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Tailoring remote patient management to optimise cardiovascular risk management in primary care: a mixed-methods implementation study informing large-scale implementation

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Abstract

Aim Remote patient management (RPM) effectively aids cardiovascular risk management, but its large-scale implementation remains challenging. Panel management may facilitate implementation by using comprehensive data to identify patients at risk of cardiovascular diseases and tailor interventions. This study evaluated the implementation strategies and clinical outcomes of a multi-component RPM intervention 'Connect@Heart'.

Methods We conducted a mixed-methods study over six months in four primary care practices in the Netherlands, evaluating two patient groups: (i) patients with a BMI < 25 received a blood pressure monitor alone (BP Box), and (ii) patients with a BMI > 25 or cardiovascular disease received a combination of a BP monitor, a scale, and an activity tracker (Lifestyle Box). Baseline and six-month follow-up assessments were performed using linear mixed-effects models, and implementation outcomes were evaluated using the RE-AIM framework.

Results Our approach achieved high enrolment, with 189 out of 200 initially interested patients (94%) participating. The intervention was associated with a significant reduction in BP levels within both groups (BP Box systolic BP from 139 ± 21 mmHg at baseline to 132 ± 18 mmHg at follow-up, $p < 0.001$ and Lifestyle Box 142 ± 16 mmHg to 131 ± 14 mmHg at follow-up, $p < 0.001$), especially for those with uncontrolled hypertension. After six months, 66% of patients performed measurements weekly. All participating practices continued using the intervention post-study.

Conclusion This study demonstrates that proactively identifying patient panels at risk for CVD and tailoring multicomponent RPM interventions to patient panels are promising implementation strategies for reaching favourable clinical outcomes at scale.

Keywords Remote patient management, Blood pressure, Cardiovascular risk, Panel management, Tailoring devices

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Introduction

Cardiovascular diseases (CVD) are the leading cause of death, imposing a substantial burden on healthcare systems, including associated costs [1, 2]. Effective prevention strategies at a primary care population level are crucial to address this issue [3, 4]. Integrating remote patient management (RPM) into conventional healthcare processes has proven effective in supporting patients and healthcare professionals (HCPs) in managing CVD risk factors [5–7]. However, the large-scale implementation of RPM within integrated care processes is challenging [8–10]. RPM involves multicomponent interventions embedded in a digital health infrastructure and is considered a complex intervention [11]. Lack of details on barriers and facilitators of RPM implementation may hinder scaling proven interventions, highlighting the need for targeted implementation strategies to address practical challenges [12].

In previous research, we identified the need for primary care HCPs to further personalise RPM for patients based on their absolute risk of CVD. We also noted the challenge of identifying the patient population at risk of CVD [13]. To address these challenges, we developed an innovative implementation strategy that involved panel management, wherein patients at increased risk for CVD are proactively identified and systematically allocated to appropriate interventions based on their specific clinical and social needs [14, 15]. Improving access to comprehensive population-level datasets with longitudinal follow-up provides opportunities to identify specific patient subgroups at high risk of developing cardiovascular disease in primary care [16, 17].

While there is a growing interest in panel management, a research gap persists regarding its potential contribution to the implementation of RPM [18, 19]. Therefore, using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [20, 21], we aimed to evaluate the implementation of the Connect@Heart RPM intervention, consisting of a blood pressure (BP) monitor, digital weight scale, activity tracker, and a dedicated smartphone app for patients, and its implementation strategy.

Methods

Study design

The study was designed as a mixed methods implementation study in four general practices within one primary care network in the Leiden region, the Netherlands. Ethical approval was granted by the Ethics Committee of the Leiden University Medical Centre (N21.126). All participants provided written consent.

Study eligibility

Patient recruitment occurred between December 2022 and April 2023. Individuals currently included in the cardiovascular integrated care programs at a Dutch primary care practice were included. Patients with a high or very high estimated cardiovascular risk are eligible to be included in the cardiovascular integrated care program within chronic disease management in the Netherlands [22]. This program offers treatment and monitoring of CVD risk factors. Enrolment status in this program is retrieved from the data from the electronic health record (EHR) [22]. Inclusion and exclusion criteria of the integrated care program are shown in Table 1. Additional inclusion criteria were age over 18 years, proficiency with smartphone technology, having access to the internet at home, and proficiency in Dutch. Additional exclusion criteria included pregnancy, unwillingness to provide informed consent, and enrolment in the cardiovascular risk management program for less than six months. A maximum of 200 participants could join (100 BP Box and 100 Lifestyle Box participants), with selection based on a first-come, first-served strategy. HCPs were chosen through purposeful sampling, specifically targeting individuals affiliated with the Connect@Heart multi-component intervention or healthcare providers for enrolled patients.

Implementation strategy

Our implementation strategy was developed based on prior research that explored the perceived barriers and facilitators of HCPs and key stakeholders (implementation managers, health insurers and IT consultants) regarding the implementation of RPM and the potential adoption of panel management to tailor RPM interventions for specific patient risk groups [13]. This research was guided by the Consolidated Framework of Implementation Research (CFIR) to identify factors that influence implementation [23, 24]. The implementation strategy consists of several components targeting the primary care population and individual patient levels (Fig. 1). At the *primary care practice population level*, specific patient subgroups are proactively screened using an algorithm integrated into the EHR system. First, patients included in the cardiovascular integrated care programs were selected. The algorithm then empanelled these patients based on their BMI levels (lower or higher than 25) and history of cardiovascular events (Table 1), which were criteria that were established in previous research [13]. The practice nurse (PN) contacted eligible patients, invited them to a group information session at a community centre, and subsequently directed them to an online enrolment site for informed consent

Table 1 Inclusion and exclusion criteria Dutch cardiovascular integrated care program

Inclusion criteria for patients with CVD:
• patients with a history of atherosclerotic CVD, including angina pectoris, myocardial infarction, chronic ischaemic heart disease, coronary sclerosis, transient ischaemic attack (TIA), cerebral infarction, intermittent claudication, or aneurysm of the abdominal aorta;
• the patient is primarily managed by the GP; and
• aged 40–80 years

Inclusion criteria for patients at high CVD risk:
• no previous CVD;
• use of antihypertensive or lipid-lowering drugs; or
• a 10-year cardiovascular risk > 10%, based on the Dutch guideline for CVRM, and: 1) either one strong CV-risk enhancing factor or two mild CV-risk enhancing factors (based on family history of CVD, physical activity, BMI, and renal function); or 2) > 1 CV risk factor (current smoker, SBP > 140 mmHg, LDL > 2.5 mmol/l, total cholesterol [TC]/high-density lipoprotein [HDL]-ratio > 8, chronic renal impairment [age < 65 years: estimated glomerular filtration rate {eGFR} < 60 ml/minute/1.73 m2; aged ≥ 65 years: eGFR < 45 ml/minute/1.73 m2, and/or {micro}albuminuria]); or
• a 10-year cardiovascular risk of > 20% and > 1 cardiovascular risk factor, as mentioned above;
• at least one modifiable risk factor;
• the patient is primarily managed by the GP; and
• aged 40–80 years

Exclusion criteria for all patients:
• limited life expectancy;
• cognitive impairment;
• no Dutch language proficiency;
• staying abroad > 3 months; and
• patient receives CVRM in the hospital or outpatient clinic from a medical specialist

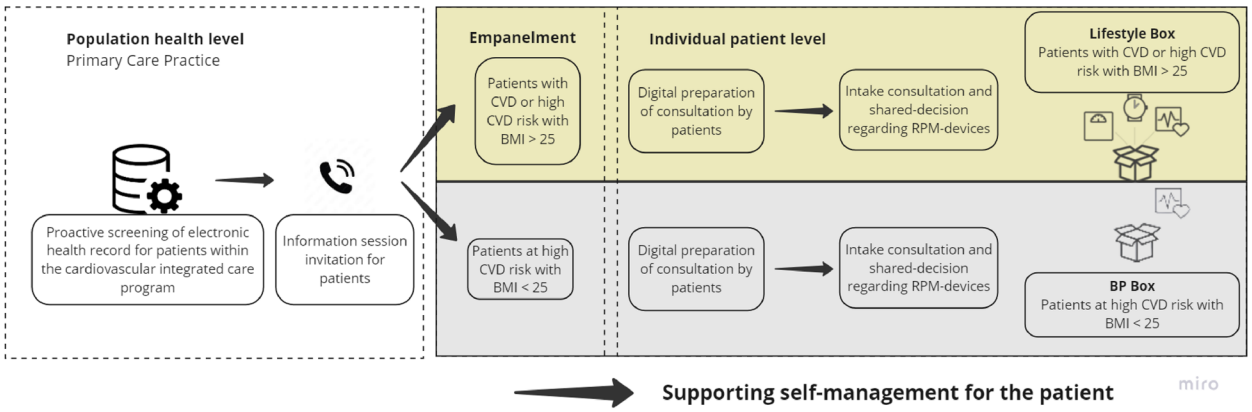

Fig. 1 Visualisation of the implementation strategy of Connect@Heart, a multi-component intervention

and comprehensive study information. At *the individual patient level*, following informed consent, patients underwent face-to-face consultations with research assistants who introduced the RPM digital infrastructure of "The Box" [25] (Fig. 1).

Intervention

The Connect@Heart multi-component [26] intervention was an iteration of an ongoing effectiveness study in the region, exploring the potential of home monitoring within primary care settings to enhance BP and weight management. This intervention is developed within a regional multistakeholder organisation established in 2012, comprising a primary care group, insurer, academic hospital, and health technology developers [13, 27]. The multiple components of Connect@Heart included"The Box" [25], an RPM technology, including a BP monitor (Wireless Blood Pressure Monitor; Withings), a step counter (Pulse Oximeter; Withings), and a weight scale (Smart Body Scale Analyzer; Withings), all connected to a data exchange platform. A dedicated app showed measurements over time and provided feedback and coaching tips. Depending on the specific patient subgroup individuals received a tailored intervention. Patients with a BMI < 25 received a BP monitor alone (BP Box), whereas patients with a BMI > 25 or a history of a cardiovascular event received a combination of a BP monitor, a weighing scale, and an activity tracker (Lifestyle Box) (Fig. 1). All devices have received CE medical certification. The setup provided digital support through the EHR for GPs and

PNs, while simultaneously transmitting measurements to a dedicated patient lifestyle app. Trained research assistants, mostly medical students supervised by experienced senior researchers, assisted patients with device setup, introduced them to the lifestyle app, and addressed any queries. Support tools were developed to assist patients with setting up The Box, including frequently asked questions, instructional videos, and automated reminders. Patients were encouraged to set personalised lifestyle goals and perform weekly BP and weight measurements. Follow-up interactions after six weeks evaluated patient engagement and addressed concerns via a research assistant technical portal. If patients had not measured for a month, the research assistant reached out to them to encourage resuming measurements or to address any other issues that may have arisen. Average measurements were automatically integrated into the primary care EHR every three months, allowing medication adjustments per the established care protocol [28] (supplementary eAppendix 1). Additionally, patients were advised to contact the PN by calling the GP practice under specific circumstances, such as individual systolic BP (SBP) measurements exceeding 180 mmHg, three consecutive measurements surpassing 140 mmHg or any arising concerns. Concurrently, patients were invited to complete a digital questionnaire on MijnGezondheid.net before annual check-ups with the PN, aiming to systematically gather standardised cardiovascular disease risk data and seamlessly incorporate it into the EHR.

