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Complete List of Authors:	Serrano-Ripoll, Maria; Balearic Islands Health Services, Primary Care Research Unit of Mallorca; Institut d'Investigació Sanitària Illes Balears Ripoll, Joana; Balearic Islands Health Services, Primary Care Research Unit of Mallorca; Institut d'Investigació Sanitària Illes Balears Llobera, Joan; Balearic Islands Health Services, Primary Care Research Unit of Mallorca; Institut d'Investigació Sanitària Illes Balears Valderas, Jose; University of Exeter, Medical School Pastor-Moreno, Guadalupe; CIBERESP; EASP Olry de Labry Lima, Antonio; CIBERESP; EASP Ricci-Cabello, Ignacio; Balearic Islands Health Services, Primary Care Research Unit of Mallorca; Institut d'Investigació Sanitària Illes Balears
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Development and evaluation of an intervention based on the provision of patient feedback to improve patient safety in Spanish primary health care centers: study protocol

Maria J Serrano-Ripoll[1-3], Joana Ripoll[1,2,4], Joan Llobera[1,2,4], José M Valderas[5], Guadalupe Pastor-Moreno[6,7], Antonio Olry de Labry Lima[6,7], Ignacio Ricci-Cabello[1,2,6]

1. Balearic Islands Health Services, Primary Care Research Unit of Mallorca, Palma de Mallorca, Illes Balears, ES
2. Institut d'Investigació Sanitària Illes Balears (IdISBa). Palma de Mallorca, Illes Balears, ES
3. Universitat de les Illes Balears. Departament de Psicologia, Palma de Mallorca, Illes Balears, ES
4. Primary Care Preventive and Health Promotion Research Network (redIAPP), ES
5. Health Services & Policy Research Group, Patient Centred Care, University of Exeter Collaboration for Academic Primary Care, University of Exeter Medical School, United Kingdom
6. Ciber de Epidemiologia y Salud Pública (CIBERESP), Madrid, ES
7. Andalusian School of Public Health. Granada, Andalucía, ES

Corresponding author:

Dr. Ignacio Ricci-Cabello. Atención Primaria Mallorca, IB-Salut. Carrer de l'Escola Graduada, 3, 07002 Palma, Balearic Islands, Spain. email: ignacio.ricci@ssib.es

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ABSTRACT

Introduction

Despite the enormous potential for adverse events in Primary Health Care (PHC), the knowledge about how to improve patient safety in this context is still sparse. We describe the methods for the development and evaluation of an intervention targeted at PHC professionals to improve patient safety in Spanish PHC centers.

Methods and analysis

The intervention will consist in using the PREOS-PC survey to gather patient-reported experiences and outcomes concerning the safety of the healthcare patients receive in their PHC centers, and feed that information back to the PHC professionals to help them identify opportunities for safer healthcare provision. The study will involve three stages: Stage 1 (developing the intervention) will involve: a) qualitative study with 40 PHC providers to optimize the acceptability and perceived utility of the proposed intervention; b) Spanish translation, cross-cultural adaptation and validation of the PREOS-PC survey; c) developing the intervention components, and; d) developing an online tool to electronically administrate PREOS-PC and automatically generate feedback reports to PHC centers. Stage 2 (piloting the intervention) will involve a 3-months feasibility (one group pre-post) study in 10 PHC centers (500 patients, 260 providers). Stage 3 (evaluating the intervention) will involve: a) a 12 month, two-arm, two-level cluster randomized controlled trial (1,248 PHC professionals within 48 PHC centers; with randomization at the centre level in a 1:1 ratio) to evaluate the impact of the intervention on patient safety culture (primary outcome), patient-reported safety experiences and outcomes (using the PREOS-PC survey), and avoidable hospitalizations ; b) qualitative study with 20 PHC providers to evaluate the acceptability and perceived utility of the intervention and identify implementation barriers.

Ethics and dissemination

The study was approved by the Ethics Committee of the Balearic Islands (CEI IB: 3686/18). The results will be disseminated in peer reviewed publications and national and international conferences.

Registration details

clinicaltrials.gov NCT03837912

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Article summary

Strengths and limitations

- We propose the use of a theory-based intervention
- Both patients´ and providers´ views have been taken into account in the design of the intervention
- The intervention has the potential to be highly scalable and sustainable for the Spanish National Health Service
- A high proportion of missing PHC professionals outcome data may compromise the validity of our findings.

Keywords

Patient Safety; Primary Health Care; Medical Errors; Quality in Health Care; Health Services

INTRODUCTION

Patient safety has been defined as "the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare",[1] and has been on the research agenda since the publication of the report 'To Err is Human'[2] in 2000.

A recent report[3] shows that around 20%-25% of the population experience harm in primary and ambulatory care settings. Most common causes of harm are related with diagnosis (either delayed or missed) or to treatment (delayed or inappropriate)-related incidents.[4] A number of factors contribute to these incidents, such as the working environment, information transfer at the primary-secondary interface,[5] doctor-patient relationship,[6] or continuing education.[7] The direct costs of harm (additional tests, treatments and health care) are around 2.5% of total health expenditure.[3]

In Spain (country with the highest Primary Health Care (PHC) frequentation figures in Europe), the PHC is organized into 2,700 PC centers, where the professionals work in teams. Each team includes on average 10 doctors, 2 pediatricians, 12 nurses, midwife, social worker, and admin staff.[8,9] During the last decade we have witnessed an increasing interest around patient safety in the Spanish PHC centers. The APEAS study,[10] which involved 48 PHC centers from 16 regions, estimated that each year 3 million adverse events occur in the Spanish PHC centers, of which around two thirds are preventable.

Improving safety culture (defined as the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management[11]) is ''*the biggest challenge to moving toward a safer health system*'' according to the Institute of Medicine.[12] Notwithstanding the increasing efforts to develop effective strategies to improve patient safety in PHC centers through enhancing patient safety culture and reducing preventable adverse events and harm,[13,14] the available evidence base concerning the effectiveness of the different strategies proposed up until now is still limited.[15,16] Enhancing patients' involvement in their own safety is currently one of the most promising strategies.[3,17] Patient Feedback interventions (based on gathering patient safety experiences and outcomes and feeding the data back to health care providers) are a promising strategy.[18] They have been tested in the hospital setting with mixed results,[19-21] but no previous studies in the PHC setting are available.[22] This is mainly due to the absence of valid and reliable tools to obtain patient safety feedback in PHC.[23] To address this gap, we developed and validated the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC) questionnaire.[24]

In this protocol paper we describe a study that aims at developing and evaluating an intervention to improve patient safety in PHC centers by providing them with patient feedback obtained through the administration of the PREOS-PC questionnaire.

METHODS AND ANALYSIS

Description of the intervention

The intervention will consist in gathering patient-reported experiences and outcomes concerning the safety of the healthcare they have received in their PHC centers during the previous 12 months. This information will be processed and fed back to their PHC professionals to help them identify potential problems, and then target improvements about problematic areas. The three key stages of the intervention are:

a) Measurement: Patients will be approached in the waiting room, the study explained, and informed consent taken. The PREOS-PC questionnaire will be self-completed using a tablet-computer. Patients will be given a choice of whether they would prefer to self-complete the questionnaire or have it facilitated by the researcher.

b) Feedback: Using a bespoke online tool, the information for each PHC centre will be collated and presented to the centers. They will receive an automatically generated "Feedback Report", which will offer comparisons with other centers and include a set of recommendations about how the safety issues identified could be addressed.

c) Action planning and change: Participating PHC centers will form an Action Planning Team. Each team will comprise around four people working in the centers. The team will be responsible for receiving the Feedback Report, considering which area(s) should be targeted, and developing, implementing and monitoring an action plan for safety improvement.

This intervention is based on the Feedback Intervention Theory (FIT), which states that behavior is regulated through comparison with standards or goals, and that feedback can draw attention to existing gaps.[25] FIT further postulates that once the gap has been identified, different methods can be followed in order to decrease it and attain the standard, including increasing the effort currently done,[25] and implementing new strategies to address the problems (Figure 1). This could result in improving proximal

outcomes (such as safety climate), and potentially impact more distal outcomes (e.g. safety events or avoidable hospitalizations).

[Figure 1 about here]

Development and evaluation of the intervention

The methods described below are based on the Medical Research Council guidance for the development and evaluation of complex interventions.[26] This study includes three stages (see in Figure 2).

[Figure 2 about here]

Stage 1: Intervention development. This stage involves:

a) Qualitative study with PHC providers: we will conduct three semi-structured interviews and four focus groups with PHC doctors, nurses, and admin staff (n=40) to examine the acceptability and perceived utility of the intervention, and to identify potential barriers towards wider implementation.

b) Translation and cross-cultural adaptation of the PREOS-PC questionnaire[24] *into the Spanish context.* The translation process, based on "state of the art" methods,[27] will consist in forward and back translation by four independent translators, followed by cognitive interviews with eight to ten participants (diverse in terms of age, sex, and educational attainment) using the "think aloud" method[28] to ensure the translated version of the questionnaire is easy to understand and complete. The cross-cultural adaptation will be carried out using an expert consultation process involving about five national experts in patient safety.

c) Development of the intervention components: we will design the Feedback Report based on evidence from previous studies[19,29,30] and from the qualitative study with PHC providers above described. The Feedback Report will show the results of the Spanish PREOS-PC questionnaire specific for each PHC centre. It will provide benchmarking data - i.e., practices will be able to see their individual scores compared to the average scores of the rest of participating. To facilitate the design of action plans to address the potential safety issues identified in the Feedback Report, we will also produce a guidance document with recommendations, good practices and materials to improve patient safety in PHC, which will be identified as a result of a literature review, including the World Health Organization,[31] the

European Union Network for Patient Safety and Quality of Care (PaSQ Joint Action),[13] the Agency for Healthcare Research and Quality,[32] and the LINNEAUS EuroPC collaboration,[33] among others. We will also produce a registry form to help PHC centers register and monitor progress of the planned actions to address the safety problems identified. The intervention materials will also include information to increase PHC providers´ awareness of the usefulness of patient elicited information as a strategy to identify potential safety problems and design strategies to address them.

d) Development of an online tool: we will develop a bespoke online tool to allow the electronic administration of the PREOS-PC to patients using tablet-computers. The data collected will be transferred to a database stored in a virtual server. Once all patient data has been collected from in each PHC centre, the tool will automatically generate and send the Feedback Reports to each centre. The tool will also be used to collect data from the healthcare professionals participating in the trial, which will be stored in a separate database. With a protected authentication password to access to the provider questionnaire and to access to the Feedback Report.

Stage 2: Piloting and refining the intervention.

We will pilot the intervention in a three-month, one-arm (pre-post) feasibility trial. This will allow to estimate the follow-up rate for the main trial; test the collection of the planned outcome data; the willingness of PHC centers, providers and patients to participate; and the trial procedures. It will also allow to examine the psychometric properties of the Spanish PREOS-PC, and introduce final changes in the instrument if needed. Participants will include PHC centers, providers and patients, with the following eligibility criteria:

i) Centers: PHC centers from the Balearic Islands Health Service.

ii) Providers: all healthcare professionals working in the centre, including administrative staff.

iii) Patients: we will invite patients who have visited their PHC centre at least once in the previous 12 months. They will have to be able to speak Spanish. Patients aged<18 will be included only if their parents or guardians agree to complete the questionnaire on their behalf. We will exclude overt psychosis/critically ill/altered mental status, and inability to provide written informed consent.

Sample size: assuming an average of 26 healthcare professionals per centre,[9] recruiting ten centers will result in approximately 260 professionals taking part in the feasibility trial. Thus, this feasibility study

would allow to detect 80% follow up rate within 95% confidence intervals of 75.1% to 84.8%. With 500 patients (50 per centre), the study is powered to detect a patient response rate to the questionnaire of 75% within 95% confidence intervals of 71.2% to 78.8%. 500 participants are sufficient to perform factor analyses and the rest of analyses planned for the evaluation of the psychometric properties of the Spanish PREOS-PC.

Recruitment: we will recruit 10 PHC centers from the Balearic Islands diverse in terms of list size, deprivation, and rurality. 500 patients will be approached and recruited in the waiting room by a research assistant and invited to complete the Spanish PREOS-PC.

Outcome measures will include: i) healthcare professionals' follow-up rate, which will be measured as the proportion of PHC professionals who successfully complete the validated Spanish version of the Medical Office Survey on Patient Safety Culture (MOSPSC)[34] at baseline and post-intervention, and; ii) patient response rate to the PREOS-PC. The MOSPSC is a recognized index in Spanish PHC and it is supported by the Ministry of Health and the main PHC society (http://www.mscbs.gob.es/organizacion/sns/planCalidadSNS/docs/MOSPS.pdf). This index will be calculated as described in the questionnaire validation study.[34]

Statistical analysis. We will calculate the proportion of healthcare providers that complete the Spanish MOSPSC at baseline and at three months post-intervention. We will also calculate the follow-up rate by type of healthcare provider (nurse, doctor, social worker, administrative, etc.). Response rate to the PREOS-PC will also be calculated (overall and by centre and patient characteristics). The evaluation of the psychometric properties of the Spanish PREOS-PC will involve the examination of floor and ceiling effects, internal consistency (inter-item correlations,[35] Cronbach´s α[36]), and construct validity (confirmatory factor analysis).

Embedded qualitative study: after the feasibility study we will conduct semi-structured qualitative interviews with 20 healthcare professionals. They will be purposefully selected to ensure variation in terms of professional roles. Thematic analysis[37] will be used to explore the acceptability and perceived utility of the intervention, as well as possible suggestions to improve the intervention delivery or content.

Results from the feasibility trial will be used to inform the potential refinements about the intervention as well as the trials procedures, with an explicit process to decide the final intervention content, including a systematic appraisal of the trial processes (both quantitative and qualitative data) and proposals for solutions to identified problems.

Stage 3: Evaluating the acceptability, perceived utility and effectiveness of the intervention.

The evaluation of the intervention will involve a 12 month, two-arm, two-level cluster randomized controlled trial (1,248 PHC professionals within 48 PHC centers; with randomization at the centre level in a 1:1 ratio). The trial timeline and CONSORT flowchart are available in Figures 3 and 4. A cluster randomized trial is proposed to avoid the risk of contamination across professionals working in the same centre. 24 PHC centers in the intervention group will receive the intervention described above. 24 centers in the control group will receive the Feedback Reports at the end of the study.

[Figure 3 about here]

Randomization will be done using a fully validated randomization algorithm. Allocation will be carried out using a non-deterministic minimization algorithm to ensure PHC centers are balanced for important characteristics (including region, deprivation, and list size) and baseline measures. Participants: staff working and patients registered in the PHC centers. Eligibility criteria will be the same than in the feasibility trial above described.

The main outcome will be the Patient Safety Climate Synthetic Index (measured with the Spanish MOSPSC) at the PHC professional level. Secondary outcomes will be evaluated at the PHC centre level, and will include i) the five scales in the PREOS-PC questionnaire (measuring PHC centre activation; patient activation; experiences of safety problems; harm; and overall rating of patient safety), and; ii) rate of avoidable hospitalizations, extracted from electronic medical records using available CIE-9 codes,[38] calculated as the number of avoidable hospitalizations per 1,000 patients in the last 12 months.

The sample size calculation is based on the trial´s main outcome measure - the Spanish MOSPSC, which produce a score ranging from 1-5. Assuming an average of 26 professionals per centre, approximately 1,248 professionals will take part in the study. Assuming a follow-up rate of 80%, we will have complete data from approximately 998 professionals. Taking into account the cluster design, and using a conservative estimation of intra-class correlation of 0.1, this sample size will allow us to detect at least a 0.3 difference in effect size (with 80% power and a significance level of 5%). This would approximately correspond to a difference of 0.8 points in the index (assuming standard deviation of 2.3 from a previous study).[39] We will recruit 75 patients per centre (3,600 in total) is the minimum number to achieve a 0.7 reliability of scale scores at the centre level.[24]

Recruitment and training of PHC centers: We will recruit 48 PHC centers from Balearic Islands and other regions in Spain, through scientific societies and key informants and purposefully selected in order to ensure variation in terms of list size, rurality and levels of deprivation. Centers will be asked to consent as a unit, with all professionals being willing to participate. Consent will also be taken from patients invited to complete the patient survey.

Data collection: Data will be collected at baseline and 12 months post-intervention (i.e. 12 months after the Feedback Reports are sent to the centers). We will monitor the progress of the intervention in all the centers. Data from patients will include patient reported experiences and outcomes of patient safety in PHC (measured with PREOS-PC) and patient sociodemographic characteristics. Data from healthcare professionals will be collected through online questionnaires and will include the perceived safety climate (with the Spanish MOSPSC), and sociodemographic and occupational characteristics. Data from centers will include rate of avoidable hospitalizations in the previous 12 months (extracted from electronic medical records), and centre characteristics (rurality, list size, number of healthcare professionals, and MEDEA deprivation index).[40]

[Figure 4 about here]

Statistical analyses: Baseline characteristics will be examined by group using frequencies (with percentages) for binary and categorical variables and means (and standard deviations) or medians

(interquartile range) for continuous variables. The results from the trial will be presented as comparative summary statistics (difference in proportions or means) with 95% confidence intervals. The primary outcome will be analyzed using a hierarchical model, with individuals (PHC professionals) nested within PHC centers in an analysis of covariance adjusted for minimization factors. All analyses will be carried out on the basis of intention-to-treat (ITT).

Strategies to monitor and improve PHC adherence to intervention protocols: Through our online tool we will monitor the competition of the providers´ questionnaire at baseline and 12 months follow-up, and also whether or not they record action plans for safer healthcare. Up to three email reminders will be send to healthcare professionals if they don´t complete the requested tasks as part of the intervention. In addition, during the trial all PHC centers will be contacted telephonically to ensure they have received the feedback report and have no problems accessing and understanding the information.

Qualitative study with PHC providers: An embedded qualitative study will be carried out with 30 PHC professionals (intervention group) to understand the way the intervention is perceived among PHC professionals in terms of acceptability, perceived utility and implementation barriers (including any unintended consequences). We will use purposeful sampling to ensure variation in terms of type of PHC professionals (doctors, nurses, administrative staff, etc.) and of centers (region, rurality, deprivation, list size). Interviews will take place in the centers or telephonically. Thematic analysis[37] will be used to identify recurrent themes and subthemes common to interviewees working in centers.

Patient and public involvement

In this study, the intervention design will be determined based on group discussions with primary health care providers. Four group discussions with researchers took place in May-June 2018 to review and comment on the intervention design and materials based on their priorities, experiences and preferences. A meeting with four patient representatives was also held in September 2018, where the study was presented and discussed with them, providing useful feedback that helped us to refine the methods for administering the patient reported questionnaire.

Trial status

The cluster Randomized Control Trial will start around July 2019 and will continue until July 2020.

DISCUSSION

The prevention and amelioration of avoidable harm is a major priority for most PHC systems. Patients are the common element across the various settings, organizations and health professionals usually involved in their health care, and therefore, they are ideally suited to reflect on the health care they receive.[41] As recently highlighted both by World Health Organization[18] and the Organization for Economic Cooperation and Development (OECD),[3] tapping into such a rich resource could contribute significantly to improving safety in PHC.

Some, but not all, the studies evaluating the use of Patient Feedback interventions in the hospital setting support the effectiveness of this type of intervention to achieve safer healthcare. For example, a study in a hospital in England observed that obtaining feedback from patients and promoting staff ownership of safety improvement processes helped to raise standards of care.[20] In Japan and Denmark, patient feedback contributed to increase awareness among professionals and develop new safety protocols about minimizing risk.[21] However, a recent study in 33 UK hospital wards found that patient feedback did not reduce harm and patient reported safety problems.[19] The authors attributed this lack of effect to poor staff adherence to the intervention, due to a lack of normative legitimacy (i.e. staff not believing that listening to patients was a worthwhile exercise) and of structural legitimacy (i.e. staff not having adequate autonomy, ownership and resource to enact change).[42] Learning from these experiences is key to achieve progress in this area. In order to address these potential barriers in our study, our training materials will aim to raise awareness about the importance of patient reported information, as a way of increasing normative legitimacy. We will also provide practices with specific recommendations and educational material to help them design and implement actions for safer care - with the ultimate objective of increasing structural legitimacy.

The methods for the development and evaluation of the intervention are in line with the Medical Research Council guidance for the development and evaluation of complex interventions,[26] including i) identification of the relevant evidence base, ii) formative work (primary qualitative research) and use of theory to develop a theoretical understanding of the likely process of change; iii) a feasibility study to test trial procedures, estimate recruitment and retention, and determine sample size, and; iv) a full scale

randomized controlled trial to assess the effectiveness of the intervention, with an embedded quality study to help understanding the mechanisms and contexts by which this intervention does (or does not) work, and identify potential barriers to implementation and wider roll out. Findings from this study will be provide useful information to confirm or revise the theoretical frameworks in which the proposed intervention is grounded.

Strengths and limitations

Our study has a number of strengths. First, the intervention has been designed to minimize costs and maximize scalability and sustainability. Since it would be delivered with a bespoke online tool to collect patients' feedback and automatically generate and send tailored Feedback Reports to PHC centers, it could be rolled out in Spanish centers with minimal external input and at a low-cost. We have taken into account in the design of the intervention both patients´ and providers´ views about the intervention in order to maximize its acceptability. The PREOS-PC questionnaire is a patient-centered instrument which was developed with strong patient input, including patient focus groups[43] and a meta-synthesis[44] of patient experiences of patient safety in PHC. However, this study also has some limitations. First, it is not possible to blind centers to the condition they have been allocated to (intervention or control). Also, there is a risk that a high proportion of missing outcome data could compromise the validity of our findings in case we experience low response rates by PHC professionals in the MOSPC questionnaire.

In conclusion, the proposed intervention based on the provision of patient feedback to PHC centers has the potential to be an acceptable, cost-effective, feasible and sustainable strategy to achieve safer healthcare provision in PHC centers. A large pragmatic cluster randomized trial in 48 PHC centers will provide solid evidence about its potential effectiveness in improving patient safety culture, patient reported safety experiences and outcomes, and avoidable hospitalizations.

ETHICS AND DISSEMINATION

Ethical approval

This study will be conducted in accordance with the ethical standards of the Research Ethics Committee of the Balearic Islands (CEI IB: 3686/18) and with the 1964 Helsinki declaration and its later amendments. All participants will sign an informed consent before participating in this study. All the information from patients and PHC professionals will be anonymized. Patients and providers will be able

to withdraw from the study at any time and without having to provide any reason for withdrawing. Any important protocol modifications will be submitted to the Ethics Committee for approval.

Dissemination

The main findings of this study will be disseminated via publications in peer-reviewed international journals. Presentations of study findings will also be offered at relevant research conferences, and national and international academic symposia and seminars.

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Author contribution

IRC designed the study with support from JMV. IRC was granted the funding for the research study. IRC and MSR drafted this manuscript. All authors revised critically and approved the final version of the manuscript. Dr. Ignacio Ricci-Cabello will act as the overall guarantor.

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Disclaimer

The funding sources had no role in the design and conduct of the study; collection, management, analysis and interpretation of the data; preparation, review and approval of the manuscript; and decision to submit the manuscript for publication.

Conflicts of interests

IRC and JMV co-developed the PREOS-PC questionnaire, which is now being licensed by Oxford Innovation ltd. The rest of the authors report no conflict of interest.

Figure captions

Fig. 1 Logic Model of the proposed intervention*

*Intervention logic model based on Feedback Intervention Theory and the COM-B (Capability, Opportunity and Motivation-Behavior) system

PREOS-PC: Patient Reported Experiences and Outcomes of Safety in Primary Care

Fig. 2 Stages for the development and evaluation of the proposed intervention

PHC, Primary Health Care; PREOS-PC, Patient Reported Experiences and Outcomes of Safety in Primary Care

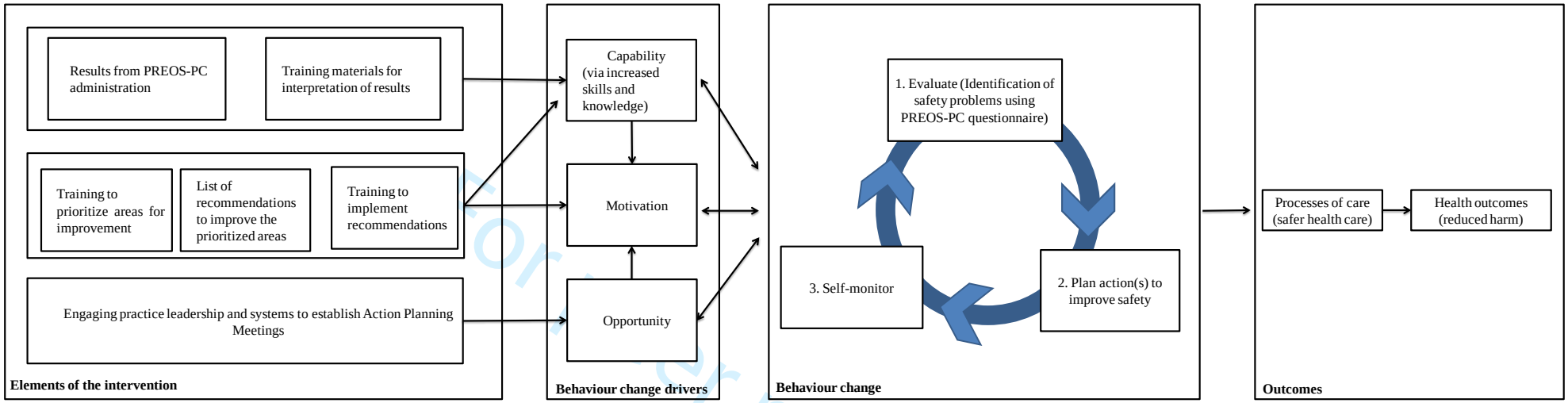
Fig. 3 Trial timeline

** PREOS-PC, Patient Reported Experiences and Outcomes of Safety in Primary Care*

***MOSPSC, Medical Office Survey on Patient Safety Culture, Provider reported patient safety culture*

Fig. 4 Consort Flowchart

ITT: Intention-to-treat, PHC, Primary Health Care



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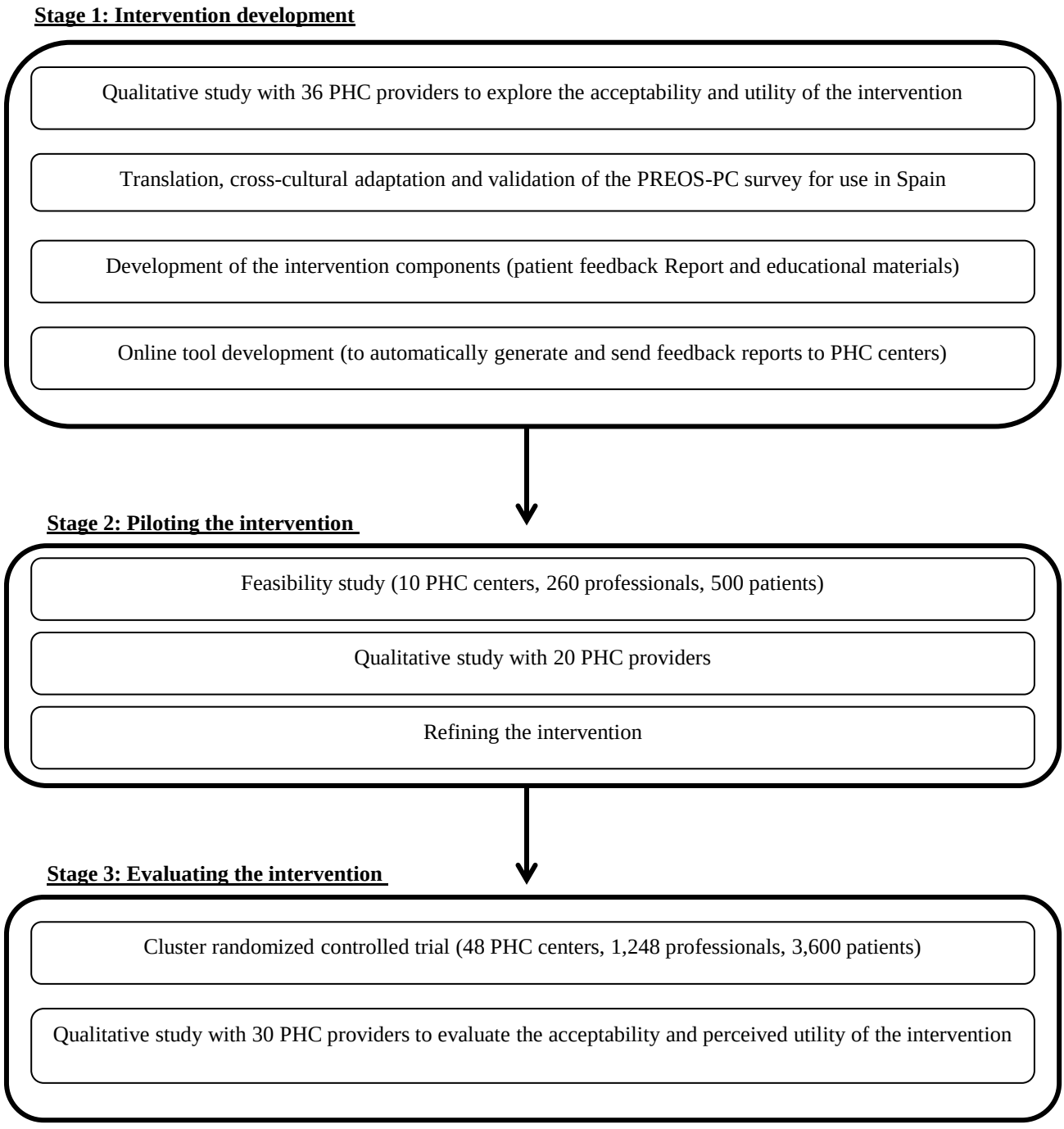
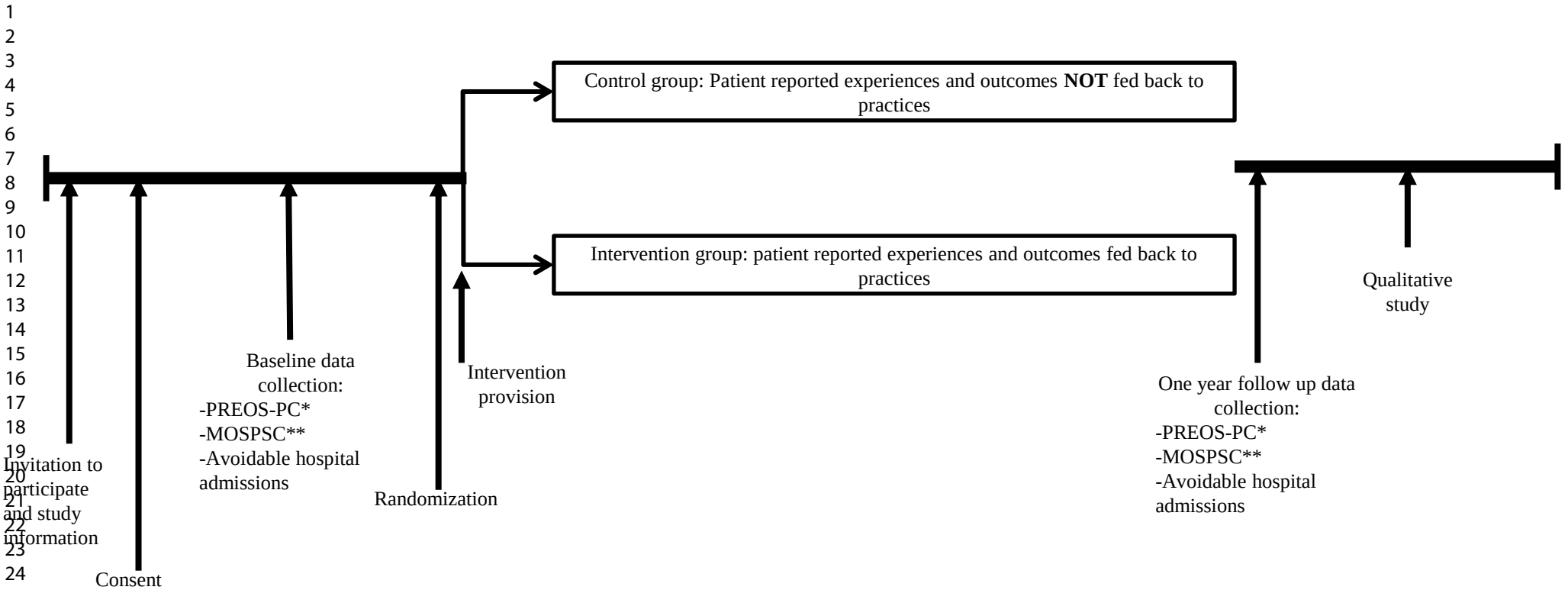


Fig. 2 Stages for the development and evaluation of the proposed intervention
PHC, Primary Health Care; PREOS-PC, Patient Reported Experiences and Outcomes of Safety in Primary Care



Recruitment and baseline data collection	Intervention provision and follow up	Follow up data collection and qualitative interviews
7 months	12 months	4 months

Fig. 3 Trial timeline

** PREOS-PC, Patient Reported Experiences and Outcomes of Safety in Primary Care*

***MOSPSC, Medical Office Survey on Patient Safety Culture, Provider reported patient safety culture*

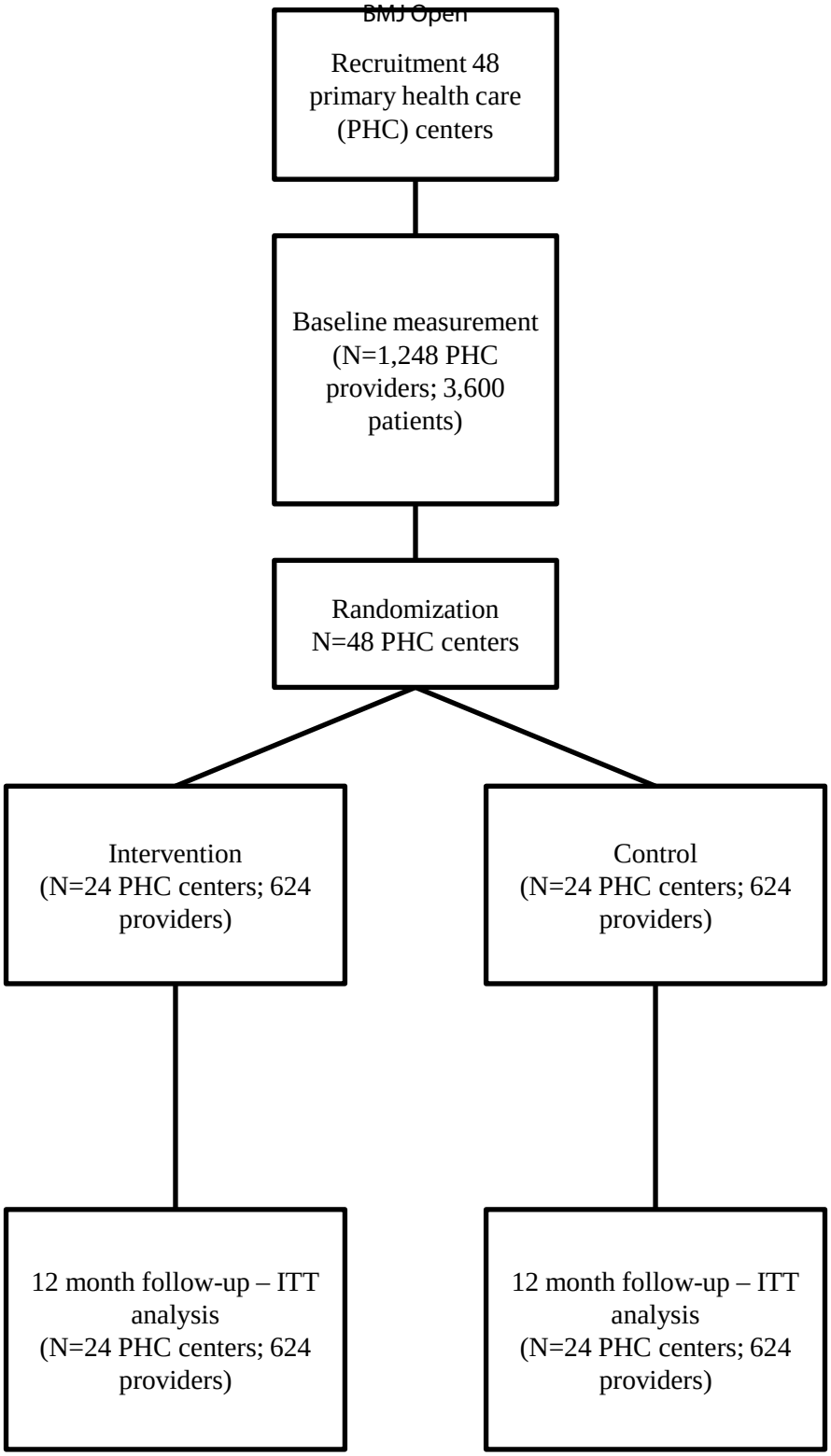


Fig. 4 Consort Flowchart
ITT: Intention-to-treat, PHC, Primary Health Care

HOJA DE INFORMACIÓN AL PARTICIPANTE PARA LA REALIZACIÓN DE UN PROYECTO DE INVESTIGACIÓN

TÍTULO DEL ESTUDIO: Desarrollo y Evaluación de una Intervención basada en el uso de Feedback proporcionado por Pacientes para la Mejora de la Seguridad del Paciente en los Centros de Atención Primaria

CÓDIGO DEL PROMOTOR: CP17/00017

PROMOTOR: Instituto de Salud Carlos III (Ministerio de Economía, Industria y Competitividad)

INVESTIGADOR PRINCIPAL: Ignacio Ricci Cabello (971 175883)

CENTRO: Institut d`Investigació Sanitària Illes Balears

INTRODUCCIÓN

Nos ponemos en contacto con usted en relación a un estudio al cual nos gustaría invitarle a participar. El estudio ha sido aprobado por el Comité de Ética de la Investigación de las Islas Baleares, de acuerdo con la legislación vigente, y se lleva a cabo respetando los principios enunciados en la declaración de Helsinki así como las normas de buena práctica clínica.

Nuestra intención es únicamente que reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en este estudio. Para ello, lea ésta hoja informativa con atención, y nosotros aclararemos las dudas que puedan surgir después de la explicación. Si tiene cualquier duda, puede dirigirse al investigador principal del estudio (Ignacio Ricci Cabello, tlf 971 175883; ignacio.ricci@ssib.es)

DESCRIPCIÓN GENERAL

El presente estudio tiene como objetivo evaluar una herramienta para mejorar la seguridad del paciente en los centros de salud de atención primaria a través de la recogida y análisis de información proporcionada por los propios pacientes. Dicha herramienta consistirá en un programa informático que permitirá: i) la recogida de información de los pacientes a través de un cuestionario validado y administrado de forma electrónica, y ii) la creación automática de informes específicos para cada centro de salud con los resultados de los cuestionarios y una serie de recomendaciones sobre cómo mejorar los problemas de seguridad identificados.

La efectividad de esta herramienta para la mejora de la seguridad del paciente será evaluada en un Ensayo Clínico Aleatorizado (ECA) con grupo control. Este ECA se llevará a cabo en 48 centros de salud de varias Comunidades Autónomas. La mitad de los centros de salud serán asignados de forma aleatoria a recibir la intervención, mientras que la otra mitad de los centros serán asignados a un grupo control. En los centros asignados al grupo intervención se utilizará la herramienta tal y como se ha descrito con anterioridad. En los centros asignados al grupo control se utilizará la herramienta para recoger la información de los pacientes, profesionales y centro de salud, pero no podrán acceder a los informes con los resultados de los cuestionarios de los pacientes hasta que no finalice el estudio. Una vez acabado el estudio los centros de salud en el grupo control tendrán acceso a los mismos materiales que los empleados en el grupo intervención durante el periodo de estudio. El ECA tendrá dieciséis meses de duración, y ha sido diseñado con la intención de que suponga la menor carga de trabajo adicional posible a los profesionales de los centros de salud participantes. El estudio conlleva las siguientes actividades:

- Mes 1 (recogida de información inicial): Durante el primer mes se llevará a cabo la recogida de información inicial, tanto de los pacientes como de los profesionales del centro de salud. Para recoger la información de los pacientes utilizaremos un cuestionario administrado mediante la herramienta anteriormente descrita. Estimamos que los pacientes tardarán una media de entre 10-15 min en completar el cuestionario. Se recogerán un total de 75 cuestionarios por centro de salud. Los cuestionarios serán administrados en el centro de salud por el propio equipo de investigación en la sala de espera. En ningún momento se solicitará al personal de los centros de salud que administren ellos mismos los cuestionarios. Para recoger información de los profesionales del centro de salud utilizaremos otro cuestionario, el cual también será administrado electrónicamente. Dicho cuestionario contendrá una serie de preguntas sobre cultura de seguridad del paciente, así como una serie de datos socio demográficos. Además se extraerá de cada centro información de las historias clínicas informatizadas sobre hospitalizaciones evitables. Toda la información recogida tanto de los pacientes como de los profesionales sanitarios y de los centros de salud será totalmente anónima y tratada con absoluta confidencialidad.
- Meses 2-15 (implementación de la herramienta): Los centros de salud asignados al grupo intervención recibirán el informe con los resultados del cuestionario. Se solicitará a cada uno de estos centros de salud que constituya un grupo de trabajo que se encargue de: revisar los resultados del informe; identificar los principales posibles problemas de seguridad detectados; acordar un plan de acción para intentar solucionar los problemas identificados, y; monitorizar la implementación de dicho plan. Los centros de salud asignados al grupo control no tendrán que desarrollar ninguna actividad adicional a su actividad clínica habitual.
- Mes 16 (recogida de información final): la información detallada previamente (ver mes 1) será de nuevo recogida en todos los centros (tanto control como intervención) con el objeto de evaluar si el uso de la herramienta ha mejorado la seguridad del paciente percibida por los propios pacientes (cuestionario de pacientes) y los niveles de cultura sobre seguridad del paciente (cuestionario de profesionales sanitarios), así como las hospitalizaciones evitables.

BENEFICIOS Y RIESGOS DERIVADOS DE LA PARTICIPACIÓN EN EL ESTUDIO

Los efectos adversos son una fuente importante de daño no solo para los pacientes, sino también para los propios profesionales sanitarios, los cuales pueden llegar a sufrir episodios de estrés o ansiedad al verse implicados en sucesos adversos. La participación en este estudio podría suponer un beneficio para el centro de salud y sus profesionales, ya que podría ayudarles a ofrecer una asistencia sanitaria más segura a través de la prevención de eventos adversos evitables.

La participación en este estudio no supone ningún riesgo sobre la salud de sus participantes, al no conllevar la extracción de muestras biológicas o la utilización de técnicas invasivas. Es posible que en algunas ocasiones el pilotaje de la herramienta previamente descrita pueda ocasionar algún tipo de disrupción en la práctica clínica habitual (por ej. que haya pacientes que presenten quejas a su centro de salud en caso de que consideren inadecuadas algunas de las preguntas del cuestionario, o considerar que ha demorado el tiempo de espera hasta ser llamado a consulta). Otro posible riesgo puede ser que la utilización de la herramienta genere algún tipo de tensión entre los profesionales del centro, por ejemplo a la hora de interaccionar para acordar y monitorizar acciones para la mejora de la seguridad.

CONFIDENCIALIDAD

El tratamiento, la comunicación, y la cesión de los datos de carácter personal de todos los sujetos participantes se ajustará a lo que se dispone en la Ley orgánica 15/1999, de 13 de diciembre, de protección de datos de carácter personal, y el Reglamento que la despliega. De acuerdo con lo establecido por dicha legislación, los participantes podrán ejercer sus derechos de acceso, modificación, oposición y cancelación de los datos, para lo cual se tendrán que dirigir al investigador principal del estudio (Ignacio Ricci, Gerència d'Atenció Primària de Mallorca; tel 971175883; ignacio.ricci@ssib.es).

Para garantizar la confidencialidad de la información obtenida, vuestros datos (incluyendo la información obtenida a través de los cuestionarios a profesionales sanitarios) serán anonimizados, por lo que será imposible identificar posteriormente a quien pertenecen.

COMPENSACIÓN ECONÓMICA

La participación en este estudio no supondrá ningún gasto asociado ni para el centro de salud ni para sus trabajadores, a parte del tiempo que dediquen los profesionales en los centros de salud asignados al grupo intervención a revisar los resultados de la encuesta y a llevar a cabo las mejoras consideradas oportunas para solucionar los problemas identificados. Es por ello que no se ofrecerá compensación económica alguna ni a los centros de salud ni a los profesionales que participen en este estudio.

PARTICIPACIÓN VOLUNTARIA

Vuestra participación en este estudio es totalmente voluntaria. Podéis decidir no participar, o cambiar vuestra decisión y retirar el consentimiento en cualquier momento, sin tener que dar ningún tipo de explicación, y sin que ello tenga ningún tipo de implicación con su relación con vuestro centro de salud.

En caso de que decida revocar su consentimiento, no se recogerán nuevos datos, aunque los ya recogidos sí que podrán ser analizados.

AGRADECIMIENTO

Independientemente de si decide o no finalmente participar en el estudio, tanto el promotor como el equipo investigador quiere agradecerle el tiempo y la atención dedicada a leer este documento informativo.

CONSENTIMIENTO INFORMADO PARA LA REALIZACIÓN DE PROYECTOS DE INEVESTIGACIÓN (dirigido a profesionales sanitarios de centros de salud de atención primaria invitados a participar en el ensayo clínico aleatorizado) (V0.1, 18-04-2018)

TÍTULO DEL ESTUDIO: Desarrollo y Evaluación de una Intervención basada en el uso de Feedback proporcionado por Pacientes para la Mejora de la Seguridad del Paciente en los Centros de Atención Primaria
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INVESTIGADOR PRINCIPAL: Ignacio Ricci Cabello (971 175883)
CENTRO: Institut d'Investigació Sanitària Illes Balears

Nombre y apellidos del participante:.....

Nombre del centro de salud: .....

☐ He leído la hoja de información que se me ha entregado.

☐ He podido hacer preguntas sobre el estudio.

☐ He podido recibir información sobre el estudio.

☐ He podido hablar con el responsable de este estudio (Ignacio Ricci Cabello).

☐ Comprendo que mi participación en este estudio es voluntaria.

☐ Comprendo que puedo retirarme del estudio:

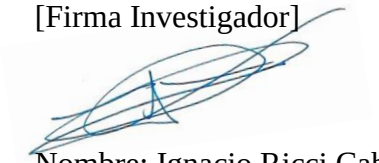
- Cuando quiera.
- Sin necesidad de tener que dar explicaciones.
- Sin que ello tenga ningún tipo de repercusión sobre el centro de salud.

☐ Comprendo que si decido retirarme del estudio los resultados obtenidos hasta el momento se podrán continuar analizando.

☐ Comprendo que tengo los derechos de acceso, rectificación, cancelación y oposición a mis datos de carácter personal de acuerdo con lo que dispone la Ley orgánica 15/1999, de 13 de diciembre, de protección de datos de carácter personal.

☐ Concedo libremente mi conformidad para participar en el estudio en las condiciones que se detallan en la hoja de información a los participantes.

[Firma del participante] [Firma Investigador]



Nombre: Nombre: Ignacio Ricci Cabello
Fecha: Fecha:

Este documento se tiene que firmar por duplicado y se tiene que quedar una copia el participante y otra el investigador.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 19
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	5

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8,9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	7
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10,11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	10,11

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Not reported
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not reported
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13,14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13,14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Development and evaluation of an intervention based on the provision of patient feedback to improve patient safety in Spanish primary health care centers: study protocol

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Primary Subject Heading:	Public health
Secondary Subject Heading:	General practice / Family practice, Health services research
Keywords:	patient safety, primary health care, Medical Errors, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health Services

Development and evaluation of an intervention based on the provision of patient feedback to improve patient safety in Spanish primary health care centers: study protocol

Maria J Serrano-Ripoll[1-3], Joana Ripoll[1,2,4], Joan Llobera[1,2,4], José M Valderas[5], Guadalupe Pastor-Moreno[6,7], Antonio Olry de Labry Lima[6,7], Ignacio Ricci-Cabello[1,2,6]

1. Balearic Islands Health Services, Primary Care Research Unit of Mallorca, Palma de Mallorca, Illes Balears, ES
2. Institut d'Investigació Sanitària Illes Balears (IdISBa). Palma de Mallorca, Illes Balears, ES
3. Universitat de les Illes Balears. Departament de Psicologia, Palma de Mallorca, Illes Balears, ES
4. Primary Care Preventive and Health Promotion Research Network (redIAPP), ES
5. Health Services & Policy Research Group, Patient Centred Care, University of Exeter Collaboration for Academic Primary Care, University of Exeter Medical School, United Kingdom
6. Ciber de Epidemiologia y Salud Pública (CIBERESP), Madrid, ES
7. Andalusian School of Public Health. Granada, Andalucía, ES

Corresponding author:

Dr. Ignacio Ricci-Cabello. Atención Primaria Mallorca, IB-Salut. Carrer de l'Escola Graduada, 3, 07002 Palma, Balearic Islands, Spain. email: ignacio.ricci@ssib.es

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ABSTRACT

Introduction

Despite the enormous potential for adverse events in Primary Health Care (PHC), the knowledge about how to improve patient safety in this context is still sparse. We describe the methods for the development and evaluation of an intervention targeted at PHC professionals to improve patient safety in Spanish PHC centers.

Methods and analysis

The intervention will consist in using the PREOS-PC survey to gather patient-reported experiences and outcomes concerning the safety of the healthcare patients receive in their PHC centers, and feed that information back to the PHC professionals to help them identify opportunities for safer healthcare provision. The study will involve three stages: Stage 1 (developing the intervention) will involve: a) qualitative study with 40 PHC providers to optimize the acceptability and perceived utility of the proposed intervention; b) Spanish translation, cross-cultural adaptation and validation of the PREOS-PC survey; c) developing the intervention components, and; d) developing an online tool to electronically administrate PREOS-PC and automatically generate feedback reports to PHC centers. Stage 2 (piloting the intervention) will involve a 3-months feasibility (one group pre-post) study in 10 PHC centers (500 patients, 260 providers). Stage 3 (evaluating the intervention) will involve: a) a 12 month, two-arm, two-level cluster randomized controlled trial (1,248 PHC professionals within 48 PHC centers; with randomization at the centre level in a 1:1 ratio) to evaluate the impact of the intervention on patient safety culture (primary outcome), patient-reported safety experiences and outcomes (using the PREOS-PC survey), and avoidable hospitalizations ; b) qualitative study with 20 PHC providers to evaluate the acceptability and perceived utility of the intervention and identify implementation barriers.

Ethics and dissemination

The study was approved by the Ethics Committee of the Balearic Islands (CEI IB: 3686/18). The results will be disseminated in peer reviewed publications and national and international conferences.

Registration details

clinicaltrials.gov NCT03837912

Protocol version 2.0 (March 20, 2019)

Article summary

Strengths and limitations

- We propose the use of a theory-based intervention
- Both patients´ and providers´ views have been taken into account in the design of the intervention
- The intervention has the potential to be highly scalable and sustainable for the Spanish National Health Service
- A high proportion of missing PHC professionals outcome data may compromise the validity of our findings.

Keywords

Patient Safety; Primary Health Care; Medical Errors; Quality in Health Care; Health Services

INTRODUCTION

Patient safety has been defined as "the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare",[1] and has been on the research agenda since the publication of the report 'To Err is Human'[2] in 2000. A recent meta-analysis estimated that around one in 20 patients are exposed to preventable harm in medical care.[3] Over the last two decades a substantial body of work has been undertaken to understand the reasons for patient safety incidents to occur in the hospital setting; but far less is known about the nature, causes or consequences of incidents in the primary care setting - which is where the majority of medical consultations take place.[4] This may be due to the assumption that primary care is a low technology environment where safety would not be a major problem. However, a recent systematic review including studies from 21 different countries[5] estimated that 2-3 patient safety incidents occur per 100 primary care consultations, and 4% of them result in severe harm (long-term physical or psychological problems or death). Most common causes of harm are related with diagnosis (either delayed or missed) or to treatment (delayed or inappropriate)-related incidents.[6] A number of factors contribute to these incidents, such as the working environment, information transfer at the primary-secondary interface,[7] doctor-patient relationship,[8] or continuing education.[9] The direct costs of harm (additional tests, treatments and health care) are around 2.5% of total health expenditure.[10]

In Spain (country with the highest Primary Health Care (PHC) frequentation figures in Europe), the PHC is organized into 2,700 PC centers, where the professionals work in teams. Each team includes on average 10 doctors, 2 pediatricians, 12 nurses, midwife, social worker, and admin staff.[11,12] During the last decade we have witnessed an increasing interest around patient safety in the Spanish PHC centers. The APEAS study,[13] which involved 48 PHC centers from 16 regions, estimated that each year 3 million adverse events occur in the Spanish PHC centers, of which around two thirds are preventable.

Improving safety culture (defined as the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management[14]) is ''*the biggest challenge to moving toward a safer health system*'' according to the Institute of Medicine.[15] Notwithstanding the increasing efforts to develop effective strategies to improve patient safety in PHC centers through enhancing patient safety culture and reducing preventable adverse events and harm,[16,17] the available evidence base concerning the effectiveness of the different strategies proposed up until now is still limited.[18,19] To

tackle this important problem, international organizations such as the World Health Organization,[20] the OECD,[10] or the US Agency for Healthcare Research and Quality[21] urge for the development of strategies focused on promoting patient engagement in patient safety - a largely unexplored area until recently.[22,23] A number of different approaches have been proposed to engage patients in their own safety.[24] One of them is based on gathering patient-reported safety experiences and outcomes, and feeding the data back to health care providers.[25] This approach has been tested in the hospital setting with mixed results,[26-28] but no previous studies in the PHC setting are available.[29] This is mainly due to the absence of valid and reliable tools to obtain patient safety feedback in PHC.[30] To address this gap, we developed and validated the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC) questionnaire.[31,32]

In this protocol paper we describe a study that aims at developing and evaluating an intervention to improve patient safety in PHC centers by providing them with patient feedback obtained through the administration of the PREOS-PC questionnaire.

METHODS AND ANALYSIS

Description of the intervention

The intervention will consist in gathering patient-reported experiences and outcomes concerning the safety of the healthcare they have received in their PHC centers during the previous 12 months. This information will be processed and fed back to their PHC professionals to help them identify potential problems, and then target improvements about problematic areas. The three key stages of the intervention are:

a) Measurement: Patients will be approached in the waiting room, the study explained, and informed consent taken. The PREOS-PC questionnaire will be self-completed using a tablet-computer. Patients will be given a choice of whether they would prefer to self-complete the questionnaire or have it facilitated by the researcher.

b) Feedback: Using a bespoke online tool, the information for each PHC centre will be collated and presented to the centers. They will receive an automatically generated "Feedback Report", which will offer comparisons with other centers and include a set of recommendations about how the safety issues identified could be addressed.

c) Action planning and change: Participating PHC centers will form an Action Planning Team. Each team will comprise around four people working in the centers. The team will be responsible for receiving the Feedback Report, considering which area(s) should be targeted, and developing, implementing and monitoring an action plan for safety improvement.

This intervention is based on the Clinical Performance Feedback Intervention Theory (CP-FIT), which states that behavior is regulated through comparison with standards or goals, and that feedback can draw attention to existing gaps.[33] FIT further postulates that once the gap has been identified, different methods can be followed in order to decrease it and attain the standard, including increasing the effort currently done,[33] and implementing new strategies to address the problems (Figure 1). This could result in improving proximal outcomes (such as safety climate), and potentially impact more distal outcomes (e.g. safety events or avoidable hospitalizations).

[Figure 1 about here]

Development and evaluation of the intervention

The methods described below are based on the Medical Research Council guidance for the development and evaluation of complex interventions.[34] This study includes three stages (see in Figure 2).

[Figure 2 about here]

Stage 1: Intervention development. This stage involves:

a) Qualitative study with PHC providers: we will conduct three semi-structured interviews and four focus groups with PHC doctors, nurses, and admin staff (n=40) to examine the acceptability and perceived utility of the intervention, and to identify potential barriers towards wider implementation.

b) Translation and cross-cultural adaptation of the PREOS-PC questionnaire[31] *into the Spanish context.* The translation process, based on "state of the art" methods,[35] will consist in forward and back translation by four independent translators, followed by cognitive interviews with eight to ten participants (diverse in terms of age, sex, and educational attainment) using the "think aloud" method[36] to ensure the translated version of the questionnaire is easy to understand and complete. The cross-cultural adaptation will be carried out using an expert consultation process involving about five national experts in

patient safety. The original version of the PREOS-PC questionnaire that will be adapted and translated into the Spanish context is available in Online Appendix 1.

c) Development of the intervention components: we will design the Feedback Report based on evidence from previous studies[26,37,38] and from the qualitative study with PHC providers above described. The Feedback Report will show the results of the Spanish PREOS-PC questionnaire specific for each PHC centre. It will provide benchmarking data - i.e., practices will be able to see their individual scores compared to the average scores of the rest of participating. To facilitate the design of action plans to address the potential safety issues identified in the Feedback Report, we will also produce a guidance document with recommendations, good practices and materials to improve patient safety in PHC, which will be identified as a result of a literature review, including the World Health Organization,[39] the European Union Network for Patient Safety and Quality of Care (PaSQ Joint Action),[16] the Agency for Healthcare Research and Quality,[40] and the LINNEAUS EuroPC collaboration,[41] among others. We will also produce a registry form to help PHC centers register and monitor progress of the planned actions to address the safety problems identified. The intervention materials will also include information to increase PHC providers´ awareness of the usefulness of patient elicited information as a strategy to identify potential safety problems and design strategies to address them.

d) Development of an online tool: we will develop a bespoke online tool to allow the electronic administration of the PREOS-PC to patients using tablet-computers. The data collected will be transferred to a database stored in a virtual server. Once all patient data has been collected from in each PHC centre, the tool will automatically generate and send the Feedback Reports to each centre. The tool will also be used to collect data from the healthcare professionals participating in the trial, which will be stored in a separate database. With a protected authentication password to access to the provider questionnaire and to access to the Feedback Report.

Stage 2: Piloting and refining the intervention.

We will pilot the intervention in a three-month, one-arm (pre-post) feasibility trial. This will allow to estimate the follow-up rate for the main trial; test the collection of the planned outcome data; the willingness of PHC centers, providers and patients to participate; and the trial procedures. It will also allow to examine the psychometric properties of the Spanish PREOS-PC, and introduce final changes in

the instrument if needed. Participants will include PHC centers, providers and patients, with the following eligibility criteria:

i) Centers: PHC centers from the Balearic Islands Health Service.

ii) Providers: all healthcare professionals working in the centre, including administrative staff.

iii) Patients: we will invite patients who have visited their PHC centre at least once in the previous 12 months. They will have to be able to speak Spanish. Patients aged<18 will be included only if their parents or guardians agree to complete the questionnaire on their behalf. We will exclude overt psychosis/critically ill/altered mental status, and inability to provide written informed consent.

Sample size: assuming an average of 26 healthcare professionals per centre,[12] recruiting ten centers will result in approximately 260 professionals taking part in the feasibility trial. A sample of 260 professionals would allow to detect a 80% follow up rate within 95% confidence intervals of 75.1% to 84.8%. With 500 patients (50 per centre), the study is powered to detect a patient response rate to the questionnaire of 75% within 95% confidence intervals of 71.2% to 78.8%. 500 participants are sufficient to perform factor analyses and the rest of analyses planned for the evaluation of the psychometric properties of the Spanish PREOS-PC.

Recruitment: we will recruit 10 PHC centers from the Balearic Islands diverse in terms of list size, deprivation, and rurality. 500 patients will be approached and recruited in the waiting room by a research assistant and invited to complete the Spanish PREOS-PC.

Outcome measures will include: i) healthcare professionals' follow-up rate, which will be measured as the proportion of PHC professionals who successfully complete the validated Spanish version of the Medical Office Survey on Patient Safety Culture (MOSPSC)[42,43] at baseline and post-intervention, and; ii) patient response rate to the PREOS-PC.

Statistical analysis. We will calculate the proportion of healthcare providers that complete the Spanish MOSPSC at baseline and at three months post-intervention. We will also calculate the follow-up rate by type of healthcare provider (nurse, doctor, social worker, administrative, etc.). Response rate to the PREOS-PC will also be calculated (overall and by centre and patient characteristics). The evaluation of

the psychometric properties of the Spanish PREOS-PC will involve the examination of floor and ceiling effects, internal consistency (inter-item correlations,[44] Cronbach´s α[45]), and construct validity (confirmatory factor analysis). We will also examine potential differences in mean scores between patients who have and have not received help completing the questionnaire.

Embedded qualitative study: after the feasibility study we will conduct semi-structured qualitative interviews with 20 healthcare professionals. They will be purposefully selected to ensure variation in terms of professional roles. They will be conducted by a researcher either face to face or telephonically, and will be audio-recorded after informed consent. The audio recordings will be transcribed and imported to the qualitative analysis software NVivo11. Thematic analysis[46] will be used to explore the acceptability and perceived utility of the intervention, as well as possible suggestions to improve the intervention delivery or content. After an in-depth reading of the transcriptions, codes will be assigned to sentences or paragraphs that had the same meanings, and then, by grouping codes, we will create and refine categories in an iterative process. The analysis will be conducted by two researchers independently. A third researcher will be involved to solve potential discrepancies.

Results from the feasibility trial will be used to inform the potential refinements about the intervention as well as the trials procedures (e.g. methods for data collection), with an explicit process to decide the final intervention content, including a systematic appraisal of the trial processes (both quantitative and qualitative data) and proposals for solutions to identified problems.

Stage 3: Evaluating the acceptability, perceived utility and effectiveness of the intervention.
The evaluation of the intervention will involve a 12 month, two-arm, two-level cluster randomized controlled trial (1,248 PHC professionals within 48 PHC centers; with randomization at the centre level in a 1:1 ratio). The trial timeline and CONSORT flowchart are available in Figures 3 and 4. A cluster randomized trial is proposed to avoid the risk of contamination across professionals working in the same centre. 24 PHC centers in the intervention group will receive the intervention described above. 24 centers in the control group will receive the Feedback Reports at the end of the study.

[Figure 3 about here]

Randomization will be done using a fully validated randomization algorithm. Allocation will be carried out using a non-deterministic minimization algorithm to ensure PHC centers are balanced for important characteristics (including region, deprivation, and list size) and baseline measures. Participants: staff working and patients registered in the PHC centers. Eligibility criteria will be the same than in the feasibility trial above described.

The main outcome will be the Patient Safety Culture, measured with the Spanish MOSPSC[43] at the PHC professional level. The MOSPSC is a recognized instrument in Spanish PHC and it is supported by the Ministry of Health and the main PHC society (http://www.mscbs.gob.es/organizacion/sns/planCalidadSNS/docs/MOSPS.pdf). The full questionnaire is available in Online Appendix 2. This validated instrument includes 67 items grouped in 13 dimensions. Patient Safety Culture will be computed either as a global score (synthetic index calculated at the health care professional level based on the mean score of the 67 items in the questionnaire [42]) or at the individual domain level. This decision will be made based on the results from the feasibility study in terms of the performance (in terms of internal consistency and sensitivity to change) of both measurement methods.

Secondary outcomes will be evaluated at the PHC centre level, and will include i) the five scales in the PREOS-PC questionnaire (measuring PHC centre activation; patient activation; experiences of safety problems; harm; and overall rating of patient safety), and; ii) rate of avoidable hospitalizations, based on data extracted from electronic medical records using available CIE-9 codes,[47,48] calculated as the number of avoidable hospitalizations per 1,000 patients in the last 12 months.

The sample size calculation is based on the trial´s main outcome measure - the Spanish MOSPSC, which produce a score ranging from 1-5. Assuming an average of 26 professionals per centre, approximately 1,248 professionals will take part in the study. Assuming a follow-up rate of 80%, we will have complete data from approximately 998 professionals. Taking into account the cluster design, and using a conservative estimation of intra-class correlation of 0.1, this sample size will allow us to detect at least a 0.3 difference in effect size (with 80% power and a significance level of 5%). This would approximately correspond to a difference of 0.8 points in the index (assuming standard deviation of 2.3 from a previous

study).[49] We will recruit 75 patients per centre (3,600 in total) is the minimum number to achieve a 0.7 reliability of scale scores at the centre level.[31]

Recruitment and training of PHC centers: We will recruit 48 PHC centers from Balearic Islands and other regions in Spain, through scientific societies and key informants and purposefully selected in order to ensure variation in terms of list size, rurality and levels of deprivation. Centers will be asked to consent as a unit, with all professionals being willing to participate. Consent will also be taken from patients invited to complete the patient survey. The intervention will be standardized across all sites and regions.

Data collection: Data will be collected at baseline and 12 months post-intervention (i.e. 12 months after the Feedback Reports are sent to the centers). We will monitor the progress of the intervention in all the centers. Data from patients will include patient reported experiences and outcomes of patient safety in PHC (measured with PREOS-PC) and patient sociodemographic characteristics. Data from healthcare professionals will be collected through online questionnaires and will include the perceived safety climate (with the Spanish MOSPSC), and sociodemographic and occupational characteristics. Data from centers will include rate of avoidable hospitalizations in the previous 12 months (extracted from electronic medical records), and centre characteristics (rurality, list size, number of healthcare professionals, and MEDEA deprivation index).[50]

[Figure 4 about here]

Statistical analyses: Baseline characteristics will be examined by group using frequencies (with percentages) for binary and categorical variables and means (and standard deviations) or medians (interquartile range) for continuous variables. The results from the trial will be presented as comparative summary statistics (difference in proportions or means) with 95% confidence intervals. The primary outcome will be analyzed using a hierarchical model, with individuals (PHC professionals) nested within PHC centers in an analysis of covariance adjusted for minimization factors. All analyses will be carried out on the basis of intention-to-treat (ITT).

Strategies to monitor and improve PHC adherence to intervention protocols: Through our online tool we will monitor the competition of the providers´ questionnaire at baseline and 12 months follow-up, and also whether or not they record action plans for safer healthcare. Up to three email reminders will be send to healthcare professionals if they don´t complete the requested tasks as part of the intervention. In addition, during the trial all PHC centers will be contacted telephonically to ensure they have received the feedback report and have no problems accessing and understanding the information.

Qualitative study with PHC providers: After post-intervention follow up we will carry out an qualitative study with 30 PHC professionals (intervention group) to understand the way the intervention is perceived among PHC professionals in terms of acceptability, perceived utility and implementation barriers (including any unintended consequences). We will use purposeful sampling to ensure variation in terms of type of PHC professionals (doctors, nurses, administrative staff, etc.) and of centers (region, rurality, deprivation, list size). Interviews will take place in the centers or telephonically. Thematic analysis[46] will be used to identify recurrent themes and subthemes common to interviewees working in centers.

Patient and public involvement

In this study, the intervention design will be determined based on group discussions with primary health care providers. Four group discussions with researchers took place in May-June 2018 to review and comment on the intervention design and materials based on their priorities, experiences and preferences. A meeting with four patient representatives was also held in September 2018, where the study was presented and discussed with them, providing useful feedback that helped us to refine the methods for administering the patient reported questionnaire.

Trial status

The cluster Randomized Control Trial will start around July 2019 and will continue until July 2020.

DISCUSSION

The prevention and amelioration of avoidable harm is a major priority for most PHC systems. Patients are the common element across the various settings, organizations and health professionals usually involved in their health care, and therefore, they are ideally suited to reflect on the health care they receive.[51] As

recently highlighted both by World Health Organization[25] and the Organization for Economic Cooperation and Development (OECD),[10] tapping into such a rich resource could contribute significantly to improving safety in PHC.

Some, but not all, the studies evaluating the use of Patient Feedback interventions in the hospital setting support the effectiveness of this type of intervention to achieve safer healthcare. For example, a study in a hospital in England observed that obtaining feedback from patients and promoting staff ownership of safety improvement processes helped to raise standards of care.[27] In Japan and Denmark, patient feedback contributed to increase awareness among professionals and develop new safety protocols about minimizing risk.[28] However, a recent study in 33 UK hospital wards found that patient feedback did not reduce harm and patient reported safety problems.[26] The authors attributed this lack of effect to poor staff adherence to the intervention, due to a lack of normative legitimacy (i.e. staff not believing that listening to patients was a worthwhile exercise) and of structural legitimacy (i.e. staff not having adequate autonomy, ownership and resource to enact change).[52] Learning from these experiences is key to achieve progress in this area. In order to address these potential barriers in our study, our training materials will aim to raise awareness about the importance of patient reported information, as a way of increasing normative legitimacy. We will also provide practices with specific recommendations and educational material to help them design and implement actions for safer care - with the ultimate objective of increasing structural legitimacy.

The methods for the development and evaluation of the intervention are in line with the Medical Research Council guidance for the development and evaluation of complex interventions,[34] including i) identification of the relevant evidence base, ii) formative work (primary qualitative research) and use of theory to develop a theoretical understanding of the likely process of change; iii) a feasibility study to test trial procedures, estimate recruitment and retention, and determine sample size, and; iv) a full scale randomized controlled trial to assess the effectiveness of the intervention, with an embedded quality study to help understanding the mechanisms and contexts by which this intervention does (or does not) work, and identify potential barriers to implementation and wider roll out. Findings from this study will be provide useful information to confirm or revise the theoretical frameworks in which the proposed intervention is grounded.

Strengths and limitations

Our study has a number of strengths. First, the intervention has been designed to minimize costs and maximize scalability and sustainability. Since it would be delivered with a bespoke online tool to collect patients' feedback and automatically generate and send tailored Feedback Reports to PHC centers, it could be rolled out in Spanish centers with minimal external input and at a low-cost. We have taken into account in the design of the intervention both patients´ and providers´ views about the intervention in order to maximize its acceptability. The PREOS-PC questionnaire is a patient-centered instrument which was developed with strong patient input, including patient focus groups[53] and a meta-synthesis[54] of patient experiences of patient safety in PHC. However, this study also has some limitations. First, it is not possible to blind centers to the condition they have been allocated to (intervention or control). Also, there is a risk that a high proportion of missing outcome data could compromise the validity of our findings in case we experience low response rates by PHC professionals in the MOSPC questionnaire.

In conclusion, the proposed intervention based on the provision of patient feedback to PHC centers has the potential to be an acceptable, cost-effective, feasible and sustainable strategy to achieve safer healthcare provision in PHC centers. A large pragmatic cluster randomized trial in 48 PHC centers will provide solid evidence about its potential effectiveness in improving patient safety culture, patient reported safety experiences and outcomes, and avoidable hospitalizations.

ETHICS AND DISSEMINATION

Ethical approval

This study will be conducted in accordance with the ethical standards of the Research Ethics Committee of the Balearic Islands (CEI IB: 3686/18) and with the 1964 Helsinki declaration and its later amendments. All participants will sign an informed consent before participating in this study. All the information from patients and PHC professionals will be anonymized. Patients and providers will be able to withdraw from the study at any time and without having to provide any reason for withdrawing. Any important protocol modifications will be submitted to the Ethics Committee for approval.

Dissemination

The main findings of this study will be disseminated via publications in peer-reviewed international journals. Presentations of study findings will also be offered at relevant research conferences, and national and international academic symposia and seminars.

Data sharing

Data from all the planned studies will be made available upon request. Anonymised patient-level data from feasibility and main clinical trials will be made available through the data sharing platform Clinical Study Data Request.

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Author contribution

IRC designed the study with support from JV. IRC was granted the funding for the research study. IRC and MSR drafted this manuscript. IRC, MSR, JR, JLL, JV, GPM and AOL revised critically the manuscript. All authors also approved the final version of the manuscript. Dr. Ignacio Ricci-Cabello will act as the overall guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Disclaimer

The funding sources had no role in the design and conduct of the study; collection, management, analysis and interpretation of the data; preparation, review and approval of the manuscript; and decision to submit the manuscript for publication.

Conflicts of interests

IRC and JMV co-developed the PREOS-PC questionnaire, which is now being licensed by Oxford Innovation ltd. The rest of the authors report no conflict of interest.

Figure captions

Fig. 1 Logic Model of the proposed intervention*

*Intervention logic model based on Feedback Intervention Theory and the COM-B (Capability, Opportunity and Motivation-Behavior) system

PREOS-PC: Patient Reported Experiences and Outcomes of Safety in Primary Care

Fig. 2 Stages for the development and evaluation of the proposed intervention

PHC, Primary Health Care; PREOS-PC, Patient Reported Experiences and Outcomes of Safety in Primary Care

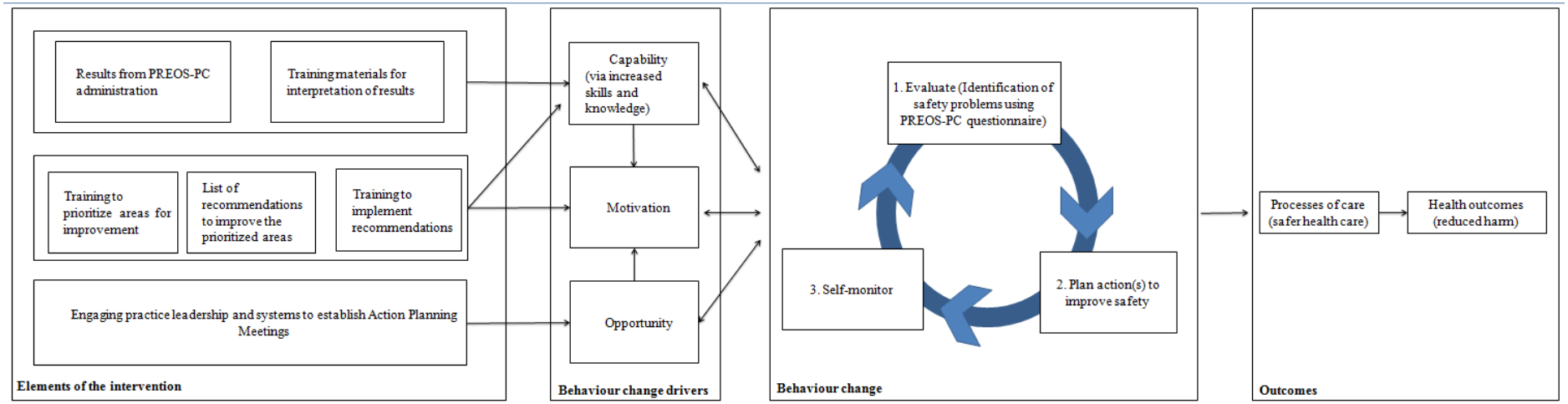
Fig. 3 Trial timeline

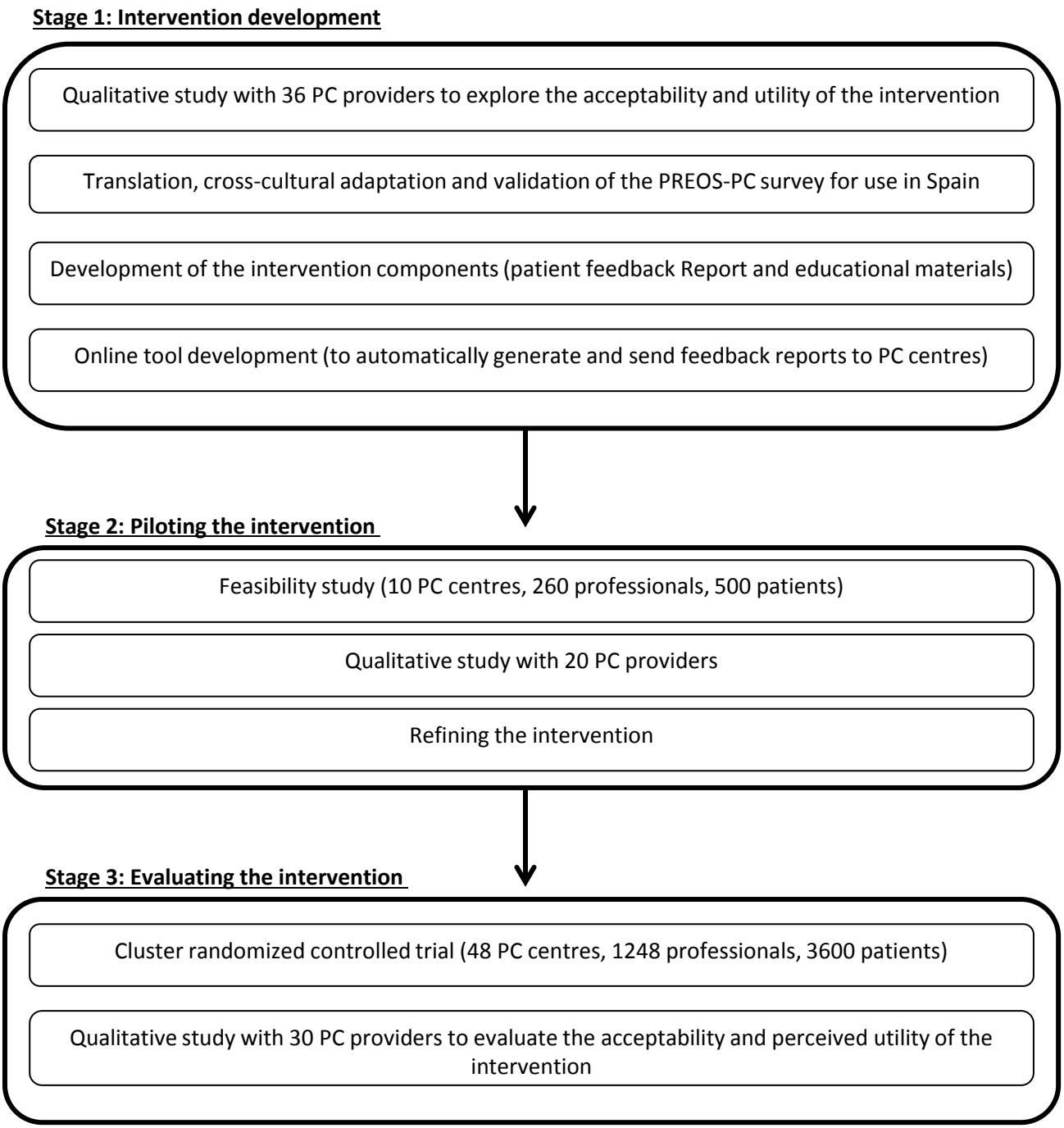
** PREOS-PC, Patient Reported Experiences and Outcomes of Safety in Primary Care*

