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Testing a workplace program to prevent computer vision syndrome and dry eye syndrome in computer users

Submission date
16/05/2025

Recruitment status
Not yet recruiting

Registration date
20/05/2025

Overall study status
Ongoing

Last Edited
20/01/2026

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The INTERVIS study is looking at ways to prevent two common eye problems—Computer Vision Syndrome (CVS) and Dry Eye Syndrome (DES)—in people who use screens like computers and tablets at work. These conditions can cause eye strain, dryness, blurry vision, and headaches. In Spain, more than half of workers may be affected. The study aims to test whether a workplace program can reduce these problems and improve workers' eye health and overall wellbeing.

Who can participate?
The study will include 200 employees who regularly use screens at work. Participants will be recruited from two locations in Spain and must agree to take part in the study by signing a consent form.

What does the study involve?
Participants will be randomly placed into one of two groups: one that receives the new intervention and one that continues with usual practices. The intervention includes:

Training on healthy eye habits (like blinking exercises and screen breaks)
Improvements to the work environment (like better lighting and screen setup)
Regular eye check-ups and early detection of problems
Personalized advice for those with symptoms (like using eye drops or special lenses)
Participants will be asked to complete questionnaires and eye tests at the beginning, after 6 months, and after 12 months.

What are the possible benefits and risks of participating?
Taking part could help reduce eye discomfort and improve quality of life at work. It may also lead to fewer sick days and better productivity. Risks are minimal, but participants may find the eye exams or questionnaires slightly time-consuming.

Where is the study run from?
The study is being carried out at Hospital del Mar in Barcelona and the University of Alicante (Spain).

When is the study starting and how long is it expected to run for?
The study will run for three years. It includes a year of follow-up for each participant to track changes over time.

Who is funding the study?
Funding has been requested from the Spanish Ministry of Science, Innovation and Universities through the Instituto de Salud Carlos III.

Who is the main contact?
Prof. Dr José María Ramada Rodilla, jramada@psmar.cat

Contact information

Type(s)
Principal investigator

Contact name
Dr Jose Maria Ramada Rodilla

ORCID ID
https://orcid.org/0000-0002-3854-1596

Contact details
Hospital del Mar, Servicio de Salut Laboral
Passeig Marítim de la Barceloneta, 25-29
Barcelona
Spain
08003
+34 609480592
jramada@hmar.cat

Type(s)
Public

Contact name
Dr Joana Guerrero Monge

ORCID ID
https://orcid.org/0009-0005-9742-2270

Contact details
Hospital del Mar, Servicio de Salut Laboral
Passeig Marítim de la Barceloneta, 25-29
Barcelona
Spain

08003
+34 665272090
joana.guerrero.monge@hmar.cat

Type(s)
Scientific

Contact name
Prof Maria Del Mar Segui Crespo

ORCID ID
https://orcid.org/0000-0003-0281-7949

Contact details
Departamento de Óptica, Farmacología y Anatomía
Universidad de Alicante
Carretera San Vicente del Raspeig s/n
San Vicente del Raspeig - Alicante
Spain
03690
+34 619987300
mm.segui@gcloud.ua.es

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PI25/00032

Study information

Scientific Title
Cluster randomized controlled trial of a workplace intervention to prevent computer vision syndrome and dry eye syndrome in workers using video display terminals

Acronym
Study INTERVIS

Study objectives
Hypothesis 1 (H1):
Significant sex-based differences exist in the prevalence of Computer Vision Syndrome (CVS) and Dry Eye Syndrome (DES) among visual display terminal (VDT) users, both in intervention and control groups.

Hypothesis 2 (H2):
A multicomponent, evidence-based workplace intervention will lead to a significant reduction in the prevalence of CVS and DES among VDT users, regardless of sex. This intervention will include:
a) Comprehensive training in healthy lifestyle behaviors (physical activity, nutritional supplementation, smoking cessation) and education on modifiable visual health risk factors associated with prolonged screen exposure (behavioral, hygienic, postural, and environmental guidelines) — health promotion, primary prevention;
b) Ergonomic optimization of fixed workstations (adjustments in viewing distance, screen tilt, ambient temperature, lighting, and glare) — primary prevention;
c) Visual health surveillance, including refraction assessment, tear film and ocular surface testing, and administration of validated symptom questionnaires — secondary prevention; and
d) Visual health counseling, incorporating guidance on corrective lenses, blinking exercises, scheduled visual breaks following the 20/20/20 rule, and the use of lubricating eye drops — tertiary prevention.

We anticipate that this integrated intervention will reduce the prevalence of CVS and DES by an estimated 65–75% in both male and female participants.

Hypothesis 3 (H3):
The proposed intervention will be cost-effective, delivering a favorable cost-benefit ratio for participating organizations through improved worker well-being, reduced absenteeism, and enhanced productivity.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/11/2025, Hospital del Mar Clinical Research Ethics Committee (c/Doctor Aiguader, 88 (Edifici PRBB). 1ª planta, espai 163.05, Barcelona, 08003, Spain; +34 93 316 06 79 / +34 93 316 06 77; ceic-psmar@imim.es), ref: 2025/12090/I

Study design
Multicenter cluster randomized controlled trial with blinded data analysis

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Quality of life, Safety

Health condition(s) or problem(s) studied
Prevention of computer vision syndrome and dry eye syndrome in workers using video display terminals

Interventions
Stratified randomization by center will be performed to assign clusters to the intervention or control group.
In the control group clusters, only the standard routine activities carried out by the Occupational Health Service (OHS) will be implemented. In the intervention group clusters, in addition to these usual activities, actions will be undertaken across the three levels of prevention (primary,

secondary, and tertiary), along with a health promotion component. In all cases, physical, anatomical, and physiological differences between men and women will be considered.

* Primary prevention actions:
- An ergonomic assessment of the workstation will be conducted, taking into account individual worker characteristics, habitual computer posture, and environmental conditions.
- Measurements will include the eye-to-screen distance and neck posture, assessed via direct observation. Two photographs will be taken: one from the sagittal plane while the participant is seated, and another from a perpendicular angle to the screen. Using Qcad Trial software version 3.19.2, the following angles will be calculated: the eye-to-screen angle (α), the viewing angle (α), and the screen tilt angle relative to the horizontal (β).
- Environmental conditions will also be evaluated. Dry temperature and relative humidity will be measured using a thermohygrometer (PCE-WB 20SD), and illuminance will be assessed using a luxmeter (ISO-TECH ILM 1337) at three different points within the workstation, with the average recorded. Additional assessments will include glare, screen reflections, localized lighting, and air conditioning status.
- Ergonomic and environmental adjustments will be made based on the standards set out in the Spanish Royal Decree 486/1997, Directive 90/270/EEC, the INSST guide (2021), and ISO 11226: 2000. When workstation setup is suboptimal, distances, angles, and heights will be modified. If ambient conditions (temperature, humidity, lighting, air velocity) are inadequate, technical adjustments will be made, such as regulating air conditioning, providing humidifiers, or adjusting lighting power.

* Secondary prevention actions:
- At the Optometry Clinic, initial screening (T0) will be conducted to detect CVS and/or DES, with follow-up assessments at 6 months (T1) and 12 months (T2).
- A multidisciplinary team of visual health professionals (ophthalmologists, optometrists, occupational physicians, and preventive medicine specialists) will perform comprehensive ocular and visual examinations.
- In addition to the standard vision checks included in occupational health surveillance for workers exposed to video display terminals (VDT), the examination will include objective and subjective refraction, ocular surface assessment (eyelids, conjunctiva, cornea), and tear film evaluation (production and quality).
- Two validated self-administered questionnaires will be used to evaluate CVS and DES symptoms: the Computer Vision Syndrome Questionnaire (CVS-Q©) (Seguí-Crespo et al., 2015) and the Ocular Surface Disease Index (OSDI©) (Schiffman et al., 2000), respectively. Based on the screening results and additional factors (comorbidities, ongoing treatments, optical correction, VDT exposure patterns such as duration and rest breaks), participants will be categorized into three risk levels:
- Low risk: Workers with no screening abnormalities, no comorbidities or treatments, and adequate VDT exposure (≤8 hours/day with regular breaks), even if uncorrected refractive errors are present.
- Moderate risk: Workers meeting low-risk criteria but not taking regular breaks.
- High risk: Workers meeting moderate-risk criteria but showing ocular surface or tear film alterations, with comorbidities, treatments, or exceeding the questionnaire thresholds.

* Tertiary prevention actions:
Based on risk classification, the following measures will be implemented:
- Low risk: Guidance on optical correction if required.
- Moderate risk: Optical correction guidance plus training on the 20-20-20 Rule using the free

mobile application Eyecare 20 20 20.
- High risk: All measures for moderate-risk individuals, plus prescription of blinking exercises and /or recommendation of lubricating eye drops.

* Health promotion actions:
The program includes several components aimed at providing comprehensive training on:
- Healthy lifestyle habits (physical activity, dietary supplementation, smoking cessation),
- and visual health factors associated with DES use (behavioral, hygienic, postural, and environmental recommendations).

These components are complementary and essential to enhancing workers' health and overall well-being.

Evaluation of the Intervention
1) Assessment of impact on visual health: The prevalence of CVS and DES will be measured using validated questionnaires and clinical tests described previously, both before the intervention (T0) and at two follow-up points (T1 and T2).

2) Process evaluation: Following widely used frameworks in the literature (Linnan & Steckler, 2002; Wierenga et al., 2012), the process evaluation will consider key indicators, including:
- Recruitment (methods used to engage participants in the program),
- Context (social and workplace factors that may influence implementation),
- Reach (number, proportion, and characteristics of participants),
- Dose delivered (quantity and nature of intervention components administered),
- Fidelity (quality and consistency of intervention implementation), - Satisfaction (participants' perceptions of the intervention upon its completion). Data for this component will be collected using qualitative methods (focus groups and/or semi-structured interviews) and a tailored ad hoc questionnaire.

3) Cost-effectiveness and cost-utility evaluation: Cost data will include:
- Implementation costs, documented by research staff records;
- Healthcare resource utilization associated with screen exposure (primary care, optometry, ophthalmology, and pharmacy);
- Other resources (e.g., humidifiers, lighting regulators, desk lamps);
- Productivity losses, including temporary disability, absenteeism, and presenteeism.
Effectiveness will be assessed using the CVS-Q© and OSDI© questionnaires. Health utility will be estimated using the EQ-5D-5L health-related quality of life questionnaire, administered at T0 and T2.

Intervention Type
Mixed

Primary outcome(s)
Prior to the intervention (T0) and at the established follow-up time points: T1 at 6 months and T2 at 12 months:
1. Variable "Prevalence of Computer Visual Syndrome (CVS)" assessed using the CVS-Q© questionnaire.
2. Variable "Prevalence of Dry Eye Syndrome (DES)" assessed using the the OSDI© questionnaire.

The presence of Computer Vision Syndrome (CVS) will be defined as a score of ≥6 on the CVS-Q© questionnaire. In accordance with the recommendations of the Dry Eye Workshop II of the Tear Film & Ocular Surface Society (TFOS DEWS II), the presence of DES will be defined as a score

of ≥13 on the Ocular Surface Disease Index (OSDI©), in combination with at least one abnormal result from ocular surface and/or tear film tests (Wolffsohn et al., 2017).

Key secondary outcome(s))
Prior to the intervention (T0) and at the established follow-up time points: T1 at 6 months and T2 at 12 months:
1. Process Evaluation Variables: the variables assessed will include recruitment, context, reach, dose delivered, fidelity, and satisfaction, as previously defined.
2. Cost-Effectiveness Variables: costs will be as described in the previous section. Effectiveness will be based on the prevalence outcomes of CVS and DES.
3. Cost-Utility Variables: costs will be as described in the previous section. Utility will be derived from the health-related quality of life outcomes (EQ-5D-5L).

Completion date
31/03/2029

Eligibility

Key inclusion criteria
Participants must have been working in the selected cluster (independent building) for at least the last year, hold a full-time contract, and be actively employed at the beginning of the study.

Participant type(s)
Employee, Health professional, Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Workers under 18 or over 70 years old;
2. Workers not currently employed in the selected cluster (independent building) for at least the past year;
3. Workers with part-time contracts;

4. Individuals who, although belonging to any of the intervention or control clusters, are not actively employed at the beginning of the study.
5. Individuals who do not consent to sign the informed consent document.

Date of first enrolment
01/04/2026

Date of final enrolment
30/10/2026

Locations

Countries of recruitment
Spain

Study participating centre
University Hospital del Mar
Passeig Marítim de la Barceloneta, 25-29
Barcelona
Spain
08003

Study participating centre
University of Alicante
Campus Universitario, Carretera de San Vicente del Raspeig, s/n,
San Vicente del Raspeig, Alicante.
Spain
03690

Sponsor information

Organisation
University Pompeu Fabra

Funder(s)

Funder type
Government

Funder Name

Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository, and will be available upon request from Professor Dr. JM Ramada (jramada@hmar.cat).
As a multicenter study with shared objectives and methodology, and requiring joint analysis of the data collected at the two participating institutions (Hospital del Mar [HMar] and the University of Alicante [UA]), the ownership of the aggregated data will be shared by the researchers from both centers.

Data collected during the different phases of the intervention will be stored in dedicated databases: data from HMar will be stored in a secure repository at Universitat Pompeu Fabra (UPF), while data from UA will be stored in a secure repository at the University of Alicante. Aggregated data from both centers will be archived in the repositories of both universities.

At HMar, the project will be supported by the Information Technology Services (SIT) of the Department of Medicine and Life Sciences (MELIS) at UPF, which has extensive experience in managing and protecting sensitive data. SIT will manage the databases using a SQL system and will oversee the handling of initial and follow-up questionnaire data collected through online survey platforms such as QuestionPro, Qualtrics, or similar tools.

At UA, the project will be supported by the University's Information Services (SI), which will provide technical and logistical support for data storage, drawing on its experience in the secure management of sensitive research data. The SI will be responsible for the administration of data from questionnaires and visual assessments, both at baseline and during follow-up, also collected via platforms such as QuestionPro, Qualtrics, or similar. Additionally, UA has a dedicated Data Protection Office that will supervise the research-related processing of data to ensure compliance with applicable regulations.

The data collected in this study will be classified into two categories. A minimal portion will consist of personal information, limited to participants' contact details (phone number and/or email), which will be encrypted to ensure security. All other data will be pseudonymized using

randomly generated identifiers, making direct identification of individuals impossible. Access to personal data will be restricted to the research team, while non-personal data, once processed for analysis, may be made available upon reasonable request in accordance with FAIR principles—ensuring that data and metadata are findable, accessible, interoperable, and reusable.

All data processing will comply with the provisions of the General Data Protection Regulation (EU Regulation 2016/679) and the Spanish Organic Law 3/2018. Written informed consent will be obtained from all participants prior to any data collection.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			20/05/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes