



VNIVERSITAT
E VALÈNCIA

Virtual Gait System Intervention in Older People (NCT05273229); 2023-01-29
Informed Consent Form

INFORMED CONSENT DOCUMENT AND COMMITMENT TO CONFIDENTIALITY

1.- INFORMATION TO THE SUBJECT OF EXPERIMENTATION.

The research project for which we ask your participation is entitled:

"Evaluation of the effectiveness of a virtual gait-based intervention program in people with neurological conditions, musculoskeletal conditions, and older people, on motor function, tone, and sensation."

In order for you to participate in this study it is necessary to have your consent, and that you know the basic information necessary for that consent to be considered truly informed. I would therefore ask you to read the following information carefully. If you have any questions, please express them, before signing this document, to the principal investigator of the project, either personally, or by telephone or by email. The data of the principal investigator of the project also appear in this document.

The basic information you should know is as follows:

1. *Objective of the study:*

The main objective of this study is to evaluate the effectiveness of a virtual gait treatment (visual illusion) comparing it with interventions combined with specific physical exercise of walking on the functional capacity of this population.

b) *Methodology to be used for the study, type of collaboration expected of you and duration of such collaboration:*

The study will contemplate the realization of five measurements that will be carried out one day before starting the program, one day after finishing it, and 1, 3 and 6 months after. That is, 5 measurements of 1h duration.

The intervention program to be carried out will last 3 months and will be carried out 3 days per week.

The sessions will be composed of two parts: in the first, you will stand while you see some images on a screen and follow the instructions that the therapist will indicate. In the second, you will perform a therapeutic exercise program aimed at the lower extremities.

You must attend the sessions at the agreed time in comfortable clothing and follow the instructions of the researcher.

1. *Preventive, diagnostic and/or therapeutic procedures available alternative to those investigated with this study:*

Therapeutic physical exercise is a widely used tool in rehabilitation that has proven to be very efficient in motor re-education in people with diferentes afecciones and

also in older people. In addition, it is essential for functional improvement in the cardiovascular and pulmonary systems, both of people with disabilities and of healthy people (Crane DA, 2017; CA Larrson, 2013; Leech KA, 2018).

What is intended in this study is to increase these benefits by including this type of therapy, as a supplementary aid.

d) *Possible discomforts and risks of your participation in the study:*

The only risk associated with this type of intervention will be fatigue. It is a slight risk, although it can appear in most sessions.

Another less likely risk is the risk of falling from performing walking exercises. This is a serious risk but very unlikely, since the sessions will be with a small group of participants (3) and at all times will be assisted by the researcher.

(e) *Measures to respond to adverse events:*

If adverse events (fatigue or falls) appear, the health team will be notified to evaluate the situation and act accordingly, ensuring rest and recovery in a monitored manner.

f) *Measures to ensure adequate compensation in the event that you suffer any damage:*

If you were harmed, you would not remain in the study. In addition, you will decide whether or not the data collected so far can be used.

g) Expected benefits from *the research: Potential benefits could be:*

- Improvement of the* motor function of the participants, in particular, the gait pattern, tone and physical abilities (endurance and strength).
- Improvement of sensory and proprioceptive perception.
- Reduction of neuropathic pain.

(h) *Consequences of non-participation:*

If you choose not to participate, this will not affect your right to health care, and that the relationship with the people who proposed to participate will be just as cordial and dedicated to those who refuse to participate as with those who do.

i) *Possibility of withdrawal at any time and consequences:*

You can withdraw from the project at any time by signing the revocation of consent that is included at the end of the document. Your withdrawal will not have any negative consequences for you, and will be accepted without problems by the research team.

(j) *Who funded the study?:*

The Universitat de València through a predoctoral grant "Atracció al Talent 2019" (INV19-01-19-01).

k) *Which institution does it? :*

Department of Physiotherapy of the University of Valencia.

l) *Free participation:*

Experimental subjects will not receive any financial compensation for participation in this study.

(m) *Forecast of subsequent use of results:*

The results will be used for teaching, research and/or scientific publication purposes.

n) *Research team:*

Pilar Serra Añó.
Núria Sempere Rúbio.
Elena Muñoz Gómez.
Sara Mollà Casanova.
Marta Inglés de la Torre.
Marta Aguilar Rodríguez.

o) *Contact details of the principal investigator for clarification or queries:*

Pilar Serra Añó
Universitat de València, Faculty of Physiotherapy.
pilar.serra@uv.es
657565150

p) The project will be carried out following the international ethical criteria set out in the Declaration of Helsinki.

2.- COMMITMENT TO CONFIDENTIALITY.

a) *Measures to ensure respect for private life and confidentiality of personal data:* Appropriate measures have been adopted to guarantee the complete confidentiality of the personal data of the experimental subjects participating in this study, in accordance with the Law on Protection of Personal Data (LOPD) 3/2018, of 5 December.

b) *Measures to access information relevant to you arising from the investigation or from the total results:* Know that you have the right to access the information

generated about you in the study. You have the right to access all your data collected from the various evaluations by making a written request to the principal investigator of the project (Pilar Serra, pilar.serra@uv.es)

c) *Measures taken because it is an anonymised study:*

An effective anonymisation system has been established that does not allow subsequent identification of the subject. In no case will the consents granted, where the subject is identified, be combined with the questionnaires used in the study. In the use made of the results of the study, for teaching, research and / or publication purposes, the due anonymisation of personal data will always be respected, so that the subjects of the research will not be identified or identifiable.

3.- CONSENT.

In the event that the subject of experimentation is of legal age:

Don/Doña ____

of legal age, holder of the DNI: ____, by this document

I manifest that:

In the event that the subject of experimentation is a minor or incapable of acting:

Don/Doña ____

of legal age, holder of the DNI : ____,

☐ father, mother, ☐ legal guardian

of _____

I hereby declare that:

I have been informed of the characteristics of the Research Project entitled: "Evaluation of the effectiveness of an intervention program based on virtual walking in people with neurological conditions, musculoskeletal conditions and older people, in motor function, tone and sensitivity"

I have read both paragraph 1 of this document entitled "information to the subject of experimentation" and paragraph 2 entitled "commitment to confidentiality", and I have been able to raise the doubts that have arisen in this regard. I think I have understood that information.

I am informed of the possibility of withdrawing at any time from the study.

By virtue of such conditions, I consent to participate in this study.

And in proof of conformity, I sign this document at the place and date indicated below.

Valencia, ____ of ____ of 20__.

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<i>Name and surname of the participant:</i>	<i>Name and surname of the father, mother or guardian (in the case of minors or incapacitated persons):</i>	<i>Name and surname From the Principal Investigator:</i>
Signature:	Signature:	Signature:

If the subject of the study is an intellectually and emotionally capable adolescent between 12 and 16 years old, his opinion must be heard and his participation in the study must be authorized by also signing this consent. In the case of minors who are not incapacitated or incapacitated, but emancipated or 16 years of age, consent cannot be given by representation and it will be the subject of the study who will sign the consent (Law 41/2002).

REVOCATION OF CONSENT

I revoke the consent given on date ____

In Valencia, to ____ of ____ of 20__.

<i>Name and surname of the participant:</i>	<i>Name and surname of the father, mother or guardian (in the case of minors or incapacitated persons):</i>	<i>Name and surname From the Principal Investigator:</i>
Signature:	Signature:	Signature: