


BMJ Open Analysis of the determinants of sleep quality in a Spanish population: a study protocol for a cross-sectional study

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ABSTRACT

Introduction Sleep problems are a growing public health concern being related, among others, to an increased risk of cardiovascular diseases or worse cognitive functioning. In addition, they can affect aspects related to personal motivation and quality of life. However, very few studies have analysed the possible determinants of sleep quality in the adult population as a whole, establishing patterns based on these determinants.

The objectives are to evaluate the determinants of sleep quality in a representative sample of the general adult population between 25 and 65 years old, and to establish patterns of sleep quality based on lifestyles, psychological factors, morbidities, sociodemographic variables, biological markers and other possible determinants.

Methods and analysis Descriptive observational cross-sectional study. The study population will include a representative sample of 500 people between 25 and 65 years old from the cities of Salamanca and Ávila (Spain) selected by random sampling stratified by age groups and sex. A 90-minute visit will be performed, during which sleep quality will be assessed. The variables collected will be: morbidity, lifestyles (physical activity, diet, toxic habits), psychological factors (depression, stress, occupational stress and anxiety), socioeconomic and work-related variables, habitability conditions of the habitual residence and rest area, screen time, relaxation techniques and melatonin as a biological marker related to sleep quality.

Discussion With the results of this work, improved interventions for behaviour modification could be designed, as well as intervention and education programmes or other research aimed at improving sleep quality.

Ethics and dissemination This study has a favourable opinion from the Ethics Committee for Drug Research of the Health Areas of Salamanca and Ávila (CEIm Code: PI 2021 07 815). The results of this study will be published in international impact journals of different specialties.

Trial registration number NCT05324267.

BACKGROUND

Importance of sleep quality and sleep habits in the Spanish population

Sleep problems are a growing concern for public health, being related, among others, to an increased risk of cardiovascular diseases¹

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The main strength of this work is the sampling method with a random selection of participants that guarantees a strong representativeness of the study population.
- ⇒ Another strength is the inclusion within the research team of professionals from different clinical specialties, which results in a more holistic approach to the study question.
- ⇒ The main limitation of the study is its design as a cross-sectional study, which prevents the establishment of causal relationships between the determinants studied and sleep quality.

or worse cognitive functioning,² in addition to their possible impact on aspects related to personal motivation and quality of life.³

A recent meta-analysis has shown a U-shaped association between an inadequate amount of sleep and all-cause and cardiovascular mortality, with those individuals having less and greater amounts of sleep (<6 hours and >8 hours, respectively) and those with the worst mortality ratios.⁴ However, sleep duration alone does not reflect neurophysiological aspects such as sleep quality, continuity and depth,⁵ which could have a very relevant importance in terms of health. For example, sleep irregularity, difficulty initiating or maintaining sleep, and the presence of non-refreshing sleep are associated with an increased risk of mortality, regardless of duration.^{6,7}

The sleep patterns of the Spanish population show that 80% sleep at least 7 hours a day⁸ with a lower sleep latency than in other neighbouring countries and significantly longer total sleep duration. In addition, only 12% admit to having irregular sleep schedules, three times less than in countries such as Italy, Germany or the UK,^{9,10} sleeping better than expected and with fewer symptoms of

insomnia than in other countries.¹¹ Some cultural factors regarding the attitude towards sleep could, in part, explain the differences objectified, such as longer working hours, a greater nightlife and different lunch and dinner times than those of the rest of European countries.

Sleep quality assessment devices and methods

Current sleep assessment methods have been classified into objective methods (polysomnography and actigraphy) and subjective methods (sleep questionnaires and diaries). A recent systematic review¹² has established an order based on the accuracy of these sleep assessment methods: questionnaire<sleep diary<non-contact devices<contact devices<polysomnography. Current subjective methods have a sensitivity between 73% and 97.7%, while their specificity is in the range of 50%–96%. Objective methods such as actigraphy have a sensitivity greater than 90%. However, its specificity is lower in comparison, being one of the limitations of this type of technology. In addition, there are other factors, such as the patient's perception of their sleep, which can only be provided by subjective methods. Therefore, sleep assessment procedures should combine objective and subjective methods. However, very few epidemiological studies include both methods. The difficulty of access to polysomnography and the proliferation in recent years of different actigraphy devices, at a much lower cost, make their inclusion in research work more realistic.

Lifestyles and sleep quality

Dietary habits are considered one of the main behavioural risk factors for human health. There is mounting scientific evidence suggesting that diet and sleep may be related. The consumption of healthy foods has been associated with better sleep quality, while a higher intake of processed foods rich in free sugars has been related to worse sleep characteristics.¹³ However, less attention has been paid to the effects of dietary patterns and specific foods on night-time sleep.¹⁴ Among the dietary patterns, the most studied has been the Mediterranean Diet, so that a high score on the adherence scales has been associated with a better sleep quality, either through a direct effect on health or through indirect effects via weight reduction.¹³ Other works suggest a potential effect of macronutrient intake on sleep variables, in particular on changes in slow waves and the rapid eye movement phase through changes in carbohydrate and fat intake.^{15 16} Finally, some studies have evaluated the intake of specific foods consumed at a given time in relation to sleep quality. Milk consumed at night, before going to bed, has shown a significant improvement in sleep quality.^{17 18} Specifically, the higher concentrations of tryptophan and melatonin could be the main responsible for the stimulating effect of drinking milk at night on sleep.¹⁹ In another study, it was reported that the consumption of fatty fish induced the presence of higher concentrations of vitamin D and omega-3 fatty acids (eicosapentaenoic acid and docosahexaenoic acid), which could partially mediate the

differences reported in relation to sleep quality versus a control group.²⁰ Among fruits, the consumption of two kiwis/day, 1 hour before bedtime for 4 weeks, significantly increased total sleep time and sleep efficiency measured by actigraphy in a sample of adults with sleep disorders,²¹ constituting its high concentration of serotonin a possible mechanism for promoting sleep.

Another behaviour related to lifestyles that has been linked to sleep quality has been physical activity. Two studies carried out on young people associated insufficient physical activity with poorer sleep quality, higher latency, as well as shorter sleep duration and efficiency, and greater use of sleep medication.^{22 23} Another work conducted in a cohort of 7706 Danish working adults found that people with more sleep problems reported less high-intensity physical activity in leisure time. Specifically, the weekly duration of high-intensity physical activity in free time was 139 (95% CI 111–168), 129 (95% CI 101–158) and 122 min (95% CI 92–151) in sedentary workers with sleep problems <1, 1–3 and ≥3 days per week, respectively.²⁴ On the other hand, within our field, it has been reported that completing a greater daily total number of steps, aerobic steps and energy expended when walking could be correlated with less insomnia.²⁵

The relationship between smoking and sleep quality has also been addressed, although to a lesser extent than the two previous behaviours. A relationship has been established between a greater number of sleep disorders and higher doses of nicotine in cigarettes.²⁶ Additionally, better sleep quality may be associated with lower levels of abstinence, craving and urges to smoke.²⁷ Another much less studied aspect, especially in young people, is the relationship between sleep problems and addictions to other toxic substances. It is known that cocaine can seriously alter the sleep pattern of its users, affecting sleep maintenance, causing its fragmentation and altering its architecture.^{28 29} For its part, marijuana use has been associated with a decrease in sleep quality in women.³⁰

Finally, higher alcohol consumption was associated with poorer sleep quality and greater odds of snoring, as well as shorter sleep duration.³¹

Psychological disorders and sleep quality

A remarkable relationship has been shown between sleep quality and perceived stress,³² especially perceived stress in the workplace. Concerns and/or conflicts within the workplace have been associated with difficulty in initiating sleep and with the presence of unrefreshing sleep,³³ with those jobs that involve performing repetitive tasks being associated with a greater number of days with difficulty initiating and maintaining sleep. Among the different occupations, those where it is more frequent to find situations of high perceived stress, such as police or security forces, stand out. In a sample of police officers, the prevalence of poor sleep quality increased as levels of perceived stress increased.³⁴ However, as a result of the recent COVID-19 pandemic, it is the health professions that have required greater attention due to sleep quality

disorders.³⁵ In addition to the situations of healthcare or specific situations with a high level of stress such as the COVID-19 pandemic, other aspects such as doctor-patient relationships, the psychosomatic state or the environment could also have a decisive influence on sleep quality.³⁶ Inclusion in specific stress management and coping skills programmes could be useful to improve sleep quality in certain population groups.³⁷ On the other hand, among those with poor sleep quality, the proportion of depressive symptoms is higher.³⁸

Comorbidities and sleep quality

There is no doubt that the sleep quality is closely related to the associated comorbidities that people present. In a cross-sectional survey of rural Japanese population that included 3403 people (mean age: 51.0 years, 52.6% women), the Pittsburgh Sleep Quality Index (PSQI) total score increased as the number of morbidities of each individual increased in a linear manner ($p < 0.001$). The overall PSQI score increased by 0.374 for each additional condition,³⁸ with cerebrovascular disease having the worst ratios in relation to sleep quality. Relationships between sleep disorders and the presence of other processes such as cancer,³⁹ fibromyalgia,⁴⁰ kidney transplant,⁴¹ gastro-oesophageal reflux,⁴² HIV infection⁴³ or back pain⁴⁴ have been independently reported. In older populations, nocturnal polyuria is relatively common and can lead to serious sleep disturbances, partly due to the need to get up to urinate, but also with greater difficulty falling asleep after nocturnal awakenings and increased morning sleepiness.⁴⁵

Other determinants of sleep quality

There are many other determinants related to sleep health. A difference in sleep quality is described based on some socioeconomic or intrinsic factors of the same person.⁴⁶ For example, in a comparison of some populations, Caucasian women had the best sleep latency components, while black men had the worst.⁴⁷ In an American population sample, women were twice as likely to have insomnia as men (OR=1.6, 95% CI: 1.1, 2.4; $p=0.01$).⁴⁸ The place or neighbourhood of residence is also relevant, since insomnia has been associated with living in more disadvantaged places, with more violence or with more noise.⁴⁹ Internet and online gaming addiction has also been associated with sleep problems, especially in adolescents,^{50 51} while screen time appears to be a determinant of sleep quality in adults.⁵² On the other hand, among the biological markers that have been related to the quality of sleep, we find cortisol, melatonin or vitamin D.^{53 54}

Justification for the study

The Spanish population has suffered a terrible economic crisis in the last decade, together with the health emergency of the recent COVID-19 pandemic and other factors of an economic and social nature, which have shaken the health of our population in a way that has not yet been sufficiently evaluated. To all, this has been added

a progressive deterioration of eating habits, greater physical inactivity and an increasingly ageing population. The latter increases morbidity and the appearance of pathologies such as cancer, cardiovascular diseases, depressive disorders and anxiety.

On the other hand, a society that is increasingly aware of social networks, in continuous connection to screens and the recent increase in teleworking can decisively influence the quality of sleep. These and other undetermined factors such as the recent lockdown and the restrictions generated by the pandemic, the habitability conditions of the home and social relations could decisively influence our sleep health.

For all these reasons, an in-depth study of the determinants of sleep in our population is especially relevant. As far as we know, it would be the first study that addresses all these variables in a large sample of the adult population, being able to identify those that have a greater weight in our quality of sleep, using objective and subjective methods to measure it.

The objectives of this manuscript are to present the study protocol of a cross-sectional study whose main objective is to evaluate the determinants of sleep quality in a representative sample of the general Spanish adult population, between 25 and 65 years old, and to establish patterns of sleep quality based on lifestyles, psychological factors, morbidities, sociodemographic variables, biological markers and other possible determinants.

METHODS/DESIGN

Design

This is a study protocol of a cross-sectional observational descriptive study. The study was registered in ClinicalTrials.gov (NCT05324267); date of trial registration: 12 April 2022.

Participants

The study population will include a sample of 500 people between 25 and 65 years old from the cities of Salamanca and Ávila (Spain).

Inclusion criteria

People who at the time of sampling are 25, 35, 45, 55 or 65 years old, assigned to the Health Service of Castilla y León, Spain (SACYL), residents of the cities of Salamanca or Ávila, who agree to participate in the study and do not meet any of the exclusion criteria.

Exclusion criteria

Subjects who are in a terminal situation or who cannot travel to health centres to perform the corresponding examinations, as well as women who are pregnant at the time of inclusion in the study, will be excluded.

Sample size calculation

An estimate of the sample size has been made based on the estimated score on the PSQI. The estimates made in the study by Gomez-Garcia *et al* in a sample of Spanish nurses

have been taken into account, with a mean PSQI score of 6.8 points and an SD of 3.38.⁵⁵ With these premises, a random sample of 500 individuals is sufficient to estimate, with a confidence of 95% and a precision of ± 0.32 points, the population mean of values that are expected to have an SD of around 3.38 points. The percentage of loss to follow-up is expected to be 15%.

Recruitment

Through random sampling stratified by age groups and sex, 500 people will be selected. To obtain this sample, we will work with the SACYL health card database. It is planned to cover through replacement those people who do not wish to participate or whose contact is impossible, in such a way that 100 individuals (50 women and 50 men) will be selected from each of the age groups (25, 35, 45, 55 and 65 years).

The status

Participant recruitment began on 1 June 2022. Participant evaluations are scheduled to be completed in October 2023.

Study variables

Sleep assessment

Accelerometry sleep assessment (Actigraph)

This system continuously captures accurate and reliable information about sleep/wake, circadian rhythms, and physical activity, providing detailed sleep/wake reports and graphs, and calculating sleep statistics, such as sleep onset, latency, quantity, and efficiency using several validated scoring algorithms. The Actigraph system uses an accelerometer worn on participants' wrists for 5 days, and can measure total sleep time, sleep efficiency and minutes awakening after sleep onset. The Actigraph GT3X+ model (Actigraph, Pensacola, Florida, USA) will be used. The Actigraph GT3X+ has been previously validated and is considered a reliable method for estimating sleep characteristics in both the adult and adolescent populations.⁵⁶ All sleep parameters will be determined using Actilife 6 software (V.6.13.1, ActiGraph, Pensacola, Florida, USA).

Sleep assessment using the PSQI

This is a valid and highly reliable instrument specifically designed to measure sleep quality.⁵⁷ It is made up of 19 questions, which are grouped into 7 main components. Each component is scored from 0 to 3 points, with a lower score indicating no problems, while a higher score denotes worsening problems in the following order: (a) subjective quality of sleep (very good vs very poor), (b) sleep latency (≤ 15 min to > 60 min), (c) sleep duration (≥ 7 hours to < 5 hours), (d) sleep efficiency ($\geq 85\%$ to $< 65\%$ hours of sleep/hour in bed), (e) sleep disturbances (not during the past month vs ≥ 3 times per week), (f) use of sleeping medications (none vs ≥ 3 times per week) and (g) dysfunction daytime (not a problem vs a very big problem). Subsequently, the seven components are added to obtain a total score from 0 to 21 points.

Assessment of lifestyles

Physical activity

The Actigraph GT3X+ device also records data on daily physical activity, sedentary time, daily steps and kilocalories expended. The intensity of physical activity (light, moderate and intense) will be determined according to the cut-off points proposed by Freedson *et al.*⁵⁸

Dietary habits

To obtain data on habitual intake, the Food Frequency Questionnaire (FFQ) will be used, which is a validated questionnaire for the general population, especially to assess the intake of food in general, energy and macronutrients, although it also allows assessing micronutrient and vitamin intake.⁵⁹ In addition to this information, information will also be collected on the food groups included in the FFQ that one has consumed in the last 7 days after 18:00, as well as the intake of stimulant substances with caffeine or theine, relaxing substances such as infusions, supplements of melatonin or tryptophan and spicy foods. On the other hand, adherence to the Mediterranean Diet pattern will be evaluated through the Mediterranean Diet Adherence Screener whose score range is from 0 to 14 points, considering high adherence when the score is 9 or more points.⁶⁰

Other lifestyles

In relation to tobacco consumption, questions will be asked to determine smoking status, as well as addiction in smokers through the Fagerstorm test⁶¹ and the smoking rate, which takes into account the number of cigarettes consumed per day and the number of years one has been smoking. In relation to alcohol consumption, the type and quantity of alcohol consumed in the last 7 days will be collected. Finally, questions will be asked about the consumption of toxic substances and, in those people who manifest their consumption, the Drug Abuse Screening Test-10 will be carried out.⁶²

Evaluation of morbidity and drug consumption

The presence of comorbidities will be collected through the Charlson Comorbidity Index.⁶³ In addition, questions will be asked about coronavirus infection and the presence of other diseases not included in the Charlson Comorbidity Index, such as obstructive sleep apnoea syndrome, fibromyalgia, chronic pain, polyuria, hypothyroidism, hyperthyroidism, high blood pressure, obesity, cardiac arrhythmias and chronic rhinitis. The consumption of drugs, the schedule for taking each of them, as well as the use of sleeping devices (mandibular splints or continuous positive airway pressure devices) will be assessed.

Assessment of psychological factors

Among the psychological factors that can condition the sleep quality, depression, anxiety, stress and occupational stress will be evaluated. The presence of depression will be evaluated through the Patient Health Questionnaire-9,⁶⁴ anxiety through the Generalized Anxiety Disorder-7⁶⁵

and the presence of stressful events will be evaluated through the Life of Threatening Events,⁶⁶ while occupational stress will be explored with the Occupational Stress Questionnaire (ERI/DER).⁶⁷

Other determinants

Sociodemographic and economic variables

Variables such as race, sex, marital status, level of education, employment status and working hours, frequency of trips and jet lag, and economic variables such as annual family income will be collected.

Habitability conditions of the habitual residence

Aspects such as the number of people sleeping in the room, presence of children, size of the bed, type of pillow, and presence of noise, lights or blinds will be recorded. In addition, the type of dwelling and the air conditioning conditions of the habitual dwelling and the average temperature will be recorded. Pollution levels will also be determined based on the neighbourhood/area of the dwelling.

Use of screens and new technologies

The average daily screen time and specifically about screen time prior to sleep will be asked.

Relaxation techniques

Questions will be asked about the implementation of relaxation techniques and the frequency with which they are done.

Biological markers

A blood sample will be performed and the plasmatic value of melatonin will be determined. Quantification will be performed by adapting the method described by Viljoen *et al.*⁶⁸ A method will be developed to determine plasma melatonin by high-performance liquid chromatography (HPLC) with double diode detection and HPLC with diode array detection mass spectrometry. The analysis will be carried out in the Department of Analytical Chemistry, Nutrition and Bromatology of the University of Salamanca.

For a general and graphic view of the determinants of sleep quality that will be studied, see [figure 1](#).

Structure and planning of visits

Once the sample has been selected, the study staff will contact the participants by telephone offering them participation in the study and checking the exclusion/inclusion criteria. Those who initially agree to participate will meet to make a visit with the contact person in charge of carrying out the evaluations. The visit will last approximately 90 min. During it, the study will be explained, the signed informed consent will be collected and those questionnaires that are not self-administered will be completed. Finally, the accelerometer will be placed and the self-administered questionnaires will be delivered. Five days later, each participant will be summoned again



Figure 1 Graphic summary of the determinants of sleep quality analysed.

to return the accelerometer and the completed questionnaires, and to perform the blood draw.

The study will be carried out at the Faculty of Nursing of the University of Salamanca. The research group is made up of 10 researchers from different specialties: Preventive Medicine and Public Health, Pneumology, Nursing, Psychology, Physiotherapy, and Nutrition and Dietetics. The person in charge of carrying out the evaluations is a nurse specifically trained for it. The person who will carry out the statistical analysis will be blinded to who carried out the evaluations of the participants.

Statistical analysis plan

An analysis plan has been established to respond to the objectives set out in the study, which includes the following phases:

1. Descriptive analysis: the normal distribution of the variables will be verified with the Kolmogorov-Smirnov test. Quantitative variables will be expressed as means \pm SD or median (IQR) according to their distribution, and qualitative variables as number and frequency distribution.
2. Bivariate analysis: the difference in means between quantitative variables will be estimated with the Student's t-test or Mann-Whitney U test and the differences between qualitative variables with the X^2 test. To evaluate the relationship between quantitative variables of more than two categories, the analysis of variance and

the Least Significant Difference test will be used in the posterior contrasts. An analysis of covariance will be carried out to adjust the results for the variables that may affect as confounding factors. To analyse the relationship of the quantitative variables with each other, the Pearson or Spearman correlation will be used, as necessary.

3. Multivariate analysis of variance: it will be used in cases where there is more than one dependent variable to identify if the changes in the independent variables have significant effects on the dependent variables. Factors associated with the presence or absence of poor sleep quality will also be analysed using logistic regression.
4. A cluster analysis will be carried out including the possible determinants of sleep quality to find groups of people based on the variables studied in relation to sleep quality.
5. To analyse the weight of each determinant on the quality of sleep, the variables will be standardised and a principal component analysis will be carried out.
6. In all cases, for the hypothesis contrast, an α risk of 0.05 will be set as the limit of statistical significance. The statistical program used will be SPSS V.25.0.

Patient and public involvement

Prior to the start of the study, a pilot study was carried out with five randomly chosen participants (two men and three women with different ages) in the offices of a healthcare centre. The participants in this pilot study received all the information and in a post-evaluation interview, they were asked about different aspects related to the objectives of this work, the methodology used, the duration of the evaluations and the population to whom this research is addressed. This has allowed the research team to adjust times, include new relevant information, rule out superfluous or repeated information, and establish a plan to disseminate the study results to the general public, apart from the established publication plan. It is intended to inform the general public of the results of the study by disseminating news to the media, through scientific news agencies and a podcast widely disseminated on social networks.

DISCUSSION

This manuscript presents the study protocol of a cross-sectional study whose objective is to analyse the determinants of sleep quality in a representative sample of Spanish general adults. The very nature of the study (cross-sectional study) prevents establishing causal relationships between the possible determinants studied and sleep quality. However, the results will allow us to establish valid working hypotheses to continue investigating either through longitudinal studies or controlled clinical trials.

This study addresses one of the great concerns shared by citizens, such as understanding the determining factors of health, using an interdisciplinary approach that

integrates biological, epidemiological, environmental, socioeconomic and behavioural factors approaches. The results of this work could allow the design of improved interventions to modify certain behaviours, as well as intervention programmes, education and other primary care interventions aimed at improving sleep quality.

Social impact

Problems related to the presence of poor sleep quality have a clear negative impact on people's quality of life, which translates into repercussions in the family, work and social spheres. The social sphere is affected when the person with sleep problems shows less social contact, given that negative social attitudes increase, with the deterioration of social skills. All this causes a withdrawal of the person and less contact with the environment.

Clinical impact

Poor sleep quality is related to the presence of diseases such as fibromyalgia, joint pain and mental health problems, among others. The study of the main determinants of sleep and its relationship with other morbidities could be of special interest after such a critical period as the global COVID-19 pandemic, which has affected the population not only in its physical state but also in the psychological state, having a direct impact on the quality of sleep.

Healthcare impact

A multitude of disorders seen in consultations could be caused by poor sleep quality. The results of this work could analyse the characteristics that are present in the profile of people who have poor sleep quality, initiating interventions aimed at changing or modulating the behaviours associated with this problem.

Economic impact

In sleep disorders, it is common that work productivity is also affected; since insomnia alters cognitive functions, the people with insomnia have less concentration during the day and worse memory in the performance of their work. Some cases also cause delayed entry to work and increased absenteeism due to sick leave. In addition, morbidity related to alterations in sleep quality also has an impact on health spending due to increased demand for care.

The publication of this study protocol has a double objective. On the one hand, it will keep researchers, funding organisations and society updated on the relevance of this topic. On the other hand, it will help to increase the transparency in the conduct of the research that is required by the records of research projects and will give others the opportunity to know and understand the deviations that may occur during the study.

Ethical approval and consent to participate

This study has a favourable opinion from the Ethics Committee for Drug Research of the Health Areas of Salamanca and Ávila (CEim Code: PI 2021 07 815). Participants will be contacted by phone to arrange a visit

with study staff. The participants will be informed of the objectives of the project and the risks and benefits of the explorations that will be carried out, and later they must sign the informed consent before starting the study. In addition, the recommendations of the Declaration of Helsinki⁶⁹ will be followed throughout the study. In the same way, the confidentiality of the subjects included will be guaranteed at all times in accordance with the provisions of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights and Regulation (European Union) 2016/679 of the European Parliament and of the Council, of 27 April 2016, on Data Protection (RGPD).

Dissemination

The results of this study will be published in international impact journals of different specialties. A first publication of the study protocol will be made, and the main and secondary results will be published. In addition, the preliminary results will be presented at a national and an international congress. The project will be linked to the completion of a doctoral thesis by compendium of articles. Likewise, the general public will be informed through news broadcast to the media, scientific news agencies and a podcast for wide dissemination on social networks.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research.

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