BMC Health Services Research

RESEARCH

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Participatory care plan for primary care patients with long-term diseases: results after a 36-month follow-up of a randomized controlled trial

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Abstract

Background A patient care plan can be one way to ensure the coordination and continuity of care, as well as the allocation of limited healthcare resources appropriately to an aging population. This study aimed to analyze any changes in health-related outcomes within and between groups of patients with a participatory patient care plan after 36 months.

Methods The OSUVAT study was a pragmatic randomized intervention study in a primary care setting involving 605 patients with diabetes (DM), coronary artery disease (CAD), or hypertension (HA). The intervention was a participatory structured care plan. The control was usual care. The follow-up of 12 and 36 months included 592 patients. Measurements were conducted at baseline, 12 months, and 36 months. The outcome variables were health-related quality of life, body mass index, HbA1C, LDL-cholesterol, and blood pressure. In addition, achievement of the treatment goals set by the Finnish Current Care Guidelines was assessed for blood pressure, LDL cholesterol, and HbA1C.

Results Over 36 months, there were no significant differences in all patients between the intervention and control groups. With CAD, diastolic blood pressure decreased in the intervention group by 3 mmHg (95% CI -6 to 0) whereas in the control group, it increased by 3 mmHg (95% CI 0 to 6). There was a favorable time trend for LDL cholesterol in all patients in both groups [control −0.32 (-0.42 to -0.24), intervention −0.39 (-0.49 to -0.30)].

Conclusions The care plan implemented for all patients with common chronic diseases and relatively effective disease management does not appear to provide significant benefits. Patients with coronary artery disease experienced a modest benefit from the care plan in terms of blood pressure. More extensive studies of targeting care planning with different patient groups and different settings are needed.

Trial registration Clinical Trials registration number: NCT02992431, registered on December 14th, 2016.

Keywords Primary healthcare, Chronic diseases, Hypertension, Coronary artery disease, Diabetes, Care plan, Care planning, Health-related quality of life, Clinical outcomes, Aging population

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Key points

- Participatory care planning among patients with hypertension, coronary artery disease, and diabetes for unselected patients is not better than usual care.
- Patients with coronary artery disease might benefit from care planning.
- More research on targeting care planning is needed.

Background

The aging population and the growing number of chronic diseases and multimorbidity [1–3] put healthcare and its delivery in a new situation. The focus of care in tackling more complex problems is shifting from simply repairing to maintaining the health and the quality of life of our patients [4, 5]. There is a workforce shortage in healthcare [6, 7]. At the same time, healthcare requirements are growing, for example, due to the aging of population and the growing obesity epidemic, which compel us to find new ways to treat our growing number of patients effectively [8].

Care plans have been used to coordinate care, strengthen information continuity, and promote patient participation. Their purpose is both gather information about the patient's disease and management and highlight the patient's wishes and perspectives on their disease and treatment [9]. Although care plans have been used for decades, their prevalence remains low [10–14]. According to a Cochrane review, a care plan has had a slight benefit in the management of diabetes, blood pressure, asthma and depression, and self-care, but not in perceived health [15]. On the one hand, recent studies have found that care plans promote the achievement of treatment goals, increase adherence to treatment, improve self-rated health, and decrease depression scores [12, 13, 16–19]. On the other hand, there is also evidence that a care plan does not have an impact on clinical outcomes or health-related quality of life [19–21]. The background of care plans and the recent research on the topic are described in more detail in the thesis [22].

This study aimed to analyze the changes in health-related outcomes within and between groups of patients with a participatory patient care plan after 36 months. Primary one-year follow-up results have been reported earlier [21].

Methods

This was a secondary analysis of the Participatory Patient Care Planning in Primary Care (4PHC) study (ClinicalTrials.gov Identifier: NCT02992431), which was a pragmatically randomized study in the municipal Siilinjärvi Health Center. In total, 605 agreed patients (age ≥ 18 years) from the normal patient flow with hypertension (HA), coronary artery disease (CAD), or diabetes (DM) were stratified and then randomized to the intervention and usual care group and followed up for 36 months. Out of all 605 patients initially enrolled in the study, these analyses included all 592 patients who had at least one follow-up evaluation after the first measurement: 589 patients at 12 months follow-up and 534 patients at 36 months follow-up. Both the clinical measures and patient-reported outcomes were collected. The study protocol has been reported in detail in the former article that reported results after one year [21].

In the intervention group, the patients received the preparatory patient activation self-care questionnaire form (supplementary file) and a request to attach records of self-monitored measurements, such as blood glucose and blood pressure values [23]. The patients had an appointment with a nurse and a general practitioner, and a participatory care plan was mutually accepted by the patient and the personnel. Themes included in the care plan were need of care, goal of treatment, treatment implementation and means, support, monitoring and evaluation and medication according to our national guidance [24]. Measurements (blood pressure in a sitting position, waist measurement, weight, and length) were conducted at the nurse´s visit. Patients randomized to the intervention group received a copy of their care plan. The care plan process is described in detail in our former article [21]. The usual care group had the same measurements as the intervention group in a nurse's office and a visit to the general practitioner or the general practitioner phoned a follow-up call as in usual care. The patient-reported and clinical outcomes were measured at baseline, 12 months, and 36 months.

Patient-reported outcomes and sociodemographic factors

Health-related quality of life (HRQOL) was measured with the 15D [25]. The score ranges from 0 to 1 and the minimum important change in quality of life detected by the 15D is 0.015 [26]. Educational background, relationship status and other socio-demographic factors were asked in the questionnaire. Accordingly, the presence of other chronic diseases was asked. Self-reported diseases were atrial fibrillation, cardiac insufficiency, osteoarthritis, back pain, rheumatism, dementia, depression, asthma, or COPD. Depressive symptoms were measured with the 21-item Beck's Depression Inventory [27]. The number of drinks per week (first two questions of Audit-C [28]) and current smoking (yes or no and number of cigarettes per day) habits were asked in the question form. Physical activity was measured with the Kasari fit [FIT = Frequency (F) x Intensity (I) x Time (T)] index [29].

Clinical outcomes

Disease-specific outcomes were blood pressure, glycemic control measured with hemoglobin A1c (HbA1c),

and dyslipidemia treatment status, assessed by measuring with low-density lipoprotein cholesterol (LDL-C). The nurse measured the patient's weight in light clothing and their height, and the body mass index (BMI) was then calculated as weight (kg)/height $(m)^2$.

Statistical methods

The descriptive statistics were presented as means with standard deviation (SD), as medians with interquartile range (IQR), or as counts with percentages. The groups were compared using the t-test, Mann-Whitney test, and Pearson's chi-square test based on their types of data distribution. Repeated measurements were obtained at different time points, including baseline and 12 and 36 months. Repeated measures of the changes in primary and secondary outcomes were compared between the control and intervention using mixed-effects models and an unstructured covariance structure (i.e., the Kenward- Roger method for calculating df). The fixed effects included group, time, and group×time interactions. Mixed models allowed for the analysis of unbalanced datasets without imputation; therefore, we analyzed all available data with the full analysis set. Effect sizes (Cohen's d) were calculated to determine the magnitude of the difference in changes between the three disease groups. Pooled estimates of mean differences were estimated using a meta-analysis method (random-effects model). The Kaplan-Meier method was used to estimate information of the cumulative proportions of survival, and differences between groups were tested by using the Log-rank test. The α level was set at 0.05 for all tests. The Stata 18.0, StataCorp LP (College Station, TX, USA) statistical package was used for the above analyses.

Table 1 Characteristics of the patients at baseline

Measurements at baseline	Control *N* = 300	Intervention *N* = 292	*P*-value
Age, mean (SD)	69(9)	69(9)	0.40
Women, n (%)	151(50)	158(54)	0.36
Education years, mean (SD)	10.2(3.1)	10.1(3.1)	0.63
Living alone, n (%)	81(27)	73(25)	0.56
Working status, n (%)			0.25
Working	31(10)	35(12)	
Unemployed	6(2)	12(4)	
Retired	263(88)	245(84)	
Smoking, n (%)	30(10)	33(11)	0.63
Alcohol consumption per week, median (IQR)	1(0,2)	1(0,2)	0.38
Physical activity, Kasari FIT index, mean (SD)	40(20)	42(20)	0.29
Disease, n (%)			0.96
Hypertension	125(42)	120(41)	
Coronary artery disease	53(18)	50(17)	
Diabetes	122(41)	122(42)	
Number of diseases, mean (SD)	2.4(1.2)	2.5(1.2)	0.92
Waist, cm, mean (SD)			
Women	99(17)	98(14)	0.71
Men	105(12)	105(13)	0.86
Fasting plasma glucose, mmol/l, mean, (SD)	6.64(1.42)	6.55(1.18)	0.44

n number, *SD* standard deviation, *%* percentage, *IQR* interquartile range, *FIT* frequency, intensity, time

Results

Nearly one in five patients suffered from CAD and over 40% of the patients had HA and/or DM. The mean age of the participants was 69 years at baseline and their mean body mass index was slightly below obesity (30 kg/m2). On average, the participants had two chronic diseases. The basic characteristics of the two study groups are presented in Table 1.

Table 2 shows the change from baseline to 36 months in HRQoL, BMI, blood pressure, HbA1c, and LDL. There were no significant differences among all patients between the intervention and control groups. With CAD, diastolic blood pressure decreased in the intervention group 3 mmHg (95% CI −6 to 0) whereas in the control group, it increased 3 mmHg (95% CI 0 to 6). There was a favorable time trend for LDL cholesterol with all patients in both groups [control − 0.32 (−0.42 to −0.24), intervention − 0.39 (−0.49 to −0.30)].

All the changes over time are presented in more detail for different disease groups in Fig. 1. Over 36 months, there was a favorable time trend for BMI with DM, systolic blood pressure with HA, and LDL cholesterol with all disease categories. In addition, a favorable trend was found for diastolic blood pressure with CAD in the intervention group (time and group interaction, $p = 0.017$). On average, the treatment goals were achieved for HbA1C for patients with DM and for diastolic blood pressure for all patients with HA in all measurement points. In addition, a diastolic blood pressure goal was achieved on average with the patients of CAD and DM in the intervention group. The treatment goals of systolic blood pressure and LDL cholesterol were not achieved in any of the patient categories with intervention or control.

In Fig. 2 the difference in change between the usual care and intervention groups by disease is represented by Cohen's effect size. There were no significant changes in health-related quality of life, BMI, LDL cholesterol and HbA1C in any disease group between the intervention and the usual care. The overall effect size of the intervention was 0.02 (CI −0,06 to 0,10). For CAD, the change in MAP favored intervention [0.46 (95% CI: 0.03 to 0.90)].

During the 36-month follow-up, twelve patients in the intervention group and nine in the control group died. The Kaplan-Meier estimate was 4.4% (95% CI: 0.3 to 7.6)

Table 2 Change from baseline to 36 months in health-related quality of life and clinical outcome measures in all patients and those with hypertension, coronary artery disease, and diabetes in the intervention and usual care groups

	Baseline		Change from baseline to months 36		*P*-value*
	Control Mean (SD)	Intervention Mean (SD)	Control Mean (95% CI)	Intervention Mean (95% CI)	
ALL					
Number	300	292			
Health-related quality of life (15D), mean (SD)	0.875(0.095)	0.869(0.095)	−0.008 (−0.016 to 0.000)	−0.006 (−0.014 to 0.002)	0.74
Body mass index, kg/m2 mean (SD)	29.6(6.2)	29.2(5.2)	−0.4 (−0.6 to 0.1)	−0.1 (−0.4 to 0.1)	0.19
Blood pressure, mmHg, mean (SD)					
Systolic	145(17)	145(18)	−2 (−4 to 1)	−3 (−5 to 0)	0.56
Diastolic	82(10)	82(11)	0 (−2 to 1)	−2 (−3 to 0)	0.26
Hemoglobin A1c, mmol/mol, mean (SD)	41.7(8.8)	40.9(8.0)	1.9 (1.3 to 2.5)	1.8 (1.2 to 2.4)	0.73
LDL cholesterol, mean (SD)	2.61(0.95)	2.69(0.99)	−0.32 (−0.42 to −0.24)	−0.39 (−0.49 to −0.30)	0.32
HA					
Number	125	120			
Health-related quality of life (15D), mean (SD)	0.893(0.081)	0.879(0.083)	−0.011 (−0.023 to 0.002)	−0.007 (−0.020 to 0.005)	0.73
Body mass index, kg/m2 mean (SD)	28.2(5.9)	27.9(4.6)	−0.4 (−0.9 to 0.1)	0.2 (−0.3 to 0.6)	0.098
Blood pressure, mmHg, mean (SD)					
Systolic	148(18)	147(18)	−4 (−8 to −1)	−1 (−4 to 3)	0.18
Diastolic	85(10)	84(10)	−3 (−5 to −1)	−1 (−3 to 1)	0.28
Hemoglobin A1c, mmol/mol, mean (SD)	37.8(3.5)	36.8(4.2)	1.8 (1.3 to 2.4)	1.7 (1.2 to 2.2)	0.63
LDL-cholesterol, mmol/l, mean (SD)	2.95(0.93)	3.09(0.98)	−0.32 (−0.48 to −0.17)	−0.47 (−0.63 to −0.32)	0.18
CAD					
Number	53	50			
Health-related quality of life (15D), mean (SD)	0.860(0.105)	0.865(0.088)	−0.003 (−0.023 to 0.018)	−0.009 (−0.029 to 0.012)	0.70
Body mass index, kg/m2, mean (SD)	28.3(5.5)	28.1(4.4)	0.2 (−0.2 to 0.7)	−0.2 (−0.7 to 0.2)	0.17
Blood pressure, mmHg, mean (SD)					
Systolic	144(16)	144(19)	1 (−4 to 6)	−5 (−10 to 0)	0.11
Diastolic	79(9)	82(10)	3 (0 to 6)	−3 (−6 to 0)	0.008
Hemoglobin A1c, mmol/mol, mean (SD)	38.2(4.6)	38.6(3.9)	1.1 (0.3 to 2.0)	1.5 (0.7 to 2.3)	0.54
LDL-cholesterol, mmol/l, mean (SD)	2.22(0.81)	2.26(0.78)	−0.31 (−0.51 to −0.11)	−0.40 (−0.59 to −0.20)	0.57
DM					
Number	122	122			
Health-related quality of life (15D), mean (SD)	0.864(0.102)	0.860(0.107)	−0.007 (−0.019 to 0.005)	−0.004 (−0.016 to 0.009)	0.70
Body mass index, kg/m2, mean (SD)	31.7(6.2)	30.9(5.6)	−0.6 (−0.9 to −0.2)	−0.4 (−0.8 to −0.1)	0.50
Blood pressure, mmHg, mean (SD)					
Systolic	144(16)	144(19)	0 (−4 to 4)	−4 (−8 to 0)	0.21
Diastolic	80(10)	81(11)	0 (−2 to 2)	−1 (−4 to 1)	0.22
Hemoglobin A1c, mmol/mol, mean (SD)	46.7(10.7)	45.5(9.4)	2.3 (1.0 to 3.5)	2.0 (0.7 to 3.2)	0.76
LDL-cholesterol, mmol/l, mean (SD	2.44(0.91)	2.48(0.94)	−0.34 (−0.48 to −0.20)	−0.32 (−0.46 to −0.17)	0.82

SD standard deviation, *CI* confidence interval, *LDL* low-density lipoprotein,

**P*-value for the differences in the changes between the intervention group and the usual care group

and 3.2% (1.7 to 6.0), respectively. The groups did not differ ($p = 0.48$).

Discussion

To the best of the authors' knowledge, this is the first study monitoring the influence of a participatory care plan for three years in a real life setting in primary care among patients with hypertension, coronary artery disease or diabetes. A difference between usual care and the participatory patient care planning process was obtained only regarding mean blood pressure and diastolic pressure among patients with CAD. The mean LDL declined in all patient groups during the 36-month follow-up. BMI decreased among patients with DM over the study period.

Since the Cochrane review [15], more studies have emerged on the effectiveness of care plans. Three of the studies conducted in the context of primary healthcare were randomized. In a study published in 2016, care plans were selectively made for patients who were already in poorer health at the baseline, but making the plan had no impact on the quality of life or daily activities of the

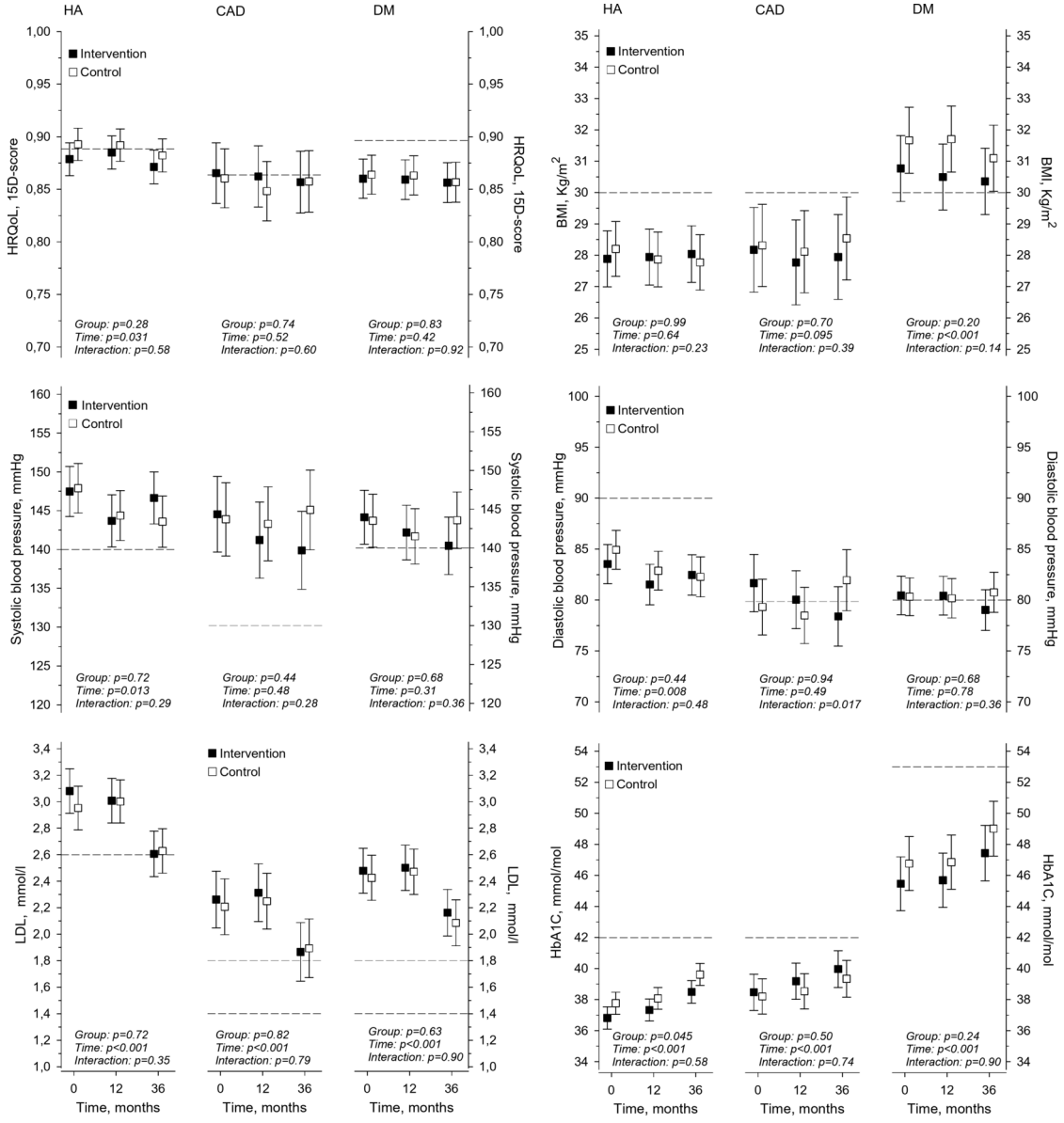

Fig. 1 Change in HRQoL, BMI, systolic and diastolic blood pressure, HbA1C and LDL during the 36month follow-up in the intervention and control groups for patients with hypertension, coronary artery disease and diabetes. The whiskers show the 95% confidence intervals. The dotted line shows the age- and sex-matched HRQoL in the Finnish general population for HA, CAD and DM [29]. For BMI, the dotted line shows the obesity level, 30 kg/m2. For blood pressure, LDL and HbA1C, the dotted line shows the treatment goal according to current care guidelines [30–32]. The interaction represents a group x time interaction

patients. That study did not measure any clinical outcomes [20]. In an Australian study of patients with multimorbidity, patients' self-rated health improved over a six-month follow-up period. However, the intervention was isolated from standard care and significantly intensified in comparison with usual care [18]. Moreover, in a previous Australian study, primary care patients with either coronary artery disease or type 2 diabetes and depression had no change in clinical outcomes after six months of follow-up. Depression scores declined during intensive treatment in intervention patients [19]. Our study is in line with these studies since there were no significant changes in clinical outcomes between the groups even in the long term except for the mean and diastolic blood pressure in the CAD group. Health-related quality of life did not decrease among these patients during the follow-up, so we can assume that both groups received good care and effective management of their diseases.

There were changes in care guidelines during our follow-up period. For patients with DM, the recommendation to use SGLT-2 and GLP-1 medications was implemented in 2019 and included in Finland's national

