UNIVERSITÀ DEGLI STUDI DEL PIEMONTE ORIENTALE

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PhD in Medical Sciences and Biotechnology

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"Nursing care models in primary care and hospital settings: implementation and evaluation"

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Summary

Chapter 1

General Introduction

The PhD project is a part of the research line “Advanced Management of Elderly in hospital and primary care”. The overall objective of this line is to contribute to the improvement of patient- and organizational-related outcomes by developing and implementing different patterns of care. The research line consists of five work packages. This dissertation approaches two of them: 1) developing inpatient care models and 2) models for managing frailty in the elderly at home. The research line is embedded in the Aging Project (University of Eastern Piedmont).

Nursing care delivery

Health care organizations are constantly changing. Organizational modifications are needed to account for evolving disease patterns, technologies, and societal values (e.g. patients have higher expectations of being involved in care decision making). Moreover, changes in organization and structure influence nursing staff and the care delivery system (1,2). Over the years, many care delivery systems have been developed and implemented: total patient care, functional nursing, team nursing, primary nursing, and patient-centered care (3). They refer to the framework in which nurses organize the care for patients, and differs in clinical decision making, work allocation, communication, and management (3,4).

Several adaptations and combinations of the care delivery system have arisen. Nursing care models have been operationalized in different settings (e.g. hospitals, home care, ambulatory care etc.) and for specific patient populations such as older adults, people with mental health needs, or chronic conditions (5). The rationale for selecting different care models ranges from nursing staff availability to patient outcomes (6).

The care delivery system is a component of the professional practice model (PPM). Although the terms are often used interchangeably, they are not synonymous. The care delivery model focuses on how care is structurally organized to facilitate nursing work, while PPM defines the structures and processes that support nurses in delivering care (3,7). Slatyer et al. identified seven key elements of the PPM: the care delivery system, leadership; nurses' independent and collaborative practice; environment; nurse development (nursing education) and reward; research/innovation; and patient outcomes. Most of the analyzed PPMs refer to hospital settings and none to primary care (8). Advanced practice nursing, nursing Case Management are some PPN described in the literature. Numerous variations exist, and the reasons for implementation are costs, nurse availability, patient care needs, and individual and organizational preferences (7).

Evaluation of nursing practice models is important to produce knowledge for nursing clinical practice and direct benefit for patients (9). Research examining the contribution of the nursing practice model to health

care has been primarly conducted in the acute care setting and has focused on staffing, work environment and patients outcomes[1] (10). Evidence highlights the positive effect of nursing on reducing adverse patient outcomes (6,11,12).

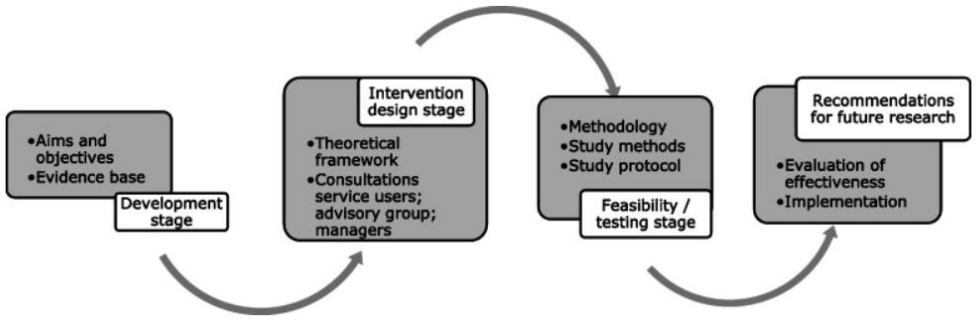
Nursing care delivery is considered a complex intervention due to several interacting components and presents several problems for evaluators. The answer to "How do the nursing care models work?" is important to understanding the whole range of effects. Therefore, the Medical Research Council (MRC) framework is widely utilized to support the design and evaluation of complex interventions and identify potential barriers to implementation and effectiveness (13–15), also in nursing research (16).

Aim

Through the MRC framework (figure 1), this dissertation examines the effects of nursing models on patient outcomes in hospital settings and primary care. More specifically, it provides insight into the added value that changes/introduction of the nursing model bring to practice. The following research questions were defined:

1) What are the effects of primary nursing on the patient-, staff-and organizational outcomes in a hospital setting?
2) What are the barriers and facilitators identified during the introduction of new nursing roles in primary care?
3) What are the effects of Family Community Nursing on patient outcomes?

Figure 1: MCR framework-key elements of the development and evaluation process



[1] Patient outcomes in nursing were defined as “relevant, based on nursing scope and domain of practice and for which there is empirical evidence linking nursing inputs and interventions to outcomes”(17). Different inpatient outcomes exists, (18–20) which can be groupped in 3 cathegories: patient functional status (including health status, well-being and self-care skills), patient safety (including adverse events) and patient satisfaction with nursing care (21).

Outilne

Chapter 2 presents the study protocol examining the effects of Primary Nursing on patient-, staff-,and organizational related outcomes in hospital settings. Chapter 3 describes barriers and facilitators of nursing role implementation in primary and community care, and the necessary preconditions for successful implementation were individualized through a systematic integrative review. The expected effects of Family and Community Nursing in primary care are presented in Chapter 4. The study protocol aims to explore the effects of the nursing model on patient and organizational outcomes. A prospective controlled study was designed. Chapter 5 describes REACTion Project, an example of FCN intervention in real-life conditions. The final chapter (Chapter 6) summarizes the main findings and presents future directions for research and practice.

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Chapter 2

Primary Nursing: before-after study protocol.

Background

Health care systems are faced with the challenge of employing care delivery models that optimize patient outcomes, enhance cost-effectiveness, and maintain staff satisfaction (1). Large numbers of nursing care delivery systems have been introduced. The dominant care delivery systems mentioned in the literature include team/functional nursing, primary nursing (PN), and patient-focused care (2). PN is a delivery system that emerged in the 1970s and continues to be rolled out widely. Manthey refers to PN as the solution to the fragmentation of care and lack of accountability inherent in team nursing. The foundation of PN is a client-focused care-delivery system specifically designed to facilitate nurses in establishing and maximizing patient therapeutic relationships. More specifically, PN focuses on continuity of care, beginning with admission and ending with discharge. A primary nurse is responsible for the same patient's care throughout the patient's hospitalization. Associate nurses may be responsible for care when the primary nurse is off duty and provide care according to the established care plan (3).

The PN, as a care delivery system, is defined by four elements, which differentiate it from the others: 1) responsibility for relationship and decision making; 2) work allocation and patient assignments; 3) communication among staff members and 4) management and leadership philosophy (4). The implementation of primary nursing requires the necessary knowledge (5).

The effects of the implementation of primary nursing

Studies has focused mostly on nursing staff and patient outcomes. Recent Cochrane reviews, examining the effect of introducing primary nursing on staff-related outcomes, found that the intervention decreases nursing staff turnover. Still, the evidence is uncertain because few studies have been conducted (6,7). Melchior et al. investigated PN concerning work-related factors (8,9). The two studies showed that burnout levels did not change, but psychiatric nurses experienced more autonomy and perceived the work as less complex. A cross-sectional study highlighted the nurses' and pediatric patients' satisfaction with the implementation of PN (10). Moreover, PN improved nurses' opportunities to get to know their patients (11). Dal Molin et al. explored the effect of PN on staff, organization, and patient outcomes: PN improved nurses' competence as well as patient outcomes (urinary tract infection and venous catheter infection)(12).

Butler highlighted the need for larger studies focused on a diverse range of outcomes: patients-, staff-related outcomes (6). Thus, a protocol study was designed. The study hypothesized that PN : 1) decreases the number of healthcare-associated infections and other adverse effects 2) increases patient's satisfaction, and 3) reduces staff-related outcomes such as burnout, missed nursing care, and intention to leave.

Objective

The trial aims to evaluate PN implementation on patient-, staff- and organization-related outcomes

Methods

Study design and setting

The study is a multi-center, prospective before-after trial with participating hospitals (centers) in Piemonte and Emilia-Romagna. The study started in 2019.

Participants

Eligible patients are invited to participate within 48 hours of admission in the study ward. If they were able to understand and provide consent for participation, they would be included. Also, nurses are recruited to collect data on nursing staff- and organizational-related outcomes. Nurses are included if they have worked in the ward for at least six months and have consented to the study.

Procedures

The study involves three phases:

- Phase 1: PN pre-implementation data collection (t_0).

In this phase, data regarding the center, nurses and patients are collected.

i) Each Center provided descriptive information: name of the hospital, classification level (DM 70/2015), the wards' names in the study, number of beds, hospitalization volumes, nursing staff, and the care delivery system.
ii) After enrolling patients, nurses recorded the following data using a standardized content request form (CFR): demographics (date of birth, sex, and the number of previous hospitalizations in the last 12 months), date of admission, date of discharge, death or patient transfer, discharge diagnosis, patient outcomes, and other medical records helpful in describing the sample.
iii) Nurse related data has been collected using an online questionnaire after obtaining their informed consent. The nurses complete the survey before and after the PN implementation. The survey contains questions comprising burnout, intention to leave, job satisfcation and missed nursing care. Also, demographic characteristics of the respondents has been gathered for descriptive purpose (age, sex, highest achieve level of education in nursing, years working in the current hospital and ward).

- Phase 2: nursing staff training and practice implementation of the care delivery model.

Nurses have received specific education on the principles and application of the PN by skilled nurses.

The University of Eastern Piedmont has provided a postgraduate course to train nursing leaders in facilitating the successful implementation of PN across healthcare settings. This course is propaedeutic to care delivery system implementation. PN implementation includes: a) the assignment of patients to the primary nurse within 24-48 hours after patient admission; b) the formalization of at least three interviews to facilitate nurse-patient relationship and communication during hospitalization; c) the planning of care on the specific and prevalent health problem through the application of shared tools; d) continuity of care and the exchange of information between healthcare professionals. PN implementation is considered complete when at least 80% of the patients are under the charge of primary nursing.

- Phase 3: post-implementation data collection (t_1). Nurses provides the same procedure described at t_0.

Outcomes

Primary outcome

Primary outcome includes healthcare-associated infections: surgical site infection, catheter-associated urinary tract infection, urinary tract infection, pneumonia, central-line bloodstream infection (13). Onset is determined according to clinical signs and culture.

Secondary outcomes

Patient outcomes

1. Adverse events

Adequately trained nurses collect information about the number of pressure ulcers, patient falls, and death. A pressure ulcer is defined as a localized injury of the skin and/or underlying tissue, usually over a bony prominence, as the result of pressure (14). The fall is described as an unexpected event in which the participants come to rest on the ground, floor, or lower level (15).

2. Patient functional status

Functional status is measured with the Barthel Index (15) at admission and hospital discharge. The tool assesses a patient's independence or dependence on ten everyday activities such as feeding, bathing, dressing, grooming, bowel and bladder control, toilet use, transfers, mobility, and stair use. The cumulative score for the Barthel Index ranges from 0 to 100; a higher score is considered good functional status (that indicates a greater ability to perform everyday tasks without assistance).

3. Patient satisfaction

Patient satisfaction with caring behaviors received is measured with the Caring Behaviours Inventory (CBI) (16). Patients complete the questionnaire at discharge without the aid of the nursing staff. The tool consists of 24 items describing five dimensions of care: assurance of human presence, professional knowledge and skill, respectful, positive "connectedness", and attentiveness to the other. Responses are given on a six-point

Likert-type scale ranging from 1 (Never) to 6 (Always).' A higher total sum score indicates a higher prevalence of caring behaviors. The patient satisfaction measure exhibited a high reliability (Cronbach's alpha = 0.94).

Staff-related outcomes

4. Nurse Burnout

The Maslach Burnout Inventory (MBI), consisting of 22 items, is used to operationalize 3 dimensions of burnout: emotional exhaustion, depersonalization, and personal accomplishment. Responses are given on a 7-point Likert-type scale ranging from 0 (Never) to 6 (Always).' Higher scores reflect greater degrees of work-related burnout.

5. Intent to leave and job satisfaction

Nurse intention to leave is measured by a single item that asks nurses whether they have any plans to leave their present nursing position, while nursing staff satisfaction is rated on a 5-point Likert scale from 1 (extremely dissatisfied) to 5 (extremely satisfied).

6. Missed Nursing Care

The MISSCARE Survey tool measures the prevalence of missed interventions and reasons for missed care. The survey includes a cover page with questions about participant demographic and professional characteristics; part A, with 24 items related to omitted or missed care; and part B, with 17 items on reasons for missed nursing care. The items in part A are answered on a Likert-type scale and scored from 1 (highest level of missed care) to 5 (no missed care). In part B, the items are scored from 1 (a significant factor) to 4 (not a reason for unmet nursing care). Internal consistency, evaluated with Cronbach's alpha, is 0.94 (17).

Organizational-related outcomes

7. Nurse turnover and sick leave (number of sick days)

Sample size

The sample size of the study was estimated based on the expected reduction in healthcare-related infections after the PN implementation.

The parameters used for the calculation are:

- pre-intervention incidence of infections of 7.5% People per Year (PA)
- 35% reduction in the incidence of infections corresponding to an IRR of 0.65
- Alpha = 0.05
- Beta = 0.2
- Power = 0.8

The samples were considered independent as the patients included in the study at t_0 and t_1 will be different (heterogeneous wards). The calculation was carried out using the following procedure suggested by Lehr's rule (18) for an estimation of the sample size for data distributed according to Poisson's law. The parameters used for computation are:

$\lambda 1$, = Incidence of infections at pre-intervention per person-year (0.075)

$\lambda 2$, Incidence of post-intervention infections per person-year (0.049)

n1, n2= sample size for the two groups

The sample size estimated is n = 1421.

The estimate was corrected for correlation within groups (hospitals) by considering an Intraclass Correlation Coefficient (ICC) of ρ = 0.02. The sample size was corrected for DE (Design Effect)

$$DE = 1+(m-1)\rho$$

(m is the number of structures considered in the study (assuming the participation of 15 wards).

The effective sample size was calculated as:

$$n_i^* = \boldsymbol{n_i} * DE = 1819$$

To consider the different expected lengths of stay in acute, long-term, and rehabilitation wards, the following allocation procedure is used(19):

$$n_{ih} = \left(\frac{1/\sqrt{c_h}}{\sum_{h=1}^{L} 1/\sqrt{c_h}} \right) \boldsymbol{n_i}$$

c_h are the expected lengths of stay for *h=1*, ..., L (L=15). For the calculation, 6.9 days were considered for acute wards, 25.5 days for rehabilitation, and 24.1 days for long-term care. The calculated sample size (per group) is 130 for the acute wards, 70 for rehabilitation, and 68 for long-term care.

Computations were performed using R software version 3.3.5 (R Core Team, 2015).

Statistical Analysis

Data will be summarised by median (I and III quartiles) for continuous variables and by percentages (absolute frequencies) for qualitative variables. Possible comparisons between groups will be carried out using Wilcoxon-Kruskal-Wallis tests for continuous variables and Pearson chi-square tests for qualitative variables. The estimation of incidence ratios of healthcare-related infections will be based on a Poisson model. A multivariable model will be estimated to adjust the estimates by reference center and by confounding factors by considering them as model covariates. A significance of 0.05 will be considered for the evaluation of significant effects.

Discussion

The rising demand for quality in healthcare affects the nursing care delivery system. It emphasizes the need for an adequate nursing care model. The study will improve understanding of staff-, patient and organization related outcomes after PN implementation. The impact of staffing on patient and nurse outcomes suggests that hospitals may avert both preventable mortality and low nurse retention in acute-care settings (20,21).

Moreover, staffing level is associated with missed nursing care. Outcomes of missed nursing care include poorer patient satisfaction, poorer nursing job satisfaction, increased patient adverse events and hospital length of stay (22). To planning this multi-centre (MC) trial, researchers used the data from a previous study (Dal Molin et al. (12)) to better understand how the intervention works and select the most appropriate primary and secondary outcome measures. A strength of this study is that researchers are collecting an extensive set of data that will provide useful information for the evaluation. In addition, this MC trial is able to include i) different hospitals and geographical locations, ii) a more comprehensive range of diseases, and iii) compare results among centres. All of which increases the generalizability of the study.

Although a cluster randomized controlled trial is the "gold standard", a before-after study was chosen considering the logistical challenges of evaluating a care delivery system in an MC study; first, a consensus among investigators was developed to create the study protocol. Then, strategies that maintained workgroup commitment were adopted: continuous communication and preparatory activities. These steps follow the guide on organizing the MC trial (24).

Also, we considered other factors affecting the trial conduction: i) nursing education and ii) participant recruitment. Centres selected a nursing leader to attend the course provided at University of Eastern Piedmont. Education is indicated as the first stage to drive change during intervention implementation (23). Thus, in Italy, a unique postgraduate course is available at the University of Eastern Piedmont to improve nursing managerial competencies in PN implementation. Also participant recruitment is a crucial area in this research. Factors that can influence participant enrolment are recruiter and participant characteristics (25). Therefore, the research team prepared and disseminated appropriate recruitment material, ensuring that nurses were fully informed about the study. In addition, the researchers identified a study coordinator and provided regular updates to the centres.

By introducing and evaluating PN, researchers hope to contribute to the existing evidence and drive the choice of an effective nursing care delivery model.

Trial status

The Local Ethics Committee approved the trial with protocol ID CE 106/19 (Additional file 1) in May 2019. This study started in 2019 and has continued through the COVID-19 pandemic. The pandemic and various "lockdown" measures are impinging on centres' ability to conduct the trial. Additional file 2 lists the centres and describes the trial status.

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Chapter 3

Barriers and facilitators to the implementation of nurse's role in primary care settings: an integrative review

Article under review

Background

In recent years, the progressive epidemiological changes in large part due to the aging population, the increase in non-communicable diseases (NCDs), and the recent COVID-19 pandemic have necessarily led to a rethinking of the people's needs for assistance, redefining the models of care for the most vulnerable age groups (1,2).

NCDs, such as heart disease, stroke, cancer, diabetes, and chronic lung disease, have become the leading cause of disability and death worldwide (3). In 2017, one in eight people was aged 60 years or older, and it is estimated that there will be one person over 60 for every six and five people by 2030 and 2050, respectively (4).

To counteract this emerging public health problem, the World Health Assembly of the World Health Organization (WHO) has launched an initiative named Decade of Healthy Aging 2020-2030 (5) aimed to promote autonomy among the elderly while designing new patient-focused care models and identifying long-term care needs. If no action is taken, health spending, tax burden, and health inequalities, especially in low and middle-income countries, are all expected to increase significantly in the nearby future (6). Thus, there is a growing consensus among citizens that strengthening the resilience of national healthcare systems will help mitigate the impact of the epidemiological changes.

The recent COVID-19 pandemic has further increased the complexity of care and created an even greater demand for chronic care services carried out at the patient's home (7,8). This has led to an in-depth reflection on current models of care, raising the important issue of what role nurses should play to help meet the increasingly complex healthcare needs of the community.

In most countries, one of the main reasons for developing and implementing the nurse's role is to improve access to healthcare, especially in those settings where medical resources are scarce (9). Another equally important reason for developing nursing nurses' roles is that this process is critical to further promote the quality of care by providing support to chronic patients through on-site follow-up activities, thereby reducing hospital admissions and readmissions (10).

However, the implementation of nursing roles is not unique at an international level. There are, in fact, cultural, regulatory, and organizational factors specific to individual contexts that should be taken into account besides the nursing skill-mix level (11). Thus, the epidemiological evolution we are witnessing requires the redefinition of the roles of the various professionals involved in primary care assistance aimed to enhance professional collaboration and, at the same time, redefine the nursing skills (12). In particular,

the heterogeneity of nursing contexts and roles at the international level calls for the need to define new strategies for implementing nursing roles in primary care settings (13).

In light of these considerations, the WHO guidelines have set the standards to achieve a sustainable primary healthcare system in line with the legislation, organization, and health priorities of each individual nation, prioritizing disease prevention and promoting health. By offering effective services in the field of prevention, promotion, treatment, rehabilitation, and palliative care, the ambitious goal of this initiative is that of fulfilling people's health needs throughout their lives in a sustainable way (14). Therefore, it is becoming increasingly clear how theoretical and clinical skills acquired by nurses through training and retraining will be key to the implementation of care roles and the improvement of health outcomes in primary care settings (15).

However, a large body of literature has pointed to several factors influencing the effectiveness of nurse's role implementation in the primary care settings (13). Thus, the purpose of this study was to identify the facilitators and barriers encountered during nurse's role implementation from the stakeholders' perspective (i.e., nurses, physicians, and patients).

Methods

Study design

The research question was addressed through an integrative review method that allows using original qualitative research and quantitative research on barriers to and facilitators of nurse's role implementation in primary care settings (16). This integrative review combines data from studies conducted using various designs and provides an in-depth analysis of this complex theme. The Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) was used (17).

Search Strategy

The search was performed using the two databases Medline and CINAHL, up to the 9th of June 2020. We developed search strategies for each database (Additional file 3). Search strategies consisted of keywords and controlled vocabulary terms (Table 1). We also scanned reference lists of all included studies and key references (i.e., relevant reviews). We limited our searches to English and Italian for feasibility reasons.

Table 1: Terms used in search strategies

MeSH terms*	Relevant key words**
Nurse practitioners	Nurse practitioner, advanced nurse practitioner
Nurses, Community Health Family Nurse Practitioners Nurses, Public Health	Family nurse practitioner, family health nurse, community health nurse, district nurse, public health nurse, rural nurse
Primary health care Community Health Services	Primary care, community care, community health care, district
Nurse's Role	Nurse role

*MeSH terms were combined in three different searches using Boolean operators AND, and the search terms within each box were combined with OR.
** Keywords were searched using truncation and phrase symbols when appropriate.

Eligibility criteria

We included primary studies that used qualitative or quantitative study designs and mixed methods approaches. We excluded case studies, editorials, commentaries, and reviews. We included studies that focused on stakeholders' perceptions of how nurse's role implementation is developed. Stakeholders include nurses, general practitioners, patients, and other individuals or professional categories directly or indirectly affected by nurse's role implementation in primary care settings. We included any types of nurses working in primary care settings. Primary care was defined as follows: "*The provision of universally accessible, integrated person-centred, comprehensive health and community services provided by a team of professionals accountable for addressing a large majority of personal health needs. These services are delivered in a sustained partnership with patients and informal caregivers, in the context of family and community, and play a central role in the overall coordination and continuity of people's care"*(18).
We excluded studies focused on nurses or nursing practice concepts conducted in settings other than primary care (e.g., hospital emergency departments). Studies conducted in mixed settings were included if the results related to primary care could be clearly identified among the overall findings.

Selection of studies

Two review authors independently scanned each title and abstract obtained from the electronic databases to determine if these fulfilled the inclusion criteria. Then, full-text publications of the selected studies were retrieved to confirm they met inclusion criteria. At all stages, we resolved any disagreements between the authors *via* discussion or, if required, by seeking a third reviewer's opinion.

Data extraction

We perform data extraction using the Consolidating Framework for Research Implementation (CFIR). The CFIR structure supports the exploration of essential factors encountered during implementation through formative evaluations (19) (Table 2). The framework emphasizes the multi-level influences on nurse's role

implementation, from external influencers to organizational and core implementation process components, and provides a pragmatic organization of constructs.

We also extracted information on study characteristics (i.e., author, date of publication, country, aims, study design, study population, and study setting) and a description of the nurse's role (i.e., training and details about any interventions delivered).

Table 2: Descriptions of CFIR domains

Domain	**Definition**
Intervention characteristics	The characteristics of the intervention being implemented include whether the intervention is perceived to be developed external or internal to the organization, there is evidence supporting its effectiveness, and its implementation will be advantageous to its alternatives. Other characteristics include how the intervention is presented, its adaptability, complexity and whether it can be tested on a smaller scale.
Outer setting	The external context of the organization includes patient needs and the ability to meet them, networks with other organizations, pressure to implement the intervention and external policies and incentives to adopt the intervention.
Inner setting	Features of the organization including its structural characteristics (such as size, age of the organization and division of labour), networks and communication (such as connections and information sharing between individuals, units and services), cultural norms and values, implementation climate, organizational capacity and readiness for change.
Characteristics of individuals	Staff knowledge and belief about the intervention, their ability to execute their respective aspects of the implementation, and their individual stage of change. Other characteristics include individual identification with the organization and other personal attributes.
Process	Active change process, the purpose of which is to promote uptake of the intervention by the organization. This is influenced by the level of planning prior to implementation, and engaging organization stakeholders through appointing implementation leaders and champions of the intervention. This includes the ability to execute the implementation of the intervention as planned and to continuously reflect on and evaluate the quality of implementation and intervention as it progresses.

Data synthesis

Three review authors read the selected studies and applied the CFIR framework, moving between the framework themes. Relevant data of each theme were extracted from all primary data sources. The review author, after discussing each emerging theme, definition, and boundaries, revised and compiled the CFIR framework in line with the emerging categories.

Quality appraisal

Whittemore and Knafl (2005) state that assessing the quality of the included evidence is not essential in a supplementary review (16). All studies meeting the inclusion criteria, regardless of their methodological quality, were retained in the review to examine all evidence of the factors that influenced the nursing role implementation in practice settings.

Results

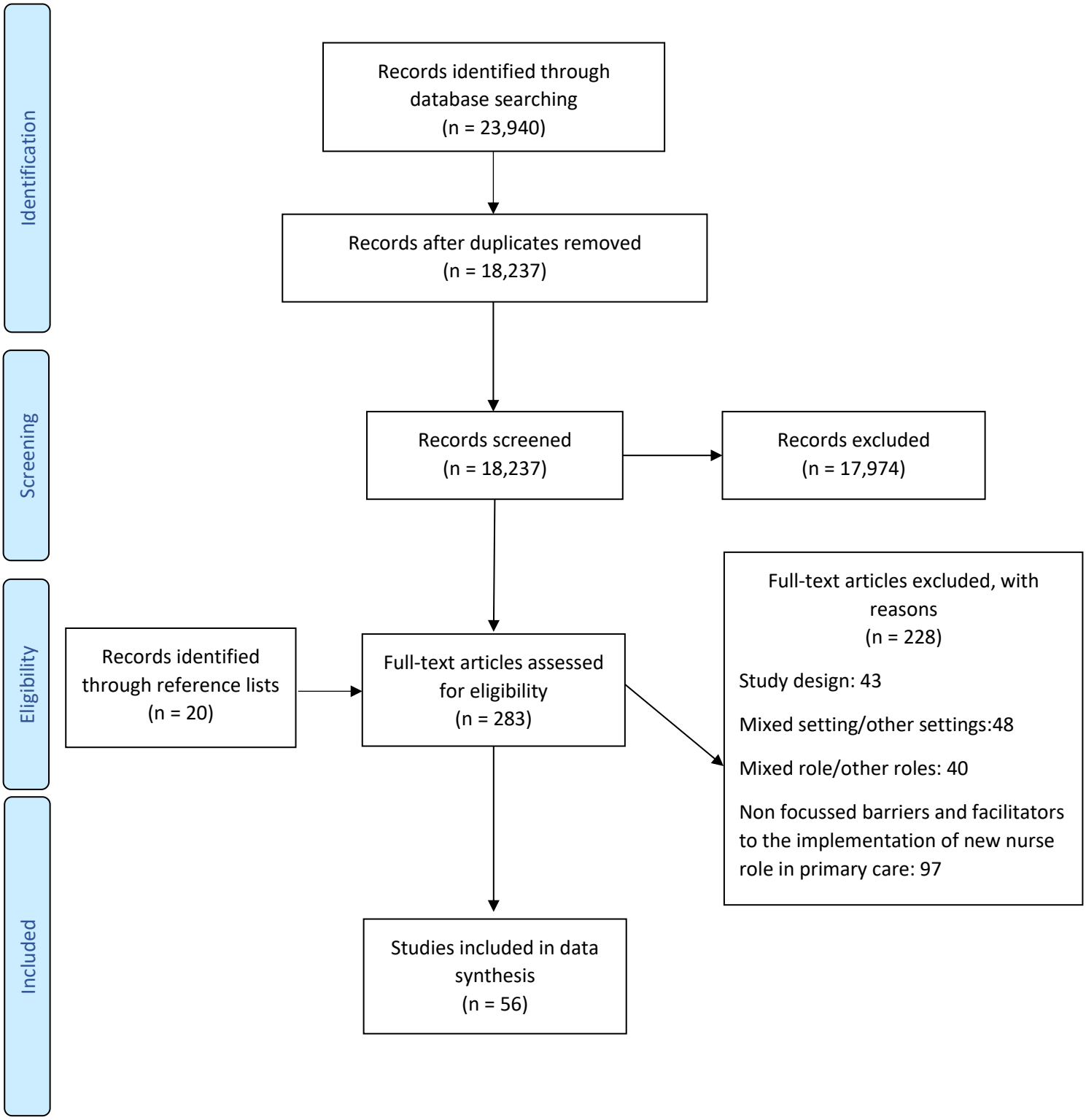
Characteristic of the included studies

We screened 18,257 records and considered 283 full texts for inclusion in this integrative review. Fifty-six papers met the inclusion criteria (20,21,30–39,22,40–49,23,50–59,24,60–69,25,70–75,26–29), and six papers (30,45,47,49,59,61) derived from three unique studies (Figure 2).

Studies were conducted across 13 countries: 9 studies in Oceania (26,32,35,44,60,66,68–70), one in Asia (36), 21 in Europe (20,21,51–54,57,58,62,65,67,73,22,74,29,33,34,41–43,46), 24 in North America (23,24,40,45,47–50,55,56,59,61,25,64,71,72,75,27,28,30,31,37–39), and one in Latin America and the Caribbean (63). Thirty-six studies employed a qualitative design either descriptive (20,22,25,38,41,42–44,46,48,52,53–59,61,62,64,25,69,71,73,29,31,36), grounded theory (51,70,74), phenomenological approach (32,40), or ethnographic research (26,35,39). Fourteen studies used a quantitative design -cross sectional approach- (21,24,27,60,63,72,75,28,30,34,37,45,47,49), while 6 used a mixed method (23,33,50,65,66,68).

Participants included registered nurses, nurse practitioners, general practitioners, health leaders (chairpersons of health boards), managers, nursing leaders, key informants (e.g., university employees, Ministry of Health employees, policy makers), health and social care professionals, administrators, and patients (Additional file 4).

Figure 2: PRISMA flow diagram



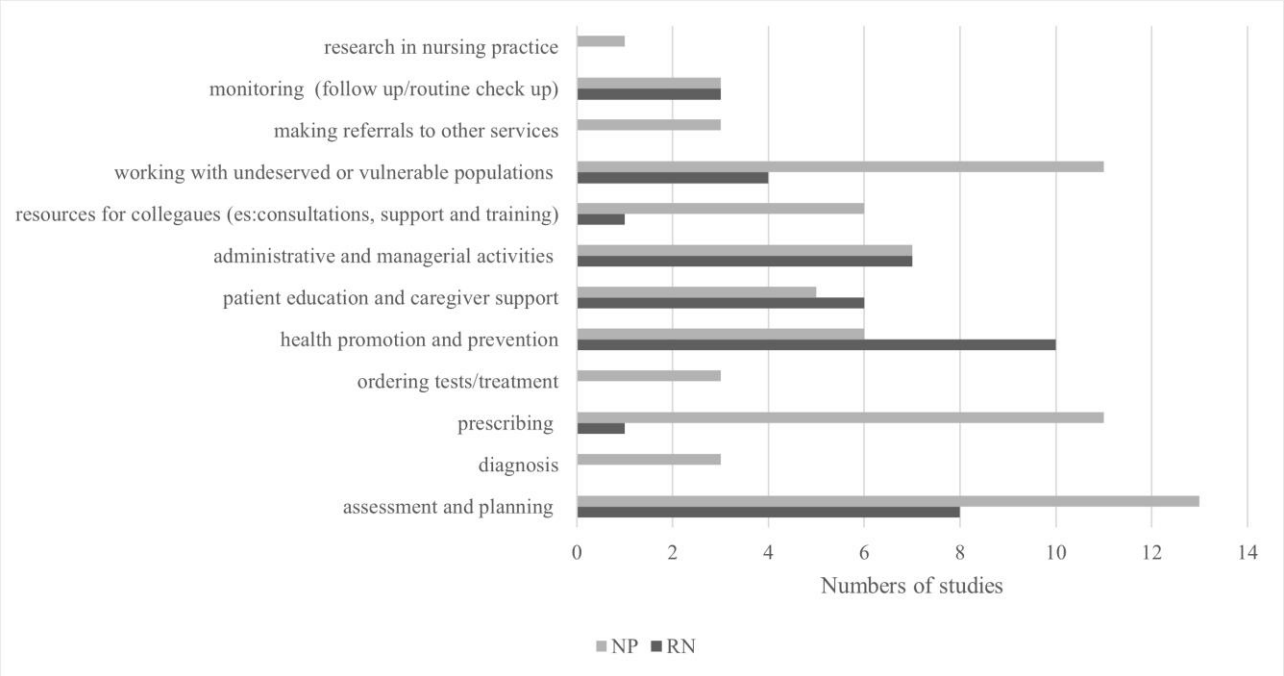
Nursing role and tasks

A number of studies took into account nurse practitioners working in advanced roles (APN) (21,23,37–42,44–47,24,48–56,59,26,61–64,66–69,72,74,27,75,28–31,35) and registered nurses working in advanced practice levels or with specialist designations (20,22,60,65,70,71,73,25,32,33,36,42,43,57,58). In these studies, the title “registered nurse” was often replaced by the following definitions: "community nurse", "family health nurse", "public health nurse", "mental health nurse", "community matron", "mental health nurse of community", or ''district nurse".

A number of studies specified nurses’ qualifications, ranging from bachelor's degree to post-graduate qualification attainment (e.g., master's degree, doctorate in nursing) (24,25,38–42,44,48,49,51,52,26,53,56,63,64,66–69,72,74,27,75,28–31,35,36).

The main tasks carried out by nurse practitioners (NPs) and registered nurses (RNs) are illustrated in Figure 3. All nurses worked in primary care settings, including general practice, health care centers, and rural/remote areas.

Figure 3: Stacked bar chart showing tasks reported for nurse practitioner and registered nurse



Legend: NP-nurse practitioner, RN-registered nurse

Factors influencing implementation

The frequency of identification of barriers and facilitators in each domain is summarized in Table 3, while the specific determinants can be found in Additional file 5.

Table 3: Barriers and facilitators in each CFIR domain

Domain	Themes	Barriers N° of studies (%)	Facilitators N° of studies (%)
1. Intervention Characteristic			
	scope of practice	16 (28,6)	13 (23,2)
	adaptability	0	1 (1,8)
	trialability	0	1 (1,8)
	workload	7 (12,5)	0
	education	14 (25)	7 (12,5)
	funding	11 (19,6)	2 (3,6)
2. Outer setting			
	patient factors	6 (10,7)	21 (37,5)
	external policies	5 (8,9)	0
3. Inner setting			
	culture	9 (16,1)	0
	workforce and organization	10 (17,9)	8 (14,3)
	communication	8 (14,3)	7 (12,5)
	implementation climate	26 (46,4)	28 (50)
	resources	9 (16,1)	1 (1,8)
4. Individual characteristics			
	team acceptance	30 (53,6)	24 (42,9)
	self confidence	4 (7,1)	3 (5,4)
	personal attributes	1 (1,8)	2 (3,6)
	individual stage of change	2 (3,6)	0
5. Process			
	planning	2 (3,6)	4 (7,1)
	stakeholder engagement	4 (7,1)	8 (14,3)
	development and implementation	2 (3,6)	8 (14,3)
	evaluation	4 (7,1)	2 (3,6)

The integrative review identified similar barriers and facilitators for both advanced role and a general nursing role. When factors are more referred to APN, we clearly indicated in the text. The main factors are listened below.

Intervention characteristics

Barriers

With regard to the CFIR domain, nurses pointed to four main factors affecting nures's role implementation: 1) scope of practice; 2) nursing workload; 3) nursing education; and 4) funding.

Restrictions of nurse scope of practice and autonomy was the most frequently reported barrier to APN role implementation (21,23,53,55,56,24,28,31,35,44,45,47,48). Arbitrary laws (31), state restriction, hospital regulations (28), and health care professionals' expectations (35,55) all contributed to restrict the independence of nurses and limit the full potential of their roles. For instance, some regulations required nurses to be supervised by physicians when exercising their prescriptive authority (38–40). In addition, physicians often advocated the use of certain protocols (21) or required their supervision (45) through collaborative practice agreements (23,31).

Other studies identified *excessive caseload numbers and complex cases* as barriers (25,30,32,57,58) to care provision (33,71). Furthermore, *patient care complexity*, alongside other non-clinical functions—mainly administrative and/or bureaucratic—, further increases the nurses' workload (57).

Education was identified as a barrier to nurse's role development in 13 studies. In particular, nurses expressed their concerns about the educational programs available to them, often questioning the adequacy of the training received (41,56,63), deemed insufficient to help them develop the skills required (25,45,62,65,70). Nurses also complained about the existence of barriers to training opportunities and ongoing education (50), such as the lack of information regarding course availability (26), the difficulty in taking time off work to attend courses (26,54), the need to travel long distance to reach the location where the course was being taught (32), and the lack of funding to cover education-related expenses (26,51). In regard to the latter, *funding to sustain the nurse position* was regarded as a barrier to nurse's role implementation across 11 studies (21,23,66,36,39,42–44,50,52,54).

Facilitators

Nurses mainly indicated two facilitators of nurse's role implementation: *i)* adaptability of the nursing role to the existing context (53) and *ii)* trialability (46). Education and training were also reported as factors facilitating nurse's role implementation. Educational resources such as master's degree programs were generally thought to improve nurses' clinical skills and provide job retraining opportunities, especially in primary care settings (26,29,36,46). Moreover, additional experiences, such as residency or fellowship programs after graduation, were felt as supporting role transitions in primary care (30). One study reported

that motivating nurses to study represented an additional important factor in attaining advanced practice levels (62). Another facilitator was represented by nurses being satisfied with their full scope of practice (24–29) or working autonomously (27,30–33). Other facilitators included expanding nurse's practice to carry out tasks normally performed by physicians (29,35,36) or putting nurses in charge of the communications between the patient and other care providers (29,34).

Outer setting

Barriers

Patient-related factors were reported as key barriers across several studies. From a patient perspective, one of the main factors negatively impacting the acceptance of the nursing role was the lack of knowledge and understanding of such role (42,48,56,68,69,72). Other factors included negative patients' prior experience (68) and patients' preference and medical condition (68,69).

Five studies analyzing external policies from a nurse perspective identified prescribing restrictions (38–40) and remuneration policies (46,48) as barriers to nurse's role implementation.

Facilitators

Also in this case, most of the facilitators identified were related to *patient-related factors*. Generally, the care provided by nurses was regarded by patients as highly satisfactory (21,41,50,65,67) due to the many advantages it afforded, such as a more patient-centered communication (46,50,62,68,69) and the provision of personalized solutions to better meet their needs (25,35,36,57). Patients also described how their access to care would be quicker and easier (34,50). Several studies emphasized the patients' acceptance of the nursing role (23,36,48,63,66,68) thanks to knowledge and role recognition (59,61) and nurse-community connection (50).

Inner setting

Barriers

Barriers identified across studies were linked to organizational factors and were reported by different health care professionals (i.e., nurses, managers, and doctors).

Recruitment and retention of nurses were viewed as barriers due to the difficulty in recruiting and retaining qualified nurses (20,29,62,65). Organizational factors, such as lack of long-term human resource planning (52) and career opportunities (62) as well as uncertain employment (20,26,29,55), all negatively influenced nursing role implementation. This barrier quite often led to high staff turnover among nurses (20) and increased intention to leave, especially among newly hired nurses (20,72).

A few studies referred to the *organization's culture, hierarchical structure* (29,36,48), and *difficulties*

in adopting a flexible approach to service delivery (73) as main barriers to nurse's role implementation. The nursing practice was overshadowed by the more dominant medical model (51,58,61,63), prioritizing medical solutions to health problems rather than promoting patient wellness-centered care (35,43).

The *nature and quality of communications* were among the environmental factors regarded as barriers to information access and support in rural areas. These were mainly due to isolation (32,33), poor internet connection, and lack of electricity to run equipment (64). Also, lack of information sharing between staff administrators and health professionals was associated with negative consequences (38,64,72). Some studies reported that lack of shared understanding of the patients' needs affected the team's ability to provide care (57,70,71).

Unfavorable implementation climate was the most frequently reported barrier to nurse's role implementation. The professional *relationship between health workers and other inter-professional workers* (22,41,42,56) along with the lack of regulation of nursing role (22,41,42) hindered nurse's role implementation (42). In particular, the *lack of professional collaboration* was described as a strong obstacle to nurse's role development (24,29,39,41,42,48,67,74), with nurses emphasizing how counselors and secondary care providers would often refuse their referrals (24,39,41,42,48,67,74) or choose not to share with them critical information (41). Among the causes of professional collaboration breakdown was the lack of support from physicians, managers, and administrative staff (26,30,33,43,44,64,72). In general, nurses felt that they had not received enough collegial and managerial support (26), the same level of access to resources as that granted to physicians (38,40), or the same respect as that paid to their peers (30,72). Consequently, nurses complained about the invisibility of their role in the community (22,38,72).

