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REVIEW ARTICLE

Organisational models in primary health care to manage chronic conditions: A scoping review

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Abstract

Chronic diseases are increasing incessantly, and more efforts are needed in order to develop effective organisational models in primary health care, which may address the challenges posed by the consequent multimorbidity. The aim of this study was to assess and map methods, interventions and outcomes investigated over the last decade regarding the effectiveness of chronic care organisational models in primary care settings. We conducted a scoping review including systematic reviews, clinical trials, and observational studies, published from 2010 to 2020, that evaluated the effectiveness of organisational models for chronic conditions in primary care settings, including home care, community, and general practice. We included 67 international studies out of the 6,540 retrieved studies. The prevalent study design was the observational design (25 studies, 37.3%), and 62 studies (92.5%) were conducted on the adult population. Four main models emerged, called complex integrated care models. These included models grounded on the Chronic Care Model framework and similar, case or care management, and models centred on involvement of pharmacists or community health workers. Across the organisational models, self-management support and multidisciplinary teams were the most common components. Clinical outcomes have been investigated the most, while caregiver outcomes have been detected in the minority of cases. Almost one-third of the included studies reported only significant effects in the outcomes. No sufficient data were available to determine the most effective models of care. However, more complex models seem to lead to better outcomes. In conclusion, in the development of more comprehensive organisational models to manage chronic conditions in primary health care, more efforts are needed on the paediatric population, on the inclusion of caregiver outcomes in the effectiveness evaluation of organisational models and on the involvement of social community resources. As regarding the studies investigating organisational models, more detailed descriptions should be provided with regard to interventions, and the training, roles and responsibilities of health and lay figures in delivering care.

KEYWORDS

chronic disease, community, general practice, nursing, organisational model, pharmacist, physician, physiotherapist, primary health care

1 | INTRODUCTION

Chronic diseases also named non-communicable diseases have been defined as a pandemic responsible for over 70% of deaths worldwide (World Health Organization, 2020). The increase of chronic conditions is deeply related to a variety of components, such as population ageing, globalisation and urbanisation, genetics, social determinants of health (SDOH) and lifestyle-related behaviours including harmful alcohol abuse, smoking, sedentary habits, and unhealthy diet (World Health Organization, 2020). In particular, SDOH and behaviours are key factors in determining the increasing occurrence of chronic conditions, such as type 2 diabetes and hypertension, in children and young adults, which are reflected in a high number of unmet needs and medical costs (Miller et al., 2016). This phenomenon has led to one of the greatest health challenges of our time, called multimorbidity, namely the compresence of two or more chronic diseases (World Health Organization, 2016). Moreover, the ageing segment of the population is incessantly growing across the world, leading to an increased demand for human resources and innovative models to deliver care, especially in primary healthcare settings (Adan et al., 2020).

A considerable amount of literature has been published on the development of targeted complex interventions such as the Chronic Care Model, Case Management and interventions based on multidisciplinary work (Bodenheimer et al., 2002; Smith et al., 2016). In particular, the Chronic Care Model was developed to improve quality of care in primary health care for patients with chronic illness through the improvement of self-management and decision support, systems for clinical data, re-designing of the delivery system, involvement of community resources and healthcare organisations (Bodenheimer et al., 2002; Wagner et al., 1996). A recent review on the Chronic Care Model in primary care reported as the most tested interventions self-management support, delivery system design and decision support. Fewer studies on interventions regarding the healthcare organisation and community resources were mentioned (Reynolds et al., 2018). It is apparent that a large body of literature on this topic focused the attention on specific interventions, however, such focus has until now mostly neglected how to harmonise the interventions to constitute an integrated plan of care (Adan et al., 2020; Wallace et al., 2015). In addition, management programmes are typically designed for a single disease, calling for the need to rethink and focus on health systems and organisations of care able to manage multimorbidity and address the socio-cultural challenges of comprehensive and patient-centred care (Kastner et al., 2018; Salisbury et al., 2018). For this reason, health organisations have recently started to take some steps in order to better address multimorbidity challenges, however current evidence still suggests poor results in the resulting clinical outcomes (Smith et al., 2016).

Nowadays, it still exists a knowledge gap regarding the optimal length, role, and task attribution of each component of the interventions (Kastner et al., 2018; Smith et al., 2016). Furthermore, despite some evidence regarding the positive impact of interventions aimed at improving outcomes in chronic patients (Reynolds et al., 2018; Yeoh et al., 2018), it seems still unclear which kind of outcomes should be measured to properly assess their effectiveness (Smith et al., 2016). The inclusion of patient-reported outcomes might improve the transfer of evidence into practice, but greater efforts are needed regarding the identification of clinical outcomes on which there is still room for improvement (Kastner et al., 2018; Smith et al., 2016). For instance, case management seems effective on patient-reported outcomes, although uncertain results emerged on mortality and use of services (Stokes et al., 2015).

Most of the studies on chronic care have to date focused on the elderly as the chosen target population, suggesting the need to shift the focus on younger and paediatric patients to impact social outcomes like absenteeism at school or work (Smith et al., 2016).

To the best of our knowledge, just a few previous works have successfully mapped the methods used by the existing studies, and moreover, such studies have considered just a specific model of care, e.g. the Chronic Care Model (Reynolds et al., 2018) or case management (Reilly et al., 2015). A systematic overview of recent studies on models of chronic care in the primary care setting would inform professional and policy stakeholders on the current gaps in the evidence and features of methods used to guide future research and organisational model development.

What is already known?

- Chronic diseases are increasing incessantly and often evolve into multimorbid conditions.
- Primary health care plays a fundamental role in addressing chronic conditions.
- Effective organisational models in primary health care are needed to address patients' complex needs in long-term chronic care.

What this paper adds?

- Greater efforts are needed to develop organisational models that (a) suit the needs of paediatric populations and families, (b) be effective also on less investigated outcomes and (c) involve community and social resources.
- Self-management support and the multidisciplinary team are the most common components across organisational models that were mostly evaluated on clinical outcomes; more complex organisational models seem to be more effective.
- The intervention applied, the training, roles, and responsibilities of figures involved should be described deeply in scientific papers.

Therefore, the main objective of this study is to properly assess, and map methods, interventions and outcomes investigated by researchers over the last decade regarding the effectiveness of chronic care organisational models in primary care settings.

2 | METHODS

We performed a scoping review following the steps of the method defined by Levac, Colquhoun, and O'Brien (Levac et al., 2010): the identification of the research question, then of the relevant studies, the selection of the studies, data charting, and the collection, summary, and report of the results.

We adopted the Preferred Reporting Items for Systematic reviews and meta-analysis extension-Scoping Reviews (PRISMA-ScR) statement (Tricco et al., 2018; File S1).

2.1 | Research question identification

Based on previous literature findings (e.g., Reynolds et al., 2018; Smith et al., 2016; Stokes et al., 2015) and accordingly to the scoping review method—the research questions should be broad in the inquiry focus, however specific in the concepts, populations and endpoints of interest (Levac et al., 2010)—we identified the following research questions: (a) which research methods have been used in investigating the effectiveness of healthcare organisation models for chronic conditions in primary health care in the last decade? (b) What types of organisational models and combinations of components have been investigated? (c) Which type of outcomes has been investigated to assess the effectiveness of models? (d) Which models for chronic conditions have been documented to have affected investigated outcomes in terms of effect trends?

2.2 | Relevant studies identification and selection

We defined the search strategy including the keywords and MeSH terms related to the concepts of organisation of care, chronic conditions, and primary care and searched in Medline-OVID, CINAHL, Scopus electronic database, and in grey literature (File S2). References were managed with Mendeley to remove duplicates.

We included studies that: (a) were systematic reviews, meta-analyses, randomised control trials, clinical trials, observational studies (e.g. cohort, retrospective and cross-sectional studies, with and without control group); (b) have been published from 1 January 2010 to 7 July 2020; (c) have been written in English or Italian (d) involved paediatric and adult populations; (e) investigated models of chronic care according to the 'delivery arrangements' and the 'implementation strategies' categories as defined by the Effective Practice and Organisation of Care Taxonomy (Norwegian Knowledge Centre for the Health Services, 2016); (f) have been conducted in the primary care setting (including home care, community and general practice).

We excluded studies regarding single interventions that did not provide information on the different figures involved and their responsibilities (e.g., only self-management or medication support, motivational interview). Furthermore, we decided to exclude studies regarding screening programmes, chronic conditions as mental health, obesity and weight management, oncology and palliative care, substance, and alcohol abuse, studied both alone and in association with another chronic condition. Additionally, studies regarding school or prison settings, economic evaluation or quality improvement were also excluded. We excluded systematic reviews that did not meet the inclusion and exclusion criteria; we systematically reviewed their references to include the studies that met all criteria and were not yet been included through our selection process by the electronic database.

Two authors (J.L., E.A., see authors) performed independently the title and abstract screening. After reaching a common agreement, the studies for full-text screening have been selected. The same process was adopted for the full-text screening by three authors (J.L., E.A., F.C., see authors) and disagreements have been solved by a fourth author (L.S., see authors).

2.3 | Data charting and results collation, summary, and report

We developed an extraction table to collect data regarding (a) research methods: study design and duration, sample size and characteristics; (b) types of models and combinations of components; (c) number and types of outcomes (d) effect trends in terms of improvement or worsening of outcomes.

Two reviewers (J.L., E.A., see authors) independently extracted the data and a third reviewer (F.C., see authors) checked for accuracy. In order to synthesise information, the researchers built two tables, the first one including the methods used by the studies (Table 1) and the other describing the components of the organisational models of care and the outcomes (Table 2).

Extracted outcomes were pooled in six categories, according to their nature and scope described in the original articles. The number of citations retrieved across the studies was counted to estimate to which extent the outcomes were used to evaluate the effectiveness of the analysed model.

3 | RESULTS

Through the electronic search and the analysis of the excluded reviews citations, 6,540 studies have been identified, of which 67 have been included (Figure 1).

TABLE 1 Methods of included studies

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Mateo-Abad, Fullaondo, et al. (2020)	Quasi-experimental	COPD, CHF, or DM	856	Primary care/hospital care – integrated Spain, UK Croatia, Poland, Italy	8–12	*N.* contacts with health care providers (general practitioners [GPs], nurses, specialists, others), social services, hospital; duration of hospitalisations, visits to emergency rooms, clinical control of the examined conditions (BMI, heart rate, BP, HbA1c, creatinine, depression symptoms, oxygen saturation, glycaemia), functional status (Barthel index), patient's satisfaction
Mateo-Abad, Fullaondo, et al. (2020)	Quasi-experimental	COPD, CHF, or DM	200	4 healthcare areas Spain	9–12	*N.* contacts with health care providers (GPs, nurses, specialists, others), social services, hospital; duration of hospitalisations, visits to emergency rooms, clinical control of the examined conditions (BMI, heart rate, BP, HbA_{1c}, creatinine, depression symptoms, oxygen saturation, glycaemia), functional status (Barthel index), patient's satisfaction
Mattei da Silva et al. (2020)	RCT	Hypertension	94	Primary healthcare clinic Brazil	12	BP BMI, waist circumference, treatment adherence, QoL
van den Dries et al. (2020)	Cluster pragmatic non-inferiority RCT	Atrial fibrillation	1,240	26 primary care practices Netherlands	24	All-cause mortality Cardiovascular/non-mortality and hospitalisation, major adverse cardiac events, stroke, major bleeding, clinically relevant non-major bleeding, QoL, cost-effectiveness.
Ang et al. (2019)	Retrospective	Chronic diseases	1,440	Frontier Family medicine clinic Singapore	72 (36 pre, 36 post)	Mortality rate Utilisation frequencies and charges for specialist outpatient clinic, polyclinic, ED attendances and emergency, non-day surgery inpatient; all-cause admission
Bloom et al. (2019)	Retrospective chart review	DM	150	Patient Aligned Care Team (VA) USA	6, 12	HbA_{1c} BP, appropriate statin intensity, weight loss, initiation of insulin, access to care
Buja et al. (2019)	Quasi-experimental	DM	602 GPs	Local health unit – general practice Italy	24 (12 pre, 12 post)	% of diabetic patients that had at least: 1 creatinine level measurement annually; 1 lipid profile measurement annually; treated with cholesterol lowering drugs; 2 HbA_{1c} annually; 1 microalbuminuria annually

TABLE 1 (Continued)

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Hudon et al. (2019)	Systematic review	Physical Chronic diseases	20 studies	Primary care setting (including ED) USA, Switzerland, Sweden, Australia, Canada, UK	NR	Self-management, QoL, health and functional status, patient satisfaction, ED and clinic visits, hospital admission, length of stay, ED and inpatient cost, quality of care, patient motivation and goal setting, access to care, care coordination, communication, laboratory tests ordered
Kong et al. (2019)	Group-based RCT	Type 2 DM	300	Community Health Service Centre China	9	Health behaviours (frequent smoker – ≥1 cigarettes/day, frequent drinker -average intake of 25 g pure alcohol/day, physical activity – ≥1 time(s)/week, self-reported low-fat diet) BMI, waist circumference, fasting glycaemia, HbA_{1c}, BP, serum lipid, QoL
López-Liria et al. (2019)	Prospective observational	Chronic diseases	1,086	Patients-home Spain	14 years (Follow-up NS a priori)	Barthel Index
Moczygemba et al. (2019)	Retrospective	Chronic diseases	624	Family medicine clinics USA	6–12	Unplanned hospital admissions and ED visits
Parekh et al. (2019)	Systematic review	Asthma and COPD	4 studies	Home care, family practice (VA) USA	Median 6 (3–6 IQR, 3–12 min–max)	BP, BMI, self-reported physical activity, mental health status, self-efficacy, QOL, healthcare access, disease management, asthma symptom free days, asthma related QOL and unscheduled healthcare use; night symptoms, asthma exacerbations, medication use, pulmonary function, absenteeism, general health status, ED and urgent care utilisation, hospitalisations, asthma severity, albuterol use, home asthma triggers, coping skills, self-management behaviour, use of steroids
Schuttner et al. (2020)	Retrospective cohort	NR	22,095	944 VA Health clinics USA	12	QoL
Soto-Gordoa et al. (2019)	Observational cohort	DM, heart failure, COPD	16,603	12 Integrated healthcare organisations Spain	12	Hospital admissions, *n*. contacts with primary care services
Ballo et al. (2018)	Retrospective matched cohort	CHF	5,283	General practice Italy	48	Heart failure hospitalisation, all-cause mortality

(Continues)

TABLE 1 (Continued)

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Fleisher et al. (2018)	Retrospective chart review	Parkinson		Patient's home USA	24	Feasibility (*n.* people reached, visit numbers and duration, time spent travelling to and from visits, protocol adherence, therapeutic recommendations at each visit), patient's satisfaction, hospital, or ER visit
Hudon et al. (2018)	Mixed method (RCT+qualitative)	DM, CVD, respiratory/ musculoskeletal disease, chronic pain	247	Primary care practices Canada	6	Psychological distress Patient activation
Maeng et al. (2018)	Retrospective cohort	DM	5,500	Primary care sites USA	12	% of patients meeting three predefined targets concurrently (HbA_{1c} < 8%; systolic BP < 130 mmHg/ diastolic BP <80 mmHg, LDL < 100 or <70 mg/dl for patients with CHD or CKD) and % patients meeting each individual target All-cause acute inpatient admissions, ED visits, physician office visit, cost of care
Luo et al. (2018)	Observational	DM	943	9 General practice clinics Singapore	48	Frequency of assessment and control of HbA_{1c}, BP, LDL
Nelson et al. (2018)	RCT	CKD +obesity or DM risk factors	125	Patient's home India	12	Patient activation score BMI, HbA_{1c}, C-reactive protein, QoL, therapeutic adherence
Rosland et al. (2018)	Observational	DM, hypertension	808 clinics	Primary care clinics USA	48	7 clinical outcome (LDL < 100 in CAD or DM, BP < 160/100 and BP < 140/90 in DM, HbA_{1c} < 9% in DM, and BP < 160/100 and BP < 140/90 in hypertension) and 8 clinical process measures (LDL in the last year + aspirin prescription, in CAD; HbA_{1c} in the last year, aspirin prescription, foot exam, retinal exam, renal function testing, and ACE-inhibitor/ARB prescription in DM)
Turner et al. (2018)	Retrospective	Hypertension in DM	2,354	2 primary care clinics USA	12	Systolic BP defined as <140 mmHg
Wan et al. (2018)	Cohort	Type 2 DM	53,436	Primary care general outpatient clinics China	60	All-cause mortality CHD, heart failure, stroke, retinopathy, nephropathy, neuropathy, end-stage renal disease, sight-threatening diabetic retinopathy events, service use rates

TABLE 1 (Continued)

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Yeoh et al. (2018)	Systematic review	DM, heart failure, hypertension, COPD	25 studies	Primary care	Median 12 (12–23 IQR, 2–48 min–max)	HbA_{1c} , BP, Lipid, LDL BMI, weight, foot exam, eye exam, smoking status, self-management plan made, PACIC score, costs, predicted CHD risk, hospitalisation, QoL
Ameh et al. (2017)	Controlled interrupted time-series study	HIV with hypertension or DM	878	12 primary healthcare facilities South Africa	30	CD4 count and BP
Chmiel et al. (2017)	Cross-sectional	Type 2 DM	303	30 small primary care practices Switzerland	36	% of patients still treated according to CCM, reasons for discontinuing the use of the CCM, HbA_{1c} , BP, LDL, compliance with CCM - PACIC
Holtrop et al. (2017)	Cluster RCT	Type 2 DM	1,403 (886 diabetes)	10 primary care practices USA	12	HbA_{1c}
Jack et al. (2017)	Systematic Review	Chronic diseases	34 studies	Community USA	Median 12 (9–19 IQR, 0.5–36 min–max)	Utilisation of health services (ED visits, Hospitalisations, Urgent care visits, Medication use, scheduled primary care provider appointments, maintenance appointments for a chronic condition); costs (program costs, overall costs, savings from changes in utilisation or both)
Markle-Reid et al. (2017)	Pragmatic RCT	Type 2 DM and multiple (≥2) Chronic diseases	159	4 communities Canada	6	Physical QoL, SF–12 subdomain and MCS scores, depressive symptoms, anxiety, self-efficacy, self-management activities, physician visits, hospitalisations, home care
Panattoni et al. (2017)	Quasi-experimental	Hypertension, DM	11,190	2 primary care clinics USA	36 (24 pre and 12 post)	BP, HbA_{1c} Provider experience
Price-Haywood et al. (2017)	Retrospective observational	DM, hypertension		A safety net medical home USA	22	*N*. patients achieved their HbA_{1c} or BP goals, magnitude of change, time to reach goals
Mercer et al. (2016)	Cluster RCT	Chronic diseases	152	8 general practices Scotland	12	QoL, well-being, costs, anxiety, and depression; self-efficacy; self-esteem; level of engagement and retention; Health service utilisation and prescribing data;
Petek and Mlakar (2016)	Retrospective cohort	Type 2 DM	132	Primary care centre Slovenia	36 (12 pre, 12 post)	% of performed actions in diabetes management
Ramli et al. (2016)	Pragmatic Cluster RCT	Type 2 DM	888	Public primary care clinics Malaysia	12	% patients achieving $HbA_{1c} < 6.5\%$ % patients achieving BP ≤ 130/80, BMI < 23 kg/m^2, waist circumference < 90 cm (men) or <80 cm (women), total cholesterol ≤ 4.5, triglycerides ≤ 1.7, LDL ≤ 2.6, HDL ≥ 1.1 mmol/L

(Continues)

TABLE 1 (Continued)

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Luo et al. (2016)	Quasi-experimental pre–post	CHF, COPD, CHD, DM, Asthma	4,000	165 Primary care practices USA	24 (12 pre, 12 post)	% of patients with LDL < 100 mg/dl, HDL ≥ 40 (male) or ≥50 mg/dl (female), total cholesterol ≤ 200 mg/dl, systolic BP < 140, diastolic BP < 80 mmHg, BMI ≥ 30, BMI ≥ 40, weight loss (kg); for diabetes % patients with HbA_{1c} < 7%, systolic BP < 140, diastolic BP, LDL < 100 mg/dl or all optimal outcome
Cooney et al. (2015)	Pragmatic RCT	CKD	2,199	13 Community-based Outpatient Clinics (VA) USA	11	Primary clinical outcome: BP, Primary process outcome: PTH % patients at goal BP, QoL, burden of CKD, End-stage renal disease, all-cause mortality, phosphorus and urine albumin/creatinine ratio; *n*. antihypertensive medications prescribed, appropriate treatment with ACEI/ARB/phosphorus binders/Vitamin D/sodium bicarbonate, medication adherence; % patients seen by nephrology, QoL, Kidney Disease QoL (KDQOL) acceptability of the intervention, satisfaction
Jiao et al. (2015)	Prospective cohort	DM	18,188	General Outpatient Clinics China	36	Time to first occurrence of CHD, stroke, heart failure, a composite of the former three cardiovascular diseases, death from any cause
Ku and Kegels (2015)	Pre–post	Type 2 DM	203	Health centres (Barangay Health Stations) Philippines	12	PACIC score, HbA_{1c}
Mitchell et al. (2015)	Systematic review	Chronic disease	14 studies	Primary and secondary care settings	Median 12 (12–18 IQR, 9–24 min–max)	HbA_{1c}, BP, LDL, HDL, total cholesterol, BMI, smoking status, physical exercise, medication use, % meeting targets in HbA_{1c}, Systolic BP, LDL, diabetes well-being, eye check, time to death or readmission, Minnesota Living with Heart Failure scale, Spirometry FEV_1, Shuttle walk test, QoL, Chronic Respiratory Questionnaire, Dermatology QoL

TABLE 1 (Continued)

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Reilly et al. (2015)	Metanalysis	Dementia (Alzheimer's disease, vascular dementia or mixed)	13 studies, 9,615 participants	Communities USA, Europe, Hong Kong, Canada, India	Median 12 (6–16 IQR, 0.25–36 min–max)	*N.* patients admitted to residential/nursing homes, days per months in nursing home, time to institutionalisation, hospital admission (*n.* nights, *n.* people admitted to hospital), mortality, QoL (participants, carers), carer burden Cognition, behavioural, depression/mood (participants, carers), function/dependency, carer distress, carer well-being, social support, carer satisfaction with health plan and with care, costs
Stewart et al. (2015)	RCT	Atrial fibrillation	335	Mainly patient's own home USA	12, 24	All-cause mortality, unplanned readmission
Stokes et al. (2015)	Metanalysis	Chronic disease	36 studies	Primary care NR	Median 14 (12–24 IQR, 6–60 min–max)	Health–self-assessed health status, mortality; total cost of care, primary and non-specialist care and secondary care utilisation, patient satisfaction
Edwards et al. (2014)	Retrospective cohort	DM +1 another defined chronic conditions	1978	Patient's home USA	36, 48	Hospitalisation
Frei et al. (2014)	Cluster RCT	Type 2 DM	326	30 small primary care practices Switzerland	12	HbA_{1c} Cardiovascular risk factors, systolic and diastolic BP, LDL, PACIC score, QoL
Jiao et al. (2014)	Longitudinal comparative	DM	2,144	General Outpatient Clinics China	12	HbA_{1c}, observed cardiovascular events and predicted 10-year cardiovascular risks, BP, lipid profiles, BMI
Ku and Kegels (2014)	Two-step before–after quasi-experimental	Type 2 DM	164	Non-highly urbanised city Philippines	12	HbA_{1c}, BMI, waist circumference, waist–hip ratio of the cohort, diabetes knowledge and care-related skills of the healthcare workers
Mosquera et al. (2014)	RCT	Chronic diseases	201	UTH High-Risk Children's Clinic as a medical home USA	1.83 years (1.41–2.29 IQR)/1.95 years (1.43–2.31 IQR)	Mortality, ICU admission, hospital stay >7 days, costs ED visits, hospitalisations, ICU admissions and length of stay (days), hospital days, clinic and hospital costs, total *n.* serious illnesses
O'Neill et al. (2014)	Retrospective	Hypertension	126	1 VA Medical Centre USA	3.4 ± 1.9/3.4 ± 1.6 weeks	BP
Shani et al. (2014)	Cohort	Type 2 DM	2024	Primary care clinics Israel	24	BP, LDL, urine microalbumin, HbA_{1c}, fundoscopy (at least one measure per year)

(Continues)

TABLE 1 (Continued)

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Solorio et al. (2015)	Retrospective cohort	Type 2 DM	1,483	Sea Mar Community Health Centre offers primary care services USA	12	Processes of care measures (*n.* HbA_{1c}, cholesterol, microalbumin urine, retinal eye, foot exams); intermediate diabetes outcome measures HbA_{1c} < 7%, LDL < 100 md/dl, BP < 130/80; health care utilisation measures (*n.* primary care visits, at least 1 referral to ophthalmology, and at least 1 referral to endocrinology)
Adair et al. (2013)	Parallel RCT	Hypertension, DM, CHF	2,135	6 primary care clinics USA	12	% of disease-specific care goals met for each patients (tobacco use, BP, HbA_{1c}, LDL, retinal exam, microalbuminuria test, pneumonia vaccination, echocardiography, beta-blocker/ACEI/ARB prescription) % goals met by patients/each diagnosis and the achievement of each individual goal; predictive role of factor (age, sex, self-identified race, language spoken, insurance type, educational attainment; patients' perceptions of care) measure costs
Eley et al. (2013)	Mixed method (RCT+qualitative)	Type 2 DM, hypertension, ischaemic heart disease	285	General practices Australia	6–12	QoL
Low et al. (2013)	Pragmatic non-randomized CT	Hypertension	486	Private primary care Malaysia	6	% patients who achieved target BP < 140/90 (without DM) or <130/80 mmHg (with DM) BP
Marsteller et al. (2013)	Cluster RCT	Chronic diseases	49 physicians 904 patient 178 staff 7 guided care nurses	3 healthcare delivery systems, 8 primary care practices, 14 team USA	12 for patients; 36 for physician and nurses; 24 for staff	Physicians', staff members, Guided care nurses (GCN) satisfaction with provided care, time physicians spent managing these patients, physicians' knowledge of their chronically ill older patients and the practice's care coordination activities, Guided Care physicians satisfaction with the Guided Care program, time and effort spent to participate in and to evaluate the program, perceived usefulness of the GCN; nurses' satisfaction with their Guided Care roles, staff-perceived quality of care provided
Tu et al. (2013)	Interventional cohort	HIV	269	2 urban community health centres Canada	36	Rate pneumococcal vaccination, syphilis screening, tuberculosis screening, ART uptake, on-treatment viral load suppression

TABLE 1 (Continued)

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Berdine and Skomo (2012)	Single cohort	Hypertension, atherosclerosis, Atrial fibrillation, CHF, CHD, DM, dyslipidaemia, obesity, chronic pain	200	Primary care medical practice USA	36	BP, HbA_{1c}, LDL, total cholesterol, triglycerides, HDL, BMI
Coburn et al. (2012)	RCT	CHF, CHD, Asthma, DM, hypertension, hyperlipidaemia	1736	Community USA	60	Mortality All-cause mortality within subgroups of risk strata and primary diagnoses
Fihn et al. (2011)	Cluster RCT	Stable ischaemic heart disease	183 primary care providers 703 patients	Medical centre and community-based primary care clinics (VA) USA	4,8,12	Concordance with practice guidelines, provider satisfaction, symptoms on the Seattle angina questionnaire
Fokkens et al. (2011)	Quasi-experimental	Type 2 DM	59 practice + 1,100 patients	General practices Netherlands	12	Organisation of care
Houweling et al. (2011)	RCT	Type 2 DM	230	A general practice Netherlands	14	HbA_{1c} BP, cholesterol HDL, % patients achieving target HbA_{1c} < 7% and 8.5%, BP < 140/90, lipid profile (according to CDV risk), % patients: referred to an ophthalmologist after not having visited 1 for the last 2 years and to an internist for starting insulin therapy, in whom checked for feet at risk, referred to, whose diabetic/antihypertensive/lipid-lowering drugs were intensified, QOL, diabetes-related symptoms, patients' satisfaction, *n.* patient visits, *n.* contacts practice nurse-GP
Lupari et al. (2011)	Systematic review	Chronic diseases	8 studies	Patient home NR	NR	Hospital readmission, lengths of stay, QoL, functionality and patient perceived satisfaction, caregiver strain or burden, costs
Reilly et al. (2011)	Retrospective	Chronic diseases	867	10 Primary care trusts	18 (9 pre, 9 post)	Hospital admissions, emergency admission by ED and by general practitioner, length of stay for hospital and emergency admission, elective admission

(Continues)

TABLE 1 (Continued)

Authors (Year)	Study design	Chronic condition/s	Patients included (*N*)	Setting Country	Follow-up/observed period, months	Primary outcomes Secondary outcomes
Ciccone et al. (2010)	Pre–post feasibility study	Established CVD, CVD risk, DM, Heart failure	1,160	20 GPs group offices (83 GPs) Italy	6, total 18	Health behaviours (smoker, drinker, physical activity, light diet) QoL, adherence to therapy schemes, *n*. patients reached BP optimal standard level, cholesterol, HbA_{1c}, routine assessment/monitoring of BP at home, glycemia self-monitoring, detection/management of symptoms of worsening heart failure
Gray et al. (2010)	Analysis of data from RCT	CAD, DM, congestive heart failure, COPD	152	Family health network Canada	12 or 18	Quality of care Service use (appointments with physicians, hospital admissions, ED visits, day surgeries), costs
Hotu et al. (2010)	RCT	Type 2 DM, diabetic nephropathy, Hypertension	65	Community, specialist outpatient clinic New Zealand	12	BP 24-hr urine protein excretion, HbA_{1c}, total cholesterol and any change in cardiac parameters of LV mass/BSA, LA volume/BSA and E/E
Marsteller et al. (2010)	Cluster RCT	Chronic diseases	49 physician 904 patients	8 primary care practices USA	12	Physicians' satisfaction with specific processes in their care, time physicians spent, physicians' knowledge of patients, practice's care coordination activities
Peters-Klimm et al. (2010)	RCT	CHF	197	Primary care practices Germany	12	Health-related QoL, heart failure self-care, patient-reported quality of care Prescribing behaviour, hospital admissions and stays, primary care activity (*n*. practice attendances, referrals to a cardiologist)

Abbreviations: BMI, body mass index; BP, blood pressure; CAD, coronary artery disease; CCM, chronic care model; CHD, coronary heart disease; CHF, chronic heart failure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; DM, diabetes mellitus; ED, emergency department; GP, general practitioner; HbA_{1c}, glycosylated haemoglobin; HDL high-density lipoprotein cholesterol; ICU, intensive care unit; IQR, interquartile range; LDL, low-density lipoprotein cholesterol; *N*, number; NR, not reported; NS, not specified; PACIC, patient assessment of chronic illness care; QoL, health-related quality of life; RCT, randomized control trial; VA, veteran affairs.

3.1 | Research methods of the included studied

The main study designs were observational (25, 37.3%), with a median observed period of 24 months (12–48 IQR, 1–168 min–max), and randomised control trial (22, 32.8%), for which two studies were embedded in a mixed-method study (Eley et al., 2013; Hudon et al., 2018), with a median follow-up of 12 months (8.25–12 months IQR, 3–60 months min–max). To a lesser extent studies were quasi-experimental (11, 16.4%) and systematic reviews (8, 11.9%), of which two were metanalyses (Reilly et al., 2015; Stokes et al., 2015; Table 1).

The majority of studies (57, 85.1%) focused on adult patients, while one was specific to the paediatric population (Mosquera et al., 2014) and four were mixed (Jack et al., 2017; Luo et al., 2016; Reilly et al., 2011, 2015). The effectiveness of the programmes has been investigated on a single disease or on a multimorbid population in 36 (53.7%) and 31 (46.3%) studies respectively and the most targeted diseases were diabetes (39 studies, 58.2%), hypertension (14 studies, 20.9%) and chronic heart failure (12 studies,17.9%; Table 1). Thirty-six studies reported among the inclusion criteria age limits: in 21 studies (26.9%) the cut-off minimum age for inclusion was 18 years old and in the other eight (11.9%) 65 years old. On the other hand, the maximum cut-off age for inclusion reported in 10 studies (14.9%) ranged between 58 (Mattei da Silva et al., 2020) and 85 (Cooney et al., 2015) years old. Other selection criteria mainly focused on being frequent users of the services (Hudon et al., 2018, 2019) or being classified as complex according to a risk stratification (e.g., Mateo-Abad, Fullaondo, et al., 2020; Mateo-Abad, González, et al., 2020), absence of cognitive impairment or psychiatric disorders (Holtrop et al., 2017; Hotu et al., 2010), cancer and short life expectancy – range between 3 and 12 months (Ciccone et al., 2010; van den Dries et al., 2020), pregnancy (Luo et al., 2018), severe renal disease and dialysis (Ku & Kegels, 2014), insufficient language skills (Frei et al., 2014).

3.2 | Types of models and combinations of components

We identified four categories of studies according to the models investigated: complex integrated care models, often grounded on the Chronic Care Model framework (39, 58.2%); Case/Care Management (19 studies, 25.4%); involvement of pharmacist role (6, 9%); and involvement of Community Health worker role (3, 4.5%; Table 2; File S3).

All the complex integrated care models investigated included at least one strategy to ensure coordination and/or quality of care, such as the identification of a team coordinator or the adoption of specific protocols and evidence-based guidelines. The introduction of a multidisciplinary team (37 out of 39 studies, 94.8%) and of strategies to support self-management and patient education (35 out of 39 studies, 89.7%) were the most common elements, followed by the adoption of a specific tool to share information (24 out of 39 studies, 35.8%) such as the electronic medical record.

All case/care management models were based on at least one strategy to ensure coordination and/or quality of care, in particular care coordination (100%), use of protocols and/or guidelines (12 out of 19, 63.2) and a risk stratification method (11 out of 19, 57.9%). The other common elements were the inclusion of case/care manager in a multidisciplinary team and self-management support (both 16 out of 19, 84.2%) followed by multiple contacts modalities (13 out of 19, 68.4%) such as face-to-face visits and phone calls (Table 2; File S3).

All models based on the introduction of the pharmacist role included at least one strategy to ensure coordination and/or quality of care, a strategy for medication management and adherence improvement and one for self-management and education support.

All Community Health Worker models were characterised by a strategy to support self-management and patient education, and multiple contact modalities (Table 2).

3.3 | Frequency and types of outcomes

As regarding the outcomes, patients' clinical outcomes were the most studied: specifically, the most used (Table 1; Figure 2; File S4) were blood pressure (30 times), HbA_{1c} (27 times), lipid profile (14 times), mortality (13 times) and body mass index (12 times).

Quality of life (19 times) was the leading outcome among those investigated in the category of the patient-reported outcomes and behaviours, followed by satisfaction (9 times), and treatment adherence (five times). Hospitalisation and emergency department visits were the main indexes adopted to describe services use, 19 and 11 times, respectively. In the category of provider-reported outcomes and performance, performance was the item most frequently assessed in terms of both exams prescribed or executed (19 times) and process measures (18 times) such as time spent, number of visits and coordination activities. Costs were evaluated 14 times across the studies, while caregiver outcomes were the least investigated item (seven times; Figure 2; File S4).

3.4 | Effect trends

Among the fifty studies out of 67 (74.6%) that evaluated effects of models on patient clinical outcomes, 42 (84%) reported at least one statistically significant improved endpoint e.g. mortality (Ang et al., 2019; Wan et al., 2018), blood pressure and HbA_{1c} (Bloom et al., 2019; Mattei da Silva et al., 2020). Of these, 26 studies (out of 42, 61.9%) indicated also non-significant effects e.g., BMI and lipid profile (Kong et al., 2019; Table 2).

All but three (88.4%) of 26 studies (out of 67, 38.8%) that evaluated effects on patient-reported outcomes and behaviours found

TABLE 2 Element and effect trends of models

Authors/Year	Types and combinations of components of organisation models							
	Risk stratification	Care coordination and continuity strategies	Care plan	Protocols, paths, evidence-based guidelines	Regular communication among HCPs	Provider training	Social/ community resources involvement	Tools for information sharing
Complex integrated care model								
Mateo-Abad, Fullaondo, et al. (2020)	●	●	●		●			●
Mateo-Abad, Fullaondo, et al. (2020)	●	●	●		●			●
Schuttner et al. (2020)		●						
van den Dries et al. (2020)				●		●		
Ang et al. (2019)					●			●
Buja et al. (2019)		●		●				●
Kong et al. (2019)		●		●		●		●
Soto-Gordoa et al. (2019)	●	●						●
Ballo et al. (2018)		●		●				●
Fleisher et al. (2018)	●			●	●			●
Luo et al. (2018)		●		●				●
Markle-Reid et al. (2018)		●	●		●	●		
Rosland et al. (2018)		●				●		
Turner et al. (2018)		●		●		●		●
Wan et al. (2018)	●			●				
Yeoh et al. (2018)			●	●	●		●	●
Ameh et al. (2017)		●		●				
Chmiel et al. (2017)				●		●		●
Mercer et al. (2016)		●	●			●		
Petek and Mlakar (2016)		●		●				●
Ramli et al. (2016)		●		●		●	●	●
Jiao et al. (2015)	●			●				
Ku and Kegels (2015)		●				●	●	●
Mitchell et al. (2015)[a]	●	●	●	●	●	●		●
Stewart et al. (2015)	●	●	●	●	●		●	
Edwards et al. (2014)	●	●	●		●			
Frei et al. (2014)				●		●		●
Jiao et al. (2014)	●			●				
Ku and Kegels (2014)		●				●		●
Mosquera et al. (2014)		●			●			●
Shani et al. (2014)		●		●				●
Low et al. (2013)		●	●	●	●	●		
Tu et al. (2013)		●		●	●		●	●
Fihn et al. (2011)	●			●	●			●
Fokkens et al. (2011)	●	●		●				●
Houweling et al. (2011)				●		●		
Gray et al. (2010)	●	●					●	
Ciccone et al. (2010)	●	●	●	●	●	●		●

					Outcomes				
Multidisciplinary team	Medication management/ adherence improvement strategy	Patient education/self-management support	Multiple contact modalities	Predefined follow-up frequency	Patient clinical outcomes	Patient-reported outcomes and behaviour	Service use	Provider-reported outcomes and performance	Caregiver outcomes
●	●	●	●	●	=		+/=		
●	●	●	●	●	+/=		+/=		
●		●				+ −			
●	●	●		●	+/=	=			
●		●			+		+/=		
●		●						+	
●		●			+/=	+/=			
●	●	●	●				+		
●	●	●			+		−		
●	●	●	●	●			+[b]		
●		●			+/=			+/=	
●		●	●	●	+/=	+/=			
●		●			+/=			+/=	
●	●	●	●		+				
●		●			+		+		
●		●	●		+/=	+/=	+/=		
●	●	●		●	+				
●	●	●		●	+/=	+/=		+	
●		●				+/=			
●		●			=			+/=	
●	●	●			+/=				
●		●			+/=				
		●	●	●	+	+			
●		●	●	●	+/=	+/=	+/=	+/=	
●	●	●	●	●	+/=				
●				●	+/=				
●	●	●		●	+/=	+/=			
●		●			+				
●		●	●	●	+/=			+	
●			●		+		+		
●	●	●		●	+/=			+	
●		●			+				
●		●						+	
●	●	●	●			=		+	
●		●		●		+/=		+/=	
					=		+/=		
●			●				=		
●	●	●		●	+	+		+	

(Continues)

TABLE 2 (Continued)

Authors/Year	Types and combinations of components of organisation models							
	Risk stratification	Care coordination and continuity strategies	Care plan	Protocols, paths, evidence-based guidelines	Regular communication among HCPs	Provider training	Social/ community resources involvement	Tools for information sharing
Hotu et al. (2010)		●			●		●	
Case/Care management								
Mattei da Silva et al. (2020)	●	●	●	●	●			●
Hudon et al. (2019) [a]	●	●	●	●	●		●	●
López-Liria et al. (2019)		●						
Hudon et al. (2018)	●	●	●			●		●
Holtrop et al. (2017)	●	●	●	●		●		●
Jack et al. (2017)[a]	●	●					●	
Luo et al. (2016)	●	●						●
Reilly et al. (2015)[a]		●	●	●			●	
Solorio et al. (2015)		●				●	●	●
Stokes et al. (2015)[a]	●	●	●	●	●		●	
O'Neill et al. (2014)	●	●	●					
Adair et al. (2013)		●		●	●	●		●
Eley et al. (2013)		●		●	●	●		
Marsteller et al. (2013)		●		●			●	
Coburn et al. (2012)	●	●	●	●		●		●
Lupari et al. (2011)[a]		●						
Reilly et al. (2011)	●	●		●				●
Marsteller et al. (2010)		●		●			●	
Peters-Klimm et al. (2010)	●	●		●		●		●
Pharmacist involvement								
Bloom et al. (2019)	●	●						
Moczygemba et al. (2019)	●			●				●
Maeng et al. (2018)	●	●		●				●
Panattoni et al. (2017)	●	●	●			●		●
Cooney et al. (2015)		●	●					●
Berdine and Skomo (2012)	●							●
Community Health Worker involvement								
Parek et al. (2019)[a]								
Nelson et al. (2018)						●	●	●
Price-Haywood et al. (2017)	●		●	●				●

Note: +, improvement of that/those outcome/s; −, worsening of that/those outcome/s; =, not statistically significant change of that/those outcome/s.

[a]Data refer to a synthesis of the systematic review result.

[b]Improvement not tested for statistical significance.

at least one statistically significant effect e.g. on patient activation (Nelson et al., 2018), patient satisfaction (Stokes et al., 2015) and health behaviours (Kong et al., 2019).

Data on service use were available for 23 (out of 67, 34.3%) studies, of those 19 (82.6%) reported at least one statistically significant effect. One study (Ballo et al., 2018) indicated a worsening of the hospitalisation rate, while others reported improved service use in services as emergency department visits, intensive care unit admissions (Mosquera et al., 2014) and hospitalisations (Soto-Gordoa et al., 2019).

					Outcomes				
Multidisciplinary team	Medication management/ adherence improvement strategy	Patient education/self-management support	Multiple contact modalities	Predefined follow-up frequency	Patient clinical outcomes	Patient-reported outcomes and behaviour	Service use	Provider-reported outcomes and performance	Caregiver outcomes
●	●	●		●	+/=				
?		●	●	●	+	+			
●	●	●	●		+/=	+/=	+/=		
●		●			+				
●		●	●			+/=			
		●			+				
●		●	●		+/=	+/=	+/=		
●		●	●		+/=				
	●	●	●	●	=	=	+/=		+/=
	●	●	●		=		+	+	
●	●	●	●	●	=	+	=		
●	●	●	●		+/=				
●		●	●		+/=	+			
●		●				=			
●		●	●					+/=	
●	●	●	●	●	+				
●						+	=	+	+[b]
●							+		
●		●	●					+/=	
●	●			●		+/=	=	=	
●	●	●			+			+	
	●	●		●			+/=		
●	●	●			=		+		
●	●	●			+/=			+/=	
●	●	●	●		=	=		+/=	
●	●	●		●	+/=				
	●	●	●		+/=	+/=	+/=		
		●	●	●	+	+/=			
	●	●	●		+/=				

Twenty studies (out of 67, 29.8%) evaluated outcomes in the 'Provider-reported outcomes and performance' category. All but one (Peters-Klimm et al., 2010) found at least one statistically significant improvement in items such as complete diabetes follow-up performed (Buja et al., 2019; Shani et al., 2014) as well as knowledge and self-assessed skills of the staff (Ku & Kegels, 2014).

Both systematic reviews (Lupari et al., 2011; Reilly et al., 2015) on the case management model, that assessed caregiver outcomes

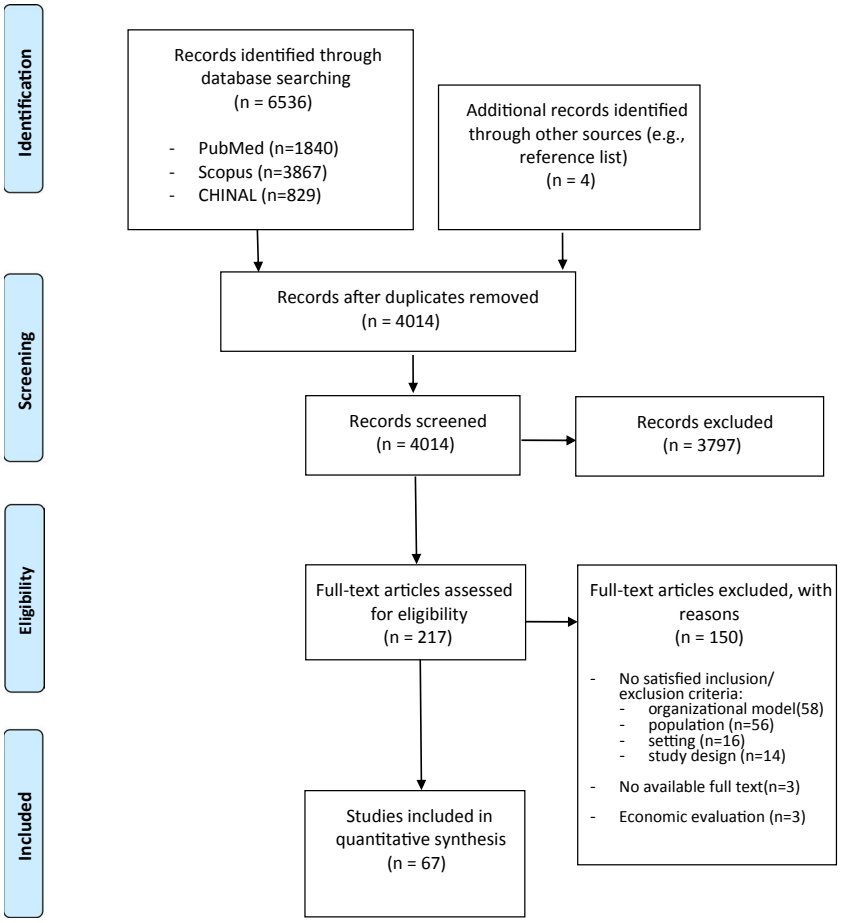

FIGURE 1 Flow diagram search and selection process of scoping review (Tricco et al., 2018)

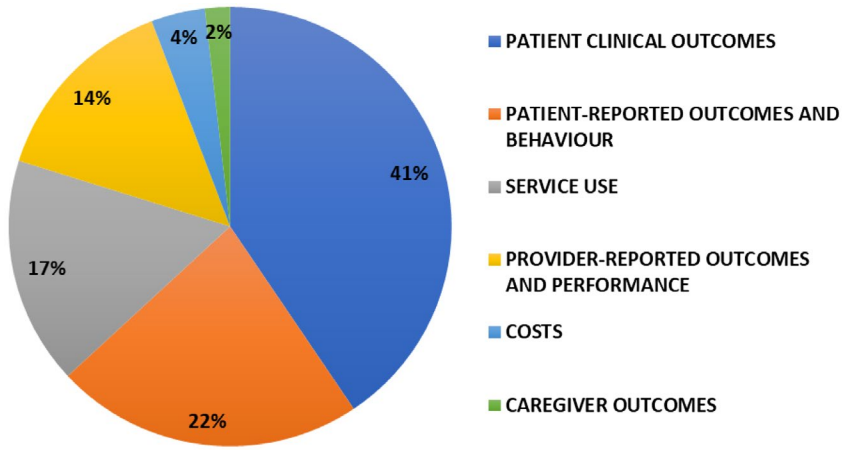

FIGURE 2 Outcome categories

evaluation, found at least one improvement, although only Reilly et al. (2015) evaluated outcomes quantitatively.

4 | DISCUSSION

This review provides an analysis and a summary of the methods of studies that were aimed at investigating organisational models of care to tackle chronic care challenges. Furthermore, our study examined the nature and the specific components of those organisational models, in an attempt to understand the effect trends.

Among the 67 studies included, the observational study design was the most encountered, followed by randomised control trials. Just two studies were meta-analyses. According to our findings, another recent review showed a greater prevalence of observational studies (Jimenez et al., 2021), demonstrating the increasing use of the observational design to investigate efficacy questions and to develop clinical recommendations (Gershon et al., 2021).

All but five of the reviewed studies were conducted on adult populations, revealing a chronically low level of focus regarding the paediatric patients in primary care, as reported by previous reviews (Adams & Woods, 2016; Reynolds et al., 2018). The proportion of children and young adults with obesity, Type 2 diabetes, asthma, hypertension, food allergies, and depression is rising steadily, even if in less extension compared to adults and the elderly, increasing health costs and family burden in caregiving (Miller et al., 2016). Therefore, models of care embedding interventions in social (e.g., school) and clinical settings are needed to address the paediatric population health needs and to slow the increase in chronic conditions in future adult and older generations.

Most of the population exclusion criteria were clinical in nature and they referred to cognitive impairment and psychiatric disorders as well as short life expectancy due to cancer, while those non-clinical referred to language barriers. The majority of the investigated models targeted a specific disease, predominantly diabetes in line with a previous review (Reynolds et al., 2018), although studies regarding multimorbid populations were almost half of the included studies. These findings underline the efforts undertaken by researchers toward the optimisation of models for effective management of multimorbidity, despite recent reviews claimed the shortage of clinical guidelines with this focus (Kastner et al., 2018).

Amid the heterogeneity of organisational components, we discerned four categories of models, namely complex integrated care model, that includes the models grounded on Chronic Care Model or similar framework, case or care management, and models centred on a specific figure as pharmacists and community health workers. Complex integrated care models were the most detected models, reflecting the popularity of the Chronic Care Model (Bodenheimer et al., 2002) in primary and secondary studies on this topic (Reynolds et al., 2018). Self-management support and education intervention, as well as, multidisciplinary team were the most reported components, and the explicit involvement of social or community resources was the component least retrieved, consistently with previous evidence (Kastner et al., 2018; Reynolds et al., 2018).

Effectiveness was investigated mainly at the clinical level, which represented 41% of outcomes analysed, consistently with the review on the outcomes assessed in Chronic Care Model interventions performed by Drouin and colleagues (Drouin et al., 2015). Surrogate outcomes were the most assessed outcomes, while hard outcomes, including death or major cardiovascular events, represented 4,6% of 390 outcomes. Caregiver outcomes were the least explored.

However, a recent review of interventions to enhance primary care found, differently from our study, that healthcare costs and resource use were the most investigated outcomes (Jimenez et al., 2021). Patient-reported outcomes, mental health outcomes and hard outcomes as mortality remain poorly investigated, despite their relevance: a Delphi survey recently defined them as a core outcome set for the research in multimorbidity (Smith et al., 2018). Additionally, caregiver outcomes should be systematically and deeply assessed in order to be able to answer the need to implement strategies to sustain families and caregivers (Wolff et al., 2020).

Concerning the effect trends, almost one-third of the included studies reported only significant effects, referred to both specific and different categories of outcomes. Aside from two studies that reported only not significant effects, all the remaining studies demonstrated at least one significant statistical improvement that was detected in over 80% of studies in every category of outcomes.

The co-presence of statistically significant and non-significant results was found both in the same category and across different outcomes categories.

Firstly, contrasting results were found both among multiple outcomes of the same category and regarding the same outcome over time. An example of the first case is reported in van den Dries et al. (2020), in which an improvement was found in all-cause mortality and non-cardiovascular mortality but not in cardiovascular mortality or stroke. On the other side, mixed results of the same outcome across multiple follow-ups are shown in Berdine and Skomo study (2012) study, in which an improvement in HbA_{1c} and systolic blood pressure was detected after 1 year but not in the third year.

Differences were also found between different categories, as shown in the study of Solorio et al. (2015), where an improvement was found in the numbers of diabetes exams executed but not in clinical outcomes.

Our findings reflect the problem of lack of significance over time in clinical outcomes, which arguably arises due to the temporary efforts in implementing interventions during experiments. Thus, experimental interventions do not translate into an effective implementation as part of the organisational model in the long term. Furthermore, contrasting results in different types of outcomes suggest that targeting specific outcomes might be more effective, and, on the other hand, they highlight the need to build more well-designed interventions aimed at improving several aspects in order to maximise effectiveness.

In comparing models and related components with effect trends, more complex interventions seem to relate to better outcomes across all categories, in line with previous reviews (Nolte et al., 2014). It also seems that those organisational changes focused on the development of a specific figure are likely going to be less effective more frequently and be more at risk of bearing contrasting results in the literature. However, the heterogeneity of definitions and components of models has led to inconclusive results on a possible association with effect trends. These findings further highlighted the essential need for precision and consistency in the description of programmes, models and interventions (Nolte et al., 2014).

An interesting result of our review is the opportunity to highlight the global efforts toward the empowerment of primary care, drawing an international representation of international studies, including the Philippines, Malaysia, Italy, China, and South Africa, that found significant results, in a field more commonly represented, above all, by studies of the United States.

One of the main strengths of this review has been the adoption of a broad definition of the term 'organisational model'. This decision enabled us to include all the research papers describing the effects of changes that occurred at the organisational level.

Furthermore, we chose to not limit the studies in terms of age limit and study design, allowing us to broadly map the existing studies on this topic.

Our review has several limitations. Regarding the population selection criteria, we decided to exclude some non-communicable diseases such as obesity, depression, and cancer. The quality assessment of the included studies has not been performed, given that the scoping review method does not necessarily require this step. Regarding this respect, the limitation of bias has been improved through systematic research of the databases, thorough proper screening of the articles and data extraction. All the steps have been performed by three independent reviewers.

Another limit refers to the adoption of a broad search string chosen by the authors in order to detect the greatest number of pertinent papers to review, which could have led to miss the retrieval of specific studies.

4.1 | Implication for research

Although we did not conduct a quality assessment, we observed that none of the included studies adopted a specific checklist to accurately report interventions, for example, the Template For Intervention Description And Replication (Hoffmann et al., 2014). This reflects a missed distinction between the scope of the theoretical frameworks (e.g., Chronic Care Model) compared to the checklist that should describe the intervention characteristics. Greater efforts are necessary to improve the quality of the descriptions of each intervention, in order to facilitate the replicability of the implementation of effective models of care (Smith et al., 2016). Moreover, it might be useful to provide data on the level of implementation, beyond how it has been done, using tools as the Patient Aligned Care Team Implementation Progress Index (PI2). This would be valuable to help clinicians and stakeholders in evaluating the effectiveness of interventions and to what extent these interventions should be transferable into practice to maximise efficacy.

As for the methods, rigorous observational studies might be considered a valid alternative to randomised control trials in order to contain costs and ensure ethical aspects. Although some concerns regarding the use of not experimental design, several methods might be used to ensure the validity of observational studies to test the effectiveness. For example 'empirical calibration', meant as a smaller experimental study conducted alongside the larger observational study, might be used to demonstrate observational design reliability in the context (Schuemie et al., 2020).

In measuring performance, most of the studies evaluated outcomes comparing them to the expected standard of care or to a cross-sectional baseline data collection, however, these methods are insufficient to evaluate the effectiveness of interventions. In selecting outcomes, greater efforts should be devoted to including measures on caregivers, population, and community.

As for the interpretation of the outcomes, more information should be discussed in the practice implications section of the research papers, given the encountered difficulty in assigning a positive or negative connotation to the findings. For example, a higher number of primary care visits could be considered both because due to the increase of the waiting list or in contrast as a way of improving patient adherence and engagement. Medication use could be interpreted as improved patient adherence, increased symptom control, or worsening in clinical stability, e.g., use of albuterol or narcotics. This point highlights the importance to evaluate multiple outcomes, beyond those clinical in nature.

Further systematic reviews with meta-analysis might be useful to understand which organisational models are most effective for each chronic condition and for the multimorbidity.

5 | CONCLUSION

The evidence suggests that complex models integrating multiple innovative components may achieve better results across different outcomes. Multidisciplinary teams, self-management and patient education interventions and strategies targeting the coordination and continuity of care are nowadays considered consolidated components of innovative and effective models for the management of chronic care patients. Greater efforts are needed to implement risk stratification and to ensure the most appropriate delivery of care. This would increase the efficiency of time and cost management and it would achieve the expected changes in the effectiveness of interventions. Additionally, greater attention should be devoted to the children and young adults, given the current increase of chronic conditions in that population, and to mental health comorbidities.

Taking also into account the feedbacks coming from the literature, future efforts might be directed towards the development of flexible models, that can answer to the contextualised local need, improving community and social resources involvement as well as community health workers participation in the multidisciplinary teams.

CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTION

JL, EA, FC, LS: Have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; JL, EA, FC, EM: Been involved in drafting the manuscript or revising it critically for important intellectual content; JL, EA, FC, EM, LS: Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

DATA AVAILABILITY STATEMENT

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

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SUPPORTING INFORMATION

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