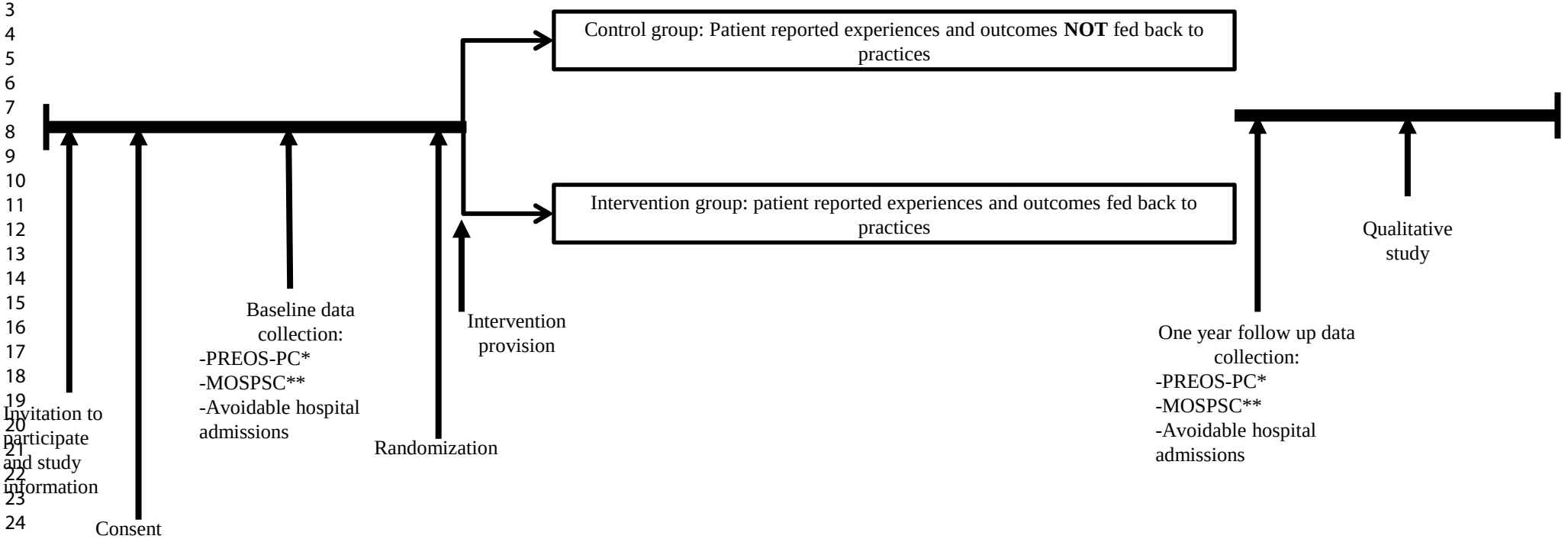
***MOSPSC, Medical Office Survey on Patient Safety Culture, Provider reported patient safety culture*

Fig. 4 Consort Flowchart

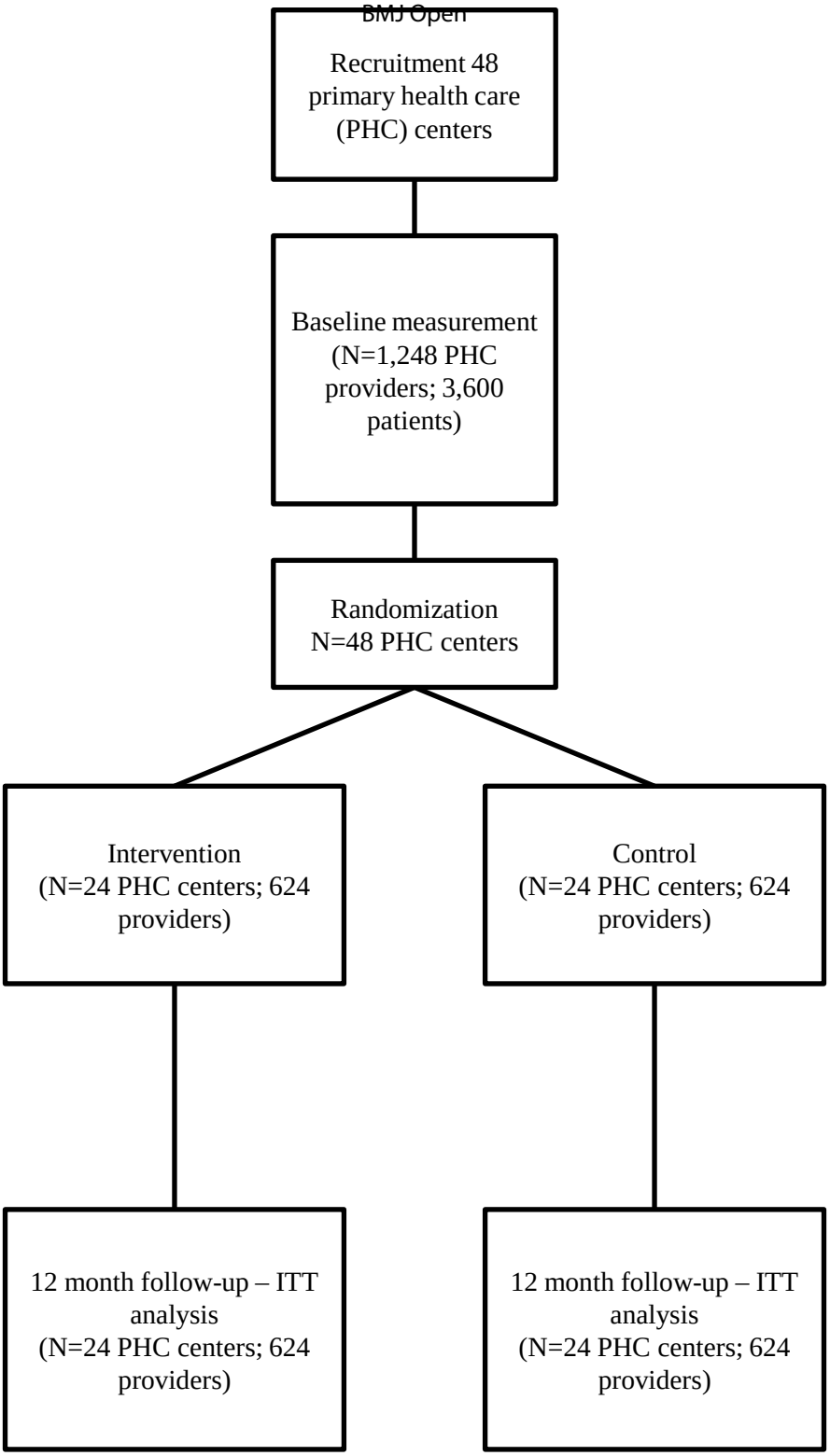
ITT: Intention-to-treat, PHC, Primary Health Care




Stage 1: Intervention development
Qualitative study with 36 PC providers to explore the acceptability and utility of the intervention
Translation, cross-cultural adaptation and validation of the PREOS-PC survey for use in Spain
Development of the intervention components (patient feedback Report and educational materials)
Online tool development (to automatically generate and send feedback reports to PC centres)
Stage 2: Piloting the intervention
Feasibility study (10 PC centres, 260 professionals, 500 patients)
Qualitative study with 20 PC providers
Refining the intervention
Stage 3: Evaluating the intervention
Cluster randomized controlled trial (48 PC centres, 1248 professionals, 3600 patients)
Qualitative study with 30 PC providers to evaluate the acceptability and perceived utility of the intervention



Recruitment and baseline data collection	Intervention provision and follow up	Follow up data collection and qualitative interviews
7 months	12 months	4 months


Recruitment 48 primary health care (PHC) centers
Baseline measurement (N=1,248 PHC providers; 3,600 patients)
Randomization N=48 PHC centers
Intervention (N=24 PHC centers; 624 providers)
Control (N=24 PHC centers; 624 providers)
12 month follow-up – ITT analysis (N=24 PHC centers; 624 providers)
12 month follow-up – ITT analysis (N=24 PHC centers; 624 providers)

Online Appendix 1. English (original) version of the PREOS-PC questionnaire (compact version)

1. Thinking about the health care you have received in your GP surgery in the last 12 months, how often did the following apply to your GPs?

	Always	Often	Sometimes	Rarely	Never	Does not apply
They were available when you needed to see or talk to them	☐	☐	☐	☐	☐	☐
They encouraged you to talk about any concerns about your health care	☐	☐	☐	☐	☐	☐
They told you what side effects of your treatments to watch for (such as feeling sick or diarrhoea)	☐	☐	☐	☐	☐	☐
They took your concerns seriously	☐	☐	☐	☐	☐	☐

2. Thinking about the health care you have received in your GP surgery in the last 12 months, how often did you do the following?

	Always	Often	Sometimes	Rarely	Never	Does not apply
Tell your GPs, nurses or other staff at the surgery when you thought something was wrong with your health care	☐	☐	☐	☐	☐	☐
Make a suggestion to your GPs, nurses or other staff at the surgery when you thought something could be done to improve the service provided	☐	☐	☐	☐	☐	☐

Next we would like to ask you if you have experienced any safety problems in your GP surgery. By **safety problems** we mean those problems that may happen **when a patient receives health care that might lead to harm to their health or wellbeing**. We do not mean just 'health and safety' issues, but problems such as not being examined or treated when necessary, or receiving a wrong diagnosis or the wrong medication.

The next question contains a list of safety problems that may happen in GP surgeries that might help you to better understand what we mean by safety problems.

3. Thinking about the health care you have received in your GP surgery in the last 12 months, were there any safety problems related to the following? (Please put a cross in **all** the boxes that apply.)

The diagnosis of your health problem	☐
Medication prescribed or given to you at your GP surgery	☐
Other treatments prescribed or given to you at your GP surgery	☐
Vaccines prescribed or given at your GP surgery	☐
Blood tests and other laboratory tests ordered or carried out at your GP surgery	☐
Tests for diagnosis and follow-up, ordered or carried out at your GP surgery (other than blood and laboratory tests, such as ECG or X-rays)	☐
Your appointments	☐
Your health records	☐
None of the above	☐

4. Thinking about the health care you have received in your GP surgery in the last 12 months, were there any communication problems with the following?

	Yes	No
Between you and GPs, nurses or other health-care staff in your GP surgery	☐	☐
Among GPs, nurses or other health-care staff in your GP surgery	☐	☐
Between GPs, nurses or other health-care staff in your GP surgery and other health-care professionals (such as consultants or hospital nurses)	☐	☐

Next we would like to ask you whether you have been harmed as a result of the health care provided in your GP surgery. By harm, we mean those situations in which health care itself causes a problem to patients' health or wellbeing. Problems in health care can cause harm to patients. Sometimes this is because the health care is not as good as it might have been. For example, a patient who has symptoms of cancer that need further investigation according to current guidelines sees her GP, but the GP does not recognise the importance of the symptoms and takes no action. Months later the cancer is finally diagnosed, but at a stage that is more advanced than when the patient first visited the GP.

Harm can also happen even with high-quality health care, for example, when a patient is given the right medication but develops an unexpected reaction that makes them feel unwell.

Please fill in the next question (5) even if you said in questions 3 and 4 that you had not experienced any safety problem in the last 12 months.

5. Do you think you have experienced any of the following types of harm as a result of the health care provided in your GP surgery in the last 12 months?

	Not at all	Yes, some	Yes, a lot	Yes, extreme	I don't know (yet)
Harm to your physical health	☐	☐	☐	☐	☐
Harm to your mental health	☐	☐	☐	☐	☐
Harm that limited your usual social activities (such as seeing friends or shopping)	☐	☐	☐	☐	☐
Harm that led to increased health-care needs (such as needing medications or tests)	☐	☐	☐	☐	☐
Harm that led to increased personal-care needs (such as needing help preparing meals or cleaning)	☐	☐	☐	☐	☐
Harm that led to increased financial needs	☐	☐	☐	☐	☐

6. On the scale below, please circle a number from 0 to 10 to show how safe you think the health care you received in your GP surgery was in the last 12 months.

Completely unsafe 0 1 2 3 4 5 6 7 8 9 10 Completely safe

7. What things, if any, does your GP surgery do well to make sure that health care is provided safely?

8. What changes, if any, would you suggest to your GP surgery to make sure that health care is provided safely?

SECCIÓN G: PUNTUACIONES GLOBALES

PUNTUACIONES GLOBALES SOBRE LA CALIDAD

1. En general, ¿cómo puntuaría a su centro de salud en cada una de las siguientes dimensiones de la calidad asistencial?

		Pobre	Regular	Bueno	Muy Bueno	Excelente
Centrado en el paciente	Responde a las preferencias individuales de los pacientes, a sus necesidades y valores.	☐	☐	☐	☐	☐
Efectivo	Se basa en el conocimiento científico.	☐	☐	☐	☐	☐
A tiempo	Minimiza esperas y demoras potencialmente perjudiciales.	☐	☐	☐	☐	☐
Eficiente	Garantiza unos cuidados coste-efectivos (evita el despilfarro, la sobreutilización, o el mal uso de los servicios).	☐	☐	☐	☐	☐
Equitativo	Ofrece la misma calidad asistencial a todos los individuos con independencia de su sexo, raza, etnia, nivel socioeconómico, idioma, etc.	☐	☐	☐	☐	☐

PUNTUACIÓN GLOBAL EN SEGURIDAD DEL PACIENTE

2. Globalmente, cómo puntúa el sistema y los procedimientos clínicos que su centro de salud ha puesto en marcha para prevenir, detectar, y corregir problemas que potencialmente pueden afectar a los pacientes:

Pobre ☐ Regular ☐ Bueno ☐ Muy Bueno ☐ Excelente ☐

SECCIÓN H: PREGUNTAS SOBRE SU TRABAJO EN EL CENTRO DE SALUD

1. ¿Cuánto tiempo lleva trabajando en este centro de salud?

☐ Menos de dos meses
☐ De dos meses a menos de un año
☐ De un año a menos de tres años
☐ De 3 años a menos de 6 años
☐ De 6 años a menos de 11 años
☐ De 11 años a menos de 20
☐ Más de 20 años

2. Habitualmente, ¿cuántas horas trabaja en este centro de salud?

☐ De una a 4 horas por semana
☐ De 5 a 16 horas por semana
☐ De 17 a 24 horas por semana
☐ De 25 a 32 horas por semana
☐ De 33 a 40 horas por semana

3. ¿Qué puesto tiene en el centro de salud? Marque la categoría que mejor refleje su trabajo.

☐ Médico ☐ MIR ☐ Enfermera / Matrona
☐ Gestores:
  ☐ Coordinador médico
  ☐ Responsable del área administrativa
  ☐ Responsable de enfermería
☐ Trabajador social
☐ Administrativos y otro personal no sanitario
☐ Otros profesionales sanitarios en el centro de salud:
  ☐ Auxiliar de enfermería
  ☐ Odontologos
  ☐ Fisioterapeuta (de todos los tipos)
  ☐ Otros profesionales

4. ¿Qué nº de TIS tiene adscritas al cupo?

☐ <500 ☐ 500-1000 ☐ 1000-1500 ☐ 1500-2000 ☐ >2000

5. Edad ☐☐

6. Sexo ☐ Varón ☐ Mujer

7. Situacion laboral ☐ Fijo ☐ Interino ☐ Eventual

8. Turno de trabajo ☐ Sólo Mañana ☐ Sólo tarde ☐ Mañana y tarde

9. Realiza guardias ☐ Si ☐ No

SECCIÓN I: SUS COMENTARIOS SOBRE LA SEGURIDAD DEL PACIENTE/CALIDAD DE LA ASISTENCIA EN SU CENTRO

MUCHAS GRACIAS

17936

CUESTIONARIO SOBRE SEGURIDAD DEL PACIENTE EN ATENCION PRIMARIA.

VERSIÓN ESPAÑOLA MODIFICADA DEL MEDICAL OFFICE SURVEY ON PATIENT SAFETY CULTURE (MOSPS-AHRQ)

GOBIERNO DE ESPAÑA — MINISTERIO DE SANIDAD, POLÍTICA SOCIAL E IGUALDAD

INSTRUCCIONES PARA CUMPLIMENTAR LA ENCUESTA

Por favor, piense en cómo se hacen las cosas en su **centro de salud/consultorio**.

El término **profesional sanitario** hace referencia a los médicos, enfermeras, residentes y otros: fisioterapeutas, auxiliares de enfermería, odontólogos, etc.

El término **personal no sanitario** hace referencia al resto de trabajadores del centro (administrativos, trabajadores sociales…). El término **personal** o **equipo** hace referencia al conjunto de las personas que trabajan en el centro de salud.

Si alguna pregunta no le afecta o no sabe responder, por favor, marque "No lo sé/ No procede".

Si usted trabaja en más de una consulta, responda atendiendo únicamente a los hechos del lugar donde pasa la consulta la mayor parte del tiempo.

SECCIÓN A: LISTADO DE ASPECTOS RELACIONADOS CON LA SEGURIDAD DEL PACIENTE Y LA CALIDAD

Los siguientes enunciados describen hechos que pueden ocurrir en el día a día del centro de salud/consultorio y que afectan a la seguridad de los pacientes y a la calidad asistencial. En su opinión, ¿con qué frecuencia han ocurrido los siguientes hechos en su centro de salud/consultorio en los últimos doce meses?

	Diariamente	Semanalmente	Mensualmente	Varias veces en los últimos 12 meses	Una o dos veces en los últimos 12 meses	Ninguna vez en los últimos 12 meses	No lo sé/ No procede
Acceso a la atención sanitaria							
1. El paciente no consiguió una cita para consultar un problema de salud agudo en las siguientes 48h.	☐	☐	☐	☐	☐	☐	☐
Identificación del paciente							
2. Se utilizó la historia clínica de otro paciente.	☐	☐	☐	☐	☐	☐	☐
Historias clínicas							
3. La historia clínica del paciente no estaba disponible cuando se precisó.	☐	☐	☐	☐	☐	☐	☐
4. La información clínica se archivó en la historia clínica de otro paciente.	☐	☐	☐	☐	☐	☐	☐
Equipamiento médico							
5. El equipamiento médico no funcionó adecuadamente, precisaba reparación o sustitución.	☐	☐	☐	☐	☐	☐	☐
Medicación							
6. Una oficina de farmacia contactó con el centro o la consulta para clarificar o corregir una prescripción.	☐	☐	☐	☐	☐	☐	☐
7. La lista de medicación del paciente no se supervisó durante la consulta.	☐	☐	☐	☐	☐	☐	☐
Diagnósticos y pruebas complementarias							
8. Los resultados de algunas pruebas de laboratorio o de imagen no estaban disponibles cuando se precisaron.	☐	☐	☐	☐	☐	☐	☐
9. Un resultado crítico anormal en alguna prueba de laboratorio o de imagen no fue supervisado en el día.	☐	☐	☐	☐	☐	☐	☐

SECCIÓN B: INTERCAMBIO DE INFORMACIÓN CON OTROS DISPOSITIVOS ASISTENCIALES

En los últimos 12 meses, ¿con qué frecuencia ha tenido problemas en su centro para intercambiar información precisa, completa, adecuada y oportuna, con cada uno de los siguientes dispositivos asistenciales?

	Diariamente	Semanalmente	Mensualmente	Varias veces en los últimos 12 meses	Una o dos veces en los últimos 12 meses	Ninguna vez en los últimos 12 meses	No lo sé/ No procede
1. Problemas con servicios externos de pruebas complementarias (laboratorio, diagnóstico por imagen...).	☐	☐	☐	☐	☐	☐	☐
2. Problemas con otras consultas médicas fuera del centro.	☐	☐	☐	☐	☐	☐	☐
3. Problemas con oficinas de farmacia.	☐	☐	☐	☐	☐	☐	☐
4. Problemas con hospitales.	☐	☐	☐	☐	☐	☐	☐

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SECCIÓN C: TRABAJANDO EN EL CENTRO DE SALUD

¿Cuál es su grado de acuerdo con los siguientes enunciados?:

	Muy en desacuerdo	En desacuerdo	Ni de acuerdo, ni en desacuerdo	De acuerdo	Muy de acuerdo	No lo sé/ No procede
1. Cuando alguien tiene excesivo trabajo los compañeros le ayudan.	☐	☐	☐	☐	☐	☐
2. En este centro hay un buen ambiente de trabajo entre los componentes del equipo.	☐	☐	☐	☐	☐	☐
3. En este centro, sentimos que atendemos con prisas a los pacientes.	☐	☐	☐	☐	☐	☐
4. Este centro forma a su personal **no** sanitario en los nuevos procedimientos de trabajo que se ponen en marcha.	☐	☐	☐	☐	☐	☐
5. En este centro, nos tratamos mutuamente con respeto.	☐	☐	☐	☐	☐	☐
6. Tenemos demasiados pacientes asignados para el número de profesionales sanitarios que tiene el centro.	☐	☐	☐	☐	☐	☐
7. En este centro se asegura que el personal **no** sanitario tenga la formación necesaria para su trabajo.	☐	☐	☐	☐	☐	☐
8. Este centro está más desorganizado de lo que debiera.	☐	☐	☐	☐	☐	☐
9. Tenemos procedimientos adecuados para evaluar que el trabajo en el centro se ha realizado correctamente.	☐	☐	☐	☐	☐	☐
10. Al personal **no** sanitario se le pide realizar tareas para las que no ha sido formado.	☐	☐	☐	☐	☐	☐
11. Tenemos suficiente personal **no** sanitario para manejar la carga de trabajo de los pacientes.	☐	☐	☐	☐	☐	☐
12. En este centro tenemos problemas con la organización y distribución del trabajo.	☐	☐	☐	☐	☐	☐
13. Este centro promueve el trabajo en equipo para el cuidado de los pacientes.	☐	☐	☐	☐	☐	☐
14. Este centro tiene demasiados pacientes para hacer frente a todo de forma eficiente.	☐	☐	☐	☐	☐	☐
15. El personal **no** sanitario del centro realiza sus tareas según los procedimientos que tienen establecidos.	☐	☐	☐	☐	☐	☐
16. Este centro forma a su personal sanitario en los nuevos procedimientos de trabajo que se ponen en marcha.	☐	☐	☐	☐	☐	☐
17. En este centro se asegura que el personal sanitario tenga la formación necesaria para su trabajo.	☐	☐	☐	☐	☐	☐
18. Al personal sanitario se le pide realizar tareas para las que no ha sido formado.	☐	☐	☐	☐	☐	☐
19. El personal sanitario del centro realiza sus tareas según los procedimientos que tienen establecidos.	☐	☐	☐	☐	☐	☐

SECCIÓN D: COMUNICACIÓN Y SEGUIMIENTO

¿Con qué frecuencia ocurren las siguientes situaciones en tu Centro de Salud?

	Nunca	Rara Vez	A veces	La mayoría de las veces	Siempre	No lo sé/ No procede
1. Los profesionales sanitarios del centro son receptivos a las propuestas de mejora de los **no** sanitarios.	☐	☐	☐	☐	☐	☐
2. En este centro, se anima al personal **no** sanitario a expresar puntos de vista alternativos.	☐	☐	☐	☐	☐	☐
3. El centro recuerda a sus pacientes cuándo deben citarse para revisiones o para actividades preventivas.	☐	☐	☐	☐	☐	☐
4. El personal **no** sanitario teme hacer preguntas cuando algo parece que no está bien.	☐	☐	☐	☐	☐	☐
5. En este centro se registra si nuestros pacientes crónicos siguen bien su plan de tratamiento.	☐	☐	☐	☐	☐	☐
6. En nuestro centro se realiza un seguimiento cuando no se recibe el informe de un paciente que estamos esperando que nos remita un especialista de otro centro.	☐	☐	☐	☐	☐	☐
7. El personal **no** sanitario siente que sus errores son utilizados en su contra.	☐	☐	☐	☐	☐	☐
8. Todo el equipo habla abiertamente de los problemas del centro.	☐	☐	☐	☐	☐	☐
9. En este centro se hacen revisiones a los pacientes que precisan un seguimiento.	☐	☐	☐	☐	☐	☐
10. Es difícil expresar libremente cualquier desacuerdo en este centro.	☐	☐	☐	☐	☐	☐
11. En este centro, buscamos la manera de prevenir los errores para que no vuelvan a ocurrir.	☐	☐	☐	☐	☐	☐
12. El personal **no** sanitario está dispuesto a notificar fallos que observan en el centro.	☐	☐	☐	☐	☐	☐
13. El personal sanitario siente que sus errores son utilizados en su contra.	☐	☐	☐	☐	☐	☐
14. El personal sanitario está dispuesto a notificar fallos que observan en el centro.	☐	☐	☐	☐	☐	☐

SECCIÓN E: APOYO DE LOS LIDERES

1. ¿Está usted en una posición de liderazgo con responsabilidad para tomar decisiones en la gestión de los recursos de su centro de salud? (coordinador médico, responsable de enfermería, responsable administrativo).

☐ **SÍ (continúe en la seccion F)** ☐ **NO (responda a las preguntas de la 1 a la 4 que se muestran a continuación y luego prosiga el cuestionario en la sección F)**

¿Cuál es su grado de acuerdo con los siguientes enunciados?:

	Muy en desacuerdo	En desacuerdo	Ni de acuerdo, ni en desacuerdo	De acuerdo	Muy de acuerdo	No lo sé/ No procede
1. Los responsables de su centro no están invirtiendo suficientes recursos para mejorar la calidad asistencial en este centro de salud.	☐	☐	☐	☐	☐	☐
2. Los responsables de su centro pasan por alto los fallos relacionados con la asistencia que ocurren una y otra vez.	☐	☐	☐	☐	☐	☐
3. Los responsables de su centro dan prioridad a los procesos relacionados con la mejora de la atención a los pacientes.	☐	☐	☐	☐	☐	☐
4. Los responsables de su centro a menudo toman decisiones basadas en lo que es mejor para el centro en lugar de lo que es mejor para los pacientes.	☐	☐	☐	☐	☐	☐

SECCION F: EN EL CENTRO

¿Cuál es su grado de acuerdo con los siguientes enunciados?:

	Muy en desacuerdo	En desacuerdo	Ni de acuerdo, ni en desacuerdo	De acuerdo	Muy de acuerdo	No lo sé/ No procede
1. Cuando hay un problema en nuestro centro, valoramos si necesitamos cambiar la manera en que hacemos las cosas.	☐	☐	☐	☐	☐	☐
2. Los procesos de nuestro centro son buenos para prevenir fallos que pueden afectar a los pacientes.	☐	☐	☐	☐	☐	☐
3. En este centro se producen fallos con más frecuencia de lo que debieran.	☐	☐	☐	☐	☐	☐
4. Si no cometemos más fallos que afecten a nuestros pacientes, es por casualidad.	☐	☐	☐	☐	☐	☐
5. Este centro modifica sus procesos para garantizar que los mismos problemas no vuelvan a ocurrir.	☐	☐	☐	☐	☐	☐
6. En este centro, es más importante realizar más trabajo que la calidad de la atención.	☐	☐	☐	☐	☐	☐
7. Después de introducir cambios para mejorar la asistencia, comprobamos si funcionan.	☐	☐	☐	☐	☐	☐

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 22
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	5

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8,9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9,10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9,10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	14
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11,12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11,12

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Not reported
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not reported
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.