos derechos en forma permanente sin esperar a cambio ningún pago ni retribución. Tengo conocimiento de que mi imagen puede editarse, copiarse, exhibirse, publicarse o distribuirse y renuncio al derecho a examinar y/o autorizar la reproducción del producto final en que aparezca mi imagen. Además, renuncio a cualquier derecho,pagos u otra compensación resultantes del uso de mi imagen, o relacionada con ella.

Nombre y apellido_____

Firma _____

Fecha _____

9.5 APPENDIX: Record sheet used for daily data collection

<table>
<tr><td colspan="3">Nivel 2
JUEGO FRED
ID:</td><td>FECHA</td><td>ESCRIBIR EL MINUTO</td><td colspan="2">BORG</td><td colspan="3">SIGNOS VITALES INMEDIATAMENTE AL FINALIZAR</td><td colspan="3">SIGNOS VITALES PASADOS 5' DESPUES DE FINALIZAR</td></tr>
<tr><td colspan="3">Dia n</td><td rowspan="2">COMPLETA ACTIVIDAD</td><td rowspan="2"></td><td>FIN PARTE 1</td><td></td><td>TA</td><td>FC</td><td>%SpO2</td><td>TA</td><td>FC</td><td>%SpO2</td></tr>
<tr><td colspan="3">SIGNOS VITALES ANTES DE INICIAR</td><td>FIN PARTE 2</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>TA</td><td>FC</td><td>%SpO2</td><td rowspan="2">NO COMPLETA ACTIVIDAD</td><td rowspan="2"></td><td rowspan="2">FIN PARTE 3

(INMEDIATAMENTE AL FINALIZAR)</td><td rowspan="2"></td><td colspan="2">LE GUSTA?</td><td>SI
NO</td><td colspan="3" rowspan="2">OBSERVACIONES:</td></tr>
<tr><td></td><td></td><td></td><td colspan="2">ES MOTIVADOR PARA MEJORAR SU CONDICION FISICA</td><td>SI
NO</td></tr>
</table>

9.6 APPENDIX: Evaluation tools: indices, questionnaries and tests

9.6.1 Barthel Index

Índice de Barthel	
	Valoración
Comer	
Independiente	10
Necesita ayuda para cortar la carne o el pan, extender la mantequilla, etc	5
Dependiente	0
Lavarse	
Independiente: es capaz de lavarse entero usando la ducha o el baño	5
Dependiente	0
Vestirse	
Independiente: es capaz de ponerse y quitarse toda la ropa sin ayuda	10
Necesita ayuda, pero realiza solo al menos la mitad de la tarea en un tiempo razonable	5
Dependiente	0
Arreglarse	
independiente: incluye lavarse la cara y las manos, peinarse, maquillarse, afeitarse, etc…	5
Dependiente	0
Deposición (valorar la semana previa)	
Continente: ningún episodio de incontinencia	10
Ocasional: un episodio de incontinencia, necesita ayuda para administrarse enemas o supositorios	5
Incontinente	0
Micción (valorar la semana previa)	
Continente: ningún episodio de incontinencia	10
Ocasional: como máximo un episodio de incontinencia en 24 horas; necesita ayuda para el cuidado de la sonda o el colector	0
Incontinente	0
Usar el retrete	
Independiente: usa el retrete, bacinilla o cuña sin ayuda y sin manchar o mancharse	10
Necesita una pequeña ayuda para quitarse y ponerse la ropa, pero se limpia solo	5
Dependiente	0
Trasladarse (sillón/cama)	
Independiente	15
Mínima ayuda física o supervisión verbal	10
Necesita gran ayuda (persona entrenada), pero se sienta sin ayuda	5
Dependiente: necesita grúa o ayuda de dos personas; no puede permanecer sentado	0
Deambular	
Independiente: camina solo 50 metros, puede ayudarse de bastón, muletas o andador sin ruedas; si utiliza prótesis es capaz de quitársela y ponérsela	15
Necesita ayuda física o supervisión para andar 50 metros	10
Independiente en silla de ruedas sin ayuda ni supervisión	5
Dependiente	0
Subir escaleras	
Independiente para subir y bajar un piso sin supervisión ni ayuda de otra persona	10
Necesita ayuda física de otra persona o supervisión	5
Dependiente	0

9.6.2 Short Physical Performance Battery (SPPB)

PROTOCOLO PARA ADMINISTRAR LA BATERÍA DE DESEMPEÑO FÍSICO (THE SHORT PHYSICAL PERFORMANCE BATTERY)

Todas las pruebas deberían realizarse en el mismo orden en que aparecen en este protocolo. Las instrucciones para los participantes aparecen en cursiva negrita y deberían leerse tal cual.

1) PRUEBAS DE EQUILIBRIO

El participante debe poder mantenerse en pie sin servirse de un bastón o andador. Puede ayudar al participante a levantarse.

Empecemos ya con la evaluación. Me gustaría que intentara mover el cuerpo para realizar diferentes movimientos. En primer lugar, le describiré los movimientos y se los mostraré. A continuación me gustaría que los intentara realizar. Si no puede hacer un movimiento concreto o cree que no sería seguro intentarlo, dígamelo y pasaremos al siguiente. Por favor, es importante que no intente ningún ejercicio que le parezca que podría no ser seguro.

¿Tiene alguna pregunta antes de empezar?

A. De pie con los pies juntos:

1. ***Ahora le enseñaré el primer movimiento.***
2. (Demostración) ***Intente por favor mantenerse de pie con los pies juntos durante aproximadamente 10 segundos.***
3. ***Puede usar los brazos, doblar las rodillas o mover el cuerpo para mantener el equilibrio, pero intente no mover los pies. Trate de mantener esta posición hasta que le diga que pare.***
4. Colóquese al lado del participante para ayudarle a adoptar la posición indicada.
5. Ofrezca al participante únicamente el apoyo necesario en el brazo para evitar que pierda el equilibrio.
6. Una vez el participante tenga los pies juntos, pregúntele ***"¿está listo?"***
7. Entonces puede soltarlo y empezar a contar el tiempo, tras decirle al participante: ***"Preparado, comience"***
8. Detenga el cronómetro y diga ***"Pare"*** transcurridos 10 segundos o cuando el participante abandone la posición o se agarre de su brazo.
9. Si el participante no es capaz de mantener la posición durante 10 segundos, tome nota del resultado y pase a la prueba de "modo y velocidad de andar".

B. Posición de pie semi-tándem:

1. ***Ahora le enseñaré el segundo movimiento.***
2. (Demostración) ***Por favor, colóquese de pie y con la parte lateral del tacón de un pie trate de tocar el dedo gordo del otro durante 10 segundos aproximadamente. Puede situar delante cualquiera de los dos pies, el que le resulte más cómodo.***
3. ***Puede usar los brazos, doblar las rodillas, o mover el cuerpo para mantener el equilibrio, pero intente no mover los pies. Trate de permanecer en esta posición hasta que le diga que pare.***
4. Colóquese al lado del participante para ayudarle a adoptar la posición de semi-tándem.
5. Ofrezca al participante únicamente el apoyo necesario en el brazo para evitar que pierda el equilibrio.
6. Una vez el participante tenga los pies juntos, pregúntele ***"¿está listo?"***
7. Entonces puede soltarlo y empezar a contar el tiempo tras decirle al participante: ***"Preparado, comience"***
8. Detenga el cronómetro y diga ***"Pare"*** transcurridos 10 segundos o cuando el participante abandone la posición o se agarre de su brazo.

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9. Si el participante no es capaz de mantener la posición durante 10 segundos, tome nota del resultado y pase a la prueba de modo y velocidad de andar.

C. Posición de pie tándem:

1. ***Ahora le mostraré el tercer movimiento.***
2. (Demostración) ***Por favor colóquese de pie con el talón de un pie delante de los dedos del otro y en contacto con ellos durante 10 segundos aproximadamente. Puede situar delante cualquiera de los dos pies, el que le resulte más cómodo.***
3. ***Puede usar los brazos, doblar las rodillas, o mover el cuerpo para mantener el equilibrio, pero intente no mover los pies. Trate de permanecer en esta posición hasta que le diga que pare.***
4. Colóquese al lado del participante para ayudarle a adoptar la posición de tándem.
5. Ofrezca al participante únicamente el apoyo necesario en el brazo para evitar que pierda el equilibrio.
6. Una vez el participante tenga los pies juntos, pregúntele ***"¿está listo?"***
7. Entonces puede soltarlo y empezar a contar el tiempo tras decirle: ***"Preparado, comience"***

2) PRUEBA DE MODO Y VELOCIDAD AL ANDAR

Ahora voy a observar cómo camina normalmente. Si suele usar un bastón o alguna otra ayuda y cree que lo necesita para andar una distancia corta, puede usarlo.

A. Primera prueba de modo y velocidad al andar:

1. ***Éste es nuestro recorrido. Quiero que camine hasta el final del recorrido a su velocidad normal, como si estuviera caminando por la calle para ir a comprar.***
2. Haga una demostración del ejercicio para el participante.
3. ***Camine y no se pare hasta llegar al final de la cinta. Yo caminaré con usted. ¿Se siente seguro?***
4. Haga que el participante se coloque en pie, con los dos pies sobre la línea de inicio.
5. ***Cuando quiera que comience, le diré: "Preparado, comience".*** Cuando el participante asimile esta instrucción, diga: ***"Preparado, comience."***
6. Pulse el botón de *start/stop* para poner en marcha el cronómetro cuando el participante comience a caminar.
7. Camine detrás y hacia un lado del participante.
8. Pare el cronómetro cuando uno de los pies del participante haya atravesado completamente la línea de llegada.

B. Segunda prueba de modo y velocidad al andar:

1. ***Ahora quiero que repita el recorrido. Recuerde que debe caminar a su velocidad normal y llegue hasta el final del recorrido, cruzando la línea de llegada.***
2. Haga que el participante se coloque en pie, con los dos pies tocando la línea de salida.
3. ***Cuando quiera que comience, le diré: "Preparado, comience".*** Cuando el participante asimile esta instrucción, diga: ***"Preparado, comience."***
4. Pulse el botón de *start/stop* para poner en marcha el cronómetro cuando el participante comience a caminar.
5. Camine detrás y hacia el lado del participante.
6. Pare el cronómetro cuando uno de los pies del participante haya atravesado completamente la línea de llegada.

3) PRUEBA DE LEVANTARSE DE UNA SILLA

Levantarse de una silla una sola vez:

1. ***Hagamos la última prueba de movimiento. ¿Cree que sería seguro para usted intentar levantarse de una silla sin utilizar los brazos?***
2. ***La siguiente prueba mide la fuerza de las piernas.***
3. (Demuestre y explique el procedimiento.) ***En primer lugar, cruce los brazos por delante del pecho y siéntese con los pies en contacto con el suelo; a continuación intente levantarse sin descruzar los brazos.***
4. ***Por favor levántese sin descruzar los brazos ni apartarlos del pecho.*** (Anote el resultado).
5. Si el participante no pudiera levantarse sin usar los brazos, dígale ***"Vale, intente levantarse usando los brazos"***. Éste será el final de su prueba. Anote el resultado y vaya a la hoja de puntuación.

Levantarse varias veces seguidas de una silla:

1. ***¿Cree que será seguro para usted levantarse 5 veces seguidas de una silla sin usar los brazos?***
2. (Haga una demostración y explique el procedimiento): ***Por favor levántese hasta adoptar una posición erguida tan RÁPIDAMENTE como pueda cinco veces seguidas, sin pararse. Tras levantarse cada vez, vuélvase a sentar y levántese de nuevo. Mantenga los brazos cruzados delante del pecho. Estaré cronometrándolo.***
3. Una vez el participante se halle sentado, diga: ***"¿Preparado? Levántese"*** y comience a cronometrar.
4. Cuente en voz alta cada vez que se levante el participante, hasta llegar a cinco.
5. Pare si el participante se cansa o se queda sin aliento realizando este ejercicio.
6. Pare el cronómetro cuando se halle en posición erguida tras levantarse la quinta vez.
7. Pare también si:
8. ● El participante usa los brazos.
9. ● Transcurrido un minuto, si el participante no ha acabado el ejercicio.
10. ● A su juicio, si teme por la seguridad del participante.
11. Si el participante se para y parece estar fatigado antes de completar la prueba, confírmelo preguntándole: ***"¿Puede continuar?"***
12. Si el participante contesta afirmativamente, continúe cronometrando. Si el participante contesta que no, detenga el cronómetro y vuélvalo a poner a cero.

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Identificación del estudio:_____ Fecha:__/__/____ Iniciales del examinador:_____

1) PUNTUACIÓN TESTS DE EQUILIBRIO:

A. Posición de pie con los pies juntos:

Mantenida durante 10 segundos □ 1 punto
No mantenida durante 10 segundos □ 0 puntos
No intentado □ 0 puntos

Si el resultado es de 0 puntos, de por finalizada la prueba de equilibrio.

En caso de que el participante no intentara la prueba o no la superase, señale con un círculo el motivo:

Lo intentó pero no pudo 1
El participante no pudo mantener la posición sin ayuda 2
No lo intentó, usted se sintió inseguro 3
No lo intentó, el participante se sintió inseguro 4
El participante no entendió las instrucciones 5
Otro (especifíquelo)_____6
El participante se negó 7

Número de segundos que aguantó si no llegó a 10 seg: __,__ seg

B. Posición en pie semi-tándem:

Mantenida durante 10 segundos □ 1 punto
No mantenida durante 10 segundos □ 0 puntos
No intentado □ 0 puntos (marque con un círculo el motivo mencionado anteriormente)

Si el resultado es de 0 puntos termine la prueba de equilibrio

Número de segundos que aguantó si no llegó a 10 seg: __,__seg

C. Posición en pie tándem:

Mantenida durante 10 segundos □ 2 puntos
Mantenida de 3 a 9,99 seg □ 1 punto
Mantenida durante < 3 seg □ 0 puntos
No intentado □ 0 puntos (marque con un círculo el motivo mencionado anteriormente)

Número de segundos que aguantó si no llegó a 10 seg: __,__ seg

D. Puntuación total de la prueba de equilibrio_____ (suma de los puntos)

Comentarios:_____

Puntuación de la batería SPPB. Traducido de la versión original autorizada por el Dr. Jack M. Guralnik para el proyecto de investigación: "Validación de las medidas de movilidad para identificar precozmente discapacidad y predecir hospitalización y otros resultados adversos, en la atención primaria a personas mayores". Proyecto financiado por Fondo de Investigación Sanitaria, investigador principal: Julio Cabrero-García.

Identificación del estudio:_____ Fecha:__/__/____ Iniciales del examinador:_____

2) PUNTUACIÓN EN LA PRUEBA DE MODO Y VELOCIDAD AL ANDAR:

Longitud del recorrido de la prueba de andar: Cuatro metros □ tres metros □

A. Tiempo para la primera Prueba de modo y velocidad al andar (seg)

1. Tiempo para 3 ó 4 metros__ __,__ __seg
2. Si el participante no intentó realizar la prueba o no lo consiguió, señale con un círculo el motivo:

Lo intentó pero no fue capaz	1
El participante no podía caminar sin ayuda	2
No lo intentó porque usted se sentía inseguro	3
No lo intentó porque el participante se sentía inseguro	4
El participante no entendió las instrucciones	5
Otro (especifíquelo) _____	6
El participante se negó	7

Rellene la puntuación y pase a la prueba de "levantarse de una silla".

3. Ayuda para el primer recorrido andando …… □ ninguna □ bastón □ otra

Comentarios:

_____

_____

_____

B. Tiempo para la segunda Prueba de modo y velocidad al andar (seg)

1. Tiempo para 3 ó 4 metros __ __,__ __
2. Si el participante no intentó realizar la prueba o no lo consiguió, señale con un círculo el motivo:

Lo intentó pero no fue capaz	1
El participante no podía caminar sin ayuda	2
No lo intentó porque usted se sentía inseguro	3
No lo intentó porque el participante se sentía inseguro	4
El participante no entendió las instrucciones	5
Otro (especifíquelo) _____	6
El participante se negó	7

3. Ayuda para el segundo recorrido andando …… □ ninguna □ bastón □ otra

¿Qué tiempo ha registrado en el más rápido de los dos recorridos?

Anote el más corto de los dos tiempos __ __,__ __ seg

[Si sólo se ha hecho un recorrido, anote el tiempo] __ __,___ ___ seg

Si el participante no pudo hacer el recorrido: □ **0 puntos**

Puntuación de la batería SPPB. Traducido de la versión original autorizada por el Dr. Jack M. Guralnik para el proyecto de investigación: "Validación de las medidas de movilidad para identificar precozmente discapacidad y predecir hospitalización y otros resultados adversos, en la atención primaria a personas mayores". Proyecto financiado por Fondo de Investigación Sanitaria, investigador principal: Julio Cabrero-García.

Para el recorrido de 4 metros		**Para el recorrido de 3 metros**	
Si el tiempo supera los 8,70 seg:	□ **1 punto**	Si el tiempo supera los 6,52 seg	□ **1 punto**
Si el tiempo está entre 6,21 y 8,70 seg:	□ **2 puntos**	Si el tiempo está entre 4,66 y 6,52 seg	□ **2 puntos**
Si el tiempo está entre 4,82 y 6,20 seg:	□ **3 puntos**	Si el tiempo está entre 3,62 y 4,65 seg	□ **3 puntos**
Si el tiempo es inferior a 4,82	□ **4 puntos**	Si el tiempo es inferior a 3,62 seg	□ **4 puntos**

Puntuación de la batería SPPB. Traducido de la versión original autorizada por el Dr. Jack M. Guralnik para el proyecto de investigación: "Validación de las medidas de movilidad para identificar precozmente discapacidad y predecir hospitalización y otros resultados adversos, en la atención primaria a personas mayores". Proyecto financiado por Fondo de Investigación Sanitaria, investigador principal: Julio Cabrero-García.

Identificación del estudio:_____ Fecha:__/__/____ Iniciales del examinador:_____

3) PUNTUACIÓN TEST DE LA SILLA:

Levantarse de una silla una sola vez

		SÍ	NO	
A.	Se puede levantar seguro sin ayuda	□	□	
B.	Resultados:			
	El participante se levantó sin usar los brazos	□	□	Vaya a la prueba "levantarse de una silla varias veces"
	El participante usó los brazos para levantarse	□	□	De por finalizada la prueba; anote 0 puntos.
	No se completa la prueba	□	□	De por finalizada la prueba; anote 0 puntos.

C. Si el participante no intentó realizar la prueba o no lo consiguió, señale con un círculo el motivo:

Lo intentó pero no fue capaz	1
El participante no podía levantarse sin ayuda	2
No lo intentó porque usted se sentía inseguro	3
No lo intentó porque el participante se sentía inseguro	4
El participante no entendió las instrucciones	5
Otro (especifíquelo) _____	6
El participante se negó	7

Levantarse varias veces seguidas de una silla

		SÍ	NO
A.	Seguro levantándose cinco veces	□	□

B. Si logra levantarse las cinco veces, anote el tiempo en segundos.

Tiempo que ha tardado en levantarse cinco veces _ _,_ _ seg

C. Si el participante no intentó realizar la prueba o no lo consiguió, señale con un círculo el motivo:

Lo intentó pero no fue capaz	1
El participante no podía levantarse sin ayuda	2
No lo intentó porque usted se sentía inseguro	3
No lo intentó porque el participante se sentía inseguro	4
El participante no entendió las instrucciones	5
Otro (especifíquelo) _____	6
El participante se negó	7

Puntuación de la batería SPPB. Traducido de la versión original autorizada por el Dr. Jack M. Guralnik para el proyecto de investigación: "Validación de las medidas de movilidad para identificar precozmente discapacidad y predecir hospitalización y otros resultados adversos, en la atención primaria a personas mayores". Proyecto financiado por Fondo de Investigación Sanitaria, investigador principal: Julio Cabrero-García.

Puntuación de la prueba "levantarse varias veces seguidas de una silla"

El participante no consigue levantarse 5 veces seguidas o lo hace en un tiempo superior a 60 seg	□ 0 puntos
Si tarda 16,70 seg o más	□ 1 punto
Si tarda entre 13,70 y 16,69 seg	□ 2 puntos
Si tarda entre 11,20 y 13,69 seg	□ 3 puntos
Si tarda 11,19 o menos	□ 4 puntos

Puntuación de la batería SPPB. Traducido de la versión original autorizada por el Dr. Jack M. Guralnik para el proyecto de investigación: "Validación de las medidas de movilidad para identificar precozmente discapacidad y predecir hospitalización y otros resultados adversos, en la atención primaria a personas mayores". Proyecto financiado por Fondo de Investigación Sanitaria, investigador principal: Julio Cabrero-García.

Identificación del estudio_____ Fecha_____ Iniciales del examinador_____

Puntuación total de las pruebas de resistencia y deterioro físico

Puntuación de las pruebas

Puntuación de la prueba de equilibrio _____**puntos**

Puntuación de la prueba de modo y velocidad al andar _____**puntos**

Puntuación de la prueba "levantarse de la silla" _____**puntos**

Puntuación total _____ **puntos (suma de los puntos indicados arriba)**

Puntuación de la batería SPPB. Traducido de la versión original autorizada por el Dr. Jack M. Guralnik para el proyecto de investigación: "Validación de las medidas de movilidad para identificar precozmente discapacidad y predecir hospitalización y otros resultados adversos, en la atención primaria a personas mayores". Proyecto financiado por Fondo de Investigación Sanitaria, investigador principal: Julio Cabrero-García.

9.6.3 EuroQol 5D-5L

Cuestionario de Salud

Versión en español para España

(Spanish version for Spain)

Debajo de cada enunciado, marque UNA casilla, la que mejor describe su salud HOY.

MOVILIDAD

No tengo problemas para caminar ❑
Tengo problemas leves para caminar ❑
Tengo problemas moderados para caminar ❑
Tengo problemas graves para caminar ❑
No puedo caminar ❑

AUTO-CUIDADO

No tengo problemas para lavarme o vestirme ❑
Tengo problemas leves para lavarme o vestirme ❑
Tengo problemas moderados para lavarme o vestirme ❑
Tengo problemas graves para lavarme o vestirme ❑
No puedo lavarme o vestirme ❑

ACTIVIDADES COTIDIANAS *(Ej.: trabajar, estudiar, hacer las tareas domésticas, actividades familiares o actividades durante el tiempo libre)*

No tengo problemas para realizar mis actividades cotidianas ❑
Tengo problemas leves para realizar mis actividades cotidianas ❑
Tengo problemas moderados para realizar mis actividades cotidianas ❑
Tengo problemas graves para realizar mis actividades cotidianas ❑
No puedo realizar mis actividades cotidianas ❑

DOLOR / MALESTAR

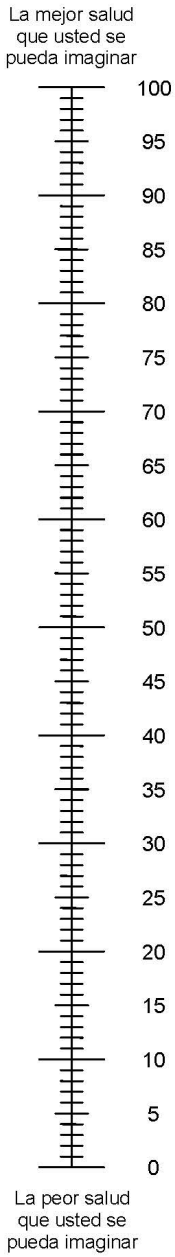
No tengo dolor ni malestar ❑
Tengo dolor o malestar leve ❑
Tengo dolor o malestar moderado ❑
Tengo dolor o malestar fuerte ❑
Tengo dolor o malestar extremo ❑

ANSIEDAD / DEPRESIÓN

No estoy ansioso ni deprimido ❑
Estoy levemente ansioso o deprimido ❑
Estoy moderadamente ansioso o deprimido ❑
Estoy muy ansioso o deprimido ❑
Estoy extremadamente ansioso o deprimido ❑

- Nos gustaría conocer lo buena o mala que es su salud HOY.
- La escala está numerada del 0 al 100.
- 100 representa la mejor salud que usted se pueda imaginar. 0 representa la peor salud que usted se pueda imaginar.
- Marque con una X en la escala para indicar cuál es su estado de salud HOY.
- Ahora, en la casilla que encontrará a continuación escriba el número que ha marcado en la escala.

SU SALUD HOY = ☐



9.6.4 Software Usability Scale

ESCALA DE USABILIDAD PARA SOFTWARE

Basado en la escala de evaluación de software SUS - System Usability Scale
- Digital Equipment Corporation 1986 -

Fecha:	
Código:	
Género:	Femenino ◯ ◯ Masculino
Edad:	

1. Me gustaría utilizar este sistema con asiduidad

Me gustaría volver a probar estos ejercicio, o incluso utilizarlos de manera habitual durante el día a día.

	1	2	3	4	5	
Completamente en desacuerdo	◯	◯	◯	◯	◯	Completamente deacuerdo

2. Me parece que este sistema es más complejo de lo que debería

Me ha parecido complicado entender cómo funcionan los ejercicios.

	1	2	3	4	5	
Totally Disagree	◯	◯	◯	◯	◯	Totally Agree

3. Me ha parecido que el sistema es fácil de utilizar

Me ha parecido sencillo utilizar los ejercicios, y enseguida he entendido qué es lo que había que hacer.

	1	2	3	4	5	
Completamente en desacuerdo	◯	◯	◯	◯	◯	Completamente deacuerdo

4. Me parece que necesito ayuda para utilizarlo

No soy capaz de utilizar el sistema solo, y necesitaría a alguien de guía al lado para utilizarlo

	1	2	3	4	5	
Completamente en desacuerdo	○	○	○	○	○	Completamente deacuerdo

---

5. Me parece que el sistema está bien integrado

Me parece que todas las opciones estan bien colocadas y enseguida encuentro lo que quiero hacer dentro de los ejercicios.

	1	2	3	4	5	
Completamente en desacuerdo	○	○	○	○	○	Completamente deacuerdo

---

6. Me parece que hay muchas incongruencias en el sistema

No entiendo para nada los ejercicios ni cómo hay que utilizar el programa en el ordenador.

	1	2	3	4	5	
Completamente en desacuerdo	○	○	○	○	○	Completamente deacuerdo

---

7. Me parece que la mayoría de la gente puede aprender a utilizar este sistema rápidamente

Yo creo que cualquiera puede utilizar estos ejercicios y aprender a utilizar el programa fácilmente

	1	2	3	4	5	
Completamente en desacuerdo	○	○	○	○	○	Completamente deacuerdo

---

8. Este sistema me parece incómodo de utilizar

	1	2	3	4	5	
Completamente en desacuerdo	○	○	○	○	○	Completamente deacuerdo

---

9. Me encuentro cómodo utilizando el sistema

Me encuentro cómodo y lo uso con seguridad y sabiendo para qué sirve cada cosa

	1	2	3	4	5	
Completamente en desacuerdo	○	○	○	○	○	Completamente deacuerdo

10. Me da la sensación de que necesito aprender a utilizar el sistema antes de utilizarlo

Sin conocimiento previo o un cursillo, no sería capaz de utilizar estos ejercicios yo solo

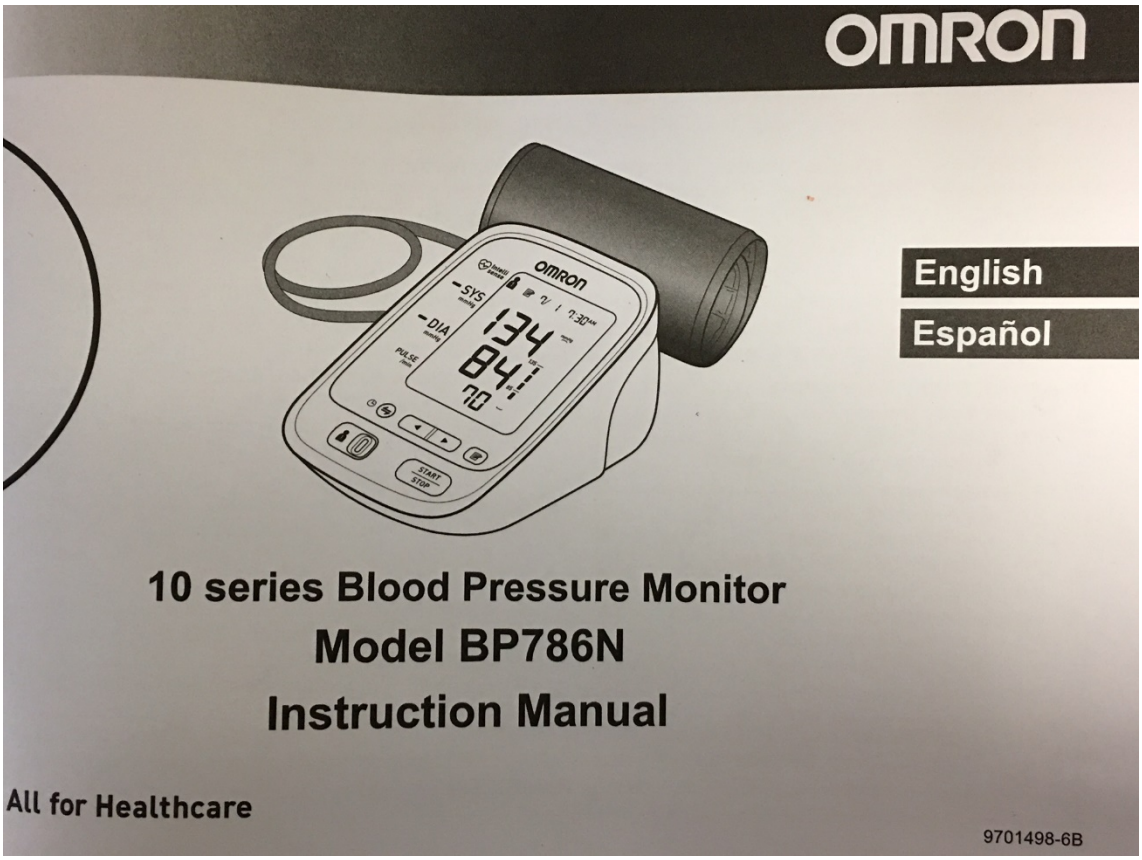
	1	2	3	4	5	
Completamente en desacuerdo	○	○	○	○	○	Completamente deacuerdo

9.6.5 Borg Scale

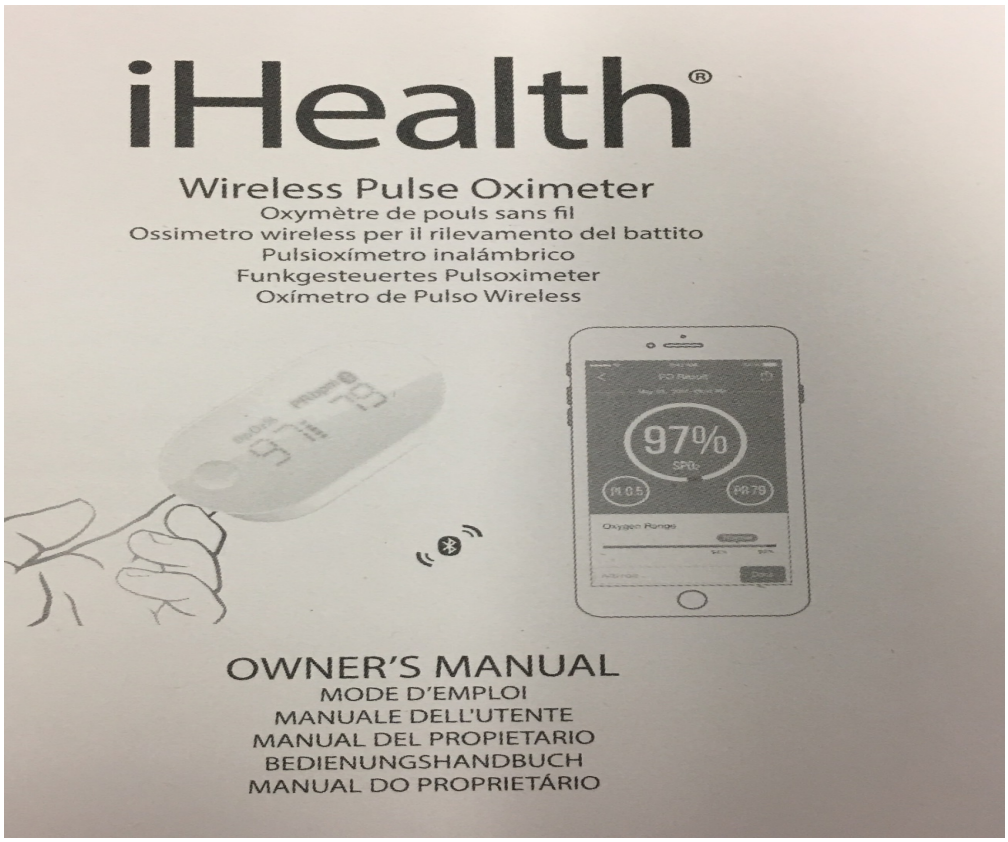
ESCALA DE BORG MODIFICADA	
0	NADA
1	MUY LEVE
2	LEVE
3	MODERADA
4	ALGO DURO
5	DURO
6	
7	MUY DURO
8	
9	
10	MUY, MUY DURO

9.7 APPENDIX: Devices used to take physiological constants for biofeedback

9.7.1 Blood pressure and heart rate measuring device



9.7.2 Blood Oxygen Saturation Level measuring device



9.8 APPENDIX: Human Subjects and HIPAA .COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)- Ethical Committee (University of Louisville), KY (USA)

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name: IRANZU MUGUETA (ID: 6194582)
- Institution Affiliation: University of Louisville (ID: 410)
- Institution Email: imugu01@louisville.edu
- Institution Unit: Computer& Science
- Phone: 8528964

- Curriculum Group: Human Research
- Course Learner Group: Human Subjects and HIPAA Research
- Stage: Stage 1 - Basic Course
- Description: Investigators with VA appointments conducting research at the Louisville VAMC should contact the Louisville VAMC regarding any additional training requirements.

- Record ID: 22438644
- Completion Date: 24-Feb-2017
- Expiration Date: 23-Feb-2021
- Minimum Passing: 85
- Reported Score*: 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	24-Feb-2017	3/3 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	24-Feb-2017	5/5 (100%)
Informed Consent (ID: 3)	24-Feb-2017	5/5 (100%)
History and Ethics of Human Subjects Research (ID: 490)	24-Feb-2017	7/7 (100%)
Assessing Risk - SBE (ID: 503)	24-Feb-2017	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	24-Feb-2017	5/5 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	24-Feb-2017	3/3 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	24-Feb-2017	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	24-Feb-2017	5/5 (100%)
Cultural Competence in Research (ID: 15166)	24-Feb-2017	5/5 (100%)
HIPAA in the Research Setting - Basic (ID: 16762)	24-Feb-2017	9/9 (100%)
Basics of Information Security, Part 1 (ID: 1423)	24-Feb-2017	5/5 (100%)
Basics of Information Security, Part 2 (ID: 1424)	24-Feb-2017	5/5 (100%)
University of Louisville (ID: 704)	24-Feb-2017	No Quiz
Research with Older Adults (ID: 16502)	24-Feb-2017	5/5 (100%)
Research Involving Subjects at the End-of-Life (ID: 16658)	24-Feb-2017	5/5 (100%)
External IRB Review (ID: 16711)	24-Feb-2017	5/5 (100%)
Hot Topics (ID: 487)	24-Feb-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kd0651443-ae33-4687-b90c-df5702b4a009-22438644

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
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Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- Name: IRANZU MUGUETA (ID: 6194582)
- Institution Affiliation: University of Louisville (ID: 410)
- Institution Email: imugu01@louisville.edu
- Institution Unit: Computer& Science
- Phone: 8528964

- Curriculum Group: Human Research
- Course Learner Group: Human Subjects and HIPAA Research
- Stage: Stage 1 - Basic Course
- Description: Investigators with VA appointments conducting research at the Louisville VAMC should contact the Louisville VAMC regarding any additional training requirements.

- Record ID: 22438644
- Report Date: 24-Feb-2017
- Current Score**: 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 490)	24-Feb-2017	7/7 (100%)
HIPAA in the Research Setting - Basic (ID: 16762)	24-Feb-2017	9/9 (100%)
Informed Consent (ID: 3)	24-Feb-2017	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	24-Feb-2017	3/3 (100%)
Assessing Risk - SBE (ID: 503)	24-Feb-2017	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	24-Feb-2017	5/5 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	24-Feb-2017	3/3 (100%)
Basics of Information Security, Part 1 (ID: 1423)	24-Feb-2017	5/5 (100%)
Basics of Information Security, Part 2 (ID: 1424)	24-Feb-2017	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	24-Feb-2017	4/4 (100%)
Hot Topics (ID: 487)	24-Feb-2017	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	24-Feb-2017	5/5 (100%)
University of Louisville (ID: 704)	24-Feb-2017	No Quiz
Cultural Competence in Research (ID: 15166)	24-Feb-2017	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	24-Feb-2017	5/5 (100%)
Research with Older Adults (ID: 16502)	24-Feb-2017	5/5 (100%)
Research Involving Subjects at the End-of-Life (ID: 16658)	24-Feb-2017	5/5 (100%)
External IRB Review (ID: 16711)	24-Feb-2017	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kd0651443-ae33-4487-b90c-d75702b4a009-22438644

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name: IRANZU MUGUETA (ID: 6194582)
- Institution Affiliation: University of Louisville (ID: 410)
- Institution Email: imugu01@louisville.edu
- Institution Unit: Computer& Science
- Phone: 8528964

- Curriculum Group: U of L General Population
- Course Learner Group: Institutional Compliance - U of L General Population
- Stage: Stage 1 - Basic Course

- Record ID: 22438643
- Completion Date: 24-Feb-2017
- Expiration Date: 23-Feb-2021
- Minimum Passing: 80
- Reported Score*: 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Institutional Compliance Awareness (ID: 16760)	24-Feb-2017	1/1 (100%)
Basics of Information Security, Part 1 (ID: 1423)	24-Feb-2017	5/5 (100%)
Basics of Information Security, Part 2 (ID: 1424)	24-Feb-2017	5/5 (100%)
Conflict of Interest Institution-Specific Policies (ID: 15104)	24-Feb-2017	3/3 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kc32a2192-0e59-4293-8926-aa51650b5bca-22438643

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- Name: IRANZU MUGUETA (ID: 6194582)
- Institution Affiliation: University of Louisville (ID: 410)
- Institution Email: imugu01@louisville.edu
- Institution Unit: Computer& Science
- Phone: 8528964

- Curriculum Group: U of L General Population
- Course Learner Group: Institutional Compliance - U of L General Population
- Stage: Stage 1 - Basic Course

- Record ID: 22438643
- Report Date: 24-Feb-2017
- Current Score**: 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Conflict of Interest Institution-Specific Policies (ID: 15106)	24-Feb-2017	3/3 (100%)
Institutional Compliance Awareness (ID: 16760)	24-Feb-2017	1/1 (100%)
Basics of Information Security, Part 1 (ID: 1423)	24-Feb-2017	5/5 (100%)
Basics of Information Security, Part 2 (ID: 1424)	24-Feb-2017	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?ko32a2192-0e59-4293-8928-aa5165065bca-22438643

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
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Web: https://www.citiprogram.org

9.9 APPENDIX: Ethical Committee approval from the University of Louisville, KY (USA)

UNIVERSITY OF LOUISVILLE

Human Subjects Protection Program Office
MedCenter One – Suite 200
501 E. Broadway
Louisville, KY 40202-1798
Office: 502.852.5188 Fax: 502.852.2164

DATE:	March 08, 2017
TO:	Adel S Elmaghraby, Ph.D.
FROM:	The University of Louisville Institutional Review Board
IRB NUMBER:	17.0136
STUDY TITLE:	Designing Exercise Games (ExerGames) with Biofeedback
REFERENCE #:	636739
IRB STAFF CONTACT:	Jacqueline S. Powell, CIP Senior IRB Analyst Jspowe01@Louisville.edu 852-4101

This study was reviewed on 03/08/2017 by the Chair of the Institutional Review Board and approved through the Expedited Review Procedure, according to 45 CFR 46.110(b), since this study falls under Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

The following items have been approved:

Submission Components			
IRB Study Application		Approved as Submitted	
Study Document			
Title	Version #	Version Date	Outcome
Advertisement	Version 3.0	03/01/2017	Approved
Ethics committee approval	Version 1.0	02/06/2017	Reviewed
Consent	Version 2.1	03/02/2017	Approved
Protocol	Version 2.0	03/02/2017	Approved

This study now has final IRB approval from 03/08/2017 through 03/07/2018.

For guidance on using iRIS, including finding your approved stamped documents, please follow the instructions at https://louisville.edu/research/humansubjects/iRISSubmissionManual.pdf

Site Approval
If this study will take place at an affiliated research institution, such as KentuckyOne Health, Norton Healthcare or University of Louisville Hospital, permission to use the site of the affiliated institution is necessary before the research may begin. If this study will take place outside of the University of Louisville Campuses, permission from the organization must be obtained before the research may begin (e.g. Jefferson County Public Schools). Failure to obtain this permission may result in a delay in the start of your research.

Privacy & Encryption Statement

The University of Louisville's Privacy and Encryption Policy requires such information as identifiable medical and health records: credit card, bank account and other personal financial information; social security numbers; proprietary research data; dates of birth (when combined with name, address and/or phone numbers) to be encrypted. For additional information: http://security.louisville.edu/PolStds/ISO/PS018.htm.

Implementation of Changes to Previously Approved Research
Prior to the implementation of any changes in the approved research, the investigator will submit any modifications to the IRB and await approval before implementing the changes, unless the change is being made to ensure the safety and welfare of the subjects enrolled in the research. If such occurs, a Protocol Deviation/Violation should be submitted within five days of the occurrence indicating what safety measures were taken, along with an amendment to revise the protocol.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs)
In general, these may include any incident, experience, or outcome, which has been associated with an unexpected event(s), related or possibly related to participation in the research, and suggests that the research places subjects or others at a greater risk of harm than was previously known or suspected. UPIRTSOs may or may not require suspension of the research. Each incident is evaluated on a case by case basis to make this determination. The IRB may require remedial action or education as deemed necessary for the investigator or any other key personnel. The investigator is responsible for reporting UPIRTSOs to the IRB within 5 working days. Use the UPIRTSO form located within the iRIS system to report any UPIRTSOs.

Continuation Review Requirements
You are responsible for submitting a continuation review 30 days prior to the expiration date of your research study. Investigators who allow their study approval to expire have committed significant non-compliance with federal regulations. Such lapses may require reporting to federal agencies, a program audit by compliance auditors to ensure that subjects were not enrolled during the expired period, and may lead to findings of serious and continuing non-compliance if expiration were to occur a second time.

1099 Information (If Applicable)
As a reminder, in compliance with University policies and Internal Revenue Service code, all payments (including checks, pre-paid cards, and gift certificates) to research subjects must be reported to the University Controller's Office. Petty Cash payments must also be monitored by the issuing department and reported to the Controller's Office. Before issuing compensation, each research subject must complete a W-9 form. For additional information, please contact the Controller's Office at 852-8237 or controll@louisville.edu

The committee will be advised of this action at a regularly scheduled meeting.

If you have any questions, please contact the IRB analyst listed above or the Human Subjects Protection Program office at hsppofc@louisville.edu.

Peter M. Quesada

Peter M. Quesada, Ph.D., Chair

Social/Behavioral/Educational Institutional Review Board

PMQ/jsp

Full Accreditation since June 2005 by the Association for the Accreditation of Human Research Protection Programs, Inc.

9.10 APPENDIX: Information sheet, informed consent and advertisement for the study in Louisville,KY (USA)

UofL Institutional Review Boards
IRB NUMBER: 17.0136
IRB APPROVAL DATE: 03/08/2017
IRB EXPIRATION DATE: 03/07/2018

Subject Informed Consent Document

DESIGNING EXERCISE GAMES (ExerGames) WITH BIOFEEDBACK

Investigator(s) name & address: PI. Dr. Adel Elmaghraby, Iranzu Mugueta (Exchange Researcher), and Dra. Begonya Garcia-Zapirain (Visiting Professor), Department of Computer Engineering and Computer Science, Duthie Center Room #237, Innovative and Emerging Technology Lab, Speed School of Engineering, 132 Eastern Pkwy, Louisville, KY 40292

Site where study is to be conducted: Duthie Center Room #237, Innovative and Emerging Technology Lab, Speed School of Engineering, 132 Eastern Pkwy, Louisville, KY 40292

Phone number for subjects to call for questions: 502-852-8964

Introduction and Background Information

You are invited to participate in a research study. The study is being conducted by Dr. Adel Elmaghraby, Iranzu Mugueta and Dra. Begonya Garcia-Zapirain. The study is sponsored by the University of Louisville, Department of Computer Engineering and Computer Science. The study will take place at Innovative and Emerging Technologies Laboratory. Approximately 10 subjects will be invited to participate.

Purpose

The purpose of this study is to improve the physical condition though the game and so, decreasing the risk of frailty. At the same time, collect data with sensors before, after and 5 minutes after finish the exercise to verify that the exercise is safe and cardiovascular.

Procedures

The first procedures will be administering the Short Physical Performance Battery (SPPB) because with this battery we can identify the frail subjects. This is, we do the screening of frailty. If you get <10 points in SPPB, it means that you are frail and will participate in the study or control group.
After that, in the first and in the final session, you will fill two questionnaires (Barthel Index and EQ-5D™questionnaire).
You will realize 3 session on week with the ExerGame (FRED), of 20min each, for 6 weeks.
In each session, blood pressure, oxygen saturation and heart rate will be taken, before, after and 5 min after finish the exercise. The researcher will be attend each session.
The ExerGame FRED involve lower limb exertion, upper limb exertion and body exertion. There is not any devices because the kinect sensor recognize the movement of the body.
The level of the exertion is moderate. For this reason, It will be taken the vital signs before, after and 5 minutes after finish. Subjects should not exceed their previously calculated maximum heart rate. For this reason, the exercise is designed not to exceed a moderate intensity ie 76% of the maximum heart rate
At all times, in case the subject feels bad the subject will leave the activity and will be assisted to him.

UofL Institutional Review Boards
IRB NUMBER: 17.0136
IRB APPROVAL DATE: 03/08/2017
IRB EXPIRATION DATE: 03/07/2018

Potential Risks

There are not potential physical risks associated with elderly persons performing this kind of physical activity because they are exercises designed for elderly people. However, we want to be very careful, so for this reason the researcher will be present in the room and the vital signs will be taken at the beginning of exercise will indicate that the subject is ready to start with. It will be taken again before exercise and 5 minutes after finish. In Spain no subject left the exercise at any time.
Therefore, we do not foresee any physical, psychological, social or legal risks associated with this experimental procedure.

Benefits

The possible benefits of this study include the choice to improve the physical condition of the people. The information collected may not benefit you directly. The information learned in this study may be helpful to others.

Compensation

You will not be compensated for your time, inconvenience, or expenses while you are in this study.

Confidentiality

Total privacy cannot be guaranteed. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. While unlikely, the following may look at the study records:

The University of Louisville Institutional Review Board, Human Subjects Protection Program Office, Office for Human Research Protections (OHRP).

Conflict of Interest

This study involves no conflict of interest because neither the institution nor the investigator will be compensated for your participation in it.

Security

Your information will be kept private by following methods:

An automatically generated ID number will be used to identify subjects. The only subject identifying information will be the consent forms, which will be locked into file cabinets and computer encrypted files in University of Louisville Innovative and Emerging Technologies Laboratory. Principal investigators (PI) have combinations and passwords. Publications or presentations of the findings of this study will not include any names or other identifying information of subjects.

Voluntary Participation

Taking part in this study is voluntary. You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. If you decide not to be in this study or if you stop taking part at any time, you will not lose any benefits for which you may qualify.

UofL Institutional Review Boards
IRB NUMBER: 17.0136
IRB APPROVAL DATE: 03/08/2017
IRB EXPIRATION DATE: 03/07/2018

You will be told about any changes that may affect your decision to continue in the study.

Contact Persons, Research Subject's Rights, Questions, Concerns, and Complaints

If you have any concerns or complaints about the study or the study staff, you have three options.

a. You may contact the principal investigator at 502-852-8964.

b. If you have any questions about your rights as a study subject, questions, concerns or complaints, you may call the Human Subjects Protection Program Office (HSPPO) (502) 852-5188. You may discuss any questions about your rights as a subject, in secret, with a member of the Institutional Review Board (IRB) or the HSPPO staff. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

c. If you want to speak to a person outside the University, you may call 1-877-852-1167. You will be given the chance to talk about any questions, concerns or complaints in secret. This is a 24 hour hot line answered by people who do not work at the University of Louisville.

Acknowledgment and Signatures

This informed consent document is not a contract. This document tells you what will happen during the study if you choose to take part. Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in the study. You are not giving up any legal rights to which you are entitled by signing this informed consent document. You will be given a copy of this consent form to keep for your records.

Subject Name (Please Print)	Signature of Subject	Date Signed
Printed Name of Legal Representative (if applicable)	Signature of Legal Representative	Date Signed
Relationship of Legal Representative to Subject		
Printed Name of Person Explaining Consent Form	Signature of Person Explaining Consent Form (if other than the Investigator)	Date Signed
Printed Name of Investigator	Signature of Investigator	Date Signed

List of Investigators:	Phone Numbers:
Dr. Adel Elmaghraby	(502)852-0470
Iranzu Mugueta	(502)852-8964
Dra. Begonya Garcia-Zapirain	(502)852-0476

UofL Institutional Review Boards
IRB NUMBER: 17.0136
IRB APPROVAL DATE: 03/08/2017

Advertisement to be used to recruit subject volunteers for the research study:

VOLUNTEERS WITH INTEREST OF EXERCISE GAMES (ExerGames) ARE INVITED FOR RESEARCH STUDY

We are seeking volunteers who are interested in using computer games for health. The game is an exercise game (ExerGame) based on Kinect and encourages users to exercise through an interactive dialog. The ExerGame is called FRED and was developed and tested in Spain. The current experiment is conducted at the University of Louisville Computer Science & Computer Engineering Department. Male and female volunteers of age 65 and above who are interested in experiencing ExerGame are needed for this research experience.

Each volunteer will be invited for 18 visits (three sessions of 20 minutes per week for 6 weeks). The purpose of this research is to improve the physical condition through the game and by doing so, decreasing the risk of frailty. At the same time, basic data (blood pressure, heart rate and oxygen level) will be collected before and after the exercise.

For further information contact Dr. Adel Elmaghraby, phone: (502) 852-0470, University of Louisville Speed School of Engineering, Duthie Center Room #237, Innovative and Emerging Technology Lab, 132 Eastern Pkwy, Louisville, KY 40292

E-mail: adel@louisville.edu
iranzumugueta@gmail.com
maria.garcia-zapirain@louisville.edu

9.11 APPENDIX: Research Disclosure in USA

Send completed form to:
University of Louisville
Office of Technology Transfer
300 East Market Street, Suite 300
Louisville, KY 40202

File No.

UNIVERSITY OF LOUISVILLE
Research Disclosure Form

Please provide a title for your research and a brief description. Research includes new innovations, processes, products, apparatus, compositions of matter, living organisms—OR improvements to (or new uses for) things that already exist. Use additional sheets and attach descriptive materials to expand answers to questions. (Sketches, drawings, photos, reports and manuscripts will be helpful.)

1. Title of Research:

FRED: Exergame to prevent dependence and functional deterioration associated with aging. Using technology with biofeedback for the improvement of frailty

1a. Suggested "Keywords" (3-10 total): frailty, elderly people, exergame, physical activity, kinect, xbox, biofeedback

2. Description of Research (please use an extra page if necessary and include the best way you presently know of practicing the research):

The goal of this research is to develop a commercial, low cost tool (FRED) for the improvement of frailty. The proposed game is FRED which has been developed using a 3D unity motor, and needs a Kinect game controller connected to a computer and a screen or TV.
The game FRED consists of various scenarios. Each scenario represents one or more steps in a simplified process to produce txakoli. The user starts to carry out the different activities which, as well as being remote controlled and in order, correspond to a specific movement of the upper and/or lower extremity. Apart from the physical activity, the game requires attention, coordination of movement, balance, accuracy and spatial orientation.
These scenarios are developed in a logical order to ensure that the individuals who perform them find a meaning to the activity. Each movement is designed by taking into account both biomechanical and neuromotor parameters and evidence features of sufficient extent to be recognized by the Kinect sensor.

1

9.12 APPENDIX: Scientific Contributions

9.12.1 Iranzu Mugueta-Aguinaga, Begonya Garcia-Zapirain. Is Technology Present in Frailty? Technology a Back-up Tool for Dealing with Frailty in the Elderly: A Systematic Review. A&D, 2017, 8(2): 176-195. URL:http://www.aginganddisease.org/EN/10.14336/AD.2016.0901

Aging and Disease
www.aginganddisease.org
Volume 8, Number 2; 176-195, April 2017
http://dx.doi.org/10.14336/AD.2016.0901

Review

Is Technology Present in Frailty? Technology a Back-up Tool for Dealing with Frailty in the Elderly: A Systematic Review

Iranzu Mugueta-Aguinaga[1], Begonya Garcia-Zapirain[2,3]

[1]Rehabilitation Service, Cruces Universitary Hospital, Plaza Cruces s/n, 48903, Barakaldo, Spain.
[2]DeustoTech – Deusto Foundation, Avda Universidades, 24, 48007, Bilbao, Spain
[3]Engineering Faculty, University of Deusto, Avda. Universidades, 24, 48007, Bilbao, Spain

[Received July 19, 2016; Revised August 31, 2016; Accepted September 1, 2016]

ABSTRACT: This study analyzes the technologies used in dealing with frailty within the following areas: prevention, care, diagnosis and treatment. The aim of this paper is, on the one hand, to analyze the extent to which technology is present in terms of its relationship with frailty and what technological resources are used to treat it. Its other purpose is to define new challenges and contributions made by physiotherapy using technology. Eighty documents related to research, validation and/or the ascertaining of different types of hardware, software or both were reviewed in prominent areas. The authors used the following scales: in the area of diagnosis, Fried's phenotype model of frailty and a model based on trials for the design of devices. The technologies developed that are based on these models accounted for 55% and 45% of cases respectively. In the area of prevention, the results proved similar regarding the use of wireless sensors with cameras (35.71%), and Kinect™ sensors (28.57%) to analyze movements and postures that indicate a risk of falling. In the area of care, results were found referring to the use of different motion, physiological and environmental wireless sensors (46,15%), i.e. so-called smart homes. In the area of treatment, the results show with a percentage of 37.5% that the Nintendo® Wii™ console is the most used tool for treating frailty in elderly persons. Further work needs to be carried out to reduce the gap existing between technology, frail elderly persons, healthcare professionals and carers to bring together the different views about technology. This need raises the challenge of developing and implementing technology in physiotherapy via serious games that may via play and connectivity help to improve the functional capacity, general health and quality of life of frail individuals.

Key words: Frailty, kinect, exergaming, serious games, robots, virtual reality

According to the World Health Organization (WHO), it is estimated that there are more than 605 million people over 60 years of age in the world. The proportion of elderly persons will go on increasing over the coming decades – by the year 2025 it is estimated that there will be 1,200 million elderly persons throughout the world and two out of every three will be living in developing counties [1].

Spain is currently one of the countries in the world with the highest life expectancy after Japan, but when one speaks of life expectancy in terms of good health, the situation worsens in relation to other countries such as France, Sweden, Australia and Japan. For this reason, it is important to highlight the fact that living longer is not always a synonym for good quality of life and health [2].

