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## Effect of shared care on blood pressure in patients with chronic kidney disease:

a cluster randomised controlled trial

### Abstract

#### Background

Chronic kidney disease (CKD) is highly prevalent in patients with diabetes or hypertension in primary care. A shared care model could improve quality of care in these patients

#### Aim

To assess the effect of a shared care model in managing patients with CKD who also have diabetes or hypertension.

#### Design and setting

A cluster randomised controlled trial in nine general practices in The Netherlands.

#### Method

Five practices were allocated to the shared care model and four practices to usual care for 1 year. Primary outcome was the achievement of blood pressure targets (130/80 mmHg) and lowering of blood pressure in patients with diabetes mellitus or hypertension and an estimated glomerular filtration rate (eGFR) <60 ml/min/1.73 m<sup>2</sup>.

#### Results

Data of 90 intervention and 74 control patients could be analysed. Blood pressure in the intervention group decreased with 8.1 [95% CI = 4.8 to 11.3]/1.1 [95% CI = -1.0 to 3.2] compared to -0.2 [95% CI = -3.8 to 3.3]/-0.5 [95% CI = -2.9 to 1.8] in the control group. Use of lipid-lowering drugs, angiotensin-system inhibitors and vitamin D was higher in the intervention group than in the control group (73% versus 51%, 81% versus 64%, and 15% versus 1%, respectively, [*P* = 0.004, *P* = 0.01, and *P* = 0.002]).

#### Conclusion

A shared care model between GP, nurse practitioner and nephrologist is beneficial in reducing systolic blood pressure in patients with CKD in primary care.

#### Keywords

chronic renal insufficiency; diabetes; glomerular filtration rate; hypertension; primary health care.

### INTRODUCTION

The high and rising prevalence of chronic kidney disease (CKD) — which amounts to 13% in the general population in the US and 7% in primary care in the UK — places a burden on healthcare facilities.<sup>1,2</sup> Of the risk factors contributing to CKD, diabetes and hypertension are the most common.<sup>3</sup> CKD can progress to end-stage renal disease. The awareness of CKD is predominantly fostered by the recognition that it is an important risk predictor for coronary events and cardiovascular mortality.<sup>4,5</sup> Timely intervention that is directed at cardiovascular risk factors can decrease the loss of renal function and the incidence of cardiovascular disease.<sup>6-8</sup> Guidelines provide recommendations for treatment of CKD;<sup>9,10</sup> however, treatment targets are often not met.<sup>11-13</sup>

There is a significant evidence gap in how to best organise the care for patients with CKD.<sup>14</sup> A multidisciplinary approach has been proposed;<sup>15</sup> shared care between primary and secondary care has been successful in the treatment of other chronic conditions.<sup>16</sup> Observational studies on shared care for patients with CKD show promising results,<sup>17</sup> but the effectiveness of shared care for patients with CKD has not yet been proved in randomised trials.<sup>18</sup>

This study developed a shared care model for patients with CKD in primary care in

which the nurse practitioner played a central role and a nephrologist and a nephrology nurse could be consulted. In a cluster randomised controlled trial the study tested whether the model led to improved quality of care in patients with CKD and diabetes or hypertension. Lowering of blood pressure was the primary outcome.

### METHOD

#### Setting

The study involved nine general practices (54 231 patients) that are part of the Academic Practice-based Research Network of Radboud University Nijmegen Medical Centre in The Netherlands.<sup>19</sup> Usual care for patients with diabetes and hypertension in these practices is given in a structured setting with the help of nurse practitioners. Patients with diabetes or hypertension are seen every 3 months. Once a year an extensive control including renal function monitoring is performed according to the national evidence-based practice guidelines.<sup>20,21</sup> Blood pressure measurements are performed according to a protocol, which requires a rest period and noting the mean of two measurements.

Adult patients (aged >18 years) who were treated for hypertension or type 2 diabetes mellitus by their GP and had an estimated glomerular filtration rate (eGFR) measurement of <60 ml/min/1.73 m<sup>2</sup> were

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**Submitted:** 15 March 2013; **Editor's response:** 15 April 2013; **final acceptance:** 23 May 2013.

#### ©British Journal of General Practice

This is the full-length article (published online 25 Nov 2013) of an abridged version published in print. Cite this article as: **Br J Gen Pract** 2013; **DOI: 10.3399/bjgp13X675386**

### How this fits in

Chronic kidney disease (CKD) is highly prevalent in patients with diabetes or hypertension in the primary care setting and leads to a large rise in cardiovascular risk. Although CKD guidelines are clear, implementation in primary care is poor, partly because of lack of confidence from GPs and partly because of lack of time. A shared care model between the GP, nurse practitioner, and a nephrology team is an effective way to reduce blood pressure in patients presenting to primary care who have CKD and diabetes or hypertension. Given the societal burden of CKD, this model may prove to be cost effective in lowering cardiovascular morbidity and mortality.

included. GPs were informed which patients lacked the annual information on renal function, so they could have them tested and include them if an eGFR of  $<60\text{ml}/\text{min}/1.73\text{m}^2$  was newly found. Exclusion criteria were:

- serious medical or psychiatric conditions;
- drug or alcohol abuse;
- specialist CKD care in the last year;
- inability to understand Dutch (including cognitive disorders); and
- participation in another intervention trial.

Eligible patients were invited to take part in the study when they visited the practice for a regular consultation until a minimum of 20 and a maximum of 28 patients per practice were recruited. Patients were included if they had given written informed consent and if a second eGFR-measurement was still  $<60\text{ml}/\text{min}/1.73\text{m}^2$ .

Randomisation was carried out at the general practice level because the intervention involved changes to the practice organisation. Practices were stratified by the mean blood pressure of all eligible patients and then randomly allocated to intervention or control group. In the control practices, patients were identified and included at the start of the study. To avoid bias by study inclusion, patients were asked to give written informed consent only at the time of the final measurement at the end of the trial; their GPs and nurse practitioners were informed of the patient's study inclusion or exclusion status at that time.

To show a clinically relevant difference in the decline of blood pressure of 5 mmHg

(standard deviation of blood pressure difference 10 mmHg,  $\alpha = 0.05$ ,  $\beta = 0.20$ , and intraclass correlation coefficient (ICC) 0.03) the study was powered to contain nine practices with 25 patients per practice.

### Intervention

The multifaceted intervention consisted of the training of professionals, structured care by nurse practitioners, and the opportunity to ask advice from a nephrology team. In spring 2008, nurse practitioners and GPs of intervention practices were trained by a nephrology team. Blood pressure measurement and treatment, proteinuria, cholesterol lowering, blood-glucose management, and lifestyle advice were the main issues. A protocol, based on the Kidney Disease Outcomes Quality Initiative (KDOQI) guideline, was provided with treatment goals and treatment advice.<sup>10</sup>

During the following intervention year, nurse practitioners received two extra training sessions on treatment of hyperparathyroidism and anaemia. The nurse practitioner saw patients every 3 months for a 20-minute consultation, in which blood pressure treatment was the main aim. Patients and nurse practitioners decided together which other treatment goals were to be prioritised. GPs supervised the consultation afterwards. GPs and nurse practitioners could, if necessary, consult a nephrology team in a protected digital environment.<sup>22</sup>

### Outcome

Lowering of blood pressure was the primary outcome and was ascertained according to the difference between the usual blood pressure measurement at baseline and the study blood pressure measurement after 1 year. At the end of the trial, blood pressure and the number of patients meeting the blood pressure target (130/80 mmHg) were compared between the control and intervention groups. Other quality-of-care variables were kidney-disease measures and the number of patients that reached the treatment goals. Additionally, functional status and the use of angiotensin system inhibitors and lipid-modifying agents were measured. The number of consultations with the nephrologist and the number of referrals were described.

At baseline, the nurse practitioner collected data in the intervention group. After 1 year the same measurements were performed in patients in both intervention and control practices. Study blood pressure was measured with an oscillometric device (Stabil-O-Graph). After a 5-minute rest,

three measurements were taken with the patient in a sitting position; the mean of the last two measurements was used for analysis. In patients with atrial fibrillation, blood pressure was measured manually with a sphygmomanometer. The latest noted usual blood pressure measurement before inclusion was used as the baseline value for blood pressure.

Clinical chemical analyses were performed by the laboratory of the Canisius Wilhelmina Hospital in Nijmegen, The Netherlands. Creatinine, calcium, phosphate, and parathyroid hormone (PTH) were measured by a Roche modular analyser. Blood samples for PTH analysis were put on ice immediately after blood sampling and, where possible, analysed within 2 hours. If this was not possible, samples were centrifuged and saved in a refrigerator until analysis. Serum creatinine was measured enzymatically with calibration

traceable to the international standard (isotope dilution mass spectrometry [IDMS]) reference material. The eGFR was calculated from the Modification of Diet in Renal Disease (MDRD) equation.<sup>23</sup> Calcium levels were corrected for albumin levels. Haemoglobin was measured on a Sysmex XE-2100 instrument. Albuminuria was defined as an albumin:creatinine ratio of  $\geq 2.5$  mg/mmol or  $\geq 3.5$  mg/mmol in male or female patients respectively.

COOP-WONCA charts were used to obtain additional information about the patient's functional capacity.<sup>24</sup>

### Statistical analysis

Descriptive analyses were used to describe the characteristics of the patients in both groups. As a result of the hierarchical structure of the study (patient nested within practices), multilevel analyses were performed that took account of the variability associated with each level of nesting.

A random intercept model with other variables that were fixed was used. For dichotomous variables, a multilevel logistic model was performed. Blood pressure change between intervention and control group was analysed by analysis of covariance with the follow-up blood pressure measurement as an outcome and the baseline blood pressure measurement (last noted blood pressure in the patient file) as a covariate. As the number of practices was relatively small, a cluster-level analysis was performed by analysing summary measures from each cluster as a sensitivity analysis.<sup>25</sup>

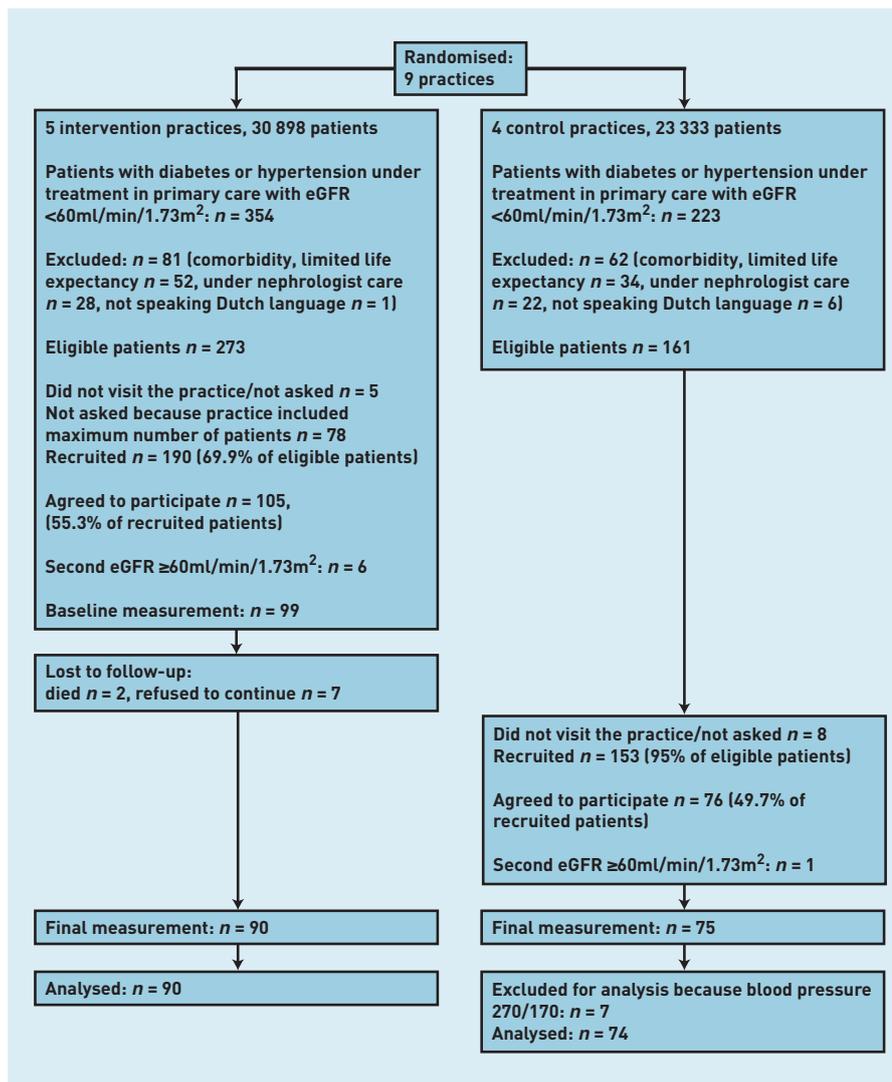
The ICC was calculated from pre-intervention blood pressure data from both intervention and control group.

SAS Proprietary Software 9.2 was used for all analyses and multilevel analyses were performed with PROC MIXED for continuous outcomes and PROC GLIMMIX for dichotomous variables.

### RESULTS

Figure 1 shows a flowchart of participating practices and patients. Five intervention practices included 16, 12, 20, 23, and 28 patients respectively; four control practices included 6, 23, 19, and 27 patients. Nine patients from four practices in the intervention group did not finish the trial: two died (of lung carcinoma and heart failure), three stopped because their general condition worsened, and four no longer wished to come for extra control visits. One patient in the control group was excluded from the analysis because of extreme blood

Figure 1. Flow chart of participating practices and patients.



pressure values that were considered to be invalid measurements (270/170 mmHg). Usual systolic blood pressure at baseline did not differ between the intervention and control groups, whereas diastolic blood pressure was lower in the intervention group (Table 1).

The decrease in systolic blood pressure in the intervention group was 8.1 mmHg (95% confidence interval [CI] = 4.8 to 11.3) compared with 0.2 mmHg (95% CI = -3.8 to 3.3) in the control group (Table 2). The decrease in diastolic blood pressure did not differ between intervention and control group. The ICC was 0.11 for systolic blood pressure and 0.15 for diastolic blood pressure. Blood pressure after 1 year was lower in the intervention group than in the control group: systolic blood pressure was 8.2 mmHg (95% CI = 3.6 to 12.9) lower, diastolic blood pressure was 4.7 mmHg (95% CI = 1.1 to 8.4) lower (Appendix 1). The number of patients that reached the treatment goal for systolic blood pressure in the intervention group (44.4%) was higher than in the control group (21.6%) (odds ratio [OR] 2.9 [95% CI = 1.4 to 5.8];  $P = 0.003$ ). For diastolic blood pressure these percentages were 71.1% and 50.0% respectively (OR 2.5; 95% CI = 1.3 to 4.7;  $P = 0.007$ ) (Table 2). More patients in the intervention group received renin-angiotensin system inhibitors, lipid-

lowering drugs, and vitamin D than patients in the control group. Laboratory values did not differ between the intervention and control groups, with the exception of PTH, which was lower in the intervention group (Table 2).

During the intervention, cholesterol and low-density lipoprotein (LDL) levels decreased in the intervention group, parallel with an increase in the use of lipid-lowering drugs (Appendix 2).

In 31 patients in the intervention group, 50 consultations were performed between the GP and nephrologist; none of these resulted in a referral. In the intervention group, two patients were referred to a nephrologist; in the control group, one patient was referred.

## DISCUSSION

### Summary

The shared care model for patients with CKD and diabetes or hypertension leads to a significant and clinically relevant systolic lowering of blood pressure in the intervention group compared with the control group; in addition, there was also a better achievement of blood pressure targets along with increased use of renin-angiotensin system inhibitors. The intervention also led to lower PTH levels, along with an increased use of vitamin D, as well as leading to an increased use of lipid-lowering drugs. Although LDL cholesterol decreased in the intervention group, LDL levels at the end of the study did not differ between the intervention and control groups.

It is promising that blood pressure targets were better met in the shared care practices, because a lower blood pressure is associated with better patient outcome.<sup>6</sup> Hypertension management is generally recognised as a primary care task, but blood pressure management in patients with CKD in primary care is not as effective as it is in nephrology.<sup>26</sup> Underlying factors are that the GP's confidence in treating CKD is lower than in treating diabetes and hypertension, and that blood pressure targets in CKD are often regarded with scepticism.<sup>27,28</sup> A discussion is ongoing with regard to optimal blood pressure targets.<sup>29</sup> Systolic blood pressure of <120 mmHg is associated with stroke and diastolic blood pressure of <60 mmHg is associated with increased mortality in older people who are frail.<sup>30,31</sup> Nephrologists could be of help in the titration of antihypertensive agents.

Albuminuria did not change during the study. This was due to the fact that albuminuria treatment goals had been met

**Table 1. Patient characteristics at baseline, derived from the electronic patient record**

Characteristic	Control group, n <sup>a</sup> (%)	Intervention group n <sup>a</sup> (%)
Sex, male	39 (52.7)	34 (37.8)
Age, years	72.4 (8.2)	73.9 (8.0)
Creatinine, µmol/l	117.6 (21.2)	109.0 (24.9)
eGFR, ml/min/1.73m <sup>2</sup>	50.0 (6.7)	49.1 (7.9)
Systolic usual office blood pressure, mmHg <sup>b</sup>	142.5(15.1)	142.7 (17.6)
Diastolic usual office blood pressure, mmHg <sup>b</sup>	80.4 (8.2)	74.9 (9.2)
Diabetes, %	26	34
Hypertension, %	69	81
Myocardial infarction, %	4	12
Heart failure, %	3	5
Transient ischaemic attack, %	6	6
Cerebrovascular accident, %	6	10
Peripheral artery disease, %	5	13

*Comorbidity is based on ICPC (International Classification of Primary Care) coding in the problem list in the electronic patient record. <sup>a</sup>Values are given as mean and standard deviation, or number (percentage). <sup>b</sup>In one patient in the control group, a usual blood pressure at baseline could not be found in the electronic patient file. eGFR = estimated glomerular filtration rate. Usual office blood pressure is the blood pressure as noted in the electronic patient record.*

**Table 2. Outcome measures in the intervention and control group at  $t = 1$  year**

Variable	Treatment goal	Control group	Intervention group	Difference for continuous variables <sup>a</sup> between intervention and control group (95% CI)	P-value
Sample, <i>n</i>		74	90		
<b>Systolic study blood pressure</b>	<130mmHg	142.9 (16.8)	134.7 (15.7)	-8.2 [-12.9 to -3.6]	<0.001
Treatment goal reached ( <i>n</i> , %)		16 (21.6)	40 (44.4)	2.9 (1.4 to 5.8) <sup>a</sup>	0.003
Δ systolic blood pressure $t = 1$ year minus $t = 0$ (95% CI)		0.2 [-3.6 to 3.8]	-8.1 [-11.3 to -4.8]		
<b>Diastolic study blood pressure</b>	<80mmHg	80.9 (11.2)	73.8 (9.6)	-4.7 [-8.4 to -1.1]	0.010
Treatment goal reached ( <i>n</i> , %)		37 (50.0)	64 (71.1)	2.5 (1.3 to 4.7) <sup>a</sup>	0.007
Δ diastolic blood pressure $t = 1$ year minus $t = 0$ (95% CI)		0.5 [-1.80 to 2.9], <i>P</i> = 0.64	-1.1 [-3.2 to 1.0], <i>P</i> = 0.30		
Weight, kg	n/a	80.8 (15.0)	79.8 (14.9)	-1.0 [-5.7 to 3.6]	0.720
Waist circumference, cm	<80 female, <94 male	100.7 (14.9)	101.2 (12.9)	0.5 [-3.8 to 4.8]	0.230
Treatment goal reached, <i>n</i> (%)		8 (10.8)	5 (5.6)	0.5 (0.2 to 1.6) <sup>a</sup>	0.220
Creatinine, μmol/l	n/a	114.2 (24.6)	110.9 (25.4)	-3.3 [-11.1 to 4.4]	0.640
eGFR MDRD, ml/min/1.73m <sup>2</sup>	n/a	49.4 (8.0)	48.6 (8.7)	-0.7 [-3.3 to 1.9]	0.830
Fasting glucose, mmol/l	<7	6.5 (1.4)	6.4 (1.4)	-0.1 [-0.6 to 0.3]	0.500
Treatment goal reached, <i>n</i> (%)		58 (78.4)	68 (75.6)	0.9 (0.4 to 1.8) <sup>a</sup>	0.670
HbA1c, %	<7	6.4 (0.9)	6.4 (0.8)	0.01 [-0.2 to 0.3]	0.880
Treatment goal reached, <i>n</i> (%)		63 (85.1)	69 (76.7)	0.6 (0.3 to 1.3) <sup>a</sup>	0.180
Total cholesterol, mmol/l	n/a	4.8 (1.2)	4.6 (1.1)	-0.2 [-0.5 to 0.2]	0.320
HDL cholesterol, mmol/l	n/a	1.4 (0.4)	1.4 (0.4)	-0.04 [-0.2 to 0.1]	0.850
Total cholesterol/HDL	n/a	3.7 (1.1)	3.6 (1.2)	-0.04 [-0.4 to 0.3]	0.550
LDL cholesterol, mmol/l	<2.5	2.6 (1.1)	2.5 (0.9)	-0.1 [-0.4 to 0.2]	0.570
Treatment goal reached, <i>n</i> (%)		34 (46.0)	47 (52.2)	1.3 (0.7 to 2.4) <sup>a</sup>	0.430
Triglycerides, mmol/l	n/a	1.8 (0.8)	1.7 (0.9)	-0.1 [-0.3 to 0.2]	0.320
Haemoglobin, mmol/l	>6.8	8.9 (0.8)	8.7 (0.8)	-0.2 [-0.4 to 0.1]	0.360
Treatment goal reached, <i>n</i> (%)		74 (100)	90 (100)	-	-
MCV, fl	n/a	90.7 (4.0)	91.7 (4.0) <sup>b</sup>	0.9 [-0.3 to 2.2]	0.060
Serum albumin, g/L	35-50	43.7 (2.5)	43.3 (2.3)	-0.5 [-1.2 to 0.3]	0.820
Treatment goal reached, <i>n</i> (%)		73 (98.7)	90 (100)	-	0.270
Sodium, mmol/l	n/a	140.8 (2.7)	140.4 (2.1)	-0.4 [-1.2 to 0.3]	0.420
Potassium, mmol/l	n/a	4.38 (0.42)	4.89 (0.54) <sup>c</sup>	0.51 (0.36 to 0.66)	0.030
Calcium, mmol/l	<2.54 l	2.32 (0.12)	2.28 (0.09)	-0.04 [-0.08 to -0.01]	0.050
Treatment goal reached, <i>n</i> (%)		71 (96.0)	90 (100)	-	0.050
Phosphate, mmol/l	<1.5 l	1.01 (0.17)	1.04 (0.14)	0.03 [-0.02 to 0.08]	0.660
Treatment goal reached, <i>n</i> (%)		74 (100)	90 (100)	-	-
Parathyroid hormone, pmol/l	<7.7 ; if eGFR 15-30:<12	8.2 (3.7) <sup>b</sup>	6.1(2.6) <sup>d</sup>	-2.1 [-3.2 to -1.1]	0.020
Treatment goal reached, <i>n</i> (%)		43 (59.7)	62(87.3)	3.2 (1.5 to 6.8) <sup>a</sup>	0.002
Urine albumin/creatinine, mg/mmol	<25 male, <35 female	6.8 (33.4) <sup>c</sup>	3.9 (6.6) <sup>c</sup>	-2.9[-10.8 to 5.0]	0.560
Treatment goal reached, <i>n</i> (%)		72 (98.6)	82 (97.6)	0.6 (0.01 to 7.0) <sup>a</sup>	0.680
Body mass index, kg/m <sup>2</sup>	25	28.4 (4.6)	28.9 (4.7)	0.4 [-1.0 to 1.9]	0.680
Treatment goal reached, <i>n</i> (%)		13 (17.6)	15 (16.7)	0.9 (0.4 to 2.1) <sup>a</sup>	0.880
Positive smoking status, <i>n</i> (%)	Not smoking	10 (13.5)	11 (12.2)	-	0.810

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by a large number of patients at baseline. In a sub-analysis no albuminuria differences between patients with and without diabetes were found.

#### Strengths and limitations

A strength of the study is that it used a cluster randomised trial design. Usual care for patients with diabetes and hypertension in the practices was already well organised,

**Table 2 continued. Outcome measures in the intervention and control group at *t* = 1 year**

Variable	Treatment goal	Control group	Intervention group	Difference for continuous variables <sup>a</sup> between intervention and control group (95% CI)	P-value
<b>WONCA functional health status</b>					
Overall health	n/a	3.0 (0.8) <sup>c</sup>	3.0 (0.8) <sup>c</sup>	-0.04 [-0.28 to 0.22]	0.420
Daily activities	n/a	1.7 (1.0) <sup>c</sup>	2.1 (1.2) <sup>c</sup>	0.34 (0.03 to 0.73)	0.270
Feelings	n/a	1.7 (0.9) <sup>b</sup>	1.8 (1.0) <sup>c</sup>	0.09 (0.98 to 0.16)	0.970
Physical fitness	n/a	3.1 (0.8)	3.4 (1.0) <sup>c</sup>	0.22 [-0.07 to 0.52]	0.150
Social activities	n/a	1.2 (0.7)	1.6 (1.0) <sup>c</sup>	0.33 (0.06 to 0.60)	0.120
Change in health	n/a	3.0 (0.5)	2.8 (0.6) <sup>c</sup>	-0.17 [-0.34 to -0.003]	0.060
<b>Medication</b>	n/a	47 (63.5)	73 (81.1)	n/a	0.010
C09 agents acting on the RAAS system	n/a	n/a	n/a	n/a	n/a
Lipid modifying agents	n/a	38 (51.4)	66 (73.3)	n/a	0.004
Vitamin D	n/a	1 (0.6)	14 (15.5)	n/a	0.002

Values are given as mean and standard deviation (or standard deviation of difference), or number (percentage). <sup>a</sup>Odds ratio for discrete variables. <sup>b</sup>Two missing values.

<sup>c</sup>One missing value. <sup>d</sup>Three missing values. eGFR = estimated glomerular filtration rate. HbA1c = glycated haemoglobin. HDL = high-density lipoprotein. LDL = low-density lipoprotein. MCV = Mean Corpuscular Volume. MDRD = Modification of Diet in Renal Disease. RAAS = renin-angiotensin-aldosterone system. SD = standard deviation.

WONCA = World Organisation of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians.

which makes the additive value of the shared care model robust. Baseline blood pressure values were at a relatively low level; in practices with less-favourable baseline blood pressure levels, it may be possible to see even more improvement.

Potential bias in the usual-care group was reduced by informing these patients, GPs, and nurse practitioners about the study at the end of the trial.

The setting in research practices enabled retrospective collection of usual blood pressure measurements to serve as baseline measurements for the control group. A further strength is that, before entry, participants had had two consecutive measurements of eGFR <60ml/min/1.73m<sup>2</sup> to confirm a diagnosis of CKD.

Several limitations need to be mentioned. The first is a potential selection bias: although identified at the beginning of the trial, patients in the control group were asked for their informed consent 1 year after randomisation of their practice took place.

As a second limitation, it should be mentioned that a pragmatic recruitment procedure was followed: when the maximum number of patients in one cluster was reached, the inclusion in that practice was stopped. This may have caused a selection of patients who were relatively healthy to adhere to the control visits. On the other hand, not all practices reached the required minimum of 20 patients.

A third limitation is that it was necessary to rely on usual blood pressure measurements to serve as baseline values. It is well known that usual blood pressure measurements lead to higher results than blood pressure measurements in a study setting.<sup>32</sup> The fact that the usual blood pressure measurement in the control group did not differ from the study blood pressure levels at the end of the study reduces concerns about comparability of usual and study blood pressure measurements in this trial.

A further point to be noted concerns generalisability. The population in this study was mainly white, so the results are not representative of a population with a greater proportion of patients of other ethnicities or racial groups, who may have different blood pressure outcomes.

#### Comparison with existing literature

The effect of structured care by nurses was assessed in an observational study by Richards *et al.*<sup>33</sup> Patients with CKD were enrolled in a disease management programme. Blood pressure decreased with 9/5 mmHg, but only in patients without diabetes or proteinuria. In secondary care, several studies have been performed on the nurses' role in managing patients with CKD, with varying success. A study on older patients referred to a multidisciplinary care clinic with a nephrologist and a specialised nurse showed a 50% reduction of the risk for all-cause mortality in an observational

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### Funding

The Dutch Kidney Foundation funded this study: SHARING-study (SHARed care for patients with chronic kidney disease In Nephrology and General practice) (PV 35).

### Ethical approval

This study was performed according to the Code of Conduct for Health Research which has been approved by the Data Protection Authorities for conformity with the applicable Dutch privacy legislation and was in accordance with the Helsinki Declaration of 1975, as revised in 1983. Ethical approval was not required according to the accredited Medical Research Ethics Committee Arnhem/Nijmegen (ABR NL16590.091.07). Trial registration: Sharing study: SHARed care for patients In Nephrology And General practice; Netherlands Trial Registration TC 1140 <http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=1140>.

### Provenance

Freely submitted; externally peer reviewed.

### Competing interests

Jack Wetzels has received grant support from Amgen, Genzyme, and Pfizer on occasions unrelated to this study. The Department of Primary and Community Care at Radboud University Nijmegen Medical Centre received a grant from Amgen for the contact study (implementation of telenephrology).

### Acknowledgements

Marjan Schoneveld and Wouter Koop of the laboratory of the Canisius Wilhelmina Hospital, Nijmegen, were very helpful in organising the laboratory tests. We thank the participating patients, the GPs, and the assistants of the NMP (Nijmegen Monitoring Project) practices. Furthermore, we thank Lea Peters-van Gemert for the practical aspects of the trial and Reinier Akkermans for his statistical advice.

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study.<sup>34</sup> In a comparison between additional intensive nurse-practitioner support and nephrologist care, the blood pressure decrease in the intervention group was 3/2 mmHg more ( $P<0.001$ ) than in the control group.<sup>35</sup> However, in a randomised trial in which patients were randomly assigned to a nurse-coordinated team in secondary care, or to usual care in general practice, no effect on cardiovascular risk-factor control or on clinical endpoints was found.<sup>36</sup>

The opportunity to ask advice from a nephrologist has been studied in a shared care system in the UK.<sup>17</sup> Patients were treated in primary care that was sustained by continuous feedback from nephrologists on the laboratory and blood pressure results. Blood pressure decreased and the prescribing of renin-angiotensin system inhibitors increased.

In summary, the existing literature endorses this study's findings that structuring care for patients with CKD is beneficial in reducing blood pressure. However, study designs were mainly observational with, consequentially, low

levels of evidence. Cluster randomised trials like this are scarce; the Quality Improvement in CKD study (a cluster randomised trial to compare quality-improvement interventions to lower systolic blood pressure in CKD in primary care) showed that audit-based education led to blood pressure lowering of 2.4 mmHg.<sup>37</sup>

### Implications for practice

It is promising that an intervention of shared care showed lowering of systolic blood pressure during a 1-year intervention, even in practices that already had a well-structured care for patients with diabetes or hypertension. Statements on more-relevant endpoints, such as cardiovascular events and hospital admissions, would need larger and longer cluster randomised trials.

Future studies should provide information on cost effectiveness. CKD has a high financial burden. This model of care aims to provide optimal care at the cheapest level possible, and may be cost-effective in lowering cardiovascular morbidity and mortality but this requires future study.

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## Appendix 1. Overview of blood pressure measurement results

Parameter	Baseline		t = 1 year	
	Control	Intervention	Control	Intervention
n	73	90	74	90
Systolic usual BP, mmHg (%)	142.5 (15.1)	142.7 (17.6)	-	-
Diastolic usual BP, mmHg (%)	80.4 (8.2)	74.9 (9.2)	-	-
Systolic study BP, mmHg	NA	137.1 (16.5)	142.9 (16.8)	134.7 (15.7)
Diastolic study BP, mmHg	NA	75.4 (10.7)	80.9 (11.2)	73.8 (9.6)

BP = blood pressure.

## Appendix 2. Changes in outcome measures (other than blood pressure) in intervention group between baseline and t = 1 year (n = 90)

Variable	Baseline	t = 1 year	Difference (95% CI) between baseline and t = 1 year	P-value
Weight, kg	79.5 (14.3)	79.8 (14.9)	0.3 [-0.4 to 1.1]	0.340
Waist circumference, cm	101.3 (12.7)	101.2 (12.9)	-0.1 [-1.1 to 0.9]	0.790
Creatinine, µmol/l	109.0 (24.9)	110.9 (25.4)	1.8 [-2.0 to 5.6]	0.340
eGFR MDRD, ml/min/1.73m <sup>2</sup>	49.1 (7.9)	48.6 (8.7)	-0.5 [-1.9 to 0.9]	0.470
Fasting glucose, mmol/l	6.1 (1.5)	6.4 (1.4)	0.3 [0.07 to 0.53]	0.010
HbA1c, %	6.3 (0.7)	6.4 (0.8)	0.07 [-0.01 to 0.14]	0.080
Total cholesterol, mmol/l	4.9 (1.1)	4.6 (1.1)	-0.3 [-0.5 to -0.1]	<0.001
HDL cholesterol, mmol/l	1.3 (0.4)	1.4 (0.4)	0.03 [-0.04 to 0.11]	0.400
Total cholesterol/HDL	4.0 (1.2)	3.6 (1.2)	-0.36 [-0.55 to -0.17]	<0.001
LDL cholesterol, mmol/l	2.9 (1.0)	2.5 (0.9)	-0.35 [-0.52 to -0.19]	<0.001
Triglycerides, mmol/l	1.7 (0.8)	1.7 (0.9)	-0.01 [-0.16 to 0.14]	0.880
Haemoglobin, mmol/l	8.8 (1.0)	8.7 (0.8)	-0.09 [-0.13 to 0.04]	0.170
MCV, fl	91.8 (3.7) <sup>a</sup>	91.7 (4.0) <sup>b</sup>	-0.01 [-0.7 to 0.7]	0.970
Serum albumin (g/L)	43.3 (2.3) <sup>c</sup>	43.3 (2.3)	0.02 [-0.4 to 0.4]	0.910
Sodium, mmol/l	140.1 (2.2)	140.4 (2.1)	0.33 [-0.12 to 0.79]	0.150
Potassium, mmol/l	4.7 (0.6) <sup>a</sup>	4.89 (0.54) <sup>d</sup>	0.14 [0.02 to 0.26]	0.020
Calcium, mmol/l	2.36 (0.09)	2.28 (0.09)	-0.08 [-0.10 to -0.06]	<0.001
Phosphate, mmol/l	1.15 (0.15)	1.04 (0.14)	-0.10 [-0.14 to -0.07]	<0.001
Parathyroid hormone, pmol/l	6.2 (3.5) <sup>e</sup>	6.1 (2.6) <sup>e</sup>	-0.36 [-0.94 to 0.22]	0.220
Urine albumin/creatinine, mg/mmol	3.0 (5.7) <sup>a</sup>	3.9 (6.6) <sup>a</sup>	0.78 [-0.20 to 1.76]	0.120
Body mass index, kg/m <sup>2</sup>	28.9 (4.6)	28.9 (4.7)	-0.04 [-0.30 to 0.21]	0.740
Smoking status, number of patients smoking (%)	13(14.4)	11(12.2)		n/a
<b>WONCA functional health status:</b>				
Overall health	2.9(0.9)	3.0(0.8) <sup>c</sup>	0.10 [-0.10 to 0.31]	0.320
Daily activities	1.8 (1.1)	2.1(1.2) <sup>c</sup>	0.21 [-0.02 to 0.44]	0.070
Feelings	1.8 (1.1)	1.8(1.0) <sup>c</sup>	-0.01 [-0.24 to 0.21]	0.910
Physical fitness	3.5 (0.9)	3.4(1.0) <sup>c</sup>	-0.14 [-0.33 to 0.06]	0.170
Social activities	1.5 (0.9)	1.6(1.0) <sup>c</sup>	0.01 [-0.20 to 0.22]	0.910
Change in health	2.9 (0.6)	2.8(0.6) <sup>c</sup>	-0.08 [-0.25 to 0.09]	0.350
Agents acting on the RAAS system (%)	66 (73.3%)	73 (81.1%)		0.020
Lipid modifying agents (%)	53 (58.9%)	66(73.3%)		<0.001
Vitamin D (%)	1(1.1%)	14 (15.5%)		<0.001

Values are given as mean and standard deviation or number (percentage). <sup>a</sup>One missing value. <sup>b</sup>Two missing values. <sup>c</sup>Three missing values. eGFR = estimated glomerular filtration rate. HbA1c = glycated haemoglobin. HDL = high-density lipoprotein. LDL = low-density lipoprotein. MCV = Mean Corpuscular Volume. MDRD = Modification of Diet in Renal Disease. RAAS = renin-angiotensin-aldosterone system. WONCA = World Organisation of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians.