STUDY PROTOCOL

English translation of the protocol approved by the Research Ethics Committee of Aragón (CEICA)

Foot Type-Based Intervention Proposal for Addressing Musculoskeletal Discomfort in Assembly-Line Workers in Sustained Standing

Original title (Spanish): Propuesta de intervención basada en el tipo de pie para el abordaje del malestar musculoesquelético en trabajadores de cadena de montaje en bipedestación mantenida

Official Title	Foot Type-Based Intervention Proposal for Addressing Musculoskeletal Discomfort in Assembly-Line Workers in Sustained Standing
NCT number	NCT07920523
Document date	20 November 2024 (protocol version 3, "V3 20/11/2024")
Document	Study protocol, including the planned statistical analysis (section 4.6). Complete translation of the CEICA academic research project form ("Memoria de trabajo académico"), version 3.
Unique Protocol ID	PI24/176 (CEICA reference C.P. - C.I. PI24/176)
Ethics approval	Research Ethics Committee of Aragón (CEIC Aragón, CEICA). Favourable opinion of 17 April 2024 (minutes no. 08/2024; protocol version 2, 10 April 2024). Amendment (protocol version 3, 20 November 2024) approved on 4 December 2024 (minutes no. 22/2024).
Sponsor	Universidad San Jorge, Zaragoza, Spain
Study site	BSH Electrodomésticos España S.A., Montañana plant, Zaragoza, Spain
Doctoral candidate and directors	Alejandro J. Almenar Arasanz (doctoral candidate); Cristina Cimarras Otal and Luis E. Roche Seruendo (thesis directors), Universidad San Jorge

Investigators' clarifications on the approved protocol

Added in October 2026. The approved text and its translation (pages 2 onwards) are not modified.

1. Annex I: the ticked box ("the work is entirely included within the objectives of a study already approved by a Research Ethics Committee") refers to the approval of this study by CEICA on 17 April 2024; version 3 was submitted as an amendment to that approved study.

2. Section 1 (funding): "2014–2015" is a typographical error for 2024–2025. In the randomized trial, the safety shoes and insoles were purchased by BSH Electrodomésticos España S.A., and the Cátedra Empresa Sana funds only the publication costs.

3. Sections 3.4, 4.1 and 4.6 (Procedure) assign pseudonymization and data analysis to different team members. In the randomized trial, both pseudonymization and data analysis were performed by Alejandro J. Almenar Arasanz.

4. Section 4.6 (Statistical analysis): "mean and interquartile range" for non-normal variables should read "median and interquartile range".

5. Section 4.6 (Sample size calculation): the standard deviation of 4 used in the GRANMO calculation for the trial was taken from a low back pain index (reference 19) as an approximation, because no previous data on the Cornell questionnaire were available.

About this translation

1. This is a complete English translation of the protocol form submitted to and approved by CEICA (version 3, 20 November 2024). The Spanish original is the authoritative version.

2. Removed for privacy: national identity numbers, telephone numbers and e-mail addresses of the investigators, the link to the online questionnaire and handwritten signatures. Removals are marked "[removed]". No other content has been added, removed or modified.

3. In the original, text added by the amendment (version 3) is highlighted in red. It is shown here in dark red and preceded by "[V3]". The amendment concerned the first (cross-sectional) phase: inclusion of office workers in sustained sitting, recalculation of the phase-1 sample size and extension of data collection to December 2024. The description of the second phase (randomized trial) was not modified.

4. Instructions printed on the CEICA form are shown in grey italics; section headings that the form layout repeats are shown once. Notes in square brackets are translator's notes.

5. The trial was registered on ClinicalTrials.gov retrospectively. Differences between this protocol and the trial as conducted and reported are described in the registry record. The investigators' clarifications on page 1 correct clerical errors in the approved text without modifying it.

English translation prepared in October 2026 for registration purposes.

ACADEMIC RESEARCH PROJECT FORM (DOCTORAL THESIS, BACHELOR'S OR MASTER'S DISSERTATION) FOR CEICA

TITLE	Propuesta de intervención basada en el tipo de pie para el abordaje del malestar musculoesquelético en trabajadores de cadena de montaje en bipedestación mantenida [Foot type-based intervention proposal for addressing musculoskeletal discomfort in assembly-line workers in sustained standing]
VERSION AND DATE	[V3] V3 20/11/2024
PLACE WHERE THE STUDY IS CONDUCTED	BSH MONTAÑANA / UNIVERSIDAD SAN JORGE
BACHELOR'S / MASTER'S / DOCTORATE (identify as appropriate)	DOCTORATE
CENTRE / FACULTY – UNIVERSITY	UNIVERSIDAD SAN JORGE / FACULTY OF HEALTH SCIENCES
Is the study part of a study already approved by CEICA or by an ACCREDITED Research Ethics Committee outside Aragón?	Yes ☐ No ☒

If yes, complete this first page and attach the opinion of the Research Ethics Committee that evaluated it and the tutor's declaration (Annex I).

STUDENT

Name and surname	Alejandro J. Almenar Arasanz
National ID number / E-mail / Telephone	[removed]
Workplace	Universidad San Jorge

DIRECTOR / TUTOR 1

Name and surname	Cristina Cimarras Otal

National ID number / E-mail / Telephone	[removed]
Workplace	Universidad San Jorge

DIRECTOR / TUTOR 2

Name and surname	Luis E. Roche Seruendo
National ID number / E-mail / Telephone	[removed]
Workplace	Universidad San Jorge

The personal data that may appear in this communication will be incorporated into the processing system for which the Instituto Aragonés de Ciencias de la Salud (IACS) is responsible. The data will be processed for the management and follow-up of the studies evaluated by CEICA. The data will be deleted once the management and/or processing of the application has been completed and they are no longer necessary. You have the right to access, rectify and erase the data, as well as the other rights granted by data protection legislation, before IACS, with address at the Centro de Investigación Biomédica de Aragón, Avda. San Juan Bosco 13, 500009 Zaragoza, or by request to protecciondedatos.iacs@aragon.es.

GLOSSARY

- **Anonymization:** process by which it is no longer possible, by reasonable means, to establish the link between a piece of data and the subject to whom it refers. It also applies to biological samples.
- **BIGAN:** health big-data platform (managed by IACS) that provides pseudonymized access to data from the Aragón Health System for management and research purposes.
- **Biobank:** public or private non-profit establishment that holds one or more collections of biological samples of human origin for biomedical research, organized as a technical unit with criteria of quality, order and purpose.
- **Centre:** institution where a study is carried out (hospital, health centre, nursing home, faculty, private clinic, school, etc.). In case of doubt, reference should be made to the place from which participants come (hospital, school, sports club, etc.).
- **Confidentiality undertaking:** document that students and residents carrying out any activity in the public health system must sign (model established in Order SSI/81/2017).
- **Informed consent:** free and conscious expression of will, validly given by a capable person or by his or her authorized representative, preceded by adequate information.
- **CEICA opinion:** document certifying that CEICA has evaluated a research project and that the project complies with the applicable legal regulations and ethical criteria.
- **Survey:** collection of information on physical or digital media, with or without direct interaction with the source subject.
- **Interview:** collection of information with direct interaction with the source subject, through verbal answers.
- **Research team:** group of investigators who jointly carry out a specific project.
- **Primary data source:** when data are collected directly from the study participant and for the purpose of the study.
- **Secondary data source:** when data already collected (and therefore recorded) for a purpose other than the study (clinical care, teaching, etc.) are used.
- **Research group:** group of investigators with a common track record (publications, funding), led or coordinated by a Principal Investigator, grouped around a research topic and not necessarily by clinical or departmental affiliation.
- **Participant information sheet:** document informing potential participants of the nature of the study so that they can give their informed consent.
- **Intervention (intervention study):** any action to be performed on a person because of his or her participation in a study (it may be a pharmacological or physiotherapy treatment, or an educational, behavioral or psychological intervention).

- **Principal investigator:** investigator who leads the project and is responsible for its design, conduct and the dissemination of results. If the study is multicentre, there must be a principal investigator at each centre who is responsible for the patients, data and/or samples.
- **Biological sample:** any biological material of human origin that can be stored and may contain information on the genetic make-up of a person.
- **Usual clinical practice:** procedures carried out purely for healthcare reasons, independently of whether or not a person participates in a research study.
- **Research project:** scientific procedure intended to gather information and formulate hypotheses about a given social or scientific phenomenon.
- **Sponsor:** individual, company, institution or organization responsible for initiating, managing, organizing and funding a study. It may coincide with the investigator.
- **Pseudonymization:** processing of personal data in such a manner that they can no longer be attributed to a data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures ensuring that the personal data are not attributed to an identified or identifiable natural person.

1. SCOPE AND FUNDING OF THE PROJECT

Is it a multicentre project? Yes ☐ No ☒	*If yes, a list of centres with their principal investigator in Aragón must be submitted.*
Does the study have specific funding? Yes ☒ No ☐	Income: funding from Cátedra Empresa Sana (24,000 euros) in years 2014–2015 Total expenses (13,800 euros): • Personnel: 2,800 euros • Publications: 6,000 euros • Material: 5,000 euros *[Amounts and years reproduced as in the original.]*
Does it require any resources of the institution (diagnostic tests, facilities, ...)? Yes ☐ No ☒	*If yes, specify:* [blank in the original]

2. STUDY CHARACTERISTICS

2.1 Is it research with medicines? Yes ☐ No ☒

If yes, choose one option:

1) ☐ It is an observational study regarding treatment with medicines (EOM). In this case, specify: ☐ prospective data collection ☐ retrospective data collection ☐ cross-sectional data collection

2) ☐ It is an interventional study: clinical trial with medicines. In this case it must be submitted according to the instructions of the AEMPS [Spanish Agency of Medicines and Medical Devices] (https://www.aemps.gob.es/medicamentos-de-uso-humano/investigacionclinica_medicamentos/ensayosclinicos/#n-espanola).

2.2 Is it research with medical devices? Yes ☐ No ☒

If yes, choose one option:

1) ☐ It is an observational study regarding the use of the medical device

2) ☐ It is an interventional study: clinical trial with medical devices. In this case it must be submitted according to the CEICA standard operating procedure for this type of study (https://www.iacs.es/investigacion/comite-de-etica-de-la-investigacion-de-aragon-ceica/).

SPONSOR (mandatory for clinical trials and observational studies with medicines and medical devices; it may be the principal investigator)

Company identification / name and surname	[blank in the original]
Tax ID / national ID number	[blank in the original]
E-mail	[blank in the original]
Telephone	[blank in the original]

2.3 Is it research with invasive procedures? Yes ☐ No ☒

(Definition: any intervention performed for research purposes that involves a physical or psychological risk for the participant.) If yes, an insurance policy must be taken out or minimal risk must be justified.

2.4 Does the research include minors or persons unable to give consent? Yes ☐ No ☒

If yes, an information and informed consent document addressed to the guardian/legal representative/family member and another addressed to the minor (adapted to his or her capacity) must be submitted. Review the CEICA template.

2.5 Are biological samples used in the study? Yes ☐ No ☒

If yes, choose one or more options:

1) ☐ Surplus samples from clinical care are used, with consent for the project. The information and consent document (CEICA template) must be submitted.

2) ☐ Surplus samples from clinical care are used without consent. This must be adequately justified in the ethical aspects section (art. 58.2, Law 14/2007).

3) ☐ Samples are collected specifically for this study. The information and consent document (CEICA template) must be submitted.

4) ☐ A private collection of samples is created. For the creation of a new collection, submit the documentation required for its evaluation and indicate the registration number (no. _____) (see CEICA website).

5) ☐ Samples already collected in a private collection are used. The collection must be identified (in the methodology section). In this case, identify the collection number and the person responsible: _____

6) ☐ Samples are requested from an authorized biobank. In this case, identify the biobank: _____. The request to the biobank must be submitted.

2.6 Are genetic analyses performed? Yes ☐ No ☒

2.7 Are embryos, human embryonic cells or human fetal cells or tissues used? Yes ☐ No ☒

The IACS or the responsible institution must be contacted for subsequent authorizations.

3. PROCESSING OF PERSONAL DATA

Personal data means any data (age, sex) or any information (numerical, alphabetical, graphic, acoustic) concerning an identified or identifiable natural person; an identifiable person is one whose identity can be determined, directly or indirectly (that is, data that have not been irreversibly anonymized at source).

3.1 Are personal data collected or processed in the study? Yes ☒ No ☐

If yes, tick the applicable option:

☒ The informed consent of the data subject is requested. *(Submit the information and consent document, CEICA template.)*

☐ Data obtained for another purpose that have been pseudonymized (e.g., clinical record, other research, other registers) in accordance with Additional Provision 17 of Organic Law 3/2018 are used.

☐ Other. Specify:

Tick the categories to which the data collected belong:

☒ Identifying data (name, address, e-mail, national ID number, clinical record number, telephone, signature, IP address, geolocation, image/voice, other)

☒ Personal data: date of birth, place of birth, parents' names, workplace, economic data, sex, marital status, children, academic qualification, other

☐ Opinion data

☐ Especially sensitive data: health, ethnicity, religion, political opinion, sex life or sexual orientation, trade union membership, special educational needs

3.2 If data are collected directly from the data subject (primary source), specify the procedure

(Example: interview, paper survey, e-mail, telephone, web applications, ...)

Data will be collected through a Oneforms questionnaire [Microsoft Forms]: [link removed]. It will be provided to the workers by e-mail (see attached e-mail template).

3.3 If data are not collected directly from the data subject (secondary source), tick the option and specify

☐ *Data are collected from an existing register (e.g., clinical record) with the consent of the data subject.*

☐ *Data from another similar research project, for which the consent of the data subject was obtained, are reused. Permission from the person responsible for the data, the consent form with which they were obtained and the undertaking to use pseudonymized data must be submitted (see website).*

☐ *Data obtained for another purpose and without consent for research are used (e.g., clinical record or other register). In this case, indicate: ☐ the student (if a member of staff of the centre) accesses the clinical record directly (submit the authorization of the person responsible for the data; if it is the clinical record, the management's authorization for access to the data for this study must be submitted); ☐ the student receives the data already pseudonymized (submit the undertaking to use pseudonymized data, see website).*

Note: bachelor's students and those without an employment relationship with the hospital/centre have no access to the clinical record; whenever this source is used, they must obtain pseudonymized data, and the tutor must guarantee that the data are provided to the student without identification. In all cases, explain the origin of the data and the person responsible for them.

☐ *Data from BIGAN. Submit the report of the Biocomputing Unit (link to the application) and the undertaking to use pseudonymized data (website).*

3.4 Once the information and data have been obtained, how is the participants' privacy guaranteed?

☐ Only aggregated data are used (i.e., data corresponding to groups of people and not to each of those people)

☐ The data are anonymized (the data cannot be associated with an identified or identifiable person because the link with all information identifying the subject has been irreversibly destroyed)

☒ The data are pseudonymized or coded (direct identifiers are replaced by a code/pseudonym known only to the research team)

Explain how and by whom the measure adopted is carried out:

A member of the group (Cristina Cimarras) will code the data with a random number associated with the identification number used by the company BSH. This process will be carried out with Microsoft Excel 2010. For data processing, the investigator in charge of pseudonymizing the data will pass a database without the employee number to the investigator in charge of analyzing them (Alejandro Almenar).

3.5 Data retention period

Specify the date of destruction (at least month and year):

All data, from both the first and the second phase of the project, will be kept at most until February 2029 or after the defense of the doctoral thesis.

3.6 Data processors (not to be completed for anonymous data)

A data processor is any natural or legal person, public authority, service or other body that processes personal data on behalf of the controller. If a third party (outside the institution) processes project data, a data processor contract must be signed. A model can be downloaded from https://seguridad.salud.aragon.es/plantillas/

Indicate which persons will process the data collected, specifying who will have access to identifying data:

The research team.

Are all persons authorized to process the data subject to a confidentiality agreement signed with the centre? Yes ☒ No ☐

3.7 Will data be transferred to third parties? Yes ☐ No ☒

In case of transfer, specify: the data transferred are ☐ identified ☐ pseudonymized ☐ anonymized; to whom they are transferred; which data are transferred; for what purpose; how the data are pseudonymized or anonymized; whether there are international transfers (company and country; in this case, the express consent of the participant must be requested for this transfer).

3.8 Will audio/video recordings be made? Yes ☐ No ☒

Remember that the express consent of the data subject is required to make recordings. In case of recording, specify where they will be stored and the security measures applied, the retention period, the purpose and, if computer applications or cloud storage are used, the service provider, its legal residence and the link to its privacy policy.

3.9 Information security measures: description of the computer systems to be used

Servers containing personal data must be located in the territory of the EU (Royal Decree-Law 14/2019).

System in which the data will be stored (personal computer, corporate servers, external company or body, cloud service provider, etc.)	Password-protected computer and Microsoft 365 OneDrive with Universidad San Jorge credentials
Applications to be used for data processing (Excel, SPSS, etc.)	Excel, SPSS
Online applications or cloud storage: provider, legal residence and privacy policy	Microsoft 365 OneDrive with Universidad San Jorge credentials: https://privacy.microsoft.com/es-es/privacystatement

3.10 Information security measures: devices

Will any removable device (USB drive, external hard disk, etc.) be used, and will it be encrypted?	No
If corporate computer systems are not used, are backups made?	No
Security measures for paper documents (custody, access)	NO

General recommendations on data use

- *Do not use Wi-Fi networks to transmit sensitive information.*
- *Use strong passwords and change them periodically.*
- *Always encrypt sensitive information to be sent by e-mail.*
- *Make sure that operating systems and applications are always up to date.*
- *On personal computers, always use antivirus software and keep it up to date.*
- *Never open e-mail attachments from senders you do not recognize.*
- *Do not use social networks to communicate sensitive information.*

- *The mobile phone is an insecure device for handling sensitive information, and the antivirus programs that can be installed offer little protection.*
- *Use corporate applications whenever possible.*
- *The use of USB drives or other removable devices is strongly discouraged.*

4. DESCRIPTION OF THE RESEARCH PROJECT

(Complete the fields or attach the complete protocol with equivalent information.)

4.1 Tasks of the research team

Explain briefly who participates in the study, in what capacity and what tasks they will carry out, as well as their affiliation (current position). Tutors/directors must sign Annex I.

BSH (company)

- Jose Antonio Villalba, head of the medical services of BSH in Aragón. Responsible for the study design and for the logistics of its implementation at BSH. Responsible for recruiting the subjects and sending forms by e-mail. Management and distribution of insoles in phase 2 of the study.

Mutua MAZ

- Belén Lacarcel, Jose Luis Ballestín and Andrés Alcazar: study design.

Universidad San Jorge

All Universidad San Jorge investigators are responsible for the study design and for writing publications.

- Cristina Cimarras: study design and writing of publications; director of the doctoral thesis.
- Ana Vanessa Bataller: study design, data processing and writing of publications.
- Juan Rabal: study design, data processing.
- Luis Enrique Roche: expert adviser on podiatry, study design; director of the doctoral thesis.
- Alejandro Almenar: doctoral candidate, study design; performs the measurements and the pseudonymization of the data; writing of publications.

Background and rationale

[This section has no heading in the original form; the heading has been added for readability.]

Workers in the manufacturing industry usually spend most of their working day standing, performing repetitive movements with the upper limbs. Workers who spend a large proportion of the working day standing have a considerably higher level of musculoskeletal disorders (MSDs) than other populations (1).

Static positions in sustained standing may be one of the mechanical causes of low back pain in the workplace [2-6], and are also associated with MSDs in the lower limbs and feet [7-9].

Variations in foot type are thought to be an intrinsic risk factor for MSDs owing to altered movement of the lower limb [10-11].

In addition to possible MSDs in the lower limb, a non-neutral foot morphology may lead to altered foot function and be associated with conditions of the lumbar spine, as some studies indicate, because of the alteration in the kinetic chain [11-12].

The following foot types are described in the healthy adult population on the basis of specific morphological characteristics [13]:

- **Rectus or normal:** rearfoot and forefoot well aligned.
- **Flat (planus):** the foot showing a lowered longitudinal arch or plantar vault and valgus deviation of the heel [15].
  - *Congenital flatfoot:*
    - *Flexible*
    - *Rigid:* rigid flatfoot is secondary to bone abnormalities.

  - *Acquired flatfoot:* secondary to various conditions such as joint hyperlaxity, tendon injuries, chronic inflammatory rheumatic diseases, neuropathic arthropathy or trauma. It may also be flexible or rigid:
    - *Flexible:* the flexible or mobile flatfoot shows collapse of the plantar arch only in the standing position, but without treatment a spasm of the peroneal muscles may appear, gradually leading to a rigid, spastic flatfoot due to contracture of this muscle group.
    - *Rigid*

  Individuals with flat feet have been found to have greater foot mobility than those with cavus feet. Consequently, studies analyzing running and gait have found that people with flat feet are more susceptible to tissue stress injuries [10].

  Flat feet are associated with hallux valgus, hallux rigidus and posterior tibial tendon dysfunction [13]. In addition, the excessive pronation generated in a flat foot may be associated with plantar fasciitis, Achilles tendinopathy and patellofemoral syndrome [16].

- **Cavus:** the foot with an increased height and width of the longitudinal arch. As a result, the rearfoot and forefoot are closer together and its lateral weight-bearing border is greatly reduced. It is usually asymptomatic, but it may cause discomfort, recurrent foot or ankle sprains and tired feet. It has different aetiologies: neurological, idiopathic, increased tone, congenital or secondary to trauma (scars, fractures...) [15].

  People with cavus feet have been found to have less foot mobility and to be more susceptible to injuries related to reduced shock absorption or increased peak plantar pressures [10].

  Cavus foot types have been associated with claw-toe and hammer-toe deformities [13].

  In the cavus foot the ankle joint is not affected, but the subtalar joint may be limited. The plantar fascia, and especially the extensor of the first toe and the common extensor of the toes, are under greater tension than usual, and the toes are contracted in a claw position, without contact of the toe pulps with the ground [15].

Both flat and cavus foot types also have a higher risk of stress fractures.

To know the foot type, its characteristics must be measured, whether structural or of alignment, and ideally a combination of both under dynamic, not only static, conditions [17].

There are different ways to assess and classify feet according to their morphology [11-14]:

- Non-quantitative visual inspection
- Foot Posture Index*
- Anthropometric values
- Radiographic evaluation
- Footprint or plantar pressure parameters: regarding kinetic assessment or plantar pressures, subjects with cavus feet have been found to show lower pressure in the medial arch and higher plantar pressure in the heel and forefoot compared with people with normal or flat feet [10].

Assembly-line workers at BSH use safety footwear to carry out their work in sustained standing. Until now, the workers' foot type has not been taken into account when implementing the safety footwear. For all the above reasons, we consider that assessing the workers' foot type and implementing a specific insole with the safety footwear would reduce musculoskeletal discomfort in workers with a non-neutral foot type. In addition, it would be interesting to know whether age, sex, as well as the work section, shift or years of work in sustained standing, could influence musculoskeletal discomfort as well as the subjects' foot type.

On the other hand, in the health sciences, numerous fields and specialties rely on the exploration and visual representation of data. The need to analyze large numbers of features and multivariable data poses the challenge of presenting this information in a way that is understandable and easy to interpret. These tasks have become increasingly simple thanks to the development of machine learning algorithms that make it possible to take decisions or make predictions based on the patterns of large datasets, which have evolved towards neural networks (algorithms that imitate the brain) and artificial intelligence algorithms [18].

The creation of a large database including the baropodometry and FPI of each subject and, on that basis, the implementation of artificial intelligence algorithms for an objective foot classification not based on observer-

dependent aspects could represent a qualitative leap in reliability and in reducing the time needed to perform foot-type identification tests, compared with existing methods. To date, no similar study has been published in the literature.

4.3 Bibliography

(Must be cited in the text above.) [References reproduced as in the original.]

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4.4 Hypothesis

(Statement to be demonstrated)

The implementation of insoles specific to the non-neutral foot type in assembly-line workers in sustained standing could reduce the workers' musculoskeletal discomfort over 3 months in the lower limbs and feet, as well as in the lumbar spine.

4.5 Objectives

Primary objectives

- To classify the foot type (cavus, neutral or flat) of the workers of BSH.
- To evaluate the change in musculoskeletal discomfort, with the Cornell questionnaire, before and after implementing insoles specific to the workers' non-neutral feet in the safety footwear.

Secondary objectives

- To assess the correlation of foot type and the different morphological variables with the workers' musculoskeletal discomfort.
- To develop an artificial intelligence algorithm for image recognition of footprints, to characterize the footprint in correlation with the FPI.
- [V3] To analyze the morphological variables and the musculoskeletal discomfort of the foot in office workers in sustained sitting and to determine whether there are differences from workers in sustained standing during their working day.

4.6 Methodology

(All the following fields must be detailed:) Study design. Participants: inclusion/exclusion criteria; method of recruitment (who makes the initial contact with participants and how; submit any study dissemination material); sample size (and its justification); randomization (if applicable). Information sources: detailed variables (data to be collected), origin of the data, when and how they are collected, and the period of time to which they refer. Procedures: describe separately purely clinical-care procedures and research-specific procedures; submit the surveys or forms to be used (link in the case of online surveys); assessment of the risk of the experimental procedures and measures to minimize it. Statistical analysis. Consideration of the gender perspective: detail the measures adopted so that the study results can reflect possible differences by sex/gender. Limitations of the study. In the case of biological samples: type and number of samples, how they are collected, where and by whom they are analyzed, and when they are destroyed (or their final destination).

Study design

- First phase: cross-sectional study.
- Second phase: randomized clinical trial.

Participants

The study participants will be assembly-line workers of BSH, [V3] as well as office workers who are in sustained sitting during their working day.

Inclusion criteria, first phase:

- Subjects who spend most of their working day in sustained standing.
- [V3] Subjects who spend most of their working day in sustained sitting.

Exclusion criteria, first phase:

- Subjects who have undergone foot surgery or who have major injuries of the lower limb or spine.
- Pregnant women.

Inclusion criteria, second phase:

- Subjects who spend most of their working day in sustained standing.
- Subjects who have participated in the first phase of the study.

Exclusion criteria, second phase:

- Workers who wear their own insoles.
- Subjects who have undergone foot surgery or who have major injuries of the lower limb or spine.
- Pregnant women.

The head of the BSH medical service will send the potential volunteers, by e-mail (see attached template), the participant information sheet and the link to the Oneforms form, in which they must indicate by ticking a box that they have read the information sheet and that they consent to participate in the study.

Sample size calculation

[V3] Three sample size calculations are therefore performed for the first, cross-sectional study: one to determine the number of workers in sustained standing, another for those who work in sustained sitting, and the last for the cross-sectional comparison of both groups. For this calculation, standard formulas for observational studies in finite populations are applied, considering a confidence level of 95% and a margin of error of 5%.

[V3] Parameters used:

- [V3] Confidence level (Z): 1.96 (corresponding to 95%)

- [V3] Expected proportion (p): 50% (0.5), as a conservative value to maximize the sample size.
- [V3] Margin of error (e): 5% (0.05)
- [V3] Population sizes:
  - [V3] Workers in sustained standing (N = 988)
  - [V3] Workers in sustained sitting (N = 206)

[V3] The general formula for calculating the sample size in a finite population is:

$$n = Z^2 \cdot p \cdot (1 - p) / e^2$$

[V3] This initial result is adjusted for the finite population size using:

$$n_{adjusted} = n / [1 + (n - 1) / N]$$

[V3] Substituting the values in the formula, considering a confidence level of 95% (Z = 1.96), a margin of error of 5% (e = 0.05) and an expected proportion of 50% (p = 0.5) to maximize representativeness: for workers in sustained standing (N = 988), the required sample size is 277 participants, whereas for workers in sustained sitting (N = 206), the necessary sample is 134 participants.

[V3] The calculation for the comparative study seeks to detect a significant difference between both groups. For this, we use the formula based on statistical power and the expected effect size:

$$n_{comparative} = 2 \cdot (Z_\alpha + Z_\beta)^2 \cdot \sigma^2 / d^2$$

[V3] Where:

- [V3] Zα = 1.96: 95% confidence level.
- [V3] Zβ = 0.842: 80% power.
- [V3] σ = 0.5: estimated standard deviation.
- [V3] d = 0.15: minimum detectable difference (15%).

[V3] Substituting the values in the formula, a total of 153 participants is obtained, which, if distributed equally, would be approximately 77 participants per group.

[In the original, the three formulas are inserted as images; they are reproduced here as text.]

For the second part, which is the experimental study, the sample size was calculated with the GRANMO calculator and was based on the main variable, which is the musculoskeletal discomfort index assessed with the Cornell Musculoskeletal Discomfort Questionnaire. Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 6 subjects are needed in each group to detect a difference equal to or greater than 7 units. A standard deviation of 4 in the low back pain index is assumed [19].

Randomization

[Sub-heading added for readability.]

The participants in the second phase will be randomized with the program https://www.randomizer.org/ by an independent investigator who will not be involved in the process of recruiting the subjects.

To ensure that the control and intervention groups are homogeneous and comparable, block randomization will be stratified taking into account the foot type, gender, age and weight of each subject.

Procedure

First phase of the study, cross-sectional study

The initial e-mail sent to potential participants will include the participant information sheet and a link to the Oneforms form, which contains, on the one hand, the box for accepting participation in the study, a record of personal data (BSH employee number digits, sex, year of birth, length of service in the company, section and shift), as well as the Cornell musculoskeletal discomfort questionnaire.

If the study inclusion criteria are not met, the data collected in the initial Oneforms questionnaire will be deleted directly from the database and will not be kept for later analysis.

Volunteer subjects who have signed the informed consent (tick box in the online form for the first part of the project) will undergo a first assessment in a place set up for the measurements near their workstation, which will ensure that no one outside the study can know the assessments performed on them. A specialized health

professional (Alejandro Almenar), belonging to the research group of Universidad San Jorge, will perform the measurements with a pressure platform to make a static and dynamic baropodographic recording of both feet, an assessment of the foot type with the FPI (Foot Posture Index) through visual analysis, as well as other variables such as the subject's weight, plantar arch length, foot width and arch height using a 3D scanner. The same investigator who performs the measurements will pseudonymize the data so that another investigator of the group (Juan Rabal) can analyze and process the data without knowing or being able to identify the workers through this coded information.

Second phase, experimental study

The subjects who meet the inclusion criteria and who have participated in the previous phase will be randomized into two groups (control and intervention). The intervention group will be given insoles adapted for non-neutral feet. The control group will be given neutral insoles (like those they have been wearing until the time of the study, but of the same material and characteristics as the specific ones for cavus and flat feet). At that same moment, they must complete the discomfort questionnaire again, which will be available through a Oneforms link sent by e-mail by the medical service.

The subjects must wear the insoles for 3 months in the safety footwear and, at the end of this period, musculoskeletal discomfort will be assessed again with the same questionnaire, available through the Oneforms link that will be sent by e-mail by the medical service.

The insoles corresponding to each group will also be provided by the BSH medical service. The Universidad San Jorge investigators will coordinate with them to provide the information on which type of insole should be given to each worker according to the randomization of the groups.

Information sources

The main variable of the study will be:

- **Musculoskeletal discomfort:** it will be assessed with the "Cornell Musculoskeletal Discomfort Questionnaire"; this questionnaire is validated and translated into Spanish. This variable will be collected at the initial assessment in the first phase of the project, as well as before and after (3 months) the implementation of the insoles.

Other variables:

- **Personal information:** BSH employee number digits (company identifier), sex, year of birth, years of experience in the company, section, work shift. These variables are intended to be correlated with musculoskeletal discomfort as well as with foot type. Older subjects or those with more years working in sustained standing may have greater flattening of the plantar arch, or more discomfort; on the other hand, there may be gender differences. The section in which they work may be influencing the discomfort that workers suffer in some part of their body, since some sections are more physically demanding than others. The work shift may be influencing the musculoskeletal discomfort that workers suffer.
- Weight (kg)
- Height (cm)
- Foot type (cavus, flat, neutral): assessed with the FPI (Foot Posture Index)
- With the pressure platform, the following variables will be obtained:
- Footprint length, left and right foot (mm)
- Length of the CoP line, left and right foot (mm)
- Surface area, left and right foot (cm^2.1)
- Mean and maximum pressure, left and right foot (gr/cm^2.1)
- Forefoot and rearfoot load, left and right foot (%.1)
- Medial and lateral load, left and right foot (%)
- Fick angle, left and right foot (°.1)
- Hallux surface area, left and right foot (cm^2)
- Toes surface area, left and right foot (cm^2)
- Surface area of metatarsals I to V, left and right foot (cm^2)
- Surface area of the medial and lateral arch, left and right foot (cm^2)

- Surface area of the medial and lateral rearfoot, left and right foot (cm^2)
- Percentage of load on the hallux, left and right foot
- Percentage of load on the other toes, left and right foot (%)
- Percentage of load on metatarsals I–V, left and right foot (%)
- Percentage of load on the medial and lateral arch, left and right foot (%)
- Percentage of load on the medial and lateral rearfoot, left and right foot (%)
- Time on the ground, left and right foot (ms)
- Duration of the phases of the step (rockers), left and right foot (ms)
- Percentage of the footprint travelled by the centre of force (COF), left and right foot (%)
- Percentage of the footprint not travelled by the centre of force (COF) at the START and END of the footprint, for both left and right foot (%)
- Plantar arch height (cm), loaded and unloaded: assessed with the anthropometric platform
- Plantar arch length (cm), loaded and unloaded: assessed with the anthropometric platform
- Total foot length (cm), loaded and unloaded: assessed with the anthropometric platform
- Midfoot width (cm), loaded and unloaded: assessed with the anthropometric platform
- AHI (Arch height index): ratio between the arch height measured at half the length of the foot and the foot length (dimensionless measure)
- FMM (Foot mobility measure): ratio between loaded and unloaded change in midfoot height and width (dimensionless measure)
- Plantar arch height (cm), loaded and unloaded: assessed with the anthropometric platform
- Plantar arch length (cm), loaded and unloaded: assessed with the anthropometric platform
- Total foot length (cm), loaded and unloaded: assessed with the anthropometric platform
- Foot width (cm), loaded and unloaded: assessed with the anthropometric platform

[The suffix ".1" after some units and the repetition of the last four items are reproduced as in the original.]

Statistical analysis

- Normality tests will be applied to the variables using the Kolmogorov–Smirnov test. Variables meeting normality criteria will be expressed as mean and standard deviation, and non-parametric ones as mean [sic] and interquartile range.
- To analyze the change in the musculoskeletal discomfort variables, a related-samples t test or its non-parametric equivalent will be performed.
- To analyze the relationship between the initial degree of discomfort and the quantitative secondary variables, a Pearson correlation will be performed for normal variables and a Spearman correlation for non-normal variables. To analyze the relationship between the initial degree of discomfort and the qualitative secondary variables, a correlation with the chi-square test will be performed.
- All statistical tests will be performed with IBM SPSS software, version 2.21 [as in the original].

Development of artificial intelligence algorithms

From a sample of footprints obtained with the Freestep software (Ortomecánica, Madrid), the aim is to predict the FPI. For this purpose, a neural network will be applied, a computational model capable of identifying patterns and of classifying and predicting data. This machine learning technique learns directly from the input data. To develop this model, MATLAB (MathWorks, USA) will be used, a programming and numerical computing platform used by millions of engineers and scientists to analyze data, develop algorithms and create artificial intelligence models.

4.7 Ethical aspects

(Risk/benefit balance, justification if exemption from informed consent is requested, healthcare implications, implications for the participant or his or her family, compensation for participants, insurance policy.)

- The development of the project will be based on the Declarations of the World Medical Association of Helsinki and on the Code of Ethics of the Association of Medical and Physiotherapy Colleges of Spain. Each

subject will be informed of the nature of the study, the voluntary nature of participation in it, the proposed objectives, as well as the possible adverse effects that might occur during its conduct. Each subject will be asked to give consent to participate in the study through the forms link. The study will be suspended at any time if the patient so wishes.

- This study does not pose any risk to the participating workers. The workers will participate voluntarily, undergoing the assessments during working time (lasting about 10 minutes), but they will not have to make up the time spent on them afterwards. The works council of the plant is aware of the research project and has approved it (**see attached document of acceptance by the works council**).
- In addition, in the second phase of the project the worker will receive insoles adapted to his or her foot type free of charge, which he or she may keep after the end of the study. The worker may notice some change in the perception of musculoskeletal discomfort, or some discomfort in the foot, until the body adapts to the new insoles.
- The company's medical service will not use the data collected in this study in any way that could harm the worker.

4.8 Timeline and work plan

Development stages, duration, estimated start and end (at least month and year). Places where the project is to be carried out, facilities to be used.

[Planned months are marked "X" (shaded in the original). Months added by the amendment (version 3) are marked "V3" (shaded in red in the original).]

ACTIVITIES 2024 / MONTH	J	F	M	A	M	J	J	A	S	O	N	D
Recruitment of study subjects (first phase)			X	X								
Measurement of the initial study variables (first phase)				X	X	X	X				V3	V3
Data analysis (first phase)									X	X	X	X

ACTIVITIES 2025 / MONTH	J	F	M	A	M	J	J	A	S	O	N	D
Intervention (second phase, with implementation of the insoles)	X	X	X									
Data analysis (second phase)				X	X	X						
Development of the AI algorithm	X	X	X	X	X	X						

ACTIVITIES 2026 / MONTH	J	F	M	A	M	J	J	A	S	O	N	D
Writing of articles, publication in impact journals and writing of the final doctoral thesis document	X	X	X	X	X	X	X	X	X	X	X	X

Documentation to be submitted

[Heading added for readability.]

WE REMIND YOU of the documentation to be submitted, as applicable, together with this form for the evaluation of the project (digital format):

1. *Signed tutor's declaration (Annex I).*
2. *Participant information sheet and informed consent (see template on the CEICA website), or request for waiver of the information sheet/informed consent and authorization for access to records (e.g., clinical record).*
3. *Economic report / source of funding.*
4. *Insurance policy certificate (if applicable).*
5. *CE marking certificate and technical data sheet (if it is a medical device).*
6. *Undertaking to use pseudonymized data ONLY if section 3.3 applies (use of data from a secondary source) (available on the CEICA website).*
7. *Responsible declaration for observational studies with medicines (EOM) without commercial interest, if applicable (see model on the CEICA website).*
8. *If the study is carried out at the university, the university's authorization for the processing of personal data must be submitted, unless data from the Aragón Health System are used.*
9. *If the study is carried out at a school, nursing home, association, sports club, private clinic or similar, the authorization of the person in charge of the centre for conducting the study must be submitted (free format).*

ANNEX I. DECLARATION OF THE ACADEMIC TUTOR OF THE WORK

Director/Tutor 1	Cristina Cimarras Otal
Director/Tutor 2	Luis Enrique Roche Seruendo
Director/Tutor 3	[blank in the original]

For the purposes of the ethical evaluation by CEICA of the research work entitled: [blank in the original], to be carried out under my supervision by the student: [blank in the original], in the Bachelor's/Master's/Doctorate programme: [blank in the original],

I DECLARE that:

- The work will be carried out under my supervision and direction. I will guide the planning and scientific validity of the research project submitted.
- I have reviewed/participated in the drafting of the documentation submitted by the student.
- The information provided by the student is truthful. Specifically, I confirm that (tick only what applies):

  ☐ The data will be delivered to the student and used exclusively in pseudonymized form. Essential for bachelor's students or students who are not staff of the centre (if the data come from the clinical record).

  ☒ Any direct interaction with people will be carried out under supervision by qualified staff.

  ☐ The biological samples or personal data used by the student have been collected under the informed consent of the source subjects or the express authorization of the management of the centre for access to the data, if the student is staff of the centre (clinical records, data already recorded).

  ☒ The student has signed the centre's confidentiality undertaking.

  ☒ The work is entirely included within the objectives of a study already approved by a Research Ethics Committee (the opinion is attached).
- I will ensure that the work complies with the ethical requirements of research and, in particular, those referring to guaranteeing the confidentiality of the information used and the free decision of people to participate.
- I confirm that authorization has been obtained from those responsible for the healthcare centres and/or services for carrying out the project. No resources of the system will be used without authorization.

Date: 20/11/2024

Signatures of the tutors: Cristina Cimarras Otal, Luis E. Roche Seruendo [handwritten signatures removed]