



Original Article/Research



Introduction of novel complex integrated care models supported by digital health interventions in European primary settings: a scoping review

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ABSTRACT

Introduction: There remains the need to develop comprehensive organisational care models supported by digital health interventions (DHIs) to manage chronic conditions in primary healthcare.

Objective: this review aimed to identify and map methods, interventions and outcomes investigated regarding the introduction of novel complex integrated care models supported by DHIs in the European primary care setting, as well as the level of integration achieved.

Methods: a scoping review to identify literature from 2013 to 2023 in the European context was conducted across PubMed, Scopus and Web of Science. DHIs description, care models and outcomes were reported using the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines.

Results: A total of 53 studies was included. The models introduced, along with a DHI, at least one innovation in their structure or in the modality of care delivery: either a new figure (44%), interprofessional collaboration (37%), new functions like person-centred care (59%) or population stratification (11%). As regarding the DHIs, 56% implemented monitoring/management platforms and apps for chronic conditions. The most frequent combination of care model-DHI was the introduction of an app/platform, supported by phone calls/texts and electronic health records, paired with the introduction of a new healthcare professional/person centred care/multidisciplinary team. All the studies reaching statistically significant outcomes introduced, along with one or more DHIs, either a new figure or a multidisciplinary team as part of the organizational change to support the technology.

Conclusions: novel complex integrated care models are focusing on introducing multidisciplinary perspectives and personalization of care, in line with the complex needs of chronic patients. The predominant development of monitoring/management platforms for patients is a further confirmation of this trend. Future research efforts should focus on the investigation of the effectiveness of current complex integrated care models integrating DHIs.

Introduction

European Countries are currently under pressure to strengthen their health care. Increasing elderly population, changing demographics, pollution, as well as the substantial prevalence of chronic diseases constitute an important burden for the sustainability of healthcare systems, which have been also heavily battered by the gripping effects of the COVID-19 pandemic. In this complex context, the World Health Organization (WHO) has highlighted, in occasion of the Declaration of Astana on Primary Health Care in the 21st Century, the key role of

primary care, in consideration of the challenges that health systems are currently facing [1-3]. Innovative primary health care models and healthcare innovations (WHO, 2018) have been researched intensively over the last 20 years. Complex care models, often grounded on Chronic Care Model, emerged in a recent review as those most studied and seeming to lead to better outcomes, mostly on clinical outcomes and rehospitalization rates [4]. However, as Longhini underline, there remain the need to develop more comprehensive organisational models of care to effectively manage chronic conditions in primary health care and prevent disease progression.

In this landscape, E-health interventions have been having an

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important and rapid development, further exponentially boosted by the COVID-19 pandemic. Information and Communication Technologies have been increasingly used in remote care strategies. The term “digital health” has historically been addressed as “telemedicine” or “telehealth”, which refers to communication and interaction tools between health care professionals and patients that provide remote health services and care as alternative to face-to-face appointments [5]. Health-care professionals and policy makers have begun to look at digitalization of healthcare to provide more services and reduce distances [6-8], with significant attention to the potential for digital technology to augment impact, through the adoption of risk stratification models and assistive technology [9,10]. Digital Health Interventions (DHIs), delivered through digital technologies are utilized formally and informally by healthcare providers, patients, and stakeholders. Examples encompass mobile health (mHealth) tools like SMS or smartphone apps, telehealth systems for remote clinical services, wireless medical devices, software aiding clinical decisions, medical imaging, health information technology (HIT), and patient portals. Additionally, advanced data analytics and artificial intelligence (AI) can function independently or as integrated elements within these digital health tools [11,12]. The FDA currently approves and regulates digital treatments that meet the definition of software as a medical device (SaMD), however low-risk SaMD, consumer health and wellness apps are still not regulated [13]. Moreover, WHO released specific guidelines to describe the use of DHIs for health system strengthening, taking into account the impossibility to provide an exhaustive list of existing digital health technologies, given the pace of development of the field [12]. Wienart et al. [14], have recently introduced another sub classification, introducing the concept of Digital Public Health (DiPH). DiPH interventions refer to all those activities whose core field of action is at the population rather than individual level, including the areas of health promotion and disease prevention, as well as healthcare and management.

Some reviews of the literature have begun to map and synthesize the evidence regarding the complex ecosystem of DHIs currently available for clinical practice. Kraef et al. (2020) performed a systematic review and meta-analysis to determine the effectiveness of digital telemedicine interventions designed to improve outcomes in patients with multimorbidity [15]. The included articles did not contain an evaluation of costs or cost-effectiveness and showed no improvement or small improvements in the intervention groups. As health systems start to think about the post- COVID era, expectations remain high for digital medicine to deliver a new era of healthcare, in line with the prospects brought by the digital revolution. However, what’s required is the wide deployment of these technologies effectively embedded within sustainable and smoothly working innovative models of care, considering a safe and proper use of the data they generate. Amid the heightened interest, digital health has in fact been characterized by implementations rolled

out in the absence of a careful examination of the evidence base on benefits and harms [1,16]. Moreover, it is important to consider the current state of the health systems, often characterized by professional cultures, silo-working, the absence of a strategy for primary care computing, or multiple public/private sector models that have hindered standardisation [17], as well as a different and fragmented degree of integration across health services [18].

To date, no studies have explored the role of the introduction of DHIs [14] in shaping innovative models of care in primary care and the main characteristics of such complex interventions from a digital and organizational perspective. Moreover, the level of health services integration that such interventions are currently providing is unknown.

We aimed to assess and map methods, interventions and outcomes investigated regarding the introduction of novel complex integrated care models supported by digital health interventions in the primary care setting, and the level of integration achieved by the newly introduced models of care.

Methods

Study Design

A scoping review was performed to identify studies that described the introduction of complex integrated care models supported by digital health interventions in the primary care setting (eg, limited to outpatient, general practices and long-term care). The items of the scoping review were reported using the PRISMA- ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines [19]. The protocol of this review is available for consultation in the Open Science Framework database.

Search strategy

Systematic search queries of the databases MEDLINE/PubMed, Scopus and Web of Science were used to identify references published or available online between January 1, 2013 and November 11, 2022 (Multimedia appendices 1-7). The studies selected for inclusion were: studies with primary designs or systematic and scoping reviews (following the same inclusion criteria) published in English or Italian, with an available abstract. The rationale for the search cut-off was based upon the rapid development of digital health technology and acquisition of digital skills by consumers, both characteristics achieved in the last ten years [20], and the obsolescence of digital technologies in use in the early 2000s. For this review, only articles were included. Editorials, narrative reviews, conference papers, books, workshops and grey literature were excluded, along with concept papers and articles concerning the development and validation of digital technologies.

Textbox 1: Useful Definitions

eHealth: cost-effective and secure use of information and communication technologies (ICT) in support of health and health-related fields. It encompasses multiple interventions, including telehealth, telemedicine, mobile health (mHealth), electronic health records (EHR), big data, wearables, and even artificial intelligence.

Digital health intervention: A digital health intervention is defined as a discrete functionality of digital technology that is applied to achieve health objectives and is implemented within digital health applications and ICT systems, including communication channels such as text messages. World Health Organization. Recommendations On Digital Interventions For Health System Strengthening. 2019.

Primary care: The provision of universally accessible, 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.

European Commission, Expert Panel on effective ways of investing in Health (EXPH), Tools and Methodologies for Assessing the Performance of Primary Care [Internet]. 2018.

The search was performed using a three-step search strategy [21]: 1) exploratory search in two databases to identify descriptors and keywords, followed by construction of the search string for each database; 2) definition and search in all databases; 3) manual search for additional sources in references of selected studies.

The search strategy focused on the following 3 main sets of terms: 1) primary care, 2) digital health technologies, 3) models of care (see complete research string in Multimedia Appendix 1).

The target populations chosen within this context were patients/consumers, all the health professionals working at the community and primary care levels, and/or population stakeholders (eg communities, health systems, and the government). The primary care setting included general practices, ambulatory care, and long-term settings such as nursing homes.

Interventions had to target prevention, screening, monitoring or management using at least one FDA/WHO approved or nonregulated digital health technology (eg, telehealth, mHealth, HIT, data analytics, and AI) [11,13] implemented at the primary care level with a care model. The authors chose to include the most comprehensive list of terms referring to digital health technologies used in DHIs (including interventions targeting both individuals and populations), found in the first exploratory search of the relevant literature. Outcomes of interest included clinical, economic and humanistic outcomes [22]. For this review, articles featuring solely Electronic Healthcare Records, either in terms of description of the tool or used for data mining research interests, were excluded. Moreover, all the studies that used electronic healthcare records as data mining tool for retrospective studies, as well as artificial intelligence algorithms used for epidemiological predictions or estimates not implemented as a tool in the clinical practice were excluded. Other exclusion criteria were constituted by studies conducted only in acute care (eg, hospital settings), and DHIs associated with treatment and diagnosis (except for the use of mobile phones for ambulatory dermatological conditions), medical imaging for diagnosis.

Screening and selection process

Study selection followed the PRISMA steps: identification, screening, eligibility, and inclusion.

All the titles and abstracts underwent dual review by two researchers (EM and GM), with group discussion and third-party adjudication provided by a third researcher (EA and FC) in case of discrepancies in eligibility criteria. Subsequently, following the same process, full texts and reference lists of included studies were analysed.

Data extraction and synthesis

The title and abstract screening identified a large body of articles (>1400). The full text analysis involved all articles pertaining to the geographical region of Europe (inclusion of countries based on the list of countries of the European Council, 47 members).

The data were managed and stored through EndNote and a database was created using a spreadsheet in Microsoft Excel 2018. After data form piloting and group discussions conducted by all extractors to ensure consistency in the reporting of definitions and variables of interest, data selected for extraction were *Author, Year, Study Design, Digital Intervention, Organizational model of care delivery, Setting, Country, Recruitment and Inclusion criteria, Number of participants, time of Follow-up, Primary and Secondary outcomes, statistically significant results*.

Two authors (EM and GM), independently extracted all relevant data using the defined extraction form, based on the JBI template. All fields of the data extraction form of each article were examined for completeness by a second reviewer. Data were analysed qualitatively, with narrative analysis, and quantitatively, through absolute and relative frequencies (EM and JL). The analysis of the integration of care has been performed using the classification provided by Goodwin et al. [18]

Furthermore, an additional synthesis has been performed to group

the outcomes by patient population, with the following groups of patient categories: healthy adults, general practice's patients, patients at risk of developing a chronic condition, patient with one chronic condition or with multimorbidity, linking the population with the related research outcomes (Table 3).

Results

Content analysis of the extracted variables was conducted to uncover recurrent topics, models of care and digital health interventions currently introduced in the European clinical practice, as per research questions.

The digital health interventions have been organized into two categories of the overarching grouping classification given by WHO based on the targeted primary user (WHO, 2018), interventions for clients and interventions for healthcare providers, due to their pertinence for the research topic. The themes were then further subdivided based on the type of technology used: 1) app/platforms used either for health promotion for monitoring and management of symptoms and diseases, 2) computer based clinical decision support systems, 3) systems of teleconsultation or virtual clinics approaches, 4) electronic healthcare records and information and communication technologies.

The research string in the three different databases yielded a total of 18938 records, of which 1556, conducted worldwide, were eligible for full text review. In the European context 233 articles had been deemed eligible for final full-text review. 53 articles describing introduction of complex integrated care models supported by DHIs have been included for data extraction. Fig. 1 reports the Flow chart of study selection for scoping review adapted from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-SR).

The main study design was constituted by randomized controlled trials (35, 65%), followed by a variety of other research designs: pilot/feasibility studies and descriptive studies (7, 13%), quasi experimental studies (6, 11%), cohort studies (3, 6%), cost-effectiveness studies (2, 4%) and mixed methods studies (1, 2%). Most of the articles (35, 65%) have been published between 2013 and 2017. The most prolific countries to have implemented digital health technologies in primary care seem to be The Netherlands (14, 26%), followed by the United Kingdom (13, 24%) and Spain (9, 16%). As regarding the setting, most of the articles described as context of the study the setting of health districts and primary health centres (32, 59%), followed by GP practices (16, 30%). The other contexts were long term care facilities and outpatient centres. Specifics of the study characteristics can be found in Table 1.

In terms of diseases of interest, the DHIs introduced in the primary care setting targeted different chronic and multimorbid populations, with special attention to diabetes, cardiovascular diseases, chronic lung diseases, mental health and dermatology. Other populations of interests were the frail population, at risk of developing a disease, and the general population/clients of GP practices.

Types of models and combinations of components

In terms of the use of DHIs, half of the included studies focused on the application of monitoring/management platforms and apps for chronic conditions (30/53, 56%), followed by the use of apps/platforms promoting a healthy lifestyle to reduce the risk of developing a disease (9/53, 17%), teleconsultation systems/virtual clinics (7/53, 13%) and other digital health interventions such as computer based decision support systems (4/53, 9%), electronic healthcare records with specific functions and simple information and communication technologies such as the telephone.

The complex integrated care models investigated, introduced, along with the previously described categories of digital intervention, at least one innovation in their structure or in the modality of care delivery: either a new figure (24/53, 44%), modalities of multidisciplinary

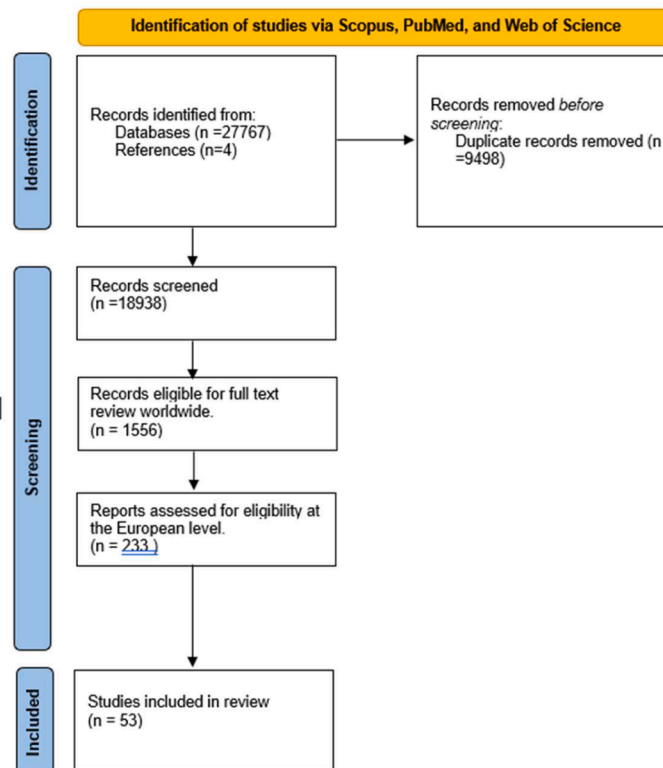


Fig. 1. Flow chart of study selection for scoping review adapted from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-SR).

collaboration (20/53, 37%), new functions or competences for existing HCPs, such as the introduction of person-centred care (32/53, 59%) or population stratification strategies (7/53, 13%).

In most cases, the authors combined at least a couple of digital health interventions, pairing them with the introduction of a combination of organizational changes to the existing care models. Table 2 explored all the possible combinations of DHIs extracted from the articles included in this review, along with the associated organizational changes introduced, the level of integration achieved by the intervention and the outcomes investigated. The most frequent combination (19%) resulted to be the introduction of an app/platform, supported by ICT (often structured phone calls or standardized text messages) and EHRs, paired with the introduction of a new healthcare professional, person centred care (often in the form of individualized care plans) and the integration of a multidisciplinary team. Other frequent combinations were the 1) introduction of app/platforms aided by computer based clinical decision support systems plus EHR/ICT (13%), with the introduction of new healthcare professionals (often nurses) and the application of population stratification strategies; 2) systems for teleconsultations or virtual clinics plus EHR/ICT (13%), implemented with the support of new ad-hoc figures, person centred care and multidisciplinary teams.

Health services integration

In terms of forms of integration, half of the studies focused on horizontal integration (22/53, 50%), with the development of multidisciplinary teams and/or care networks that support a specific client group (e.g. for older people with complex needs). Fewer models were based on vertical integration (10/53, 19%), with integrated care across primary, community, hospital and tertiary care services resulting in protocol-driven care pathways for people with specific diseases (such as COPD and diabetes) and/or care transitions between hospitals to intermediate and community-based care providers. Just one study seemed to address sectoral integration, combining horizontal and vertical

programs of integrated care. Moreover, many studies (29/53, 54%) promoted people-centred integration, intended as integrated care between providers and patients and other service users to engage and empower people through health education, shared decision-making, supported self-management, and community engagement, which in many cases was supported by an ad hoc digital support tool for health promotion. On the contrary, just a minority of studies addressed whole-system integration (4/53, 7%), focusing on public health interventions to support both a population based and person-centred approach to care.

Outcomes

52% of the articles (28 out of the 53) chose to investigate a clinical primary outcome, among these Haemoglobin A1c has been selected as primary outcome 25% of the times and constituted the most studied primary outcome. 39% (21 out of 53) of the total of the studies chose economic primary outcomes, in particular hospital admission, selected as primary outcome 29% of the times. The remaining 9% (5 out of 53) focused on humanistic primary outcomes, with special interest for quality of life, chosen as primary outcome 80% of the times.

Overall, the studies presented mixed results, (e.g. significant and non-significant changes simultaneously for a specific outcome), for all types of outcomes. Looking at the general trend of the outcomes, primary and secondary outcomes were predominantly clinical, investigated 138 times, whereas economical outcomes have been investigated in total 92 times and humanistic outcomes on a minor scale, 39 times in total. No identified studies examined outcomes related to dimensions such as environmental, social and spiritual.

In terms of patient population, the investigators targeting populations such as chronic multimorbidity and GP clients focused mainly on process and economic outcomes, while the investigators introducing DHIs and organizational changes in specific patient populations, such as diabetes mellitus cardiovascular diseases or frail populations /at risk of developing a condition, targeted clinical primary outcomes. For the full

Table 1
Characteristics of the included studies.

Author	Year	Study Design	Setting	EU Country	N of participants	Follow up (M)	Primary and secondary outcomes
Bardsley et al. [23]	2013	cost-effectiveness	Home/monitoring center	UK	2317	12	Number of GP or practice nurse contacts by patients and number of clinical readings recorded on general practice systems.
Steventon et al. [24]	2013	RCT	Home/monitoring center	UK	2426	12	Primary outcome: Hospital admission. Secondary outcome: mortality; proportion of people admitted to permanent residential or nursing care that was paid for at least in part by the local authority; number of weeks receiving domiciliary social care paid for at least in part by the local authority; number of inpatient hospital bed days, emergency admissions, elective admissions, admissions for falls, outpatient emergency visits; length of hospital stays; number of contacts with general practitioners and practice nurses and associated national costs of hospital care, social care and general practice care.
Rixon et al. [25]	2015	RCT	Home/monitoring center	UK	578	12	Primary outcome: Quality of life. Secondary outcomes: anxiety and depression.
Basuved et al. [26]	2016	RCT	GP practice	UK	167	12	Primary outcome: change in HbA1c: reduction in HbA1c \geq 6 mmol/mol (0.5%) at 12 months. Secondary outcomes: lipids, blood pressure, weight (kg and BMI) and renal function (eGFR).
Ali et al. [27]	2021	RCT	Health district	S	224	9	Primary outcome: general self-efficacy, hospitalization and death 6 months after randomization
Barenfield et al. [28]	2022	Mixed- Methods				9	Meaningfulness of combined digital platform and structured telephone support and detail of specific functions considered meaningful. Technology skills: ability to use technical equipment such as a smart-phone, digital tablet or computer.
Avila et al. [29]	2018	RCT	home/monitoring center	B	90	3	Primary outcome: change in the exercise capacity following the intervention. Secondary outcomes: daily physical activity, Steps, sedentary time, active energy expenditure, and duration of moderate and vigorous physical activity.
Bleijenberg et al. [30]	2017	cost-effectiveness	GP practice	NL	3092	12	Health Care Utilization, Costs, and Effects, Cost-Effectiveness.
Bleijenberg et al. [31]	2016	RCT	GP practice	NL	3092	12	Primary outcome: Daily functioning. Secondary outcomes: self-reported health-related quality of life (QoL), satisfaction with primary care, number of hospital admissions, admission to a nursing home or assisted-living facility, and general practice out-of-hours consultations during follow-up.
Christensen et al. [32]	2022	RCT	Health district	DK	340	24	Primary outcome: weight loss from baseline at 24 months. Secondary outcomes: change in the haemoglobin A1c (HbA1c) level, waist/hip ratio (WHR), systolic and diastolic blood pressure, total triglyceride, high-density lipoprotein and lowdensity lipoprotein cholesterol, smoking status and quality of life.
Christensen et al. [33]	2022	RCT	Health district	DK	170	6	Primary Outcome: mean body weight. Secondary outcomes: mean HbA1c from baseline to six months; proportion of patients whose HbA1c decreased or normalised to <6.5% at six months; changes in body composition (BMI and hip waist ratio), lipids (total cholesterol, LDL, HDL, and TG), and systolic and diastolic blood pressure, as well as changes from baseline to six months in social demography, exercise and diet habits, and quality of life and mentalwell-being.
de Batlle et al. [34]	2021	Effectiveness/cost effectiveness study	Health district	ES	76	6	Outcomes: intervention effectiveness; use of health care resources after 6 months, and estimated associated costs; and cost-effectiveness, assessed by means of the incremental cost-effectiveness ratio (ICER).
de Jong et al. [35]	2016	Retrospective	Health district	NL	203	10	Outcomes: Characteristics of health care professional using Congredi: demographic data, discipline; characteristics of patients in Congredi: demographic data; multidisciplinary combinations of health professionals in Congredi, combinations of health care professionals linked in a patient record, and number of health care professionals linked to each patient record; and activities performed by health care professionals in Congredi: frequency of activities (care, email, and process activities) and period in which activities took place per record (number of weeks).
du Pon et al. [36]	2019	RCT	GP practice	NL	193	12	Primary outcomes: Self-reported data. Secondary outcomes: HbA1c, body mass index (BMI), systolic blood pressure, and cholesterol levels.
Falgarone et al. [37]	2022	Feasibility	Health district	France	1715	as needed	Outcomes: Frequency of teleconsultation system use, profile of the types of users, association between use of the service and being in a GP-low density area, the reasons for e-consultation and what happened as a result

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Table 1 (continued)

Author	Year	Study Design	Setting	EU Country	N of participants	Follow up (M)	Primary and secondary outcomes
Gili et al. [38]	2020	RCT	GP practice	ES	221	12	Primary outcome: Depression. Secondary outcomes: health-related quality of life and functioning, positive and negative affect and general well-being.
Nagrebetsky et al. [39]	2013	Feasibility	GP practice	UK	14	12	Primary outcome: changes of HbA1c. Secondary outcomes: changes of oral glucose-lowering medication defined as changes in dose or quantity of medications at 6 months.
Larsen et al. [40]	2019	RCT	Health district	DK	2661	3	Primary outcome: attendance or non-attendance at the targeted GP-based health check. Secondary outcome: attendance or non-attendance at the Municipal Health Centre based counselling session.
Lagerin et al. [41]	2020	Feasibility	Health district	S	45	2	Primary outcome: District Nurses' identification of factors related to the quality and safety of medication use among older patients. Secondary outcome: to describe patients' experiences of this assessment.
Little et al. [42]	2016	RCT	GP practice	UK	3044	12	Primary outcome: reduction in number of GP contacts for patients with a respiratory tract infection. Secondary outcomes: use of antibiotics, symptoms, length and nature of infection, number of days of impaired activities, smoking status.
Little et al. [43]	2016	RCT	Health district	UK	826	12	Primary outcome: weight loss averaged over 12 months. Secondary outcomes: waist measurement, blood pressure, HbA 1c, liver function tests, self-reported measures of physical activity, and diet.
McManus et al. [44]	2021	RCT	Health district	UK	622	12	Primary outcome: difference in systolic blood pressure at 12 month follow-up between IG and CG. Secondary outcomes: systolic and diastolic blood pressure at six and 12 months; weight; patients' feelings of confidence about understanding their illness and their ability to manage, understand, and cope with their condition; and general health problems that occurred after receiving healthcare; drug adherence; health related quality of life; and side effects.
Lugo-palacios et al. [9]	2019	Retrospective	Government	UK	592	12	Primary outcome: hospital use. Secondary care outcomes: all emergency admissions, admissions for ACSCs, emergency attendances, GP referrals for outpatient appointments.
Martín-Lesende et al. [45]	2013	RCT	Health district	ES	58	12	Primary outcome: Number of hospital admissions that occurred in a period of 12 months post-randomisation. Secondary outcomes: length of hospital stay with a primary diagnosis of HF, CLD, mortality rates and use of other healthcare resources (emergency department attendances, home visits, appointments at the health centres and with the specialists and telephone calls).
Martín-Lesende et al. [46]	2017	quasi experimental	Health district	ES	42	12	Primary outcome: number of hospital admissions occurring 12 months before and after the intervention. Secondary outcomes: length of hospital stay and number of emergency department attendance
Pinnock et al. [47]	2013	RCT	Health district	UK	256	12	Primary outcome: Hospital Admissions and deaths. Secondary outcomes: The time until first hospital admission with a primary diagnosis of an exacerbation of COPD or all-cause deaths. Difference in mean number of bed-days for emergency admissions. The number and duration of admissions in which COPD is listed in the discharge letter as a factor in the admission. The number of exacerbations. Quality of life, anxiety and depression, Patient knowledge and self-efficacy, Engagement with process, cost effectiveness.
Nicolucci et al. [48]	2015	RCT	GP practice	IT	302	12	Primary outcome: HbA1c at 6 and 12 months. Secondary outcomes: percentage of patients with HbA1c, blood pressure and LDL at target.
Piette et al. [49]	2017	RCT	GP practice	F	103	NA	Primary outcome: delay, in days, between the initial GP's consultation and the dermatologist's reply allowing the patient or the GP's to begin treatment. Secondary outcomes: number of dermatology visits prevented and proportion of patients and GPs satisfied with the service, number of unusable photographs.
Ramallo-Fariña et al. [50]	2020	RCT	Health district	ES	2334	24	Primary outcome: mean change in HbA1c at 24 months. Secondary outcomes: BMI, weight, waist circumference, waist-to-hip ratio, blood pressure. Total, high-density lipoprotein (HDL), and low-density lipoprotein (LDL) cholesterol, triglycerides, and fasting serum glucose, serum creatinine and glomerular filtration rate.
Riippa et al. [51]	2014	quasi experimental	Health district	FIN	876	6	Outcomes: Patient activation.
Ronda et al. [52]	2018	RCT	Health district	NL	2778	12	Primary outcome: the proportion of patients that shifted to the correct treatment setting at one year follow-up. Secondary outcomes: number of different types of advice and the markers they were based on. Reasons for non-adherence to the advice.

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Table 1 (continued)

Author	Year	Study Design	Setting	EU Country	N of participants	Follow up (M)	Primary and secondary outcomes
Salisbury et al. [53]	2016	RCT	GP practice	UK	641	12	Primary outcome: the proportion of participants responding to treatment, defined as maintaining or reducing their cardiovascular risk after 12 months. Secondary outcome: cardiovascular risk score, blood pressure.
Sanchez et al. [54]	2018	RCT	Health district	ES	1088	24	Primary outcome: 24-month incidence of T2D confirmed by oral glucose tolerance testing. Secondary outcomes: self-reported physical activity and dietary changes at 12 months in a subsample.
Shah et al. [55]	2021	pilot/feasibility	home/ monitoring center	UK	35	14 days	Outcomes: total duration of phone calls
van der Weegen et al. [56]	2015	RCT	Health district	NL	199	9	Primary outcome: average minutes per day of PA per patient. Secondary outcomes: general self-efficacy, exercise self-efficacy, and quality of life.
van Gelder et al. [57]	2017	RCT	Health district- Hospital	NL	3004	12	Primary outcome: difference in referral rate between the telenephrology and control group, defined as the number of patients referred to secondary renal care. Secondary outcomes: difference in consultation rates by telephone or telenephrology and Quality of Care defined as adherence to the advised monitoring criteria from the Dutch interdisciplinary CKD guideline.
van Vugt et al. [58]	2016	pilot/feasibility	Health district	NL	132	6	Outcomes: self-reported diabetes self-care, diabetes-related distress, and emotional wellbeing.
Talboom-Kamp et al. [59]	2017	pilot/feasibility	Health district	NL	215	15	Primary outcome: usage of the online self-management platform. Secondary outcomes: mean number of sessions and mean number of services used.
Voncken-Brewster et al. [60]	2014	pilot/feasibility	Health district	NL	16	12	Outcomes: patients' self-management, patients' health status, the impact on the organization of care, and the level of application use and appreciation.
Orozco-Beltran et al. [61]	2017	quasi experimental	Hospital + Primary Care Centres	ES	521	12	Primary outcome: control of blood pressure and HbA1c. Secondary outcomes: visits to emergency services and hospital admissions.
Talboom-Kamp et al. [62]	2017	Cohort	Outpatient Clinics	NL	247	18	Primary outcomes: control of INR, n and type of severe complications. Secondary outcomes: use of platform, evaluation of self-management (self-monitoring INR+ self-dosage medication), evaluation of self-efficacy, evaluation sociodemographic characteristics and quality of life.
Karhula et al. [63]	2015	RCT	Health district	FIN	565	10	Primary outcomes: self-evaluated, health-related quality of life. Secondary outcomes: blood pressure, weight, waist circumference, triglycerides, total cholesterol, low-density lipoprotein, and high-density lipoprotein.
Littlewood et al. [64]	2015	RCT	GP practice	UK	691	24	Primary outcome: depression at 4 months. Secondary outcomes: depression; measures of mental health and health-related quality of life; treatment preference; acceptability of cCBT and experiences of users.
Plaete et al. [65]	2016	quasi experimental	GP practice	B	426	1	Outcomes: Self-reported fruit and vegetable intake assessed at baseline, 1 week, and 1-month postbaseline.
Priebe et al. [66]	2020	RCT	GP practice	D	1245	3	Primary outcome: pain intensity. Secondary outcomes: physical and mental wellbeing, as well as anxiety, depression and stress symptoms.
Romero-Sanchiz et al. [67]	2017	Cost effectiveness	GP practice	ES	296	12	Outcomes: cost-effectiveness and cost utility.
van den Brekel-Dijkstra et al. [68]	2016	pilot/feasibility	Health district	NL	230	6	Outcomes: participation rate, number of patients at increased risk for cardiovascular disease, self reported measures of lifestyle changes.
van Doorn-van Atten et al. [69]	2018	quasi experimental	Health district	NL	214	6	Primary outcome: nutritional status. Secondary outcomes: diet quality, appetite, physical functioning and quality of life.
Tabak M. et al. [70]	2014	RCT	Hospital + Primary Care Centres	NL	29	9	Primary outcome: use and satisfaction with telehealth program. Secondary outcomes: number of hospitalizations, length of stay, emergency department visits, number of COPD exacerbations; 6-minute walk test, dyspnoea and quality of life.
Kivi, M. et al. [71]	2014	RCT	Primary health centre	S	92	3	Primary outcome: measure of depression. Secondary outcomes: worsened depression or elevated risk of suicide during treatment.
Nordgren et al. [72]	2014	RCT	Primary health centre	S	100	12	Primary outcome: generic psychological well-being. Secondary outcomes: anxiety, depression, worsened depression or elevated risk of suicide, quality of life from a health perspective.
Iljaz et al. [73]	2017	RCT	GP practice	SLO	120	12	Primary outcome: change from baseline of HbA1c at 1 year. Secondary outcomes: the change from baseline of HbA1c, Body Mass Index, Patients' Functional Health Status, blood lipids, and blood pressure.
Holmen et al. [74]	2014	RCT	GP practice	N	151	12	Primary outcome: Change in HbA1c level after 1 year. Secondary outcome: self-management.

(continued on next page)

Table 1 (continued)

Author	Year	Study Design	Setting	EU Country	N of participants	Follow up (M)	Primary and secondary outcomes
Parsons et al. [75]	2019	RCT	Hospital + Primary Care Centres	UK	446	12	Primary outcome: HbA1c at 12 months. Secondary outcomes: HbA1c at 3, 6 and 9 months; percentage of people achieving the HbA1c target of ≤ 53 mmol/mol (7%) at 12 months; and total serum cholesterol, weight, BMI and waist circumference.

Health district: general term to indicate all the forms of Health district, Community Health Centre, Primary Care Centre, Municipal Health Centre.

European Countries:

UK: United Kingdom; S: Sweden; B: Belgium; NL: The Netherlands; DK: Denmark; ES: Spain; IT: Italy; F: France, Fin: Finland; Slo: Slovenia; N: Norway; D: Germany.

description of the outcomes investigated by population refer to Table 3.

Among the studies with primary outcomes available, 23 studies (42%) showed a statistical significance in primary outcomes. Among these, 10 of the studies focused on multimorbidity, chronic lung diseases or cardiovascular diseases, 7 on diabetes mellitus, 2 on mental health, 4 on the general population. In Table 2 are underlined the combinations of DHIs and organizational changes that demonstrated statistical significance. A statistically significant improvement in relevant measured outcomes has been found at least one time for each introduced DHI or combination of DHIs. DHIs are frequently implemented as a combination of technologies, however despite all the possible combinations, all the studies reaching statistically significant outcomes introduced, along with one or more DHIs, either a new figure or a multidisciplinary team as part of the organizational change to support the technology.

Discussion

Amidst the rapid digital transformation of the primary care delivery system in the last 10 years, this is the first comprehensive outline of the DHI types introduced in the primary care settings across the European context along with the organizational changes needed to complement the introduction of the new technologies. Moreover, the scoping review has analysed the grade of integration currently achieved by the complex integrated care models in which the DHIs have been deployed as well as the outcomes investigated in the context of the introduction of such complex interventions.

The identified DHIs were predominantly focused on the introduction of apps and platforms aimed at monitoring and managing the most prevalent chronic diseases. Such interventions were often administered along with structured support provided by healthcare professionals, mostly nurses. Indeed, the results highlighted that all the studies presenting statistically significant outcomes introduced either a new figure or a multidisciplinary team as part of the organizational change to support the technology. This underlines that in the European context, despite the fast development of new technologies [77], technology alone doesn't seem to be sufficient to drive change in outcomes in the primary care setting [78]. A reason behind this could be that digital health literacy is not consistently proceeding at the same pace of technological development [79], leaving patients with technical solutions that they might not be able to use [80,81]. However, it is interesting to note that the studies presenting statistically significant primary outcomes regarding the introduction of DHIs have been published over the last 5 years. A possible interpretation of this finding could be that adherence to technological prescriptions and digital literacy have recently started to improve, also thanks to the digital implementation boosted by the COVID-19 pandemic [77]. Technology is becoming part of everyday life, however, it's important to also consider the results of a recent study from Quinn et al. [82], highlighting that the vast majority of users (96.3%) tend to utilise unaccredited health information coming from unverified sources to answer some questions regarding their health. All these factors emphasize how guidance and professional support remain key aspects to avoid disinformation and empower users toward prevention and disease self-management in primary care, supported by

digital health strategies [83]. In support of this, it's interesting to notice that the apps or platforms for disease management and health prevention, the most prevalent type of DHIs introduced by the studies, are often administered along with structured phone support delivered by a trained health professional [27,40,44,48,60]. Moreover, risk stratification algorithms have started to appear, as a trend of the last 5 years [35,36,48,51,76], in population stratification models used to identify different levels of needs and interventions [84]. This is consistent with the fact that healthcare systems are shifting their focus on primary care, and especially toward the needs of the populations at risk of developing a disease [85]. Digital health, along with innovative models of care will certainly be at the forefront of this revolution [85]. Care is indeed expected to move from the hospital into the community and the home [86-88]. The trends of combinations of DHIs and organizational changes identified in this review demonstrate the beginning of this shift. Hospital-at-home programs are growing [55], boosted by the Covid-19 pandemic [89], demonstrating the first approaches toward vertical integration of services. Furthermore, DHIs are increasingly focusing on personalized medicine and person-centred care [90], increasing the capability of HCPs of predicting and preventing the deterioration of chronic diseases. This element is demonstrated by the prevalence in our review of apps/platforms for disease monitoring and management, along with the introduction of multidisciplinary groups of HCPs and the consistent use of telemedicine [35,36,48,51,76].

However, to be able to sustain a shift toward a more comprehensive delivery of care at the primary care level it's necessary to achieve vertical, sectoral and whole system integration of healthcare services [18]. Most of the interventions here included achieved more simple, horizontal integration of primary care models, which translated in the development of multi-disciplinary teams and/or care networks supporting a specific client group. Systematic integration between hospital and primary care settings was rarer and often driven by governmental initiatives [9,40]. Additionally, the interventions targeted mostly chronic common conditions such as cardiovascular and chronic lung diseases, however the search string did not retrieve any articles concerning the group of cancer patients [34]. Although this may be related to the fact that this group is mostly followed by outpatient cancer clinics, the incidence of this disease as a chronic condition is expected to sharply increase in the next years [91], which may translate in an increased delivery of care from primary care HCPs. Moreover, the available evidence regarding the efficacy of DHIs in association with the current models of care is weakened by the lack of randomized controlled trials and meta-analyses investigating the effectiveness of such combinations in the clinical practice and for each specific patient population. This is an important limitation, considering the pace of implementation of digital health initiatives [1,92].

Limitations. It is important to notice that often the clinical setting of the studies was not well described and therefore it results difficult to draw conclusions regarding the difference among health districts and primary health centres for example. A similar issue is encountered when looking at the standard of practice, often left without further explanations regarding the specific features of what has been considered 'standard of practice'.

Table 2
Introduction of complex interventions in the primary care settings composed by Digital Health Interventions and the related organizational change.

Introduction of complex interventions in the primary care settings				Level of integration achieved by the intervention				Outcomes investigated		
Digital Health Intervention (DHI)	N art	Organizational change	N art	Horizontal	Vertical	Sectoral	Whole system	Clinical	Humanistics	Economics
App/platform + CDSS	2	Multidisciplinary team + PCC	1 (Lesende et al., 2016) *	√						●●
		PCC	1 (Lagerin et al., 2020) *	√				●	●	
App/platform + CDSS + Teleconsultation/virtual clinic	2	Population stratification + PCC	1 (Priebe et al., 2020) *		√			●●●●	●	
		New figure + PCC	1 (Tabak et al., 2014)	√				●●●●	●●	●●●●●●●●
App/platform + CDSS + Teleconsultation/virtual clinic + EHR/ICT	4	New figure + PCC + multidisciplinary team	3 (Bardsley Et Al., 2013, Steventon Et Al., 2013; Rixon Et Al., 2015*)	√ √ √				●●●●	●	●●●●●●●●●●
		PCC	1 (Ronda et al., 2018)		√					●●●●
App/platform + CDSS + EHR/ICT	7	New figure + population stratification + PCC	4 (Bleijenberg et al., 2016 *; Bleijenberg et al., 2017; Larsen et al., 2019; Lugo-Palacios et al., 2019)			√	√ √ √		●	●●●●●●●●●●
		Population stratification + PCC + multidisciplinary team	2 (Orozco-Beltran Et Al., 2017 * Van Den Brekel-Dijkstra Et Al., 2016)		√		√	●	●	●●●●
		PCC + multidisciplinary team	1 (Ramallo-Fariña Et Al., 2020)	√				●	●●●●●●●●	
EHR/ICT + Teleconsultation/virtual clinic	7	New figure + PCC + multidisciplinary team	4 (Riippa et al., 2014 Basuved et Al., 2016 De Jong et al., 2016 Piette et al., 2017 *)	√	√ √ √			●	●	●●●●●
		multidisciplinary team	1 (Van Gelder et al., 2017)		√					●●
		PCC	1 (Shah et al., 2021)		√					●
		New figure	1 (Gili et al., 2020) *	√				●		
App/platform + EHR/ICT	19	New figure + PCC + multidisciplinary team	8 (Christensen et al.,2022a,* Christensen et al.,2022b, Ali et al., 2021, Barenfield et al., 2022, Voncken-Brewsten et al., 2014, Pinnock et al., 2013, De Battle et Al., 2021, McManus et al., 2021*)	√ √ √ √ √ √ √ √				●●●●●	●	●●●●●●●●●●●●●●●●
		New figure + multidisciplinary team	2 (Larsen et al., 2013*, Nicolucci et al., 2015*)	√ √				●●●●		
		PCC + multidisciplinary team	3 (Plaete et al., 2016*, Sanchez et al., 2018*, Iljaz et al., 2017)	√ √ √				●●	●●●●	
		New figure + person centred care	5 (Talboom-Kamp et al., 2017a*, Holmen et al., 2014, Parsons et al., 2019, Karhula et al., 2015, Littlewood et al., 2015*)	√ √ √ √ √				●●●●●	●	●●●●●●●●●●
		New figure	1 (Salisbury et al., 2016)		√				●	
App/platform	11	PCC + Multidisciplinary team	6 (Van Der Weegen et al., 2015*, Van Vugt et al., 2016, Talboom-Kamp et al., 2017b, Van Doorn-Van Atten et al., 2018, Martin-Lesende et al., 2013* Martin-Lesende et al., 2017*)	√ √ √ √ √ √				●●●●	●	●●●●●●●●●●
		New figure + PCC	2 (Du Pon et al., 2019, Avila et al., 2018)	√ √				●	●●●●	●
		New figure	3 (Romero-Sanchiz et al., 2017, Kivi et al., 2014, Nordgren et al., 2014)	√ √ √				●●●●	●	●
App/platform + TC/virtual clinic	2	Multidisciplinary team + PCC	1 (Little et al., 2016) *	√				●	●●●●●●	
		New figure	1 (Falgarone et al., 2022)	√						●●●●●●

TC: teleconsultation; VC: virtual clinic; EHR: electronic healthcare record; App/platform: app/monitoring platform for disease monitoring/health promotion

Outcomes investigated
 ●: primary outcomes
 ●: secondary outcomes
 ●: outcomes coming from studies where primary outcomes were not specified.
 *: statistically significant primary outcomes

Table 3
Type of primary outcomes investigated by patient population

Population	Outcomes		
	Clinical	Economics	Humanistics
Chronic Multimorbidity	Control of blood pressure and HbA1 [61]	Differences in numbers of GP and PN contacts over twelve months [23] Hospital Admission [24] Characteristics of HCPs using the digital tool [35] Patient activation toward DHI [51] Identification by nurses of factors related to the quality and safety of medication use among older patients [41] Hospital use [9] N of hospital admissions [46]	Quality of Life [25]
Cardiovascular Diseases	General self-efficacy [27] General self-management [60] Exercise capacity - average oxygen uptake [29] Likelihood to attend the targeted GP-based health check [40] Difference in systolic blood pressure at 12 month [44] Proportion of participants maintaining or reducing their cardiovascular risk after 12 months [26] Control of INR and incidence of severe complications [62].	Meaningfulness for patients of combined digital platform and structured telephone support [28] Number of hospital admissions [45] Average minutes per day of PA per patient [56] Usage of the online self-management platform [59]	Self-evaluated, health-related quality of life [63]
Diabetes Mellitus	Reduction in HbA1c \geq 6 mmol/mol (0.5%) at 12 months [26] Weight loss from baseline at 24 months [32] Mean body weight [33] Changes in physical and mental health status [76] Changes in HbA1c [39] HbA1c at 6 and 12 months [48] Change in HbA1c levels from baseline to 24 months [50] Self-reported diabetes self-care [58] Change from baseline of HbA1c at 1 year [73] Change in HbA1c level after 1 year [74] HbA1c at 12 months [75]	Usage of the e-Vita online care platform [36]	Self-evaluated, health-related quality of life [63]
Chronic Lung Disease	General self-efficacy [27] General self-management [60] Changes in physical and mental health status [76] N of deaths [47]	Meaningfulness for patients of combined digital platform and structured telephone support [28] N of hospital admissions [45] N of hospital admissions [47] Average minutes per day of PA per patient [56] Use of web portal [70] Proportion of patients that shifted to the correct treatment setting (primary vs nephrology care) at one year follow-up [52] N of patients referred to secondary renal care compared to control [57]	
Kidney Diseases		Delay, in days, between the initial GP's consultation and the dermatologist's reply, and the consequent beginning of treatment [49] cost effectiveness at 12-month follow-up [67]	
Dermatology Diseases			
Nervous system, Mental Health and Psychiatric Diseases	Pain intensity [66] Measure of depression [71] Psychological well-being [72] Presence and severity of depression [38] Presence and severity of depression at 4 months [64]		
Populations at risk for morbidity/frail population	Weight loss averaged over 12 months [43] 24-month cumulative incidence of T2D confirmed by oral glucose tolerance testing [54] Nutritional status [69] Self-reported fruit and vegetable intake assessed at baseline and postbaseline [65]	Intervention participation rate [68] incremental cost per quality-adjusted life-year [30]	Daily functioning [31]
General Population		Frequency of teleconsultation system use [37] Total duration of phone calls for patients in Covid-19 virtual ward [55]	

Legenda:

GP: general practitioner

PN: practice nurse

HCPs: healthcare professionals

Conclusions

This is the first comprehensive outline of all the types of DHIs that have been introduced in the primary care settings across the European context in the last 10 years along with the organizational changes needed to complement the introduction of the new technologies. The identified DHIs were predominantly focused on the introduction of apps and platforms aimed at monitoring and managing the most prevalent chronic diseases, in particular diabetes, cardiovascular diseases and chronic lung disease. All the studies presenting statistically significant outcomes introduced either a new figure or a multidisciplinary team as part of the organizational change to support the technology. The prevalence of complex integrated care models applying forms of horizontal integration across Europe highlights the common challenge of achieving comprehensive integration across primary, community, hospital, and tertiary care services. Future research efforts should focus on the development of transversal communication and management platforms across services, along with the investigation of the effectiveness of current complex integrated care models introducing DHIs in their clinical practice.

Summary table

- Novel complex integrated care models are focusing on introducing multidisciplinary perspectives and personalization of care, in line with the complex needs of chronic patients.
- The predominant DHIs introduced in clinical practice in the European context are app and platform for disease monitoring and management
- All the studies presenting statistically significant outcomes introduced either a new figure or a multidisciplinary team as part of the organizational change to support the technology.
- The current level of integration achieved by European health services seem to remain horizontal integration, with the development of multi-disciplinary teams and/or care networks that support a specific client group.

Multimedia Appendix 1

MEDLINE Search Via PubMed

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Ethical approval

Due to the nature of the study, a scoping review, ethical approval from an ethical committee was not needed.

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CRedit authorship contribution statement

E. Mezzalira: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Software, Visualization, Writing – original draft, Writing – review & editing. **F. Canzan:** Conceptualization, Funding acquisition, Methodology, Resources, Supervision, Validation, Writing – review & editing. **G. Marini:** Data curation, Formal analysis, Writing – review & editing. **J. Longhini:** Data curation, Formal analysis, Validation, Writing – review & editing. **C Leardini:** Conceptualization, Funding acquisition, Supervision, Writing – review & editing. **L. Saiani:** Funding acquisition, Supervision, Writing – review &

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Declaration of competing interest

No conflicts of interest to report by the authors.

Supplementary materials

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