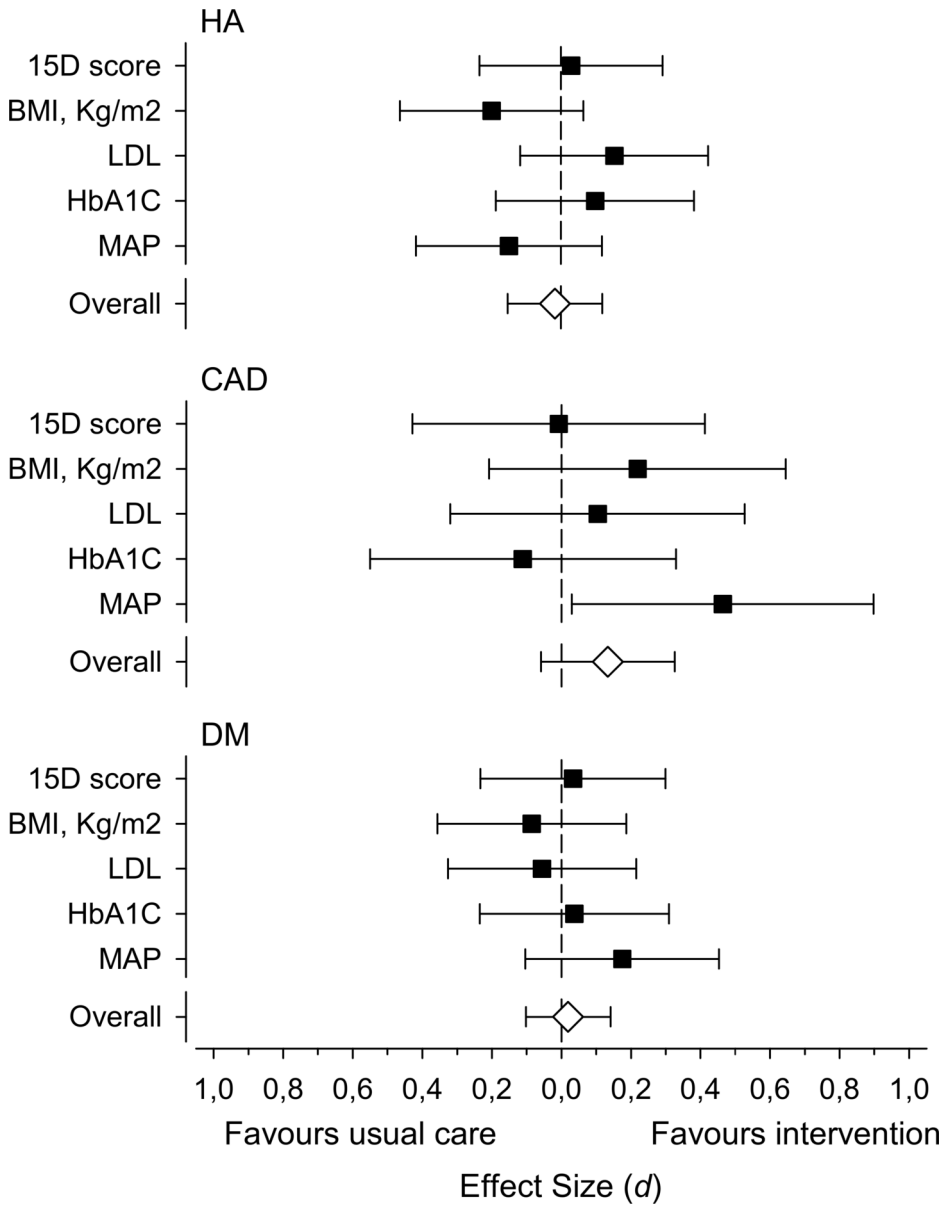

Fig. 2 Effect sizes (Cohen's d) were calculated to determine the magnitude of the difference between the change of the three disease groups in health-related quality of life (15D), body mass index (BMI), low-density lipoprotein cholesterol (LDL), Hemoglobin A1c (HbA1C), mean arterial pressure (MAP) and overall. Effect sizes of 0.20, 0.50 and 0.80 were considered small, medium, and large, respectively. Adjusted for baseline value

current care guidelines for diabetes one year earlier [33]. The ESC guidelines with new recommendations for dyslipidemia treatment were published in August 2021 [34] and our national dyslipidemia guideline was updated in October 2020 [35, 36]. In Finland, education on the new recommendation started even earlier. We have evidence from other situations that increasing doctors' awareness of treatment guidelines influences their prescribing practices [37]. There were changes at the organization level too, since the health center of Siilinjärvi was forced to give up the designated general practitioner to all patients due to a shortage of personnel in 2019. Hence, our study was conducted in a real-life setting and made it possible to observe the effects of such interventions in the treatment of primary healthcare patients within the evolving and developing healthcare system.

In our study, the management of diabetes among DM patients at baseline was excellent, and 81% of the patients had HbA1c levels below the recommended threshold given in the Finnish Current Care Guideline for Type 2 Diabetes [22, 32, 38]. The patients were a good representation of the patients of the health center when comparing them with the patients in the Finnish Diabetes Quality Register [38]. Nevertheless, even though HbA1c levels

increased during the 36-month follow-up, they were still below the recommended levels with most of the patients. Some patients may have previously suffered from hypoglycemia since the mean HbA1c was so low. The BMI of the patients with DM in both groups decreased during the follow-up. The recommendation to use new diabetes medication for patients with DM may have improved the situation [33]. It is also likely that the more participatory way of engaging with the patient and the use of the self-care form for all patients 12 months onward influenced the patient´s ability to manage their self-care daily. There was also a slight reduction in systolic blood pressure in the intervention group. It is known that SGLT-2 inhibitors have a beneficial effect on blood pressure.

CAD patients benefited significantly from the care plan as their diastolic blood pressure and mean arterial pressure decreased. During the research period, a treatment chain for arterial diseases was completed in North Savo in December 2021 and a digital treatment path for patients with coronary heart disease was introduced [39]. According to a national survey, North Savo was one of four wellbeing services counties in Finland where the follow-up treatment of patients with CAD was clearly organized [40]. Based on previous research, patients with CAD benefit from intensive monitoring [41]. As well, the patients with CAD in our study may have received a more regular follow-up from the health center, which may have impacted the treatment outcomes.

Interestingly, LDL levels decreased strongly in all patients between the 12-month and 36-month follow-ups from 2018 to 2021. The change in treatment recommendations may explain at least some of the decrease in cholesterol levels, as a decreasing trend can also be seen in the LDL levels of patients in the National Diabetes Registry [38]. Furthermore, new drugs such as PCSK9 and the information directed to doctors have increased the awareness of dyslipidemia and intensified its treatment [34]. It may be possible that both physicians and patients were more specific about the treatment and their goals as they knew they were involved in the study. It is also feasible that the care plan clarified the treatment goals and the importance of the medication, possibly improving the patients' adherence to the medication [13, 17]. However, it is possible that also patients in the control group may have received a care plan after a year from follow-up, which may have decreased the difference between groups.

It is interesting to be able to follow the primary care patients and their real-life management with common chronic diseases for three years. Although the patients were older, their mean HRQoL remained rather stable and was at a rather good level when compared to the age and sex-matched general population in Finland [30]. Moreover, the treatment balance remained quite the same except for the LDL, which decreased in all patient groups, maybe due to new recommendations. We can wonder why the LDL was not treated to the target until the new recommendation. In the future there could be additional decreases in cholesterol levels if the medication will be further intensified. Another explanation can be that the work in primary care is volume work, meaning that there is always a new patient behind the door. Once one is treated well enough, there is always a new one needing the doctor´s attention more. There are no simple explanations for poor blood pressure control. The poor medication adherence and clinical inertia, especially with "near-target" patients, are the two most important reasons explaining the failure in achieving good blood pressure control in hypertensive patients [42–47]. In this study, the blood pressure was measured by the nurse. It is also possible, that the home blood pressures were lower, and the decisions were made in trusting them.

Strengths and limitations

There are some strengths worth mentioning. Firstly, this was a randomized controlled trial from a normal patient flow with a rather long follow-up and the dropout was very low. It concerned the usual diseases managed in primary healthcare. The results included both clinical outcomes and patient-reported outcome measurements. Patients with DM were representative of the average patient population at the Siilinjärvi health center when compared to the national registry. A limitation may be that the study concerned only patients in one Finnish health center and generalization of the results must be done with caution nationally and internationally. The fact that we don't know the medication used for the patients can also be considered a limitation.

Conclusions

It remains to be determined whether, despite the participatory approach, it is easier to achieve treatment goals with medication than with lifestyle changes [48]. For future studies, we should follow the patients for an even longer period of time to see how new treatment recommendations are implemented in practice and which actions from the patients' perspective and treatment decisions from the healthcare personnel side are most effective for improving patient well-being.

Abbreviations

BMI	Body mass index
CI	Confidence interval
HbA1C	Haemoglobin A1c
HRQoL	Health-related quality of life
LDL-C	Low-density lipoprotein cholesterol
MAP	Mean arterial pressure
n	Number
SD	Standard deviation
%	Percentage

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12913-025-12660-6.

Supplementary Material 1.

Acknowledgements
The authors wish to acknowledge the Siilinjärvi Health Center staff for collecting the data. Special acknowledgment goes to research nurses Nina Koskinen and Nina Serguskin for their work in organizing and collecting the data in the health center. We also wish to extend our gratitude to Pia Jauhiainen for data storage.

Authors' contributions
NT and PM contributed to the design of the study. NT, HK, and PM contributed to the data collection. NT, UM, HK, and PM contributed to the data analysis and interpretation of the data. NT wrote the main manuscript text and HK prepared figures and tables. All authors critically revised the draft manuscript and approved the final content.

Funding
Primary Health Care Unit of Northern Savo Hospital District and Siilinjärvi Health Center have participated in funding the present study. NT has received grants from the Kuopio University Hospital Research Foundation, the Finnish Medical Foundation, the Finnish Foundation for General Practice, and the General Practitioners in Finland. The funders did not take part in the study design, data collection and analysis, or preparation and publishing of the manuscript.

Data availability
The data of the current study are not publicly available due to protection of individual privacy but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study protocol was approved by the Research Ethics Committee of the Northern Savo Hospital District (410/2016). Written informed consent to participate was obtained from all participants. Our study adhered to the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 27 September 2024 / Accepted: 26 March 2025
Published online: 12 April 2025

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