Hemodialysis Self-Management Intervention Randomized Trial (HED-SMART): A Practical Low Intensity Intervention to Improve Adherence and Clinical Markers in Patients on Hemodialysis

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ABSTRACT

BACKGROUND: Poor adherence to treatment is common in hemodialysis patients. However, effective interventions for this population are lacking. Small study trials of behavioral interventions have yielded improvements, but clinical effectiveness and long-term effects are unclear.

STUDY DESIGN: Multi-center parallel (1:1) design, blinded randomized controlled trial.

SETTING & PARTICIPANTS: Patients undergoing maintenance hemodialysis enrolled in 14 dialysis centers.

INTERVENTION: Eligible patients were randomized to either usual care (control) (N= 101) or HED-SMART (intervention) (n=134). HED SMART developed using the principles of problem solving and social learning theory, was delivered by healthcare professionals over 4 group sessions.

OUTCOMES AND MEASUREMENTS: Serum potassium and phosphate, interdialytic weight gains (IDWG), self-reported adherence and self-management skills at 2 weeks, 6- and 9-months post-intervention.

RESULTS: A total of 235 participants were enrolled (response rate 49.6%). The study was completed by 74.8%. HEDSMART IDWG were significantly lowered across all four assessments relative to baseline in HED-SMART ($p<.001$) in contrast IDWGs in controls showed no change except at 3 months when it worsened significantly. Improvements in mineral markers were noted in HED-SMART at time 3 ($p<.001$) and time 4 for potassium levels ($p<.001$). Phosphate levels improved in HED-SMART only at time 3 ($p=.03$), but these effects were not maintained at 9 months post intervention (time 4). Significant differences between groups were found in secondary outcomes across all time points: self-reported adherence, self-

management skills and self- efficacy.

LIMITATIONS: Low proportion of patients with diabetes

CONCLUSIONS: HED-SMART provides an effective and practical model for improving health in HD patients. The observed improvements in clinical and self-report adherence, if supported and maintained at the longer follow-up, could significantly reduce ESRD-related complications in the longer term. Given the feasibility of this kind of program, it has strong potential for supplementing usual care.

Trial Registration: ISRTN31434033

Keywords: self- management; intervention; adherence; hemodialysis

INTRODUCTION

In End Stage Renal Disease (ESRD), besides dialytic procedures, patient self-management, or the ability and willingness of patients to change and subsequently maintain appropriate behaviors regarding diet, fluid intake and medicines is critical to maximizing good clinical outcomes. Adherence to this complex regimen is poor[1] contributing to morbidity, avoidable hospitalization, disability and death.[2] Self-management education facilitates the acquisition of knowledge and skills to improve disease management and has been found to improve health outcomes across a range of chronic diseases.[3,4] Rigorously conducted randomized controlled trials (RCT) of self-management interventions specifically designed for patients on hemodialysis are however, limited.[5,6,7,8] These systematic reviews indicate that prior interventions utilizing a self-management approach have shown benefit in self-care knowledge, quality of life and behavior yet are constrained by small sample sizes, highly selected patients, lack of control group and/or randomization and fairly short follow-ups. Further concerns are the limited data on clinical measures, and the use of rather intensive, non-pragmatic interventions, which have been poorly described, all making replicability and applicability difficult to assess. It is therefore not known whether similar effects can be achieved with a brief program or maintained in the long term.

Given this lack of good quality evidence, we conducted a randomized controlled trial (RCT) to assess the short- and long- term effects of a practical, low-intensity self-management intervention for hemodialysis patients who are socioeconomically disadvantaged and from a diverse ethnic background. It was hypothesized that the HEmoDialysis Self-MAnagement Randomized Trial (HED-SMART) intervention would improve clinical outcomes, self-reported adherence, self-efficacy and self-management skills, in comparison to usual care.

METHODS

Study Design

The study methodology has been detailed elsewhere.[9] In brief, the study was a multicenter, parallel-group blinded randomized controlled trial, with adult patients on hemodialysis randomized to either the intervention arm (HED-SMART) arm or 'usual care' arm (Control). Ethics approval was received from the National University of Singapore Institutional Review Board and written informed consent was obtained from study participants. The trial was registered at Current Controlled Trials (ISRTN31434033).

Setting and Participants

Patients were recruited from 14 of the 24 dialysis centers run by the National Kidney Foundation (NKF) Singapore, a non-profit charitable organization, which serves socioeconomically disadvantaged and middle income patients with ESRD in Singapore. Patients are admitted to the NKF program following means testing and are typically assigned to a dialysis center nearest to their residence. NKF dialysis centers are located within the community, island wide, and are run by nurses with a team of nephrologists working in rotation.

The participating dialysis centers were selected based on variability in size, location and proximity to designated facilities/sites hosting the intervention. There were no significant socio-demographic or ethnic differences across the dialysis centers in lieu of Singapore's urban planning policies that ensure equal representation of ethnic groups in all parts of the island.

Data were collected between January 2009 and June 2012. Inclusion criteria included being on HD for a minimum of 6 months, attendance for hemodialysis at one of the 14 selected NKF dialysis centers and aged over 21 years. Exclusion criteria

included current significant psychiatric disorders, learning disability or dementia, current medical disorder limiting life expectancy (all as recorded on medical records and verified by nurse managers), hearing impairment, and inability to communicate in English, Mandarin or Malay that precluded research participation.

Randomization and Blinding

To minimize contamination, the unit of randomization was dialysis shift within each of the participating dialysis centers, using computerized randomization (1:1 allocation ratio). Dialysis shifts rather than dialysis centers were preferred to diminish the influence of differences in practices. Allocation of randomization was concealed from study participants until consent and baseline assessment was completed. Consenting patients indicated their preferred language for intervention at baseline to guide subsequent arrangements for those allocated to HED-SMART. Healthcare professionals delivering the intervention were notified of the allocation after baseline assessment and before the first session; however, research assessors and all other staff remained blind to allocation at all assessment points.

Study Arms

Intervention. The intervention was developed with the MRC Framework for the evaluation of interventions to improve health.[10] Based on social-cognitive theory[11], the HED-SMART intervention was designed to enhance patients' confidence and capability for self-management (imparting skills and strategies to support behavior change) and to target previously identified needs in this population.[12]

The program was specifically designed for delivery in a 'real-world' setting, keeping the time commitment for both participants and facilitators to levels that could be readily achieved in most settings. It was delivered in group-format over 3 core

sessions plus 1 booster session (total contact 8 hours). An additional telephone follow-up call was scheduled in the interim between the core curriculum and booster session.

The sessions were interactive and targeted self-management behaviors related to fluid, diet, and medication through goal setting, barrier identification and problem solving. Learning was elicited rather than taught, with facilitators using a non-didactic approach. Participants were encouraged to share insight and experiences so as to yield a platform for identifying strengths, unknown resources and discovering new strategies for problem solving through peer support.[13] The intervention was delivered in addition to usual care and participants also received the '*Healthy Eating for People on dialysis'* educational booklet.

The intervention was made available in English (n=6), Mandarin (n=5) or Malay (n=3), hence a total of n=14 groups were conducted.

Two renal health care professionals (Medical Social Worker; Renal Nurse or Renal Dietician) worked in pairs to facilitate the groups. Intervention facilitators completed a 2-day training course and received the HED-SMART manual detailing content and procedures for each session. Three pilot groups were run prior to the main program to refine procedures and establish competence and fidelity for facilitators (*n*=6). Periodic review of sessions, monthly calls or briefings were conducted thereafter to address issues/provide feedback, and ensure maintenance of skills and consistency across sites.

Usual care control. Patients randomized to the control condition received standard renal care, which included the '*Healthy Eating for People on dialysis'* educational booklet.

Incentives

All participants received S$10 at each evaluation completed (S$40 total). Intervention participants received an additional travel reimbursement of S$25 for each intervention session attended, to cover travel on non-dialysis days (S$100 total).

Measures

Measurements were taken at baseline [T1], 1 week post-intervention (after completion of core-curriculum) [T2], 3 months (following telephone call and booster session) [T3] and 9 months post-intervention [T4; no contact/maintenance phase].

The primary outcomes were serum potassium, phosphate levels and interdialytic weight gains (IDWGs). IDWGs were calculated as follows: the mean of absolute pre- to post-dialysis body weight at the midweek dialysis sessions over the assessment period (up to 4 weeks prior to T0 baseline; ±4 weeks for T2-T4); and the ratio of mean absolute IDWG to patient's mean dry weight at each midweek assessment (up to 4 weeks prior to T0 baseline; ±4 weeks for T2-T4) expressed as IDWG%. Values ≥4.0% were considered suboptimal.[14,15]

Biochemical data were collected through regularly scheduled blood work (samples drawn pre-dialysis) and were analysed in both continuous [i.e. change in mean serum levels from baseline to follow-up assessments] and categorical forms [i.e. % participants meeting clinical targets across assessments]. The KDOQI target ranges were used as the reference category.

Secondary outcomes included self-report adherence, self-efficacy and self-management skills.

Self-reported adherence was measured with the Renal Adherence Behaviour Questionnaire (RAAQ)[16], which includes 5 subscales: adherence to fluid restrictions; potassium and phosphate, sodium intake; adherence in times of difficulty; and self-

care. The self-care subscale was subsequently dropped due to a low reliability coefficient (α = .363). Higher scores in all subscales signify better adherence.
The Medication Adherence Questionnaire was used to determine self-reported adherence to patients' prescribed medication[17] with higher scores signifying better medication adherence.

Self-management skills were measured using the self-monitoring and insight, constructive attitudes and approaches, skill and technique acquisition, and health service navigation subscales of the Health Education Impact Questionnaire Version 2 (HeiQ), a validated tool for evaluating self-management interventions.[18]

Self-efficacy was measured using a validated six-item scale.[19] Higher scores indicate better self-efficacy. Eight additional, similarly constructed renal-specific items were added to measure confidence regarding dialysis-specific recommendations related to fluid intake, diet and medication.[9] The internal reliability coefficient for these new items was high (α=0.92), hence an aggregate score was computed.

Sociodemographic data for age, gender, ethnicity, marital status, living arrangements, income and employment were assessed using a brief checklist.

Statistical Analyses

All analyses were performed in accordance with the CONSORT statement[20] using IBM SPSS Statistics 20.0 (Chicago, IL, USA). Chi-square tests and analyses of variance (as appropriate) were used to evaluate differences between study arms, and between dropouts and those who completed the study.

Changes within groups over time were assessed by mixed model repeated measures analysis of variance with two factors; time (T1/T2/T3/T4) and group (HED-SMART vs. usual care). When differences between trial arms at baseline were observed, these values were entered as covariates. Prior to analyses, the assumptions

regarding normality, homogeneity of variance and covariance, and sphericity were checked. Huynh–Feldt or Greehouser-Geisser corrections were applied when and as appropriate. All p values <.05 were considered statistically significant. Effect sizes were estimated using Cohen *d*.

Primary analyses were based on intention-to-treat (ITT) population, (all randomly assigned participants, including those without post-baseline observations). Missing values were imputed using the last Observation Carried Forward (LOCF) method.[21] As sensitivity analysis, per protocol (PP) approach was used in which participants with missing data were excluded.

RESULTS

Sample Characteristics

A total of 956 dialysis patients receiving care at the participating dialysis centers were assessed for eligibility. Of these participants, 532 (55.6%) were deemed eligible. A total of 259 (48.7%) provided consent and 235 (44.2%) completed the baseline assessment and were subsequently randomized (based on dialysis shift) to HED-SMART intervention (n=101) or usual care (n=134) [see figure 1]. Patients' characteristics were similar between groups at baseline (Table 1).

Insert Table 1.

Retention and Completion Rates

Overall retention through study completion was 82.1% (*n*=193). Complete case data (per protocol) for all clinical markers and questionnaires across all time points was 80% (*n*=189). Attrition rates were significantly greater in the intervention (25.7%; *n*=26) than usual care (11.9%; *n*=16) (*p*=.01). This was largely due to not being able to form a preferred language group for *n*=6 participants randomized to intervention arm

(no commencement rather than discontinuation). There were no differential attrition rates between study arms when these subjects were excluded.

Insert Figure 1.

The only significant differences between study completers and those who withdrew or were lost to follow-up were in dialysis vintage (5.44±4.30 years vs. 7.69±6.32 years; p=0.04), adherence at difficult times (18.63±3.29 vs. 20.17±3.35; p=.007), and mean IDWGs (2.46±.69 vs. 2.12±.57; p=0.006) respectively, signifying shorter dialysis vintage and lower adherence (self-reported and as indexed by IDWGs) at baseline for completers. Little MCAR test was non-significant indicating that the data were likely to be missing completely at random. Four participants died of cardiovascular causes during the course of the study (two from each study arm) and were excluded from the analyses. No other adverse events were reported.

Attendance

The majority of HED-SMART participants (n=69; 60.5%) attended all four sessions, 89 (87.2%) attended three sessions and 94 (92.2%) attended between one and two sessions. Six participants did not receive the allocated intervention, as we were unable to form preferred language groups. There were no differences in any of the baseline characteristics between these subgroups.

Primary Outcomes

HED-SMART participants demonstrated significant improvements on all clinical outcomes across the study period relative to baseline and usual care. Significant effects were consistently noted at T3 and some, but not all of these effects persisted at T4 (see Table 2).

Insert Table 2.

Repeated-measures ANOVAs revealed a significant time-by-group interaction

effect for mean IDWG (F=6.32, p=0.001) and percentile IDWGs (F=4.59, p=0.005). Post hoc comparisons indicated significant IDWG reductions from baseline (T1) to all follow-up assessments in HED-SMART: at 1 week (T2; p_{mIDWG}<0.001; d=-0.59; $p_{\%IDWG}$<0.001; d=-0.53), 3 months (T3; p_{mIDWG}=0.004; d=-0.42; $p_{\%IDWG}$=0.01; d=-0.37) and 9 months post-intervention (T4) for mean (p_{mIDWG}=.002; d=-0.46) and percentile IDWGs ($p_{\%IDWG}$=0.002; d=-0.46). Usual care controls had worsening only at T3 (p=0.02 d=0.29 for mean IDWGs) relative to baseline. Percentile IDWGs for controls remained unchanged (with an improvement between T3 and T4).

The reductions in IDWGs were significant relative to usual care at both T2 (p_{mIDWG}=0.04; d= -0.28; $p_{\%IDWG}$=.02; d=-0.31) and at T3 (p_{mIDWG}=0.02; d=-0.31; $p_{\%IDWG}$=0.02; d=-0.32) for mean IDWGs and percentile IDWs respectively. Although there were no longer significant differences between conditions in IDWGs at T4, the patterns differed between groups. Both mean and percentile IDWGs relapsed to baseline levels for usual care (p<.01) whilst for HED-SMART IDWGs remained significantly lower than baseline showing sustained effects at both T3 and T4.

The study considered IDWG% of ≥4.0% weight to be indicative of poor fluid control. At baseline 42.4% of participants in the HED-SMART program and 46.6% of those in usual care had IDWG% of ≥4.0%. Post-intervention, 32.7% vs. 48.1%; 30.6% vs. 53.4%, 30.6% vs.45.1% of HED-SMART compared to usual care had high IDWG%, at T2, T3 and T4 respectively. Group effects were significant at all follow up assessments (T2, p=0.02; T3 p=0.001; T4 p=0.03) (Table 2).

Mineral markers showed a similar pattern of improvement (see Table 2). Repeated-measures ANOVAs showed a significant time-by-group interaction effect for phosphate levels (F=2.79; p=0.04) (See figure 2). Changes in HED-SMART were

significant from baseline (T1) to 3 months post-intervention (T3)(p=.03, d=-0.32), but not from baseline to T2 or to T4. Phosphate levels increased from T3 to T4 indicating loss of effect at 9 months (p=0.05, d=0.29).

Levels of phosphate remained undifferentiated in the control group at T2 and T3, but significantly increased at T4 (p=0.03, d=0.27) relative to baseline. The differences between the groups were statistically significant at both T3 (p=0.01; d=-0.33) and T4 (p=0.03; d=-0.30), indicating significantly lower phosphate levels for HED-SMART relative to usual care. Proportions of patients achieving clinical targets were significantly higher for HED-SMART relative to usual care only at T3 (p = 0.01) (Table 2).

Potassium levels too showed a differential course within trial arms (F = 13.51; p< 0.001). The HED-SMART showed significant reductions in potassium levels relative to baseline at both T3 (p<0.001; d=-0.68) and T4 (p=0.03 d=-0.31), but not T2 (p=0.2). It is of note that improved levels were maintained at T4 despite some loss of effect from T3 to T4 (p=0.02; d =0.33). The usual care group showed no change over time. Differences between groups were significant only at T3 (p<0.001, d=0.50). Classification based on clinical targets indicated significantly lower off target values for HED-SMART compared to usual care, only at T3 (p=0.02).

PP analyses to explore the impact of missing data indicated that whilst coefficients differed, overall patterns of effects remained the same.

Secondary Outcomes

Levels of self-reported adherence, self-efficacy, and self-management skills changed differentially over time between study arms (Table 3). There were significant

time-by-group interaction effects for overall self-reported adherence (F=6.86, $p<0.001$), adherence to fluid restrictions (F=4.65, $p=0.004$), adherence to potassium and phosphate intake (F=5.06, $p=0.002$), adherence in times of difficulty (F=4.49, $p=0.005$), skills and technique acquisition (F=3.60, $p=0.2$), health services navigation (F=5.78, $p=0.001$), disease-related self-efficacy (F=2.66, $p=0.5$), and dialysis treatment-related self-efficacy (F=6.63, $p<0.001$). However, there were no significant interaction effects for adherence to sodium intake (F=2.36, $p=0.07$), adherence to medications (F=2.46, $p=0.07$), self-monitoring and insight (F=2.20, $p=0.1$), or constructive attitudes and approaches (F=0.07, $p=0.9$).

The usual care control group showed little variation over time, with only some decline in T2 on overall self-reported adherence, adherence to potassium and phosphate intake, adherence in times of difficulty, and treatment-related self-efficacy. In contrast, improvements were noted consistently from baseline to all follow-up assessments for HED-SMART. The effects were greatest from baseline to T2, leveling off in T3 and T4. These changes remained statistically significant at T3, and most importantly at 9 months post-intervention (T4), relative to baseline. The only exceptions were adherence in times of difficulty, and disease and treatment self-efficacy, where changes were only significant at T2, and not subsequent follow-ups. Group comparisons also indicated that secondary outcomes at all follow-ups were improved in HED-SMART relative to usual care (see Table 3).

DISCUSSION

The current study reports the results of a RCT to explore the effectiveness of a self-management intervention for patients with ESRD on hemodialysis in comparison to usual care. The HED-SMART program was found to reach a representative proportion of those contacted and considered to be eligible and had a good retention

rate.

There was evidence of improvement on all clinical outcomes for HED-SMART relative to baseline. These were consistently noted at 3 months post-intervention, in line with previous work.[7,22] Although there was no further improvement at the final follow-up, relapse was modest. IDWGs and potassium levels increased from T3 to T4, but still remained significantly lower than baseline indicating persisting effects. Phosphate levels relapsed back to baseline at T4, but were still significantly lower in HED-SMART than usual care.

This loss/attenuation of effect after the completion of a structured self-management program is related to the impending challenge of maintaining behavior change and has been reported elsewhere in the chronic illness literature.[23,24] This has implications on how to structure and deliver programs so as to address difficulties around transitioning patients from organized, structured support back to usual care. The finding that improvements were most marked at 3 months, where contact was reduced, to a telephone call and booster session, seem to suggest that delivery of self-management techniques may be possible with minimal contact in order to prevent relapse. These could be easily woven into the planned program and routine care to provide an ongoing line of support to reinforce the gains of the core intervention program. The use of personal digital devices and mobile technology may be particular useful.

The primary trial outcomes were chosen as objective indicators of disease management with established associations with longer-term complications and mortality.[25,26,27] They are however distal outcomes for an intervention that seeks to empower patients to be active managers and may also be influenced by factors other than behavior, such as prescribed medications, hyperparathyroidism, inflammation

and dialysis dose.[28] Self-management skills, self-efficacy and self-reported adherence reflect more proximal effects that are a prerequisite for behavior change and hence better clinical outcomes. HED-SMART yielded benefits in the skills patients gained and their confidence at 3 months post-intervention and these effects were maintained at the 9 months follow-up assessment for skills acquisition. These indicated a greater understanding by the participants of their condition and treatment, and greater confidence in their ability to navigate health services, manage treatment and affect the course of their illness. Participants in HED-SMART also improved significantly more than the usual care on self-reported adherence to fluid and diet restrictions. Changes in behavior therefore followed a similar trajectory as that of clinical markers. Encouragingly the observed effect sizes reflect findings of a meta-analysis of a range of chronic illness self-management programs.[29]

Despite the success of the project, there are study limitations that need to be considered. First and foremost, the trial recruited a convenience sample of eligible participants rather than a probability-based sample, which limits generalizability to other populations. Although the current sample represents fairly well the national HD population and other renal registries [49], the rate of diabetes was lower in this sample. Replication is therefore warranted. Moreover, self-selection bias cannot be ruled out. It is possible that volunteers were highly motivated to change their behavior, thereby influencing the study outcomes in a positive direction. Furthermore, since we used broad inclusion criteria and did not confine recruitment to those poorly controlled, ceiling effects could have been experienced by participants who either met clinical targets or were already close to achieving them. However, even with these potential ceiling effects, the intervention was shown to improve outcomes and significantly protect against the likelihood of subsequent non-adherence and poor

clinical markers.

For some participants access to the HED-SMART was difficult because of problems scheduling preferred language groups. The program was delivered in three languages (English, Mandarin, Malay) so as to better represent the national population, but this multi-language approach coupled with delivery in group format and restrained resources, led to attrition between recruitment and commencement. Finally, because of the multifaceted nature of the HED-SMART program, in regards to its delivery methods and content, it is not possible to identify what aspects of the intervention were responsible for the observed effects. It should be recognized that the support participants received from each other during the group sessions and increased attention from trial staff could have contributed to the observed improvements. Future work should consider including a matched attention control condition to determine these potential confounding effects.

In conclusion, this trial indicates that a theory-based self-management intervention for patients with ESRD on hemodialysis is capable of initiating and maintaining improvements in clinical markers, self-management skills, self-efficacy and self-reported adherence up to 9 months post-intervention. Future research is needed to identify the intervention processes that led to these positive improvements, the subpopulations more likely to benefit, as well as the cost-effectiveness of the program. Work towards better implementation and refinement of HED-SMART to include ongoing support is critical to inform translation of this intervention into usual care.

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Table 1. Participants' Characteristics

	Total sample *M±Sd /%(N)*	**HED-SMART** *M±Sd / %(N)*	**Usual Care** *M±Sd /%(N)*	***p***
Age (years)	53.5 (10.4)	53.1 (10.5)	53.9 (10.4)	0.5[a]
Age at diagnosis (years)	43.4 (13.5)	42.9 (13.3)	43.7 (13.8)	0.7[a]
Age left education (years)	16.7 (6.0)	17.1 (7.4)	16.4 (4.7)	0.3[a]
Education level				
Illiterate/primary	71 (30.2)	28 (27.7)	43 (32.1)	0.1[b]
Secondary	147 (62.6)	69 (68.3)	78 (58.2)	
Tertiary	17 (7.2)	4 (4)	13 (9.7)	
Gender, (female)	41.7% (98)	46.1% (47)	38.3% (51)	0.3[b]
Ethnicity				0.9[b]
Chinese	56.8% (133)	55.9% (57)	57.6% (76)	
Malay	34.2% (80)	35.3% (36)	33.3% (44)	
Indian	6.4% (15)	6.9% (7)	6.1% (8)	
Others	2.5% (6)	2% (2)	3.1% (4)	
Relationship status (married)	66.5% (155)	67.3% (68)	65.9% (87)	0.9 [b]
Employment, (employed)	45.6% (93)	37.5% (33)	51.7% (60)	
Perceived ability to work (able to work)	56.8% (129)	51.0% (52)	61.6% (77)	
Income[1,2]				
S$0- S$2,000	51.5% (119)	58.4% (59)	46.2% (60)	0.1[c]
S$2,001 - S$4,000	21.2% (49)	15.8% (16)	25.4% (33)	

S$4,001 - S$6,000	4.8% (11)	5.0% (5)	4.6% (6)	
> S$6,000	3.9% (9)	5.0% (5)	3.1% (4)	
Time on dialysis				
6-12 months	8.5% (20)	8.8% (9)	8.3% (11)	0.8
13-24 months	14.5% (3.4)	15.7% (16)	13.5% (18)	
> 24 months	77.0% (181)	75.5% (77)	78.2% (104)	
Time on dialysis (years)	5.68 (4.76)	5.83 (5.09)	5.81 (4.53)	0.9[a]
Primary Cause of ESRD				
Glomerulonephritis	28.9% (68)	26.5% (27)	30.8% (41)	
Diabetic Nephropathy	25.9% (61)	27.5% (28)	24.8% (33)	
Polycystic Kidney Disease	8.1% (19)	8.8% (9)	7.5% (10)	
Hypertension				
CCI	4.89 (2.23)	4.88 (2.19)	4.90 (2.27)	0.9[a]
Kt/V	1.61 (0.20)	1.63 (0.18)	1.60 (0.22)	0.4[a]
nPCR g/kg/day	1.01 (0.26)	1.01 (0.21)	0.99 (0.30)	0.6[a]
Hemoglobin (g/dl)	11.54 (1.47)	11.55 (1.27)	11.54 (1.61)	0.9[a]
Albumin (g/dl)	34.81 (2.99)	34.62 (3.03)	34.95 (2.97)	0.4[a]

Note: CCI = Charlson Comorbidity Index; nPCR = Normalized Protein Catabolic Rate

[1] † ‡N = 189 as N = 14 participants ticked option 'do not wish to answer' for income and N = 32 indicated 'do not know'

[2] Income brackets are equivalent to US dollars as follows: S$2000 = US$1600; S$4000 = US$3200; S$6000 = US$4800. The median monthly household income of the Singapore population was S$3770 in 2014 (MOM).

[a]Use of independent-samples *T*-test.

[b]Use of χ^2-test.

[c] Use of Fisher exact test as the number of expected count is <5.

Table 2. Primary outcomes: Clinical markers across assessment points for trial arm (ITT values)

		HED-SMART		Usual care			
		M±Sd	%[1]	*M±Sd*	%[1]	p^2 *(M)*	p^3*(%)*
IDWG (kg)	T1	2.49±0.71	43.6%	2.46±0.69	44.5%	0.7	0.9
	T2	2.31±0.60	25.7%	2.50±0.74	44.5%	0.03	0.003
	T3	2.32±0.54	30.7%	2.55±0.72	51.7%	0.006	0.002
	T4	2.31±0.60	32.7%	2.45±0.71	43.8%	0.1	0.09
IDWG (percentile)	T1	3.93±1.01		3.93±1.07		0.9	
	T2	3.67±0.85		4.00±1.19		0.02	
	T3	3.72±0.80		4.04±1.11		0.02	
	T4	3.68±0.86		3.90±1.11		0.1	
Phosphate (mg/dL)	T1	5.16±1.45	48.0%	5.15±1.27	44.4%	0.9	0.07
	T2	5.05±1.44	51.0%	5.33±1.22	58.6%	0.1	0.9
	T3	4.86±1.30	41.2%	5.30±1.18	51.1%	0.01	0.03
	T4	5.03±1.16	43.0%	5.38±1.06	48.8%	0.02	0.9
Potassium (mEq/L)	T1	5.00±0.64	51.0%	4.89±0.52	38.3%	0.1	0.6
	T2	4.93±0.57	58.2%	4.91±0.60	37.6%	0.8	0.2
	T3	4.72±0.55	32.4%	5.00±0.59	46.6%	<.001	0.1
	T4	4.86±0.60	40.2%	4.96±0.55	39.8%	0.2	0.4

[1] Percentages of participants with values off clinical targets

[2] Between group comparisons on mean clinical levels

[3] Between group comparisons on proportions of clinical markers outside clinical targets

Table 3. Secondary outcomes: Self-reported adherence, Self-Efficacy and Health Education Impact Subscales

			HED-SMART			**Usual Care**	***p*[a]**	***d***
		***p*[b]**			***p*[b]**			
RABQ Total	T1	a	92.2 ± 10.9	T1	a	90.2 ± 13.0	.229	.16
	T2	b	95.9 ± 11.8	T2	b	87.6 ± 14.8	.000	.60
	T3	b	94.7 ± 11.8	T3	c	90.0 ± 13.6	.007	.33
	T4	b	95.2 ± 11.4	T4	c	91.4 ± 12.0	.017	.29
		***p*[b]**			***p*[b]**			
Fluid	T1	a	38.44 ± 5.42	T1	a,b	37.74 ± 6.55	.388	.12
Restrictions	T2	b	40.14 ± 5.99	T2	a	36.76 ± 7.04	< .001	.51
	T3	b	39.61 ± 5.96	T3	b	37.86 ± 6.41	.036	.24
	T4	b	39.83 ± 6.10	T4	b	38.65 ± 6.20	.148	.17
		***p*[b]**			***p*[b]**			
Potassium and	T1	a	19.83 ± 2.95	T1	a	19.59 ± 2.77	.536	.08
Phosphate	T2	b	20.49 ± 2.66	T2	b,c	19.09 ± 3.21	< .001	.46
Intake	T3	b	20.66 ± 2.95	T3	a,c	19.29 ± 3.12	.001	.43
	T4	b	20.43 ± 2.97	T4	a,c	19.54 ± 3.00	.025	.29
		***p*[b]**			***p*[b]**			
Sodium Intake	T1	a	7.62 ± 1.82	T1	a	7.41 ± 1.84	.387	.12
	T2	b,c	8.03 ± 1.73	T2	a	7.29 ± 1.86	.002	.41
	T3	a,c	7.88 ± 1.78	T3	a	7.47 ± 1.68	.069	.24
	T4	b,c	8.13 ±1.63	T4	a	7.51 ± 1.65	.005	.38
		***p*[b]**			***p*[b]**			
	T1	a	19.12± 3.14	T1	a	18.75 ± 3.50	.398	.11

