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Postural control and balance in a cohort of healthy people living in Europe: posturography-derived normative data

Submission date	Recruitment status	[_] Prospectively registered
15/01/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/02/2023	Other	

Plain English summary of protocol

Background and study aims
In the last 20 years, posturography (techniques that measure posture and stance) has been widely used in the medical field. The aim of this study is to collect data from posturography of a wide set of healthy volunteers from various European countries using a force platform and a standardized method of measurement.

Who can participate?
Healthy volunteers aged between 7 and 86

What does the study involve?
Participants are assessed using the Romberg test with a force platform. In the Romberg test the standing participant is asked to close their eyes and their swaying is measured with a force platform, an instrument that measures the ground reaction forces to quantify balance and gait.

What are the possible benefits and risks of participating?
These results could be used as normal values for posturography assessments in similar populations. Because the force platform method in itself is biased and may interfere with a correct diagnosis of a good or bad posture, percentile values are presented that would be more helpful to professionals in understanding posturography recordings. Ultimately, participants can have an assessment of their stability by comparing it with a representative sample.

Where is the study run from?
University of Palermo (Italy)

When is the study starting and how long is it expected to run for?
September 2014 to December 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Antonino Patti
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Postural control and balance in a cohort of healthy people living in Europe: posturography-derived normative data

Study objectives
The main aim of this study was to identify values of normality threshold common to all subjects and independent of anthropometric parameters and sex in the sway patterns of healthy subjects during quiet standing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Palermo - Consiglio di Dipartimento SPPF Prot. n. 290 /2014; punto all'ordine del giorno numero 10; approval number: 290-2014/MEDF-02/11

Study design
Observational cross sectional study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
The subjects did not have to be professional sportsmen

Interventions
Data were collected from 2014 to 2016. Detailed descriptions of the study sampling and recruitment approaches, standardization, data collection, analysis strategies, quality control activities, and inclusion criteria were approved by all operators who participated in the research. A random cluster sampling of 914 healthy subjects aged between 7.0 and 85.99 years, stratified by age, was carried out. The subjects did not have to be professional sportsmen.

Posturography values were measured using the FreeMed posturography system, including the FreeMed baropodometric platform and FreeStep v.1.0.3 software. The system had been calibrated to sample postural sway at 25 Hz, in real time. The sensors, coated with 24 K gold, guaranteed repeatability and reliability of the instrument (Sensor Medica, Guidonia Montecelio, Roma, Italy). Participants were asked to take the standardized Romberg test position on the baropodometric platform for 51,2 sec. Data from the platform were converted in accordance with instructions provided by the manufacturer and transformed into coordinates of CoP. The following parameters of the statokinesigram were considered in open eyes conditions: length of sway path of the CoP (SP); ellipse surface area (ES); coordinates of the CoP along the frontal (X; right-left; x-mean) and sagittal (Y; forward-backward; y-mean) planes.

To provide percentile values of our cohort, data were processed to obtain five curves corresponding to the following percentiles: 10th, 25th, 50th, 75th, and 90th. Distance-weighted least squares was used to represent the percentile on appropriate graphs. The measurements were obtained, providing age-specific percentile values related to each posturography component considered.

Intervention Type
Other

Primary outcome(s)
Postural sway at 25 Hz measured using the FreeMed posturography system during quiet standing

Key secondary outcome(s))
N/A

Completion date
31/12/2016

Eligibility

Key inclusion criteria

1. A random cluster sampling of 914 healthy subjects aged between 7.0 and 85.99 years, stratified by age, was carried out
2. The subjects did not have to be professional sportsmen

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
914

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
19/09/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Italy

Spain

Türkiye

Study participating centre
University of Palermo
Department of Psychology and Educational Science
Italy
90144

Sponsor information

Organisation
University of Palermo

ROR
https://ror.org/044k9ta02

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Antonino Patti (antonino.patti01@unipa.it). Datasets: Raw data, not processed and anonymous. Personal data of participants will be kept confidential. Anthropometric measurements of participants will be provided anonymously. Data will be available after completion of analysis and it will be disposed of in 5 years as per university policy. The data will be shared anonymously upon request from the researchers with journals and the working research groups. Consent from the guardians while assents from the children (participants) have been taken before the trial. Each participant will be given a proper trial registration no. at the beginning of trial. All the data will be linked anonymized. Ethical approval has been acquired from the research ethics committee of University of Palermo.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2018	27/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes