Exploring the potential of self-monitoring kidney function after transplantation : from patient acceptance to replacing outpatient care

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CHAPTER 5

Self-monitoring of renal function during the first year after kidney transplantation: a randomised trial on safety and feasibility

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Submitted

ABSTRACT

Self-monitoring creatinine could decrease the frequency of outpatient visits and improve rejection detection after kidney transplantation. In this non-inferiority trial, the safety and feasibility of self-monitoring creatinine supported by an online self-management system in the first year post-transplantation was investigated.

119 kidney transplant patients were randomized to standard care (N=65) or to self-monitoring creatinine with part of outpatient visits replaced by telephone consults (N=54). Primary outcome was kidney function (eGFR), secondary outcomes included number of visits. Twenty intervention patients were interviewed on their experience with self-monitoring.

No differences were found between intervention and control group for the development of eGFR over time (*p*. 544). Number of outpatient visits was significantly reduced (*p* .007), but the degree of reduction was suboptimal. Self-monitoring enhanced early rejection detection in 3 out of 5 cases, none were missed. Satisfaction was high; 95% of the interviewed patients would recommend self-monitoring.

Taking into account the non-inferiority to standard care, the reduction in visits and the high level of satisfaction, self-monitoring may play a useful role in post-transplantation care.

INTRODUCTION

Several studies have shown that patient self-monitoring can have significant clinical benefits for different chronic diseases, including reductions in HbA1c[1-4], improvements in blood pressure control[5-9], improved asthma control[10] and reductions in thromboembolic events[11, 12]. Self-monitoring has further been shown to lead to a higher quality of life[13-16] and more patient empowerment[16-19]. In addition, patients seem to prefer self-monitoring above regular care[8, 13, 14, 16, 17, 19].

Self-monitoring may also be a promising approach for follow-up of kidney transplant patients, with the frequent outpatient appointments constituting a high burden to healthcare systems and to patients. As many of these appointments are routine visits to monitor kidney function, self-monitoring creatinine and blood pressure at home has the potential to replace part of these visits by telephone contacts[20]. Further, as self-monitoring allows for measurements to take place more frequently, speed of rejection detection may be improved which could in the long run lead to improved kidney-graft survival[21-26].

To the best of our knowledge, there are no studies available that report on the usability of self-monitoring kidney function. Results from a pilot study of our own group did show that self-monitoring of creatinine and blood pressure is very well accepted by patients[27]. Our objective therefore was to investigate whether self-monitoring kidney function supported by a Self-Management Support System (SMSS) can lead to a reduction in number of outpatient visits in the first year post-transplantation without compromising on quality of care. To this end, we conducted a randomized controlled trial, comparing quality of care (eGFR, blood pressure, satisfaction, quality of life) and number of outpatient contacts between self-monitoring patients and patients receiving standard care.

METHODS

The ADMIRE study (Assessment of a Disease management system with Medical devices In RENal disease) was a randomized controlled trial (RCT) among kidney transplant patients performed at the University Medical Centre of Leiden (LUMC), The Netherlands. The study protocol was reviewed and approved by the Institutional Review Board of the LUMC (protocol number P11.188).

2.1. Participant recruitment and assignment

Power calculation used the within-group standard deviation for differences in renal function of two historic kidney transplant cohorts (3.8 ml/min). The tolerance limit for differences between groups was set to 3.0 ml/min. With a robust beta (power of 95%), an alpha of .05 and 2-tailed testing, a sample size of at least 42 per group was needed.

Patients were eligible for participation if their living donor transplantation was scheduled or if they were still hospitalized after having received a kidney from a deceased donor within period of inclusion (March 2012 - May 2014), were ≥18 years of age, mastered the Dutch language sufficiently, had sufficient computer skills and access to Internet, could perform the required actions independently and had a creatinine level of ≤300 µmol/l within 4 weeks post-transplantation (due to lower reliability of the creatinine device for values >300 µmol/l). Patients were excluded if they had insufficient understanding of the treatment and/or had a history of incompliance.

During a pre-transplant appointment with a nurse-practitioner aimed at informing patients about the transplantation procedure in the LUMC, patients were shortly introduced to the study and received a detailed description of the study design and informed consent form. If a signed informed consent form was not returned within 2 weeks from the appointment, patients were contacted by the primary investigator to inform whether they were (still) interested in participation. Each participant was assigned a study number in consecutive order. Study numbers were allocated to either the intervention or control group according to a pre-set randomization schedule with a 1:1 ratio. The randomization list was produced by means of random permutations of therapies within blocks of length 10 with 5 occurrences of each of the two therapies per block. A Statistical Package for the Social Sciences (SPSS) program (syntax) was written for this purpose by the statistician. For the last 6 months of inclusion, a new randomization list was created by the statistician with a 2:1 ratio as the intervention-control distribution became skewed. The randomization procedure was blinded for the project members directly involved in patient recruitment.

2.2. Materials

Patients received a StatSensor® Xpress-i™ Creatinine Hospital Meter (Nova Biomedical, Waltham, USA) and measurement accessories (i.e. test strips, control solution and safety lancets for capillary blood sampling) to self-monitor creatinine. Further, they received a Microlife WatchBP® Home (Microlife, Heerbrugg, Switzerland), an oscillometric device for blood pressure self-measurement on the upper arm. Both devices had a memory function and the option to download stored values to a computer. Test results were registered in an Internet-based self-management support system (SMSS). For

creatinine, a feedback system was available. The feedback appeared directly after registration of a new creatinine value and consisted of a traffic light with corresponding text to support interpretation (see figure 1). Values registered in the SMSS were automatically sent to the electronic hospital system and thus visible for the treating nephrologist(s).

The SMSS further entailed an eLearning module with measurement instructions and information on kidney anatomy, the transplantation procedure, medication and lifestyle.

2.3. Intervention procedure

After being instructed through eLearning, all intervention patients received the self-monitoring devices and supplementary instructions. Patients were carefully instructed that they were supposed to take action themselves upon the system's feedback, as their nephrologist(s) would not systematically check registered home-based values. Patients were encouraged to practice using the creatinine and blood pressure devices during the remainder of their hospital stay. Home-based measurements had to be performed according to a fixed frequency, being daily during the first 4 weeks (phase 1), every other day for week 5-9 (phase 2), twice a week for week 10-15 (phase 3) and weekly from week 16 onwards (phase 4). This scheme was based upon the usual frequency of laboratory testing, which gradually decreases after time.

For intervention patients, every other face-to-face (ftf) visit with regular hospital-based laboratory analysis was replaced by a telephonic consult to discuss self-monitored creatinine and blood pressure from week eight after transplantation on. A reminder for nephrologists to schedule a telephone consult instead of a ftf visit was shown repetitively in the patients' electronic hospital file. The treating nephrologist eventually decided whether a patients' clinical condition allowed for a ftf consult to be replaced by a telephonic one. The control group received standard care, excluding the use of a creatinine device at home. All their follow-up appointments took place in the outpatient clinic of the LUMC.

In addition, 20 patients were interviewed concerning their experiences and satisfaction with self-monitoring kidney function after transplantation using a semi-structured protocol (see appendix). Over time both intervention and control patients completed questionnaires, a baseline questionnaire at day of discharge and twelve months after discharge.

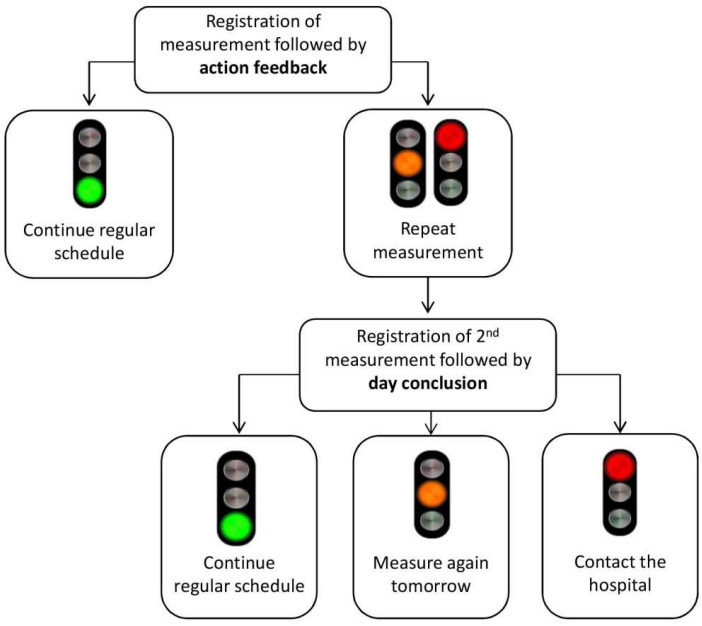


Figure 1. SMSS feedback system.

2.4. Measures

Serum creatinine (µmol/l) values measured around baseline (0-30 days post-discharge) and 12 month follow-up (301 -426 days post-discharge) were obtained from the electronic hospital file. The width of these timeframes was determined by the availability of at least 1 creatinine value per patient. The same timeframes were used to obtain systolic and diastolic blood pressure (mmHg). A mean serum creatinine and systolic and diastolic blood pressure was calculated for baseline and follow-up using the available measurements within the two timeframes. Kidney function (eGFR) was calculated with the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula[28]. Number of outpatient contacts, serious adverse events (SAEs, i.e. hospitalizations) and rejection episodes within 365 days from discharge were obtained from the electronic hospital file. To investigate whether replacing ftf visits with telephonic consults led to a decrease in total healthcare consumption, total number of minutes spent per patient in the first 365 days from discharge was calculated including all ftf visits (10 minutes), telephonic consults (5 minutes) and separate laboratory analyses (5 minutes). Self-monitored values registered online were obtained from the SMSS.
Both the intervention and control group completed the Short Form-12 (SF-12) [29] to measure quality

of life. This questionnaire contains 12 multiple-choice items covering Physical Component Summary (PCS), and the Mental Component Summary (MCS). The Partners in Health scale[30] (PiH) was used to measure self-efficacy regarding self-management behaviour. The PIH contains 12 items on a nine-point scale. The Client Satisfaction Questionnaire(CSQ-8) [31] was used to measure satisfaction with care and consists of 8 items that are rated on a four-point scale. All questionnaires were completed at baseline and 12-month follow-up.

The interviews were recorded and transcribed in full. Answers to questions relating to satisfaction with self-monitoring after kidney transplantation (1. If possible, would you like to continue self-monitoring supported by the SMSS? Why (not)?, 2. Would you recommend self-monitoring kidney function supported by the SMSS to other kidney transplant patients? Why (not)?) were extracted from the data and categorized.

2.5. Data analysis

Baseline continuous variables are reported as mean (SD, standard deviation) or median (IQR, interquartile range) in case of skewed data. Categorical variables are reported in percentages. The baseline characteristics of the intervention and control group were compared using independent t-tests for continuous variables and chi-square tests for categorical variables. Linear mixed modelling was used to compare intervention and control patients concerning the change in kidney function (eGFR), blood pressure, QoL (physical and mental component scale), level of satisfaction with care and self-management behaviour over time. Linear mixed modelling is the recommended method for analysing repeated measures, as it accounts for correlation between repeated measurements of the same patient.

To analyse the difference between intervention and control patients for number of ftf and telephonic consults, total number of reimbursable minutes spent over 365 days post-discharge (including ftf visits, telephonic consults and laboratory analysis only) and number of SAEs, univariate linear regression was used.

Besides univariate linear mixed models and linear regression analyses, sensitivity analyses were performed using multivariate models adjusting for significant baseline difference(s) between the two study groups. Missing baseline data were imputed using multiple imputations (n=10).
For the variables with a hypothesized non-inferior outcome (eGFR, blood pressure, quality of life, satisfaction, number of SAEs), only the per protocol population was included in the analyses. Including intention-to-treat patients would dilute the potential difference between intervention and control patients, facilitating a non-inferior result. For the variables with an expected difference between the

intervention and control group (number of outpatient visits, number of telephonic consults and amount of self-management behaviour), both intention-to-treat and per protocol analyses were performed.

For intervention patients only, self-monitored creatinine trends were compared to laboratory trends in case the latter showed an increase of >10%. Time frames with a >10% laboratory increase and at least 3 available self-monitored creatinine values within the same time frame were taken into account (see figure 2). Number of cases in which both laboratory and self-monitored creatinine trends showed an increase of >10% were selected and divided by total number of laboratory-based creatinine increases of >10%.

All statistical analyses were performed with SPSS 23 for Windows (IBM Corp, Armonk, NY). P-values of <0.05 were considered significant.

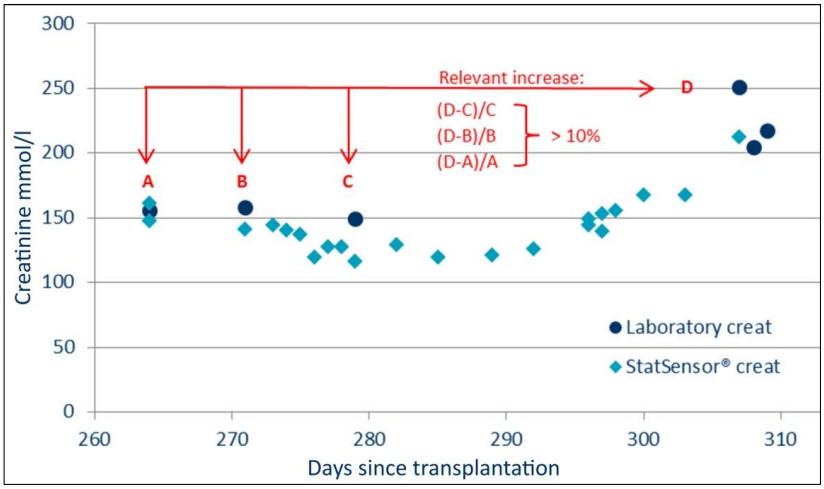


Figure 2. Method of comparing creatinine trends as analysed by the laboratory (dots) and measured by the StatSensor® creatinine device (diamond shape).

RESULTS

Within period of inclusion, in total 217 patients received a kidney transplant of which 155 were considered eligible for participation. The main reasons for ineligibility were insufficient mastery of the Dutch language (N=25, 40%) and no access to a computer or too limited computer skills (N=16, 26%).

Within the eligible population, 119 patients (77%) signed an informed consent. The main reason for not wanting to participate was the anticipated additional burden of self-monitoring (N=17, 47%). Sixty-five patients were randomized to the intervention group. After randomization, 3 patients dropped out because of graft dysfunction, death and cancellation of transplantation (none was study related). Four patients cancelled their participation before starting to self-monitor kidney function at home, because of limited trust in the creatinine device, difficulties when logging on the SMSS, business rush or a worsened condition post-transplantation. The number of patients eligible for intention-to-treat analysis was 62 in the intervention and 51 in the control group. See figure 3 for the study flow-chart. Sample characteristics are shown in table 1 for both the intention-to-treat and per protocol population. Intervention and control group were similar on all variables, except for diabetes. The intervention group contained significantly more patients with diabetes, which pertained to both the intention-to-treat and per protocol population (*p* .03 and .01, respectively). Sensitivity analyses adjusting for diabetic status were therefore performed. The interviewed population was a representative sample of all intervention patients with a mean age of 51 years, a 70/30 male/female ratio, 50% pre-emptive and 85% living donor transplantations.

3.1. Self-monitoring kidney function after transplantation is non-inferior to regular care

Figure 4 shows the development over time of eGFR, quality of life and blood pressure. Significant improvements over time were found for eGFR (*p* .025, 95% CI [.546 – 8.066]), systolic (*p* .009, 95% CI [-11.481 – -1.673]) and diastolic blood pressure (*p* .018, 95% CI [-6.499 – -.623]) and physical (*p* .000, 95% CI [14.855 – 32.384]) and mental QoL (*p* .004, 95% CI [3.809 – 19.408]), independent of study group (see table 2). Mean number of SAEs for both the intervention and control group is shown in figure 5. Total number of SAEs was similar for intervention and control patients (*p* .117, 95% CI [-1.012 – .114]), see table 3. Sensitivity analyses controlling for diabetes led to a loss of the statistically significant improvement over time for eGFR, blood pressure and quality of life (data not shown). Number of SAEs was significantly lower for the intervention compared to the control group when controlling for diabetes (*p* .046, 95% CI [-1.178 – -.010]).

Level of general satisfaction about care remained stably high over time in both study groups with a mean score of around 29 on a scale with a maximum of 32 (see figure 4 and table 2). During the interviews, intervention patients also reported high levels of satisfaction with self-monitoring (N=20). Nineteen out of 20 interviewees (95%) would recommend self-monitoring to other kidney transplant patients. Further, 15 out of 20 (75%) indicated they would have liked to continue self-monitoring beyond the first year post-transplantation.

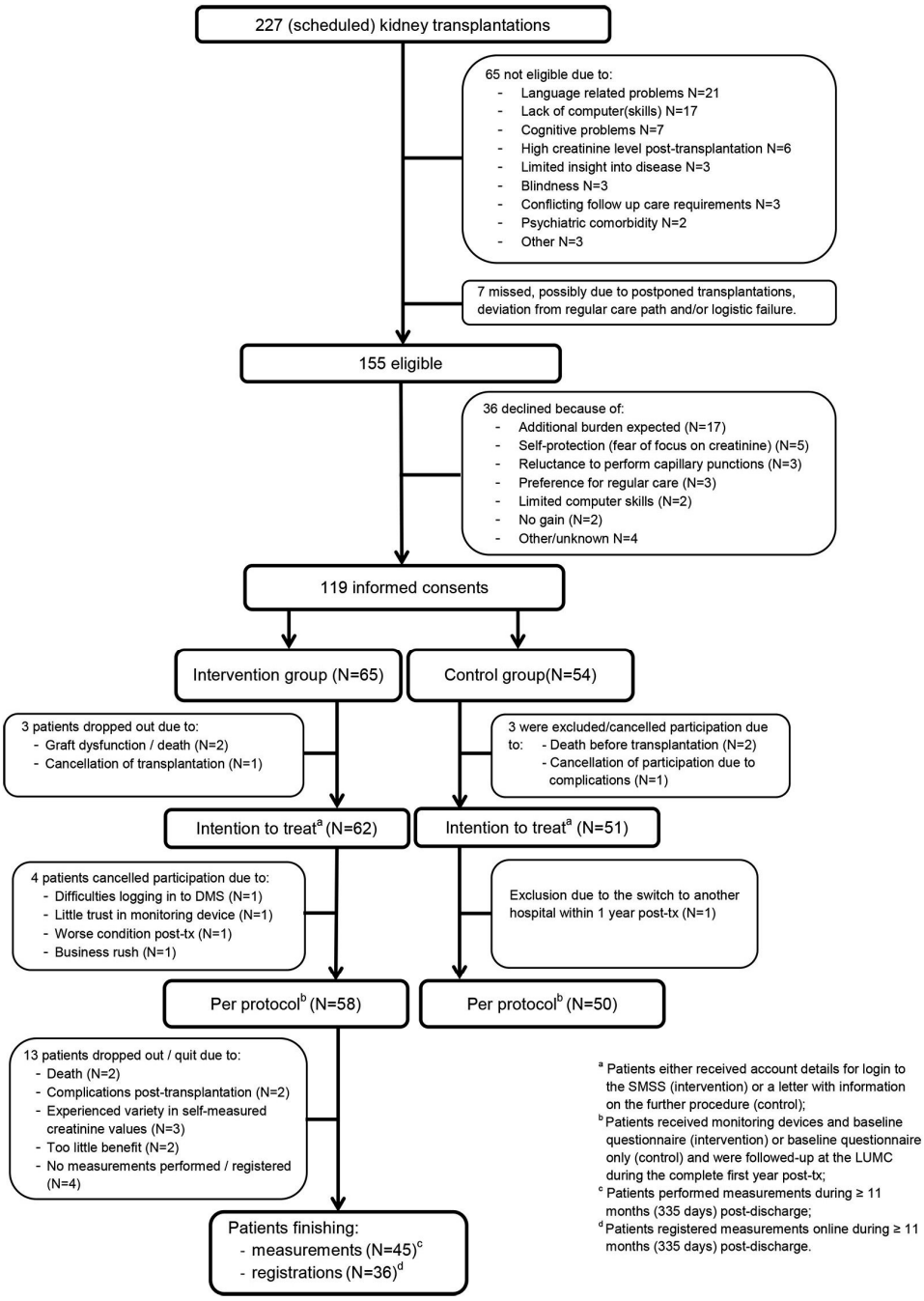


Figure 3. Study flowchart.

Table 1. Baseline characteristics

		Intention-to-treat population			Per protocol population		
		Intervention N=62	Control N=51	*p*	Intervention N=58	Control N=50	*p*
Sex, male N (%)		40 (65)	27 (53)	.25	37 (64)	27 (54)	.33
Age at tx (mean, SD)		52 (14)	51 (13)	.51	52 (14)	50 (14)	.68
Living together/married (N, %)		44 (71)	36 (71)	>.99	43 (74)	35 (70)	.67
Educational level (%)[1]				.59			.49
	Low	17 (27)	13 (25)		17 (29)	12 (24)	
	Middle	12 (19)	15 (29)		12 (21)	15 (30)	
	High	17 (27)	20 (39)		17 (29)	20 (40)	
Paid job, yes (N, %)[1]		24 (39)	23 (45)	.84	24 (41)	23 (46)	>.99
Origin, Dutch (N, %)		56 (90)	46 (90)	>.99	53 (91)	45 (90)	>.99
Underlying disease (N, %)				.47			.43
	Familial/hereditary diseases	15 (24)	12 (24)		13 (22)	11 (22)	
	Primary glomerulonephritis	9 (15)	10 (20)		8 (14)	10 (20)	
	Pyelonephritis	3 (5)	6 (12)		3 (5)	6 (12)	
	Secondary glomerular/ systemic diseases	10 (16)	8 (16)		10 (17)	8 (16)	
	Vascular diseases	13 (21)	6 (12)		13 (22)	6 (12)	
	Other/unknown	12 (19)	9 (18)		11 (19)	9 (18)	
Diabetes, yes (N, %)		13 (21)	3 (6)	.03	13 (22)	2 (4)	<.01
BMI (mean, SD)		25 (4)	25 (4)	.24	26 (4)	24 (4)	.15
Former transplantation, yes (N, %)		7 (11)	8 (16)	.58	6 (10)	8 (16)	.40
Dialysis dependency pre-transplantation (N, %)		33 (53)	27 (53)	>.99	32 (55)	26 (52)	.85
PRA, median (median, IQR)		4 (1)	4 (4)	.30	4 (1)	4 (4)	.25
Living donor (N, %)		54 (87)	45 (88)	.81	50 (86)	44 (88)	.80
HLA incompatibility (mean, SD)		3 (2)	3 (2)	.15	3 (2)	3 (2)	.15
Primary graft function (N, %)		56 (90)	45 (88)	.77	52 (90)	44 (88)	>.99
eGFR (CKD-epi) (mean, SD)		49 (16)	53 (17)	.22	49 (16)	52 (17)	.27
No. anti-hypertensive medications (mean, SD)		1 (1)	1 (1)	.70	1 (1)	1 (1)	.96
Blood pressure (mean, SD)	Systolic	138 (14)	135 (13)	.34	137 (14)	135 (13)	.36
	Diastolic	82 (9)	83 (8)	.78	82 (9)	83 (8)	.71

[1] Imputed data

Table 2. Additional decline or additional increase of the intervention group compared to standard care using linear mixed model analyses.

	Intention-to-treat analysis				Per protocol analysis			
	Estimate	95% CI		*p*	Estimate	95% CI		*p*
		Upper	Lower			Upper	Lower	
eGFR[1]	NA[2]	NA		NA	1.41	-3.74	6.56	.544
Systolic blood pressure[1]	NA	NA		NA	4.37	-2.20	10.94	.189
Diastolic blood pressure[1]	NA	NA		NA	.81	-3.13	4.74	.685
Quality of life- physical[1]	NA	NA		NA	2.69	-9.67	15.04	.667
Quality of life- mental[1]	NA	NA		NA	3.20	-7.72	14.12	.562
Satisfaction[1]	NA	NA		NA	.42	-.54	1.38	.381
Self-management behaviour	.46	-5.03	5.95	.867	.69	-4.86	6.23	.806

[1] Per protocol analysis only due to the hypothesized non-inferiority of self-monitoring to regular care; [2] Not applicable

Table 3. Difference in outcome of the intervention group compared to regular care using linear regression analyses.

	Intention-to-treat analysis				Per protocol analysis			
	Estimate	95% CI		*p*	Estimate	95% CI		*p*
		Upper	Lower			Upper	Lower	
No. of ftf consults	-2.39	-4.14	-.64	.007	-2.62	-4.32	-.92	.003
No. of telephonic consults	1.44	.36	2.52	.009	1.53	.42	2.64	.007
Total no. of minutes	-33.48	-63.97	-2.99	.032	-38.84	-69.69	-7.98	.014
No. of SAEs[1,2]	NA	NA		NA	-.45	-1.01	.11	.117

[1] Per protocol analysis only due to the hypothesized non-inferiority of self-monitoring;

[2] Serious Adverse Events, complications requiring an overnight stay in the hospital

3.2. Significant reduction in number of outpatient visits

Mean number of ftf consults, telephonic consults and total number of minutes spent of both the intervention and control group are shown in figure 5. Self-monitoring led to a significant decrease in number of outpatient visits for the intention-to-treat population, with 16.02 (SD 4.93) and 18.35 (SD 3.91) ftf visits for the intervention and control group, respectively (*p* .007, 95% CI [-4.023 – -.651]), see table 2. Total number of reimbursable minutes spent per patient (including ftf, telephonic consults and laboratory analysis) was significantly lower for self-monitoring patients, with 286.13 (SD 90.96) minutes for the intervention versus 319.61 (67.91) minutes for the control group (*p* .032, 95% CI [-63.967 – -2.991]). Sensitivity analyses with patients treated per protocol only and controlling for diabetes gave no substantially different results (data not shown).

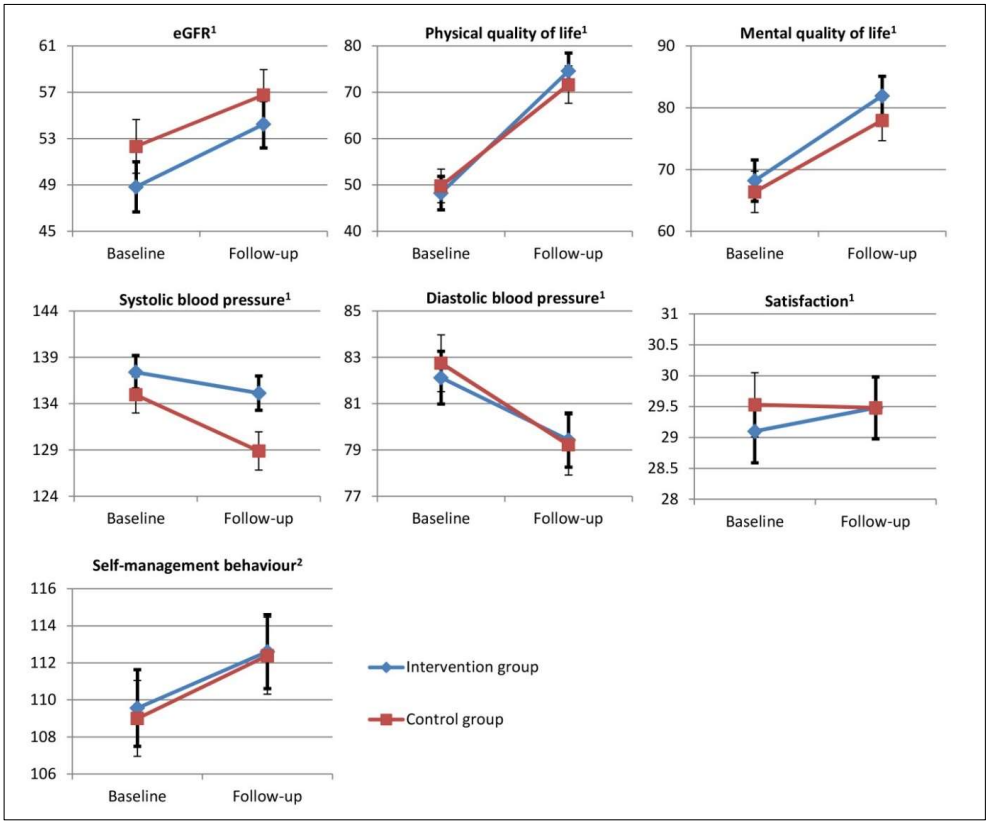
3.3. Physician's interaction with SMSS and self-monitoring

Following our protocol (i.e. replacing half of the ftf visits by a telephonic one after the first period of eight weeks after transplantation), the expected difference in number of ftf visits between intervention and control patients should have been 6 (given that a patients' clinical condition allowed for visits to be replaced). As the actual difference between intervention and control group was 2.3 visits, we further investigated doctors' involvement with the study protocol. Per doctor (N=15), total number of ftf appointments and telephonic consults for patients in the intervention group was calculated and compared to total number of logons to the SMSS. For this purpose, only patients that performed and registered measurements during the full study period were considered (N=36). For 10 doctors (67%), the number of logons to the SMSS equalled at least the number of telephonic consults with self-monitoring patients. Comparing number of logons to total number of consults (either ftf or telephonic), 10 doctors (67%) had checked the values in the SMSS in less than half of their appointments. Three of them had never logged on to the SMSS although having had multiple (telephonic) consults.

3.4. Level of self-efficacy regarding self-management behaviour similar in both study groups

Self-reported self-management behaviour increased significantly over time for both the intervention and control group (*p* .030, 95% CI [.419 – 8.239]) No difference between intervention and control group over time was observed (see figure 4 and table 2).

Figure 4. Mean score on variables measured repeatedly over time. Blue diamond = intervention group, red square = control group.



[1] Per protocol population; [2] Intention to treat population.

3.5. Detection of rejection episodes and other relevant creatinine increases (>10%)

In total 12 rejection episodes took place, five of which concerned intervention patients. In three cases, rejection was detected earlier thanks to the creatinine values measured at home. In one case rejection could not have been detected earlier as the concerning patient did not perform any measurements in the period preceding the rejection episode. In the fifth case, the individual measurements did show an increasing trend, but not enough for the system to generate the advice to contact the hospital. For 71 laboratory-based creatinine trends, a steady increase of more than 10% was found. In half of the concerning timeframes (N=36), the minimum required number of three self-monitored and registered creatinine values between two laboratory measurements was available for comparison to

laboratory-based creatinine trends. Home-based creatinine trends were similar to laboratory-based creatinine trends in 78% of the 36 analysable timeframes.

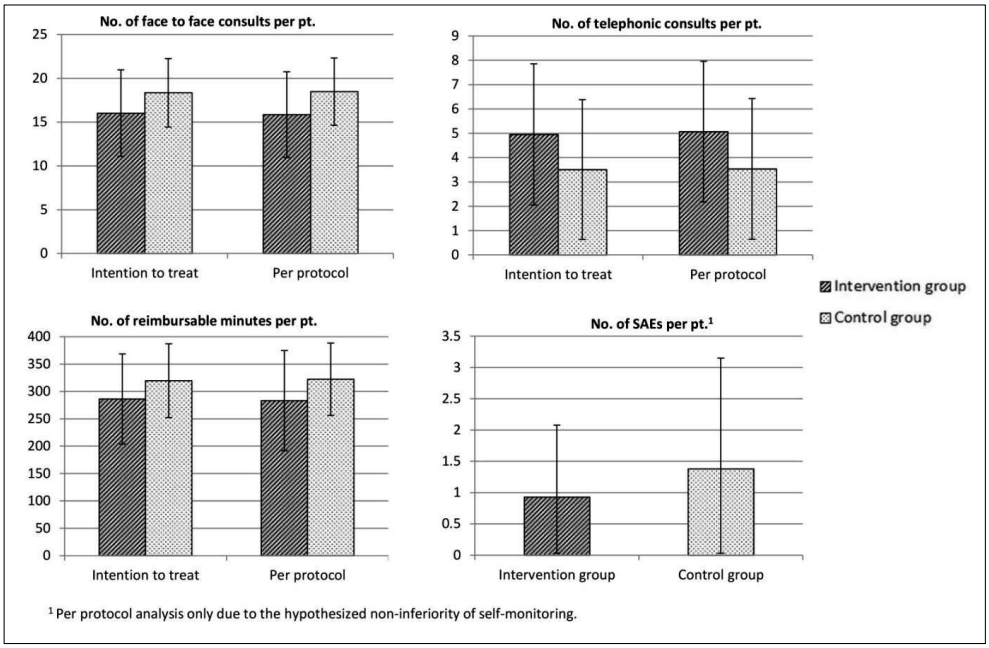


Figure 5. Care consumption and number of SAEs per patient.

DISCUSSION

In the first year after kidney transplantation intensive monitoring of kidney function is required to detect potential rejection episodes and other causes of kidney function at an earliest stage. In this study, self-monitoring kidney function after transplantation led to a significant decrease in number of ftf visits and total number of minutes contact time spent per patient. This was achieved without compromising on quality of care, indicated by the absence of differences between intervention and control patients for kidney function, blood pressure, quality of life and general satisfaction over time. Furthermore, results suggest that self-monitoring is safe with regard to discovering deteriorations in kidney function. As the accuracy of the creatinine device used is insufficient for detecting current renal function with a single creatinine measurement[32-34], several measurements are needed to obtain a reliable trend[34]. For the detection of clinically relevant increases in creatinine (>10%), we found a

similar trend for home-based and laboratory-based creatinine levels in 78% of all available cases, which is 10% higher than what has been reported before[34]. Five intervention group patients experienced a rejection episode. In three cases, the developing rejection was detected before the scheduled control appointment due to the creatinine measurements performed at home, while no rejection episode was missed.

This study shows that self-monitoring kidney function at home can safely reduce the high number of outpatient visits post-transplantation. This is beneficial for both patients and the health care system. Patients can save time and effort during their recovery from the transplantation and in the longer term, having to pay less visits to the hospital limits the interference of post-transplant follow-up with daily life. Further, the lower amount of outpatient appointments will reduce the burden on health resources and healthcare budgets. The actual difference in number of outpatient visits between the intervention and control group was, however, smaller than expected. Other studies have also reported that reductions in regular care using telehealth were lower than expected[35, 36]. Leimig et al.[36] state that this is most likely due to patients' hesitancy to lose ftf contact with healthcare professionals and hesitancy of the clinic personnel to use the telehealth equipment[36]. Our data are in concordance with this description, but only regarding the health care professionals. We observed a hesitance in the doctors to replace ftf visits with telehealth, despite the fact that these professionals were fully trained in the protocol. Two potential causes for the limited SMSS use by doctors can be distinguished. First, some of the doctors were critical about the accuracy of the creatinine device that was used. It has been concluded before that doctors need to feel confident in order to share control with patients[37] and that diagnostic confidence is key to incorporating telehealth into a transplant clinic[36]. Second, during the kick-off meeting for this study, several doctors stated that 'outpatient care of kidney transplant patients goes beyond checking creatinine and blood pressure'. Doctors generally feel highly responsible for ensuring that high-quality care is achieved[37-39] and using self-reported and patient acquired creatinine and blood pressure data may interfere with their perception of their professional responsibility. It is therefore important to emphasize that self-monitoring and telehealth can support doctors in their delivery of healthcare instead of competing with it[40].

The hesitations regarding self-monitoring did not seem to apply to patients. Patients were very positive about self-monitoring kidney function after transplantation, taking into account the near unanimous recommendation of self-monitoring to other kidney transplant patients. High levels of satisfaction with self-monitoring have been found before[8, 15-17, 41]. In these studies, however, self-monitoring patients also reported a higher level of general satisfaction than their fellow patients receiving regular care. This was not confirmed in the current study. Level of satisfaction measured with the CSQ was

already high at the first measurement for both intervention and control patients, leaving little room for improvement over time. Two other factors may have further contributed to the equal levels of satisfaction with care. First, the CSQ may have been too general to capture more subtle differences in satisfaction as it referred to 'all' care patients had received. Second, as the number of ftf visits that was replaced by a telephonic consult was lower than expected, intervention and control patients received more similar care, potentially resulting in equal levels of satisfaction.

To the best of our knowledge, this is the first study to investigate the potential of self-monitoring kidney function to replace part of the highly frequent outpatient visits after kidney transplantation. The fact that we used an RCT design is an important strength, as an RCT is the most robust design when studying intended treatment effects, eliminating potential confounding by indication. Further, due to the use of linear mixed modelling and multiple imputations, both addressing the issue of missing data, all patients could be included in the analyses. The reported results concerning the involvement of doctors in the self-monitoring protocol adds to the clinical relevance of this paper.

Our findings must also be evaluated within the context of the limitations of this study. First, all participants were recruited from a single centre. Second, nearly 90% of our study participants were transplanted with a kidney from a living donor. Third, from all kidney transplantations that were performed during period of inclusion, 44% of the transplant patients were ineligible for participation or did not want to participate. This could suggest that self-monitoring kidney function after transplantation is suitable for a selected group of kidney transplant recipients only.

In conclusion, this study shows that self-monitoring kidney function after transplantation has the potential to increase patient satisfaction and accelerate the detection of kidney function deterioration while reducing healthcare consumption at the same time. With the growing availability of other techniques, for example dried blood spot techniques (DBS), even more analyses can now be performed with capillary samples obtained at home. It has recently been shown that DBS techniques can successfully be applied for the analysis of immunosuppressant medication concentration and creatinine[42, 43], the most important parameters to be monitored after kidney transplantation. Using a system in which all home measurement results are combined, reference values that are tailored to an individual patient and to which both patients and healthcare professionals have access, self-management of kidney transplant patients can be elevated to a higher level.

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