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A Self-Management Approach for Dietary Sodium Restriction in Patients With CKD: A Randomized Controlled Trial

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Rationale & Objective: Patients with chronic kidney disease (CKD) are particularly sensitive to dietary sodium. We evaluated a self-management approach for dietary sodium restriction in patients with CKD.

Study Design: Randomized controlled trial.

Setting & Participants: Nephrology outpatient clinics in four Dutch hospitals. 99 adults with CKD or a functioning kidney transplant, eGFR ≥25 mL/min/1.73m^2, hypertension, and sodium intake >130 mmol/day.

Intervention: Routine care was compared with routine care plus a web-based self-management intervention including individual e-coaching and group meetings implemented over a 3-month intervention period, followed by e-coaching over a 6-month maintenance period.

Outcomes: Primary outcomes were sodium excretion after the 3-month intervention and after the 6-month maintenance period. Secondary outcomes were blood pressure, proteinuria, costs, quality of life, self-management skills, and barriers and facilitators for implementation.

Results: Baseline eGFR was 55.0±22.0 mL/min/1.73m^2. During the intervention period, sodium excretion fell in the intervention group from 188(SE, 8) to 148(8) mmol/day (P<0.001), but it did not change significantly in the control group. At 3 months, the mean sodium excretion was 24.8 mmol/day (95%CI, 0.1 to 49.6; P=0.049) lower in the intervention group. At 3 months, systolic blood pressure (SBP) fell in the intervention group from 140(3) mmHg to 132(3) mmHg (P<0.001), but was unchanged in the control group. The mean difference in SBP across groups was –4.7 (–10.7 to 1.3, P=0.1) mmHg. During the maintenance phase, sodium excretion rose in the intervention group, but remained lower than at baseline at 160(8) mmol/day (P=0.01), while it fell in the control group from 174(9) at the end of the intervention period to 154(9) mmol/day (P=0.001). Consequently, no difference in

sodium excretion between groups was observed after the maintenance phase. There was no difference in SBP between groups after the maintenance phase.

Limitations: Limited power, post-randomization loss to follow-up, Hawthorne effect, lack of dietary data, short-term follow-up.

Conclusions: A coaching intervention reduced sodium intake at 3 months. Efficacy during the maintenance phase was diminished, possibly due to inadvertent adoption of the intervention by the control group.

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Index words

Sodium; blood pressure; chronic kidney disease; transplantation; lifestyle; behavioral intervention; co-creation.

Plain-language summary of article

The SUBLIME lifestyle intervention aimed to reduce sodium intake and blood pressure in hypertensive patients with chronic kidney disease (CKD). Hypertension is common in patients with CKD and is usually treated with multiple medications. High sodium intake is a major contributor to hypertension, but is not effectively targeted in routine care. This is partially because improving dietary habits and reduction of sodium intake is not easy for most people, and requires substantial coaching and costs to achieve. SUBLIME helped patients to reduce their sodium intake. However, over time the effects somewhat diminished, and further research is needed to improve its effectiveness in the long term.

Introduction

Patients with chronic kidney disease (CKD) are particularly sensitive to excess sodium[1], and are strongly advised to limit sodium intake.[2–4] Observational studies revealed the potential of moderately reduced sodium intake, suggesting every gram less sodium intake is associated with a 15% lower risk of cardiovascular complications, a 15% lower risk for end stage renal disease (ESRD) in diabetic CKD[5], and a 10% lower risk for ESRD in nondiabetic CKD.[6]

Current approaches to reduce sodium intake are largely unsuccessful: an analysis of >10,000 CKD patients revealed that average sodium intake in CKD patients was 164 mmol/day, even in the dedicated setting of the nephrology outpatient clinic.[7] Behavioral approaches may be more fruitful in achieving sodium restriction.[8,9] Hypertensive patients receiving behavioral counseling in the Trials of Hypertension Prevention I and II had a 25% lower risk of cardiovascular events after 10–15 years follow-up.[8] Likewise, the Effects of Self-monitoring on Outcome of Chronic Kidney Disease (ESMO) study, which was based on self-regulation theory, successfully reduced sodium excretion and blood pressure (BP) in patients with CKD.[9]

Several studies showed that self-regulation theory-based interventions are associated with good outcomes.[10–14] A qualitative study in CKD on barriers and facilitators for sodium restriction yielded several recommendations for future intervention.[14] More recently, a quantitative study in CKD revealed barriers to target for achieving sodium reduction.[15] Recommendations from these studies were incorporated in the present self-regulation theory-based study.

One-to-one counseling required in behavioral interventions is costly. Use of E-Health may improve affordability. To investigate this, we designed the *SodiUm Burden lowered by*

Lifestyle Intervention: self-Management and E-health technology (SUBLIME). The SUBLIME intervention included group counseling and a web-based self-management program, and was followed by a maintenance phase. We evaluated the SUBLIME intervention for efficacy and explored costs, barriers and facilitators for implementation of SUBLIME intervention into clinical practice.

Methods

Trial Design

SUBLIME was a randomized controlled trial that compared routine care with routine care plus a web-based self-management dietary sodium reduction intervention delivered through individual e-coaching and group meetings during a 3-month intervention period, followed by e-coaching during a 6-month maintenance period.

Participants

Participants were recruited from June 2014 to March 2015 at nephrology outpatient clinics of the four participating centers in the Netherlands: Leiden University Medical Center, Leiden; St. Antonius Hospital, Nieuwegein; University Medical Center Groningen, Groningen; and ZGT Hospital, Almelo. Inclusion criteria were age ≥18 years; CKD stages 1–4, and renal transplant recipients (RTR) if estimated glomerular filtration rate (eGFR) was ≥25 mL/min/1.73m^2(no upper limit); urinary sodium excretion at the last two visits >130 mmol/day or >150 mmol/day at the last visit; systolic blood pressure (SBP) >135 mmHg or diastolic blood pressure (DBP) >85 mmHg or well-controlled BP with antihypertensive therapy; sufficient command of the Dutch language; ability to use the Internet; and written informed consent. Exclusion criteria were rapidly and persistently progressive renal function loss, not from acute, intermittent origin; SBP >170 mmHg, or DBP >95 mmHg, or SBP <95

mmHg not responding to withdrawal of antihypertensive medications; history of cardiovascular events <6 months ago; renal transplantation <1 year ago; medical conditions likely to interfere with the completion of the study; previous participation in a similar study.

The medical ethics board approved the study protocol (METc2014/075). The study is registered at ClinicalTrials.gov (NCT02132013), and was performed in accordance to the Declaration of Helsinki.

Intervention

Participants visited outpatient clinics at baseline, 3, and 9 months for anthropomorphic and BP measurements; blood sampling; 24-hour urine collection; assessment of medication use; and filled out a questionnaire at each time point. The baseline questionnaire was distributed directly after randomization, as the baseline questionnaire was different for intervention and control group.

Figure 1 presents a schematic overview of the SUBLIME intervention delivered to the participants randomized to the intervention group during the 3-month intervention phase and during the maintenance phase. The coaching was done by dietitians, lifestyle coaches or research nurses, who were trained by certified lifestyle professionals (i.e. professionals with a degree in Lifestyle Counseling). The 3-month intervention began with baseline face-to-face intake, when a home BP monitoring device (Microlife Watch BP Home) was distributed. The coach also gave participants access and instructions to a web-based self-management program dedicated to sodium restriction. This program consisted of modules addressing self-regulation theory components; exercises to strengthen intrinsic motivation; self-monitoring with a detailed interactive food diary (designed to visually show the effect of different food choices on sodium intake), self-efficacy (identifying barriers and possible solutions), goal

setting, social support, dealing with relapse; and a summary page delineating a 'Plan for Change'. Coaches then viewed the Plan for Change and applied motivational interviewing supporting patients in attaining goals. Participants and their partners were invited to attend two scheduled 2-hour group coaching sessions (Figure 1) during the 3-month intervention phase. Group size ranged from 3-12 participants. During these sessions the coach addressed self-monitoring, skills to decline salty snacks, relapse prevention, and knowledge about 'hidden' sodium in processed foods. During the 3-month intervention phase, participants also received individual coaching via telephone or email (e-coaching), with a minimum of two individual coaching sessions. During the 6-month maintenance phase, participants were instructed to complete web-based self-management modules and participants could receive 1–4 individual e-coaching sessions (Figure 1).

Outcomes

The primary outcome of sodium excretion was measured by one 24-hour urine collection. Blood and urinary electrolytes were measured with routine laboratory procedures. Secondary outcomes were BP, costs, proteinuria, health-related quality of life, and self-management skills, and evaluation of barriers and facilitators for implementation. eGFR was calculated with the CKD Epidemiology Collaboration formula.[16] BP was measured at the outpatient clinic, in upright position, after 5 minutes rest with an automated oscilometric device (WatchBP Home, Microlife), three times with a 1-minute interval.[17] The mean of the second and third reading was used for analysis. Proteinuria was measured in 24-hour urinary collection. Changes in number of prescribed medications and dosage were explicitly asked at the end of the intervention phase and the maintenance phase, and were registered in the Case Report Forms. The questionnaires included sociodemographic factors, Short Form-12[18], EuroQol-5D[19], and Partners In Health scale.[20] Health-related quality of life was measured

using the Short Form (SF)-12. Scoring ranged from 0-100, higher scores indicating better quality of life. Self-management skills were assessed using the Partners In Health (PIH) scale. A four-item questionnaire was used after the active intervention-maintenance phase, assessing patients' healthcare consumption. Additionally, data on medication use (type and dosage) and time receiving E-coaching were gathered. These healthcare consumption data were used for explorative calculation of healthcare costs, to explore affordability of the intervention.[21] Case Report Forms were used to ascertain medical- and travel expenses. Sick leave from work was assessed using two questions in the baseline questionnaire. Relevant cost categories were consultations with the nephrologist, the general practitioner, the dietician, nursing days, sick leave, and travel expenses.

After completion of the study we organized focus groups to evaluate the intervention and identify barriers and facilitators for implementation. The focus groups were led by representatives of the Dutch Kidney Patients Association, each session was observed by two note-takers from a third party. One note-taker attended all four focus groups (W.O.), her registration served as basis for qualitative analysis and was confirmed by the second observer from (O.A.B.H.).

Furthermore, a process evaluation with the providers was conducted using the MIDI questionnaire.[22]

Sample Size

To detect a difference of 2 grams salt (corresponding to 34 mmol sodium/day), achieve a 2-sided significance of 0.05, a power of 80%, and accounting for 10% drop-out, 42 patients were required in each group. Based on data from previous studies[9,23–25] expected standard deviation was 40 mmol/day.

Randomization

Randomization was performed by an independent data management organization. The SURVEYSELECT procedure was used for randomization using the software program SAS (Cary, North Carolina, USA). Participants were stratified per participating center ensuring equal group size. Until all participants were allocated, randomization was concealed from research staff. Upon receipt of signed informed consent, the local study coordinator allocated a study number and contacted the data management center to receive the randomization result.

Statistical Analysis

Data are reported as mean±standard deviation (SD) and mean (SE) for normally distributed continuous data, or median (1^{st}-3^{rd} quartile) for skewed continuous data. Categorical data are reported as frequency. We performed an intention-to-treat analysis on primary and secondary outcomes using linear mixed-effects model analysis (LMM) with restricted maximum likelihood approach and scaled identity covariance structure for sodium excretion, SBP and DBP at baseline, 3-, and 9 months, using all three time points in one model. Fixed effects were treatment group, time, and time × treatment group, random effect was participant number. We report estimated marginal means and standard error (SE) for continuous

outcomes in our LMM. Within-group differences over time of sodium excretion and BP were tested using paired samples t-test.

Within-group differences over time of PIH and SF-12 were tested using Wilcoxon Signed Rank test. Between-groups differences of PIH and SF-12 were tested using Mann-Whitney test. Mean change from to baseline of intervention compared to control of PIH and SF-12 was tested using independent samples t-test. Occurrence of antihypertensive dose reduction or increase between control and intervention was compared with Fisher's exact test.

P-values <0.05 were considered statistically significant. Analyses were performed with PASW Statistics, version 22.0 (SPSS Inc.) and STATA Statistical Software: Release 13 (StataCorp.).

Results

We randomized 99 patients: 52 intervention and 47 control (Figure 2). Five patients did not attend baseline measurements. Participants were 56.6±12.4 years old, and 44% were RTR. Baseline characteristics were similar between control and intervention groups (Table 1). Five participants were lost to follow-up (Figure 2), and not all participants returned their 24-hour urine collection after baseline.

Logging-data revealed that 44/50 participants used the program, with most participants using the program the first 2–4 months. A total of 1647 recordings of dietary intake were registered (37.4 days per participant) during the study. Participants registered 4256 (55.4%) meals and 3428 (44.6%) snacks. Eight participants stopped registering within one month, 11 registered

for >6 months. Within the period that the participants registered, most registered every other day.

Outcomes after 3-Month Intervention Phase

In the intervention group, sodium excretion reduced from 188±63 mmol/day to 148±55 mmol/day at three months (Figure 3). LMM confirmed that this was a significant reduction with estimated marginal mean (EMM) from 188(SE, 8) to 148(8) mmol/day (P<0.001 for within-group difference) at three months (Table 2). The control group demonstrated a nominally but non-significant reduction in sodium excretion. Compared with control, this reflected an effect of the intervention of –24.8 (95%CI, –49.6 to –0.1; P=0.049 for between-group difference) mmol/day (Table 2). There was a concomitant drop in SBP from 140±16 to 131±14 mmHg; and DBP from 84±9 to 80±9 mmHg in the intervention group (Figure 4). LMM confirmed this with EMM from 140(3) to 132(3) mmHg (P<0.001 for within-group difference, Table 2). In comparison, SBP in control changed non-significantly from 139(3) to 136(3) (P=0.2 for within-group difference). The mean difference in SBP across groups was –4.7 (–10.7 to 1.3, P=0.1) mmHg. After the intervention phase, eleven participants had proteinuria ≥1.0 g/d (6 intervention, 5 control). Median proteinuria compared to baseline did not markedly change in the intervention group (P=0.07 for within-group difference), nor in the control group (P=0.2 for within-group difference).

Antihypertensive drug use in the control group reduced in 1 and increased in 3 participants whereas it reduced in 5 and increased in 3 participants in the intervention group (Fisher's exact test, P=0.2 for dose-reduction, P=0.9 for dose-increase). Participants received 2.8±1.2 times E-coaching. Four participants had 1 E-coaching moment and 8 did not request/ receive E-coaching (2 due to drop-out) according to the coaches' logs.

Outcomes after 6-Month Maintenance Phase

The effect on sodium excretion persisted in the intervention group at 157±64 mmol/day (Figure 3). LMM confirmed this with EMM from 188(8) to 160(8) mmol/day (P=0.01 for within-group difference, Table 2). Control demonstrated a reduction to 154±40 mmol/day (Figure 3). This is reflected in LMM (Table 2), demonstrating no significant between-group difference in sodium excretion between intervention and control group (Table 2). A drop in SBP was observed from 140±16 to 131±14 mmHg in the intervention group (Figure 4). LMM confirmed this with EMM from 140(3) to 132(3) mmHg (P<0.001 for within-group difference, Table 2). In comparison, SBP in control decreased from 139(3) to 135(3) (P=0.1 for within-group difference). The mean difference in SBP across groups was -4.3 (-10.2 to 1.7, P=0.2). After the maintenance phase, eleven participants had proteinuria ≥1.0 g/d (5 intervention, 6 controls). Median proteinuria compared to baseline did not markedly change after the maintenance phase in the intervention group (P=0.07 for within-group difference), nor in control (P=0.3 for within-group difference).

Antihypertensive drug use reduced in 5 participants and increased in 3 participants, in both control and intervention (Fisher's exact test, both P=0.9). Participants received 2.1±0.6 times E-coaching, 17 participants did not request or receive E-coaching (5 due to drop-out) according to the coaches' logs.

Quality of Life and Self-Management Skills

At baseline, PHS was similar between groups (P=0.87, Table 3). After the intervention phase, PHS was higher in intervention compared with control (P=0.04), this difference remained after the maintenance phase (P=0.01). At baseline, MHS was similar between groups

(P=0.75), and remained so after the intervention phase (P=0.11). After the maintenance phase, the intervention group reported higher MHS than controls (P=0.01).

At baseline, PIH-score was similar between groups (P=0.11, Table 3). Likewise, after the intervention and maintenance phase, no between-group differences in PIH-score were observed (P=0.63 and P=0.53, respectively).

Costs

The average total costs per patient for the 9-month intervention were $506 (€451) in the intervention group and $460 (€410) in the control group. This difference in costs are mainly explained by higher costs in dietary care intervention versus control.

Barriers and Facilitators for Implementation: Focus Groups

Twenty-one intervention participants participated in focus groups. Additionally, 5 partners and 1 daughter took part. Each focus group consisted of 5–6 participants per center. Although all intervention components were evaluated, the focus groups focused on the web-based self-management program. The participants deemed the exercises in the program clearly formulated and user-friendly, but questioned whether it was necessary to complete exercises that addressed motivation "because we were already motivated, otherwise we would not have participated". The most reported barrier for using the program was filling out the interactive diary as this was time-intensive; not all products were available in the database, or hard to find. Another barrier was difficulty estimating sodium content from restaurant meals or combined products. Participants generally valued the 'options for change' menu, where alternative food products could be chosen. Participants expressed they used the 'change options' to cut sodium intake, and to plan compensation for excess sodium intake.

When asked to what extent the modules gave insight in actual sodium consumption, participants reported they highly valued the monitoring module (average 8.3/10). This module gave visual feedback, showing the amount of sodium participants consumed by consuming certain foods, and how this added up compared with their self-determined goal of maximal daily sodium consumption.

Most participants valued the e-coaching, and mentioned the importance of personal contact with the coach prior to the e-coaching. The majority would have appreciated "an unannounced reminder contact" in the maintenance phase to aid their program adherence. The group meetings were valued for practical advice, rise of awareness, exchange of experiences and contact with fellow patients. Participants stressed the importance of partner/family support. Two partners of participants reported their own antihypertensive medication was reduced. Participants appreciated the objective feedback on 24-hour sodium excretion and blood pressure as helpful to reduce sodium intake and would have liked even more frequent feedback in the form of objectively measured parameters, such as urinary sodium excretion. Overall, participants valued participation in SUBLIME with 7.8/10, and would recommend use of the program to others.

Process evaluation and fidelity

The web-based self-management program was used by 44 unique users. Although participants were instructed to use the program throughout the intervention, focus groups revealed that it was used primarily in the first months. During the first months, the program was used intensively; daily or every few days. Only few participants used the program >6 months, which is supported by the logging data. Most participants registered their dietary

intake in the evenings. Registrations were spread over the categories of meals; breakfast (19%), lunch (19%), and dinner (18%), and to a lesser extent snacks in the morning (14%), afternoon (14%) and evening (16%). Participants appreciated the feedback on 24-hour sodium excretion and blood pressure as helpful to reduce sodium intake and would have liked even more frequent feedback by objective data. Furthermore, participants mentioned the importance of personal contact with the coach prior to the e-coaching. Finally, support of partner and family was mentioned as an important factor in reducing sodium intake.

Regarding the evaluation with the providers, 8 out of 11 filled out the MIDI questionnaire. The providers indicated that the web-based self-management program gave them better insight in the situation of the participants, particularly their motivation, activities, and nutrition intake. A disadvantage was the time needed to familiarize oneself with the program and to use it. The providers felt they were capable of doing the activities needed to carry out the SUBLIME intervention.

Discussion

In this small and short-term trial, we demonstrated that the SUBLIME intervention reduced sodium intake after the 3-month intervention phase. After the maintenance phase, sodium intake decreased in both groups, suggesting that the apparent efficacy during the maintenance phase may have been diminished by inadvertent adoption of the intervention by the control group. BP decreased from baseline, without between-groups differences at 3 months and at 9 months post-baseline.

The effect we observed on sodium intake is comparable to interventions in other populations. The PREMIER study in untreated (pre)hypertensive patients consisted of biweekly behavioral counseling in the first half year aiming at weight reduction alone, or combined with adherence to the DASH-diet, or advice-only.[26] Sodium excretion was reduced with 31.6, 32.6 and 20.6 mmol/day respectively, which is comparable to the 41 mmol/day change achieved in our intervention phase, and also in line with 44 and 33 mmol/day reductions achieved in the TOHP-trials.[8] Few studies investigated behavioral interventions in CKD for sodium restriction. The MASTERPLAN study, performed in a setting similar as SUBLIME, was a nurse-led intervention with eleven treatment targets, including adherence to sodium intake <2000 mg (90 mmol) per day.[27] MASTERPLAN did not address all components of self-regulation theory and had a long intervention phase of two years, averaging 7.2 outpatient clinic visits yearly.[27,28] MASTERPLAN had no effect on sodium excretion (150 versus 148 mmol/day).[28] A multidisciplinary behavioral approach was shown effective in the ESMO intervention in CKD, which also successfully reduced sodium excretion and BP in the short term.[9]

Higher sodium intake correlates with higher antihypertensive drug use in 141 patients with CKD stage 4 and 5.[29] In SUBLIME there was more dose-reduction in the intervention

group after the intervention phase, while after the maintenance phase both groups displayed a similar incidence of dose-reduction, in line with the effects on sodium intake.

The study has several strengths. The intervention was based on a sound theoretical framework and was designed in a multidisciplinary setting, with input from psychologists, nephrologists, dietitians, representatives from the Dutch Kidney Patients Association, and in co-creation with patients. Our study population consisted of several CKD stages, and also included RTR as these patients also commonly have hypertension and high sodium intake.[30] Further, the intervention was evaluated using logging data and focus groups to identify barriers and facilitators for implementation in clinical practice.

Limitations of the study include lack of dietary data, and post-randomization loss to follow-up, short-term follow-up, and small sample size. Statistical power was limited first, by sample size, and second, because the power calculation was based on the treatment effect observed in the ESMO-study, i.e. a reduction of 30.3 mmol/day. We anticipated a larger effect for the present study but this was apparently overly optimistic, particularly for the maintenance phase. Furthermore, the preponderance of male participants in our study may affect generalizability. Finally, sodium intake may have been subject to the so-called Hawthorne-effect.[31] Participants' awareness of being in a sodium intervention study might have affected the outcome even without exposure to the intervention. For instance, control participants might have become more vigilant about sodium intake simply by being enrolled in the SUBLIME study. Frequent 24-hour urinary sodium measurements during the study may have motivated control participants to achieve gradual, significant, reduction in sodium intake that was observed, even without the active coaching. The different time course of sodium reduction between the groups may be of interest. In the intervention group, the largest sodium reduction occurred during the intervention phase, i.e. when participants most actively used the web-based self-management program, as evidenced by the logging data. In the focus

groups, participants reported that their acquired insights into their diet affected their use of the web-based self-management program. As well, they indicated that after achievement of their target sodium intake they stopped using the program regularly, which occurred when sodium reduction became similar to that in the control group. A logical interpretation would be that a combination of selection effect (motivation for sodium reduction), awareness of being studied, and feedback from urinary sodium exerted a gradual effect on sodium intake that was accelerated and intensified by the coaching program.

The feedback by our participants obtained in the focus groups provides important lessons from our study for future interventions. First, participants considered feedback from objective data, such as 24-hour urine sodium, highly useful. Second, they desired face-to-face contact with their personal coach prior to E-coaching sessions, thus favoring blended care over a pure e-Health approach. Moreover, they considered social support from partner and family essential. Also, the intervention should be tailored to personal sodium-reduction barriers, and to personal preferences, such as whether or not to participate in group sessions. Finally, the web-based self-management program should be user-friendly. Future studies should elucidate whether effectively accounting for these factors can further enhance the efficacy of sodium management in patients with CKD on a long-term basis, and whether these principles can also be applied for management of other dietary factors.

In conclusion, the SUBLIME study presents a potentially effective strategy for dietary sodium restriction in CKD in clinical practice, although future larger and longer term studies are needed to test long-term efficacy.

Article information

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Data sharing statement: The trial protocol and deidentified participant data are available upon reasonable request until 2 years after publication of the manuscript, via the corresponding author. The data can be made available to researchers who provide a methodologically sound proposal in their request. Reuse of the data can be permitted upon reasonable request via the corresponding author.

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Table 1. Baseline Characteristics.

	Total	Control	Intervention
n	94	44	50
Age, years	56.6 ± 12.4	58.2 ± 13.2	55.1 ± 11.5
Female gender, *n*	15 (16%)	8 (18%)	7 (14%)
eGFR (CKD-EPI), mL/min/1.73m^2	55.0 ± 22.0	54.3 ± 21.6	55.6 ± 22.6
History of DM, none	65 (69%)	30 (68%)	35 (70%)
DM I	7 (7%)	3 (7%)	4 (8%)
DM II	22 (23%)	11 (25%)	11 (22%)
History of Dialysis, *n*	27 (29%)	12 (27%)	15 (30%)
Renal Transplant Recipient, *n*	41 (44%)	19 (43%)	22 (44%)
Antihypertensive drug use, *n*	90 (96%)	41 (93%)	49 (98%)
Number of classes	2.0±1.0	2.0 ± 1.1	2.1 ± 1.0
RAAS-blockade, *n*	70 (74%)	32 (73%)	38 (76%)
Beta-blocker, *n*	41 (44%)	15 (34%)	26 (52%)
Calcium channel antagonist, *n*	33 (35%)	16 (36%)	17 (34%)
Diuretic, *n*	40 (43%)	22 (50%)	18 (36%)
Calcineurin-inhibitor use	27 (29%)	12 (27%)	15 (30%)
Possession of HBPM	64 (68%)	35 (80%)	29 (58%)
Uses never	11 (17%)	6 (17%)	5 (17%)
Uses daily	5 (8%)	2 (6%)	3 (10%)
Uses weekly	19 (30%)	10 (9%)	9 (31%)
Uses monthly	29 (45%)	17 (49%)	12 (41%)
Body mass index, kg/m^2	28.6 ± 5.3	28.4 ± 5.0	28.7 ± 5.6
Caucasian, *n*	89 (95%)	40 (91%)	49 (98%)
Higher educated, *n*	39 (41%)	19 (43%)	20 (40%)

Abbreviations: eGFR, estimated glomerular filtration rater; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration formula; DM, diabetes mellitus; RAAS, renin–angiotensin–aldosterone system; HBPM, home blood pressure monitor.

Table 2. Linear Mixed Effects Model of the SUBLIME Intervention

	Mean[a] (SE) Intervention			Mean[a] (SE) Control			Effect of Intervention (95% CI)[b]	
	0	**3**	**9**	**0**	**3**	**9**	**Δ 0-3 months**	**Δ 0-9 months**
Na, mmol/24-hour	187.6	147.5†	159.3[c]	188.8	173.5	153.6[d]	−24.8*	6.9
	(7.9)	(8.2)	(8.4)	(8.5)	(8.8)	(8.6)	(−49.6 to −0.1)	(−17.8 to 31.6)
	N=45	N=40	N=43	N=44	N=40	N=37	N=85	N=80
Systolic BP, mmHg	139.6	131.8†	131.5†	139.2	136.1	135.3	−4.7	−4.3
	(2.5)	(2.5)	(2.5)	(2.6)	(2.7)	(2.6)	(−10.7 to 1.3)	(−10.2 to 1.7)
	N=44	N=41	N=44	N=44	N=39	N=38	N=84	N=80
Diastolic BP, mmHg	83.9	80.5[e](1.4	79.2†	83.3	81.7	80.1[e]	−1.8	−1.5
	(1.4)	)	(1.5)	(1.5)	(1.5)	(1.5)	(−5.5 to 2.0)	(−5.2 to 2.3)
	N=44	N=41	N=44	N=44	N=39	N=38	N=84	N=80

[a] Estimated marginal means and standard error (SE).

[b] Effect of interaction term time × treatment with 95% confidence interval (CI), these N refer to the number of participants that had both baseline and follow-up outcome measurements available.

† *P*<0.001 versus baseline within group; [c]*P*=0.01 versus baseline within group; [d]*P*=0.001 versus baseline within group; [e]*P*=0.03 versus baseline within group; * *P*=0.049 difference in change versus control group.

Abbreviations: SE, standard error; CI, confidence interval; N, Numbers analyzed; BP, blood pressure;

Table 3. Self-management skills and health-related quality of life

	Median [IQR] Intervention			Median [IQR] Control		
	0	3	9	0	3	9
PIH-score	86 [72-102]	93 [79-101]	91 [76-104]	97 [82-105]	96 [84-104]	96 [80-106]
	N=40	N=36	N=35	N=35	N=37	N=31
SF-12, PHS	79 [59-92]	90[a] [65-92]	92[b] [58-92]	83 [54-92]	54 [33-92]	58 [38-92]
	N=48	N=44	N=43	N=39	N=37	N=40
SF-12, MHS	83 [72-90]	83 [69-93]	86[b] [75-93]	83 [73-93]	80 [47-87]	80 [64-87]
	N=47	N=45	N=42	N=40	N=38	N=40

Data are shown as median [IQR], and comparisons were made with Mann Whitney between groups and Wilcoxon Signed Rank within groups. MHS, Mental Health Summary score; PHS, Physical Health Summary score; PIH, Partners in Health scale; SF, Short Form. Cronbach's Alpha of PIH: 0.93. Cronbach's Alpha of SF-12: 0.86 for PHS and 0.84 for MHS.

[a]*P*=0.04 between-groups difference; [b]*P*=0.01 between-groups difference.

Legends to Figures

Figure 1. Schematic overview of the SUBLIME intervention

Figure 2. CONSORT Flow diagram of the SUBLIME intervention.

Figure 3. Sodium excretion as assessed by 24-hour urine collection at baseline, after intervention (3 months) and maintenance phase (9 months). Within-group change at 9 months compared to baseline (paired samples t-test) was for intervention P=0.01 and for control P=0.001. * denotes P=0.049 versus control group. Error bars represent standard error of mean.

Figure 4. Office BP, after intervention (3 months) and maintenance phase (9 months).Within-group change in SBP at 9 months compared to baseline (paired samples t-test) was for intervention P<0.001 and for control P=0.09. Within-group change in DBP at 9 months compared to baseline (paired samples t-test) was for intervention P<0.001 and for control P=0.03. Error bars represent standard error of mean. SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure.