BMJ Open

Epidemiological study on gender bias and low-value practices in primary care: a study protocol

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To cite: Carrillo I, Lopez-Pineda A, Pérez-Jover V, *et al*. Epidemiological study on gender bias and low-value practices in primary care: a study protocol. *BMJ Open* 2023;**13**:e070311. doi:10.1136/bmjopen-2022-070311

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-070311).

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Received 18 November 2022
Accepted 21 April 2023

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ABSTRACT

Introduction Evidence shows that gender has a substantial impact on health behaviours, access to and use of health systems and health system responses. This study aims to assess gender bias in patients subjected to low-value practices in the primary care setting and to develop recommendations for reducing adverse events that women experience for this reason.

Methods and analysis A Delphi study will be performed to reach a consensus on the 'Do Not Do' recommendations with a possible gender bias. A retrospective cohort study in a random selection of medical records will then be carried out to identify the frequency of adverse events that occur when the selected 'Do Not Do' recommendations are ignored. Qualitative research techniques (consensus conference and nominal group) will be carried out to develop recommendations to address any gender bias detected, considering barriers and facilitators in clinical practice.

Ethics and dissemination The study was approved by the ethics committee of San Juan de Alicante Hospital (San Juan de Alicante, Spain) Reference N. 21/061. We will disseminate the research findings via peer-reviewed articles, presentations at national and international scientific forums and webinars.

Trial registration number The study was registered at ClinicalTrials.gov (NCT05233852) on 10 February 2022.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Qualitative and quantitative data will be triangulated to strengthen the robustness of the findings.
⇒ The 'Do Not Do' recommendations that are susceptible to gender bias in primary care setting and could cause a severe adverse event in the patient will be identified through consensus of health professionals.
⇒ As one primary care physician will conduct the retrospective review of each medical record due to legal schemes, an information bias could be introduced.
⇒ Variables inherent to the prescriber (such as the age or mentalhealth) or to the centre (such as the population size or the location) could not be included in the cohort study as confounders.

INTRODUCTION

Overuse, that is, overdiagnosis and overtreatment, diminishes the quality of care in all health systems and countries.[1] Overuse refers to the provision of health services in circumstances where the potential risk of harm to the patient exceeds the potential benefit.[2] It represents a risk to both patient safety[3] and health system sustainability.[4 5] Overuse occurs when otherwise useful tests and treatments are administered to patients who do not need them, or when interventions are ineffective or even harmful.

Although conceptually there is no doubt about what overuse is, these low-value practices cannot always be easily identified. In 2007, the UK's National Institute for Health and Clinical Excellence revived the study of overuse with its proposed set of low-value practices (or 'Do Not Do' recommendations[6]). Other groups followed their lead, including the Choosing Wisely campaign, in over 20 countries[7]; the Less is More Medicine movement, which works to counter the belief that 'if a clinical practice is good, the more it is done, the better'[8]; and the Right Care Alliance, which aims to achieve universal, safe and effective patient-centred health systems.[9] In 2013, the project Commitment to the Quality of Scientific Societies in Spain was created, with aims including the identification of 'Do Not Do' practices.[10]

Regarding the frequency of overuse, the volume of patients subjected to low-value practices or 'Do Not Dos' varies widely by type of practice and country, ranging from 1% to 80%.[10] The use of potentially unsuitable medicines might be as high as 57.6%.[11] In Spain, polypharmacy, one manifestation of overuse, has increased from 2.5% (2005) to 8.9% (2015). In absolute terms, this increase

is higher in women (from 2.7% to 9.5%) than in men (from 2.3% to 8.5%).[12] In primary care, the SOBRINA study[13] showed that from 2018 to 2019, 55.1% of patients received at least one intervention classified as 'Do Not Do' related to benzodiazepines, Non-steroidal anti-inflammatory drugs (NSAIDs), lipid-lowering agents, antibiotics, paracetamol and ibuprofen. The percentage of medical records with more than one 'Do Not Do' was 18.5% in those over 29 years old. Women received a greater number of prescriptions that ignored the 'Do Not Do' recommendations than men (frequency-adjusted rate 49.4% vs 41.8%; p<0.0001).

In the USA, where 18% of the gross domestic product is spent on the health sector, overuse represents an additional annual cost. According to the most optimistic estimates,[5] the total cost ranges from US$75.7 to US$101.2 billion, whereas other studies put the figure as high as US$158–226 billion.[14] In Spanish primary care, the extra cost of ignoring recommendations on the appropriate use of benzodiazepines, NSAIDs, lipid-lowering agents, paracetamol and ibuprofen amounted to €290 million per year between 2015 and 2017, and in 2018 it reached 2.8% of total pharmaceutical expenses, considering only the cost of prescriptions issued.[13] Overuse has also been linked to safety incidents. In hospitals, 0.2%–15.0% of patients report adverse events due to low-value practices[15] and, in primary care, the SOBRINA study estimated that 5.1% of adult patients suffered adverse events when 'Do Not Do' recommendations were ignored.[13] Once again, women experienced more adverse events linked to these practices than men (frequency-adjusted rates 4.9% vs 4.0%, p=0.047).

There is evidence that shows that gender, as a social construct, has a substantial impact on health behaviours, access to and use of health systems, and health system responses.[16] Gender bias can be defined as a systematic error in the social construction of the disease's history and symptoms, which produces inequitable responses to health problems from the health services, as well as discriminatory responses by professionals.[17] This bias can happen at any time during the care process, yet there are hardly any interventions focused on eliminating it.[18] The presence of gender inequalities in healthcare is associated with the belief that the risks in men and women are similar, when in fact they are not, which leads to women's problems going untreated. Likewise, health professionals may perceive and act on gender-based differences that do not exist. These biases have resulted in a failure to address and interpret differences in the experience of the disease, the expression of symptoms (with many women diagnosed with non-specific symptoms) and the provision of health services, and they have prompted calls for woman-centred healthcare.[19 20]

The fact that some diseases are more often attributed to men and others to women have generated a bias in diagnostic criteria and access to complementary tests or treatments[13]; these should be considered when analysing the causes of overuse. Although there are various theoretical approaches to applying gender analysis to health, the most widely used are the Liverpool School of Tropical Medicine Model[21] and the one proposed by the Women and Gender Equity Knowledge Network in a report for the WHO Commission on Social Determinants of Health.[22] The former lays out a set of issues to be considered when analysing differences or similarities between women and men. The second helps to explain the role of gender as a determinant of health and to identify how gender biases are introduced into health systems.

Women are negatively affected by a gender bias in the therapeutic effort, and they experience greater delays in diagnosis.[23–25] Recent studies also highlight differences in the frequency with which some 'Do Not Do' recommendations are ignored between male and female patients. Moreover, the number of adverse events due to overtreatment is also higher in women.[13] However, gender bias has not yet been investigated as a possible cause of this overuse, which means that interventions aimed at reducing it do not consider the differential impact on female patients, who are particularly and negatively affected by its consequences. In addition, there are practically no studies on overuse in primary care in relation to gender bias. Therefore, the overarching aim of this research is to assess gender bias with regard to low-value practices in the primary care setting, seeking to reduce its impact on women, including in terms of adverse events.

Specific aims

1. To analyse whether the differences in the frequency of adverse events due to ignoring 'Do Not Do' recommendations are due to biological causes or to gender bias.
2. To identify gender-related factors that explain differences in the frequency with which 'Do Not Do' recommendations causing adverse events are ignored.
3. To establish practice-based recommendations to correct overuse caused by gender bias.
4. To develop methodological recommendations so that future research on overuse systematically includes a gender perspective.

MATERIALS AND METHOD

Study design

This is a mixed methods research study combining a retrospective cohort study with qualitative research techniques (Delphi, consensus conference and nominal group). The study was registered on ClinicalTrials.gov (NCT05233852) on 10 February 2022.

Definitions

Overuse: the provision of healthcare in the absence of evidence or when the potential benefit of the procedure or treatment does not outweigh its risks.[26]

'Do Not Do' recommendations: practices included in the Commitment to Quality initiative list of recommendations, developed following the methodology proposed by the Choosing Wisely campaign to avoid overuse. In this

study, overuse is defined as continuing to do what should not be done (ignoring the 'Do Not Do').

Adverse event: harm caused by medical management or a complication instead of the underlying disease, resulting in prolonged hospitalisation and/or disability at the time of discharge from medical care.[27]

Gender bias in health: differences in treatment between women and men that are not justifiable based on scientific evidence. This gender bias may involve approaching a clinical situation differently or similarly, according to the available scientific evidence, depending on the patient's gender. In other words, this bias is produced by assuming differences between men and women when there are none, or by ignoring the differences when evidence calls for a differentiated approach.[28]

Study phases

This study will consist of the following three phases.

Phase 1. Gender bias as a cause of adverse events due to ignoring 'Do Not Do' recommendations in women (objectives 1 and 2)

First, a Delphi study will be performed to reach a consensus on the 'Do Not Do' recommendations that should be included in a retrospective cohort study, which will review a random selection of medical records to quantify the frequency of adverse events caused by ignoring 'Do Not Do' recommendations. The period of this study phase is from 1 November 2021 to 31 August 2023 (22 months). The design of this study will consider the experience in the SOBRINA protocol[29] and Ruiz-Cantero *et al*'s recommendations for analysing gender bias in epidemiological studies.[16]

Delphi technique

Panel. Fifty health professionals from family medicine, cardiology, intensive care and geriatrics will be invited to participate as members of the expert panel. Inclusion criteria are more than 10 years of professional experience along with some experience in studies from a gender perspective in the health sector. Professionals will be excluded if they have no time to respond. Recruitment will be done with snowball sampling.

Materials. The qualitative study will be carried out from 1 November 2021 to 30 September 2022. The 'Do Not Do' recommendations for avoiding overuse, as agreed by the scientific societies and included in the Commitment to Quality led by the Ministry of Health, will be included in the round 1 Delphi questionnaire. The researchers will select the proposals based on the recommendations made by scientific societies in primary healthcare and others whose scope of expertise includes this level of care. Additionally, a webinar will be held on the topic 'Overuse in primary care associated with gender bias' with national topic experts to help identify the recommendations to be included. The wording of the round 1 questionnaire will be piloted by a group of 10 experts who meet the same criteria for inclusion as the expert panellists.

Procedure. After panellists accept the invitation to participate and provide informed consent, an online, password-protected platform will be used to collect their responses. For each 'Do Not Do' recommendation included in the questionnaire, the panellists will evaluate if it is susceptible to gender bias in the primary care setting, considering three aspects: (1) if it is still a relatively frequent 'Do Not Do' in primary care; (2) its frequency of application is different between men and women, with a probable association with gender; and (3) if ignoring the 'Do Not Do' could cause a severe adverse event in the patient. Panellists will mark their level of agreement/disagreement on a scale of 0 (strongly disagree) to 10 (strongly agree). The resulting score will be the sum of the three scales. The 'Do Not Do' recommendations that yield a score of 20 points or more will be retained (consensus criterion) and those scoring under 10 points will be discarded. The rest will be subjected to a second Delphi round to determine if any of the 'Do Not Dos' has sufficient consensus to be included in the study. Two to three rounds are planned (depending on the degree of consensus reached on each proposal), and two to three reminders will be sent to panellists to encourage participation. During the Delphi survey phase, participants will have access to a call centre and email account to resolve any technical difficulties that arise.

Cohort study

Subjects. A random selection of patients attending primary care consultations in selected health departments in Alicante, Castellon and Valencia provinces between 1 January 2022 and 31 December 2022 will be performed. The percentage of medical records with at least one 'Do Not Do' is expected to be 50%.[13] Accepting an alpha risk of 0.05 and an accuracy of 2.5%, the minimum sample size is calculated to be 1538 medical records (50% women). The study sample will be stratified by age group and sex, considering the frequency of visits collected in the National Health System's information system for primary care in 2018. They will be grouped into three age groups: 18–59 years, 60–74 years and over 75 years, considering the reference ages in previous studies.[30] A simple randomised procedure, k=5, will be applied to select the medical records of patients attended during the previous 3 years.

Materials. Data will be drawn from the electronic medical records database of primary care (Abucasis) between 15 March 2023 and 31 August 2023. Medical records will be reviewed and adverse events identified through a trigger tool, used previously in the SOBRINA study[13] and based on recommendations by Rosenberg *et al*.[31]

Reviewers. Forty primary care physicians (with gender parity in the group distribution) will review medical records. Reviewers will be trained on the tool using anonymised records.[4] During training, they will review the same cases, and concordance will be analysed using Cohen's kappa coefficient, with scores of 0.63 or more indicating acceptable agreement and scores of 0.84 or

more, excellent. When an excellent level of concordance is achieved, the training will conclude.

Procedure. Following training, each reviewer will individually assess a selection of medical records to code and record data. In the cases where adverse events occur, the reviewers will evaluate their severity and the extent to which the harm can be attributed to ignoring the 'Do Not Do' recommendation, using two scales of 0–7 points (proposed by Woods *et al*[32]), where the higher the score, the greater the severity and intensity of the relationship between overuse and harm. Incidents with a severity score above 3 will be considered as adverse events, and those with an intensity score of above 4 will be considered as caused by overuse. A blinded recording system will be used by the research team.

Study variables. The primary study variables will be the frequency of drug prescriptions ignoring 'Do Not Do' recommendations (crude rate and adjusted rate using 2018 Primary Health Care Information System (PCIS) data as reference population) by sex and age group, and the frequency of adverse events related to 'Do Not Dos', classified by severity, sex and age group. Rates will be calculated according to the total number of prescriptions for a given set of patients who meet the specifications (pathology and age) contemplated in the recommendation and the total number of patients attended in that period, respectively. Other variables will include age and sex of the patient, number of drugs consumed per day, sex of the prescriber, requests for diagnostic tests (clinical analyses, radiology relevant to the diagnosis) and referrals. The treatments associated with these 'Do Not Dos' will be identified using the Anatomical Therapeutic Chemical Classification System and the diagnoses based on the International Classification of Diseases, 10th revision.

Data analysis. The frequencies with which the 'Do Not Do' recommendations are ignored and the number of adverse events that occur will be compared between male and female patients and reviewers. The χ^2 test with Yates correction will be used to compare the frequency of ignoring 'Do Not Do' recommendations in men and women, and the Cochran-Mantel-Haenszel test to analyse differences in the adjusted rate between the sexes. To determine the possible interaction effects between patient sex and other variables (age of the patient, sex of prescriber, number of drugs consumed per day), logistic regression analyses will be performed, obtaining an OR with men as the reference group. Statistical significance will be set at $p<0.05$ (two-tailed) for all tests. Analyses will be performed using the SPSS v.28 statistical package and the RStudio V.1.1.463 programming language.

The 'Do Not Dos' with statistically significant differences in frequency-adjusted rates between male and female patients and those causing adverse events will be retained for the next phase. All information collected during the medical records review will be available for the subsequent analysis.

Phase 2. Development of recommendations to reduce the gender bias contributing to adverse events caused by ignoring 'Do Not Do' recommendations (objective 3)

The objective of phase 2 will be to develop recommendations to reduce the gender bias contributing to adverse events caused by ignoring 'Do Not Do' recommendations. The period of this study phase will be carried out from 1 September 2023 to 29 February 2024 (6 months).

Participants. Medical and pharmacy professionals in Spain who have experience in health studies with a gender perspective (ie, authors of two or more papers on the topic and/or members of relevant national commissions) will be invited to participate. Participants will be excluded if they cannot commit sufficient time to review the results of the previous study phase, to the face-to-face session and to the two remote sessions planned. A total of 24 professionals will be needed, and recruitment will be carried out using snowball sampling in the health services involved in this study. Participants will be informed of the objectives and conditions of their voluntary and unpaid participation in this study.

Procedure. A consensus conference will take place to discuss the results of phase 1, the causes of any differences, and the contribution of a gender bias to these differences. Participants will be included in one of three groups that will take part in an initial meeting, with the aim of presenting and discussing the results of phase 1. The discussion will be oriented toward achieving the objectives of this study phase and will be based on the recommendations of the Liverpool School of Tropical Medicine, the Women and Gender Equity Knowledge Network and those of the Red-Caps. The plenary debate will consider the following points in the interpretation of results (to be revised with contributions from participants): biological differences; factors associated with age, stereotypes, traditional family roles and health beliefs associated with certain pathologies; and systemic biases due to gender. Participants will consider the indications for pathologies where differences can be expected due to factors intrinsic to sex as well as prescriptions that should not be differentiated by sex (ie, where gender factors may be at play in differential prescription patterns). Successive rounds of debate will examine gender bias as a potential cause of adverse events due to ignoring the 'Do Not Do' recommendations. The debate will be kept active until data saturation and sufficient consensus are achieved in each group. The conclusions of the groups will be triangulated to determine the consistency and validity of the proposals.

Phase 3. Development of proposals to introduce a gender perspective in future overuse studies (objective 4)

To develop methodological recommendations so that future research on overuse systematically includes a gender perspective, we will apply nominal group techniques. This study phase will be from 1 March 2024 to 31 December 2024 (10 months).

Participants. A total of 32 participants will be needed: 16 health professionals for the first round and 16 health and social researchers (including those with experience in the use of social networks for social marketing) for the second. Professionals with experience in health studies with a gender perspective (ie, authors of two or more papers on the topic and/or members of national commissions about the topic) will be invited to participate in this study phase; for the second round, they should have participated in campaigns aimed at professionals to reduce overuse. Participants will be excluded if they cannot commit sufficient time to the face-to-face session and the remote session planned for each group. Professionals who participated in one study phase will not be excluded from participating in a subsequent phase. Recruitment will be through snowball sampling in the health services involved in this study. Participants will be informed of the objectives and conditions of their voluntary and unpaid participation.

Procedure. Participants will be assigned to one of four groups of eight participants, who will all follow the same procedure in parallel. The first two groups will be asked to propose recommendations for reducing overuse in light of the causal factors identified. The second two groups will develop recommendations on the aspects to consider in future research on overuse to avoid gender bias in data capture and analysis. The script of questions for these groups will be based on the studies by Ruiz-Cantero *et al*.[16] Key questions and clusters (on topics or issues from which participants' assessments should be obtained) will be defined to elicit strategies to reduce overuse aimed at professionals, considering the sex of the prescriber, female patients, managers and health policy-makers.

In each session, proposals will be presented to a panel to facilitate debate. Finally, weights will be assigned individually through an anonymous voting system to rank the value of each proposal. Discourse analysis will be performed with tools such as NVivo, coding the information into mutually exclusive categories. The results of the different groups will be triangulated to determine the consistency and validity of the proposals, considering concordance among participants and spontaneity (the number of times the same idea is presented independently). Participants will then rank the ideas in order of their relevance to the study objective. Proposals yielding a consensus of 85% or more will be retained. Finally, and depending on the conclusions, the recommendations will be formulated to facilitate their translation to clinical practice and/or their dissemination to the general public.

Patient and public involvement

None.

DISCUSSION

This research project will assess the presence of a gender bias in low-value practices in the primary care setting by comparing the frequency of adverse events due to ignoring 'Do Not Do' recommendations between male and female patients. It will analyse the foreseeable causes of this bias and elicit expert proposals to correct it and to incorporate the gender perspective systematically in future studies on overuse.

This project examines how gender-sensitive indicators are constructed, observing the health consequences of gender as a social construct and thus attempting to explain whether the observed differences between the sexes in health status are due to gender inequalities or inequities.[24] Sex-disaggregated results only show differences between women and men in a specific health dimension; they do not always indicate gender-sensitive variables. Therefore, we must deepen the analysis of these differences to correctly interpret their impact on women's health.

Exploring the 'Do Not Do' recommendations in the primary care covers many cases of overuse (overdiagnosis and overtreatment) in this setting. In recent years, awareness has grown around overuse and the problems it causes to patients. It poses a threat to health system sustainability, particularly for national health systems such as the Spanish one. Both the Ministry of Health and the regional health authorities have initiated campaigns in cooperation with scientific societies to tackle this problem. Initiatives range from information campaigns to changes in prescription assistance algorithms. At the same time, advocates have highlighted the need to move towards woman-centred healthcare, directly addressing gender bias in response to health problems. So far, this perspective has rarely been applied to studies of overuse.

The results of the comparisons of prescriptions ignoring the 'Do Not Do' recommendations between women and men can be classified into one of three categories:

- Prescriptions that similarly ignore 'Do Not Do' recommendations in both male and female patients (eg, NSAIDs in patients with high blood pressure, heart failure, chronic kidney disease or liver cirrhosis[13]).
- Prescriptions that ignore different 'Do Not Do' recommendations in male and female patients due to sex-specific factors (eg, drugs with different pharmacokinetic profiles in male and female patients).
- Prescriptions that ignore 'Do Not Do' recommendations differentially between male and female patients in a way that is attributable to mental health and gender factors (eg, the prescription of anxiolytics, hypnotics and analgesics[33 34]).

The findings of this study may contribute to improving safety in female patients by reducing unnecessary risks in primary care, and its results could lay the foundation for differential health policy strategies. At the scientific-technical level, this project will develop new guidelines in clinical reasoning for avoiding health inequities in clinical decision-making. The study should serve to establish guidelines and recommendations for including gender perceptions in overuse research, an aspect that has not been addressed until now.

On the other hand, the study of gender as a social construct requires an interdisciplinary approach to consider its impact on health system responses from a holistic and transversal perspective. In this way, we aim to promote understanding of the gender construct in the field of health, opening a new line of work around the study of overuse present in all healthcare systems; to contribute to broadening the scope of approaches considered in the debate on women-centred healthcare; and, finally, to propose research methodologies that incorporate a gender perspective in this topic area. Broadly speaking, this project pursues advances in woman-centred care, reducing unnecessary and unequal risks in the primary care setting. In that sense, it is oriented along the lines proposed by Gagliardi *et al*,[19] and it seeks to overcome the existing gap in the design of interventions to correct the gender bias, as highlighted by Alcalde-Rubio *et al*.[18] On the other hand, the differential implementation of guideline recommendations (including 'Do Not Dos') in women and men could result in underuse due to gender bias, which should also be addressed in the future.

Difficulties, possible biases and limitations

To encourage good response rates among the professionals invited to participate in the qualitative study, we will use reminders and tools that we know are comfortable and versatile for group dynamics. If necessary, meetings will be organised remotely to facilitate participation.

Because one primary care physician will conduct the retrospective review of each medical record due to legal schemes, an information bias could be introduced. Reviewers will receive previous training to control this bias. In addition, we expect some inherent limitations in the available data sources, namely, the quality of the records in the databases, which will limit the information available from each medical record.

Variables inherent to the prescriber (such as the age or mental health) or to the centre (such as the population size or the location) that cannot be included in the cohort study might confound the results.

According to data from the Ministry of Health (2019), attendance to primary care is higher in women (5.9%) than in men (4.5%), and on average, more women present with active problems than men (8.1% vs 6.9%). Comparisons using adjusted rates will control for these effects. The qualitative phase analysing the potential causes of gender bias will consider income level, unemployment and migrant status. Depending on the pathology, the possible diagnostic delays identified in women in some specific pathologies will also be considered. In this way, we will consider whether the combined effects of socioeconomic risk factors and female sex require specific attention.

ETHICS AND DISSEMINATION

This research project will be carried out following the principles of the Declaration of Helsinki, the Council of Europe Convention (Oviedo) and the UNESCO Universal Declaration. There are no ethical aspects of the research that threaten the rights of the patients, as stipulated in Act 41/2002. The study follows the principles of the Organic Law 3/22 March 2007, for the effective equality of women and men, and the recommendations of the IV World Conference on Women, Beijing (1995). Data coding will be performed by blinded researchers, respecting the confidentiality of patients and professionals. The study protocol was approved by the Ethics Committee of San Juan de Alicante Hospital. Because of its epidemiological approach, it is exempt from the requirement for patients' informed consent. The study was registered (clinicaltrials.gov) with the identifier of NCT05233852.

Data from medical records will be extracted by patients' attending physicians, following the rules and protocols for epidemiological studies, and they will be dumped into a single online database with restricted access. Only anonymised data will be used. Double-blinding will prevent the identification of any patient or the doctors and nurses who attend them. Access to the data set will be the responsibility of both principal investigators. Additionally, verbatim transcripts from the qualitative sessions, where participants rank the proposals emerging from the debate, will be temporally recorded, following a longstanding policy on the use of audio and video materials obtained during the group sessions, so that these are obtained only with consent; are registered in electronic databases that meet the requirements described above, with exclusive access to the research team; and are deleted once the results' reports have been prepared and approved by those who participated in the group techniques. Data security is guaranteed through firewall systems and nightly backups.

The dissemination plan includes peer-reviewed journals, presentations at national and international scientific forums and three webinars about the research topic. The Strengthening the Reporting of Observational Studies in Epidemiology recommendations will be followed for dissemination purposes.

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Funding This work is supported by Project Prometeu 2021/061 granted by Conselleria de Innovación, Universidades, Ciencia y Sociedad Digital, Generalitat Valenciana.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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