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EMAeHealth, a digital tool for the self-management of women's health needs during pregnancy, childbirth and the puerperium: protocol for a hybrid effectiveness-implementation study

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ABSTRACT

Introduction EHealth can help health service users take a more active role in decision-making and help health professionals guide the patient in this process. A digital tool has been designed to support maternal education (ME), and it is organised into four areas: (1) information, (2) communication, (3) health self-management and (4) clinical data. The main objective of the study is to evaluate the effectiveness of the EMAeHealth digital tool, and assess its usability and acceptability under routine conditions.

Methods and analysis Hybrid implementation-effectiveness design: (1) A cluster randomised, prospective, longitudinal, multicentre clinical trial to evaluate the effectiveness of EMAeHealth in (A) improving health-related quality of life (primary outcome), (B) improving self-efficacy for labour and childbirth and self-efficacy in breast feeding and (C) reducing the number of visits to the obstetric emergency services and health centre in situations of 'non-pathological pregnancy', 'false labour pains' and 'non-pathological puerperium'. The EMAeHealth intervention plus usual care will be compared with receiving only usual care, which includes traditional ME. N=1080 participants, 540 for each study arm. Two measurements will be made throughout the pregnancy and three in the first 16 weeks post partum. (2) A mixed-method study to evaluate the usability and acceptability of the tool, barriers and facilitators for its use, and implementation in our health system: focus groups (women, professionals and agents involved) and a quantitative analysis of implementation indicators. Analysis: It will be carried out by intention to treat, using mixed models taking into account the hierarchical structure of the data and per protocol to evaluate the effectiveness of the express use of the digital tool.

Ethics and dissemination Clinical Research Ethics Committee of Euskadi, Spain, (Ref: PI2020044) approved this study. The results will be actively disseminated through manuscript publications and conference presentations.

Trial registration number NCT04937049.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ EMAeHealth is the prototype of a digital tool that supports decision-making during the pregnancy and post partum. One strength is that it has been designed through Collaborative Action Research and is intended to be a complement to Maternal Education.
⇒ A hybrid efficacy-implementation design will allow the effectiveness of EMAeHealth to be evaluated while collecting data on the implementation of the tool in 'real-world' conditions.
⇒ Both patients and professionals have participated in the previous Collaborative Action Research and will be involved in the evaluation of the tool and in its implementation.
⇒ One of the main strengths of the efficacy-implementation study is that it will result in an effective tool that will be perfectly adapted to the needs of the target population.
⇒ A weakness is that it is possible the results cannot be directly extrapolated to a different context and it would be necessary to adapt the tool to the context where it will be implemented.

INTRODUCTION

Need to adapt maternal education to the current context

Antenatal education classes, including 'childbirth education programmes', 'prenatal classes' and antenatal groups, are attended by a large percentage of pregnant women worldwide.[1–3] Both the high attendance of maternal education (ME) classes, and the fact that they take place at a time of transition, when readiness for change is higher, suggest that ME can be a valuable window of opportunity.[1 2] However, the benefits of these programmes for participants and their newborn infants remain unclear, and classes are not normally based on the expressed needs of attendees, but rather on the messages that the educators

themselves believe they should impart.[1] It may be that studies aimed at evaluating the effectiveness of ME have tended to have methodological weaknesses, such as small sample sizes, lack of control for variables that could affect the delivery process and consideration of only part of the delivery process.[1] Whatever the case, it has also been found in our setting that ME classes have not been associated with an improvement in most birth variables, whether physical or psychological, and have even increased birth anxiety in foreign women[3]; in this study, it was concluded that a new approach to these classes would be necessary. Other authors have come to the same conclusion, in light of their results.[4 5] There is therefore a need to reorient ME by focusing on women's needs and to evaluate the effectiveness of any initiatives to improve ME.

In order to establish a feasible and effective perinatal education programme, tailored to our setting, the team—following guidance published by the UK Medical Research Council for the development and evaluation of complex interventions in primary care—undertook: (A) a qualitative study with 30 women, exploring their needs during pregnancy and post partum; (B) two literature reviews on women's needs at these times and theoretical models of health education and (3) seven discussion and consensus sessions with an expert panel of midwives, gynaecologists, paediatricians, paediatric and postpartum nurses.[6 7] The aim was to involve women and professionals in the process of designing the new ME. Subsequently, a study was conducted to establish priorities with respect to ME using the Delphi technique and the nominal group approach. The objective of this study was to identify and prioritise the most important issues in ME in order to set goals and evaluate their achievement, that is, to 'make ME evaluable'.[8]

The needs expressed by women in our population changed throughout pregnancy: initially they needed information to know that 'everything was going well'; next, they needed more emotional support, to feel confident and self-reliant in dealing with their fears about childbirth and childcare; and finally, they needed more postpartum support and less pressure regarding breast feeding. They also preferred a comprehensive perinatal education programme—covering pregnancy, post partum, breast feeding and parenting—rather than just prenatal; and one that was more participatory and flexible and allowed for greater partner involvement. These were the results of the study with focus groups of women.[6]

Accordingly, ME was redefined as a complex intervention, which should extend from the beginning of pregnancy to the end of the puerperium, focusing on the needs of women and with the involvement of multiple health professionals. It would be an intervention whose general objective should be to enable women to make appropriate decisions to: (1) improve their health level and that of their family, (2) choose and responsibly face their birth and parenting model, and (3) maintain family and social support networks. The new model of ME includes multiple interventions capable of responding to the health needs of each woman at different moments of the childbearing process.[7 8]

Design and relevance of an eHealth tool to support ME: EMAeHealth

EHealth interventions are becoming increasingly important and frequent.[9] EHealth can help the health service user to take a more active role in decision-making and enable the health professional to guide the patient in this process.[10] It can also contribute, at organisational level, to a more patient-centred model of healthcare.[11]

In addition, young women from all social strata consistently use the Internet as a source of information about their health.[12–15] The information available on the websites they consult is positively correlated with the decisions they make about their health during the pregnancy and post partum.[12 16] Pregnant and postpartum women use the internet because it offers immediate, detailed, entertaining, personalised or practical information.[13 17]

However, the lack of participation of health professionals in integrating healthcare and new technologies is felt,[12 18] since the currently available range of information is not always reliable[19] or contextualised.[20] As the origin of a website has a direct effect on reliability, the participation of health professionals in the use, advice and generation of new technologies is essential.[15 21]

This team has designed a prototype digital tool called EMAeHealth involving healthcare professionals and patients, using a collaborative research process.[21] The website, adapted to our context of implementation, is organised into four areas: (1) an information area, which is open to the public, provides information based on evidence and is permanently updated by healthcare professionals; (2) a communication area, which allows women to contact others in a similar situation, through forums or conversations, or consult their own midwife (3) a health self-management area, which has valid and reliable self-assessment instruments for checking or reflecting on their own health needs, and decision support tools such as the detection of the onset of labour or the detection of warning signs and symptoms in the post partum; and (4) a clinical data area, which allows women to keep their clinical data, to add the most recent, and share data with other professionals if they wish, under secure conditions. The tool is conceived as a complement that can reinforce ME; with resources that facilitate its accessibility, immediacy and continuity, as well as improving its results. Its incorporation into the Osakidetza-Basque Health Service corporate website will encourage its adoption by patients and professionals, as well as its safe use. The usual phases for the development of a digital tool are analysis, development, testing and production. The prototype is the result of the analysis, a proposal of the architecture and technical requirements that the digital tool must have in order to respond to the users' needs. This is followed by development—or programming—and testing, which are carried out almost simultaneously, to detect and solve errors. Once the tool is ready, it is deployed in a

production environment, making it available to all users of the system, in our case the Osakidetza-Basque Health Service corporate website.

Study of the effectiveness of the tool while we are collecting useful information for its implementation in routine conditions

The evaluation of the effectiveness of digital tools aimed at health education during pregnancy is scarce and has had controversial results:[22 23] the quality, reliability and effectiveness of current pregnancy apps is yet to be determined,[15 22 23] and consequently, such studies to evaluate effectiveness are absolutely essential, especially if the digital tool comes from the healthcare system. In addition, there are barriers and facilitators that modify both the use of digital technology and its effectiveness in healthcare, where further study is needed.[13 16 17 24–26] Fortunately, there are hybrid designs that enable testing of the clinical intervention and, at the same time, during the trial, gathering information on its application and/or its potential for application in real-world conditions.[27] There are also frameworks, such as the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) Planning and Evaluation Framework, and Consolidated Framework for Implementation Research (CFIR), which can help in the task of studying the degree of adoption of an innovation, and guide in the data collection, analysis and interpretation of barriers and facilitators to implementation.[28 29] Therefore, we conducted this study to find out if complementing traditional perinatal care with a tool—designed through a collaborative action-research process—translates into better health outcomes for women than those obtained with traditional care alone. In addition, we want to know if this type of tool is useful and acceptable to its users in real-life conditions.

OBJECTIVES

The main objective of the study is twofold: on the one hand to evaluate the effectiveness of the EMAeHealth digital tool and its components (Information Area, Communication Area, Health Self-Management Area and Clinical Data Area), and on the other to assess the usability and acceptability of the tool under routine conditions.

The following are proposed as specific objectives:

- To develop, test and deploy the EMAeHealth tool,[21] with the structure described above, capable of offering information, responses via algorithm, links to available resources, secure data archiving and monitoring, connection between various systems and the possibility of data analysis establishing continuous feedback and readjustment of the information presented. To provide it with content related to pregnancy, childbirth and post partum.
- To evaluate the effectiveness of the tool in (1) improving health-related quality of life, (2) improving self-efficacy for labour and childbirth and self-efficacy in breast feeding and (3) reducing the number of visits to the obstetric emergency services and health centre in situations of 'non-pathological pregnancy', 'false labour pains' and 'non-pathological puerperium'.
- To evaluate the usability and acceptability of the tool by women and professionals, and any barriers to its implementation.
- To estimate the differential impact that EMAeHealth could have, based on sociodemographic and/or population characteristics.

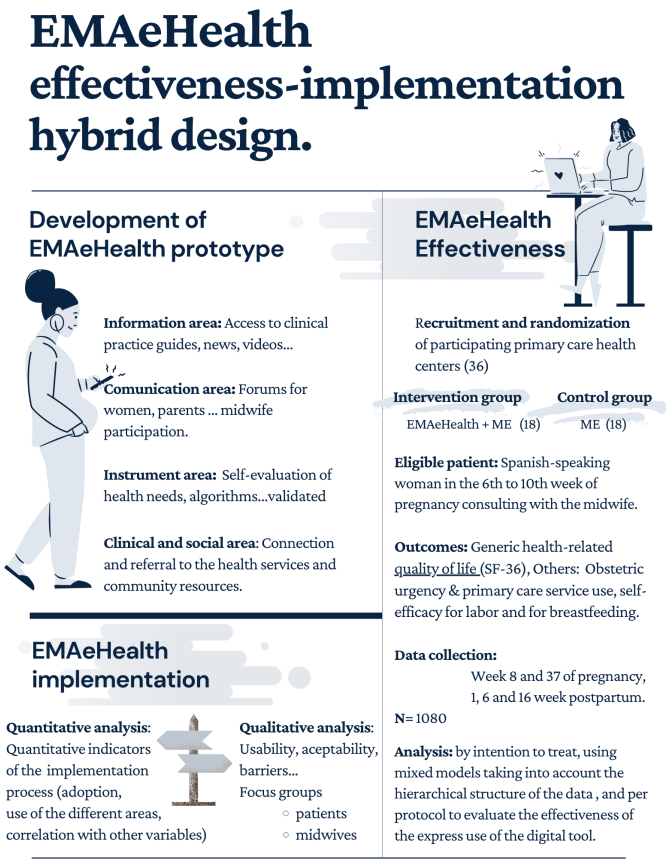

Figure 1 EMAeHealth design description. ME, maternal education; SF-36, Short Form 36.

METHODS AND ANALYSIS

This is an Effectiveness-implementation hybrid design type I,[26] which combines (1) a multicentre, longitudinal, prospective, cluster randomised clinical trial to evaluate the effectiveness of EMAeHealth and (2) a mixed-method study to evaluate the usability and acceptability of the tool, barriers and facilitators for its use and implementation in our health system. The mixed-method study is made up of a qualitative study by focus groups (women, professionals and agents involved) and a quantitative analysis of implementation indicators (figure 1).

For the effectiveness study, we have chosen a cluster randomised design to avoid, among other issues, contamination bias among women from the same centre, since they are likely to coincide, for example, in ME classes. In addition, as the intervention has been designed for shared decision-making, it did not seem appropriate

for the same midwife to have women belonging to both control and intervention.

The study is being conducted between 2021 and 2023, with the first year dedicated to the development of the EMAeHealth digital tool. The general structure of the tool is described in the introduction. In the development of the prototype, the International Patient Decision Aid Standards were applied, using a collaborative action research process, involving experts and patients, with qualitative research techniques, as well as focus groups, prioritisation and consensus techniques.[21] At this time, we are finalising content editing and software development and testing. We expect to start recruitment in July 2022. The participants will be followed up for a year, the period of time that the intervention lasts. The final months of 2023—first months of 2024 will be dedicated to the analysis and diffusion of results.

Regarding the study population, all Osakidetza-Basque Health Service public primary care centres that have midwives who are interested in optimising their clinical practice by adopting innovations will be eligible. In order to consider the centre eligible, the requirement will be that at least 50% of the midwives belonging to the centre have signed a collaboration agreement, as well as the approval of the Head of the Primary Care Centre.

Osakidetza-Basque Health System is the public healthcare system of the Basque Country, a region located in the north of Spain. Osakidetza was created by the Health Department of the Basque Government in 1983. All the public hospitals and primary care centres of the Basque Region are under this organisation, structured into several Integrated Health Organisations (IHO) spread throughout the Basque country. More than 30 000 professionals work for Osakidetza, and it could be considered the largest organisation in the Basque Country.

For the study of clinical effectiveness, an active surveillance system will be established to identify eligible patients, who are Spanish-speaking pregnant women attending their first appointment with the midwife between week 6 and 10 of gestation. Regarding their clinical profile, they are low-risk pregnant women. The midwives participating in the study will be in charge of recruiting them consecutively until they have the necessary sample from among the people using and not using the EMAeHealth tool (figure 2).

Regarding the mixed-method study, to evaluate the quantitative implementation indicators, all pregnant women who have seen their midwives at the start of gestation at the health centres will be included for 1 year after the implementation of EMAeHealth. The same goes for the qualitative evaluation, through focus groups of women and professionals from the health centres (model consent form as an online supplemental file 1).

Random assignment of centres

The eligible centres will be randomised centrally, blindly, and electronically, in the Biocruces-Bizkaia Research Institute, stratified by IHO and in a 1:1 ratio. Therefore,

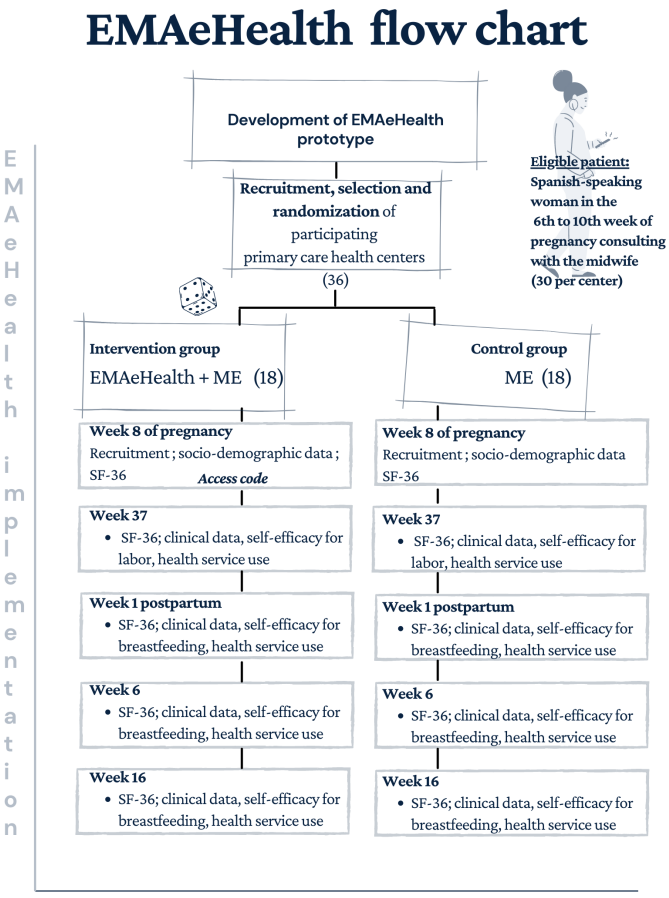

Figure 2 EMAeHealth effectiveness flow chart. ME, maternal education; SF-36, Short Form 36.

the intervention allocated centres will have access to EMAeHealth, while it will not be accessible for the control group centres. IHOs are groups of health centres within the same geographical area, with similar characteristics and population, under the direction of the same hospital. Therefore, we assume that there are no pre-existing differences in the quality of care provided between centres that belong to the same IHO.

Intervention centres

All the patients in these centres, in the first consultation with the midwife, will be informed that EMAeHealth is available to them, and they will be told about the content of the tool. In addition, they will be invited to participate in the study of its clinical effectiveness. If the answer is affirmative, they must sign the consent form and will be provided with a link to the forms (baseline measurements and questionnaires for each measurement) to fill in electronically. Participants sign a consent form approved by the Ethics Committee and can leave the study whenever they want (model consent form as an online supplemental file 1).

Control centres

Patients in these centres will not have EMAehealth. They will receive, like the intervention group, the usual care and the possibility of attending ME sessions, but not

EMAeHealth. After being informed of the clinical effectiveness study, they will be asked for consent to participate (see online supplemental file 1). Women who sign the consent form for participation in the study will be provided with the link to the forms for each measurement.

Outcomes

Access to EMAeHealth by women and professionals during the study period will be through access codes, which will allow the research team to track the use made by users of the tool while ensuring the confidentiality of the data. It also makes it possible, under safe conditions, to link this use with clinical variables from medical records and with the record of the forms filled in electronically at each measurement.

Results of clinical effectiveness: The primary outcome is change in Health-related quality of life (QoL), measured with the Spanish version of the Short Form 36 (SF-36) questionnaire.[30] The secondary variables are the number and reasons for visits to the obstetric emergency service and to the health centre for non-pathological pregnancy situations, and the labour stage at the time of going to the hospital for suspected labour onset (measurement is carried out using the Bishop test/dilation in cm, effacement and breaking of waters (YES/NO)) . As indirect indicators of autonomy in managing their own health and well-being, self-efficacy for labour and childbirth and self-efficacy in breast feeding will be measured using the Spanish version of Lowe's CBSEI scales[31] and the Breastfeeding Self-Efficacy Scale—SF,[32] respectively.

Measurements of these variables will be performed at weeks 8 and 37 of pregnancy, and at weeks 1, 6 and 16 post partum. Contact with the woman and the response to the questionnaires will be carried out electronically (via mobile phone).

QoL is a parameter that has been defined and recently taken into account as a health indicator by WHO.[33] The concept of QoL could be defined as an individual's assessment of their own state in relation to their needs,[33] so it seems appropriate that it should be the primary outcome measure. The Spanish version of the SF-36 questionnaire has been used to assess the health-related QoL perceived by pregnant women in several studies,[33 34] showing good psychometric characteristics. The SF-36 questionnaire is made up of eight domains, of which four are oriented towards physical aspects and another four towards mental aspects of health-related QoL. In addition, two summaries are made of this physical and mental component, which explain between 80% and 85% of the variance of the eight domains.[30] The scores of the questionnaire are transformed on a scale from 0 to 100 points; the higher the score, the better the perception of health-related QoL. A difference of five points in the domain score, or between 2 and 3 points in the summary score is considered clinically relevant.[30]

Self-efficacy is one of the key factors influencing women's confidence and ability to cope with childbirth, and the Childbirth Self-Efficacy Inventory has been shown to be a valid and reliable instrument to measure maternal confidence in childbirth. The Spanish version of the Childbirth Self-Efficacy Inventory shows adequate psychometric properties (ie, internal consistency and validity). Moreover, self-efficacy is a variable which is sensitive to external modifications, so we believe it may be suitable as one of the secondary measures to assess the effectiveness of using EMAeHealth.

Similarly, breastfeeding self-efficacy is a mother's confidence in her ability to breastfeed and is highly predictive of breastfeeding behaviours. The Spanish version of the BSES-SF can be considered a valid and reliable measure of maternal breastfeeding self-efficacy.

Indicators of the implementation process: Qualitative indicators: Usability and acceptability of the tool by patients and professionals, as well as barriers and facilitators for its use and adoption in the health system. The qualitative evaluation will be carried out through focus groups of women and professionals, between 6 and 8 per group and as many as necessary until the discourse is saturated.[35] A semistructured script will be developed for the sessions, based on the theoretical constructs of the CFIR,[28] which will also serve as the basis for the analysis. The CFIR includes 37 constructs within 5 main domains: intervention characteristics, outer setting, inner setting, individual characteristics and implementation process. Overall, the CFIR aims to help identify potential factors (ie, barriers and facilitators) that are believed to influence implementation. Sessions will be audiorecorded and moderated by an expert in qualitative techniques while an assistant will take notes. Later the sessions will be transcribed and analysed. Quantitative indicators: adoption and frequency of the use of EMAeHealth and its areas according to stratification profiles and correlates with other variables (indicators: patients exposed to the digital tool, by centre and group; women with access to EMAeHealth who access the tool once; frequency of use of the tool, frequency of use of the different functions of the tool, etc).

Predictive, modifying and confounding variables: Patients: Age, parity, nationality, race, social class, educational level, marital status, work situation, distance to hospital, spontaneous pregnancy versus assisted reproductive technique, obstetric history and other clinical characteristics. Professionals: Sex, age, length of time in the position, type of contract, profile of adoption of innovations by professionals, measured by means of a questionnaire by Borracci *et al*, 2013.[36] Health centres: reference IHOs, number of midwives and participation rate, rural or urban environment, and population served (figure 3).

Statistical methods

EMAeHealth clinical effectiveness results: quantitative comparisons will be made between intervention and control centres, with an intention-to-treat approach. Mixed models (linear or generalised as appropriate to

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT**	*January 2022-june 2022*	0	*week 8 of pregnancy*	*week 37 of pregnancy*	*Week 1 postpartum*	*Week 6 postpartum*	*Week 16 postpartum*	*June 2023-Dec 2023*
ENROLMENT:	January 2022-june 2022. Enrollment of participants will be after allocation of the centers. It will be done, for both arms, consecutively, until complete the sample (Total N=1080)							
Eligibility screen	Spanish-speaking woman around the 8th week of pregnancy consulting with the midwife of eligible centers.							
Informed consent	First consultation with the midwife between week around 8th week of gestation							
Allocation		The eligible health centers will be randomized centrally, blindly, and electronically, in Biocruces-Bizkaia Research Institute, stratified by Integrated Healthcare Organization (IHO) and in a 1: 1 ratio. Therefore, the participating centers will have access to EMAeHealth, while it will not be accessible to the control group centers.						
INTERVENTIONS:								
EMAeHealth +traditional ME (usual care)			←	—	—	—	→	
traditional ME (usual care)			←	—	—	—	→	
ASSESSMENTS:								
Baseline: Socio-demographic data and SF-36			X					
Outcomes: SF-36, clinical outcomes, self-efficacy for labor, self-efficacy for breastfeeding, health service use				X	X	X	X	X
Predictive, modifying and confounding variables			X	X	X	X	X	X

Figure 3 SPIRIT timetable. ME, maternal education; MS, maternal education; SF 36, Short Form 36; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials. **This period is approximate. It depends on the availability of EMAeHealth on the Osakidetza-Basque Health Service corporate website.

the variable under study), which take into account the hierarchical structure of the data (patients grouped by midwives, midwives grouped by centre), will be used and 95% CIs will be calculated. Likewise, per-protocol analysis will be carried out, in which the effectiveness of the express use of both the tool in general and in particular of some of its components will be evaluated, adjusting for possible confounding factors. Statistical analysis will be carried out by a professional who is not part of the research team.

Implementation process: For the qualitative evaluation of the tool and its implementation, the analysis of the focus groups, facilitated by the ATLAS.ti software programme, will be structured in three phases: a deductive analysis to determine which CFIR constructs influence its use in real life, followed by an inductive analysis to identify others not included in the CFIR framework that could influence its use, and a third validation phase using triangulation. The analysis results report will be provided to each patient and professional, who will have the opportunity to provide feedback to the team of analysts with their comments ('response validity').

For the quantitative evaluation, the distribution of the indicators associated with the use and scope of the tool as well as its components will be described. Measures of central tendency, dispersion and proportions will be calculated, with 95% CIs, and the relationship between the indicators and the predictor/confounding variables will be analysed using mixed models.

Study size

For the clinical effectiveness study, 18 centres will need to recruit 30 patients each, in each arm of the study (N=1080). This will make it possible to detect a difference of two points as significant in the mental component of the SF-36 test, with an alpha error of less than 5% and power greater than 80%. A 10-point SD is assumed for the mental SF-36 and an intracluster correlation of 0.01.

The calculation took into account the cluster design of the study and it was carried out using the National Institute of Health GRT sample size calculator* which assumes that the analysis will employ mixed-model regression methods.

* Research Methods Resources: National Institutes of Health. (Accessed on 2 January 2020). Available from: https://researchmethodsresources.nih.gov/grt-calculator

Patient involvement

In the previous studies, multidisciplinary groups of midwives, nurses, paediatricians, epidemiologists, psychologists and pregnant and postpartum women were involved in the description and prioritisation of ME needs, as well as in the redesign of the ME and the design of an EMAeHealth tool to complement it.[3 6–8 8 15 21] In this study, patients will be involved in testing the tool under construction, assessing its usability, acceptability and evaluating barriers and facilitators for its implementation in 'real-world conditions'. In addition, women will participate as study subjects in the evaluation of the effectiveness of the digital tool.

ETHICS AND DISSEMINATION

The study protocol has been reviewed and ethics approval obtained from the by the Clinical Research Ethics Committee of Euskadi, Spain in November 2020 (Ref: PI2020044). This approval covers all centres included in the study. Participation in this study will be voluntary; individual written (or online) consent will be sought from all participants. Each participant will receive a study information sheet that outlines the project and expectations in plain language

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Contributors IA-P, CP-P, PB-G and MEC designed the EMAeHealth program, with EMA-Q Group's collaboration, AG-A has collaborated on the statistics and on the revision of the article; All of them have been involved in the design of the protocol and have collaborated in writing the manuscript; all authors read, contributed and finally approved the manuscript. Contributors: AG-A (statistics) and patients involved.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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REFERENCES

1 Gagnon AJ, Sandall J. Individual or group antenatal education for childbirth or parenthood, or both. *Cochrane Database Syst Rev* 2007:CD002869.
2 Antenatal education evidence review Final.docx. Available: https://www.nice.org.uk
3 Artieta-Pinedo I, Paz-Pascual C, Grandes G, *et al*. The benefits of antenatal education for the childbirth process in Spain. *Nurs Res* 2010;59:194–202.
4 Billingham K. Preparing for parenthood: the role of antenatal education. *Community Pract* 2011;84:36–8.
5 McMillan A, Barlow J, Redshaw M, *et al*. Birth and beyond: a review of the evidence about antenatal education, 2009. Available: https://www.researchgate.net/publication/258369289_Birth_and_beyond_a_review_of_the_evidence_about_antenatal_education
6 Paz Pascual C, Artieta Pinedo I, Grandes G, *et al*. [Perceived needs of women regarding maternity. Qualitative study to redesign maternal education]. *Aten Primaria* 2016;48:657–64.
7 Artieta-Pinedo I, Paz-Pascual C, Grandes G, *et al*. Framework for the establishment of a feasible, tailored and effective perinatal education programme. *BMC Pregnancy Childbirth* 2017;17:58.
8 Paz-Pascual C, Artieta-Pinedo I, Grandes G, *et al*. Consensus on priorities in maternal education: results of Delphi and nominal group technique approaches. *BMC Pregnancy Childbirth* 2019;19:264.
9 World Health Organization. Digital health. Available: https://www.who.int/ehealth/en/
10 Ruiz-Azarola A, Perestelo-Pérez L. Participación ciudadana en salud: formación y toma de decisiones compartida. Informe SESPAS 2012 [Citizens' participation in health: education and shared decision-making SESPAS Report 2012]. *Gac Sanit* 2012;26:158–61.
11 Mora J. Cómo avanzar Con El paciente. Modelo afectivo efectivo. The Institute for health and strategy s.l. (Si-Health), 2019. Available: https://www.sihealth.es/es/publicaciones-eventos/publicaciones/
12 Bert F, Gualano MR, Brusaferro S, *et al*. Pregnancy e-health: a multicenter Italian cross-sectional study on internet use and decision-making among pregnant women. *J Epidemiol Community Health* 2013;67:1013–8.
13 Hughson J-AP, Daly JO, Woodward-Kron R, *et al*. The rise of pregnancy Apps and the implications for culturally and linguistically diverse women: narrative review. *JMIR Mhealth Uhealth* 2018;6:e189.
14 O'Higgins A, Murphy OC, Egan A, *et al*. The use of digital media by women using the maternity services in a developed country. *Ir Med J* 2014;107:313–5.
15 Artieta-Pinedo I, Paz-Pascual C, Grandes G, *et al*. An evaluation of Spanish and English on-line information sources regarding pregnancy, birth and the postnatal period. *Midwifery* 2018;58:19–26.
16 Wallwiener S, Müller M, Doster A, *et al*. Pregnancy eHealth and mHealth: user proportions and characteristics of pregnant women using web-based information sources-a cross-sectional study. *Arch Gynecol Obstet* 2016;294:937–44.
17 Lupton D. The use and value of digital media for information about pregnancy and early motherhood: a focus group study. *BMC Pregnancy Childbirth* 2016;16:171.
18 Rodger D, Skuse A, Wilmore M, *et al*. Pregnant women's use of information and communications technologies to access pregnancy-related health information in South Australia. *Aust J Prim Health* 2013;19:308–12.
19 Brown HM, Bucher T, Collins CE, *et al*. A review of pregnancy iPhone apps assessing their quality, inclusion of behaviour change techniques, and nutrition information. *Matern Child Nutr* 2019;15:e12768.
20 Kraschnewski JL, Chuang CH, Poole ES, *et al*. Paging "Dr. Google": does technology fill the gap created by the prenatal care visit structure? Qualitative focus group study with pregnant women. *J Med Internet Res* 2014;16:e147.
21 Artieta-Pinedo I, Paz-Pascual C, Bully P, *et al*. Design of the maternal website EMAeHealth that supports decision-making during pregnancy and in the postpartum period: collaborative action research study. *JMIR Form Res* 2021;5:e28855.
22 Overdijkink SB, Velu AV, Rosman AN, *et al*. The usability and effectiveness of mobile health technology-based lifestyle and medical intervention Apps supporting health care during pregnancy: systematic review. *JMIR Mhealth Uhealth* 2018;6:e109.
23 Roch G, Borgès Da Silva R, de Montigny F, *et al*. Impacts of online and group perinatal education: a mixed methods study protocol for the optimization of perinatal health services. *BMC Health Serv Res* 2018;18:382.
24 Berland GK, Elliott MN, Morales LS, *et al*. Health information on the Internet: accessibility, quality, and readability in English and Spanish. *JAMA* 2001;285:2612–21.
25 Risling T, Martinez J, Young J, *et al*. Evaluating patient Empowerment in association with eHealth technology: Scoping review. *J Med Internet Res* 2017;19:e329.
26 Leonardsen A-CL, Hardeland C, Helgesen AK, *et al*. Patient experiences with technology enabled care across healthcare settings- a systematic review. *BMC Health Serv Res* 2020;20:779.
27 Curran GM, Bauer M, Mittman B, *et al*. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012;50:217–26.
28 Damschroder LJ, Aron DC, Keith RE, *et al*. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50.

29 Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health* 2013;103:e38–46.
30 Vilagut G, Ferrer M, Rajmil L. El Cuestionario de Salud SF-36 español: una década de experiencia y nuevos desarrollos [The Spanish version of the Short Form 36 Health Survey: a decade of experience and new developments]. *Gac Sanit* 2005;19:135–50.
31 Cunqueiro MJ, Comeche MI, Docampo D. Childbirth self-efficacy inventory: psychometric testing of the Spanish version. *J Adv Nurs* 2009;65:2710–8.
32 Oliver-Roig A, d'Anglade-González M-L, García-García B, *et al*. The Spanish version of the breastfeeding self-efficacy Scale-Short form: reliability and validity assessment. *Int J Nurs Stud* 2012;49:169–73.
33 Martínez-Galiano JM, Hernández-Martínez A, Rodríguez-Almagro J, *et al*. Quality of life of women after giving birth: associated factors related with the birth process. *J Clin Med* 2019;8:324.
34 Schubert KO, Air T, Clark SR, *et al*. Trajectories of anxiety and health related quality of life during pregnancy. *PLoS One* 2017;12:e0181149.
35 Hennink MM, Kaiser BN, Weber MB. What influences saturation? estimating sample sizes in focus group research. *Qual Health Res* 2019;29:1483–96.
36 Borracci RA, Giorgi MA, Giorgi G, *et al*. Perfil de difusión Y adopción de innovaciones de Los cardiólogos en Argentina. *Rev Med Chil* 2013;141:49–57.

Patient information sheet for clinical trial and consent

Patient Information Sheet

For years we have been trying to improve the initiatives we carry out at Osakidetza to improve care for women during pregnancy and postpartum. We are therefore contacting you to ask for your consent to participate in a study your health center and midwife are collaborating in.

Invitation to participate and description of the procedure

Your health center and particularly your midwife are actively collaborating with the Bizkaia Primary Care Research Unit, part of the Biocruces-Bizkaia institute, to promote maternal education that is better adapted to the needs of women today. As a result, our research team is developing a website to support Maternal Education and we want to know how effective it is, so we would like to ask for your participation.

This website will offer rigorous information, selected by health professionals, on topics of interest throughout the period of pregnancy, childbirth and postpartum. It will enable women to access their clinical data securely, and will contain and offer resources at key moments in the maternity/paternity process. It will inform and support women in leading a healthy lifestyle, helping in the development of a birth plan that is adapted to each woman, advising on the appropriate choice at the onset of childbirth and offering care in the first days postpartum.

The website will be available to some randomly selected health centers, while others will not have this resource. We are doing this to compare the results on the health of women who use this resource (which you access with a password provided by your midwife) with those of women who do not have access to it.

Your participation in the study, regardless of your reference health center (with or without the website) will consist of filling in a series of sociodemographic questionnaires (e.g. age, level of studies, profession) and clinical questions (such as quality of life related to health or perception of self-efficacy during the birth process and breastfeeding), and it will also involve giving us permission to collect data from your medical records related to your pregnancy, childbirth and postpartum history.

The questionnaires must be completed at the beginning of pregnancy (approximately week 8), at weeks 24 and 34-36, and at weeks 1 and 6 postpartum. You fill it in online; your midwife will ask you for your mobile phone number and/or email address, and you will be sent a link to access the questionnaires. You will be able to complete them on a mobile phone, tablet or computer.

If you decide that you wish to participate, we will ask you to sign the attached consent form, which will be filed with the rest of the study documents.

Data processing and protection

The data that we collect via your mobile phone will be processed in an anonymized form, since it will be accessed with a numerical code, and confidentiality will be guaranteed at all times. The data collected for the study will be identified by this code, so that it does not include information that can identify you, and only your study doctor/researchers will be able to relate this data to you and your medical records. Therefore, your identity will not be disclosed to any person,

except in cases of medical emergency or legal requirement. The processing, communication and transfer of personal data of all participants will comply with the provisions of the law.

This study complies with the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data, and of Organic Law 3/2018, of 5 December 2018 on the Protection of Personal Data and guarantee of digital rights that repeals Organic Law 15/1999 of 5 December 1999, on the protection of personal data. Personal data will be processed by the Basque Health Service, Osakidetza. No data will be transferred to third parties, except under legal obligation. The patient will be informed that they have the right of access, rectification, deletion of their data, and limitation or opposition to its use. In addition, further information on data protection can be found at the following website: http://www.osakidetza.euskadi.eus/protecciondatos

Benefits and risks

Participation in the study is entirely altruistic and carries no risk to you. The only cost that can be incurred is the time dedicated to answering the questions in the questionnaires. You are not required to answer questions that you consider to be private.

In return, you will be collaborating with research dedicated to the evaluation and improvement of the health service.

Voluntary participation

Your participation in the study is entirely voluntary.

Right to withdraw from the study

You have the right to withdraw from the study at any time without consequence to you.

Who to contact about the study

You can contact the Lead Researcher, Isabel Artieta, on tel. 946007711 if you need any clarification or want to resolve any doubts regarding the study.

The Coordinating Center for the study is the Bizkaia Primary Care Research Unit, which is part of Biocruces-Bizkaia and is located in Building 3, C/Plaza de Cruces, s/n. 48903 Barakaldo (Bizkaia). Tel. 946006637.

This study has been supervised and approved by the Basque Clinical Research Ethics Committee. (CEIm)

DECLARATION OF CONSENT

Study Title: "**Effectiveness and usability of a website for the self-management of women's health needs during pregnancy, childbirth and the postpartum period: EMAeHealth**"

Centre: **Bizkaia Primary Care Research Unit (Biocruces-Bizkaia Institute)**

I (name and surname) declare that

……

I have read the information sheet given to me.

I was able to ask questions about the study.

I have received enough information about the study.

I understand that in case of doubt I can go to the lead researcher:

Isabel Artieta. Zuazo Health Center (Barakaldo). Tel. 946007711

I understand that my participation is voluntary and that at any time, without explanation and without any impact on my medical care, I can withdraw from the study.

I freely give my consent to participate in the study.

DATE: PARTICIPANT'S SIGNATURE

The data collected will be added to a computer database in anonymized form, and be used to evaluate the research. This study complies with the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data, and of Organic Law 3/2018, of 5 December 2018 on the Protection of Personal Data and guarantee of digital rights that repeals Organic Law 15/1999 of 5 December 1999, on the protection of personal data. Personal data will be processed by the Basque Health Service, Osakidetza. No data will be transferred to third parties, except under legal obligation. The patient will be informed that they have the right of access, rectification, deletion of their data, and limitation or opposition to its use. In addition, further information on data protection can be found at the following website: http://www.osakidetza.euskadi.eus/protecciondatos

THIS STUDY HAS BEEN EVALUATED AND APPROVED BY THE BASQUE CLINICAL RESEARCH ETHICS COMMITTEE (CEIm)

Focus groups of patients and focus groups of professionals and consent

Patient Information Sheet

In Osakidetza, we are trying to improve care for women during pregnancy and postpartum, and we would like your participation in a focus group in order to **get your opinion about the EMAeHealth website** that we have developed.

Invitation to participate in a focus group and description of the procedure

Your health center and particularly your midwife, together with researchers from the Bizkaia Primary Care Research Unit (Biocruces-Bizkaia), are looking into how to promote care that is better adapted to the needs of women today. To achieve this goal, as you know, a website called EMAeHealth has been designed.

As we would like to get a better idea of the opinions of the users about this new resource for Maternal Education - in terms of its ease of use, appropriateness and effectiveness - we would like to invite you to attend a focus group to explore these issues in depth. This participation is voluntary and only means attending a focus group meeting once. This meeting will be held on xxxxx (date), at xxxx (address) and will last approximately 90 minutes. The discussion will be moderated by two researchers from the Research Unit (xx and xx) and will be attended by other web users (between 6 and 8 of them) from different health centers, to talk about the topics under discussion.

Data processing and protection

The conversation generated by the group will be recorded entirely in audio to facilitate its subsequent transcription and analysis, with the collaboration of the qualitative studies research company xxx, which complies with the relevant legislation on data protection and is based in the Basque Country. We assure you that your opinions will be anonymized and that the confidentiality of the data collected will be guaranteed at all times. The audio files of the recordings and their corresponding transcripts (with names previously removed) will be stored in the computers of the Research Unit, access to which is restricted to researchers and

password-protected. Before the start of the recording, each participant will sign a consent form to authorize their participation in the study.

This study complies with the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data, and of Organic Law 3/2018, of 5 December 2018 on the Protection of Personal Data and guarantee of digital rights that repeals Organic Law 15/1999 of 5 December 1999, on the protection of personal data. Personal data will be processed by the Basque Health Service, Osakidetza. No data will be transferred to third parties, except under legal obligation. The patient will be informed that they have the right of access, rectification, deletion of their data, and limitation or opposition to its use. In addition, further information on data protection can be found at the following website: http://www.osakidetza.euskadi.eus/protecciondatos

Benefits and risks

During the focus group discussion, the moderators will explain in detail what the technique involves, and you will be able to ask any questions or raise doubts throughout the entire session to make sure that you feel comfortable in that situation. You will also be given all kinds of opportunities to express your opinions freely and voluntarily, guaranteeing you an atmosphere of respect and confidentiality at all times. The main benefit of this participation is sharing your experience about the website, reflecting on ways to improve it and adapt it to the objective of promoting Maternal Education to meet your needs, thus contributing to the improvement of our health system.

Moreover, the moderators will take measures to minimize the impact of any potential risk that you or other participants may perceive or feel during the discussion in the group (such as fatigue, discomfort with any questions or conflict between participants). For example, you can take breaks, remain silent, state that you wish not to continue in the study, request more information about the objectives and procedures of the study and so on.

We remain at your entire disposal to offer any clarifications and answer your questions. If you need more details, you can contact the lead researcher of the study or the Bizkaia Primary Care Research Unit:

- **Isabel Artieta. Zuazo Health Center (Barakaldo). Tel. 946007711**
- **Bizkaia Primary Care Research Unit (Biocruces-Bizkaia). Tel. 946006637.** (Maite Espinosa)

Healthcare Professional Information Sheet

For years we have been involved in improving the initiatives we carry out in Osakidetza to improve care for women during pregnancy and postpartum. Therefore, we are contacting you to request your participation in a focus group, in order to **get your opinion about the EMAeHealth website** that we are developing.

Invitation to participate in a focus group and description of the procedure

We work with the Bizkaia Primary Care Research Unit (UIAPB) - Biocruces Bizkaia, in the development of strategies to promote Maternal Education that is better adapted to the needs of women today. To achieve this goal, as you know a website, EMAeHealth, has been designed, which we intend to subject to a constant process of improvement and updating.

As we would like to hear the opinions of the professionals about this new resource for supporting maternal education - in terms of its ease of use, suitability and effectiveness - we would like to invite you to attend a group conversation, or focus group, to analyze these issues in depth. Participation is voluntary and only requires you to attend once. This meeting will be held on xxxxx (date), at xxxx (address) and will last approximately 90 minutes. The conversation will be moderated by two researchers from the Research Unit (xx and xx) and will be attended by other professional users of the web (between 6 and 8 people), from different health centers, to talk about the topics under discussion.

Data processing and protection

Following the methodology of a focus group, the conversation generated by the group will be recorded entirely in audio to facilitate its subsequent transcription and analysis. In this task, the qualitative studies company xxx will collaborate with the UIAPB researchers. The company XXX (description) meets all the applicable requirements in terms of quality and data protection, and is based in the Basque Country, at (address xxx). The opinions of the participants will be processed in anonymized form and the confidentiality of the data collected will be guaranteed at all times. The audio files of the recordings and their corresponding transcripts (previously anonymized) will be stored on the computers of the Research Unit,

access to which is restricted to researchers and password-protected. Before the start of the recording, each participant will sign a consent form to authorize their participation in the study.

This study complies with the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data, and of Organic Law 3/2018, of 5 December 2018 on the Protection of Personal Data and guarantee of digital rights that repeals Organic Law 15/1999 of 5 December 1999, on the protection of personal data. Personal data will be processed by the Basque Health Service, Osakidetza. No data will be transferred to third parties, except under legal obligation. The patient will be informed that they have the right of access, rectification, deletion of their data, and limitation or opposition to its use. In addition, further information on data protection can be found at the following website: http://www.osakidetza.euskadi.eus/protecciondatos

Benefits and risks

At the beginning of the session, the moderators will explain in detail what the technique involves and you will be able to clarify any doubts about the interview. Likewise, the participants will be able to express their opinions freely, in a climate of respect and confidentiality. Participation in the group is entirely altruistic, the main benefit being the possibility of sharing your experience about the website with other colleagues, reflecting on ways to improve it and adapt it to the objective of promoting Maternal Education that is more appropriate to the needs of women today.

Moreover, the moderators will take measures to minimize the impact of any potential risk that you may perceive during the development of the focus group (such as fatigue, discomfort with any questions or conflict between participants). You can withdraw your participation if you wish at any time, even during the interview itself. We remain at your entire disposal to offer any clarification or to answer your questions. If you need more information, you can contact the lead researcher of the study or the Bizkaia Primary Care Research Unit:

- **Isabel Artieta. Zuazo Health Center (Barakaldo). Tel. 946007711**
- **Bizkaia Primary Care Research Unit (Biocruces-Bizkaia). Tel. 946006637.** (Maite Espinosa)

Thank you very much.

DECLARATION OF CONSENT

Study Title: "**Effectiveness and usability of a website for the self-management of women's health needs during pregnancy, childbirth and the postpartum period: EMAeHealth**"

Centre: **Bizkaia Primary Care Research Unit (Biocruces-Bizkaia Institute)**

I (name and surname) declare that

....
I have read the information sheet given to me.
I was able to ask questions about the study.
I have received enough information about the study.
I know that in case of doubt I can go to the lead researcher:

Isabel Artieta. Zuazo Health Center (Barakaldo). Phone 946007711

I understand that my participation in the focus group is voluntary and that I can leave the meeting at any time, without explanation and without repercussion.
I freely give my consent for the meeting to be audio recorded and for the content of the meeting, including my contributions, to be transcribed in anonymized form for later analysis and research purposes.

DATE: PARTICIPANT'S SIGNATURE.

The data collected will be added to a computer database in anonymized form, and be used to evaluate the research. This study complies with the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data, and of Organic Law 3/2018, of 5 December 2018 on the Protection of Personal Data and guarantee of digital rights that repeals Organic Law 15/1999 of 5 December 1999, on the protection of personal data. Personal data will be processed by the Basque Health Service, Osakidetza. No data will be transferred to third parties, except under legal obligation. The patient will be informed that they have the right of access, rectification, deletion of their data, and limitation or opposition to its use. In addition, further information on data protection can be found at the following website: http://www.osakidetza.euskadi.eus/protecciondatos

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