Professional isolation of nurses was reported as being an additional barrier in seven studies (24,30,32,33,50,51,64) due to the lack of integration with other health professionals in the workplace (32,51). These studies also pointed to the fact that the common goals were neither *shared with* nor *clearly communicated* to nurses by their employers (30,32). Furthermore, the contractual context was also shown to influence the climate as the lack of a reward and incentive system (20,30) negatively affected the nurses' morale (30,55). Lastly, according to several studies, the *lack of resources* was among the barriers to nurse's role implementation (20,29,34,36,38,39,56,57,70).

Facilitators

Facilitators mainly referred to challenges for workforce development, nature and quality of communication, and implementation climate. Specifically, nurses reported that workforce challenges in primary care settings, such as changing patient case-mix (20,42) and shortages of primary care providers (26,50), favored nurse's role development. Nurses also reported that communication strategies and technology helped them establish a relationship between primary and secondary care. On-call systems connecting healthcare professionals, telemedicine equipment, and team sharing of patient information, including case-reviews,

were all crucial to the continuity of care (59,64). This is consistent with findings from other studies showing the importance of regular communication—preferably using the same electronic patient records—in the collaboration and coordination among health care professionals (34,42,50,56).

Professional trust, mutual respect, and a close doctor-nurse relationship were also seen as facilitators of nurse's role implementation and collaboration among nurses (31,32,42,46,50,51,56,61). In addition, inter-professional relationships and team working played a key role in facilitating nurse's role development (25,27,35,39,41,43,48,58). This process was even more pronounced when nurses felt trusted and supported by physicians, pharmacists, managers, and colleagues (23,24,26,29,31,38,48,64,71). Also mentoring, mainly from doctors and colleagues, was central to providing support during transition into the new role (26,30,39,41,44,64).

Characteristics of individuals

Barriers

Barriers identified across studies were primarily linked to poor team acceptance and low self-esteem among nurses. For instance, physicians' resistance (23,42,56) was associated with lack of role clarity and concern about nursing practice (24,25,47–51,66,72,26,30,36,38,43–46). Moreover, there was consensus among nurses, administrative staff, and team members that healthcare professionals were often not fully aware of the scope of the nursing practice (21,28–30,39,45,52,53,66). In addition, physicians expressed lack of trust in nurses' skills and knowledge (29,36,45,47,51,54,66,72) and were concerned about their workload, nurse-doctor competition, and fragmentation and duplication of services (51,52,66), especially when the two roles were perceived as overlapping. The other major barrier was nurse self-doubt (44,47). In one study, nurses reported that they felt uncertain when colleagues did not regarded them as a resource (61).

Facilitators

Clarity and understanding of the nursing role were identified as crucial factors to gain the physicians' acceptance (61). The nursing role was more easily understood once doctors had previous nurse-doctor collaboration experiences (23,26,41,52).

From a physician's perspective, there were some motivations to employ nurses in primary care, including complementary relationships (52,74) and enhanced quality and delivery of healthcare (28,42,66,67). Many physicians were satisfied with their collaboration with nurses (31,34,45,50). Consistently, other studies reported that nurse's role in primary care settings reduced the physicians' workload (21,42,46,62), allowing these latter to focus on other more complex cases (42,45). Fittingly, nurses felt that they were instrumental in improving quality of care and increasing patient safety (31,33,35,46,48,52,59,62) and considered their work to be valuable and worthy. Nurses expressed their

satisfaction in providing more than patient care compared to other healthcare professionals (25,41). Finally, nurses were confident in their skills and knowledge (49) and aware of their own limits (31,46).

Process

Barriers

Process barriers were related to the lack of planning regarding nurse's role utilization. In particular, it was unclear how care services would be adapted to meet changing needs (33,73). Furthermore, nurses often complained about the absence of clear leadership (71), top-down approach (56), and evaluation criteria. In two studies, nurses admitted their difficulties in identifying suitable tools to measure the outcome of their contributions (25,59).

Facilitators

Few studies highlighted the importance of developing an implementation plan with a focus on workforce integration. Review of the existing nursing service, definition of roles and functions, and team involvement were useful considerations that guided planning (43,56,65). Factors associated with better role development and integration were nurses' involvement in developing their role (e.g., drafting job description) (24,60), support from management, and strategic alliance with health authorities (24,59,61). Universities were identified as external agents to the organization formally influencing role development (63). The last facilitator was linked to the evaluation process. Nurses expressed the need to evaluate the effectiveness of their contribution (25) and identified research and audit mechanisms as resources to measure their professional outcome (41).

Discussion

This integrative review includes 56 studies addressing barriers and facilitators during nurse's role implementation in primary care settings. We have analyzed a large volume of information and experiences from the various stakeholders and identified several emerging factors influencing nurse's role implementation strategies. Although we could not separate each contribution due to the miscellaneous participation in the studies, the different stakeholders' perspectives allowed us to identify the specific barriers of and facilitators to nurse's role implementation. These are summarized below.

Barriers

Our synthesis shows that the major emerging themes regarding the barriers to nurse's role implementation pertain to the following variables: *i)* the characteristics of the intervention; *ii)* the characteristics of the individuals; and *iii)* the inner setting of the healthcare professionals' organization. Limiting factors were equally distributed among RNs and NPs, the two most represented nursing roles in primary care settings.

Barriers related to the characteristics of the intervention are mainly due to the limited availability of and access to special education, which results in nurses lacking sufficient knowledge and skills to work in primary healthcare settings. Furthermore, key determinants of independent practice such as legislations and regulations also appear to influence nurse's role implementation. Previous report showed that the restrictions to nurses' full scope of practice mainly applied to prescribing for nurses in an advanced role (76), which forced them to collaborate with or be supervised by a physician. Moreover, our analysis indicates that nurse's role implementation is dependent on the organizational setting in which it is embedded. Indeed, the decreased availability and retention of nurses are two phenomena predominantly seen in rural underserved areas, where lack of career opportunities and lower salaries compel nurses— especially newly hired ones— to relocate to other areas (77).

Consistent with previous findings (78), we show that lack of interprofessional collaboration and poor support from physicians and administrative staff has a negative impact on the implementation climate and healthcare provision, indicating that knowledge and beliefs of individuals belonging to an organization can influence individual acceptance of workforce change.

Overall, this review supports the notion that lack of role clarity among stakeholders is a significant and widespread barrier to optimal nurse's role implementation (78). This phenomenon is similar to what observed in the general practice where physicians protecting their professional boundaries and expertise can cause tension and confusion in the workplace (9).

Facilitators

Major facilitators identified under the CFIR domains are linked to *i)* the characteristics of the intervention, *ii)* the inner setting of the organization, and *iii)* the implementation process. Key factors include prior planning for role introduction and nurses' involvement in the early stage of role implementation. These findings further underscore the importance of the stakeholders' involvement in driving the implementation process and building consensus on the nurse's role (79). More broadly, nurse's role implementation should be preceded by in-depth reflections on the expected contribution of nurses to patient outcome achievement and team work (80).

With regard to challenges inherent in role development, job satisfaction and nurses' access to high-quality education are the two main themes emerging among RNs and NPs. This is in line with a previous study showing that the standardization of nursing educational requirements—especially for nurses with advanced roles in the primary healthcare setting, such as NPs—supports role enactment (76). Of note, the same study also highlights the importance of providing more interprofessional training while increasing the practice component of education.

Consistent with previous literature (78,81), we find that building collaborative relationships in the workplace favors nurse's role implementation and promotes nurses' job satisfaction. Collaborative working

does not always emerge spontaneously, which is in good agreement with Contandriopoulos *et al.* (80). From a nurse's perspective, respect, trust, and communication are the main pillars of successful doctor-nurse collaboration, as shown previously in the general practice (9). Developing an effective collaboration between nurses and physicians may ultimately improve patient outcome thanks to the added value brought by nurses to the practice (82).

Limitations

Even though this integrative review provides a comprehensive and accurate overview of the main facilitators of and barriers to nurse's role implementation in the primary care setting. It is important to note that CFIR, used to selected constructs, identifies a list of factors within general domains that are believed to influence positively or negatively nurse's role implementation, but does not rank factors in order of importance. Thus, we recommend to always consider multiple factors when implementing nurse's role. In addition, although many aspects are transversal to the different countries involved in the study, the differences among contexts (e.g., political, social, cultural) and health systems make the results described herein non-standard. Another limitation is that the studies analyzed were published between 1996 and 2020. Thus, factors reported in studies published before or after this time period may not have been included. Lastly, as the factors contributing to nurse's role implementation are quite complex, we may have missed some additional factors due to the language restrictions used in the inclusion criteria.

Conclusions

From this integrative review, the following considerations emerge in a significant and transversal way: *i)* there is sub-optimal attention to the legislative and regulatory aspects governing the nursing profession; *ii)* there is only a partially complete regulation of the autonomy of the nursing profession; *iii)* there is paucity of studies on the role of professionals and various stakeholders in nurse's role development and implementation in primary care; *iv)* there is lack of recognition of the nurse's role and skills, especially within the multidisciplinary team; and *v)* there exist barriers to nurses' training opportunities and ongoing education.

Overall, nurse's role implementation appears to be a complex process influenced by numerous factors. Thus, there cannot be simple and linear recommendations to successfully develop and implement the nurse's role in primary care. In this regard, the Medical Research Council framework (83,84) has been used to guide the development of complex interventions, especially those related to nurse's research and practice (85). However, the fact that the facilitators may become barriers if not properly addressed poses some limitations to this approach. Indeed there is growing consensus on the need to consider—and simultaneously tackle—a number of factors influencing different domains (i.e., interprofessional, interpersonal, organizational, and systemic) when designing a tailored intervention. Likewise, our findings

indicate that nurse's role implementation needs to be contextualized, looking at barriers and facilitators and involving the inputs from different stakeholders as well as the legislative and regulatory aspects specific to the country of residence. It is only through this dynamic and context-dependent implementation process that nurses will be employed to strengthen the resilience of national healthcare systems around the world.

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Chapter 4

The Family Community Nurse for older people and patients with multiple chronic conditions: study protocol.

Background

With an increasing number of older adults in society, the number of frail older people with complex care needs is rising. In addition, the rapid spread of COVID-19 added complexity to this challenge, given both the surge in demand for treatment of the acutely ill and the need to continue to deliver preventive care and manage chronic patients (1). Thus, there is an urgent requirement to modernize primary health care services to make health systems more resilient to crisis situations, more proactive and more prepared to act early in response to surges in demand for services.

In Europe, three major barriers to high-quality care for frail and older adults have been identified over the years. First, predominantly reactive care systems fails to identify many older adults' health risks, impeding the successful prevention of adverse outcomes. In addition, older adults experience a lack of autonomy in their own care process which is worsening due to COVID-19 restrictions (2). Finally, care for frail older adults living at home is often fragmented, resulting in a lack of coordination and information exchange between health care professionals (3). Improving composition, competencies and performance of primary health workforce may be the appropriate approach to overcome the challenges observed in the care of older adults (4). The COVID-19 pandemic has, in many cases, accelerated the implementation of promising innovations in primary health care to achieve a system-wide transformation of care, such as expanding and extending the roles of nurses (1). Nurse role advancement subsumes two concepts: 1) task-shifting whereby nurses take up activities formerly performed by physicians, and 2) nurses in complementary roles, such as liaison roles, eHealth monitoring and providing lifestyle advice (5). As a consequence, many countries have established a variety of roles for nurses and nursing care models in primary care that did not exist previously. The World Health Organization (WHO) has stressed the role of the Family Health Nurse as a key professional with the General Practitioner at the hub of a network of primary care services (6). The initial Family Health Nursing (FHN) role definition states that: *"The Family Health Nurse will: help individuals and families to cope with illness and chronic disability, or during times of stress, by spending a large part of their time working in patient homes and with their families. Such nurses give advice on lifestyle and behavioural risk factors, as well as assisting families with matters concerning health. Through prompt detection, they can ensure that the health problems of families are treated at an early stage. With their knowledge of public health and social issues and other social agencies, they can identify the effects of socioeconomic factors on a family's health and refer them to the appropriate agency. They can facilitate the early discharge of people from hospital by providing*

nursing care at home, and they can act as the lynchpin between the family and the family health physician, substituting for the physician when the identified needs are more relevant to nursing expertise." Literature concerning FHN highlighted diverse FHN approaches pertinent to the *specific model used by the WHO (7–9).*

Family and Community nurse in Italy

The same situation occurs in the Italian context: diversity in the FHN model exists[2] and makes it difficult to articulate a unitary definition (10). The title of Family and Community Nurse (FCN) came into use after the COmmunity Nurse Supporting the Elderly iN a changing Society (CoNSENSo) Project, which presents the same content of the FHN's work – mainly focused on enabling older adults to live at home independently as long as possible (11). The model was tested in four countries and two Italian regions (Liguria and Piedmont). The introduction of the FCN caused great interest and engagement by educationalists, health professionals, and policymakers:

1-Regional Government across Country authorized FCN role implementation as a strategy to increase primary care capacity;

2- The government founded a new master's program (2004), contributing significantly to the growing number of nurses with more advanced skills;

3- The National Nursing Council (FNOPI) published a position statement to clarify the FCN role to avoid local FCN role interpretations (12). According to the document, the Family and Community Nurses provide nursing care to the individual, the family, and the community. They participate in all areas of health promotion and prevention, work in the local community, and implement environmental and public health policies. The Family and Community Nurse as a primary care provider is able to deliver nursing care to the individual's patient panel in collaboration with other healthcare professionals.

4- The government determined the nursing staff level, recommending a maximum nurse to patient ratio of 8:50.00[3]. Attention is shifting towards the FCN workforce's productivity to help the health care system meet the demand of primary care services.

Family and Community nurses contribution to primary care

In recent years, international literature has provided evidence from advanced nursing role in primary care and interprofessional primary care teams on patient and organizational outcomes. When nurses take up tasks usually performed by physicians, the quality of care of nurse-provided intervention is at least equal to physician-led care, and seems to have positive effects on hospital admission, patient satisfaction and clinical outcomes (13–17). Hovewer, the studies suffer from methodological limitations. Also, the evidence of an

[2] FHNs are identified within different nursing practice models like 'care manager' (Puglia, Tuscany and Piedmont), 'case manager' (Emilia Romagna, Lazio), 'community nurse', 'microarea nurse' (Friuli Venezia Giulia)

[3] DECRETO-LEGGE 19 maggio 2020, n. 34

interprofessional primary care team is uncertain. Evidence was poor when nurses provide complementary roles in primary care and it is difficult to effectively evaluate distinct nursing roles in the context of primary care (18). Thus, it is unclear how nursing practice models and outcomes apply to the primary care setting.

Objective

The aim of the trial is to evaluate the effectiveness of the FCN compared to usual care. The description follows the Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) guidelines. The participant timeline recommended shows the schedule of enrollment, interventions, and assessment (Table 4). The study hypothesizes that residents in the intervention group will experience a decrease in the number of hospitalizations, emergency room visits (white and green codes) and institutionalization compared to the usual care group. In addition intervention would increase the probability of respecting care goals of patients with chronic disease who wish to remain at home as well as their quality of life.

The study addresses the following specific objectives:

1. To compare the effects of the intervention versus usual care on the use of health care services in frail and older adults;
2. To compare the effects of the intervention versus usual care on frail and older adults' self-reported outcomes (health status, disability in activities of daily living, self-care and lifestyle);
3. To determine the subgroups of older adults that benefit most from the intervention.

Table 4: Content for the schedule of enrollment, interventions, and assessments.

	STUDY PERIOD				
	Eligibility	Enrollment	Baseline	1-year follow-up	2-year follow-up
TIMEPOINT			t_0	t_1	t_2
ENROLLMENT:					
Eligibility screen	x				
Invitation to participate		x			
Informed consent		x			
Data collection			x	x	x
INTERVENTIONS:					
Usual Care				x	x
FCN				x	x
ASSESSMENTS: (See table 5)					

Methods

Study design and setting

The study is a prospective controlled trial that will be carried out in real-life primary care settings. The study involves three assessments: at baeline (t_0), after one year (t_1) and the other two years after baseline (t_3).

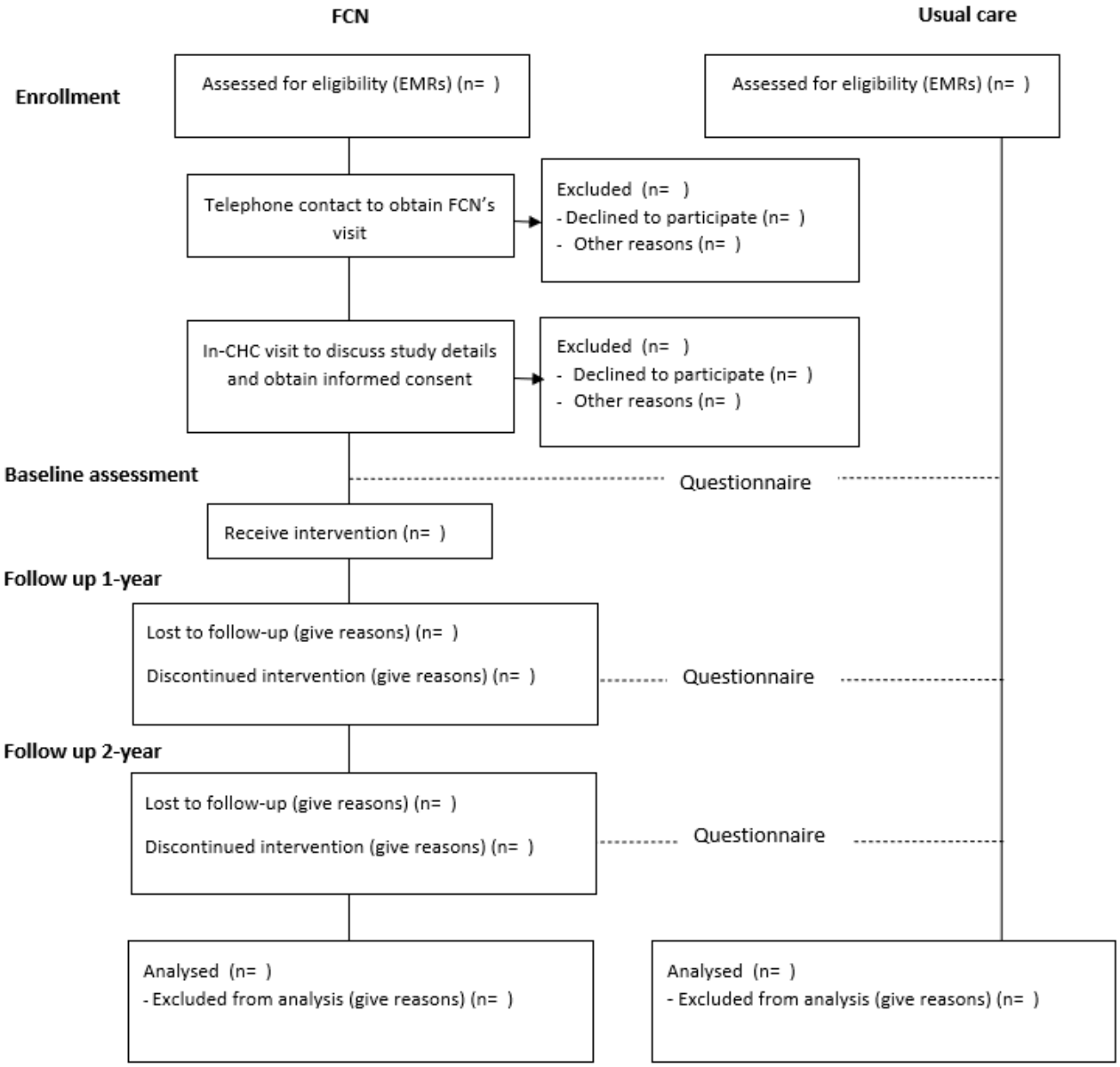
A strategic first step for this study is the development of a partnership between researchers at the University of Eastern Piedmont (Novara, Italy) and the Reference Group of the Local Health Authority (ASL Vercelli).

The study will recruit citizens in each of two neighboring Community Health Centres (CHC) in Vercelli: Santhià and Gattinara. Although these CHCs are in the same health district, they encompass diverse characteristics in terms of geography (Santhià is an urban context, Gattinara is a rural area) and structure. CHCs are centralized resources facilities that provide primary health care services in close proximity to one another[1]. The specific services vary across both CHCs in terms of access to on site professionals, connections with support services and community resources. The specific sites within the health district are selected because they serve a large and growing older adult population. Allocation units will be the CHC and not the residents, to avoid contamination bias between the intervention (FCN) and the control group (usual care).

Participants

Selection of citizens was performed through exploration of electronic health records (EHRs). The flow of participants through the study phases is presented in Figure 4. Potential frail study participants are identified using the criteria ("frail and chronic disease" criteria) adopted by the Local Health Authority: one or more deficits, one or more emergency department visits, polypharmacy (defined as the chronic use of different medications ≥ 3) or 75 years of age or older. Elderly citizens number 2265 (34,5%) in the area covered by the CHC of Santhià and 4302 (65,5%) in the municipalities of the CHC of Gattinara. The number of people with “frail and chronic disease” criteria (≤ 75 years) are 414 (15,5%) and 613 (12,5%) respectively.

Figure 4: Flow diagram of the study



Procedure

In order to participate in the study, citizens must satisfy the following inclusion criteria:

1. Recruited from the community
2. Able to speak Italian (or with an interpreter available)
3. Capable of providing informed consent or have a decision-maker who is able to provide informed consent.

Terminally ill patients or patients living in an elderly home or nursing home will be excluded. Allocation to the intervention will be communicated to eligible citizens with a client information letter. Citizens in the intervention group will be contacted by phone by a research assistant (RA), two weeks after the information

letter is sent, to obtain a verbal consent and schedule an initial visit. If there is nonverbal consent to the FCN visit it would be left to the potential patients to contact the research team or the FCN. At the time of the CHC visit, all eligible residents will be asked to participate in the study and provide a written informed consent. The FCN will provide the research team with the names of participants who have consented to the study and will be contacted to complete the questionnaire. Following participant inclusion, measurement will be collected at baseline, $t_{1,}$ and t_2.

Citizens in the control group will only be contacted by phone to obtain verbal consent and conduct the interview (questionnaire – Additional file 6).

Intervention

Residents assigned to the control group will receive usual care services through their local CHC, while residents in the intervention group will benefit from the FCN in addition to the usual care services that they currently have. The CHC covers a distinct geographic area whose residents will be served by one FCN team.
The intervention consists of the following components:

1) involvement of GPs: GPs will be informed in written form by the research team about the allocation of the FCNs. They will be invited to the in CHC-meeting with other involved parties (director of nursing, FCNs, the reference group of the LHA, representatives of integrated home care and social workers).
2) at least one visit by an FCN and participant and family assessments;
3) a tailor-made care plan with evidence-based interventions developed by the FCN;
4) nursing care coordination and navigation to link residences to the other health care professionals and community support services as needed.

In addition to these four elements, two supporting factors facilitate nursing care delivery: i) development of multidisciplinary clinical pathways of common diseases (PDTA) (diabetes, chronic obstructive pulmonary disease, and heart failure) where nurses provide patient-support in goal setting and self-management, ii) construction of procedure agreements regarding easy-access to electronic patient records and general practitioner consultation.
Because Family Community Nursing is family-driven, there is flexibility in the components in terms of the mode of delivery (e.g. setting), specific interventions/ activities emphasized and dosage.

Outcome measures

The primary outcome is the reduction of hospital admissions rate (data source - EHRs). Table 5 describes the secondary outcome measures.

Table 5: Secondary outcomes measured in the study

	Description	Time			Data source
		t_0	t_1	t_2	
Outcomes					
Primary Outcome					
Hospitalisations	Number of hospitalisations (per resident)	x	x	x	EHRs (file SDO)
Secondary outcomes					
Mortality	Death	x	x	x	EHRs (AURA)
Emergency Department visits	Number of emergency department visits (per resident) that do not result in admission.	x	x	x	EHRs (file SDO)
Polypharmacy	Number of different medications[§]	x	x	x	EHRs (file F)
	Numbers of potentially inappropriate medications, including STOPP criteria(19)	x	x	x	EHRs (file F)
Functional status	Number of hospitalisations for hip fractures (per resident)	x	x	x	EHRs (file SDO)
	Number of nursing home admissions (per resident)	x	x	x	EHRs (file FAR-SIAD)
Length of stay	Number of hospital days	x	x	x	EHRs (file SDO)
Adherence to PDTA	Loss to follow up	x	x	x	EHRs (local file)
Quality of Life	12-item Short Form questionnaire (SF-12)The SF-12 measures quality of life in two domains: a mental health component score (MCS) and a physical health component score (PCS)(20)	x	x	x	Self-administered questionnaire*
Self-care	The Self Care of Chronic Illness INventory (SC-CII) (21) includes eight Self-Care Maintenance items, five Self-Care Monitoring items, and seven Self-Care Management items. All items are rated on a 5-point ordinal response scale. Higher scores indicate better self-care. Italian version (http://self-care-measures.com/project/patient-version-sccii-italian/)	x	x	x	Self-administered questionnaire*
Functional status: Level of Activity of Daily Living (ADL) and	Katz ADL index score (22). The Katz index measures independence of ADL on six items (bathing, dressing,	x	x	x	Self-administered questionnaire*

Activity of Daily Living (IADL)	toileting, transferring, eating and the use of incontinence materials) The score range from 0 (total independence) to 6 (total dependence).				
	Instrumental Activity of Daily Living (IADL)(23) includes cooking, cleaning, transportation, laundry, and managing finances. The tool has a range between 0 and 17, with a higher scoring suggesting intact IADL abilities	x	x	x	Self-administered questionnaire*
Risks factors and lifestyle	PASSI d'Argento Questionnaire (Section 4: 4.7-4.23)	x	x	x	Self-administered questionnaire*
Falls	PASSI d'Argento Questionnaire (Section 2)	x	x	x	Self-administered questionnaire*

[§]Medications will be considered using the first three digits of the ATC code

Sample size

The sample size of the two groups involved in the study was estimated by a one-tailed Poisson modelling, using the following parameters:

- Crude hospitalization rate of 0.225
- Total reduction of 20% in hospitalization rates, within two years
- Alpha = 0.05
- Power = 0.8

G*Power 3.1 software was used. The result of the simulation shows 2473 residents for each group.

The intervention group and the control group will be matched on confounding factors such as age and sex.

Sample size for telephone interview (questionnaire)

The sample size was estimated considering a data simulation experiment of the Monte Carlo (MC) type.

Data were generated from two bivariate normal distributions, one for each group.

The distribution for the control group is a normal bivariate with the following characteristics:

$$\boldsymbol{X_1} \sim \mathcal{N}(\boldsymbol{\mu_1}, \boldsymbol{\Sigma}) \text{ ove } \boldsymbol{\mu_1} = \begin{pmatrix} \mu_{t1} \\ \mu_{t2} \end{pmatrix}, \ \boldsymbol{\Sigma} = \begin{pmatrix} \sigma_{t1}^2 & \rho\sigma_{t2}\sigma_{t1} \\ \rho\sigma_{t1}\sigma_{t2} & \sigma_{t2}^2 \end{pmatrix}$$

Where $\boldsymbol{\mu}$ is the vector of the means of the QoL for the two observation times.

The control group is assumed to be equal to μ_t1 = μ_t2 = 45 in the two intervention times as indicated in the literature.

The variance and covariance matrix $\boldsymbol{\Sigma}$ is defined considering the standard deviations for the two intervention times $\sigma_{t1} = \sigma_{t2} = 6.6$ and a correlation between repeated measures of ρ = 0.5.
For the intervention group a bivariate normal distribution with the following characteristics is sampled:

$$\boldsymbol{X_2} \sim \mathcal{N}(\boldsymbol{\mu_2}, \boldsymbol{\Sigma}) \text{ ove } \boldsymbol{\mu_2} = \begin{pmatrix} \mu_{t1} \\ \mu_{t2} \end{pmatrix}, \ \boldsymbol{\Sigma} = \begin{pmatrix} \sigma_{t1}^2 & \rho\sigma_{t2}\sigma_{t1} \\ \rho\sigma_{t1}\sigma_{t2} & \sigma_{t2}^2 \end{pmatrix}$$

Where $\boldsymbol{\mu_2}$ defines the vector of the two-time means which are equal to $\mu_{t1} = 45, \mu_{t2} = 47$, assuming an increase of 3 points in Quality of Life levels (SF-12), following intervention. The variance and covariance matrix has the same structure as in the previous case. The empirical power is calculated as the percentage of replicates that return a significant intervention effect for alpha 0.05. A sample size of 240 (120 + 120) guarantees an empirical power of 85%. A dropout rate of 30% is expected: for this reason, the sample to be enrolled for the survey will be 344 residents (170 + 170). The samples will be matched by sex, age and "frail and chronic level" with a 1:1 ratio. The calculations were performed using the software R 3.3.2 and the simr package .

Statistical analysis

Descriptive statistics using the information collected at the baseline and in the next two follow-ups will be performed.
Absolute frequency and percentage will be reported for categorical variables, while for the continuing variables the mean and standard deviation will be calculated. If the distributions of the continuous variables are not normal, appropriate transformations will be applied.
Comparisons between groups at baseline will be made using the t-test for independent samples, the chi-square test or Fisher's exact test. A p-value less than 0.05 will be considered statistically significant.

The analyses will be conducted in accordance with the intention-to-treat analysis principle.
A multi-variable Poisson model for the evaluation of the primary outcome, will be estimated. This model will take into account any confounding factors, which will be included as co-varied in the model.
The standardized rates will be calculated according to the direct method.
In addition, survival analysis will be applied to analyse the expected length of time before an event occurs, for example first admission to hospital, institutionalization, mortality and first consultation to emergency department.
The differences between the two groups (intervention vs control) will be estimated as hazard ratios with 95% confidence intervals from stratified Cox proportional hazards models. Estimates of the percentages of patients who will have events at specific time points will be based on the corresponding Kaplan–Meier curves.

The proportional hazards assumption will be confirmed through correlation tests between the weighted Schoenfeld residuals and event times.

For the outcomes detected through the administration of the self-report questionnaire, subjects belonging to the intervention and control groups will be matched on the basis of age, sex and frailty level, with a 1: 1 ratio, using the Covariate Balancing Propensity Score (CBPS (42)).

The procedure will ensure the balance of patient characteristics between the various treatment groups.

To evaluate the outcome of the matching procedure, appropriate statistical tests will be performed.

Finally, to evaluate the difference in scores between the survey times in the subject and between the groups (intervention vs comparison), a generalized multivariate mixed model will be applied.

Analyses will be performed with the use of SAS software, version 9.4 (SAS Institute, INc., Cary, NC)

Discussion

This trial would assess the impact of Family Community Nursing role implementation in a population that is particularly at risk for adverse outcomes. To our knowledge, it is one of the first Italian studies adopting the Family Community Nursing practice model to explore effects on older adults and frail people living at home. Criteria use to group patients < 75 years refer to the stratification approach (not validated) applied in LHA of Vercelli. It is a limit of the study.

Study participants will be recruited from a cohort receiving care from one FCN team provider, so the study findings may not be generalizable. In addition, proper recruitment of frail and older people could be complex (24). Thus, the study provides a mixed strategy: an initial postal approach of eligible residents and then a phone contact by a RA for logistical reasons. This approach tried to find the optimal balance between detailed information provision and simple explanation. Retention may also be challenging; previous studies have reported high attrition rates in the older population (25,26). To address this challenge, the working group and research coordinator have conducted regular meetings either in person or by teleconference to discuss the design, the recruitment processes, the barriers that will be encountered, and possible solutions. FCNs were fully informed and engaged in the study to assure their motivation to participate.

The FCN is a unique intervention for community residents for several reasons. First, it targets adults with a minimum age of 75 years and people with care-complexity (“frail and chronic criteria”). Second, Family and Community Nursing focuses on the family as a system and collaboration between health care professionals in primary care; not only are general practitioners involved, but also social workers, in order to achieve comprehensive integration of welfare issues in the care of older adults and their families. Third, FCN demands a shift from reactive care provision to a proactive integrated care approach. Reccomendations for efficient investment in FCN was developed in the context of the European Curriculum for Family and Community Nurses (ENhANCE) Project, to support policy and decision makers in including FCN in primary

care settings: implementing the Family Community Nursing role requires strongly motivated professionals focused more on health promotion, working in an adequately equipped practice setting and with advanced competences. For this reason, the University of Eastern Piedmont was commissioned, by LHA, to provide the educational program to prepare nurses. Actually an FCN European Curriculum based on 28 core competencies (30) exists, which was piloted at the University of Genoa.

Trial status

The Local Ethics Commettee approved the trial with protocol ID AslVC.Med.19.02 (Additional file 7) in September 2019. Researchers could not start the trial because FCNs were moved to the department of prevention during the COVID-19 pandemic.

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Chapter 5

Reti di assistenza comunitaria per la fragilità – REACTion project

Background

Worldwide, an increase in life expectancy and aging is leading to a vastly expanding population of older adults. The number of people aged 60 and older will increase from 1 billion in 2019 to 1.4 billion in 2030. By 2050, the global population of older people will have more than doubled, to 2.1 billion (1). Advancing age often implies an increase in chronic diseases and multi-morbidity with subsequent functional decline and social impairments (e.g. the loss of social support, financial limitations, and the lack of appropriate housing) (2,3). Moreover, the age-related process and multi-morbidity are strongly related to frailty. Frailty is a dynamic condition along a continuum from normal aging to disability (4,5) defined as "a progressive age-related decline in physiological systems that results in decreased reserves of intrinsic capacity, which confers extreme vulnerability to stressors and increases the risk of a range of adverse health outcomes" (6). Frail older people have numerous and complex health and social-related needs: i) information; ii) coordination of services and supports; iii) preventive, maintenance and restorative strategies; iv) training for older adults and caregivers; and v) person-centred approaches (7,8). In addition, the COVID-19 pandemic has increased the need for social activities and relationships (9).

The project

REACtion is funded by the European Territorial Cooperation (ETC) – Interreg V-A Italy-Switzerland. The project addresses the fourth Programme's priority, "Services for the integration of communities": improved quality of healthcare, education, and social services, as well as enhancing their accessibility by vulnerable and older people. It started in December 2020 and will continue until November 2022.

The project brings together five partners from the two countries (Italy and Switzerland) (Figure 5).

1. The University of Eastern Piedmont (Department of Translational Medicine)- Italian project lead;
2. Associazione Locarnese e Valmaggese di Assistenza e cura a Domicilio (ALVAD) - Swiss project lead;
3. Local Health Authority of Vercelli - Italian partner;
4. Local Health Authority of Novara - Italian partner;
5. The University of Turin - Italian partner

Figure 5: Geographical distribution of the partners

REACTion project supports frail and older people in continuing to live in the community through two areas of action: 1) development of shared Family and Community Nursing interventions, and 2) strengthening the capacity of rural and urban communities to facilitate inclusion, participation of older adults, and reduce loneliness and social isolation. The main idea behind the project is to create the conditions to improve health and quality of life through a "community welfare" system. Participants in the project are adults over 65, their caregivers, stakeholders and Family Community Nurses (FCNs). The project has been implemented in Vercelli (Community Health Centre of Santhià-Italy), in the southern and urban Health Districts of Novara (Italy), and the Districts of Locarno and Vallemaggia (Switzerland). The REACtion includes 6 different work packages (table 6). First, the health and social care needs of the older population will be identified in the project area. Stratification of older adults into risk categories could identify and address the distinct health care profiles and priorities of different groups comprising it. Second, tailored nursing care intervention will be designed also considering the social and physical environments in which older adults live. Intervention includes nurse training, the application of eHealth technology, and stakeholder engagement. Defining stakeholders and developing management strategies for the network are core elements in successfully delivering the project. In addition, collaborative partnership and professional integration will improve community welfare and maximize the positive impact on older adults. Third, the project provides for process and sustainability evaluation of the intervention. In May 2021, the project benefitted from another COVID-related fund and added a work package. It provides two different deliverables: 1) a learning experience through gamification

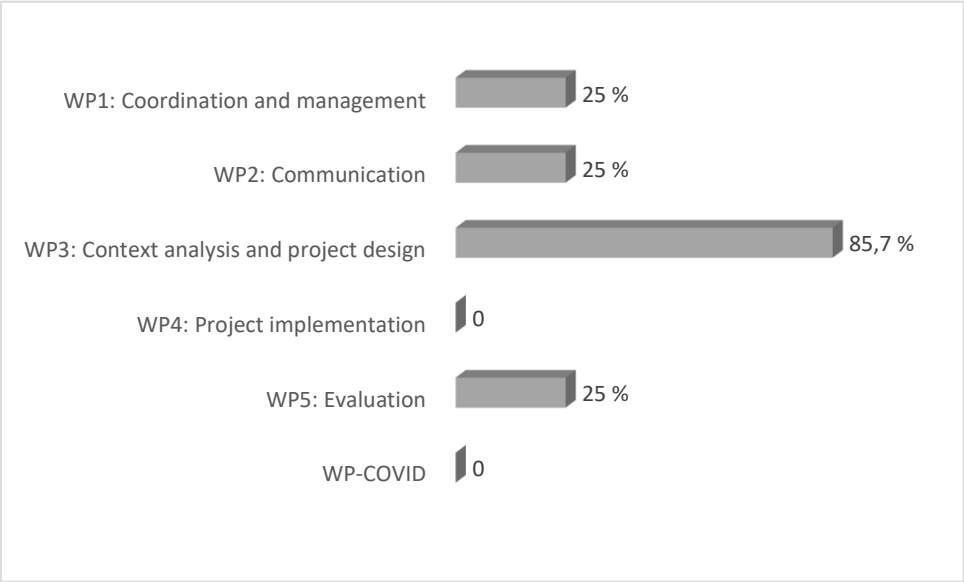
for nurses in continuing education. It allows nurses to develop knowledge and skills in a safe environment; 2) dissemination of best practices which emerged during the COVID-19 pandemic to care for older adults at home. Figure 6 provides an overview of the project status.

In conclusion, the project answers older people's needs, improving individual and community empowerment. The FCNs will play a role in facilitating older adults' control of the factors and decisions that shape their lives and access to services. The project will significantly contribute to patient care because the intervention is designed based on local realities and beneficiaries' priorities. Communication and participatory approaches support the development of the project and its sustainability. Communication is a vital task. Therefore information about the project continually flows through the standard project monitoring system, workshops (internal communication), and mass media (external communication). In addition, information from a monitoring system and the evaluation reports will be used to correct the project in progress and test the sustainability.

Table 6: Work packages description

Work package	Task (N)	Description
1.Coordination and management	1	The main objective of this WP is to ensure the successful completion of the project goals on time within the limits defined by the budgetary framework.
2.Communication	3	This WP aims to inform and engage the project's stakeholders and disseminate the project's outputs. The communication activities and channels are tailored to reach the different stakeholders and objectives.
3.Context analysis and project design	2	This WP provides a context analysis to better understand the social and health needs of older adults and which actors operate in the community. Activities are focused on defining tailored interventions for frail and older adults.
4.Project implementation	2	The objective of this WP is to develop and provide e-learning modules to improve FCN skills, and support partners during local pilot best practice implementation. Key components of the intervention include nurse training, the application of eHealth technology, and stakeholder engagement.
5.Evaluation	2	This WP aims to evaluate the development and results of the project, focusing on its impact and sustainability.
6.WP Covid	2	This WP was organized to answer specific needs that emerged during the COVID-19 pandemic. Activities are focused on training post-graduate nurses with an innovative approach and disseminating best practice.

Figure 6: Project status



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Chapter 6

General discussion

This dissertation explores the effects of nursing patterns of care and nursing practice models on patient outcomes in hospital settings and primary care. Particular attention is paid to barriers and facilitators encountered during nursing role implementation and the impact of Primary Nursing and Family Community Nursing (FCN) on patient- staff and organizational-related outcomes in primary care and hospital settings. Also, an example of FCN intervention is described in REACtion project.

In this dissertation, only results of the integrative literature review are listed. The study was performed to gain insight into factors and preconditions to implement nursing roles in primary care. Implementation of the nursing role in a health care system does not occur in isolation of the overall system because contextual and environmental issues influence the process. Concerns were raised about the sustainability of the nursing role within the current practice and policy context. In recent years, considerable investments has been made in the educational preparation for and the development of the nursing role in primary care. In Italy, master's degree programs in FCN are available and support the nurses' transition to primary care settings. Also, local authorities, policymakers, and professional associations collaborate to create a favorable environment in which nursing care can develop and maximize its impact. The most recent legislation shows interest in engaging FCNs as a key component of the Primary Health Care Team, but a clear purpose and objective for nursing in primary care are still lacking. Findings demonstrated that successful implementation of the nursing role is a complex process. Data are consistent with Sangster-Gormley et al.(1) which have sensitizing barriers and facilitators in three concepts: 1) intention (how the role is defined and the outcomes expected); 2) involvement (active participation of team members in determining the nursing role) and 3) acceptance relates to team member recognition. From this perspective, strong organizational leadership is necessary.

Two different study protocols were designed to examine the relationship between nursing care delivery model and patient outcomes. First, a prospective before and after study, and second, a prospective controlled study. Conducting randomized controlled trials (RCT) on the nursing care model would have been most desirable to assess causal effects, but performing these studies in these domains is expensive, difficult ,and only feasible on a small scale. The dissertation approaches quasi-experimental design in a situation where staffing levels and nursing care models are increasing systematically on a large scale. This design is particularly important when we need to produce data on intervention conducted in real-life conditions and a RCT cannot be performed. However, the selective exposure of the interventions may create a bias that reduces the capacity of the study to conclude on a clear causal inference between nursing care delivery and patient outcomes.

The ongoing COVID-19 pandemic has had a negative impact on the management of the trials. The COVID-19 pandemic has resulted in a series of public health policies that have crippled the healthcare system (2). This pandemic has had a substantial impact on the trial centers as they experience difficulty in the continuation of trial activities. To date, we have already placed the trials on standby. Several factors were considered: 1) difficulty in recruiting homogeneous patients in pre-post implementation PN, 2) nurses, who were trained for active participation in the study, were moved to other wards; 3) difficulty in recruiting homebound patients, 4) continuation of the trial may lead to a high drop-out rate.

Future directions

The results of this dissertation have implications for policy, education and research.

Our findings suggest that workforce planners and clinical teams need to consider specific barriers and facilitators when implementing nursing roles, and screen contextual issues. Organizations should invest in clinical leaders as a driving force for change, actively involve nurses in adapting the nursing role, and clarify intentions and expectations of how the nursing role should function. Also, nurses must understand how they themselves and/or the patients would benefit.

Education is a key component to implementation. Training programs should provide graduates and post-graduates with skills and competencies to work in specific contexts and at the advanced practice level.

Evaluation needs to combine effectiveness and implementation/process research. Future research in the field may investigate how the delivered intervention produced the change and whether the intervention was implemented as planned.

In conclusion, this dissertation highlights that the implementation and evaluation of nursing practice models and their components are complex; barriers and facilitators need to be considered when a new nursing role is implemented. Also evaluators should pay attention to several issues. Much more studies need to be performed to investigate patient-, staff- and organizational-related outcomes in order to improve nursing practice.

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Additional file

Additional file 1

Comitato Etico Interaziendale
A.O.U. "Maggiore della Carità", ASL BI,
ASL NO, ASL VCO

AOU Maggiore della Carità di Novara

Protocollo
615/CE Studio n.
CE 106/19

PARERE DEL COMITATO ETICO

A. IDENTIFICAZIONE DELLO STUDIO - SPERIMENTAZIONE CLINICA DISPOSITIVI	
MEDICI 1.Titolo completo del protocollo	*Primary Nursing: studio pre e post*
2.Promotore	Università Piemonte Orientale
3.Codice, versione e data del Protocollo	Studio PRIMARY, 1, 20-05-2019

B. IDENTIFICAZIONE DEL COMITATO ETICO (costituito ai sensi del DM 8 febbraio 2013)	
1.Denominazione del CE	Comitato Etico Interaziendale AOU "Maggiore della Carità" di Novara, ASL BI, ASL NO, ASL VCO
2.Nome e cognome del Presidente	Prof. Pier Davide Guenzi
3.Indirizzo del CE	C.so Mazzini n.18 - 28100 Novara
4.Numero di telefono	0321.3733081
5.Numero di fax	0321.3733080
6.E-mail	segreteria.scientifica@comitatoeticonovara.it

C. IDENTIFICAZIONE DEL MEDICO RICHIEDENTE	
1.Nome Cognome	Dott.ssa Cristina Torgano
2.Centro Clinico	S.C. DIREZIONE DELLE PROFESSIONI SANITARIE(NO)
3.Indirizzo del centro clinico	Corso Mazzini 18-28100-Novara-NO
4.Reparto	-

D. SEDUTA DEL COMITATO ETICO	
1.Data della seduta	05-07-2019
2.Numero del registro dei pareri del CE	CE 106/19

3.Componenti del CE presenti e qualifiche

- MAURO BRUGNANI *Esperto in nutrizione*
- PIER LUIGI CANONICO *farmacologo*
- LUISA DE SANCTIS *pediatra*
- EDOARDO FERLITO *rappresentante associazioni di volontariato*
- ARMANDO GENAZZANI *Esperto in genetica*
- LORENZO GIUDICE *esperto in materia giuridica*
- PIER DAVIDE GUENZI *esperto in bioetica*
- MARCO KRENGLI *Clinico di Area medica Specialistica*
- FRANCESCO PIA *clinico di area chirurgica*

• MARIO PIRISI *Clinico di area medica internistica*
• ALESSIA PISTERNA *farmacista del servizio sanitario nazionale*
• ROBERTO SACCO *Direttore Sanitario AOU Novara*
• PACIFICO UGLIETTI *medico di medicina generale*
• GIANFRANCO ZULIAN *medico legale*

E. DOCUMENTAZIONE ESAMINATA

• Protocollo_ver_1_20_05_2019

• Sinossi_ver_1_20_05_2019
• CRF cartacee_20_05_2019
• Lettera d'intenti_20_05_2019
• CV dott.ssa Torgano_20_05_2019
• Dichiarazione conflitto intessi_Principal_Investigator
• Dichiarazione studio spontaneo_20_05_2019
• Responsabile del disegno e analisi_20_05_2019
• Scheda Riassuntiva Dichiarativa
• Scheda DOMANDA
• PARERE DIREZIONE SANITARIA
• Elenco preliminare centri al 20_05_2019
• Consenso informato paziente_20_05_2019
• Consenso informato infermiere_20_05_2019
• consenso trattamento dati paziente_20_05_2019
• Consenso trattamento dati infermiere_20_05_2019
• Studio non su dispositivi

La Segreteria Tecnico-scientifica del CE interaziendale

_____

(Dott.ssa Cinzia Ferrari)

F. DECISIONE DEL COMITATO ETICO

1. Parere

Parere favorevole
Previa acquisizione delle seguenti modifiche:
precisare nel modulo informativo per l'infermiere il tipo di questionario on line richiesto e cosa si intende verificare. Analogamente per il questionario anonimo proposto al paziente.

La documentazione integrativa dovrà pervenire alla Segreteria tecnico-Scientifica del Comitato Etico Interaziendale per la validazione, prima di procedere con gli adempimenti di competenza.

Il dott Dal Molin non partecipa alla valutazione del protocollo né alla votazione in quanto direttamente

	coinvolto.
2. Sperimentazione da condurre presso	A.O.U. "Maggiore della Carità" di Novara
3. Numero dei pazienti previsti	nd
4. Data	05-07-2019

G. FIRMA DEL PRESIDENTE DEL COMITATO ETICO	
1. Il Comitato Etico ha espresso il parere/sospensione della decisione: ♦ verificata la sussistenza del numero legale, essendo presenti membri n.14 su n.17	
2. Nome e Cognome	Prof. Pier Davide Guenzi
3. Data	05-07-2019

Additional file 2

trial status (phase 1-before PN implementation)

Centre	Ward	Starting date	Status	Sample	Patients recruited (N)	CBI (N)	Nurses recruited
A.O.U Maggiore della Carità di Novara							
	Nefrologia-trapianti	09/09/2019	Delete	-	25	17	9
	Area cardiologica	22/11/2019	Completed	**150**	192	149	41
	Casa di cura	18/11/2019	Delete	**68**	20	14	11
	Area Chirurgica	17/02/2021	In progress	**150**	20	14	-
A.O.U San Luigi							
	Medicina	08/10/2019	Suspended	**150**	60	38	14
AUSL Ferrara							
Ospedale del Delta	Lungodegenza	13/01/2020	Suspended	**68**	10	-	
Ospedale di Argenta	Area Medica	13/01/2020	Suspended	**150**	24	19	
Ospedale di Argenta	Area chirurgica	13/01/2020	Suspended	**150**	13	9	9
OSCO Comacchio		13/01/2020	Suspended	**150**	10	-	
ASL AT							
	CAVS	-	Suspended	**70**	13	11	5
	Malattie infettive	-	Not started				
ASL Città di Torino							
Maria Vittoria	Geriatria	-	Suspended	**150**	-	-	5
Martini	Medicina	-	Not started				
Birago di Vische	Medicina	-	Not started				
Maria Vittoria	Medicina	-	Not started				
A.O. Ordine Mauriziano (TO)							
	Sub-Intensiva	-	Suspended	**60**	35	27	-
ASL CN1							
	Lungodegenza	-	Not started				

Riabilitazione	-	Not started
A.O. Santa Croce e Carle (CN)		
Medicina	-	Not started
O. Humanitas Gradenigo (TO)		
Medicina	-	Not started
Centro di Recupero e Rieducazione Funzionale (CRRF) "Mons. Luigi Novarese" (VC)		
Neuro-riabilitazione	-	Not started

Legend: CBI-Caring Behaviour Inventory; CAVS-Continuità Assistenziale a Valenza Sanitaria

Additional file 3

Search Strategy

MEDLINE

1. ((((("Nurse Practitioners"[Mesh]) OR ((((("nurse practitioner"[Title/Abstract]) OR "nurse practitioners"[Title/Abstract]) OR (("advanced nurse practitioner"[Title/Abstract] OR "advanced nurse practitioners"[Title/Abstract])))))) AND ((((("Primary Health Care"[Mesh]) OR "primary health care"[Title/Abstract]) OR "Community Health Services"[Mesh]) OR "community health services"[Title/Abstract])) AND ((((((((implement*[Title/Abstract]) OR "introduction"[Title/Abstract]) OR improve*[Title/Abstract]) OR "experience"[Title/Abstract]) OR "barrier"[Title/Abstract]) OR "barriers"[Title/Abstract]) OR "facilitator"[Title/Abstract]) OR "facilitators"[Title/Abstract])

2. ((((((family health nurs*[Title/Abstract] OR (family nurs*[Title/Abstract] OR "Nurses, Community Health"[Mesh]) OR (community health nurs*[Title/Abstract] OR (district nurs*[Title/Abstract] OR "Nurses, Public Health"[Mesh]) OR (public health nurs*[Title/Abstract] OR "Family Nurse Practitioners"[Mesh]) OR (family nurse practitioner[Title/Abstract] OR family nurse practitioners[Title/Abstract])) OR (rural nurs*[Title/Abstract])))))) AND (((((((((implement*[Title/Abstract]) OR introduction[Title/Abstract]) OR improve*[Title/Abstract]) OR "experience"[Title/Abstract]))) OR "barrier"[Title/Abstract]) OR "barriers"[Title/Abstract]) OR (("facilitator"[Title/Abstract] OR "facilitators"[Title/Abstract]))).

3. ((((((((("Primary Health Care"[Mesh]) OR "primary health care"[Title/Abstract]) OR "Community Health Services"[Mesh]) OR "community health services"[Title/Abstract])) AND ("Nurse's Role"[Mesh] OR "nurse's role"[Title/Abstract] OR "nurse's roles"[Title/Abstract] OR "nursing role"[Title/Abstract] OR "nursing roles"[Title/Abstract] OR "role nurses"[Title/Abstract] OR "role nursing"[Title/Abstract])))))) AND ((((((((implement*[Title/Abstract]) OR introduction[Title/Abstract]) OR improve*[Title/Abstract]) OR "experience"[Title/Abstract]))) OR "barrier"[Title/Abstract]) OR "barriers"[Title/Abstract]) OR (("facilitator"[Title/Abstract] OR "facilitators"[Title/Abstract])))

CINAHL

#	Query
S23	S9 AND S10 AND S22
S22	S20 OR S21
S21	TI nurs* role OR TI nurs* roles OR AB nurs* role OR AB nurs* roles
S20	(MH "Nursing Role")
S19	S10 AND S18
S18	S12 OR S13 OR S14 OR S15 OR S16 OR S17
S17	TI rural health nurs* OR TI rural nurs* OR AB rural health nurs* OR AB rural nurs*
S16	(MH "Rural Health Nursing")
S15	TI family nurse practitioner OR TI family nurse practitioners OR TI family health nurs* OR AB family nurse practitioner OR AB family nurse practitioners OR AB family health nurs*

S14	(MH "Family Nurse Practitioners")
S13	TI community health nurs* OR TI district nurs* OR TI public health nurs* OR AB community health nurs* OR AB district nurs* OR AB public health nurs*
S12	(MH "Community Health Nursing+")
S11	S8 AND S9 AND S10
S10	S6 OR S7
S9	S3 OR S4 OR S5
S8	S1 OR S2
S7	AB implement* OR AB introduction OR AB improve* OR AB experience OR AB barrier OR AB barriers OR AB facilitator OR AB facilitators
S6	TI implement* OR TI introduction OR TI improve* OR TI experience OR TI barrier OR TI barriers OR TI facilitator OR TI facilitators
S5	TI (primary care or primary health care or primary healthcare) OR TI community OR TI district OR TI community care OR TI community health care OR AB (primary care or primary health care or primary healthcare) OR AB community OR AB district OR AB community care OR AB community health care
S4	(MH "Primary Health Care")
S3	(MH "Community Health Services+")
S2	TI nurse practitioner OR TI nurse practitioners OR AB nurse practitioner OR AB nurse practitioners
S1	(MH "Nurse Practitioners+") OR (MH "Advanced Practice Nurses+")

Additional file 4

Summary of key characteristics of the included studies

First author, year	Country	Study design	Aim	Participants (N)	Setting	Nurse's Role 1.Nurse described 2.Education/training 3.Role description
Craswell, 2019	Australia	MMS	To explore the reasons why some consumers express willingness to be seen by a NP when a medical practitioner is also available.	Adults (1,318)	PHC	1.NPs 2.Master's degree 3. First point of contact (refer patients to other health professionals, prescribe medications, diagnostic and blood tests)
Drury, 2005	Australia	QS	The purpose of this paper is to describe nursing roles of registered mental health nurses working in rural and remote areas.	CMHNs (5)	Community (rural and remote areas)	1.CMHNs (RNs working in advance practice level) 2.Specific work experience in mental health. 3. Focus on community rather than just on the patient. CMHNs deliver holistic care. Responsibilities: therapeutic use of self, client assessment, ongoing monitoring, planning, implementing and evaluating care, crisis intervention, psychoeducation and caregiver support, liaison role.
Dunt, 1991	Australia	CSS	To describe educational characteristics, career structure and work experience of community nurses.	Community nurses (695)	Community (practice area: community health centre, community-based district and visiting, maternal and child health, medical clinic,	1.Community nurses (nurse working outside hospital, nursing home or nursing education centre)(RNs) 3. Activities of a community nurse's role: prevention and health promotion, assessment, direct patient care (maintenance of activities of daily living, provision of technical care and counselling), advocacy, administration (maintenance of records, liaison with other nurses or other health professionals),

					occupational health, ect.)	coordination and supervision, travel, case-sharing.
McCullough, 2020	Australia	QS	This study described and explained from the perspective of nurses, the actions and interactions involved in the delivery of PHC in remote communities.	NPs (13), Remote Area Nurses (7), nursing academics (4)	PHC (remote areas)	1.Remote Area Nurses (RN) 3.Care for the community and individuals, with a focus on illness prevention, equality of care. Role as a co-ordinator of care to facilitate access to health services.
Parker, 2013	Australia	QS	To examine Australian health care consumers' perceptions of nurse practitioners working in primary health care	77 participants to focus groups	PHC	1.NPs 2. RNs completed a masters' degree 3.NPs performed an advanced and extended clinical role (assessment and management of clients, prescribing medication, ordering diagnostic intervention, and making direct referral). NPs have whole person approach to delivering health care.

Burgess, 2010 Burgess, 2011	Canada	QS	We used a PAR approach to explore, from the perspectives of NPs the relevance of collaboration in advancing NP role integration in primary healthcare (PHC) (focus on the effects of collaboration on NP role integration)	NPs (17)	PHC	1.NPs 3. Collaborative relations with clients, colleagues and healthcare leaders. NPs developed their role as multi-faced and carry out complex client and underserved/marginalised groups and community assessment, apply evidence-based guidelines, prescribe and provide treatment, initiate health promotion and prevention programs,patient advocacy, link clients to various community resources. Holistic approach to care.

Côté, 2019	Canada	QS	To better understand the factors that impede or facilitate stakeholders in achieving an optimal use of the PHCNP role.	PHCNPs (27)	PHC	1.PHCNPs (NPs)
De Guzman, 2010	Canada	CSS	Identify the NPs' perceptions of barriers and facilitators associated with the implementation of their role in Ontario's PHUs, the NPs' job satisfaction, and the relationship between NP job satisfaction and practice dimensions.	NPs (28)	PHU (71.4% of NPs were practicing in sexual health programs. 21.4% were practicing in the prenatal/ postnatal care, 7.1% practiced in other areas, such as primary health care)	1. PHCs (NPs) 2.BScN degree and post-baccalaureate (Primary Health Care) NP certificate. 3.Provide clinical care (69.4%), clerical work (7%) and education (7%). Most respondents (89.3%) worked in an area designated as being under-serviced for physicians.
Domm, 2019	Canada	QS	To gain understanding about PHN perceptions of their evolving work and how PHN work was managed.	PHNs (42)	Urban and rural setting	1.PHNs 3. Provide health assessment, health promotion and education, administer vaccines, linking role between patient and social support.
Gould, 2008	Canada	QS	To investigate the experiences of nurse practitioners (NPs) 1 year after they were first introduced to a mostly rural Canadian province.	NPs (7)	Primary care (rural area)	1. NPs 2.Majority of NPs were licensed within the past 2 years.Interviewees had worked as RNs for an average of 21.1 years (SD = 11.9, range = 3–40 years) before becoming NPs. 3. NPs spend time with patients, patient involvement, educating patients, as part of illness prevention goals but also in order to ensure adherence to prescribed regimens.

						History taking.. Team-working and holistic approach to patient care (housing, mental health problems, financial problems).
Hunter, 2016	Canada	MMS	To determine benefits and challenges of a rural primary care NP role	Survey: 41 patients, 1 HCP, 4 physicians; Interviews: 14 patients, 1 HCP, 2 LLs and the NP.	Primary care (rural area)	1.NPs 3. NPs provide follow-up for chronic patients, acute concern, routine check-up/prevention and collaborate with clinic colleagues and HCP.
Jean, 2019	Canada Spain	QS	To develop a comprehensive understanding of the contextual factors that influence the development and implementation of APN in two countries, Canada and Spain	Nurses (32), medical doctors (10), Psychologists (2), allied health professionals (2), other (1)*	Community	1.APNs 2.The majority had a master's degree (34%) or a PhD (25.5%).
Martin-Misener, 2010	Canada	MMS	To describe how rural health board chairpersons and health-care providers define the role of NPs in Nova Scotia. It summarizes their perspectives of the health needs of rural communities, the gaps in the current model of PHC services, the envisaged activities of NPs, and the facilitators of and barriers to NP role implementation.	Chairpersons (51)	PHC (Rural Area)	1. Rural NPs 3.NP was described as generalist, partial overlap with FP. Care for patients with common urgent health issues. Provide health promotion, prevention and chronic disease management, outreach, address physical, social and mental health concerns and counsel and educate patients. Community activities: liaison role (community and FPs and community services). Work in collaboration with FPs and other health-care providers (some settings requirement for formal collaborative agreement). Most respondents(39%) indicated that NPs provided assessment and diagnosis activities . In addition, respondents reported that NP prescribed some medications (e.g. contraceptives, antibiotics), and performed procedures (<30% of respondents). Fewer than 35% indicated that NPs carried out

						consultations and referral activities. 30% of respondents indicated that NPs performed community activities (mostly carried out by PHNs/ FPNs).
Reutter, 1996	Canada	QS	To explore the public health nurse's perception of their business and experience	PHNs (28)	Community (different settings: well-child clinics, home visits, schools, rural areas)	1.PHNs 2. 24 PHNs had baccalaureate degrees, 2 PHNs had a diploma in public health nursing, 2 PHNs had an RN diploma. 3.Family and community focus; health promotion (e.g. immunization, pre-natal and post-natal education and illness/injury prevention programme.
Sullivan-Bentz, 2010	Canada	QS	To examine the influence of inter-professional relationships, particularly those with family physicians; explore the factors influencing and hindering successful transition into NP practice; and recommend ways to support new NP graduates	Anglophone & francophone NPs (23) & co-participants (physicians, NP colleagues, or administrators) (21)	PHC (rural and urban)	1.PHCNPs (NPs) 2.Anglophone NPs: "All had bachelor's degrees in nursing and 3 had master's degrees." Francophone NPs: "One was master's-prepared"
Burke, 2010	Ireland	QS	This study investigated the experiences of community nurses working in four pilot teams.	PHNs (14), CRGNs (4), PNs (3), CMHN (1)	Primary Care	1.PHNs 3.Collaborative relationships with other members of the primary care team. PHNs have geographical boundaries. PHNs treat an entire family, manage complex cases and provide health promotion.
Zug, 2016	Latin America and	CSS	To identify the current state of APN regulation, education, and practice in Latin America	Nursing leaders or key informants in their country (University	PHC	1.APNs

	the Caribbean		and the Caribbean and the perception of the APN role in PHC	employees, Educations, Ministry of Health employees, policymakers) (173)		2.master's degree is recommended" (The International Council of Nurses".

Adams, 2019	New Zealand	QS	This paper reports on the barriers and facilitators to becoming a NP in rural PHC	NPs (11), NPs candidate (4)	PHC (rural): general practices, PHOs, DHB	1.NPs 2.Clinical Master's degree 3.Primary response in medical emergencies. Managing patients with long term conditions. Working collaboratively with GPs.
Carryer, 2011	New Zealand	QS	To explore the transition from rural nurse to NP.	Nurses (21)	Primary Care (rural)	1.NPs 2.1 'authorised NP', 1 unsuccessful application, 1 application pending. Master's Degree -11 completed (not yet submitted an application), 2 commenced but not completed, 5 not started. 3.Broad scope of rural practice- across the lifespan. Community integration.
Carryer, 2017	New Zealand	QS	To consider the alignment of the NP role in New Zaeland with the goals and aspirations of the many countries facing challenges to maintaining health service delivery and reducing health disparities.	NPs (13)	PHC (rural locations)	1.NPs 2.Masters educated 3.Patient-centred approach attending to family, community, and social, political and economic factors, education, order laboratory tests, diagnose, prescribe and other tools, making the system work for patients.Collaborative model of care.
Mackay, 2003	New Zaeland	MMS	To explore perceptions of GPs in the NDHB regarding the NP role, identifying their knowledge of and perceived	GPs (47)	PHC	1.NPs 2.NPs are educated through a clinically focused master's degree programme and must

			problems with that role, and their experience of nurses in advanced practice.			meet the competencies set out by the nursing council. 3.Advance the scope of their nursing practice, expert practice, working collaboratively with other disciplines as well as across settings, leadership and consultancy in nursing, development and influence policy and nursing practice, research on nursing practice. Nurse prescribers (optional) (Nursing Council of New Zealand, 2001). GPs rated - health teaching to promote health or to prevent illness, home visits to do follow-up, evaluation of care, taking histories (favourable). Prescribing, ordering tests, physical examinations (least favourable).

Clancy, 2009	Norway	QS	Describe and analyze local decision-makers' views on public health nursing and to reflect on and discuss the relevance of those views to the future of public health nursing.	Politicians (5), administrators (6)	Community (municipality)	1. PHNs 3. PHNs discover and refer problems and support and advise parents, school children and young people. Collaboration with other professions (interprofessional and intraprofessional collaboration). Leader's role.
Lindblad, 2010	Sweden	QS	To describe the first Swedish APNs' and their supervising general practitioners' (GPs) experiences of an APN's role and scope of practice.	APNs (4), GPs who had supervised the APNs (5)	Primary Health Care Centres	1.APNs 2.Advanced Clinical Nurse Specialist's degree 3.Independent role, patient care acute health problems, such as infections (upper pulmonary infections, UTIs, otitis, dermatitis and skin problems).Right to prescribe medication and order treatment.

Ljungbeck, 2017	Sweden	QS	To investigate the opinions of managers, doctors and nurses in primary care and municipal healthcare about the role of ANPs in municipal healthcare.	Doctors in primary care(4) Managers(4)and nurses working in municipal healthcare(4)	Primary Care and Municipal healthcare	1.Specialist nurse 2. The specialist nurses must have worked in municipal healthcare as a specialist nurse for at least two years to have gained the experience and understanding that advanced nursing care requires. 3. Nurses believed the ANP would increase patient safety as the ANP be clinically competent, provide leadership and collaborative practice. Continuity of care - follow the frail elderly through different types of services and take more responsibility for the patients regarding both nursing and medical care. Personalized and person-centred care. Managers believed ANPs could educate and support other nurses. Enable healthcare of the frail elderly.
Boman, 2019	Sweden, Norway, Denmark	QS	To explore the feasibility of introducing GNSs in PHC	Older person (5), Nurses (5), Nurse leaders (5), Physician (5), Politicians (5)	PHC	1.GNSs (NPs) 2. Master's degree in advanced geriatric nursing 3. Care needs of the comorbid older patients. Focus on assessment (medical conditions, social and psychological factors, laboratory tests). Linking role

Gysin, 2019	Switzerland	QS	To explore APNs and GPs views on introducing the APN role to Swiss primary care	APNs (9), GPs (4)	Primary care	1.APNs 3.Focus on patients and their daily life, advanced care planning, technical patient care, coordination with the social sector.

Parfitt, 2007	Tajikistan	QS	To evaluate the progress of the implementation of Family Health Nursing as part of Tajikistan's health service reforms.	FHNs interviewed (18), families, FPs (9).	PHC (five rural sites).	1. FHNs. 2. Graduate certificate in Family Health Nurse (4 years curriculum) 3.One year after implementation. Implementation of FHNs was very variable across the five sites: some FNHs reported that there wasn't any real change to their role or responsibilities, others referred that they spent more time on community activities and worked in more independent ways. Five year after implementation. FHNs primary task was carried out a risk assessment for local families and drew up a plan of primary intervention (e.g. health promotion, delivering treatment or making direct referrals), in consultation or independently with the FP. FHNs were being seen as the community's first point of contact with the health system.

Lovink, 2018	The Netherlands	QS	To describe how skill mix change is organised in daily practice, what influences it and what the effects are of introducing NPs, PAs or RNs into primary healthcare for older people.	GPs (9), NPs (10), PAs (5), RNs (10).	PHC (including general practice care and community care)	1. NPs, PAs and RNs (district nurses) 2. NPs and PAs had EQF 7, RNs had EQF level 4,5 or 6. 3. NPs performed general consultations and medical care for patients from all ages (medical anamnesis, physical examination, prescription of medication, psychosocial support, referral to other discipline). RNs provided nursing care to patients with chronic diseases (nursing anamnesis,nursing procedures, psychosocial support.health education and monitoring)

						NPs and RNs performed proactive healthcare for older people (preventive home visit, screening on frailty, organisation of multidisciplinary meetings).
Van der Biezen, 2017	The Netherlands	QS	To provide insight into factors influencing the decision of GPs and managers to train and employ a PA/NP within their organisation.	GPs (32), managers (7)	Primary Care	1.NPs 2.Master's programme 3. GPs expressed different views as to whether NPs should treat chronic patients, acute problems, palliative care, gynaecologic complaints and care for elderly or young children. NPs treat minor ailments (e.g. dermatology, ear nose and throat complaints) provide social home visits and postoperative consultations. Focus on direct patient care first. Indirect tasks (meetings with other primary care professionals, coordination of elderly care, developing protocols and training support staff) were likely to be considered when NP would be more experienced.

Carr, 2002	England (UK)	CSS	To investigate GPs perceptions of the NP role in one NHS region.	GPs (225)	Primary Care	1.NPs 3.Activities that potentially should be carried out with/without protocols: diagnosis of disease in adults, health promotion, triage, prescribing, treatment, minor illness and chronic disease management. Reservations about the treatment of children.
Carr 2005	England (UK)	QS	To explore the development of public health nursing in a PCT that focused around the evaluation of a newly introduced PHN role.	HVs/PHNs and stakeholder (e.g. medical consultant, social worker, PCT Director of nursing)	Primary Care (PCT)	1.PHNs 3. Public health activity.

Crawford, 2001	England (UK)	CSS	To explore the impact of placing CMHNs full-time within primary care practices.	Primary care personnel (including reception and administration staff, GPs, nurses and health visitors)(38)	Primary care practices	1. CMHNs 3.Role perceived: liaising with the PHC team, counselling and general support. CMHNs offer clinical assessment and care, crisis intervention, psychological interventions and support, medication management and follow up.
Drennan, 2011	England (UK)	MMS	To examine the factors affecting the extent to which English policy on the introduction of CMs for people with chronic conditions was implemented.	Directors of Nursing (41), stakeholders (e.g. managers of CMs, patient rapresentatives, GPs) (30)	Primary Care (PCTs)	1.CMs 3.nurse case manager role to support people with multiple long-term conditions: assessment of physical, mental and social care needs; review medication and prescribe medicines; clinical care and health-promoting interventions; coordination; patient and caregiver education.
Drennan, 2019	England (UK)	QS	This study investigated the factors influencing workforce development of the district nurse service in metropolitan areas.	Senior nurses in provider organizations (6), CCG senior nurses (8)	Metropolitan areas	1.RNs 3. nurses provided services to housebound adults.
Kipping, 1998	England (UK)	MMS	To explore MHNs expectations and experiences of working in the community.	MHNs (survey: 447; interviews: 12)	Community (community mental health centre, residential homes, group homes and hostels and crisi teams	1. MHNs
MacDonald, 2005	England (UK)	QS	To establish whether or not community nurse practitioners were able to achieve a 'higher level of practice', as	Community NPs (22) & Clinical Managers (GPs, Senior Community Nurse, Community Nurse Managers,	Community	1.Community NPs 2.Most participants had completed the RCN Nurse Practitioner diploma, or the BSc Honours Health Studies(Primary Health Care)

			articulated by the United Kingdom Central Council	Community Managers) (17)		RCN degree. Four participants were completing the franchised RCN degree course. 3.Working in GP practices, homeless services, minor treatment centres. NPs who achieved a 'higher level of practice"/ 'intermediate stage' held consultations with patients with 'undifferentiated diagnoses' and a wide variety of acute, minor and chronic illnesses. NPs worked with 'GP overlap' were the first points of contact and were able to undertake physical examination. NPs working with 'restricted practice'; attending to patients who had had their illness previously diagnosed by the GP (minor illness:women's health problems and chronic disease such as asthma and diabetes). Informal teaching role.
Main, 2007	England (UK)	QS	To explore how health professionals perceive the current and potential role of nurse practitioners in primary care.	Organisations with different models of PC delivery (5): NPs, GPs, PNs & managers (21)	Primary Care (PCT)	1.NPs 2.ANP is 'a RN who has undertaken a specific course of study of at least first-degree (honours) level.'MSc (n=1), BSc (n=1), diploma (n=2), completing a qualification (n=4). 3.Prescribing is not part of the NP qualification.
Perry, 2005	England (UK)	QS	To explore the role of a nurse practitioner in primary care, particularly whether the provision of a nurse practitioner facilitated access to care that met the needs of patients.	PHCT (10) (nursing staff, GPs, practice manager, reception staff); patients (14)	Primary care	1. NPs 2.NP had undertaken an accredited nurse practitioner master's degree 3. Increased access to services,in terms of meeting patients needs (e.g. address social and economic needs), and number of appointments, continuing throughout the day.

Plews, 2000	England (UK)	QS	To examine the understanding and practice of public health nursing throughout the Region and identify both the constraints and opportunities that might help develop public health nursing.	Health Authorities (10), Acute Trusts (18), Community Trusts(18)**	Community	1.PHNs (HV and School nurses) 3.PHNs worked in alliance with other agencies to develop a collaborative approach to health based on needs assessment and health promotion activities.
Price, 2003	England (UK)	QS	To explore other NPs' roles in referral with the purpose of clarifying the issues and stimulating debate.	Consultants in the local general hospital (6), PCNPs (7); GP registrars (10); lecturers in a NP programm (2)	Primary care and secondary care	1.NPs 2. RCN Nurse Practitioner Diploma, or a Bachelors Degree in Nursing (NP pathway) 3. The gatekeeper role. Collaborative relationship with a GP.
Rapport, 1997	Britain (UK)	QS	To explore the responses of primary health care professionals and their patients to changes taking place within the community.	Participants (43): district nursing team leaders and members, district nursing officers, GPs, a fundholding practice manager, social workers, a social work manager, the chairmen and directors of private nursing homes, and patients.	Community	1. DNs 3. DNs are involved in a variety of direct and indirect patient care activities (patient referral and assessment, continuing of care and assessment for aids and equipment). Collaboration with other professionals.
Wilson, 2002	England (UK)	QS	To explore the views of British GPs regarding their attitudes toward developing an APN role in general practice.	GPs (25)	Primary care (medical practices)	1.NPs

Athey, 2016	USA	CSS	To examine factors that predict NP job satisfaction	NPs (8,311)	Primary Care (ambulatory clinics,hospital	1. NPs 2.Less than master's (5.9%), Master's degree (89.5%), Doctorate (4.6%)

					and other settings)	3.Collaborative relationships with physicians. Majority of NPs reported that their skills were being fully utilized. NPs who worked in ambulatory care settings reported more autonomy than those in hospitals.
Conger, 2008	USA	QS	To examine rural connectedness versus disconnectedness.	Nursing master's graduate (RHS, clinical specialist with a rural focus and FNPs)(30)	Primary Care (rural areas)	1.APNs 2.Masters degree.
Donelan, 2013	USA	CSS	To survey the role of nurse practitioners in PC and the likely effects on the health care system of expanding the supply of NP and the scope of their practice.	NPs (467), Primary care physicians (505)	Primary Care	1.PCNPs (NPs) 2.Licensed clinicians who had been trained in a primary care specialty, were actively working in primary care practice, and were providing direct patient care. 3.74.9% NPs believed they were currently able to practice "to the full extent of their education and training.Collaborative practice. Provide most primary care services with physicians. 28.3% physicians agreed NPs provide care for complex patients (multi-morbidity/ not well controlled).
Faraz, 2017 Faraz, 2019	USA	CSS	To identify factors associated with a successful transition and turnover intention of novice NPs in the PC workforce.	NPs(177)	Primary care	1.NPs 2.141 NPs held a master's degree in nursing. NP program type: Traditional master (102); Accelerated master (32); BSN master (29) DNP (9) Other (7)
Fletcher, 2007 Fletcher, 2011	USA	CSS	To compare the quality of care provided by NPs and physicians (MDs) for patients with hypertension and/ or diabetes within the VA health care system; and to assess	NPs (74), Physicians (79)	Primary Care	1.NPs 3. NPs reported working in a variety of roles with varying responsibility and independence (clinical, administrative, managing chronic/ acute patients, conducting assessments, planning care, adding/ changing medications.

			differences in perceptions, if any, between NPs and physicians regarding the role and scope of practice of NPs within the VA health care system.			Assisting/ collaborating with physicians.). Activities (reported by physicians): patient education, take history, medication review and evaluation, care for simple cases, administrative/managerial role.
Hansen-Turton, 2013	USA	CSS	Report the results of a recent assessment of the credentialing and reimbursement practices of the largest MCOs in the United States.	Representatives from HMOs (258)	Primary Care	1.NPs
Jarrell, 2016	USA	CSS	To assess the professional development and mentorship needs of the NPs as a first step toward development of effective programs to meet needs.	NPs (198):113 are nurses practicing in primary care	Primary care	1. NPs 2. 33 had a doctorate of nursing practice or other doctoral degree, and 165 had master's degrees
Kraus, 2017	USA	QS	To provide a rich descriptive understanding of how doctors and NPs feel about NP practice in primary care, particularly their independent practice, and why.	Physicians (15), NPs (15)	Primary care (private and academic practices)	1. NPs 2. PhDs (n=2), DNPs (n=2),enrolled in DNP programs (n=2); all others held a master's degree or graduate-level certificate.
Poghosyan, 2013	USA	QS	To describe NP roles and responsibilities as PCPs in Massachusetts and their perceptions about the barriers and facilitators of their SOP.	PCNPs (23)	Primary Care (community health centre, private physician practices, ambulatory, and hospital-affiliated	1.NPs (PCNPs) 2.Masters degree 3.NPs provide comprehensive primary care (e.g. preventative, episodic and chronic care).NPs have an holistic approach to patients (e.g. family dynamics).Some NPs have specialized and see patients with specific conditions. NPs have prescriptive authority.

					outpatient clinics).	
Poghosyan, 2017	USA	CSS	Examine and compare the NP patient panel, job satisfaction, turnover intentions, and organizational structures of NPs with less than three (newly hired) and more than three (experienced) years of experience in their current job.	NPs (278)	Primary Care (urban rural and suburban) (community health centre, private physician office, and hospital-affiliated outpatient clinics)	1.NPs (newly hired and experienced) 2. Master's degree/post-master's certificate (203) and Doctor of Nursing Practice (18)
Weiland, 2015	USA	QS	To elicit an understanding of the meaning of autonomy as interpreted by NPs through the lived experiences of everyday practice	NPs (9)	Primary care	1. NPs 2.Master's NP (8); DNP (1). Advanced practice certification: Family NP (7); Adult NP (1); Pediatric NP (1) 3.Autonomy for patient care (restricted in Oklahoma – require physician supervision for prescription)

* We only used data from Canada, because the practice setting of APN development and implementation was the community. In contrast, a majority of participants from Spain were employed in hospital settings.

** We only used data from nurses worked in Community Trust.

Legend: APN-Advanced Nurse Practitioner; BSN- Bachelor of Science in Nursing; CCG- Clinical Commissioning Group; CM-Community Matron; CMHN-Community Mental Health Nurse; CRGN-Community Registered General Nurse; CSS-Cross Sectional Study; DN-District Nurse; DNP-Doctorate in Nursing Programme/ Doctor in Nursing Practice; DHB-District Health Board; FHN-Family Health Nurse; FNP-Family Nurse Practitioner; FP-Family Physician; GNS-Geriatric Nurse Practitioner; GP-General Practitioner; HCP-Health Care Professional; HPN-Health Plan Nurse; LL-Local town/administration/healthcare leader; MCO-Managed Care Organization; MHN-Mental Health Nurse; MMS-Mixed Methods Study; NDHB-Northland District Health Board; NHS-National Health Service; NP-Nurse Practitioner; PA-Physician Assistants; PCNP-Primary Care Nurse Practitioner; PCT-Primary Care Trust; PCP-Primary Care Provider; PHC-Primary Health Care; PHCT-Primary Healthcare Team; PHCNP- Primary Healthcare Nurse Practitioner; PHN-Public Health Nurse; PHO-Primary Health Organization; PHU-Public Health Unit; PN-Practice Nurse; QD-Quantitative design; QS-Qualitative Study; RHN-Rural Health Specialists; RN-Registered Nurse; SOP-Scope of Practice; VA-Veterans Affairs

Additional file 5

Facilitators and barriers identified by the studies mapped on to their corresponding CFIR domains and constructs

Construct	Domain	Facilitator [reference number]	Barrier [reference number]
1. Intervention Characteristic			
	A. Intervention source		
	B. Evidence strength & Quality		
	C. Relative advantage	“Nurse full scope of practice”(1–6) “professional autonomy also related to work settings”(2,7–10) “linking role between patients and health care professionals” (3,11)“task-shifting”(3,12,13) “NPs credentialed as primary care providers”(14)	“restrictions of nurse scope of practice”(4,5,21–25,8,12,15–20) “formal collaborative practice agreement”“physician supervision, when the doctor-nurse relationship was legislated ”(16,26,27)
	D. Adapability	“adapting the nurse’s role to existing context”(25)	
	E. Trialability	“trying out the new model in small-scale projects”(29)	
	F. Complexity		"calculating staffing ratios"(30)”caseload numbers and composition”(6,7,9,31) “nurses don’t have enough time for patients’ visits or other tasks part of their role due to the heavy caseloads”(7,10,32)“the increase in administrative duties”(31)

G. Design quality & packaging	"completion of previous RN portfolio as a part of professional recognition"(1) "job description"(23) *education and training* "motivate nurses to study"(33)"master's degree program in advanced nursing"(1,3,29) "re-training program to equip already-qualified nurses"(13) "residency or fellowship program after graduation"(7) "maintaining specifical technical skills"(34)	"nurses lack of competence and skills"(6,19,33,35,36)" *education and training* "academic education not adapted to clinical need"(23) "the preparedness level of the faculties in teaching an advanced level of PHC or community health"(37) "lack of ongoing education specific to NPs needs"(38) *obstacle to training* "inability to attend training/ ongoing education (39) due to the distance (rural nurses)(9) the heavy caseloads(17) the lack of funding(1,34,40)""Inconsistent information available for the planning and completion of educational programme (Master), and difficulties negotiating time"(1)
H. Cost	"contractual agreement with physicians in order to work around reimbursement barriers"(16)"independent APN tariff, official legitimization to use the TARMED"(29)	"GPs funding mechanism"(15,17,27,41,42)"GPs lack of financial remuneration provided for training and employing NPs" (21) "under-resourced health system: decline in funds for public services"(13) "Poor availability of funds to cover NP services and positions"(24,39,43) "financial uncertainties"(44) "no clear regulation provided for billing for nurses services"(29)

2. Outer setting			
	A. Patient needs & Resources	"Patients satisfaction"(21,36,38,39,45) *benefits and advantages for patients* "nurses were able to meet the needs of patients because they see patients in their environment(6,13,31), they know client's networks(9),they are accessible through telephone dedicated line and flexible in scheduling appointments(6) and service delivery(11,39), they are good listeners and trustworthy(46) and they devise a service that is contextual (solution and proposal was adapted to meet the needs and fit the resources within the local community)" (12)"nurse have time for the patient"(29,33,39,46,47) "NP asked more questions and explained things in more detail than GPs "(45) *acceptability* "patient acceptance for nurses providing PHC(13,22,24,37,43,47) "nurse role recognition (48)"nurse connection to the rural community"(39) "NP-client interactions and role clarity are an important step in gaining acceptance"(49)	*acceptability* "patients lack of knowledge and understanding of the NP role (22,23,42,47,50)" "Confusion around understandings of how a NP differed from others type of nurses and GP"(22,46) "lack of clarity regarding reasons and circumstances to consult a NP rather than a GP"(46) "patients lack of willingness to be seen by a NP for conditions they perceive serious or complex" (46,47) "patients prior bad experience"(47) "patients opposition"(23)"appropriate training was a major concern in terms of acceptability of the nurse role"(46)
	B. Cosmopolitanism		

	C. Peer pressure		
	D. External policies & incentives		"lack of formal/status recognition of the nurse role in advanced level practice"(9)"political uncertainties (regarding legislation and scope of practice)"(44)"lack of a professional register (non-recognition of the NP role by the NMC)"(40) "health care reforms"(18)"fee-for-services system"(22)
3. Inner setting			
	A. Structural characteristics	"nurses and doctors were a part of the same organization"(33) "nurses and other health professionals working in the same environment"(51) *challenges for workforce development (nursing services)* "changing patient case-mix"(34,42) "shortage of primary care providers"(1,39) "patient demand for PHC services"(37) "new job opportunities and opportunities for career development"(10)	"lack of long-term organisation and workforce planning" (44) short-term service contracts"(34) "uncertainty about professional future"(18) "uncertainty about employment opportunities as an NP"(1,3) "recruiting suitably qualified nurses(3,33,36) and retaining them(34)" "high staff turnover and high use of agency staff"(34) "intention to leave"(34,50) "any career opportunities"(33) "lack of remuneration of nurse's overtime hours"(18,23)
	B. Networks & Communications	"nurses connection on national level facilitated sharing nursing practices"(32) "journal club with other health professionals"(52) "public awareness campaign was mentioned as a strategy for increasing public recognition"(48)	"environmental factors: poor internet connection, isolation, lack of electricity to run equipment" (52) "limited access to immediate collegial support (geographical isolation and lack of available services)"(9,10)

		"regular and effective communication(11,23,39,42) preferably use the same (electronic) patient records(42)" "support networks to get patient discharge information from the regional hospital"(52) "Communication strategies and equipment: one call'system to connect the rural provider with a specialist, e-mail, telemedicine equipment"(52) "informal team-sharing of client information and formal case-reviews"(48)	"lack or poor relations with administration and physician"(26,50,52) "lack of shared understanding of the conditions and patients' needs that impact on the ability to provide care"(31,32,35)
	C. Culture		"hierarchical structure"(3,13,22) "practice focused on individual basis" (28) "biomedical/treatment model"(30,37,40,49) "giving primacy to medical solutions rather than person centred care"(12)"Health Authorities worked on a medical model of health care"(41)
	D. Implementation climate	*interprofessional relationship and collaboration* "interdisciplinary collaboration"(2,6,12,22,30,42)"development of interprofessional teams"(12,27,30,38,41) "intersectoral collaboration and working"(41) "collaborative working(8,9,23,52) and interaction/relations(39)" "support from GPs (8,22,24,26), pharmacists and specialists in a particular area (52), managers and	*interprofessional relationship and collaboration* "interprofessional competition"(23,42) "lack of regulations of the NP role" (38) "lack of clear boundaries for the NPs' and RNs' areas of responsibility"(42,51)"lack of a vision in organizations on the NPs' role"(42) "lack of collaboration between different services and between health care professionals"(3) "lack

		Directors of Nursing"(1,3,4) and colleagues"(32)"availability of mentoring (colleague or GP)"(1,7,15,27,38,42,52) "trusting relationship with physicians and others"(4,16,23,29,42,49) *organizational incentives* "NPs were reimbursement at the rate of PCPs (HMO)"(14) *goal and feedback* "leadership and vision of how the care model should be developed"(23) *compatibility* "clarify what kind of tasks a nurse should have compared with other roles"(33) "clear role and responsibility distinction for current nursing service"(37)	of acceptance of local secondary care services or departments of nurse's referral"(4,22,27,38,42,45,53)" consultant accepting NPs referrals did not communicate with NPs directly, the letter was addressed to the patient's GP"(38) "lack of collegial and administrative support"(1,7,15,41,52) "administrators do not treat NPs and physicians equally or share information equally"(50) "lack of support, on-site visits by managers and more informal communication can lead a feeling to of being cut-off"(10)"NPs did not receive the same level of support as physicians did to deliver the same services"(16,26) "physicians have better access then NPs to organizational resources"(26) "lack of respect from other clinicians, support and administrative staff"(7) "physicians do not treat NPs as equal colleagues"(50) "nurses low visibility"(26,50,51) "professional isolation"(4,7,9,10,39,40,52) *goal and feedback* "lack of clear objectives/goals for nurse's role development and success within the clinical setting or working environment"(7,9)

			compatibility "lack of recognition of the nurse role by others (3) resulting in either a duplication of services or reduced access to potential nursing services"(6)"Perceptions that the nurse role duplicates that of other professionals"(23,36) *organizational incentives-contractual context* "low wage as compared with other colleagues, lack of bonuses or raises in salary"(7,34)"NPs felt underpaid and undervalued by health care organization"(7,18)
	E. Readiness for implementation	*access to knowledge and information* "NP access to PHU programs for their clients"(4)	*available resources* "lack of resources"(3,11,23,35)"lack of appropriate patient-care equipment and infrastructure"(13,23,26,27,31) "lack of tools to understand the resource demand and manage staff allocation"(34) "electronic health records and billing codes did not adequately reflect NP practice"(48) "electronic patients records and computer operation are not ready to integrate APNs practice"(23) "under investment in information technology"(34)
4. Individual characteristics			

	A. Knowledge & beliefs about intervention	"health care providers education about the NP role"(24) "role clarity is an important step in gaining acceptance of collegial partners"(49) *from GP's perspective – facilitators to employ nurse's role* "GPs support among the staff and the collaboration with another practice"(44)"GPs previous experience of doctor-nurse collaboration"(1,24,38,44) *from GP's perspective – reason to employ* "NPs view is complementary to the medical view of the GPs"(44,53) "NP would enhance the delivery and quality of healthcare(42,43) improving access to care (5) and increasing the total number of appointment available"(45) *from GP's perspective – changing role of GP* "more coordinating role to handle complex cases (19,42) and expand their practice(43)""reduction of doctor's workload"(21,29,33,42) *acceptability* "primary care personnel satisfaction with NPs (8,19,39) or CMHN in their practice(11)""GPs recognized the added value of APNs/NPs in primary care"(8,29,42) "Physicians acceptance of the NPs role(20) and	*acceptability* "GPs' confusion regarding the NP's scope of practice and professional role boundaries"(43)"confusion regarding job titles"(54) "lack of a common understanding of the role"(1,4,29,39–41,50,55,6,7,13,15,19,20,22,26)"lack of knowledge regarding education and/or scope of practice"(3,5,7,11,19,21,25,27,44) "stakeholders skepticism"(25,36) "poor GPs' and other nurses' acceptance of NPs"(43)"resistance and opposition by GPs"(23,24,42) "GPs reticence: there was no demonstration or evidence of a need to employ NPs to meet any major deficit in service provision(21)" "GPs concern about workload, competition, fragmentation and duplication of services"(43,44) "GPs perceived a threat from NP role"(40) "physicians lack of confidence or trust in the nurses' capabilities/competencies (3,13,17,19,20,40,43,50) "GPs perception that NPs were used as a cheap option by the Government"(43) "reluctance to consider NPs as an alternative workforce to GPs"(1)

		the new model of partnership working(13)" *From nurse's perspective* "Nurses perceived their work as being valuable and worthwhile because it is "different from" what other health professional provide(6), they had something additional to offer to patients(38)" "Nurses felt that they help provide better care and increase patient safety and satisfaction"(8,10,12,22,29,33,44,48) "Nurses perceptions that their work make a difference in clients' health practices or health status"(1,6,12)	
	B. Self-efficacy	*self confidence* "Nurses were moderately confident in their skills"(55)"awareness of own limits"(8,29) *prior work experience* "nurse level of expertise, experience(3,8)" *sense of meaning* "Nurses felt a great sense of meaning for their work"(7,55)	*self confidence* "self-doubt"(15,20)"nurses underestimated their competence"(51)"colleagues did not utilize NP as a resource"(49).
	C. Individual stage of change		"opposition from own nursing profession"(23) "nurses' unwillingness in taking on the increased responsibility inherent in the role."(40)

	D. Individual identification with organization		
	E. Personal attributes	"personality and philosophy of the physicians"(4) "nurse personal suitability to community work"(10)"nurse attribute: non-judgmental, honest, non-threatening."(6)	"personality and philosophy of the physicians"(4)
5. Process			
	A. Planning	"project illustrating the potential of the nurse role"(23) "well planned integration, definition of roles and functions and involvement of the whole team"(23) "review nurse service"(36,41) "appropriate workforce planning and training to replace (refer to demographic profile of nurses)"(34)	"lack of clarity or direction about reconfiguration of the role"(28)"uncertainty of role (as new services were adapted to meet changing needs"(10)
	B. Engaging	"strategic commitment to NP development from employing organization (beginning from support to undertake postgraduate study through to employment as an NP)"(1) "strategic alliance between NP and HA to role development and integration"(49)(48)"mentorship by policy leaders as a way to increase NPs leadership capacity"(48,49) "NP involvement in developing their role"(4) "nursing staff involvement in the	"lack of leadership to guide the change"(32)"lack of nursing leadership"(1) "lack of engagement between Director of Nursing, of District Health Boards and PHC nurses"(1) "lack of NPs' representation in important committees"(50) "lack of nurse involvement in the organizations"(26,41)

		drafting of job description”(54) “GPs engagement to help develop a new model in primary care”(29) *external change agents* “social service involvement”(11) Universities as driving force in supporting APN implementation role”(37)	
	C. Executing	"support nursing staff in their professional development based on evidence-based practice"(3)“mentorship program”(56) “team building programs to team progression during the early stages of development”(30) “team building strategies”(48,51) “ negotiation of the nurse’s role and autonomy”(23,38,53)	“project implementation from top-down and lack of information”(23)“slow implementation process”(23) “nurses felt difficult to identify any real change to their role or responsibilities”(13)
	D. Reflecting & evaluating	“nurses’ need to evaluate their effectiveness”(6)“mechanism by which NPs subjected their practice to scrutiny: meetings with other nurses and NPs, contribution to the teaching of undergraduate NPs, research and audit, personal reflection on practice”(38)	“difficulties in identifying outcomes to measure, given the nature of nurses work (immediate outcomes may be less tangible, while more objective outcomes in terms of illness prevention tend to be long-term)”(6)“lack of tools and resources to track and measure NP contributions: i.e. billing code used to track clinical services did not fully capture the holistic care provided to clients and community”(48) “lack of knowledge about outcome measures”(41) “The audit process

		was restricted to a few areas of activity”(41)”
		“lack of NPs performance feedback”(50)

Legend: APN-Advanced Nurse Practitioner; CMHN-Community Mental Health Nurse; GP-General Practitioner; HA-Health Authority; NMC-Nursing and Midwifery Council; NP-Nurse Practitioner; PCP-Primary Care Provider; PHC-Primary Health Care; PHU-Public Health Unit; RN-Registered Nurse.

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Additional file 6

Questionnaire

La persona che risponde all'intervista è:					
☐1- Il soggetto campionato					
☐2- Il Proxy---> vai al punto 1.19 e continua dalla SEZIONE 3					
SEZIONE 1: QUALITA' DELLA VITA E STATO DI SALUTE					
1.1	In generale, direbbe che la sua salute è:				
	☐1-Eccellente		☐4-Passabile		☐88-Non so
	☐2-Molto Buona		☐5-Scadente		☐99-NR
	☐3-Buona				
Le seguenti domande riguardano alcune attività che potrebbe svolgere nel corso di una qualsiasi giornata. La sua salute la limita attualmente nello svolgimento di queste attività?					
1.2	**Attività di moderato impegno fisico**, come spostare un tavolo, usare l'aspirapolvere, giocare a bocce o fare un giretto in bicicletta				
	☐1- Si, mi limita parecchio	☐2 -Si, mi limita parzialmente	☐3-No, non mi limita per nulla	☐88-Non so	☐99-NR
1.3	Salire per **qualche** piano di scale				
	☐1- Si, mi limita parecchio	☐2 -Si, mi limita parzialmente	☐3-No, non mi limita per nulla	☐88-Non so	☐99-NR
Se il soggetto campionato ha un età < 65 anni, non eseguire il test della memoria e salta direttamente al punto 1.10 Se risponde l'anziano ≥65 anni : segue il test della memoria. Pronuncia le tre parole del test lentamente e scandendole bene.					
TEST DELLA MEMORIA					
Adesso le farò un breve test che riguarda la memoria. Le dirò tre parole. Quando le avrò dette tutte e tre, le ripeterà lei. Le tenga a mente, perché tra qualche minuto le chiederò di ripeterle. Le tre parole sono:					
	casa		verde		Pane
	Per favore può ripeterle?				
Non ha importanza l'ordine con il quale l'anziano ripete le parole. Se non è in grado di ricordare tutte e tre le parole al primo tentativo, rileggile fino ad un massimo di sei volte. Se non è in grado di ripeterle dopo sei tentativi, passa alla domanda succesiva.					
1.4	L'anziano è riuscito a ripetere le 3 parole?			☐1-Si	☐2-No
Barrare le caselle senza dire all'intervistato se la risposta è corretta o errata. Ogni risposta corretta vale un punto.					
1.5	Per favore, può dirmi in che anno siamo?			☐Corretta	☐Errata
1.6	E in che mese dell'anno siamo?			☐Corretta	☐Errata
1.7	E quale giorno della settimana è oggi?			☐Corretta	☐Errata
1.8	Grazie, ora può per favore dirmi di uovo le tre parole che le ho detto prima?				
	Casa			☐Corretta	☐Errata
	Verde			☐Corretta	☐Errata
	Pane			☐Corretta	☐Errata

Fai la somma delle risposte corrette e trascrivi il punteggio nella casella accanto

Se il punteggio > 3--->Continua l'intervista andando al punto 1.9

Se il punteggio ≤3--->Chiedi all'anziano se è solo in casa e se è possibile parlare con il proxy.

--->se solo in casa e proxy non disponibile: prova a fissare un appuntamento con il proxy

--->se NON è solo in casa: chiedi all'anziano se è possibile parlare con il proxy: " A questo punto, se lei è d'accordo, avremo bisogno della collaborazione del suo famigliare o della persona che le sta vicino, per rivolgergli alcune domande sulla sua salute.

--->Se il proxy è disponibile a parlare vai al punto 1.9 al punto, al punto 1.19 e continua dalla SEZIONE 3

--->Se il proxy non è disponibile a fare l'intervista concorda un altro appuntamento

1.9	La persona che risponde da qui in poi all'intervista è:				
	☐1-Il soggetto campionato				
	☐2-Il proxy				
	☐3-L'anziano campionato ma solo per la SEZIONE 7				
Nelle ultime 4 settimane ha riscontrato i seguenti problemi sul lavoro o nelle altre attività quotidiane, a causa della sua salute fisica?					
1.10	Ha **reso** meno di quanto avrebbe voluto				
	☐1-Si	☐2-No		☐88-Non so	☐99-NR
1.11	Ha dovuto limitare alcuni **tipi** di lavoro o di altre attività				
	☐1-Si	☐2-No		☐88-Non so	☐99-NR
Nelle ultime 4 settimane ha riscontrato i seguenti problemi sul lavoro o nelle altre attività quotidiane, a causa del suo stato emotivo?					
1.12	Ha **reso** meno di quanto avrebbe voluto				
	☐1-Si	☐2-No		☐88-Non so	☐99-NR
1.13	Ha avuto un calo di **concentrazione** sul lavoro o in altre attività				
	☐1-Si	☐2-No		☐88-Non so	☐99-NR
1.14	Nelle ultime 4 settimane in che misura il dolore l'ha ostacolata nel lavoro che svolge abitualmente (sia in casa sia fuori casa)?				
	☐1-Per nulla		☐4-Molto		☐88-Non so
	☐2-Molto poco		☐5-Moltissimo		☐99-NR
	☐3-Un pò				
Le seguenti domande si riferiscono a come si è sentito nelle ultime 4 settimane. Risponda a ciascuna domanda scegliendo la risposta che più si avvicina al Suo caso. Per quanto tempo nelle ultime 4 settimane si è sentito…					
1.15	Calmo e sereno?				
	☐1-Sempre		☐4-Una parte del tempo		☐88-Non so
	☐2-Quasi sempre		☐5-Quasi mai		☐99-NR
	☐3-Molto tempo		☐6-Mai		
1.16	Pieno di energia?				
	☐1-Sempre		☐4-Una parte del tempo		☐88-Non so
	☐2-Quasi sempre		☐5-Quasi mai		☐99-NR
	☐3-Molto tempo		☐6-Mai		
1.17	Scoraggiato e triste?				
	☐1-Sempre		☐4-Una parte del tempo		☐88-Non so
	☐2-Quasi sempre		☐5-Quasi mai		☐99-NR
	☐3-Molto tempo		☐6-Mai		
1.18	Nelle ultime 4 settimane per quanto tempo la sua salute fisica e il suo stato emotivo hanno interferito nelle sue attività sociali, in famiglia, con gli amici?				
	☐1-Sempre		☐4-Una parte del tempo		☐88-Non so
	☐2-Quasi sempre		☐5-Quasi mai		☐99-NR
	☐3-Molto tempo				

Se risponde i proxy leggere le domande facendo riferimento all'anziano. Es: "Vorrei rivolgerle alcune domande molto semplici che si riferiscono alle attività di tutti i giorni del Signor…"

1.19	Un medico le ha mai diagnosticato o confermato una o più delle seguenti malattie?				
		1-Si	2-No	88-Non so	99-NR
	Insufficienza renale	☐	☐	☐	☐
	Bronchite cronica, enfisema, insufficienza respiratoria, asma bronchiale	☐	☐	☐	☐
	Ictus o Ischemia cerebrale	☐	☐	☐	☐
	Ipertensione	☐	☐	☐	☐
	Diabete	☐	☐	☐	☐
	Infarto del miocardio, ischemia cardiaca o malattia delle coronarie	☐	☐	☐	☐
	Altre malattie del cuore	☐	☐	☐	☐
	Tumori	☐	☐	☐	☐
	Malattie croniche del fegato, cirrosi	☐	☐	☐	☐

Se il soggetto campionato presenta una o più delle seguenti malattie:---> vai al punto 2.1
Se il soggetto campionato NON presenta una o più delle seguenti malattie: --->continua dalla SEZIONE 3

SEZIONE 2: SELF CARE E ASSISTENZA

Per rispondere alle seguenti domande ripensi all'ultimo mese. In una scala da 1 a 5 (dove 1 è "mai" e 5 è "sempre") quanto spesso o abitualmente mette in partica i seguenti comportamenti?

		Mai		A volte		Sempre
2.1	Assicurarsi di dormire abbastanza	☐1	☐2	☐3	☐4	☐5
2.2	Cercare di evitare di ammalarsi (es: vaccinarsi per l'influenza, lavarsi le mani)	☐1	☐2	☐3	☐4	☐5
2.3	Fare attività fisica (es: fare una camminata veloce, usare le scale)	☐1	☐2	☐3	☐4	☐5
2.4	Seguire una dieta specifica	☐1	☐2	☐3	☐4	☐5
2.5	Vedere il suo medico per l'assistenza abituale	☐1	☐2	☐3	☐4	☐5
2.6	Prendere i farmaci prescritti senza saltare una dose	☐1	☐2	☐3	☐4	☐5
2.7	Evitare sigarette e fumo di tabacco	☐1	☐2	☐3	☐4	☐5
2.8	Evitare o gestire lo stress	☐1	☐2	☐3	☐4	☐5
2.9	Monitorare le sue condizioni	☐1	☐2	☐3	☐4	☐5
2.10	Prestare attenzione ai cambiamenti di come si sente	☐1	☐2	☐3	☐4	☐5
2.11	Controllare se ha effetti collaterali dei farmaci	☐1	☐2	☐3	☐4	☐5
2.12	Controllare se si stanca più del solito nel fare le normali attività	☐1	☐2	☐3	☐4	☐5
2.13	Controllare se ha dei sintomi	☐1	☐2	☐3	☐4	☐5
2.14	Nel mese passato, ha avuto sintomi?					
	☐1-Si	☐0-No		☐88-Non so		☐99-NR

Se ha avuto sintomi nel mese passato:---> prosegui al punto 2.15
Se NON ha avuto sintomi nel mese passato e ha un età ≥65 anni : --->vai alla SEZIONE 3
Se NON ha avuto sintomi nel mese passato e ha un età < 65 anni:---> vai alla SEZIONE 5

2.15	Quanto velocemente lo ha riconosciuto come un sintomo della sua malattia in una scala da 1 a 5 (dove 0 "non l'ho riconosciuto" e 5 "l'ho riconosciuto molto velocemente")?					
	☐0	☐1	☐2	☐3	☐4	☐5

Di seguito sono elencati i comportamenti che le persone con malattie croniche usano per controllare i loro sintomi. Quando ha sintomi quanto è probabile in una scala da 1 a 5 (dove 1 "non è probabile" e 5 "molto probabile") che lei metta in atto uno dei seguenti comportamenti?

		Non è probabile		Abbastanza probabile		Molto probabile

2.16	Cambiare ciò che mangia o beve per far diminuire o scomparire i sintomi?	□1	□2	□3	□4	□5
2.17	Modificare il suo livello di attività (ad esempio ridurlo, riposarsi?)	□1	□2	□3	□4	□5
2.18	Prendere una medicina per far diminuire o scomparire i sintomi?	□1	□2	□3	□4	□5
2.19	Parlare al suo medico del sintomo al prossimo controllo?	□1	□2	□3	□4	□5
2.20	Chiamare il suo medico per avere dei consigli?	□1	□2	□3	□4	□5

Pensi ad un comportamento che ha attuato l'ultima volta che ha avuto dei sintomi.
Quanto è sicuro che il rimedio che ha usato l'ha fatta sentire meglio in una scala da 0 a 5 (dove 0 "non ho fatto nulla" e 5 "sono molto sicuro"

	□0 Non ho fatto nulla	□1 Non sono sicuro	□2	□3 Abbastanza sicuro	□4	□5 Molto sucuro

Se il soggetto campionato ha un età < 65 anni, salta direttamente alla SEZIONE 5
Se il soggetto campionato ha un età ≥65 anni : --->continua con la SEZIONE 3

SEZIONE 3: CADUTE

Le farò alcune domande sulle cadute. Pensi agli ultimi 30 giorni e mi dica se:

3.1	E' caduto a terra negli ultimi 30 giorni?				
	□1-Si	□2-No-->3.4		□88-Non so-->3.4	□99-NR-->3.4
3.2	Dove è avvenuta l'ultima caduta?				
	□1-Cucina		□6-Giardino		□88-Non so
	□2-Bagno		□7-Strada		□99-NR
	□3-Camera da letto		□8-Mezzo di trasporto		
	□4-Ingresso		□9-Altro		
	□5-Scale				
3.3	A causa di quest'ultima caduta è stato ricoverato per più di un giorno?				
	□1-Si	□2-No		□88-Non so	□99-NR
3.4	Attualmente ha paura di cadere?				
	□1-Si	□2-No		□88-Non so	□99-NR
3.5	Per la vasca da bagno o per la doccia, usa:				
	1-Tappetini antiscivolo	□1-Si	□2-No	□88-Non so	□99-NR
	2-Maniglioni	□1-Si	□2-No	□88-Non so	□99-NR
	3-Seggiolini	□1-Si	□2-No	□88-Non so	□99-NR
3.6	Negli ultimi 12 mesi, un medico o un altro operatore le ha dato consigli su come evitare di cadere?				
	□1-Si	□2-No		□88-Non so	□99-NR

SEZIONE 4: ATTIVITA DELLA VITA QUOTIDIANA

Ora le chiedo se abitualmente ha bisogno di aiuto o può fare da solo/a le attività che le dico.

Per le attività che di solito non vengono svolte (es: per gli uomini: fare il bucato) chiedi all'intervistato se è in grado di farle anche se non lo fa.

4.1	E' in grado di:	Da solo/ anche se con problemi	Se aiutato/a	No, non riesco a farlo	Non so	NR
	1-Usare il telefono	□	□	□	□88	□99

	2-Fare la spesa	☐	☐	☐	☐88	☐99
	3-Cucinare o riscaldare i cibi	☐	☐	☐	☐88	☐99
	4-Prendersi cura della casa	☐	☐	☐	☐88	☐99
	5-Fare il bucato	☐	☐	☐	☐88	☐99
	6-Prendere i farmaci	☐	☐	☐	☐88	☐99
	7-Pagare conti o bollette	☐	☐	☐	☐88	☐99
	8-Spostarsi fuori casa con i mezzi pubblici o la propria auto	☐	☐	☐	☐88	☐99
	9-Fare il bagno o la doccia	☐	☐	☐	☐88	☐99
	10-Vestirsi e spogliarsi	☐	☐	☐	☐88	☐99
	11-Andare in bagno per fare i propri bisogni	☐	☐	☐	☐88	☐99
	12-Spostarsi da una stanza all'altra	☐	☐	☐	☐88	☐99
	13-Alimentazione	☐	☐	☐	☐88	☐99
	E' in grado di:	Si, senza problemi	Ho occasionali episodi di incontinenza	Ho problemi continui di incontinenza e/o uso il catetere	Non so	NR
	14-Trattenere urine e feci	☐	☐	☐	☐88	☐99

Se la persona riesce a fare da sola tutte le 14 attività indicate--->vai alla SEZIONE 5

4.2	Per le attività che non è in grado di fare da solo/a, riceve aiuto da parte di:	1-Si	2-NO	88-Non so	99-NR
	1-Famigliari	☐	☐	☐	☐
	2-Conoscenti, amici	☐	☐	☐	☐
	3-Associazioni di volontariato	☐	☐	☐	☐
	4-Persona individuata e pagata in proprio (es: badante)	☐	☐	☐	☐
	5-Assistenza a domicilio da parte di operatori del servizio pubblico (es: ASL, Comune..)	☐	☐	☐	☐
	6-Assistenza presso centro diurno	☐	☐	☐	☐
	7-Contributi economici (es: assegno di cura, accompagnamento)	☐	☐	☐	☐

SEZIONE 5: ATTIVITA' SOCIALI E STILI DI VITA

Se la persona ha dichiarato di ricevere aiuto per le attività che non è in grado di fare da solo/a--->salta al punto 5.3

Ora consideri gli ultimi 12 mesi, cioè da_____(dire il mese) scorso a oggi.					
5.1	Ha accudito e aiutato persone che <u>non vivono</u> con lei come figli, fratelli/sorelle, amici, genitori?				
	☐1-Spesso		☐3-Quasi mai		☐88-Non so
	☐2-Ogni tanto		☐4-Mai		☐99-NR
5.2	Ha accudito e aiutato persone che <u>vivono</u> con lei come coniuge, figli, genitori ecc..?				
	☐1-Spesso--->5.3		☐3-Quasi mai		☐88-Non so
	☐2-Ogni tanto		☐4-Mai		☐99-NR

Se alla domanda 4.1 12-"Spostarsi da una stanza all'altra" l'anziano o il proxy HA RISPOSTO "Da solo/a anche se con problemi" , "Non so" o "NR" Dai tutte le seguenti domande (punti 5.3 – 5.4 – 5.5):

Ora le rivolgo qualche domanda sull'attività fisica che svolge nei vari momenti so svago.

5.3	<u>Negli ultimi 7 giorni</u>, quali di queste attività di svago ha svolto?	Si	No	Se si, chiedi	Quanti giorni la settimana?	In media per quanto tempo in ciascuno di questi giorni*?		88-Non so	99-NR
						Ore	minuti		

	1-Leggere, guardare la tv, fare lavoretti manuali, giocare a carte	□	□	→	__	__ __	__ __	□	□
	2-Passeggiare, portare il cane a spasso, andare in bicicletta	□	□	→	__	__ __	__ __	□	□
	3-Praticare attività fisica leggera come ginnastica dolce, bocce, ballo..	□	□	→	__	__ __	__ __	□	□
	4-Praticare attività fisica moderata come ballo ecc..	□	□	→	__	__ __	__ __	□	□
	5-Praticare attività fisica pesante come nuoto, corsa, ciclismo..	□	□	→	__	__ __	__ __	□	□
	6-Praticare ginnastica con attrezzi, flessioni	□	□	→	__	__ __	__ __	□	□

*Indicare il tempo in ore e minuti.Es: se 1 ora e mezza, indicare 01 nella colonna ore e 30 nella colonna minuti, se il tempo dedicato all'attività è mezz'ora indicare 00 nella colonna ore e 30 nella colonna minuti

5.4	Per le attività domestiche negli ultimi 7 giorni si è dedicato a:				
	1-Praticare attività domestiche leggere come spolverare, lavare i piatti	□1-Si	□2-No	□88-Non so	□99-NR
	2- Praticare attività domestiche pesanti come lavare pavimenti, spostare mobili	□1-Si	□2-No	□88-Non so	□99-NR
	3- Eseguire piccole riparazioni	□1-Si	□2-No	□88-Non so	□99-NR
	4- Eseguire lavori nell'orto come vangare o zappare	□1-Si	□2-No	□88-Non so	□99-NR
	5- Fare giardinaggio, curare i fiori	□1-Si	□2-No	□88-Non so	□99-NR
	6- Prendersi cura di una persona	□1-Si	□2-No	□88-Non so	□99-NR

5.5	Negli ultimi 12 mesi, un medico o un altro operatore le ha consigliato di fare attività fisica?				
	□1-Si	□2-No		□88-Non so	□99-NR

Ora vorrei farle alcune domande sul consumo di alcol.

5.6	Attualmente le capita di bere, anche se ogni tanto, vino, birra, amari, apertivi alcolici, o altri liquori?			
	□1-Si	□2-No--> 5.8	□88-Non so-->5.8	□99-NR-->5.8

5.7	Quanti/e	Beve in una giornata normale	Solo se beve meno di 1 bicchiere al di'	Quanti ne beve in una settimana normale?	88-Non so	99-NR
	1-Bicchieri di vino	__,__**	→	__,__**	□	□
	2-Lattine di birra	__,__**	→	__,__**	□	□
	3-Bicchierini di amaro, aperitivi o altri liquori	__,__**	→	__,__**	□	□

**E' possibile inserire anche mezzo bicchiere o mezza lattina scrivendo 0,5 nelle caselle. Se la quantità invece è per esempio pari a 1, inserisci 1,0

5.8	Negli ultimi 12 mesi, un medico o un altro operatore le ha consigliato di bere meno bevande alcoliche?				
	□1-Si	□2-No		□88-Non so	□99-NR

Ora vorrei farle alcune domande sul fumo

5.9	In tutta la sua vita, ha fumato in tutto almeno 100 sigarette cioè 5 pacchetti da 20 sigarette?			
	□1-Si	□2-No-->5.12	□88-Non so-->5.12	□99-NR-->5.12

5.10	Attualmente fuma sigarette?		
	□1-Si		□88-Non so-->5.12
	□2-Ho smesso da almeno un anno-->5.13		□99-NR-->5.12
	□3-No, ho smesso da oltre un anno-->5.13		

5.11	Se si, quante sigarette fuma in una giornata normale?				
	__ __			□88-Non so	□99-NR
5.12	Negli ultimi 12 mesi un medico o un altro operatore le ha consigliato di smettere di fumare?				
	□1-Si	□2-No		□88-Non so	□99-NR
Le faccio ora una domanda sul consumo di frutta e verdura. Consideri che per una porzione di frutta o di verdura s'intende un quantitativo di frutta o verdura cruda che può essere contenuto sul palmo di una mano, oppure mezzo piatto di verdura cotta..					
5.13	…pensi ora agli <u>ultimi 30 giorni</u>: di solito in <u>una giornata</u>, in totale quante porzioni di frutta o verdura mangia?				
	□1- Nessuna		□3-Tre o quattro		□88-Non so
	□2-Una o due		□4-Cinque o più		□99-NR
5.14	Ha perso peso negli ultimi 12 mesi?				
	□1-Si	□2-No-->5.16		□88-Non so-->5.16	□99-NR-->5.16
5.15	Quanto peso ha perso?				
	__,__ (Kg)			□88-Non so	□99-NR
5.16	Qual è il suo peso attuale?				
	__ __ __,__ (Kg)			□88-Non so	□99-NR
5.17	Qual è la sua altezza?				
	__ __ __ (cm)			□88-Non so	□99-NR
SEZIONE 7: DATI SOCIO-ANAGRAFICI					
Nel caso sia il proxy a rispondere, fai le domande in modo che sia chiaro che le informazioni richieste siano riferite all'accudito (Es: Mi può dire se il/la Signor/a (nome e cognome del soggetto campionato) è?)					
7.1	Lei è:				
	□1-Coniugato/a		□4-Vedovo/a		□88-Non so
	□2-Celibe/nubile		□5-Separato/a o Divorziato/a		□99-NR
7.2	Attualmente con chi vive?				
	□1-Da solo/a		□5-Nipoti		□88-Non so
	□2-Coniuge e/o compagno/a		□6-Nuora o genero		□99-NR
	□3-Figli		□7-Badante		
	□4-Fratelli/Sorelle		□8-Altri		
7.3	Qual è la sua cittadinanza?				
	□1-Italiana				□88-Non so
	□2-Straniera (specificare?) --->7.4				□99-NR
	□3-Doppia--->7.4				
7.4	Da quanti anni vive in Italia?				
	__ __ Anni				□88-Non so
					□99-NR
7.5	Durante gli ultimi 12 mesi cioè da_____(mese) a oggi, ha fatto un lavoro per cui è stato pagato?				
	□1-Si	□2-No-->7.7		□88-Non so-->7.7	□99-NR-->7.7
7.6	Attualmente ha un'occupazione lavorativa?				
	□1-Si	□2-No		□88-Non so	□99-NR
7.7	Lei riceve una pensione(tutti i tipi di pensione, anzianità o reversibilità?				
	□1-Si	□2-No		□88-Non so	□99-NR
7.8	Che titolo di studio ha?				
	□1-Nessuno		□4-Superiori		□88-Non so
	□2-Elementare		□5-Laurea		□99-NR
	□3-Media				
Le domande seguenti sono solo <u>per il proxy</u>					
Abbiamo quasi finito. Ora vorrei chiederle..					

7.13	Quanto tempo impiega per raggiungere il/la Signor/a (nome e cognome dell'accudito)?				
	☐1-Viviamo nella stessa abitazione				☐88-Non so
	☐2-Almeno 5 minuti				☐99-NR
	☐3-Fra 10-15 minuti				
	☐4-Più di 15 minuti				
7.14	Qual è il grado di parentela o relazione con il/la Signor/a (nome e cognome dell'accudito)?				
	☐1-Coniuge/convivente		☐5-Nuora, genero		☐88-Non so
	☐2-Sorella/fratello,cognato/a		☐6-Volontario		☐99-NR
	☐3-Figlia/o, nipote		☐7-Badante		
	☐4-Amico, conoscente				
7.15	Mi può dire la sua età?				
	__ __ (anni)			☐88-Non so	☐99-NR
7.16	Qual è la sua cittadinanza?				
	☐1-Italiana				☐88-Non so
	☐2-Straniera (specificare?) --->7.17				☐99-NR
	☐3-Doppia--->7.17				
7.17	Da quanti anni vive in Italia?				
	__ __ Anni				☐88-Non so
					☐99-NR
7.18	Che titolo di studio ha?				
	☐1-Nessuno		☐4-Superiori		☐88-Non so
	☐2-Elementare		☐5-Laurea		☐99-NR
	☐3-Media				
L'intervista è finita. La ringrazio per la collaborazione!					

Additional file 7

Azienda Ospedaliera Nazionale

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COMITATO ETICO INTERAZIENDALE

(istituito con Delibera n. 1116 del 07/10/2016, Delibera n. 287 del 01/03/2017 e Delibera n. 521 del 29/11/2019 ed iscritto al Registro Regionale al n° 2)

Ns. riferimento da citare sempre nella corrispondenza:
Prot. n° **AslVC.Med.19.02** del CE 19/09/2019

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Oggetto:	***"L'impatto dell'Infermiere di Famiglia e Comunità nel contesto vercellese: studio sperimentale prospettico, con gruppo di controllo"*** Codice Protocollo: **IFeC** Tipo studio: clinico, non farmacologico, monocentrico, no-profit Promotore: Dipartimento di Medicina Traslazionale - UniUPO Sperimentatore: Prof. Fabrizio Faggiano - Osservatorio Epidemiologico A.S.L. VC

IL COMITATO ETICO

Interaziendale dell'A.O. "SS. Antonio e Biagio e Cesare Arrigo" di Alessandria, ricostituito ai sensi del
D.M. 08/02/2013 e nominato con Delibera n. 1116 del 07/10/2016, Delibera n. 287 del 01/03/2017 e Delibera n. 521 del 29/11/2019, iscritto al Registro Regionale al n° 2, si è riunito in data **19/09/2019** alle ore 14.30 e, appurata la completezza della documentazione secondo la normativa vigente,

ESPRIME PARERE FAVOREVOLE

all'unanimità, all'effettuazione dello studio in oggetto, poiché non sussiste alcun elemento che possa impedirne l'attivazione.

Il Comitato Etico ha valutato ed approvato la documentazione come da elenco a pag. 4 della lettera di intenti dell'A.S.L. VC datata 11/07/2019

Il C.E. si è espresso considerando la richiesta di effettuare lo studio presso l'A.S.L. di Vercelli, sotto la responsabilità del Prof. Fabrizio Faggiano, Osservatorio Epidemiologico, verificando la sussistenza del numero legale, **essendo presenti componenti n. 12 su n. 14 dei convocati aventi diritto di voto** (vedi elenco in allegato).

SI EVIDENZIA CHE:

1) Si ritiene indispensabile che le informazioni al paziente vengano analiticamente illustrate dal medico e discusse più ampiamente possibile.

2) Il paziente, relativamente al consenso informato, è libero di consultarsi con persona/e di sua fiducia.

3) La validità dell'autorizzazione è subordinata alle disposizioni contenute nella legislazione vigente.

4) La sperimentazione clinica nell'uomo deve essere eseguita secondo i principi etici fissati nella Dichiarazione di Helsinki e che tutte le fasi degli studi clinici devono essere predisposte, attuate e descritte seguendo i principi della Buona Pratica Clinica (DM 15/7/97).

5) Il Comitato Etico dovrà essere informato:
- dell'inizio della sperimentazione e della sua conclusione
- del verificarsi, durante la sua conduzione, di sospette reazioni avverse gravi e inattese che potrebbero influire sulla sicurezza del paziente o sul proseguimento dello studio
- di ogni successivo emendamento e modifica sostanziale del protocollo approvato.

6) Il responsabile dello studio dovrà documentarne l'andamento con una relazione annuale e la sua conclusione o eventuale interruzione dovrà essere accompagnata da una relazione sintetica con i risultati ottenuti.

7) Il Comitato Etico è stato ricostituito ed opera ai sensi del DM 08/02/2013, seguendo i principi della Buona Pratica Clinica (DM 15/7/97), gli adempimenti previsti nel D.M.S. 12/05/2006 e s.m.i., contenente "*Requisiti minimi per l'istituzione e il funzionamento dei Comitati Etici per le sperimentazioni cliniche dei medicinali*", i principi indicati nelle Carte dei Diritti dell'Uomo, nelle Raccomandazioni degli Organismi Internazionali, nella Deontologia Medica Nazionale ed Internazionale ed in particolare nella revisione corrente della Dichiarazione di Helsinki, inoltre, fa riferimento alla normativa vigente in materia sanitaria.

8) Per l'attivazione della sperimentazione, una volta ottenuto il parere favorevole del Comitato Etico, è necessario attendere la stipula della convenzione (*se applicabile*) e, ove previsto, la ricezione dell'atto autorizzativo della propria Amministrazione.

Il Presidente

Dott.Paolo Toffanini