

Review article

Effectiveness of digital health interventions for chronic conditions management in European primary care settings: Systematic review and meta-analysis

Elisa Ambrosi^{a,*}, Elisabetta Mezzalana^a, Federica Canzan^a, Chiara Leardini^b, Giovanni Vita^{c,d}, Giulia Marini^a, Jessica Longhini^a

^a Dipartimento di Diagnostica e Sanità Pubblica Università di Verona Verona Italy

^b Dipartimento di Management Università di Verona Verona Italy

^c WHO Collaborating Centre for Research and Training in Mental Health and Service Evaluation Italy

^d Department of Neuroscience Biomedicine and Movement Sciences Section of Psychiatry University of Verona Verona Italy

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ABSTRACT

Background: The past decade has seen rapid digitalization of healthcare, significantly transforming healthcare delivery. However, the impact of these technologies remains unclear, with notable gaps in evidence regarding their effectiveness, especially in primary care settings.

Objective: This systematic review assesses the effectiveness of digital health interventions versus interventions without digital components implemented over the last 10 years in European primary care settings for managing chronic diseases.

Methods: Following Cochrane guidelines, we conducted a systematic review with meta-analysis. We searched multiple databases for randomized controlled trials. Inclusion criteria encompassed studies on digital health interventions for chronic disease management in primary care settings in Europe, evaluating outcomes such as hospitalizations, quality of life, and clinical measures. Data extraction and quality assessment were independently conducted by two authors, with discrepancies resolved by a third author. The certainty of the evidence was judged according to the Grading of Recommendations, Assessment, Development, and Evaluation approach.

Results: From 9829 records, 23 studies were included, with most studies conducted in the UK and Spain. The most investigated conditions were type 2 diabetes and hypertension. Interventions mainly focused on patient monitoring, self-care education, and digital communication tools. The risk of bias was low to moderate for most studies. Meta-analyses showed no significant differences between digital health interventions and usual care for hospitalizations, depressive symptoms, anxiety, HbA1c, diastolic blood pressure, weight, or quality of life, except for a small improvement in systolic blood pressure.

Conclusion: Digital health interventions have not yet demonstrated substantial benefits over traditional care for chronic disease management in European primary care. While some improvements were noted, particularly in systolic blood pressure, the impact remains limited. Further research is needed to enhance the effectiveness of digital health interventions, address current methodological limitations, and explore tailored approaches for both specific patient populations and multimorbid populations.

1. Introduction

The last decade has been characterized by the fast pace of technological innovation and digitalization of services, which has revolutionized healthcare delivery. In 2023, the World Health Organization (WHO) published the first classification of digital health interventions

(DHIs), defining for the first time the term “Digital Health Intervention” as a discrete functionality of digital technology to achieve health sector objectives [1]. This tool highlights the different ways in which digital and mobile technologies have started to be used to support health system needs. Digital health interventions feature many technologies, including telemedicine, mobile health apps, electronic health records

* Corresponding author at: Dipartimento di Diagnostica e Sanità Pubblica, Università di Verona, Verona, Italy.

E-mail address: elisa.ambrosi_01@univr.it (E. Ambrosi).

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(EHRs), wearable devices, and artificial intelligence (AI)-powered diagnostic tools. These technologies collectively aim to enhance the efficiency, accessibility, and quality of care. Telemedicine, for instance, breaks down geographical barriers, allowing patients in remote or underserved areas to consult with healthcare professionals without needing physical travel [2].

However, as Ibrahim [3] highlights in their systematic mapping of review studies on digital health for quality healthcare, the exponential rise of digital health adoption over the last two decades may have created a challenge in establishing the extent of impact from digital health technologies on quality healthcare, including ethical concerns on information security, acceptability on new practice, and whether the technology is practical and feasible to be implemented in real practice. Moreover, many gaps of evidence remain regarding the investigation of the effectiveness of DHIs in clinical practice and different patient populations [4]. Most of the studies and reviews conducted on the effectiveness of digital health interventions have, to date, focused on hospital settings and psychiatric care [3,5].

The current trajectory of healthcare delivery, with the known problems of the ageing population and the increase in chronic conditions, highlights the importance of strengthening primary healthcare to ensure long-term system sustainability of high-quality care delivery [6,7]. In this regard, the European countries have recently adhered to a new WHO strategy for the European Region [8] aiming to realize the potential of primary care, underlining that the digital age provides leapfrogging opportunities to strengthen this capacity at the practice level. However, despite the rapid digital transformation of primary care practices [9], digital health interventions (DHIs) introduced for the specific needs and contexts of primary care practice in the European countries have yet to be systematically evaluated.

Moreover, the existing studies report mixed outcomes and effects [10–12], and it is important to point out a paucity of studies carrying on analyses of digital health interventions in primary care settings for chronic diseases and patients with multimorbidity [13]. For this reason, this systematic review aims to assess the effectiveness of the digital health interventions introduced in the last 10 years in the European primary care settings for chronic diseases.

2. Methods

2.1. Design

We conducted a systematic review with meta-analysis according to Cochrane guidelines [14] and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [15]. The protocol was registered in PROSPERO database (CRD42023481786).

2.2. Literature search and inclusion criteria

Two authors independently (*blinded for reviewers*) searched Medline, Cochrane Library, Web of Science, Scopus, PsycINFO, and Cumulative Index to Nursing and Allied Health Literature, and clinicaltrials.gov, from 1st January 2013 start date until December 31st, 2023. The search strategy was developed in close collaboration with a librarian (SF 1). The search results from the two authors were compared to identify any discrepancies.

We included studies meeting the following inclusion criteria: a) randomized controlled trials (RCTs) or pilot RCTs; b) enrolling patients of all ages; c) with one or more chronic disease(s); d) investigating digital interventions defined as a discrete functionality of digital technology aimed at achieving health objectives, implemented within digital health applications and ICT systems, including communication channels such as text messages [16]; e) comparing digital interventions against usual care or enhanced usual care without digital components; f) conducted in primary care settings; g) evaluating outcomes such as

hospitalizations, quality of life, self-efficacy, weight loss, HbA1c, depression, blood pressure, use of digital health technologies; h) published in European countries (SF 2); i) published in English or Italian. Studies involving pregnant women were excluded.

2.3. Screening process and data extraction

Two authors (*blinded for reviewers*) independently reviewed the titles and abstracts of all studies. Subsequently, they examined the full texts, achieving an inter-rater agreement level of 0.84 (Cohen's kappa, Confidence Interval [CI] 95 % 0.70–0.91), indicating good reliability [25]. Any disagreements were resolved by a third author. Additionally, two authors (*blinded for reviewers*) independently extracted data, including the first author, study design, country, inclusion criteria, population characteristics, intervention details, outcomes measured (types and values at each available follow-up), and related assessment instruments. This data was organized and tracked using an Excel spreadsheet. A third author compared the two independent extractions and found no discrepancies. For missing data, the corresponding authors of the included studies were contacted for clarification.

2.4. Assessment of evidence quality and certainty

Two authors (*blinded for reviewers*) conducted the quality assessment independently. The risk of bias was evaluated using the revised Cochrane risk of bias tool for randomized trials (RoB 2) and the risk of Cochrane risk of bias tool for cluster randomized trials. A third author resolved any disagreements. The certainty of the evidence for each outcome category was assessed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [28].

2.5. Data analysis

A meta-analysis was performed by combining studies with homogeneous intervention characteristics (i.e., distinguishing digital interventions for patients from those for professionals). Studies that did not provide useful data and for which data could not be obtained from the authors were not included in the meta-analysis.

If the standard error or 95 % confidence interval (CI) were reported instead of the standard deviation (SD), these were calculated according to Cochrane's Handbook [14]. To increase the precision of the estimate, mean change scores within groups were used when available.

The intervention effect size was calculated using Hedges' *g* standardized mean difference (SMD), with SMD values of 0.20, 0.50, and 0.80 interpreted as small, moderate, and large differences between groups, respectively [14]. Given the heterogeneity among populations and intervention components [33], a random-effects model was applied. Heterogeneity was measured using the I^2 statistic, with values of 30 %–60 % indicating moderate heterogeneity and over 75 % indicating substantial heterogeneity [14]. Subgroup analysis was performed when a moderate or substantial heterogeneity was detected, and the number of studies provided was sufficient.

A sensitivity analysis was performed to test the robustness of the results within each outcome category by removing studies at high risk of bias. The analysis was conducted using Review Manager 5.4 [17] and the *metafor* package in R Software [18]. If meta-analysis was not feasible, results were summarized narratively.

3. Results

3.1. Characteristics of the studies

From a total of 9829 records, we included 23 RCTs (Fig. 1), of which six were cluster RCTs [12,19–23] (Table 1). Most of the studies were conducted in the United Kingdom [21,24–30] ($n = 8$) and Spain [12,23,31] ($n = 3$). The sample sizes ranged from 47 [29] and 2334

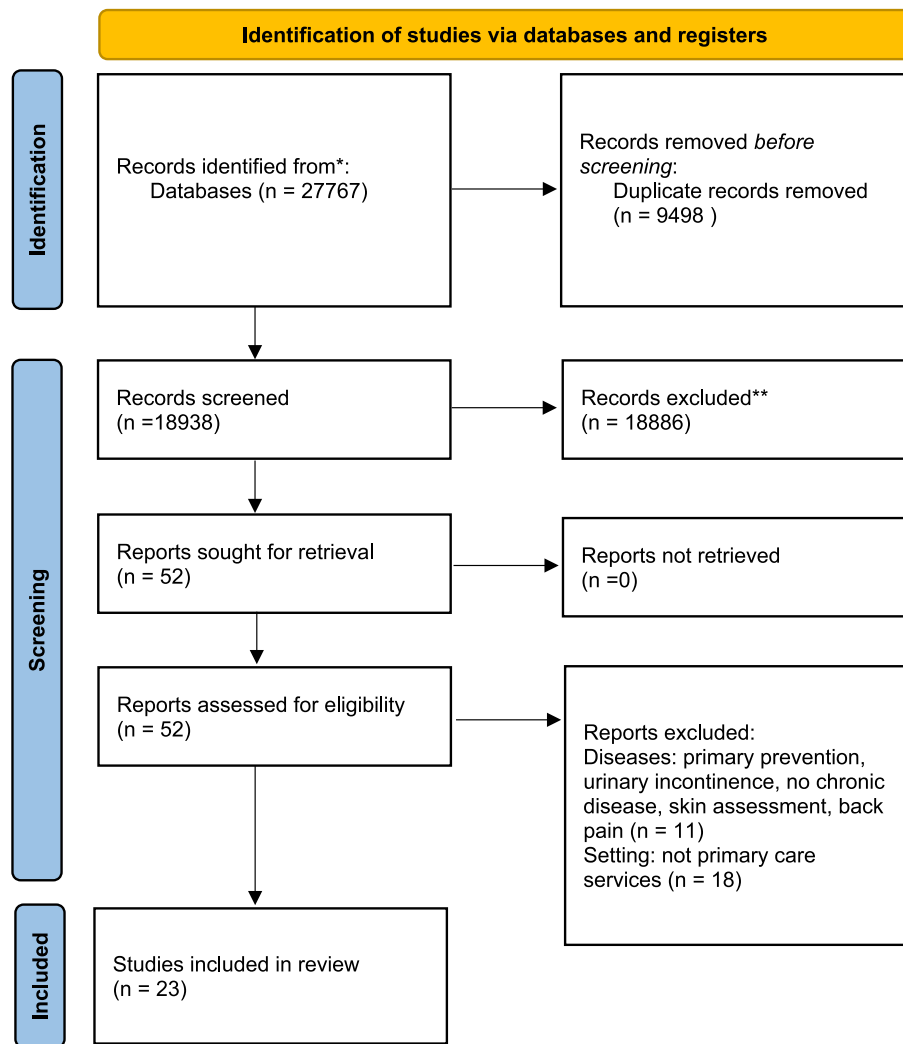


Fig. 1. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only.

[12], with a mean of 419 participants (IQR 167–502). The most frequently investigated disease was Diabetes type 2, studied in 10 studies [10–12,22,24,28,32–35], with two of these also addressing COPD [22] and cardiovascular (CVD) diseases [10]. Hypertension was the focus of five studies [23,25–27,29], while depression was investigated in four studies [19,31,36,37]. Most studies ($n = 19$) [10,11,21,23,25–38] examined digital interventions for patients (Table 1, SF3). Of these, seven studies explored interventions based on health education, aimed primarily at lifestyles changes and enhancing self-care abilities through coaching, phone calls, online consultations, digital platforms, mobile apps, goal plans [29,32,33,38], or online therapy for depression [31,36,37]. Five studies focused on remote monitoring with digital devices to measure parameters such as blood pressure and oxygen saturation [11,25–27,30], and seven studies combined online health education with remote monitoring [10,21–23,28,34,35]. Among the remaining studies, four combined digital interventions for both professionals and patients [12,19,24], evaluating clinical decision support aids [19,20], virtual clinics integrating specialist diabetes and primary care professionals [24], or training programs for professionals on disease management [12] (Table 1, SF3). The median follow-up duration was 12 months (IQR = 6–12 months, range 1.5 – 24 months).

3.2. Risk of bias

Among the 17 RCTs, one was judged to have a high risk of bias, primarily due to missing outcome data (Fig. 2). Five studies were assessed as having a moderate risk of bias, and 11 were found to have a low risk of bias. The moderate risk of bias in these studies was attributed to concerns about the randomization process in two studies, deviations from the intended interventions in one study, outcome measurement in one study, and the selection of reported results in two studies.

For the six cluster RCTs (Fig. 2), three studies were determined to have a low risk of bias, while the other three had a moderate risk of bias. The moderate risk of bias in these cluster RCTs was due to concerns in the randomization process in one study, missing outcome data in another study, and outcome measurement in one study.

4. Outcomes

4.1. Hospitalizations

Three studies evaluated hospitalization rates and found no difference between the intervention and control groups (SF 4).

4.2. Depression

Six studies investigated depressive symptoms, and five of them

Table 1
Characteristics of studies included.

Author (Year), Country	Setting	Sample size N ^a , inclusion criteria	Intervention and control
Interventions based on health coaching or online therapy			
Ali et al. (2021) Sweden	Primary healthcare center	Patients with COPD and CHF having access to a device with internet 224 patients; IG: 112; CG: 110	IG: Structured telephone support (optional number of calls + health plan co-created and followed up by patients) + digital platform support (for phone calls + access to shared health plans and self-ratings) for 6 months by HCPs CG: Usual care – no follow-up phone conversations
Christensen et al. (2022) Switzerland	General practice or in the municipality where the participant lives	Patients with T2DM, aged 18–70 years, and a BMI of 30–45 kg/m ² , with internet access via computer or smartphone. Recruitment was conducted through advertising campaigns in local newspapers, on Facebook, other social media platforms, local community channels, general practices, and patient organizations. 170 participants; IG: 100; CG:70.	IG: Lifestyle Coaching Programme: app + daily record, comments, concerns, and questions for the health coach + agreed goals for diet, physical exercise, sleep, and any other relevant lifestyle areas that the patient was motivated to improve + synchronous online consultation by health coach (weekly for 3 months + biweekly for 3 months) CG: follow-up examinations at the same frequency as the intervention group + referral to their GP for guidance about their health problems and referral to municipality programmes (education about diet, exercise)
Du Pon et al. (2019) Netherlands	8 general practices	Patients aged over 18 years with T2DM 203 participants; IG:101; CG:102	IG: online care platform (e-Vita) aimed to support patients' self-management skills + PRISMA – Proactive Interdisciplinary Self-management education program: 2 group meetings about type 2 diabetes, guided by PNs and a dietician specializing in diabetes care on blood glucose levels, medication, nutrition, physical activity, complications, and personal risk factors and in which stage of change the patients consider themselves with respect to their nutrition and physical activity, complications and personal risk factors, nutrition (fat), and the patient's individual diabetes action plans. The participants were stimulated to continue discussing their goals and actions with their HCP after completing the course.CG : two to four visits per year with the PN and at least one annual check-up with the GP. In the IG, the participants started receiving PRISMA along with usual care. The CG participants continued to receive usual care and were offered PRISMA after 6 months.
Gili et al. (2020) Spain RCT 4 arms	Primary care settings from 3 Spanish regions	Patients with major depression or dysthymia, with mild or moderate depression according to the PHQ-9; 5–9: mild depression; 10–14: moderate depression), with symptoms > 2 weeks 221 participants; IG1 (HLP): 54; IG2 (PAPP) : 56 IG3(MP) : 5; CG: 57	For all the groups: One face to face session + web-based therapeutic modules oriented on different psychological techniques. Each module lasted approximately between 40 and 60 min + 2 weekly automated mobile phone message to motivate the adherence + improved treatment as Usual improved: participating GP will receive a training program on a widely used Spanish Guide for the Treatment of Depression in Primary Care IG1: web-based modules on "healthy lifestyle psychoeducational program" focussed on the relationship between physical and mental health and physical activity, diet and sleep control IG2: web-based modules on "program on positive affect promotion" focussed on decrease depressive symptomatology and to prevent relapses using the promotion of wellbeing and positive affect IG3: web-based modules on "Brief intervention based on mindfulness" focussed on decrease depressive symptomatology using mindfulness, emphasizing the benefits of this therapy CG: improved treatment as usual
Kivi et al. (2014) Sweden	16 Primary Care Centers	Patients aged > 18, access to a computer with speakers or headphones, with depression according to the MINI, and a MADRS-S score. Participants: 92; IG: 44; CG: 46	IG1: Internet-based cognitive behavior therapy of seven modules over 12 months, each one of 8– 10 slides + workbook with fill-in diaries and exercises + CD with mindfulness and acceptance instructions were included + weekly contact via e-mail with their therapist + 3 15-minutes phone calls from the therapist.CG: usual care (visits to general practitioner, registered nurse, antidepressant drugs, waiting list for, or psychotherapy, or combinations of these alternatives)
Littlewood et al. (2015) United Kingdom RCT 3 arms	Primary care	Patients with depression who scored ≥ 10 on the PHQ-9 9691 participants; IG1 (Beating the Blues): 210 IG2 (MoodGYM) : 242; CG:239	IG 1: Computerised cognitive behaviour therapy by MoodGYM (free): 15-minute introductory video + 8 therapy sessions with homework exercises between sessions. IG2: Computerised cognitive behaviour therapy by Commercial pay-to-use program Beating the Blues®CG: usual GP care.
Payne Riches et al. (2021)	5 general practice	Patients with the last 2 years systolic BP > 130 with antihypertensive medication or systolic BP > 140 without antihypertensive medication; to own a smartphone, being responsible for household grocery	IG1: app helps to choose lower salt food in the market + advice to swaps and nutrition information + patient's sharing of successful swaps in social networks + recording of grocery shopping and grocery shopping receipts over 6 weeks + SMS was sent if the participant didn't collect

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Table 1 (continued)

Author (Year), Country	Setting	Sample size N ^o , inclusion criteria	Intervention and control
		shopping 47 participants; IG: 31; CG: 16	shopping data or didn't access the app within 7 days, or didn't use the app, for 10 days, after the first access. CG: pamphlet with advice on reducing salt.
Interventions primarily based on remote monitoring McKinstry et al. (2013) United Kingdom	20 primary care practices	Patients aged > 18 with hypertension whose last surgery BP was > 145 mmHg systolic or > 85 mmHg diastolic were asked to attend a screening assessment. 401 participants; IG:200; CG:201	IG: Self-measurement + transmission of BP to a secure website for review by the attending nurse or doctor and participant, with optional automated patient decision support by text or email for 6 months. Participants and clinicians could log on to a website to see the data, and automated SMS texts or emails could be sent to participants with feedback on their blood pressure control.CG: usual care
McManus et al. (2018) United Kingdom RCT 3 arms	142 general practices	Patients > 35 years, with hypertension, taking ≤ 3 antihypertensive agents, but with clinic blood pressure not controlled below 140/90 mm. 1182 participants; IG1 self-monitoring group: 395 IG2 the telemonitoring group: 393; CG: 394	IG1: telemonitoring group retrained to send readings via a simple free SMS text-based telemonitoring service with web-based data entry back-up + algorithm that alerted participants to contact their surgery in the light of very high or very low readings, reminded them if insufficient readings were transmitted, prompted them to make contact with their practice if their average blood pressure was above target, and presented readings to attending clinicians via a web interface. This secure web page automatically calculated mean blood pressure for each monitoring week, highlighted very high or very low readings, and presented a graphical display of blood pressure measurements.IG2 (CG2) : self-monitoring aloneCG: usual care
McManus et al. (2021) United Kingdom	76 general practices	Patients > 18, with treated hypertension, a mean baseline BP reading > 140/90 mmHg, taking no more than three antihypertensive drugs. For the digital intervention: willing to self-monitor, having access to the internet (with support of a family member if needed). N: 622 patients, 76 general practices. IG:305. CG: 317.	IG1: online instructions on how to correctly undertake self-monitoring + automated email reminders to take two-morning BP for 7 days each month + telemonitoring + feedback of blood pressure results to patients and professionals (BP very high or very low patients were advised to call their GP within 3 days; if BP was controlled for 3 consecutive months, patients were advised to reduce BP monitoring to 1 every 8 weeks or 1 every month if BP increased) + optional lifestyle advice and motivational support after nine weeksCG: usual care (routine hypertension care, with appointments and drug changes made at the discretion of the GP)
Nicolucci et al. (2015) Italy	29 GPs	Patients > 45, with type 2 diabetes, in treatment with sulfonylureas, HbA1c between 7–10 and BP > 130/80 mmHg 302 participants; IG: 153; CG: 149	IG1: weight scale, sphygmomanometer and glucometer connected to a telehealth system sending data to a web platform, accessible to each patient and his GP + "call-me button" to be contacted by the telehealth centre 24 h/day + generation of reports on measurements + reminders, alerts or notifications for the GPs or patients as needed + nursing call once a week to assess compliance with monitoringCG: standard of care without telehealth system.
Pinnock et al. (2021) United Kingdom	Primary care	Patients admitted to hospital with an exacerbation of COPD in the previous year, of all ages and with a range of comorbidities 256 participants; IG: 128; CG:128	IG1: touch screen telemonitoring equipment for oxygen saturation + daily questionnaire about symptoms and treatment use + alerts generated by algorithms based on the symptom scoreCG: usual care
Interventions combining online health education and remote monitoring Marquez – Contreras et al. (2018) SpainCluster RCT	Four primary carecenters	Patients aged over 18 years with mild to moderate hypertension, in pharmacological treatment with an antihypertensive tablet at least 1 month before inclusion 154 patients; IG: 77; CG: 77	IG: AlerHTA App for reminders of appointments and medication intake time + record personal data + recommended BP levels as objectives + doctor's advice about the prescribed treatment and posology + set reminder alarms + a calendar of appointments or events + record the results of the BP measurement; Medication Event Monitoring Systems to record how many times pills was takenCG: standard of care
Holmen et al. (2014) NorwayRCT, 3 arms	General practice	Patients aged ≥ 18 years, HbA1c level ≥ 7.1 % 151 participants; IG1: 51; IG2: 50; CG: 50	IG1: mobile phone–based self-management system Few Touch Application: blood glucose–measuring system with automatic wireless data transfer, diet manual, physical activity registration, and management of personal goals, all recorded and operated using a diabetes diary app on the mobile phone. IG2: FTA + health counselling based on behaviour change theory and delivered by a diabetes specialist nurse. Counselling was delivered through phone-based conversations each month for 4 months. The calls contained 5 structured modules developed to support self-management and the use of the FTA. A few days before the call, the diabetes specialist nurse sent a standardized text message through a secure system that allowed the participants to respond or send questions.CG: conventional care for diabetic patients, according to Slovenian professional guidelines.

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Table 1 (continued)

Author (Year), Country	Setting	Sample size N ^o , inclusion criteria	Intervention and control
Iljaž et al. (2017) Slovenia	22 solicited family practices from 6 different regions	Patients aged between 18–75 years with T2DM who are not using insulin, and have Internet connection and access to a computer; having a mobile phone; sufficient Internet and e-mail skills Participants: 120; IG: 58; CG: 62	IG: The eDiabetes app consisted of a web portal for patients and healthcare providers, with a patient-oriented interface for individualised care and education material (informational handouts, web addresses, articles, and instructions to help diabetic patients). Every two weeks, IG patients recorded data, including their body weight, blood pressure, diet, and physical activity, and completed some additional questionnaires during the study. In case of medical emergencies, a warning was issued to immediately contact the medical emergency services. CG: usual care
Karhula et al. (2015) Finland	Social and Health Care District	Patients aged over 18 years with a) T2DM from at least 3 months, HbA1c > 6.5 % within 1 year, or b) ischemic heart disease, heart failure, or both. 565 participants; IG1 (heart patients): 222; CG1 (heart patients): 86; IG2 (diabetes): 208; CG2 (diabetes) : 79	IG: Health coaching through regular calls (every 4–6 weeks) with self-management plans and self-monitoring of health parameters (BP, body weight, blood glucose level for diabetics, and step count for heart disease patients) through a remote patient monitoring system consisting of a mobile phone with specific software, a mobile personal health record app, and a set of measurement devices connected to the patient's account. CG: standard of care
Parsons et al. (2019) United Kingdom RCT 3 arms	GP practices	Patients aged between 18—80 years, with T2DM for at least 1 year, HbA1c between 58 and 119 (7.5–13 %) not receiving insulin therapy. 446 participants; IG1: 147; IG2: 148; CG: 151	IG1: self-monitoring of blood glucose + monthly telephone consultation with a trained study nurse (TeleCare) IG2 (CG2): self-monitoring of blood glucose All participants in the IG groups were offered the AccuChek 360 ^o Diabetes Management System software (as used by the study nurses) to use at home if they wanted. CG : receiving usual care + contact with their diabetes team, GP or hospital clinic, as normal
Rixon et al. (2015) United Kingdom Cluster RCT	121 General Practices	Patients aged > 18, with COPD, with a landline telephone and broadband internet connection 578 participants; IG: 334; CG: 244	IG: pulse oximeter + additional monitoring devices depending on clinical need connected to a home-monitoring system comprising a base unit with an LCD screen to allow questions about health and educational messages to be transmitted to participants, or a set-top box that is connected to a television allowing symptom questions, educational videos and a graphical history of clinical readings. CG: usual care
Van der Weegen et al., (2015) Netherlands Cluster RCT 3 arms	24 GP practices	Patients aged between 40–70 years, with T2DM or COPD, not exercising for at least 30 min, able to access a computer with an Internet connection Additional criterion: DM2 patients: BMI > 25; COPD patients: clinical diagnosis of COPD according to the GOLD-criteria stage 1–3, stable for 6 weeks, and on a stable drug regimen. 199 participants; IG1: 65; IG2: 66; CG: 68	IG: accelerometer + smartphone app + server/web application + personalised feedback on the smartphone on their amount of activity in relation to an activity goal decided with their Practice nurse (PN) after a two-week + messages (e.g., tips, encouragement, positive trend, reward, barriers, facilitators and the suggestion to adjust goals) + self-management program IG2 (CG2) : self-management program: 4 consultations with the PN at week 1, at week 2, at 2–3 months, and at 4–6 months + information booklet with the SQUASH questionnaire and a list of local PA activities + discussion about inactivity risks and the patient's PA level using the SQUASH questionnaire + barriers and facilitators to PA + PA diary + daily activity goal and plan. Consultations followed the "Five 'A's Cycle": assess, advise, agree, assist, and arrange CG: usual care
Interventions combining digital tools for health professionals to support the delivery of care			
Balestrieri et al. (2020) Italy Cluster RCT	4 GP clinics for a total of 13 GPs	Patients aged 18—65 and moderate depressive symptomatology, defined by a score ≥ 11 on the Patient Health Questionnaire (PHQ)-9 and ≥ 26 on the Inventory of Depressive Symptoms Self-Report (IDS-SR) 98 patients; IG: 66; CG: 32 patients	IG: Computerized treatment system with the following functions: (i) provide information to the GPs regarding patients' severity of depression; (ii) support the GPs in the choice of the best treatment option; (iii) increase patients' treatment adherence by means of SMS; (iv) track GPs' clinical decisions about patients' depression; (v) provide suggestions about the management of possible side effects. The platform also included a section with additional materials of potential help to the GP: how to prevent relapses, possible psychotherapeutic options and a table summarizing the properties of the most important antidepressant medications, including official dosage recommendations. CG: usual care
Basuved et al., (2015) United Kingdom	6 general practices	Patients with T2DM of > 1 year duration; HbA1c > 69 mmol/mol (> 8.5 %); age ≥ 18 years 235 patients; IG: 79; CG: 88	IG: Professional-to-professional diabetes virtual clinics for integrating specialist diabetes and primary care for: systematic case identification; a virtual clinic in which cases are jointly discussed by the GP and DVC teams, to determine clinical and therapeutic needs (risk factors, clinical data, complications and other comorbidities) and therapy review (level of optimization), self-management needs and the most appropriate care provider; formulation of a management plan (therapy changes or adjustments; lifestyle areas and targets; and individualized clinical targets); decision regarding patient care allocation to either: primary, intermediate or secondary care; a face to face

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Table 1 (continued)

Author (Year), Country	Setting	Sample size N ^o , inclusion criteria	Intervention and control
Tabeo Jungo et al. (2023) Switzerland Cluster RCT	43 general practitioner	Patients aged ≥ 65 years, were taking five or more long-term medications (≥ 90 days), with at least three chronic conditions on the basis of ICPC-2 323 participants; IG: 160; CG: 163	appointment with the most appropriate member of the clinical team to develop an agreed care plan with the patient; and follow-up by the intermediate care team to evaluate the execution of the management and care plans. CG: standard of care Structured a six-step medication review using STRIPA (Systematic Tool to Reduce Inappropriate Prescribing Assistant), a web-based electronic clinical decision support system based on the STOPP/START criteria version 2
Ramallo-Fariña et al. (2020) Spain Cluster RCT 4 arms	32 Primary health care centers	Patients with T2DM aged between 18 and 65 years, diagnosed at least 1 year before, without diabetes-related complications, using a mobile phone. 2334 participants; IG1 (PTI): 537; IG2 (PFI): 654; IG3 (CBI): 557; CG: 586	IG1: educational group program of 8 sessions every 3 months led by trained nurses + monitored by means of logs and a web-based platform and tailored semi-automated SMS for continuous support. IG2: Primary care professionals short educational program to update diabetes knowledge + decision support tool embedded into the electronic clinical record and a monthly feedback report of patients' results. IG3: Combination of the interventions for patients and professionals. CG: neither patients or families nor physicians or nurses received any additional educational or supporting activities beyond the usual activities provided by the PHCP.

Legend: CAD: coronary artery disease, CG: control group, COPD: chronic obstructive pulmonary disease, IG: intervention group, PHQ-9: Patient Health Questionnaire-9, T2DM: type 2 diabetes.

provided *meta*-analyzable data. No significant differences were found between digital interventions and usual care ($n = 1991$, $SMD = -0.00$, $95\%CI = -0.09, 0.09$, $p = 0.63$, $I^2 = 0\%$) (Fig. 3). According to GRADE, the certainty of the estimate was moderate due to serious imprecision (Table 2).

One study, with a moderate risk of bias and not included in the *meta*-analysis, also found no difference between the intervention groups and control groups at the latest follow-up (31) (SF 4).

4.3. Anxiety

Four studies examined anxiety, showing no differences between digital interventions and usual care ($n = 1293$, $SMD = 0.03$, $95\%CI = -0.08$ to 0.14 , $p = 0.87$, $I^2 = 0\%$) (Fig. 3). The certainty of the estimate was moderate due to serious imprecision (Table 2).

4.4. HbA1c

No improvements in HbA1c favouring digital interventions were found (8 studies resulting in 10 comparisons, $n = 2950$, $SMD = -0.17$, $95\%CI = -0.34, -0.00$, $p < 0.001$, $I^2 = 77\%$) (Fig. 3). According to GRADE, the certainty of the estimate was very low due to serious imprecision and very serious inconsistency (Table 2). Sensitivity analysis removing one high-risk study confirmed the estimate (35) (SF 5.1). Two subgroup analyses were performed. The first divided studies by conditions beyond diabetes (e.g., hypertension [25], BMI 30–45 [32], blood pressure over 130/80 mmHg [11] versus studies on diabetes alone (SF 6.1.1)). The second grouped telemonitoring interventions and those based on health coaching/online therapy alone or with telemonitoring (SF 6.1.2). Neither analysis explained the heterogeneity nor modified the effect.

One study with a moderate risk of bias, not pooled in the *meta*-analysis, found no difference in HbA1c at the latest follow-up as using a digital virtual clinic to support professionals [24] (SF 4).

4.5. Blood pressure

No difference was found between digital interventions and usual care or improved usual care in diastolic blood pressure (10 studies resulting in 12 comparisons, $n = 4622$, $SMD = -0.03$, $95\%CI = -0.09, 0.04$, $p = 0.35$, $I^2 = 10\%$, Fig. 3). However, improvements were found in systolic blood pressure (10 studies resulting in 12 comparisons, $n = 4619$, $SMD = -0.14$, $95\%CI = -0.20, -0.07$, $p < 0.34$, $I^2 = 11\%$, Fig. 3). The

certainty of the estimates was moderate due to serious imprecision (Table 2).

Sensitivity analysis removing one high-risk study confirmed the estimates [35] (SF 5.2, SF 5.3).

A study not pooled in the *meta*-analysis because of considerable differences in the intervention compared to the others, and with a moderate risk of bias, found an improvement only in the systolic blood pressure in favour of the digital virtual clinic supporting professionals [24] (SF 4).

4.6. Weight

No significant differences were found between digital interventions and usual care (5 studies resulting in 7 comparisons, $n = 2265$, $SMD = -0.08$, $95\%CI = -0.08, 0.09$, $I^2 = 65\%$) (Fig. 3). The certainty of the estimate was moderate due to serious imprecision (Table 2).

A subgroup analysis dividing studies with additional conditions beyond diabetes (e.g., BMI 30–45 [32] blood pressure over 130/80 mmHg [11] partially explained the heterogeneity without modifying the effect (SF 6.2).

Two studies not included in the *meta*-analysis because of the differences in the intervention compared to those included and unavailability of useful data, with moderate and low risk of bias respectively, found no difference in the outcome at the latest follow-up [24,25] (SF 4).

4.7. Quality of life

No differences were found between digital interventions and usual care in QoL measured by SF-36 or SF-12 instruments in mental (5 studies resulting in 8 comparisons, $n = 2289$, $SMD = 0.02$, $95\%CI = -0.07, 0.10$, $p = 0.39$, $I^2 = 5\%$, Fig. 3), and physical scores (5 studies resulting in 8 comparisons, $n = 2269$, $SMD = -0.05$, $95\%CI = -0.17, 0.07$, $I^2 = 41\%$, Fig. 3), nor when measured with the EuroQol Five Dimension (EQ-5D) (6 studies resulting in 7 comparisons, $n = 2611$, $SMD = 0.01$, $95\%CI = -0.12, 0.13$, $I^2 = 57\%$, Fig. 3). The certainty of the estimates was moderate due to serious imprecision (Table 2).

Two subgroup analyses were performed for QoL measured with SF-36 or SF-12 for the physical score. One analysis grouped studies on depression [16,21] and conditions other than depression [10,11,22] (SF 6.3.1), while the other grouped telemonitoring interventions and those based on health coaching/online therapy alone or with telemonitoring, partially explaining heterogeneity (SF 6.3.2). The same subgroup

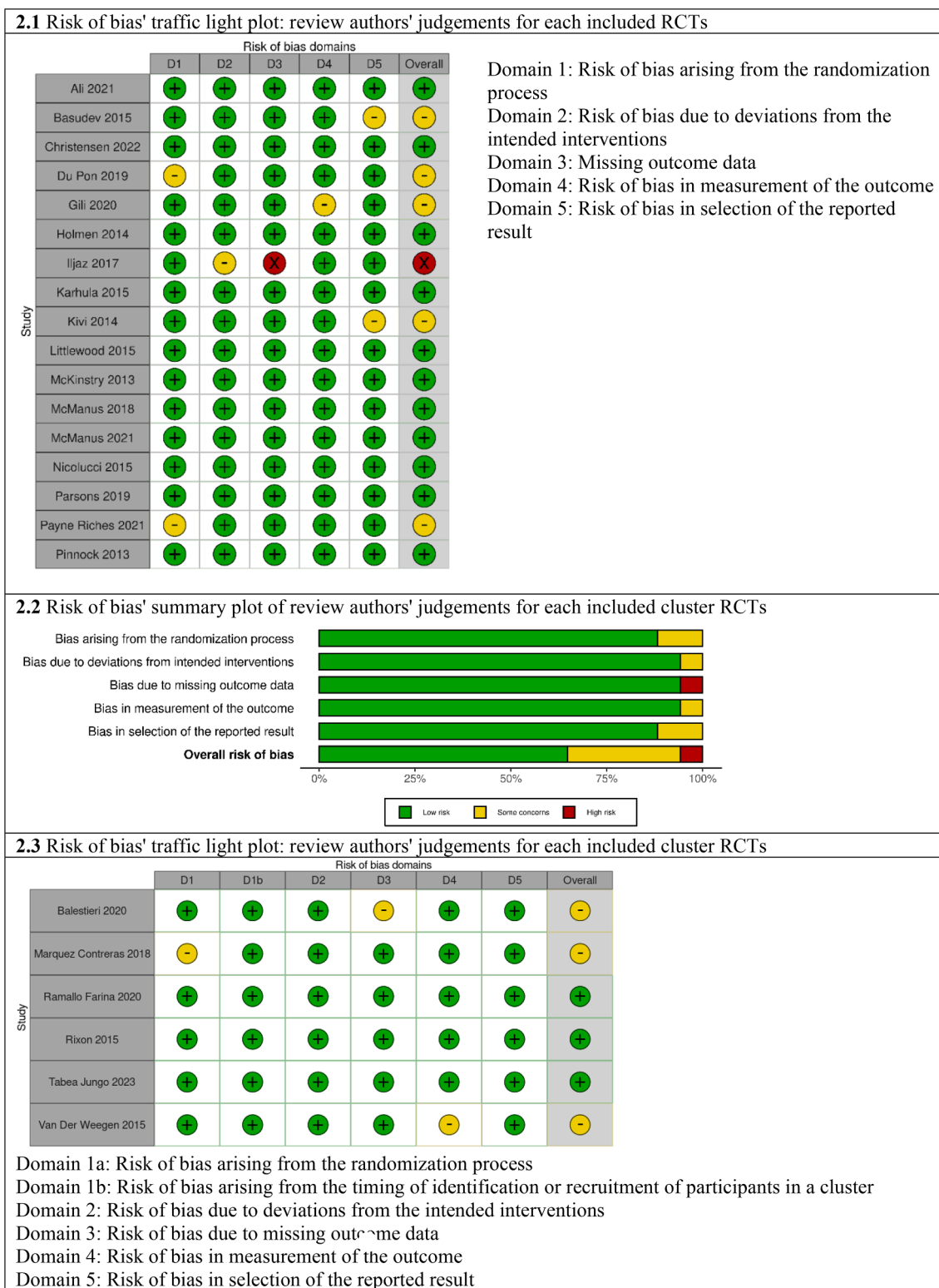


Fig. 2. Risk of bias for all the outcomes.

analysis was conducted for QoL measured with EQ-5D. The analysis by disease explained heterogeneity and showed improvements favouring digital intervention among studies on depression (SF 6.4.1), while the analysis by intervention type did not explain heterogeneity nor altered the results (SF 6.4.2).

Among studies measuring quality of life with other instruments, four

were not pooled in the meta-analysis because of the differences in the intervention compared to those included and unavailability of useful data. Of these, two studies with a moderate risk of bias found no difference in QoL [19,31], while one high-risk study found an improvement favouring the intervention [35]. One study with a low risk of bias, investigating a clinical decision support aid for professionals, found no

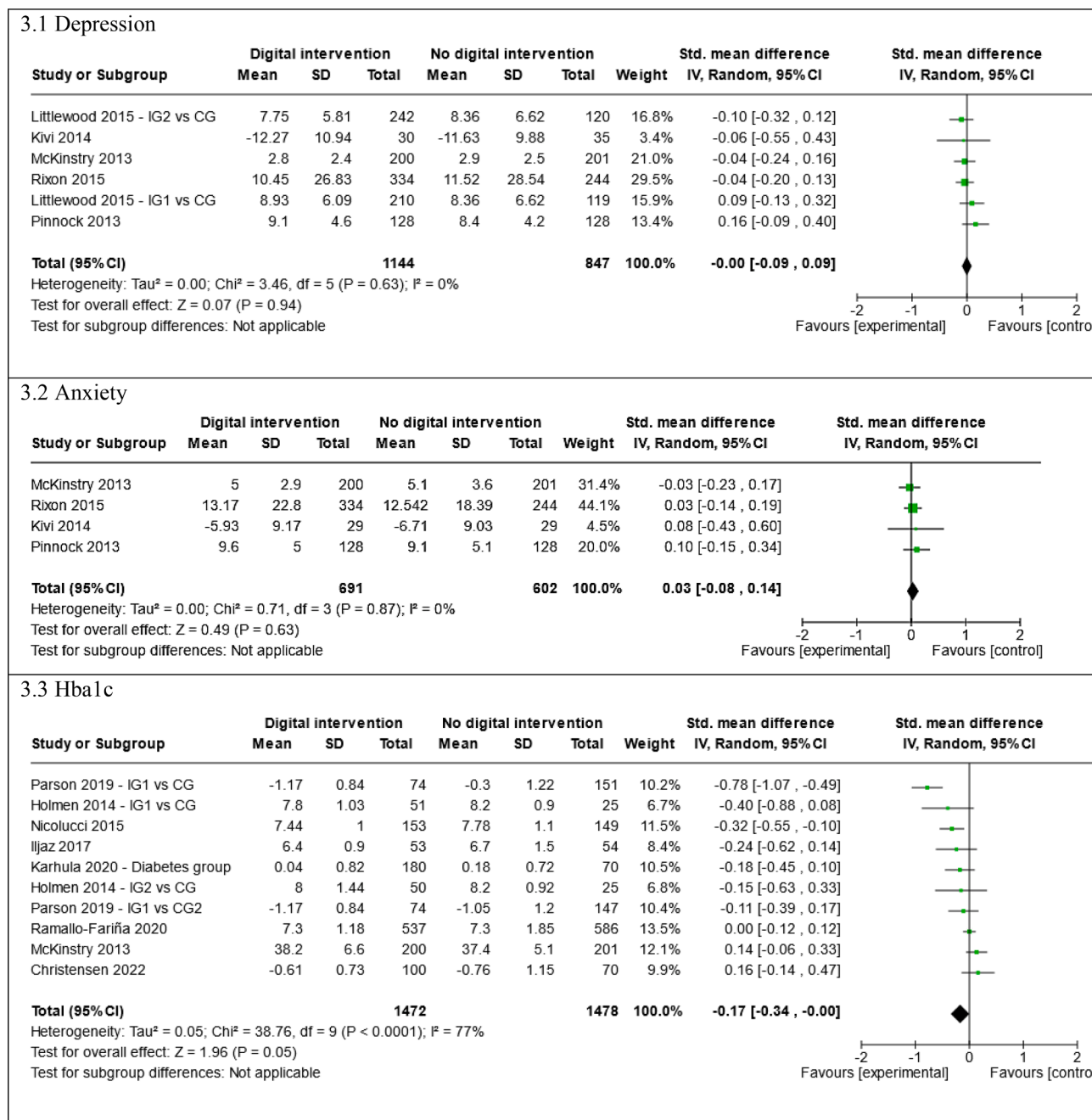


Fig. 3. Forest plots.

difference between the intervention and control group. [20] (SF 3).

5. Discussion

To the best of our knowledge, this systematic review is the first to investigate the effectiveness of existing digital health interventions (DHIs) for managing chronic conditions in primary care. The review analyzed 23 RCTs, primarily focusing on diabetes and hypertension, followed by mental health conditions such as depression. Few studies addressed other chronic diseases, such as chronic heart failure, or the management of patients with multiple conditions, highlighting the need for models that integrate services, professionals, and pathways for complex patients with multimorbidity.

Nearly all studies developed DHIs aimed at patient monitoring, self-

care education, and facilitating appointment and medication reminders. Four studies explored DHIs for professionals, including clinical decision support tools and virtual clinics for specialist integration, indicating that primary care for chronic disease management lags acute care in supporting health professionals. The risk of bias assessment for the RCTs showed that most studies had a low or moderate risk of bias, with only one study at high risk, indicating overall good methodological quality and reliable results.

Hospitalizations were the least studied outcome, suggesting a gap in research regarding hard outcomes in primary care within the European context.

Regarding the effectiveness of DHIs, the results showed no significant differences in hospitalization rates, depressive symptoms, anxiety levels, diastolic blood pressure, or weight with moderate certainty of

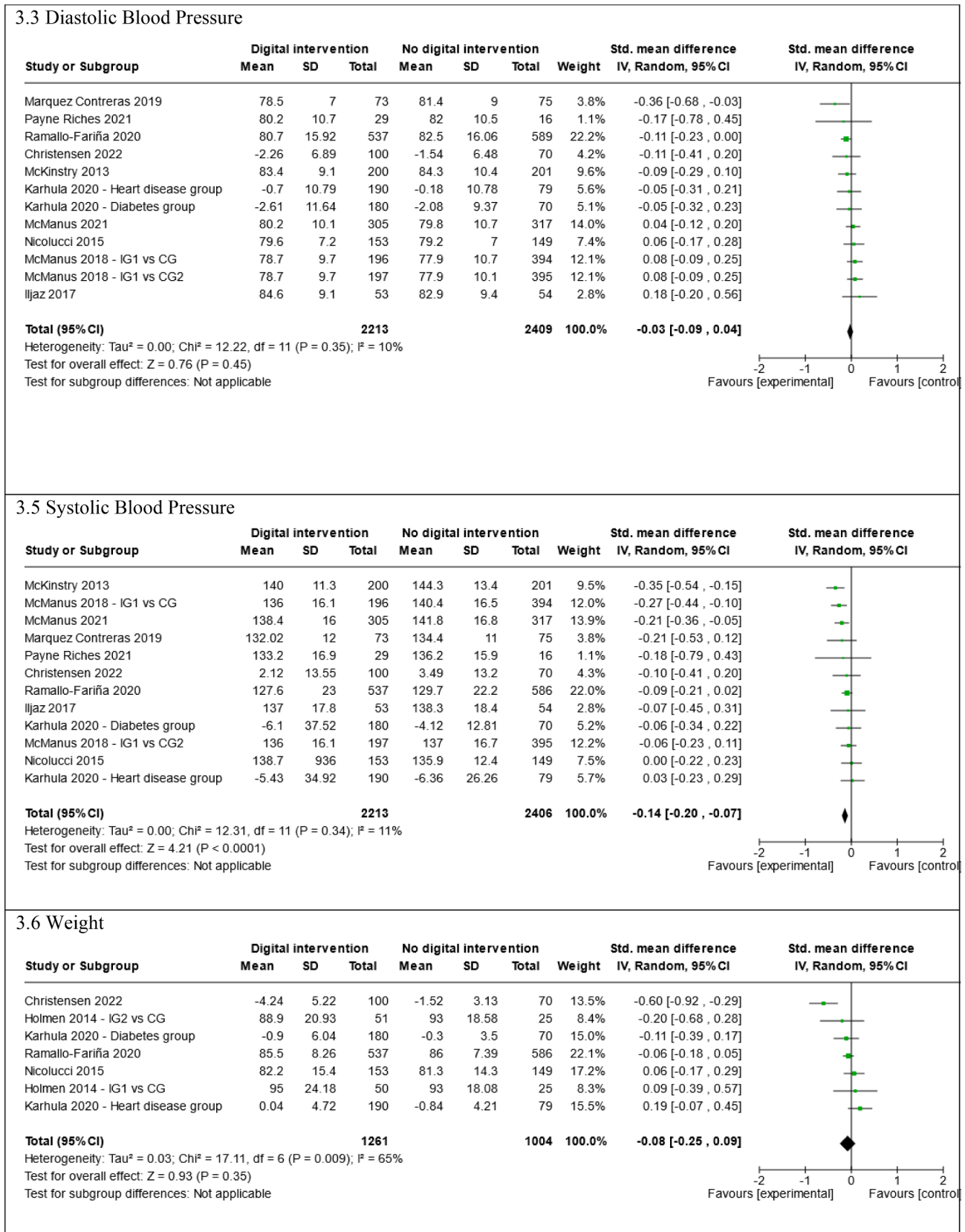


Fig. 3. (continued).

evidence, and in HbA1C with very low certainty of evidence. Quality of life did not show improvement with moderate certainty of evidence, except in studies on depression measured with the EQ-5D questionnaire.

A key consideration in interpreting these results is the directness between the intervention and the outcomes, as not all outcomes were directly impacted by the interventions investigated.

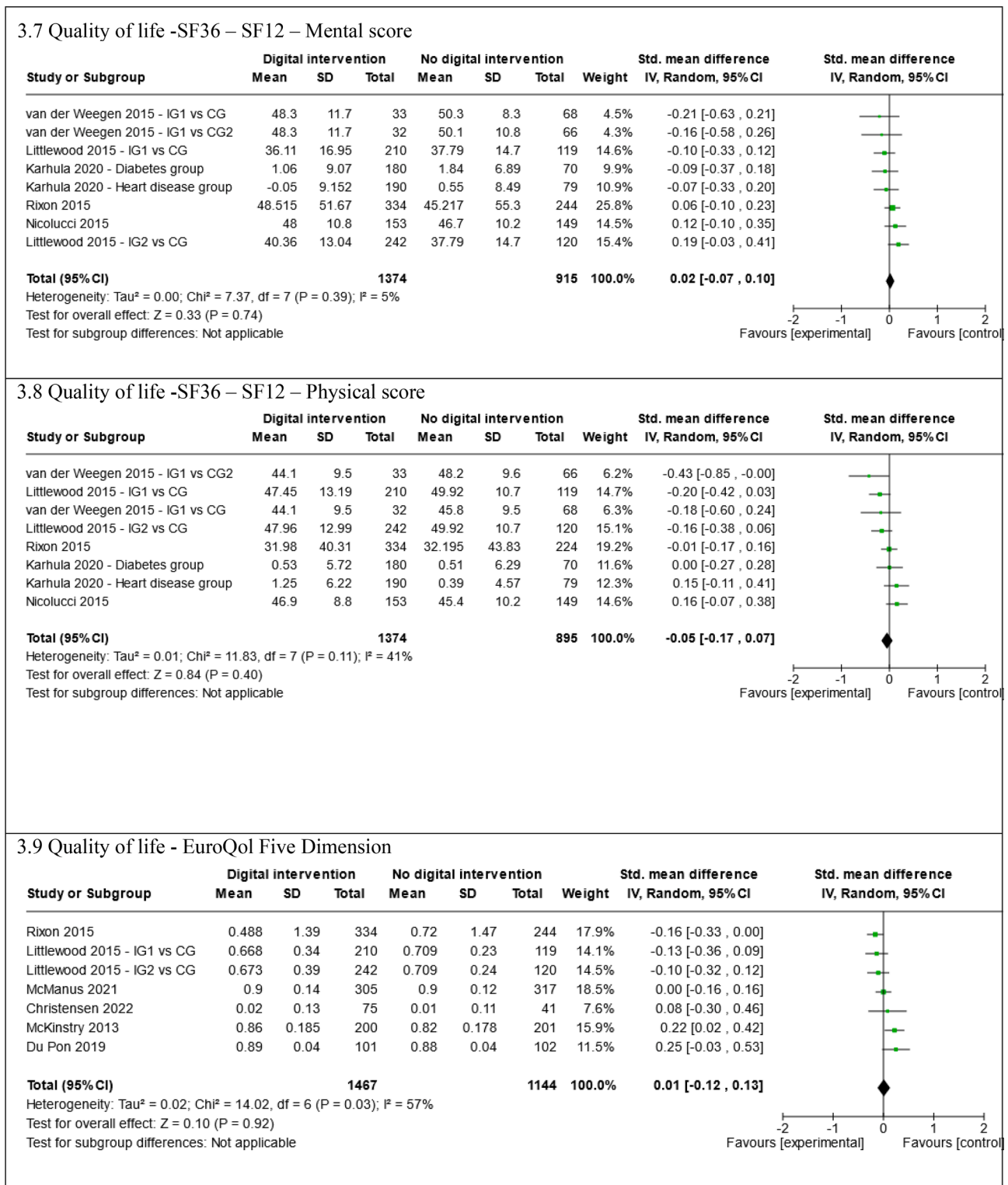


Fig. 3. (continued).

For example, the meta-analysis on depression and anxiety included studies measuring the outcomes as a direct result of intervention-based therapy for patients with depression [36,37], and as an indirect impact of hypertension and COPD interventions based on online programs to be completed by participants, telemonitoring in hypertension and COPD with automatic feedback, or educational materials [21,25,30]. Although the results did not show inconsistencies regarding the effectiveness, this calls for a more accurate selection of outcomes in future research to

allow the correct interpretation of the effectiveness of interventions and the potential for implementation to specific populations based on clinically relevant outcomes.

Interestingly, DHIs were effective tools for systolic blood pressure, with moderate certainty of evidence, even though the pooled estimate was small. Interventions were mainly based on remote monitoring with a digital platform and mobile app integrated, in some cases, with structured follow-up, reminders, phone calls or digital devices.

Table 2
Certainty of evidence according to GRADE.

Certainty assessment							N ^o of patients		Effect	
N ^o of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Digital interventions	No digital interventions	Absolute(95 % CI)	
12	randomised trials	not serious	not serious	not serious	serious ^a	none	2213	2409	SMD 0.03 SD lower (0.09 lower to 0.04 higher)	⊕⊕⊕○ Moderate
12	randomised trials	not serious	not serious	not serious	serious ^a	none	2213	2406	SMD 0.14 SD lower (0.2 lower to 0.07 lower)	⊕⊕⊕○ Moderate
10	randomised trials	not serious	very serious ^b	not serious	serious ^a	none	1472	1478	SMD 0.17 SD lower (0.34 lower to 0)	⊕○○○ Very low
7	randomised trials	not serious	not serious	not serious	serious ^a	none	1261	1004	SMD 0.08 SD lower (0.25 lower to 0.09 higher)	⊕⊕⊕○ Moderate
8	randomised trials	not serious	not serious	not serious	serious ^a	none	1374	915	SMD 0.02 SD higher (0.07 lower to 0.1 higher)	⊕⊕⊕○ Moderate
8	randomised trials	not serious	not serious ^b	not serious	serious ^a	none	1374	895	SMD 0.05 SD lower (0.17 lower to 0.07 higher)	⊕⊕⊕○ Moderate
7	randomised trials	not serious	not serious	not serious	serious ^a	none	1467	1144	SMD 0.01 SD higher (0.12 lower to 0.13 higher)	⊕⊕⊕○ Moderate
6	randomised trials	not serious	not serious	not serious	serious ^a	none	1144	847	SMD 0 SD (0.09 lower to 0.09 higher)	⊕⊕⊕○ Moderate
4	randomised trials	not serious	not serious	not serious	serious ^a	none	691	602	SMD 0.03 SD higher (0.08 lower to 0.14 higher)	⊕⊕⊕○ Moderate

CI: confidence interval; SMD: standardised mean difference

Explanations

a. OIS criterion is met, but the 95% CI overlaps no effect and fails to exclude important benefit or important harm.

b. Heterogeneity could not be explained by differences in populations, interventions or outcomes.

Recent reviews at the extra-European level found that e-health interventions, including telemedicine, decreased hospitalization rates in patients with heart failure [40–42] and COPD [43,44], HbA1c in diabetes [45], blood pressure in hypertension [46–48], depression and anxiety among older adults [49].

However, most of these reviews do not focus on primary care settings, limiting the generalizability of their findings. Most studies involve specialists in hospitals or specialized clinics, whereas primary care teams typically consist of general practitioners rather than specialized professionals. Additionally, methodological biases—such as publication bias and inadequate blinding—may further reduce the reliability of these results [45–49].

Regarding mental health, a review assessing the effectiveness of digital health interventions (DHIs) for anxiety and depression in primary care found no significant effect on anxiety and only a small effect on depression. However, this review had notable limitations, such as including only one study on anxiety and several risks of bias [39].

Therefore, although the interventions included in our review did not demonstrate effectiveness for most outcomes, the observed improvements in systolic blood pressure and quality of life in patients with depression suggest the potential of DHIs for primary care in the future, especially considering their frequent effectiveness in other clinical settings. These findings highlight the importance of further research and especially stronger intervention protocols to enhance the effectiveness of these interventions and address the limitations identified in current studies. According to a previous review, DHIs have yet to play a major role in enhancing primary care, reflecting that these technologies have not gained wide acceptance in primary care [50].

The small number of articles meeting the inclusion criteria underscores the scarcity of high-quality randomized controlled trials (RCTs) on this topic. This limitation reflects a broader challenge: balancing traditional RCTs with more adaptive trial designs in the evaluation of digital health interventions (DHIs). The fast-paced development of digital interventions often requires more flexible research designs, which RCTs typically lack, contributing to the limited inclusion of such studies. A recent scoping review [51] found that most DHIs are still evaluated through pilot or feasibility studies, with little long-term planning for RCTs and implementation science approaches. Future research should adopt innovative trial methodologies to ensure more DHIs meet rigorous inclusion standards while still generating meaningful and reliable data.

Moreover, to realize the potential of DHIs in supporting robust and sustainable primary care, further research is needed to boost the implementation of efficient and evidence-based DHIs within multi-component interventions. In our review, recommendation on the best type and combination of components in the interventions was not possible due to the high variability. Additionally, exploring patient-specific factors, intervention customization, and long-term impacts might provide deeper insights into optimizing digital health strategies.

Our review's strengths include the use of standard and rigorous methodology according to Cochrane guidelines, as well as the inclusion of all chronic diseases, including depression, to provide a comprehensive overview of studies in primary care within the European context.

While a limitation, the focus on the European context is also a key strength of this systematic review. Despite variations in healthcare structures—such as funding models, service organization, and levels of digitalization—Europe provides a unique setting for studying primary care reforms, driven by shared challenges and innovative approaches to digital health. In particular, Europe has been at the forefront of primary care transformation, especially following the Declaration of Astana and the COVID-19 pandemic [52]. European nations actively integrate multidisciplinary teams, digital health tools, and person-centered care approaches, supported by policy frameworks like the European Programme of Work (2020–2025) [53]. These developments make Europe important for examining digital health interventions (DHIs) in primary care. The World Health Organization's strategy for Europe underscores

the challenges and opportunities in using DHIs to address chronic diseases and aging populations, with European countries leading these reforms.

Moreover, despite its diversity, Europe shares common healthcare goals, such as achieving universal health coverage, while grappling with similar demographic pressures. These shared challenges make Europe a valuable context for studying DHIs, even though implementation details may vary across countries. Finally, although complete generalization across Europe may be difficult, our inclusion of studies from a range of countries (e.g., the UK, Spain) captures diverse digital health approaches. This broad perspective allows us to assess DHI effectiveness across different healthcare systems, offering insights for potential adaptation in other regions facing similar challenges.

However, our review has some limitations. First, we included only studies conducted in European areas, and in English or Italian, potentially missing informative studies from other regions. Nonetheless, we deemed it crucial to limit the geographical context due to the factors highlighted above. Second, we limited the database search to the last 10 years to provide recent and updated evidence, considering the continuous and rapid technological advancement.

6. Conclusion

Digital interventions hold promise but have yet to demonstrate substantial benefits in improving clinical outcomes for chronic diseases as compared to traditional care in European primary care. While some minor improvements were noted, particularly in systolic blood pressure, the overall impact remains limited. However, digital interventions being non-inferior to traditional ones is promising, with potential advantages in cost-effectiveness and scalability, considering also the risk of publication bias against negative results showing reduced effectiveness of digital interventions.

Continued research, focusing on overcoming current methodological limitations and exploring tailored approaches, is essential to fully realize the potential of digital health technologies in primary care.

Statement on conflicts of interest

None to declare.

Summary table

What was already known on the topic	What this study added to our knowledge
<ul style="list-style-type: none"> Digital health interventions (DHIs) like telemedicine, mobile apps, and AI tools have improved healthcare efficiency, accessibility, and quality. Evidence on the effectiveness of DHIs in European primary care for chronic conditions is limited, with most research focused on hospitals and psychiatry. 	<ul style="list-style-type: none"> Digital health interventions (DHIs) could improve systolic blood pressure No effects were found by DHIs on hospitalizations, HbA1C, or quality of life No effects were found by DHIs on depression and anxiety DHIs lag in supporting primary care professionals, this highlights important research gaps.

CRedit authorship contribution statement

Elisa Ambrosi: Writing – review & editing, Supervision, Methodology, Conceptualization. **Elisabetta Mezzalana:** Writing – review & editing, Data curation, Conceptualization. **Federica Canzan:** Writing – review & editing, Methodology, Conceptualization. **Chiara Leardini:** Writing – review & editing, Supervision. **Giovanni Vita:** Writing – review & editing, Methodology, Formal analysis. **Giulia Marini:** Writing – review & editing, Data curation. **Jessica Longhini:** Writing – original draft, Methodology, Formal analysis, Data curation.

Declaration of competing interest

The authors declare that they have no known competing financial

interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijmedinf.2025.105820>.

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