Evaluation of the implementation strategy

The implementation of Connect@Heart was evaluated using the dimensions of the RE-AIM framework. Data were collected between January and September 2023.

Reach

Recruitment and non-participation rates were assessed at the primary care practices throughout the six-month recruitment phase. The retention rate, indicating the percentage of participants who completed the study after six months, was evaluated at both three and six months. Successful retention was defined as achieving an 80% completion rate after six months, indicating the proportion of participants who continued to engage in the intervention over this period [29].

Effectiveness

The effectiveness of the Connect@Heart multi-component intervention was assessed using home BP measurements taken by the patients as part of the self-management component of the intervention (supplementary eFigure 1). The outcome focused on the change in home BP measurements and the percentage of participants who achieved the home BP measurement goals (< 135 mmHg for SBP and < 85 mmHg for diastolic BP (DBP) at six-month follow-up. Home BP measurements were determined as the self-monitored average of the last two BP measurements on a day. Weight measurements were evaluated using the same methodology for patients with a BMI higher than 25. Other outcomes included medication prescriptions (change in number and doses) extracted from the EHR. Furthermore, at six months, patients received questionnaires to assess the system usability scale (SUS) and the Client Satisfaction Questionnaire 8 (CSQ-8) [30, 31]. The SUS was used to measure the usability of the Lifestyle Box and BP Box. This questionnaire consisted of a short 10-item Likert scale, with scores ranging from 0 to 100 [30]. The CSQ-8 comprises eight items, each assessed on a 4-point Likert scale. The aggregate score spans from 8 to 32, with higher scores representing increased levels of satisfaction [32]. Achieving a total score of 20 or above signifies satisfaction at a satisfactory level. The CSQ-8 demonstrates strong reliability (Cronbach's alpha = 0.91) [31].

Adoption

Adoption was assessed at both the setting and staff levels. It was defined by the participation rate, which encompassed the number of GP practices agreeing to participate out of those invited, and the referral rate, indicating the percentage of participating clinics referring patients to the study.

Implementation

Implementation outcomes included feasibility and acceptability [33]. Feasibility was assessed through the number of participants meeting the weekly home measurement frequency targets (BP and weight every week, steps every day). Digital consultation questionnaires were assessed using log data, with usage reported as the number and percentage of weekly home measurements and completed digital questionnaires. In addition, we measured the frequency of clinical and technical contacts with HCPs and research assistants. Technical inquiries regarding devices were logged in our technical portal. Implementation acceptability was evaluated through qualitative feedback from HCPs (GPs and PNs) gathered through interviews conducted six months after the intervention commenced. These interviews focused on the multi-component format of the intervention, content, delivery, impact on workload, and potential barriers and facilitators to implementation, using the Theoretical Framework of Acceptability (TFA) (supplementary eAppendix 2) [34].

Maintenance

The primary care practice center organisation-level maintenance was computed as the percentage of HCPs continuing to refer patients to the intervention (i.e., agreeing to continue using the multi-component intervention) six months after the study had ended.

Statistical analyses

Descriptive statistics were employed to present baseline characteristics, RPM wearable usage, satisfaction, usability, and the frequency of contact moments. For home measurements of blood pressure and weight, baseline and six-months were defined as the average of the first and last two weeks of measurements. To evaluate preliminary effectiveness over a six-month intervention period, a linear mixed-effect (LME) (R-studio version 4.2, *lme4*) model was utilised. The model was evaluated using type III sums of squares. Diagnostic checks of residuals were performed to ensure assumptions of normality and homoscedasticity were met. Model fit was assessed using an ANOVA test based on likelihood ratio tests. The LME model accounted for dependence between multiple repeated measurements, controlled for baseline differences, and included cases with missing data. Random intercepts were integrated into the LME model to accommodate measurements derived from the same set of participants. Fixed factors comprised time as a continuous measure, sex, age, history of cardiovascular disease, and baseline BMI as categorial measures. Systolic and diastolic BP and weight were analysed separately. Prespecified subgroup analysis included controlled (home BP $\leq$ 135/85 mmHg) versus uncontrolled (home BP > 135/85 mmHg) BP levels [35]. The correlation between weekly BP measurements and changes in BP levels was assessed using Pearson correlations. Statistical analyses were conducted using RStudio (4.2.2). All significance tests were two-tailed with $\alpha = 0.05$.

The qualitative data obtained from interviews with HCPs were transcribed verbatim and subjected to deductive thematic analysis using the TFA framework with Atlas.ti software (version 8.4). The process involved familiarisation, framework selection (TFA) [34], indexing with existing constructs, charting through data summarisation, and interpretation [36]. Two authors (MR and NvH) ensured consistency in initial coding, establishing a shared understanding of TFA constructs [34].

Results

Reach

The cardiovascular integrated care program included 1,632 eligible patients, of whom 601 (37%) had CVD and 1,031 (63%) were at high risk of CVD. They were identified and contacted by email. A maximum of 200 patients could participate in the study, and within two weeks, 200 had registered for the information session via the primary care practice's website. Of these, 40 (20%) had CVD and 160 (80%) were at high risk. Eventually, 189 participants (94%) attended the information session over two evenings. Eight patients who could not attend the sessions still wanted to be enrolled in the study, resulting in a total of 197 participants. Eventually, 182 participants consented to be included in the study. After three months of follow-up, 15 (8%) patients were lost to follow-up. Eventually, 121 out of 182 (66%) completed the six-month assessment (see supplementary eTable 1 for patient characteristics at six months).

Out of 182 participants, 108 (59%) received the Lifestyle Box (containing a BP monitor, a scale, and an activity tracker), and 74 (41%) received the BP Box (containing just the BP monitor). Among these 74 participants, 11 did not receive the assigned intervention; they were provided with the BP Box instead of the Lifestyle Box due to a lack of available devices and were subsequently excluded from the study. Over three months, ten patients using the Lifestyle Box and five patients using the BP Box were lost to follow-up due to connectivity issues, other technological problems, or the burden of the intervention. Ultimately, data from 156 patients were analysed. Figure 2 illustrates the participant flow, and Table 2 presents their baseline characteristics.

Effectiveness

At six months of follow-up, patients using the BP Box showed significant reductions in SBP from 139 ± 21 mmHg at baseline to 132 ± 18 mmHg at follow-up; mean difference: −7.1 (95% CI −11.6 to −2.6) mmHg, $p < 0.001$) and DBP from baseline 85 ± 9 mmHg to 81 ± 8 mmHg at follow-up, $p = 0.01$, mean difference—4.7 (95% CI −6.2 to −3.2). Similar results were observed for the Lifestyle Box, with reductions in SBP from 142 ± 16 mmHg to 131 ± 14 mmHg at follow-up, mean difference:—7.1 (95% CI −9.8 to −4.4) mmHg, $p < 0.001$) and DBP from baseline 87 ± 10 mmHg to 81 ± 9 mmHg at follow-up, mean difference −4.7 (95% CI −6.2 to −3.2), $p < 0.001$) (Table 3). Overall, a 49% (95% CI: 37 to 61) relative risk reduction in uncontrolled SBP (> 135 mmHg) was found at six months (Table 4 and supplementary eFigure 2 and eTable 2). There was a weak positive significant correlation between the frequency of BP measurements and the change in SBP ($r = 0.110$, $p < 0.01$) and DBP ($r = 0.003$, $p = 0.89$).

There was a non-significant decrease in the BMI of patients using the Lifestyle Box from baseline 29.1 ± 5.3 kg/m^2 to 29.0 ± 5.7 kg/m2 at follow-up ($p = 0.6$) and weight from baseline 90.4 ± 16.8 kg to 89.7 ± 16.5 kg/m^2 at follow-up ($p = 0.4$). Additionally, the medication

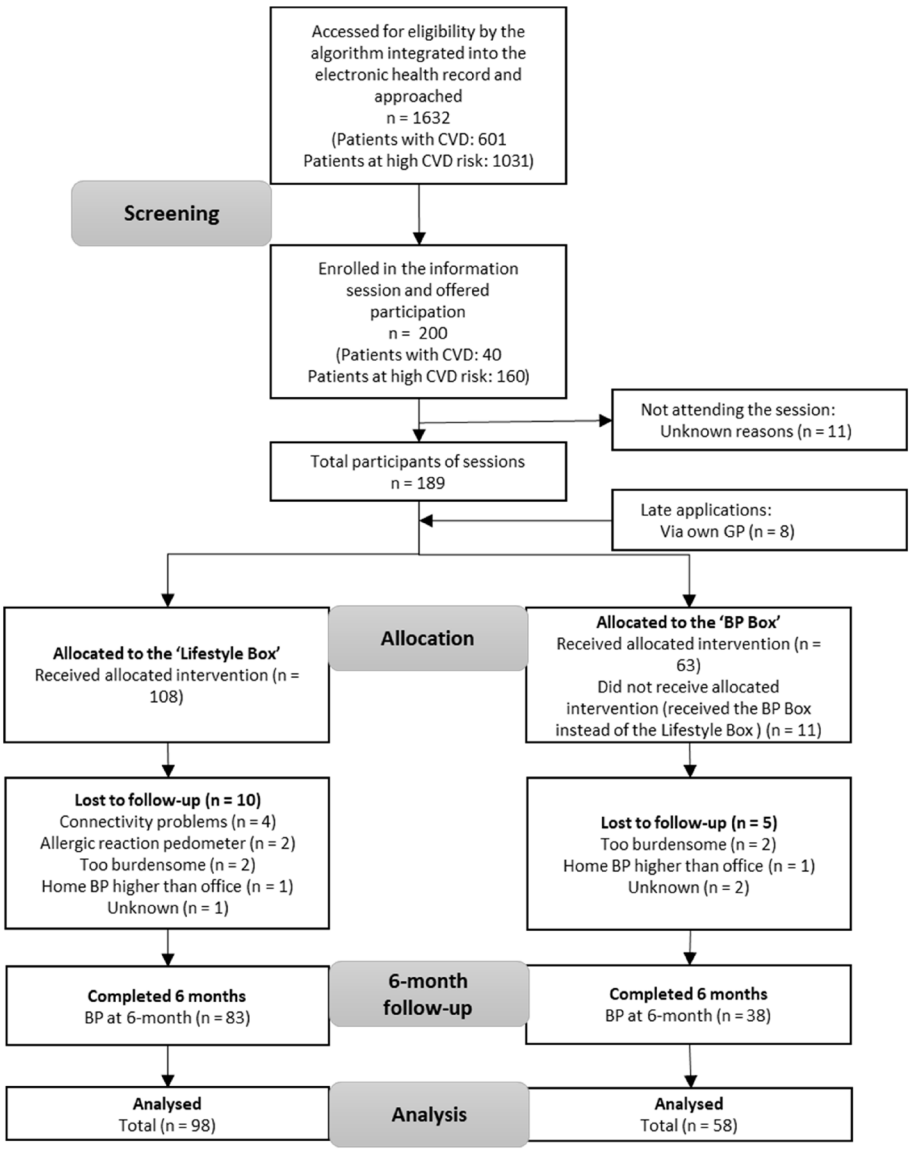

Fig. 2 Flowchart of Connect@Heart multi-component intervention

review revealed that after six months 0.3% of antihypertensive medications were switched to another type, the number of these medications was reduced in 12% of patients, and the dosage was decreased in 15.4% of cases.

The SUS questionnaire was completed by 151 patients (77%). The SUS total score for participants with the Lifestyle Box ($n=87$) indicated good usability (mean (SD): 68.4 [16]; Table 5) and OK usability for the BP Box (n =64, mean (SD): 62.3 [13]; Table 5). Patients were satisfied with the Lifestyle and the BP Box, with CSQ-8 scores (mean (SD)) of 24.8 [4] and 24.1 [3] (Table 5). Open questions revealed that patients indicated that they found it valuable to have insight into their BP and weight data. However, 26% indicated that the activity tracker was not useful or did not function properly.

Adoption

All four potential GP practices that were approached for participation consented, resulting in a 100% adoption rate for patient participation in the intervention. Additionally, all intervention participants (i.e. GPs and PNs, n= 11) approached to deliver the multi-component intervention agreed to participate. One ambassador from one GP practice, a PN, was tasked with refining workflow, explicitly managing the influx of measurements and evaluating them as they arrived.

Table 2 Baseline characteristics of participating patients

Patient characteristics	The Lifestyle Box (n = 98)	The BP Box (n = 58)
Age, mean (SD)	65 (± 10.2)	67 (± 8.7)
Gender, n (%)		
Female	39 (40)	25 (44)
Male	59 (60)	33 (56)
Systolic blood pressure, mean (SD)	142.1 (± 16.1)	138.6 (± 20.6)
Diastolic blood pressure, mean (SD)	87.3 (± 9.5)	85.4 (± 8.6)
BMI (kg/m^2), mean (SD)	29.1 (± 5.5)	24.82 (± 3.4)
Comorbidities, n (%)		
Diabetes (type II)	2 (2.1)	4 (7.0)
Stroke	9 (8.2)	2 (3.6)
Myocardial infarction	13 (13.4)	1 (1.8)
Number of antihypertensives (median [IQR])	2 [1.0, 2.0]	1 [1.0, 2.0]
Smokestatus, n (%)		
Current smoker	6 (6.2)	3 (5.3)
Used to	34 (35.1)	21 (36.8)

Table 3 Effects from using The Box over six months

Outcome	Baseline	6 months	Adjusted mean difference over 6-months [95% CI]*	*P*-value*
Systolic blood pressure				
Lifestyle Box	142.1 (± 16.1) (*n* = 98)	130.9 (± 13.9) (*n* = 83)	−7.1 [−9.8 to −4.4]	< 0.001
BP Box	138.6 (± 20.6) (*n* = 58)	131.5 (± 17.7) (*n* = 38)	−7.1 [−11.6 to −2.6]	< 0.001
Diastolic blood pressure				
Lifestyle Box	87.3 (± 9.5) (*n* = 98)	80.5 (± 9.1) (*n* = 83)	- 4.7 [−6.2 to −3.2]	< 0.001
BP Box	85.4 (± 8.6) (*n* = 58)	80.5 (± 8.2) (*n* = 38)	- 4.0 [−6.4 to −1.6]	*P* = 0.01
BMI				
Lifestyle Box	29.1 (± 5.3) (n = 98)	29.0 (± 5.7) (*n* = 83)	−0.3 [−0.9 to 0.3]	*P* = 0.6
Weight				
Lifestyle Box	90.4 (± 16.8) (*n* = 98)	89.7 (± 16.5) (*n* = 83)	−0.8 [−2.7 to 1.2]	*P* = 0.4

* Linear mixed effect model

Table 4 Percentage with raised SBP and DBP before intervention and after six months

	Baseline	Six months	Percentage Relative Risk Reduction (95% CI)
Uncontrolled (overall) (> 135/85)	121 out of 181 (67%)	62 out of 154 (40%)	49% (37% to 61%)
Uncontrolled (Lifestyle Box) (> 135/85)	65 out of 98 (66%)	31 out of 82 (38%)	52% (39% to 65%)
Uncontrolled (BP Box) (> 135/85)	56 out of 83 (68%)	31 out of 72 (43%)	45% (29% to 61%)

Implementation

The utilisation of The Box showed significant variation over six months. After six months, 34% of patients no longer performed their weekly measurements. Among the subgroup of 98 participants with a BMI exceeding 25, thus qualifying for the Lifestyle Box, 54% (53 out of 98)

Table 5 Patient usability and satisfaction outcomes

	Lifestyle Box		BP Box		Overall	
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
SUS	68.5 (± 16.48)	17.5–100.0	62.3 (± 12.55)	37.5–97.5	65.9 (± 15.25)	17.5–100.0
CSQ-8	24.8 (± 3.62)	13.0–31.0	24.1 (± 3.29)	15.0–30.0	24.6 (± 3.47)	13.0–31.0

recorded their weight in the final week of participation. Additionally, 57% (62 out of 109) of digital consultation questionnaires were completed. During the six-month intervention period, PNs received a total of ten medical consultation requests from patients regarding high (> 180 mmHg SBP) home BP measurements, following the guidelines provided during consultations with research assistants. These patients were invited to the practice for BP monitor validation and medical consultation. If necessary, new monitors were provided (n = 26). Furthermore, 121 technical queries were submitted to the technical portal. 67% of these queries were promptly resolved by resending the instruction manual via email. For the remaining 33% (41 technical issues), appointments were scheduled with research assistants to address the problems involving reconnecting, updating, or resetting the devices. Of the 121 issues, 40 (33%) were related to the BP monitor, 22 (18%) to the pedometer, 10 (12%) to the scales, and 53 (44%) to the app.

To assess acceptability, four HCPs, one GP and three PNs participated in the interviews. The most important barriers and facilitators per TFA construct are presented in Fig. 3. The HCPs expressed a positive attitude towards the Connect@Heart multi-component intervention and its implementation strategy. One PN emphasised that using the multi-component intervention saved

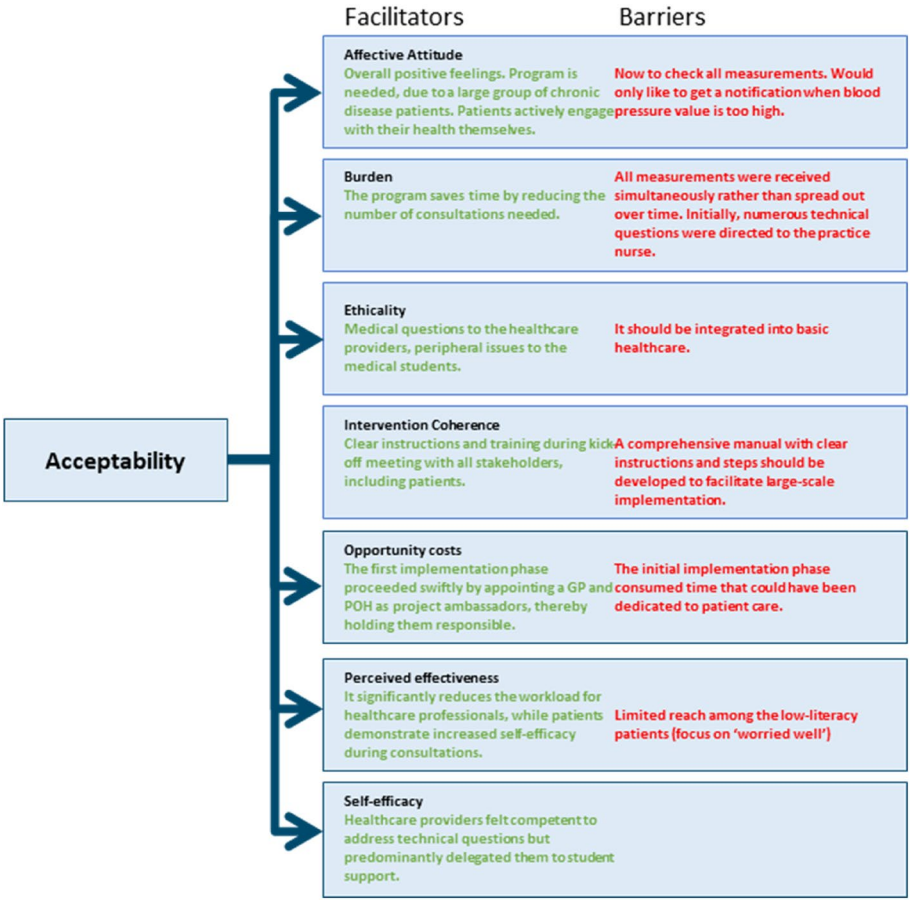

Fig. 3 Barriers and facilitators per construct of the Theory Framework of Acceptability (TFA)

time, particularly when patients also utilised the digital questionnaire (as they had already filled in some basic questions that did not need to be asked during the consultation and were already entered in the EHR). Furthermore, they noted that the multi-component intervention was seamlessly integrated into their current workflow. '*In my experience, this project appears to be successfully implemented in our workflow. Medical inquiries come to us, and others manage the technical issues I prefer not to be concerned with.' [GP]* However, a PN mentioned that the number of measurements sent to the practice at once was excessive. Initially, all measurements were sent every three months and then had to be reviewed by the PN at once, resulting in an increased workload at a fixed time rather than spread over months. This frequency was adjusted to once a month after an initial refinement during the study. Additionally, the PN supplied patients with a predetermined response if the measurements were normal or if the GP needed to adjust medication. *'I've revamped the structure with flow charts, incorporating the doctor's assistant to improve their involvement. Responding to feedback from the GPs, I've added lifestyle advice messages from Thuisarts.nl, along with customisable instant messages, for a more comprehensive approach.' [PN]* Overall, all interviewed participants were satisfied with the time savings and insights of BP measurements for both the patient and the healthcare provider. '*It reduces the workload by decreasing the number of patient visits from once every three months to once a year or every six months. This saves time by reducing the number of 30-min consultations for nurses and 15-min consultations for GPs. Fewer consulting hours have led to more available appointment slots.' [PN]* The PNs and GP recommended that a meticulously detailed implementation manual is essential for broader multi-component intervention implementation, and technical support should be delegated to a medical service centre instead of relying on students. Moreover, all stakeholders emphasised the necessity of incorporating device measurements into the EHR and asserted that the use of the multi-component RPM intervention should be fundamental to implementing structural reimbursement.

Maintenance

Of the four practices that participated in the study, all continued using the Connect@Heart multi-component intervention after the six-month intervention and funding period ended, resulting in a 100% maintenance rate at the primary care practice level. The four practices indicated that the intervention was fully integrated into their current workflow, and discussions with a prominent health insurer about funding the intervention are ongoing.

Discussion

Our study showed that the implementation of Connect@Heart achieved excellent *reach*, as evidenced by high enrolment and participation rates. The multi-component intervention displayed significant *effectiveness*, particularly in reducing BP levels among individuals at risk of or with established CVD, tailored to specific patient subgroups as well as a lower need for anti-hypertensive medication. *Adoption* was 100% regarding the four participating primary care practices. *Implementation* outcome feasibility at the patient level was moderate, with 60% continuing the multi-component intervention after six months. HCPs exhibited positive attitudes toward the multi-component intervention and implementation strategy. Lastly, *maintenance*, evaluated through the continuity of the multi-component intervention, was sustained across all practices.

Comparison to previous studies

Similar to previous research on RPM targeting hypertension, our recruitment (94%) and retention rate (81%) (*reach)* were relatively high [6, 37]. However, our implementation strategy provided an innovative approach by proactively including patients based on characteristics extracted from the EHR. These patients were invited to a group information session where HCPs and researchers outlined the possibility of remote monitoring and the study objectives. This session encouraged significant patient involvement, consistent with prior research indicating that caregiver participation results in higher engagement [38, 39]. However, such sessions risk excluding patients with limited digital literacy or mobility challenges. Being aware of limited digital literacy among several patients in general practices [40, 41], we took proactive measures to correctly inform and engage patients eligible for The Box during consultations with research assistants. If patients had not measured for a month, the research assistant reached out to them to encourage resuming measurements or to address any other issues that may have arisen. Despite these efforts, compliance with the monitoring protocol (weekly measurements) declined markedly after six months, in line with previous RPM studies [42, 43]. However, at least half of these patients had controlled BP, indicating they were on track and required less intensive monitoring (eFigure 2).

Secondly, regarding *effectiveness*, the reduction of BP within six months in both groups was substantial and clinically relevant. A larger effect was observed in patients with uncontrolled BP than those with controlled BP (eFigure 2) consistent with current literature on self-monitoring for hypertension management [6, 44]. Furthermore, our study demonstrated a reduction

in antihypertensive medication after six months. This contrasts with other literature where the number of antihypertensive medications increased [6, 45, 46]. While a possible explanation for the reduction in BP in these studies could be an increase in the number of medications, this was not observed in our study. Research suggests that even modest improvements in multiple health behaviours can have a greater and long-term beneficial impact on the self-management of chronic conditions than significant changes in only one health behaviour [42]. This finding supports the notion that promoting overall lifestyle changes, when combined with co-interventions such as systematic medication titration by healthcare providers and multiple targeted devices (as included in the Lifestyle Box), may be more effective than self-monitoring alone [47].

The findings from our previous interview study [13] were confirmed by the implementation outcomes and interviews with healthcare providers who worked with the Connect@Heart implementation strategy. The seamless integration of the Connect@Heart multi-component intervention into the existing workflow and EHR system was seen as a major additional value for the implementation of the intervention. Numerous studies have shown that systems that have patient data but are not integrated with the EHR suffer from significant usability problems due to incompatibility with workflow [48].

Strengths and limitations

Several limitations must be considered when interpreting the results of this study. As previously mentioned, patients were invited on a large scale to participate in a group information session, after which they could choose to enrol in the study. Although this approach might have resulted in selection bias, potentially favouring participants with higher levels of digital literacy and education, the inclusion criteria were broad and representative of a real-world setting. In addition, proactive technological support was offered during consultations with research assistants to increase accessibility of the intervention. Nevertheless, we recognise that requiring digital literacy and home internet access may have resulted in exclusions of some patients who could have benefited from the intervention. To address this limitation, we are currently conducting a follow-up study investigating barriers and facilitators with the use of The Box and our which proactive implementation strategy need to be adapted for specifically among patients with limited digital or health literacy.. Furthermore, this study did not include a control group, as its primary focus was on evaluating the implementation strategy. The aim was to assess how effectively the intervention could be rolled out in a real-world care setting, how patients and HCPs respond to it, and the practical challenges encountered during implementation. Nonetheless, the observed effects should be interpreted cautiously. Home measurements, however, offer the advantage of masking white coat hypertension and enabling multiple measurements over time. A matched cohort study is currently being conducted to test the clinical effectiveness of The Box compared to a control group. Lastly, the attrition rate of 40% after six months was substantial; however, this is consistent with other multi-component interventions focused on lifestyle promotion and blood pressure reduction, where dropout rates typically range from 40 to 60% over a six-month follow-up period [49, 50]. Previous research has shown that, in addition to personalised support, features such as reward systems, news feeds and automated feedback are associated with better adherence and lower attrition in digital health interventions [51]. These elements were not included in our intervention at the time of the current study, but are considered in a subsequent iteration in collaboration with a medical tech company. Furthermore, although there is limited literature on this topic, reducing the frequency of measurements once blood pressure is under control may help improve retention. Our study showed that while more frequent monitoring was weakly but significantly associated with improved systolic blood pressure outcomes, continued frequent measurements appear to offer limited additional benefit once blood pressure is well managed.

The study also has several strengths. To the best of our knowledge, this is the first implementation study investigating a multi-component RPM implementation tailored to specific patient panels at risk for CVD. The study has yielded valuable insights that can be applied to enhance the implementation strategy for large-scale RPM adoption for cardiovascular risk management. Additionally, despite the availability of various implementation theories and frameworks, the RE-AIM framework stands out as a key tool for evaluating the effectiveness and sustainability of newly implemented interventions. Using the RE-AIM framework allowed us to assess the implementation of Connect@Heart, facilitating the potential for easier replication of both the strategy and intervention. [21].

Implications for research and practice

Our results demonstrate that the implementation strategy of our multi-component RPM intervention is effective, supporting the scalability of RPM interventions overall. This scalability is due to the extensive reach achieved through proactive empanelment, facilitated by an algorithm seamlessly integrated into the EHR system, invitations to information sessions, and the subsequent tailoring of interventions to individual patients [15]. It highlights the importance of researchers, healthcare

providers, and other stakeholders adopting short-cycle iterative evaluation, adaptation, and continuous improvement when implementing multi-component interventions in routine care. Coupling this approach with routinely collected data establishes a learning health system (LHS), a cornerstone of our consortium's implementation strategy. An LHS uses routine data for real-time feedback, enabling proactive care process improvements and accelerating the integration of new knowledge into clinical workflows [43, 52]. However, as emphasised by our HCPs, there is a need to effectively manage the increased volume of transmitted data from RPM devices [53]. Applying artificial intelligence (AI) in processing data to recognise patterns, or using less complex rule-based algorithms to automatically select predefined data points, such as outliers, could decrease the burden on HCPs [54], as suggested by the GP in this study.

In the development and evaluation of implementation strategies, integrating qualitative and quantitative research methods—commonly referred to as mixed-methods research—is essential for a comprehensive understanding of the interplay between digital health interventions, their contexts, and implementation processes [55]. This mixed-methods approach is crucial for developing appropriate implementation strategies for RPM interventions, which involve multiple components requiring informed decisions, such as tailoring interventions based on patient groups identified from the EHR. Implementation outcome frameworks, such as RE-AIM, provide structured tools to evaluate the impact and implementation of interventions across various components [56]. However, evaluations conducted in real-world settings often vary significantly due to contextual factors. This variability highlights the need for adaptability and flexibility in the implementation process. As outlined above, iterative, stepwise frameworks can complement existing models, offering a more dynamic approach to evaluating and optimizing implementation efforts across diverse contexts [57, 58].

In our study, research assistants played a central role in supporting patients during onboarding and follow-up. While this contributed to strong engagement and adherence, such support may not be feasible in routine practice. To support scalability, we suggest two complementary strategies. First, integrating RPM-related medical tasks into the workflow of existing practice staff (e.g. PNs or medical students) may support continuity. For example, in our study, one practice nurse was designated as a project 'champion' and proactively adjusted workflows during each implementation cycle using co-creation with other healthcare professionals. This implied partial task-shifting but did not necessarily required hiring new personnel, as time was reallocated from in-persons consultations. Second, developing a centralised RPM (technological) coordination department or medical service centre may offer an efficient, scalable model to support primary care practices. In such a model patients receive tailored RPM devices and structured support from a central team, reducing the organisational burden on individual practices. This type of shared service infrastructure could make RPM more accessible and sustainable in routine care, particularly for smaller practices or those with limited resources [59]. Lastly, since there is no literature on this topic, reducing the frequency of measurements once blood pressure is well controlled may help improve retention. Our study showed that, while more frequent monitoring was weakly but significantly associated with improved systolic blood pressure outcomes, continued frequent measurements appeared to offer limited additional benefit once blood pressure was well managed.

Supplementary Information

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Supplementary Material 1.

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The funding sources and sponsor had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data, preparation, review, or approval of the manuscript, and the decision to submit the manuscript for publication.

Authors' contributions
MR, NvH, and HvO designed, conceptualised and defined the methods in the study. MR and NvH did data collection, visualisation, and data evaluation. MR and NvH did formal data analysis. MR, NvH, PvP, EH, DA, TB, RV, NC, and HvO drafted the manuscript and its final version. DA and HvO supervised the study. All authors contributed to the article and approved the submitted version. All authors had access to all the data.

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Data availability
The data used to support the findings of this study are included within the article. Raw data analysed during the current study are not publicly available due to confidentiality agreements but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Data were reported following the Standards for Reporting Qualitative Research (SRQR). The study was conducted according to the guidelines in the Declaration of Helsinki, and all procedures involving research study participants were approved by the Ethics Committee of the Leiden University Medical Center (N21.126). Informed consent was obtained from all the participants and/or legal guardians for the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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