Adherence in	T2	[b,c]	19.84 ± 3.27	T2	[b,c]	17.92 ± 3.71	< .001	.55
Times of	T3	[a,c]	19.39 ± 3.29	T3	[a,c]	18.53 ± 3.76	.072	.21
Difficulty	T4	[a,c]	19.61 ± 3.17	T4	[a]	18.78 ± 3.22	.050	.25
		p [b]			***p*** [b]			
Adherence to	T1	[a]	3.81 ± .690	T1	[a]	3.69 ± .835	.243	.16
Prescribed	T2	[a,c]	3.92 ± .742	T2	[b,c]	3.57 ± .842	.001	.44
Medications	T3	[b,c]	3.96 ± .689	T3	[a]	3.75 ± .927	.049	.26
	T4	[a,c]	3.93 ± .783	T4	[a,c]	3.66 ± .852	.013	.33
		p [b]			***p*** [b]			
Self-	T1	[a]	3.11 ± .380	T1	[a]	3.00 ± .375	.035	.28
Monitoring	T2	[a]	3.15 ± .407	T2	[a]	3.01 ± .396	.006	.37
and Insight	T3	[a]	3.15 ± .410	T3	[a]	2.94 ± .376	< .001	.55
	T4	[a]	3.18 ± .386	T4	[a]	2.96 ± .330	< .001	.62
		p [b]			***p*** [b]			
Constructive	T1	[a]	3.03 ± .485	T1	[a]	2.94 ± .495	.149	.19
Attitudes and	T2	[a]	3.05 ± .494	T2	[a]	2.94 ± .492	.075	.24
Approaches	T3	[a]	3.05 ± .550	T3	[a]	2.94 ± .473	.110	.21
	T4	[a]	3.00 ± .547	T4	[a]	2.91 ± .460	.136	.20
		p [b]			***p*** [b]			
Skill and	T1	[a]	2.80 ± .375	T1	[a]	2.78 ± .418	.737	.04
Technique	T2	[b]	2.93 ± .462	T2	[a]	2.75 ± .431	.004	.39
Acquisition	T3	[b]	2.93 ± .452	T3	[a]	2.74 ± .484	.002	.41
	T4	[b]	2.90 ± .472	T4	[a]	2.76 ± .432	.025	.30
		p [b]			***p*** [b]			
	T1	[a]	2.95 ± .439	T1	[a]	2.97 ± .387	.752	-.04

Health Services	T2	[b]	3.08 ± .473	T2	[a]	2.95 ± .461	.030	.29
Navigation	T3	[b]	3.06 ± .508	T3	[a]	2.90 ± .440	.011	.34
	T4	[b]	3.11 ± .533	T4	[a]	2.91 ± .452	.002	.41
		p [b]			***p*** [b]			
Disease-	T1	[a]	6.66 ± 1.76	T1	[a]	6.03 ± 1.63	.006	.37
Related Self-	T2	[b,c]	7.02 ± 1.70	T2	[a]	5.99 ± 1.77	< .001	.59
Efficacy	T3	[a,c]	6.82 ± 1.76	T3	[a]	6.02 ± 1.68	.001	.46
	T4	[a,c]	6.81 ± 1.67	T4	[b]	6.33 ± 1.74	.035	.28
		p [b]			***p*** [b]			
Treatment-	T1	[a]	7.30 ± 1.66	T1	[a]	6.91 ± 1.54	.067	.25
Related Self-	T2	[b,c]	7.71 ± 1.44	T2	[b]	6.57 ± 1.76	< .001	.70
Efficacy	T3	[b,c]	7.57 ± 1.43	T3	[b]	6.60 ±1.71	< .001	.61
	T4	[a,c]	7.48 ± 1.48	T4	[a]	6.93 ± 1.55	.007	.36

Note. Data are expressed as mean ± Sd; RABQ = Renal Adherence Behavior Questionnaire.

[a] Between group comparisons on secondary outcomes.

[b] Within group comparisons on secondary outcomes. For each outcome, and within each group, means which do not share the same superscripted letter are different from each other at the .05 level of significance.

Figure. 1 Consolidated Standards of Reporting Trials (CONSORT) diagram for patient flow from initial contact through completion of the trial.