***Correspondence should be addressed to:** Iranzu Mugueta-Aguinaga. Rehabilitation Service, Cruces Universitary Hospital, Barakaldo, Spain. E-mail: iranzu.muguetaaguinaga@osakidetza.eus

ISSN: 2152-5250

9.12.2 Iranzu Mugueta-Aguinaga, Begonya Garcia-Zapirain. FRED: Exergame to prevent dependence and functional deterioration associated with aging. A pilot three-week randomized controlled clinical trial (Phase 1). State: Submitted

Aging and Disease

FRED: Exergame to prevent dependence and functional deterioration associated with aging. A pilot three-week randomized controlled clinical trial (Phase 1)

Journal:	*Aging and Disease*
Manuscript ID	Draft
Manuscript Type:	Original Article
Date Submitted by the Author:	n/a
Complete List of Authors:	MUGUETA-AGUINAGA, IRANZU; Hospital Universitario Cruces, REHABILITATION Garciz-Zapirain, Begonya; Universidad de Deusto, Engineering Faculty
Keywords:	frailty, elderly people, exergame, physical activity, kinect, xbox one

9.12.3 Iranzu Mugueta-Aguinaga, Begonya Garcia-Zapirain. Frailty level monitoring and analysis after a pilot six-week randomized controlled clinical trial (phase 2) using FRED exergame including biofeeback supervision. State: Submitted

Frailty level monitoring and analysis after a pilot six-week randomized controlled clinical trial (phase 2) using FRED exergame including biofeeback supervision.

Iranzu Mugueta[1*], **Begoña García-Zapirain**[2]

[1]Rehabilitation Service, Cruces Universitary Hospital, Spain, [2]DeustoTech - Deusto Foundation, University of Deusto, Spain

Submitted to Journal:
Frontiers in Aging Neuroscience

Article type:
Clinical Trial Article

Manuscript ID:
265478

Received on:
07 Mar 2017

Frontiers website link:
www.frontiersin.org

9.13 APPENDIX: Copyright registry office of the Basque Government

EUSKO JAURLARITZA
HEZKUNTZA, HIZKUNTZA POLITIKA ETA KULTURA SAILA
Euskal Autonomia Erkidegoko Jabetza Intelektualaren Bizkaiko Lurralde Erregistroa

GOBIERNO VASCO
DEPARTAMENTO DE EDUCACIÓN, POLÍTICA LINGÜÍSTICA Y CULTURA
Oficina Delegada de Bizkaia del Registro Territorial de la Propiedad Intelectual de Euskadi

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Quintana, 6 - 6º D
48007 BILBAO

Jarraian adierazitako lanaren gaineko eskubideak Jabetza Intelektualaren Erregistroan inskribatzeko egin duzun eskabideari erantzunez, jakinarazi nahi dizut eskabidearen aldeko ebazpena eman dela eta, beraz, eskubide horiek Jabetza Intelektualaren Erregistro Orokorrean inskribatuta geratu direla.

Mikel Carrillo de la Peña, Jabetza Intelektualaren erregistratzailearen aldeko ebazpenaren aurka, Jabetza Intelektualaren Legearen 145.2 artikuluak xedatutakoaren araberako ekintzak bidera daitezke jurisdikzio zibilean (apirilaren 12ko 1/1996 Legegintzako Errege Dekretuak onartu zuen lege hori).

Erantsita doakizu inskripzioaren kopia.

En relación a su solicitud de inscripción en el Registro de la Propiedad Intelectual de los derechos de la obra que a continuación se indica, le notifico que la misma se ha resuelto favorablemente y que dichos derechos han quedado inscritos en el Registro General de la Propiedad Intelectual.

Contra la Resolución favorable de Mikel Carrillo de la Peña, Registrador de la Propiedad Intelectual, se podrán ejercitar ante la jurisdicción civil las acciones procedentes, de conformidad con lo establecido en el artículo 145.2 de la Ley de Propiedad Intelectual, aprobado por Real Decreto Legislativo 1/1996, de 12 de abril.

Le adjunto copia de la inscripción correspondiente.

Lana/Obra: FRED
Eskariaren zenbakia / Nº de solicitud: BI-720-16

Adeitazunez,
Bilbao,

Atentamente,
Bilbao,

Euskal Autonomia Erkidegoko Jabetza Intelektualaren Bizkaiko Lurralde Erregistroa
Oficina Delegada de Bizkaia del Registro Territorial de la Propiedad Intelectual de Euskadi

Kale Nagusia, 85 – 48011 BILBAO
Tef. 94 403 16 50 / 52 / 53 – Fax 94 403 16 51 – posta-e: kultura.bizkaia@euskadi.eus

REGISTRO TERRITORIAL
DE LA PROPIEDAD INTELECTUAL

EUSKO JAURLARITZA
GOBIERNO VASCO

GOBIERNO DE ESPAÑA · MINISTERIO DE EDUCACIÓN, CULTURA Y DEPORTE

REGISTRO GENERAL DE LA PROPIEDAD INTELECTUAL

Según lo dispuesto en la Ley de Propiedad Intelectual (Real Decreto Legislativo 1/1996, de 12 de abril), quedan inscritos en este Registro los derechos de propiedad intelectual en la forma que se determina seguidamente:

NÚMERO DE ASIENTO REGISTRAL 01 / 2017 / 282

Título: Fred

Objeto de propiedad intelectual: Programa de ordenador

Clase de obra: Programa de ordenador

PRIMERA INSCRIPCIÓN

Autor/es y titular/es originarios de derechos

- **Apellidos y nombre**: GARCIA-ZAPIRAIN SOTO, María Begoña
  Nacionalidad: España **D.N.I./N.I.F./Pasaporte**: 15253540D
- **Apellidos y nombre**: SAENZ DE URTURI BRETÓN, Zelai
  Nacionalidad: España **D.N.I./N.I.F./Pasaporte**: 72750938Y
- **Apellidos y nombre**: MUGUETA AGUINAGA, Iranzu
  Nacionalidad: España **D.N.I./N.I.F./Pasaporte**: 30646373T
- **Apellidos y nombre**: VAZQUEZ AGUADO, Jesús
  Nacionalidad: España **D.N.I./N.I.F./Pasaporte**: 14584320C

Datos de la solicitud

Núm. solicitud: BI-720-16

Fecha de presentación y efectos: 15/11/2016 Hora: 08:45

En Vitoria-Gasteiz, seis de febrero de dos mil diecisiete
El/La titular del Registro

Firmado: Mikel Carrillo de la Peña

01/2017/282

9.14 APPENDIX: Oral Communication in: XVI Congress of Zahartzaroa and IX Congress of the Navarre Society of Geriatric and Gerontology. Vitoria-Gasteiz, May 4-6, 2017.

VIVIENDO hasta el final

Zahartzaroa

ZAHARTARROAREN XVI. BATZARRA & NGGA-REN IX. BATZARRA

Vitoria-Gasteiz, 2017ko maiatzaren 4, 5 eta 6a

XVI CONGRESO DE ZAHARTZAROA Y IX CONGRESO DE LA SNGG

Vitoria-Gasteiz 4, 5 y 6 de mayo de 2017

GERIATRIA ETA GERONTOLOGIA EUSKAL ELKARGOA ZAHARTZAROA ETA NAFARROAKO GERIATRIA ETA GERONTOLOGIA ELKARTEA

LA ASOCIACIÓN VASCA DE GERIATRÍA Y GERONTOLOGÍA ZAHARTZAROA Y LA SOCIEDAD NAVARRA DE GERIATRÍA Y GERONTOLOGÍA

ZIURTATZEN DUTE:

CERTIFICAN QUE:

JESÚS VÁZQUEZ AGUADO IRANZU MUGUETA AGUINAGA, BEGOÑA GARCÍA ZAPIRAIN,

honako Izenburu hau duen Hitzaldia aurkeztu dutela:

han presentado la Comunicación Oral titulada:

EXERGAME Y FRAGILIDAD

Eta horrela jasota gera dadin eta dagozkion ondorioak izan ditzan, ziurtagiri hau egiten da.

Y para que así conste, y surta los efectos oportunos, se expide el presente certificado.

Iñaki Artaza Artabe
Zahartzaroako Presidentea
Presidente de Zahartzaroa

Francisco Uriz Otano
Nafarroako Geriatria eta Gerontologia Elkartearen Presidentea
Presidente de la SNGG

eman ta zabal zazu

Universidad del País Vasco
Euskal Herriko Unibertsitatea