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PROTOCOL

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Building capacity for health promotion by addressing nurses' role confusion: Study protocol of a pilot clustered randomised controlled trial

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Abstract

Aim: To describe the protocol for the pilot phase of a complex intervention, designed to address primary care nurses' role confusion in health promotion.

Design: A pilot clustered randomized controlled trial, with control and intervention groups.

Methods: The study will be conducted in a primary care setting. Participants will be nurses from the primary care health service working in a primary care team (PCT, 15 control group; 15 intervention group). Nurses in the experimental group will receive the ROLE-AP programme over a 3-week period. The control group will continue with the normal routine. The pilot will help determine the intervention's feasibility, acceptability, fidelity and quality of the programme components. Data collected preintervention, postintervention and 3 months after intervention will provide estimates of the intervention's preliminary effects on the main variable, nurses' degree of agreement concerning their expected role in health promotion. The study received funding from the local government in December 2019.

Discussion: Role confusion is promoting primary care nurses' omissions in their health-promoting practice, which is far from the ideal portrayed by the Ottawa Charter. Interventions are needed that reveal the most appropriate mechanisms for addressing role confusion, which requires reaching an intraprofessional agreement about the expectations for role activities. Healthcare organisations could benefit from the incorporation of a programme of these characteristics into standard practice.

Impact: This study will produce a novel and comprehensive complex intervention that is expected to build nurses' capacity in primary healthcare organizations for health promotion, which is key to increasing the quality, efficiency and sustainability of the National Health System. The programme evaluation and feasibility study will reveal how to better use existing resources in a full-scale clinical trial.

Trial registration: ClinicalTrials.gov (ID: NCT04726696).

KEYWORDS
capacity building, complex intervention, health promotion, midwives, nurses, nurses' roles, nursing, role clarification, role confusion

1 | INTRODUCTION

Health promotion (HP) is 'the process of enabling people to increase control over and to improve their health'. As highlighted in the Ottawa Charter, HP involves not only actions aimed at strengthening people's skills and capabilities, but also those aimed at changing the social, environmental and economic conditions that determine the health of the population (Nutbeam & Muscat, 1998). HP activities are ideally integrated into primary care services, as the healthcare workforce involved in such services has greater access to communities and provides integral and continuous care to the whole population (Swanson et al., 2020). Additionally, the largest actors of the workforce in primary care services, primary care nurses, are well positioned in the community and have been described as being competent to develop health-promoting roles due to their professional knowledge, skills and philosophy (Iriarte-Roteta et al., 2020).

The HP role of nurses can contribute to improved health outcomes, such as healthier lifestyles, more effective health services and healthier environments (Expert Panel on effective ways of investing in Health (EXPH), 2019), thus having an immediate impact on improved health literacy, community participation for social action and influence, and the implementation of healthy public policies, resource allocation and supportive organizational practices and settings for HP. These impacts can ultimately contribute to decreased morbidity and disability and increased life expectancy, functional independence and quality of life (Expert Panel on effective ways of investing in Health (EXPH), 2019).

Capacity building in primary care services has been identified as an attainable goal that could lead organizations to achieve the previous outcomes. Capacity building is understood as the development of sustainable skills, organizational structures, resources, commitment and leadership to enable effective HP interventions (Expert Panel on effective ways of investing in Health (EXPH), 2019). Organizations should provide their workforce with mandates for HP action in the form of rules, strategies or regulations as well as clear and congruent role descriptions that set the scope and boundaries of nurses' HP practice if HP implementation is to be accelerated (Dahl et al., 2014).

Thus far, while policies endorse the language and rhetoric of HP, this is rarely backed up with a framework for action that provides a common language and a shared understanding of what constitutes HP practice (Expert Panel on effective ways of investing in Health (EXPH), 2019). This leads to role confusion and, subsequently, to omissions, improvisation, errors and inefficiency (Mañas et al., 2018; Zhou et al., 2016). In fact, nurses' HP practice is far from the ideal portrayed by the Ottawa Charter (Iriarte-Roteta et al., 2020). Nurses' role in HP predominantly focuses on addressing lifestyles through health education and prevention. They place the responsibility of health on individuals, with a low population vision and intersectoral, political and/or community work (Iriarte-Roteta et al., 2020; Kemppainen et al., 2013).

Addressing role confusion or uncertainty about what activities professionals should perform to accomplish a specific role (Biddle, 2013) entails the design and implementation of an intervention with a strong theoretical and methodological framework that reveals the most appropriate mechanisms for reducing role confusion in HP. This step is a prerequisite for work towards improving nursing skills in HP to be effective, including training to work at the levels of policy, environments, communities and individuals, with an intersectoral approach.

1.1 | Background

The literature shows that there are currently no interventions addressing nurses' role confusion in HP. There are interventions of this type in healthcare and/or other fields, using the terms role confusion, role ambiguity or role clarification interchangeably. It distils from the work done so far, that the communication of organizational goals and role expectations needs to be explicit. Professionals need to know and understand why they are assigned a specific role and the activities and skills expected of them, as this facilitates the mental organization of the functions that they will need to perform (Ly et al., 2018). Consequently, such interventions must include the professionals who perform the role so that a greater commitment by them is achieved (Brault et al., 2014). Addressing role confusion requires, in addition, reaching an intraprofessional agreement about the expectations for role activities (Biddle, 2013; Goldstein et al., 2017; Ly et al., 2018; Olsen & Stensaker, 2014).

Role confusion research could benefit from a complex intervention approach that can help set the scene to deal with the methodological shortcomings identified and to design and evaluate a programme that addresses primary care nurses' role confusion in HP. The UK Medical Research Council's (MRC's) framework for complex interventions, which has been widely used in the field of nursing, has been selected to guide the design and evaluation of an intervention to address nurses' role confusion in HP (the ROLE-AP programme, Craig et al., 2019). This is done through five different phases: theoretical development (prephase), intervention modelling (phase I), exploratory trial (phase II); confirmatory trial (phase III), implementation and dissemination (phase IV). These phases allow for (a) a sufficient understanding of the problem to identify opportunities for intervention, (b) knowing the main components of the intervention and their interrelationships using a logic model (see Supporting Information), (c) assessing the acceptability and feasibility of the programme in the pilot phase and estimating the size effect for a

definitive randomized controlled trial (RCT), and (d) determining its effectiveness with a large-scale trial and implementing it as public policy (Craig et al., 2019). Following these stages is crucial for understanding which elements of an intervention are effective. This paper describes in detail the protocol for the pilot phase, which could help us understand if the methods and procedures are feasible and if the activities designed are appropriate and accepted by participants and could help estimate the preliminary impact of the programme.

1.1.1 | Theoretical framework

The ROLE-AP programme was designed to address nurses' role confusion in HP. The MRC's framework highlights that the development, evaluation and implementation of any complex intervention requires a strong theoretical foundation as a starting point (Craig et al., 2019).

Role theory and role confusion research form the basis for the theoretical underpinning of this study. Role theory provides methodological clues to initiate the study of any expected role. For instance, restrictions related to context or the number of functions to be performed can be put into place (Biddle, 2013). In this study, it was first resolved to restrict nurses' role in HP to those activities to be performed exclusively by frontline primary care nurses. It is also necessary to set up a list of role expectations using the criteria of relevance based on official rules, public documents concerned with the expected role, and the insights of 'experts' who have thought or taught about it. Researchers can then construct a standardized instrument that serves to evaluate respondents' expectations to determine which (if any) are held in consensus. This information is vital if any action is needed to rectify the difficulties faced by those who should execute the role (Biddle, 2013). For the present study, a standardized instrument reflecting primary care nurses' expected role in HP was constructed based on the Ottawa Charter, as it represents a legitimate and ideal portrait of practice in the HP field (Pumar-Méndez et al., 2020).

Both role theory and role confusion research emphasize that having coincident role expectations among those who execute a specific role is the first step to addressing role confusion (see Figure 1; Biddle, 2013; Card et al., 2014; Ly et al., 2018). Role theory provides two strategies that will be essential to achieve professional agreement: the internalization and acceptance of role expectations. The internalization of role expectations occurs through several mechanisms: the direct communication of role expectations, an individual's own experiences and the observation of behaviours related to the expected role. Acceptance occurs when other people influence and determine a change in one's former expectations. Both internalization and acceptance are much more likely when professionals perceive that role expectations come from a legitimate and credible source. For this purpose, Biddle (2013) highlights the importance of face-to-face communication and the use of a standardized instrument that reflects relevant role expectations. The inclusion of primary care nursing managers throughout the development of the programme has also been planned to guarantee its legitimacy and credibility.

Conversely, role clarification research emphasizes that reaching an agreement on role expectations requires interaction between professionals. It is essential for any organization to provide a space to communicate organizational goals and role expectations, formally asking team members questions about the expected role, discussing their responses, reflecting and encouraging them to seek an

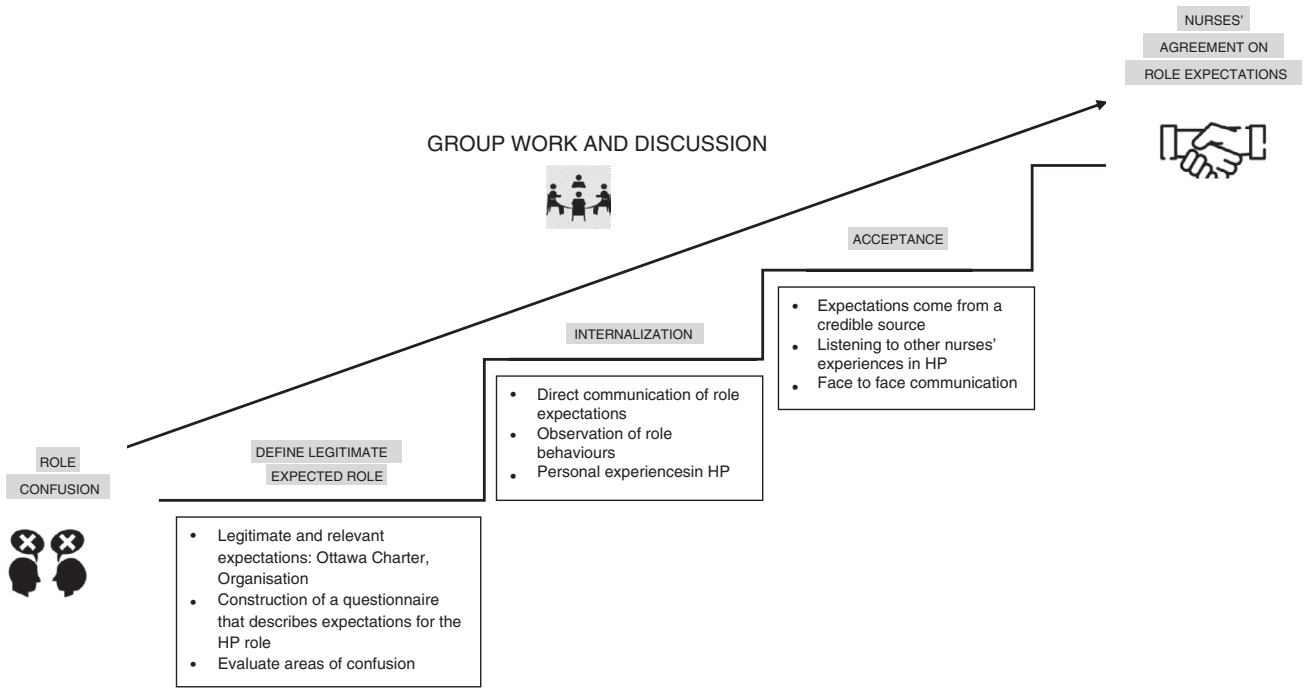

FIGURE 1 Theoretical framework

understanding of the role functions. For the renegotiation of expectations, it may be useful to use an instrument that articulates the activities of the expected role and that has been used previously with group members to determine their expectations (Goldstein et al., 2017). A group intervention package has been designed for primary care nurses, taking into account all the mentioned strategies to reach a consensus on the role.

2 | STUDY

2.1 | Aim

The aim of the study is to pilot ROLE-AP, a multicomponent programme designed to address primary care nurses' role confusion in HP.

2.2 | Objectives

The study-specific objectives are as follows:

1. To examine the feasibility of applying the programme;
2. To evaluate the fidelity and quality of the programme components;
3. To explore the acceptability of the programme by nurses participating in the intervention group;
4. To examine the trend of the main variable, nurses' degree of agreement concerning their expected role in HP at baseline (T0), immediately postintervention (T1) and 3 months after intervention (T2); and
5. To estimate the size effect for a definitive RCT.

2.3 | Proposed hypothesis

It is hypothesized that in comparison with the control group, participants in the experimental group will increase their degree of agreement concerning nurses' role in HP.

2.4 | Design/method

This is a pilot clustered RCT, which corresponds to Phase II of the MRC's framework for the development and evaluation of clinical trials in complex interventions (Craig et al., 2019). The intervention is complex, as programme development involves participants from different organizational levels; it will be flexible and it will require activities with varying degrees of difficulty on the part of those who execute or take part in the programme as a way to achieve the desired outcomes (Hawe, 2015). To achieve a novel intervention of these characteristics, studies that reveal the most appropriate mechanisms are needed. A pilot study consists of a small-scale test of the methods and procedures to be used on a larger scale, examining their feasibility, acceptability, quality and preliminary impact (Giangregorio & Thabane, 2015). This will allow for the improvement of the study design before investing resources and time on a larger scale (Craig et al., 2019). The study will be conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT; Eldridge et al., 2016).

2.5 | Trial registration

The study is registered as a primary clinical trial at ClinicalTrials.gov (ID: NCT04726696).

2.6 | Setting and participants

The study will be conducted in a primary care setting. Participants will be nurses from the primary care health service working in a PCT. A PCT consists of a group of family physicians who work in close cooperation with primary care nurses and social workers to offer primary care services to registered individuals in urban or rural areas. The inclusion criteria of participants will be as follows: being a primary care nurse in an urban or rural PCT, having at least 2 years of professional experience in primary healthcare, being a nurse attending to either the adult or paediatric population and signing the consent form for participation in the study. They will be excluded if they do not plan to be in clinical practice for the whole duration of the study.

2.6.1 | Sampling and randomization

The study will follow a clustered randomized design, with PCTs as sampling units. The main reason for this is to avoid contamination, which could occur among participating nurses working in the same PCT. The cluster design will prevent any possible interaction between nurses of the control and intervention groups in the same PCT, as this could interfere with their perceptions of their role in HP, which is more probably given the particular characteristics of this complex intervention in which masking will not be possible, and nurses in both groups will be aware of their allocation. The eligibility criteria for PCTs will be as follows: adult or paediatric nurses offering primary care services in the team and attending rural or urban populations in the region. Before randomization, the 58 PCTs meeting these criteria will be stratified according to their field of work (rural or urban) to guarantee the representativeness of the different segments of the study population. The HP activities of nurses and the perceptions they may have about their HP role may be conditioned by two factors: the organization and structure of the PCT and the characteristics of the populations to which they attend. These two factors may vary depending on whether the team is attending to rural or urban populations, so they will be considered possible confounding variables. After stratification, PCTs are randomly assigned

to one of the two groups, control or intervention (see Figure 2). R software (version 3.3.0) will be used by an independent biostatistician to create a random allocation sequence prior to the recruitment of nurses.

2.6.2 | Determination of sample size

In the early stages of the MRC's framework, the calculation of the sample size is neither appropriate nor necessary since the description of the results and the criteria of the feasibility, quality and acceptability of the intervention are prioritized over statistical inference (Craig et al., 2019). This study will follow the recommendations of Lancaster et al. (2004), including a minimum of 30 participants for the pilot study. As this is the first trial addressing nurses' role confusion in HP, the pilot phase will provide data to inform power calculations for a future larger-scale trial (Craig et al., 2019).

2.7 | Study procedure

A formal meeting will be requested with the primary care nursing managers to plan the dissemination of the project. The stratification and randomization of PCTs will be carried out before the recruitment of nurses. Subsequently, an email will be sent to all primary care nurses in the study setting, including the nursing headquarters of each PCT, which will include the description of the project and the invitation to participate in it, along with a link to the registration form. If they do not wish to participate, another link will allow us to register the main reasons for this. The recruitment process will last 2 weeks, and a reminder email will be sent after a week. Nurses wishing to participate and meeting the inclusion criteria will be allocated to the control or intervention group following the previously random sequence generated. This allocation will be dependent on the PCT to which they belong. Afterwards, they will be contacted by the research team to obtain their informed consent and administer the questionnaire for baseline measurement to them.

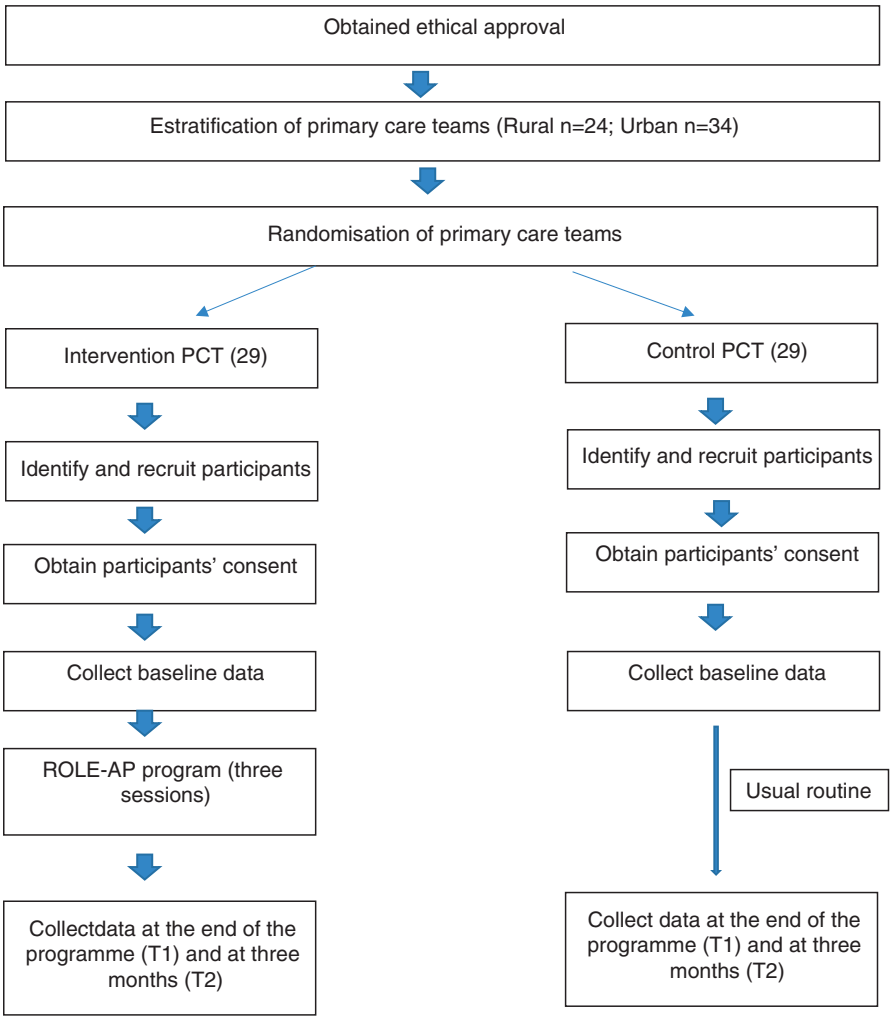

FIGURE 2 Workflow

2.8 | Intervention strategy

Nurses in the experimental group will receive the ROLE-AP programme over a 3-week period (one workshop per week). The intervention will be delivered to groups of 7–8 nurses. Each workshop will consist of two parts totalling 90–120 min containing activities that address a combination of the key components of the theoretical framework (see Table 1). All three workshops will be offered at the local university and facilitated by a researcher with a background in primary care who has led the design of the programme.

The materials that will be used have been specifically designed for this programme. Two videos have been designed with the following objectives: (1) to clarify key HP concepts and the Ottawa Charter action areas, relating real experiences, and (2) to communicate the strategic HP objectives in the local Primary HealthCare Service. Likewise, a pack of activities has been designed based on the nursing literature and on local and national experiences of HP, which will allow us to exemplify and explain the functionality of nurses' role in HP, facilitating discussion among nurses.

Nurses from the control group will continue their routine.

2.9 | Data collection

The data will be obtained through multiple methods (two questionnaires, debriefing sessions and the researcher field diary) from the participating nurses and the research team. See Table 2 for the data collection plan and evaluation times. The study outcome measures are described next.

2.9.1 | Barriers and facilitators to programme implementation (feasibility)

An essential aspect during a pilot study is to identify the barriers and facilitators that affect the programme implementation process and the achievement of the desired results. For this, the programme facilitator will use a field diary with notes from the recruitment phase until the end of the data collection period (Ohly et al., 2010). Some of the considerations to be recorded will be the barriers to the randomization and recruitment process, the degree of collaboration of the primary care managers, the perceived experience of group dynamics, compliance with the activities or necessary changes, the resources and materials used and the characteristics of the context in which the programme takes place.

2.9.2 | Acceptability of the programme by nurses

The acceptance and satisfaction of participants with the programme will be assessed by the 'Nurses' satisfaction with the ROLE-AP programme questionnaire', designed for this purpose (see Supporting Information). Three closed questions will assess the degree of satisfaction of the nurses with the programme and the recommendation and need for programmes with these characteristics. Likewise, three open questions will collect nurses' opinions about the materials used, the role of the facilitator and possible suggestions for the improvement of the programme.

2.9.3 | Fidelity of the programme

A continuous evaluation of the degree of adherence to the protocol will be carried out to examine whether the components of the programme have been developed according to the plan. A team member will make structured observations of each workshop and will use the 'ROLE-AP programme checklist' that will evaluate the following: compliance with the planned order and the timing of activities as well as the actual time spent on all the activities.

2.9.4 | Quality of the programme components

The quality of the programme components will be assessed by the abovementioned 'Nurses' satisfaction with the ROLE-AP programme questionnaire' and debriefing sessions among researchers. The questionnaire contains three open questions to gain insight into nurses' opinions about the materials used, the role of the facilitator and possible suggestions for the improvement of the programme. Debriefing sessions will obtain reflections on group dynamics (participants' reactions, degree of participation and contributions) and the work of the facilitator. Debriefing will take place at the end of each programme session, registering content for later analysis.

2.9.5 | Changes in nurses' agreement on their role in HP

Nurses' agreement on their role in HP will be measured with the 'Nurses' Role in Health Promotion Questionnaire', built using the taxonomy of activities in HP and prevention (TaxoPromo) for primary care. TaxoPromo represents a catalogue of 43 activities that should be carried out by frontline health professionals to fully develop HP and prevention in primary care and is based on the Ottawa Charter (Pumar-Méndez et al., 2020). The content of TaxoPromo has been validated by an expert panel including health professionals, managers or planners and academics or researchers with influence and experience in the fields of HP, public health and patient safety (Mujika et al., 2020).

The design of the 'Nurses' Role in Health Promotion Questionnaire' paid attention to the editing of the items, following the checklist proposed by De Vaus (2014). Content validation started with a panel of eight experts who were asked to evaluate the relevance of each individual item, which was estimated through the item-level content validity index (I-CVI). The relevance of the entire questionnaire was calculated through the average scale content validity index (SCVI/Ave,

TABLE 1 Intervention description

	Objectives	Activities	Theoretical mechanisms of change
1st session	1. Analyse the differences between the concepts of health promotion and health education 2. Understand the objective of the five action areas and the three strategies of the Ottawa Charter for HP 3. Discuss the current nursing practice in HP	• **Participatory workshop:** Facilitator will work on the concept of HP, emphasizing the difference between HP and HE. The Ottawa Charter will be explained and exemplified. • **HP video: HP versus HE** • **Work group:** Classification of HP nursing activities under the five areas of action of the Ottawa Charter. Discussion about omissions or disproportions in their daily practice.	**Legitimacy/Credibility** • Ottawa Charter • Facilitator is a researcher and a primary care nurse **Internalization of expectations** • Communication of official expectations • The functionality of the Ottawa areas is explained. Differences between HP and HE are addressed • Intraprofessional discussion, sharing experiences in HP • Nurses are aware of the relevance of the intervention. Comparisons between the practice and the ideal to be achieved will lay the groundwork for subsequent discussions **Acceptance of expectations** • Combination of written messages and statements (face-to-face messages) • Facilitator is a primary care nurse
2nd and 3rd sessions	4. Explain the HP objectives of the organization and analyse their alignment with the Ottawa Charter areas of action 4. Present and explain the role questionnaire as the expected role for HP 4. Discuss the role activities proposed in the questionnaire	• **HP objectives video**• The facilitator explains the development of the expected role in HP, explaining the questionnaire. • **Group discussion:** The facilitator exemplifies every item using national and international experiences and guides and promotes discussion among participants, asking whether the activities are part of their role in HP and why.	**Legitimacy/Credibility** • Nurses visualize primary health care managers explaining HP objectives • Nurses are aware that the HP objectives are aligned with the Ottawa Charter • Nurses understand the expected role presented based on the Ottawa Charter • Facilitator is a researcher and a primary care nurse **Internalization of expectations** • Presentation of expectations so that professionals can discuss areas of disagreement • Explain the functionality of each of the activities • Visualize and listen to real experiences **Acceptance of expectations** • Combination of written messages and statements (face-to-face messages) • Facilitator is a primary care nurse

TABLE 2 ROLE-AP programme data collection and evaluation times

Outcome	Measurement	Informant	Evaluation times		
			T0	T1	T2
Barriers to and facilitators of program implementation	Field diary	Researchers	X	X	X
Acceptability of the programme	Nurses' satisfaction with the ROLE-AP programme questionnaire	Nurses		X	
Fidelity of the programme	ROLE-AP programme checklist	Researchers		X	
Quality of the programme components	Nurses' satisfaction with the ROLE-AP programme questionnaire	Nurses		X	
Changes in nurses' agreement on their role	Nurses' Role in Health Promotion Questionnaire	Nurses	X	X	X
Sociodemographic data	Sociodemographic questionnaire	Nurses	X		

Abbreviations: T0, before intervention; T1, immediately postintervention; T2, 3 months after intervention.

Polit et al., 2007). Only two items obtained an I-CVI below 0.75 and were thus candidates for revision and possible elimination. The SCVI/Ave was calculated to be higher than 0.90. To finish the design of the questionnaire, instructions for participants and a sociodemographic data section were included in the first section. In addition, a seven-point ordinal Likert-type scale was included to measure the degree of nurses' agreement on their role expectations.

Content validation was completed using Willis' (2004) guide for cognitive interviews. In total, there was a problem of interpretation with 10 items, and they were modified taking into account the vocabulary used in the descriptors of the original TaxoPromo. Some suggested modifications were also made in the section on sociodemographic data. The reliability analysis of the scale was performed by administering the questionnaire to 30 participants with characteristics similar to those of the final sample. The Cronbach's alpha value of the scale was calculated to be 0.97.

After the content validation process and piloting, the final questionnaire comprises 47 items covering eight dimensions that capture each of nurses' functions in HP: planification, situational analysis, capacity building, development of awareness/public opinion, advocacy, development of networks, development of partnerships and intervention strategies, which reveal HP as a process (see Supporting Information).

2.9.6 | Sociodemographic factors

At baseline (T0), nurses will be asked to complete a brief questionnaire about their sociodemographic characteristics, including age, gender, years of experience in primary care, postal code, field of work (rural or urban), population attended to (adults/children) and previous training in HP.

2.9.7 | Data analysis

The methodology used will generate both quantitative and qualitative data. For the analysis of the field diary, debriefing sessions and open questions, content analysis will be carried out (Miles & Huberman, 1994) using NVivo to identify thematic categories. Quantitative data will be analysed using the SPSS statistical package with a descriptive approach. For categorical variables, frequency measures and percentages will be used. For the descriptive analysis of continuous variables, means, standard deviations (*SDs*), medians, interquartile ranges (25th and 75th percentiles) and minimum and maximum values will be used. The Shapiro–Wilk test will be used to assess the normality of the variables. To estimate the impact of the ROLE-AP programme through the comparison of means between the preperiods and postperiods of the same group, Student's *t* test will be applied for paired samples or their nonparametric complement (Wilcoxon) if the tests show that they do not approximate the normal distribution. In addition, for the results obtained from the inferential tests at T1, the effect sizes will be calculated together with their 95% confidence intervals, according to Cohen's formula. To identify the differences in the evolution of continuous dependent variables between the intervention and control groups, ANOVA or the Kruskal–Wallis test will be used if there is no normal distribution.

2.9.8 | Ethical considerations

Approval of the relevant Research Ethics Committee was obtained in October 2019. Likewise, permission was obtained from the authorities of the primary care setting. All study participants will be asked to give written informed consent. Confidentiality and voluntary participation will be assured, and participants may withdraw from the study at any time. Personal information will be collected through online forms and will be stored on a protected Google Drive account created for this purpose. Participants will be asked to identify the baseline and postintervention questionnaires with specific codes. All data processing will be done on a computer with an encrypted hard drive that will require a password to access the information. Likewise, personal data will be treated in a way that they can no longer be attributed to study participants.

2.9.9 | Validity and reliability

This study used the MRC's framework for the development and evaluation of clinical trials in complex interventions, providing rigour to the development of the intervention. Its components are all based on the strategies identified in role theory as well as in the literature about the clarification of professional roles.

The operationalization of primary care nurses' role in HP has rigorously followed a theoretical framework ad hoc. The steps identified by Biddle (2013) for the study of an expected role were followed and resulted in the construction of the 'Nurses' Role in Health Promotion Questionnaire', which went through a content validation process and obtained a high level of reliability. The CONSORT 2010 statement was used to design the study protocol (Eldridge et al., 2016).

2.9.10 | Progression criteria to a full-scale trial

The complex intervention framework does not provide specific criteria for the progression criteria to a full-scale trial. Thus, they have been adapted from those provided for internal pilot studies (Herbert et al., 2019). Criteria about recruitment and enrolment, fidelity, feasibility, outcome data and the intervention's acceptability will guide this scalation (see Table 3).

3 | DISCUSSION

The main contribution of this study is the design of a programme that addresses nurses' role confusion in HP, which is one of the main barriers to the development of nurses' capacity in HP (Iriarte-Roteta et al., 2020). This work is therefore expected to build nurses' capacity in primary healthcare organizations for HP, which is key to increasing the quality, efficiency and sustainability of the National Health System (Expert Panel on effective ways of investing in Health (EXPH), 2019). The design will reveal if an intervention of this type is feasible and accepted by participants and if the proposed mechanisms are adequate for increasing nurses' degree of agreement with their expected role in HP. This knowledge is essential, as there are no studies of this type in the field of role confusion, and therefore, such a focus will be necessary before the design of a full-scale RCT, as advised by the MRC's framework for complex interventions (Craig et al., 2019).

The programme is expected to gradually raise awareness among nurses about HP, explaining the conceptual difference between health education and HP, increasing their knowledge about the official expectations in terms of HP and becoming aware of the current situation of their HP practice in their own PCT. At the end of the sessions, nurses are expected to show satisfaction with a programme of these characteristics and to increase their agreement with their expected role in HP. The programme can help professionals and organizations identify the needed competencies for the implementation of the role so that training can be offered more efficiently (Olsen & Stensaker, 2014). It is expected that participating nurses will demand more HP training after finishing the ROLE-AP programme. Addressing role confusion can also increase the development of interprofessional collaborations for primary care professionals (Halcomb et al., 2016).

In the medium term, a programme of these characteristics could help establish a mechanism for evaluating and recording the HP activities of primary care nurses beyond those of health education, which would be necessary to evaluate the effectiveness of nurses' contributions (Bekemeier et al., 2015). Role confusion can make professionals put less effort into their work and perform far fewer activities than expected (Mañas et al., 2018). Thus, the ROLE-AP programme will lead to improvements in the organization, management and delivery of HP activities. More specifically, it is expected that the percentage and variety of HP activities will increase, contributing to the generalization of the provision of HP services and the reduction in errors of omission and commission in their development.

In addition, in the long term, it is expected that the improvement and generalization of the provision of HP services focused on positive health, the creation of supportive environments, community and political action will be reflected in the health results of the population, increasing its quality of life, well-being and health-related behaviours (Expert Panel on effective ways of investing in Health (EXPH), 2019).

3.1 | Limitations

This study opted for a cluster RCT design to avoid contamination between nurses in the intervention group and those in the control group, should the two be present in the same PCT. As with a conventional RCT, numerous potential factors could compromise the validity of the study described in this protocol and thus bias the results. The sample size could not be enough to detect statistically significant differences between the groups. Likewise, clusters were not taken into account in the sample size estimation, thus possibly obtaining misleading results. However, these aspects are not as essential as they would be in the final trial. This pilot study, which is of exploratory in nature, will include the recommended number of participants in this stage since statistical inference is not a priority (Craig et al., 2019). The results of this pilot study will help estimate the sample size necessary for a large-scale trial, taking into account the intracluster correlation coefficient.

Another limitation of this study regards the use of self-report questionnaires to assess nurses' degree of agreement. Although self-reports have many advantages, they may also lead to social desirability. Nonetheless, this limitation will be minimized by the guarantee of anonymity.

TABLE 3 Progression criteria for the final trial

Criteria	Information that will be provided with this pilot study	Aspects to consider for the full-scale trial
Recruitment and enrolment	• Number of primary care teams participating in the study • Number of participating nurses per primary care team • Percentage of primary care nurses who meet the inclusion criteria and are willing to participate within the prespecified period of recruitment • Barriers identified in terms of access to the sample during recruitment • Reasons provided for not participating in the study (a checklist will be provided) • An estimation of the sample size necessary for the full trial	• The red/amber/green system for progression criteria will be used to consider progression for the final trial • Progression without major modification if 100% of the target is reached, with the analysis and resolution of any identified barriers to successful recruitment • Progression if at least 50% of primary care teams participate in the study
Adherence	• Number of nurses withdrawing from the intervention • Number of nurses completing the program (attending al 3 sessions) • Number of nurses who change the group to which they have been allocated • Reasons for nonadherence: a list of facilitators and barriers will be provided	• Experience in the pilot will inform the main trial procedures to enhance adherence • Progression will be possible if nonadherence is not a substantial issue. If necessary, amendments will be made
Acceptability of the intervention components	• Nurses' satisfaction with the components of the ROLE-AP programme • Suggestions for improvement of the programme components	• If acceptability is low, it will be necessary to review components and reasons before full-scale trial • Suggestions will be taken into account for the full trial
Feasibility	• Barriers and facilitators identified in the following: primary care managers' collaboration, organization of the programme sessions, context, funding and material resources used, characteristics of the sample and characteristics of the facilitator of the program	• Analysis of barriers and facilitators will be considered before progression
Outcome data	• Percentage of nurses who respond the questionnaires at T0, T1 and T2 • Missing data during follow up will be identified. Percentage of participants with missing data	• 100% of nurses provide measures at T0 and T1 • 100% of nurses in the experimental group answer the satisfaction questionnaire • Actions will be required if the rate of participants decreases over time or if the number of missing data points are high, considering new techniques to follow them up or to complete the scales

4 | CONCLUSIONS

This study could support the relevance of implementing a programme to address nurses' role confusion in primary care services. Reaching intraprofessional agreement on role activities would be the first step in building nurses' capacity for HP. This is the first study to evaluate the feasibility, acceptability, quality and preliminary impact of an innovative programme that aims to realign nurses' expectations, increasing their degree of agreement in terms of the HP role. The expected results from this project should guarantee the feasibility of a larger clustered RCT aimed at evaluating the impact of the ROLE-AP programme.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors in relation to the study itself.

PEER REVIEW

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the Supporting Information section.

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