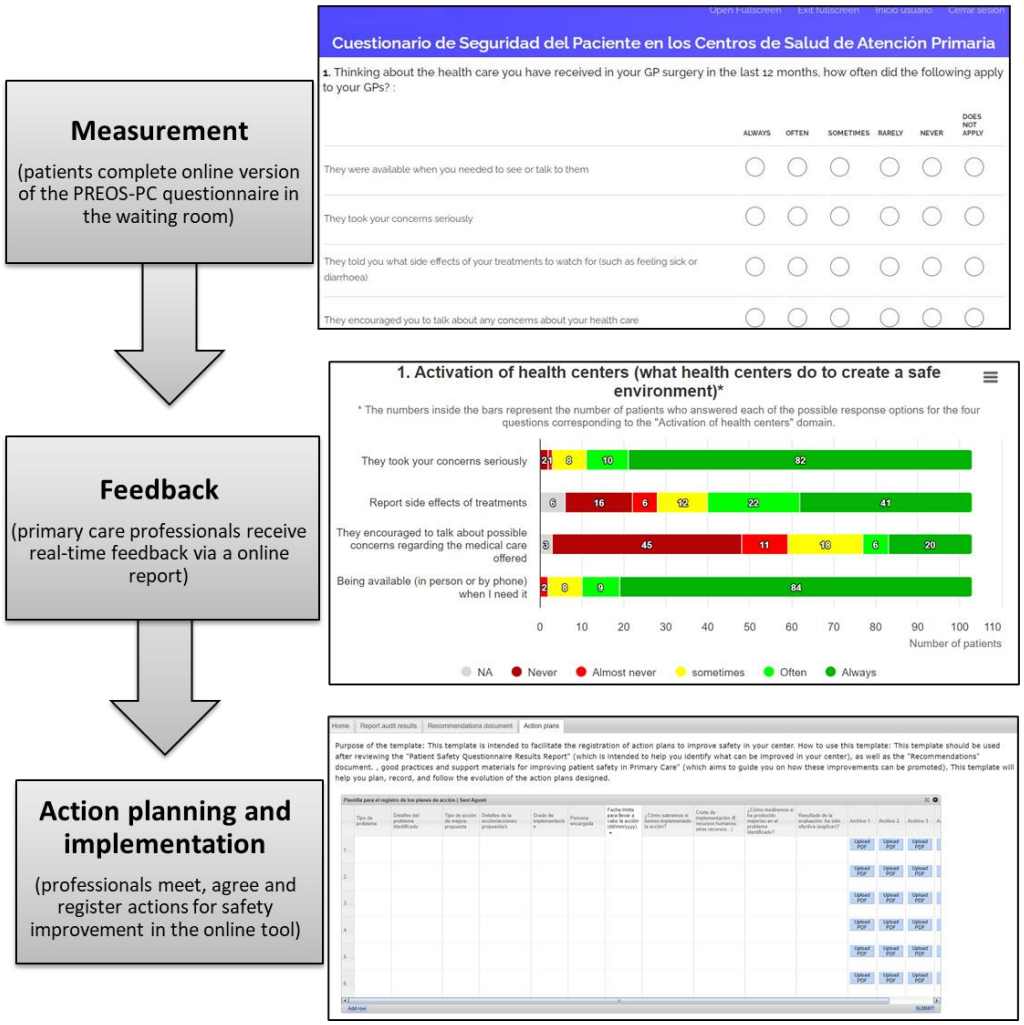
ONLINE APPENDIX 1. DETAILED DESCRIPTION OF THE METHODS IN THE SINERGIAPS TRIAL

The trial protocol is available elsewhere[1]. The reporting of this manuscript is based on the Consort 2010 statement: extension to cluster randomised trials[2]

Design: Pragmatic, phase 3, 12-month, two-arm, two-level cluster randomised controlled trial (1,248 PHC professionals within 59 PHC centres; with randomisation at the centre level in a 1:1 ratio). PHC centres were allocated to the SinergiAPS intervention group or to a waiting list control group.

Description of the SinergiAPS intervention: The SinergiAPS ("Sinergias entre profesionales y pacientes para una Atención Primaria Segura") intervention has already been described elsewhere[3]. SinergiAPS was delivered through a bespoke online tool and was targeted at the cluster level. It involved three stages (Figure 1):
a) Measurement: All patients in waiting rooms were consecutively invited to provide feedback about the safety of the healthcare they received in their centre during the previous 12 months. They did so by completing the Spanish online version of the PREOS-PC Compact questionnaire [4 5] using tablet computers. Patients were given the choice to complete the Spanish, Catalan or English version of the questionnaire. We administered 75 questionnaires per centre (based on the number of responses needed to achieve 0.7 reliability in scale scores[6]). All patients received plain language Patient Information Sheets and consent forms.
b) Feedback: From 13 January 2020, for a period of 12 months, all participating centres in the intervention group were given access to a password-protected, centre-specific feedback report, accessed through a secured link to our online platform. The report (sample available in Online Appendix 2) was automatically generated using a bespoke online tool and provided real-time information about the performance of each PHC centre in comparison with the rest of participating centres. A set of educational materials and online resources (a repository of publicly available written materials, infographics, and videos from local, national and international healthcare organizations) were also provided through the online platform. Follow-up calls were made by members of our team to ensure all centres had access to the intervention materials and to resolve technical problems, when needed.
c) Action planning and implementation: PHC centres were instructed to create an Action Planning Team (APT) responsible for receiving the Feedback Report, considering the area(s) that should be addressed, and designing action plans for safety improvement. The APTs were prompted to register their plans in a structured form available via the online tool. The intervention was meant to be self-contained, and therefore the researchers did not support centres in the analysis of the feedback report nor in the action planning and implementation.

Figure 1. Description of the components of the SinergiAPS intervention



SinergiAPS is a theory-based intervention, based on the Clinical Performance Feedback Intervention Theory, which states that behaviour is regulated through comparisons with standards or goals and that feedback can draw attention to existing gaps[7]. The SinergiAPS intervention was developed following the guidelines from the Medical Research Council[8]. The intervention was co-designed with 43 PHC professionals who participated in a qualitative study that involved four focus groups and three semi-structured individual interviews[9]. Before being trialled, the intervention was piloted in a 3-month, single-arm feasibility study in ten PHC centres[3], which showed that the intervention was feasible to be delivered; and allowed us to gather useful information that we used to refine further and improve the acceptability and potential impact of the intervention (e.g., increasing the sample of patients evaluating each centre, or improving the educational materials accompanying the feedback report).

Control group: No contact was made with the control practices after the collection of baseline data. They continued with usual care. After trial completion, they received the two feedback reports (corresponding to the baseline and to the post-intervention periods).

Randomisation: The allocation schedule for random assignment of intervention or control group to PHC centres was computer generated, including stratification by teaching centre (yes vs. no), management area (Mallorca, Catalunya Central, and Camp de Tarragona) and their baseline MOSPSC scores (terciles according to the synthetic index).

Allocation concealment mechanism: The treatment allocation for each PHC centre was kept in within the coordinator team in Mallorca until all the centres had completed the baseline data collection (both in the intervention and control centres [clusters]). Then a research assistant phoned all centres to inform them about their group allocation and emailed access to the intervention materials to those centres in the intervention group.

Blinding: Due to the nature of the intervention, PHC professionals could not be blinded to the assignment to the interventions. However, outcome assessors (i.e., questionnaire administrators, and information specialists extracting avoidable hospital admission data), and statisticians were blinded to group allocation.

Eligibility criteria:

- Eligibility of the clusters (PHC centres): we included public PHC centres from two regions (Balearic Islands and Catalonia). We included only those centres under the management area of Mallorca, Catalunya Central, and Camp de Tarragona. We excluded those centres attending specific populations or health problems (e.g., women health care centres), those that had been created recently (<12 months before the starting of the recruitment period), and those that had participated in the feasibility study described above.

- Eligibility of the PHC professionals: we included all healthcare professionals working in the centre, including administrative staff. We excluded those with less than 12 months of experience working in that centre, as well as those planning to leave their work at the centre during the next 12 months.

-Eligibility of patients: we invited patients who had visited their PHC centre at least once in the previous 12 months. Patients aged <18 were included only if their parents or guardians agreed to complete the questionnaire on their behalf. They had to be able to speak Spanish, Catalan or English. We excluded overt psychosis/critically ill/altered mental status, and inability to provide written informed consent.

Recruitment and training of PHC centres: We invited all the PHC centres from three areas (Mallorca, Catalunya Central, and Camp de Tarragona) meeting the eligibility criteria previously described. Centres were asked to consent as a unit, with all professionals willing to participate. Consent was also taken from patients invited to complete the patient survey. All informed consents were sought before randomisation. The intervention was standardized across all sites and regions.

Data collection: Data was collected at baseline and 12 months post-intervention (i.e., 12 months after the feedback reports were sent to the centres). We monitored the progress of the intervention in all the centres. Data from patients included patient reported experiences and outcomes of patient safety in PHC (measured with PREOS-PC questionnaire) and patient sociodemographic characteristics. Data from healthcare professionals was collected through online questionnaires and included the perceived safety climate (with the Spanish MOSPSC), and sociodemographic and occupational characteristics. Data from centres included rate of avoidable hospitalisations in the previous 12 months (extracted from electronic medical

records), and centre characteristics (rurality, list size, number of healthcare professionals and "Mortalidad en áreas pequeñas Españolas y Desigualdades Socioeconómicas y Ambientales"-MEDEA deprivation index).[10]

Outcomes: The primary outcome was the patient safety culture, measured with the Spanish MOSPSC[11] at the individual (PHC professional) level. The MOSPSC is a recognised instrument in Spanish PHC, and it is supported by the Ministry of Health and the main PHC society (Online Appendix 3). This instrument has been validated in a sample of Spanish PHC professionals. It includes 67 items grouped in 13 dimensions. Patient safety culture was computed both as a global score (synthetic index calculated at the healthcare professional level based on the mean score of the 67 items in the questionnaire[12]) and at the individual domain level.

Secondary outcomes were evaluated at the cluster (PHC centre) level, and included the six scales in the PREOS-PC Compact questionnaire (a psychometrically robust measure of patient safety): centre activation; patient activation; experiences of safety problems; harm; and overall rating of patient safety. An additional secondary outcome was the rate of avoidable hospitalisations, based on the definition provided by the Agency for Health Research and Quality, based on data extracted from the Minimum Basic Data Set using predefined ICD-9 codes[13] (full details available in Online Appendix 4). The rate of avoidable hospitalizations was calculated specifically for conditions such as asthma, chronic obstructive pulmonary disease, congestive heart failure, angina, diabetes, and chronic kidney disease. For each participating centre, we obtained the total number of registered patients and the total number of avoidable hospitalizations recorded during the previous 12 months.

Sample size calculation: The sample size calculation is based on the trial's main outcome measure—the Spanish MOSPSC, which produces an overall score ranging from 1 to 5. Assuming an average cluster size of 26 professionals per centre, we calculated that 1,248 professionals would take part in the study. Assuming a follow-up rate of 80%, we would have complete data from approximately 998 professionals. Considering the cluster design and using a conservative estimation of intra-class correlation of 0.1, this sample size would 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 (SD) of 2.3 from a previous study).[14] We recruited 75 patients per centre, which is the minimum number to achieve a 0.7 reliability of scale scores at the centre level.

Based on the results from a feasibility study[3], concerns that lower-than-expected healthcare professionals would agree to participate would affect the trial's ability to detect an effect of the intervention resulted in a protocol amendment. Therefore, in addition to the 48 centres initially considered, a further 11 health centres were approached to join the study during the recruitment period.

Statistical analyses: All the analyses were in accordance with our pre-specified analysis plan. Baseline characteristics were examined by group using frequencies (with percentages) for binary and categorical variables and means (and SD) or medians (IQR) for continuous variables. The results from the trial are presented as comparative summary statistics (difference in proportions or means) with 95% CI.

We used cluster specific methods because centres rather than professionals were randomised, and we expected that variance in how professionals implemented the intervention would be partly explained by the centre. Also, centres were managed in three different management areas (Mallorca, Catalunya Central and Camp de Tarragona - each of them substantially

different from the management perspective, and available resources). Therefore, we applied multilevel or mixed-effect regression models to analyse the effect of the intervention on post-intervention values adjusted for baseline or pre-intervention values. In the case of MOSPSC, the multilevel models comprised three levels: a first level defined by the professionals, a second level defined by the centre and a third level defined by the area. In the case of PREOS-PC and the rate of avoidable hospital admissions, the multilevel models comprised two levels: a first level defined by the centre and a second level defined by the area. Goodness-of-fit measures based on AIC (Akaike Information Criterion) and BIC (Bayesian Information Criterion) reported that the models with the best fit to the data were those that included random intercepts and an identity covariance structure, but without random slopes. Finally, given that the pre- and post-intervention variables analysed did not follow a normal distribution, the resampling technique was applied with an extraction of 1,000 samples in each model designed. All analyses were carried out based on intention-to-treat approach. We used SPSS V29 and applied an α level 0.05 throughout.

Deviations from the protocol due to the COVID-19 pandemic: The WHO declared COVID-19 a pandemic by March 11th, 2020 - nine weeks after the feedback report had been delivered to the PHC centres in the intervention group. This new context forced us to introduce two major modifications in the trial: 1) to reduce efforts to monitor and promote the uptake of the intervention by the PHC professionals (who were overwhelmed with an exceptional challenge as first-line workforce to contain the first wave of the pandemic), 2) to change the method for administering the PREOS-PC questionnaire to patients after the 12-month follow-up: from face to face in the waiting room (as in the baseline period) to telephonic or online administration (drawing random samples of patients from electronic health records).

Qualitative study with PHC providers: After the post-intervention follow-up, we conducted a qualitative study which involved semi-structured interviews with 15 healthcare professionals from the intervention group. This included eight doctors and seven nurses, with 14 females and one male. The mean (SD) age was 48 (6) years. The interviews aimed to understand how the intervention was perceived by the PHC professionals, focusing on acceptability, perceived utility, and implementation barriers, including any unintended consequences (interview guide available in Online Appendix 5). We used purposeful sampling to ensure variation in terms of type of professionals and of centres. Interviews took place telephonically. All 15 interviews were independently examined by two qualitative researchers. Thematic analysis[15] was used to identify recurrent themes and subthemes common to interviewees working in centres.

REFERENCES

1. Serrano-Ripoll MJ, Ripoll J, Llobera J, et al. Development and evaluation of an intervention based on the provision of patient feedback to improve patient safety in Spanish primary healthcare centres: study protocol. *BMJ open* 2019;9(12):e031367. doi: 10.1136/bmjopen-2019-031367 [published Online First: 2019/12/26]
2. Campbell MK, Piaggio G, Elbourne DR, et al. Consort 2010 statement: extension to cluster randomised trials. *Bmj* 2012;345:e5661. doi: 10.1136/bmj.e5661 [published Online First: 2012/09/07]
3. Serrano-Ripoll MJ, Fiol-deRoque MA, Valderas JM, et al. Feasibility of the SINERGIAPS ("Sinergias entre profesionales y pacientes para una Atención Primaria Segura") intervention for improving patient safety in primary care. *Family practice* 2022;39(5):843-51. doi: 10.1093/fampra/cmac015 [published Online First: 2022/03/08]
4. Fiol-deRoque MA, Valderas JM, Arias de la Torre J, et al. Evaluation of the psychometric performance of the Spanish and Catalan versions of the patient reported experiences and Outcomes of Safety in Primary Care (PREOS-PC)-Compact questionnaire. *The European journal of general practice* 2024;30(1):2296573. doi: 10.1080/13814788.2023.2296573 [published Online First: 2024/01/10]
5. Serrano-Ripoll MJ, Llobera J, Valderas JM, et al. Cross-Cultural Adaptation, Validation, and Piloting of the Patient Reported Experiences and Outcomes of Safety in Primary Care Questionnaire for Its Use in Spain. *J Patient Saf* 2022;18(2):102-10. doi: 10.1097/pts.0000000000000819 [published Online First: 2022/02/22]
6. Ricci-Cabello I, Avery AJ, Reeves D, et al. Measuring Patient Safety in Primary Care: The Development and Validation of the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC). *Annals of family medicine* 2016;14(3):253-61. doi: 10.1370/afm.1935 [published Online First: 2016/05/18]
7. Brown B, Gude WT, Blakeman T, et al. Clinical Performance Feedback Intervention Theory (CP-FIT): a new theory for designing, implementing, and evaluating feedback in health care based on a systematic review and meta-synthesis of qualitative research. *Implementation science : IS* 2019;14(1):40. doi: 10.1186/s13012-019-0883-5 [published Online First: 2019/04/28]
8. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *Bmj* 2021;374:n2061. doi: 10.1136/bmj.n2061 [published Online First: 2021/10/02]
9. Serrano-Ripoll MJ, Ripoll J, Briones-Vozmediano E, et al. Exploring primary health care professionals' perceptions about a patient feedback intervention to improve patient safety in Spanish primary health care centres: a qualitative study. *Family practice* 2020;37(6):821-27. doi: 10.1093/fampra/cmaa051 [published Online First: 2020/05/20]
10. Domínguez-Berjón MF, Borrell C, Cano-Serral G, et al. [Constructing a deprivation index based on census data in large Spanish cities(the MEDEA project)]. *Gaceta sanitaria* 2008;22(3):179-87. doi: 10.1157/13123961 [published Online First: 2008/06/27]
11. Torijano-Casalengua ML, Olivera-Cañadas G, Astier-Peña MP, et al. [Validation of a questionnaire to assess patient safety culture in Spanish Primary Health Care professionals]. *Atencion primaria* 2013;45(1):21-37. doi: 10.1016/j.aprim.2012.07.003 [published Online First: 2012/09/18]
12. Silvestre-Busto C, Torijano-Casalengua ML, Olivera-Cañadas G, et al. [Adaptation of the Medical Office Survey on Patient Safety Culture (MOSPSC) tool]. *Revista de calidad asistencial : organo de la Sociedad Espanola de Calidad Asistencial* 2015;30(1):24-30. doi: 10.1016/j.cali.2014.12.006 [published Online First: 2015/02/11]
13. Angulo-Pueyo E, Martínez-Lizaga N, Bernal-Delgado E. Wide systematic variations in potentially avoidable hospitalizations of chronically ill patients: Ecological study of primary

care areas and healthcare areas. *Revista clinica espanola* 2021;221(2):69-75. doi: 10.1016/j.rceng.2020.02.008 [published Online First: 2021/05/18]
14. Ricci-Cabello I, Pons-Vigués M, Berenguera A, et al. Patients' perceptions and experiences of patient safety in primary care in England. *Family practice* 2016;33(5):535-42. doi: 10.1093/fampra/cmw046 [published Online First: 2016/06/18]
15. Guest G. Applied thematic analysis: Sage 2012.