ISRCTN10265538 https://doi.org/10.1186/ISRCTN10265538

Testing a workplace program to prevent computer vision syndrome (CVS) and dry eye syndrome (DES) in computer users

Submission date 16/05/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 20/05/2025	**Overall study status** Ongoing	
Last Edited 17/11/2026	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

The INTERVIS study aims to prevent and reduce two common eye problems associated with prolonged screen use at work: Computer Vision Syndrome (CVS) and Dry Eye Syndrome (DES). These conditions can cause symptoms such as eye strain, dryness, blurred vision, and headaches, and are common among workers who regularly use computers and other screen-based devices. The study will evaluate whether a comprehensive workplace intervention can reduce the frequency of CVS and DES, improve workers' visual and ocular health and quality of life, and provide good value for the resources required to implement it.

Who can participate?

Employees aged 18–70 years who use video display terminals (VDTs) for at least four hours per workday. Participants must work full time, have worked in the selected work unit for at least one year, be actively employed when the study begins, and provide written informed consent.

What does the study involve?

Work units, rather than individual participants, will be randomly assigned to either the intervention group or the control group. Participants in the control group will continue to receive usual occupational health care.

The intervention will combine several preventive measures, including:
Assessment and improvement of workstation ergonomics, lighting, temperature, and humidity; education on healthy lifestyle and visual habits, including physical activity, diet, appropriate use of dietary supplements, smoking cessation, regular screen breaks, and blinking; optometric and ophthalmological screening to identify CVS, DES, and other visual or ocular problems at an early stage; and individualized recommendations based on each participant's screening results and risk profile, which may include optical correction, training in the 20-20-20 rule, blinking exercises, or lubricating eye drops when clinically appropriate.

Participants will be followed for three months and will complete questionnaires and undergo visual and ocular assessments at the beginning of the study (T0) and after three months (T1), at

the end of the intervention and follow-up period. Quality of life and information on healthcare use and sickness absence will also be collected at both time points to assess the costs and benefits of the intervention.

What are the possible benefits and risks of participating?
Participants may benefit from early identification of visual or ocular problems and from recommendations aimed at improving visual comfort and workplace conditions. However, individual benefit cannot be guaranteed. The study procedures are considered low risk. Some participants may experience minor inconvenience or temporary discomfort during eye examinations or may find the questionnaires and study visits time-consuming.

Where is the study run from?
The study is being conducted 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?
January 2027 to July 2027.

Who is funding the study?
The study is supported through existing institutional resources, facilities, infrastructure and professional time provided by the participating institutions. No specific external or internal financial grant has been awarded to fund the study, and no dedicated funding has been provided for publication costs.

Who is the main contact?
Prof. Dr José María Ramada Rodilla, jose.ramada@upf.edu, jramada@hmar.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

Hospital del Mar Clinical Research Ethics Committee Reference Number
2025/12090/I

Protocol serial number
PI25/00032

Study information

Scientific Title
Workplace intervention to prevent computer vision syndrome and dry eye syndrome in video display terminal workers (INTERVIS): protocol for a multicentre cluster-randomised controlled trial

Acronym
INTERVIS cluster-randomised trial protocol

Study objectives

Current study objectives as of 11/11/2026:
In accordance with the SPIRIT 2025 recommendations for the reporting of randomized trial protocols, the main pre-specified objectives of the INTERVIS study are:
1. To evaluate the effectiveness of the INTERVIS multicomponent workplace intervention, compared with usual occupational health care, in reducing the prevalence of Computer Vision Syndrome (CVS) and Dry Eye Syndrome (DES) among workers exposed to video display terminals (VDTs), with CVS and DES prevalence at three months as the co-primary outcomes.
2. To assess differences in the prevalence of CVS and DES between women and men and to evaluate whether sex modifies the effect of the intervention on these outcomes.
3. To evaluate the implementation of the INTERVIS intervention through a comprehensive process evaluation assessing recruitment, context, reach, dose delivered, dose received, intervention fidelity, participant adherence, participant satisfaction, and potential contamination.
4. To assess the cost-effectiveness and cost-utility of the INTERVIS intervention compared with usual occupational health care over the three-month study period, from both the National Health System and societal perspectives, using incremental cost per case of CVS and DES prevented and incremental cost per quality-adjusted life year (QALY) gained.

———

Previous study objectives as of 28/08/2026:

In accordance with the SPIRIT 2025 recommendations for the reporting of randomized trial protocols, the main prespecified objectives of the INTERVIS study are:
1. To evaluate the effectiveness of the INTERVIS multicomponent workplace intervention, compared with usual occupational health care, in reducing the prevalence of Computer Vision Syndrome (CVS) and Dry Eye Syndrome (DES) among workers exposed to video display terminals (VDTs), with CVS and DES prevalence at 12 months as the co-primary outcomes
2. To assess differences in the prevalence of CVS and DES between women and men and to evaluate whether sex modifies the effect of the intervention on these outcomes
3. To evaluate the implementation of the INTERVIS intervention through a comprehensive process evaluation assessing recruitment, context, reach, dose delivered, dose received, intervention fidelity, participant adherence, and participant satisfaction
4. To assess the cost-effectiveness and cost-utility of the INTERVIS intervention compared with usual occupational health care over the 12-month study period, from both the National Health System and societal perspectives, using incremental cost per case of CVS and DES prevented and incremental cost per quality-adjusted life year (QALY) gained

———

Previous 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

Primary study design
Interventional

Study design
Multicenter cluster randomized controlled trial with blinded data analysis

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
Current interventions as of 11/11/2026:
Stratified cluster randomization by study site will be performed to allocate clusters to either the intervention or usual-care control group. Participants in both groups will continue to receive standard occupational health care provided by the Occupational Health Service (OHS).

In the intervention clusters, participants will additionally receive the INTERVIS multicomponent intervention over a three-month period, comprising primary, secondary, and tertiary prevention with individualized risk-based management.

Primary prevention will include ergonomic and environmental workstation assessment and adaptation, together with health-promotion activities addressing healthy lifestyle habits, visual breaks, blinking, workstation ergonomics, lighting, temperature, and humidity.

Secondary prevention will consist of visual and ocular assessments at baseline (T0) and three months (T1), with no intermediate clinical assessments.

Assessments will include refraction, visual acuity, ocular surface examination, automated non-invasive tear break-up time (NIBUT), corneal fluorescein staining, CVS-Q©, and OSDI-6©.

In intervention clusters, baseline findings will be used to classify participants as low, medium, or high risk according to ocular clinical status and three modifiable factors: visual-break behavior, adequacy of corrective lenses, and ergonomic/environmental conditions.

Tertiary prevention and individualized management will include recommendations on visual breaks, blinking exercises, artificial tears, review and updating of corrective lenses where appropriate, and personalized ergonomic/environmental adjustments according to risk category. Participants in control clusters will continue to receive usual occupational health care. The full intervention will be offered to control clusters after study completion if the study hypotheses are confirmed.

Previous interventions as of 28/08/2026:

Stratified cluster randomization by study site will be performed to allocate clusters to either the intervention or usual-care control group. Participants in both groups will continue to receive standard occupational health care provided by the Occupational Health Service (OHS). In the intervention clusters, participants will additionally receive the INTERVIS multicomponent intervention over a 12-month period, comprising primary prevention, secondary prevention, and tertiary prevention with individualized risk-based management. All intervention components will take into account relevant sex-related anatomical and physiological differences.

Primary prevention actions

Primary prevention will encompass both the control of occupational risk factors and health promotion strategies.

A comprehensive ergonomic assessment will be conducted at each workstation, taking into account individual worker characteristics, usual computer-working posture, and environmental conditions.
Eye-to-screen distance and cervical posture will be assessed. Two standardized photographs will be obtained for each seated participant: one in the sagittal plane and one perpendicular to the screen. The eye-screen angle (α), viewing angle (α), and screen tilt angle (β) will be calculated using QCAD Trial version 3.19.2.
Environmental conditions will be assessed by measuring dry temperature and relative humidity using a PCE-WB 20SD thermo-hygrometer and illumination levels at three positions within the workstation using an ISO-TECH ILM 1337 luxmeter. Glare, screen reflections, task lighting, and air-conditioning performance will also be evaluated.
When workstation or environmental conditions are identified as suboptimal, appropriate technical modifications will be implemented in accordance with Spanish Royal Decrees 486/1997 and 488/1997, EU Directive 90/270/EEC, guidance from the Spanish National Institute for Safety and Health at Work (INSST), and ISO 11226:2000. These adaptations may include adjustments to

viewing distance, screen tilt and height, lighting intensity, and relative humidity.
Health promotion activities will comprise comprehensive training in healthy lifestyle behaviors and targeted education on visual ergonomics and ocular health during VDT use. Healthy lifestyle education will address outdoor physical activity, a healthy diet rich in vegetables, fish, antioxidants, omega-3 fatty acids, and carotenoids, evidence-based information on the potential role and appropriate use of dietary supplements for visual and ocular health, and support for smoking cessation. No dietary supplements will be provided as part of the intervention.
Education on visual ergonomics and ocular health will emphasize regular breaks during VDT use, complete and frequent blinking, ergonomic workstation design, and optimization of lighting, temperature, and humidity. These activities will be delivered through synchronous online training sessions and structured in-person workshops.

Secondary prevention actions

A tailored screening program will be implemented for the early identification of Computer Vision Syndrome (CVS), Dry Eye Syndrome (DES), refractive problems, and ocular surface or tear-film abnormalities. Assessments will be conducted at baseline (T0), 6 months (T1), and 12 months (T2).
Examinations will be performed by qualified visual health professionals, including ophthalmologists, optometrists, occupational physicians, and preventive medicine specialists.
In addition to routine visual examinations included in occupational health surveillance for workers exposed to video display terminals (VDTs), assessments will include objective and subjective refraction, examination of ocular surface structures (eyelids, conjunctiva, and cornea), and evaluation of tear-film quantity and quality.
Visual symptoms will be assessed using two validated self-administered questionnaires: the Computer Vision Syndrome Questionnaire (CVS-Q©) for CVS and the Ocular Surface Disease Index (OSDI©) for DES.
Based on screening findings and relevant individual and occupational factors, including comorbidities, current treatments, optical correction status, and VDT exposure patterns, participants will be stratified into three mutually exclusive risk categories. Participants with no ocular surface or tear-film abnormalities, no relevant comorbidities or ongoing treatments, questionnaire scores below the established cut-off values, no uncorrected refractive error, and adequate VDT exposure, defined as no more than eight hours per day with regular breaks, will be classified as low risk. Participants with an uncorrected refractive error and/or potentially unfavorable VDT exposure patterns, defined as more than eight hours of VDT use per day and /or insufficient or irregular breaks, but without ocular surface or tear-film abnormalities, relevant comorbidities or ongoing treatments, or questionnaire scores exceeding the established cut-off values, will be classified as medium risk. Participants presenting at least one ocular surface or tear-film abnormality, a relevant comorbidity or ongoing treatment, or questionnaire scores exceeding the established cut-off values will be classified as high risk, irrespective of refractive status, VDT exposure duration, or break patterns.

Tertiary prevention and individualized risk-based management

Interventions will be tailored according to the risk stratification and findings obtained during screening. Participants for whom optical correction is clinically indicated will receive appropriate refractive management. Participants with modifiable VDT-related behavioral risk factors will receive structured training on the 20-20-20 rule (every 20 minutes, focusing on an object at least 20 feet away for a minimum of 20 seconds), supported by the freely available Eyecare 20-20-20 application. Participants with ocular surface or tear-film abnormalities, relevant symptoms, or other clinical indications will additionally receive prescribed blinking exercises and/or lubricating ophthalmic drops, as appropriate.

These individualized measures will complement the primary and secondary prevention components and provide risk-based management according to each participant's clinical and occupational profile.

Usual occupational health care

Throughout the 12-month study period, OHS at each participating site will continue to provide standard occupational health care to participants in both intervention and control clusters. This will include occupational risk assessment, investigation and management of work-related injuries, health surveillance, smoking cessation programs, structured training, occupational health information, and return-to-work support where appropriate.

Evaluation of the intervention

1) Visual and ocular health outcomes

The co-primary outcomes will be the prevalence of CVS and DES at 12 months. Outcomes will also be assessed at baseline (T0) and 6 months (T1). CVS will be defined as a CVS-Q© score of 6 or higher. DES will be defined as an OSDI© score of 13 or higher in combination with at least one abnormal ocular surface and/or tear-film test result.

2) Process evaluation

The process evaluation will assess recruitment, context, reach, dose delivered, dose received, intervention fidelity, participant adherence, and participant satisfaction. Recruitment will describe the strategies and procedures used to approach, attract, and enroll eligible workers. Reach will describe the extent to which enrolled participants are exposed to the intervention and its individual components. Dose delivered and dose received will assess the amount of intervention provided and participant engagement, respectively. Intervention fidelity will assess consistency with the planned intervention, while participant adherence will reflect attendance relative to the intervention dose delivered. Satisfaction will assess participants' perceptions of the intervention. Data will be collected using structured questionnaires, researcher-maintained records, and focus groups. Qualitative data obtained from focus groups will be analyzed using thematic analysis.

3) Cost-effectiveness and cost-utility evaluation

Cost-effectiveness and cost-utility analyses will be conducted from both the National Health System and societal perspectives over a 12-month time horizon. All costs will be expressed in 2026 euros (€). Costs will include healthcare resource utilization, intervention implementation costs, and resources required to implement workplace adaptations. From the societal perspective, productivity losses will be considered as indirect costs and estimated using the human capital approach based on sick leave data reported by participants.

Effectiveness will be assessed separately for CVS and DES. Health utilities will be derived from the EQ-5D-3L using the Spanish value set, with measurements obtained at baseline (T0), 6 months (T1), and 12 months (T2). Quality-adjusted life years (QALYs) will be calculated using the area-under-the-curve method. Separate incremental cost-effectiveness ratios will be estimated for CVS and DES, expressed as the incremental cost per case of CVS prevented and the incremental cost per case of DES prevented, respectively. Cost-utility will be expressed as the incremental cost per QALY gained.

_____

Previous 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)

Current primary outcome(s) as of 11/11/2026:
1. Prevalence of Computer Vision Syndrome (CVS) at three months. CVS will be assessed using the validated Computer Vision Syndrome Questionnaire (CVS-Q©). A participant will be classified as having CVS when the total CVS-Q© score is ≥6. CVS will be assessed at baseline (T0) and three months (T1), with the three-month assessment representing the co-primary endpoint.
2. Prevalence of Dry Eye Syndrome (DES) at three months. DES will be defined as an OSDI-6© score ≥4 in combination with a first non-invasive tear break-up time (NIBUT) <10 seconds and/or >5 corneal fluorescein punctate spots. An objective marker will be considered positive if the threshold is met in at least one eye. DES will be assessed at baseline (T0) and three months (T1), with the three-month assessment representing the co-primary endpoint.

_____

Previous primary outcome(s) as of 28/08/2026:

1. Prevalence of Computer Vision Syndrome (CVS) at 12 months.
CVS will be assessed using the validated Computer Vision Syndrome Questionnaire (CVS-Q©). A participant will be classified as having CVS when the total CVS-Q© score is ≥6. CVS will be assessed at baseline (T0), 6 months (T1), and 12 months (T2), with the 12-month assessment representing the co-primary endpoint
2. Prevalence of Dry Eye Syndrome (DES) at 12 months.
DES will be assessed using the validated Ocular Surface Disease Index (OSDI©) together with clinical assessment of the ocular surface and tear film. DES will be defined as an OSDI© score ≥13 in combination with at least one abnormal ocular surface and/or tear-film test result. DES will be assessed at baseline (T0), 6 months (T1), and 12 months (T2), with the 12-month assessment representing the co-primary endpoint

_____

Previous 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)

Current secondary outcome(s) as of 11/11/2026:
1. Process evaluation outcomes:
Implementation of the INTERVIS intervention will be evaluated through recruitment, context, reach, dose delivered, dose received, intervention fidelity, participant adherence, participant satisfaction, and potential contamination. Quantitative indicators will be complemented by qualitative information obtained through focus groups. Process indicators will be collected during the three-month intervention period, as appropriate for each intervention component.
2. Health-related quality of life and quality-adjusted life years (QALYs):

Health-related quality of life will be assessed using the EQ-5D-3L at baseline (T0) and three months (T1). Utility values will be derived using the Spanish value set, and QALYs over the three-month study period will be estimated using the area-under-the-curve method.
3. Cost-effectiveness outcomes:
Costs will be assessed over the three-month study period from the National Health System and societal perspectives. Separate incremental cost-effectiveness ratios (ICERs) will be estimated for CVS and DES and expressed as the incremental cost per case of CVS prevented and the incremental cost per case of DES prevented, respectively.
4. Cost-utility outcome: Cost-utility will be assessed over the three-month study period by estimating the incremental cost per quality-adjusted life year (QALY) gained, comparing the INTERVIS intervention with usual occupational health care from both the National Health System and societal perspectives.

_____

Previous key secondary outcome(s) as of 28/08/2026:

Process evaluation outcomes:
1. Implementation of the INTERVIS intervention will be evaluated through recruitment, context, reach, dose delivered, dose received, intervention fidelity, participant adherence, and participant satisfaction. Quantitative indicators will be complemented by qualitative information obtained through focus groups. Process indicators will be collected throughout the 12-month intervention period, as appropriate for each intervention component
2. Health-related quality of life and quality-adjusted life years (QALYs): Health-related quality of life will be assessed using the EQ-5D-3L at baseline (T0), 6 months (T1), and 12 months (T2). Utility values will be derived using the Spanish value set, and QALYs over the 12-month study period will be estimated using the area-under-the-curve method

Cost-effectiveness outcomes:
3. Costs will be assessed over the 12-month study period from the National Health System and societal perspectives. Separate incremental cost-effectiveness ratios (ICERs) will be estimated for CVS and DES and expressed as the incremental cost per case of CVS prevented and the incremental cost per case of DES prevented, respectively

Cost-utility outcome:
4. Cost-utility will be assessed over the 12-month study period by estimating the incremental cost per quality-adjusted life year (QALY) gained, comparing the INTERVIS intervention with usual occupational health care from both the National Health System and societal perspectives

_____

Previous 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
11/07/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 11/11/2026:

Selected clusters will consist of independent work units, defined as either a standalone building or a clearly delineated work area within a large building. Eligible participants must be aged 18–70 years, hold a full-time employment contract, have worked in the selected cluster for at least one year, be actively employed at study initiation, and have occupational exposure to video display terminals (VDTs) for at least four hours per workday.

———

Previous key inclusion criteria as of 28/08/2026:

Selected clusters will consist of independent work units, defined as either a standalone building or a clearly delineated work area located on a separate floor within the same building. Eligible participants must be aged 18–70 years, hold a full-time employment contract, have worked in the selected cluster for at least one year, be actively employed at study initiation, and have occupational exposure to video display terminals (VDTs) for at least four hours per workday.

———

Previous 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
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

Current key exclusion criteria as of 11/11/2026:

1. History of ocular surgery or ocular procedures that may substantially affect the ocular surface, tear film, or visual function
2. Presence of an ocular disease or condition, other than CVS or DES, that may substantially interfere with the assessment of the study outcomes (e.g., amblyopia or clinically significant cataract)
3. Presence of a systemic disease known to substantially affect the ocular surface or tear production, including relevant autoimmune or connective tissue disorders
4. Current use of systemic or topical medications known to substantially affect tear production, tear-film stability, or ocular surface status
5. Any other ophthalmological, systemic, or neurological condition that, in the investigators' clinical judgment, could substantially interfere with the assessment of CVS or DES or act as a major confounding factor

_____

Previous key exclusion criteria as of 28/08/2026:

1. History of ocular surgery or ocular procedures that may substantially affect the ocular surface, tear film, or visual function
2. Presence of active ocular disease, other than CVS or DES, that may interfere with the assessment of visual or ocular outcomes
3. Presence of systemic diseases known to substantially affect the ocular surface or tear production, including autoimmune or connective tissue diseases such as Sjögren's syndrome
4. Current use of systemic or topical medications known to substantially affect tear production, tear-film stability, or ocular surface status
5. Any other ophthalmological, systemic, or neurological condition that, in the investigators' clinical judgment, could substantially interfere with the assessment of CVS or DES or act as a major confounding factor
6. Inability to complete the study questionnaires or undergo the scheduled optometric and ophthalmological examinations
7. Failure to provide written informed consent

_____

Previous 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

11/01/2027

Date of final enrolment

11/04/2027

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
Universitat Pompeu Fabra

ROR
https://ror.org/04n0g0b29

Organisation
University of Alicante

ROR
https://ror.org/05t8bcz72

Funder(s)

Funder type
Government

Funder Name
Institut Hospital del Mar d'Investigacions Mèdiques

Alternative Name(s)
Hospital Del Mar Medical Research Institute, Instituto de investigaciones médicas Hospital del Mar, IMIM

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
Spain

Funder Name
Universidad de Alicante

Alternative Name(s)
University of Alicante, Universitat d'Alacant

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
Current Individual participant data (IPD) sharing plan as of 11/11/2026:
The datasets generated and/or analyzed during the study will be stored in non-publicly available secure repositories and will be available upon reasonable request. Requests for access to the study data should be addressed to the corresponding author, José María Ramada Rodilla (jose.ramada@upf.edu), subject to participant confidentiality, applicable data-protection regulations, and any necessary institutional or ethics approvals.

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 baseline 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 at baseline and 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.

A minimal portion of the data 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 coded identifiers, preventing direct identification of participants. Access to personal data will be restricted to authorized members of the research team. De-identified participant data and related analysis materials may be made available upon reasonable request following completion of the trial, in accordance with applicable data-protection requirements and subject to any necessary institutional or ethics approvals.

All data processing will comply with 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 enrollment and data collection.

Previous IPD sharing plan:
The datasets generated and/or analyzed during the study will be stored in non-publicly available secure repositories and will be available upon reasonable request. Requests for access to the study data should be addressed either to the corresponding author, Begoña Domenech-Amigot (b.domenech@ua.es), or to the first author José María Ramada Rodilla (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