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

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

Study Design: Multicenter parallel (1:1) design, blinded cluster-randomized controlled trial.

Setting & Participants: Patients undergoing maintenance hemodialysis enrolled in 14 dialysis centers.

Intervention: Dialysis shifts of eligible patients were randomly assigned to either an interactive and targeted self-management training program (HED-SMART; intervention; n = 134) or usual care (control; n = 101). HED-SMART, developed using the principles of problem solving and social learning theory, was delivered in a group format by health care professionals over 4 sessions.

Outcomes & Measurements: Serum potassium and phosphate concentrations, interdialytic weight gains (IDWGs), self-reported adherence, and self-management skills at 1 week, 3 months, and 9 months postintervention.

Results: 235 participants were enrolled in the study (response rate, 44.2%), and 82.1% completed the protocol. IDWG was significantly lowered across all 3 assessments relative to baseline ($P < 0.001$) among patients randomly assigned to HED-SMART. In contrast, IDWG in controls showed no change except at 3 months, when it worsened significantly. Improvements in mineral markers were noted in the HED-SMART arm at 3 months ($P < 0.001$) and in potassium concentrations ($P < 0.001$) at 9 months. Phosphate concentrations improved in HED-SMART at 3 months ($P = 0.03$), but these effects were not maintained at 9 months postintervention. Significant differences between the arms were found for the secondary outcomes of self-reported adherence, self-management skills, and self-efficacy at all time points.

Limitations: Low proportion of patients with diabetes.

Conclusions: HED-SMART provides an effective and practical model for improving health in hemodialysis patients. The observed improvements in clinical markers and self-report adherence, if maintained at the longer follow-up, could significantly reduce end-stage renal disease–related complications. Given the feasibility of this kind of program, it has strong potential for supplementing usual care.

Trial Registration: Registered at ISRCTN with study number ISRCTN31434033.

In end-stage renal disease, care goals focus on optimal control of mineral markers and fluid management to reduce the risk for complications and mortality.[1-3] Besides dialytic procedures, patient self-management, or patients' ability and willingness to change and then maintain appropriate behaviors regarding diet, fluid intake, and medicines, is critical to maximizing good clinical outcomes. Adherence to this complex regimen is poor,[4] with nonadherence estimates of 2% to 57% for diet, 10% to 60% for fluid intake, and 12.5% to 98.8% for medication,[5] contributing to morbidity, avoidable hospitalization, and death.[6]

Self-management education facilitates patients' acquisition of knowledge and skills to improve disease management and has been reported to improve health outcomes across a range of chronic diseases.[7,8] As discussed in systematic reviews,[9-12] rigorously conducted randomized controlled trials of self-management interventions specifically designed for patients receiving hemodialysis are limited. Although prior interventions using a self-management approach have shown benefit in self-care knowledge, quality of life, and behavior, they are constrained by small sample sizes, highly selected patients, lack of control group and/or randomization, and fairly short follow-up. Further concerns are the limited data for clinical measures and the use of rather intensive nonpragmatic interventions, which have been poorly described, all making replication 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 cluster-randomized controlled trial 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 diverse ethnic backgrounds. It was hypothesized that the

Hemodialysis Self-management Randomized Trial (HED-SMART) intervention would improve self-reported adherence, self-efficacy and self-management skills, and clinical outcomes in comparison to usual care.

Methods

Study Design

The study methodology has been detailed elsewhere.[13] In brief, the study was a parallel-group, blinded, cluster-randomized controlled trial comparing HEDSMART to usual care. Ethics approval was received from the National University of Singapore Institutional Review Board, and written informed consent was obtained from study participants.

Setting and Participants

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

Participating dialysis centers were selected based on variability in size, location, and proximity to designated facilities/sites hosting the intervention. There were no significant sociodemographic or ethnic differences across the dialysis centers because of Singapore's urban planning policies, which ensure equal representation of ethnic groups in all parts of the island.

Data were collected in January 2009 to June 2012. Inclusion criteria included being on hemodialysis therapy for a minimum of 6 months, attendance for hemodialysis at one of the 14 selected NKF Singapore dialysis centers, and age older than 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.

Randomization and Blinding

To minimize contamination, the unit of randomization was the dialysis shift within each of the participating dialysis centers, using computerized randomization (1:1 allocation ratio). The 2 shifts in each dialysis center hence received different randomization assignments (HED-SMART or usual care). Dialysis shifts rather than dialysis centers were preferred as the unit of randomization to reduce the possible influence of differences in practice or center characteristics. Allocation of randomization was concealed from study participants until baseline assessment was completed.

At baseline, consenting patients indicated their preferred language for the intervention to guide subsequent arrangements for those allocated to HED-SMART. Health care 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 reference to the UK Medical Research Council Framework for the evaluation of interventions to improve health.[14] Based on social-cognitive theory,[15] the HED-SMART intervention was designed to enhance patients' confidence and capability for self-management (imparting skills and strategies to support behavior change) and target previously identified needs in this population.[16]

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 time, 8 hours). An additional telephone follow-up call was scheduled in the interval between the core curriculum and booster session.

Sessions were interactive and targeted self-management behaviors related to fluid intake, diet, and medication through goal setting, barrier identification, and problem solving. Learning was elicited rather than taught, with facilitators using a nondidactic approach. Participants were encouraged to share insight and experiences so as to yield a platform for identifying strengths and unknown resources and discovering new strategies through peer support.[17] The intervention was delivered in addition to usual care and participants also received the *Healthy Eating for People on Dialysis* educational booklet.

Across the 14 dialysis centers, the intervention was conducted in English in 6 groups, in Mandarin in 5 groups, and in Malay in 3 groups. Two renal health care professionals (a medical social worker plus a 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 before 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. Implementation fidelity was ascertained by a monthly audit of materials (eg, goal-setting sheets and intervention logs) and structured observation (comparing against a checklist) of 14 sessions. Five of these sessions were also audiorecorded and reviewed by a second rater ($\kappa > 90\%$). Facilitators were found to be consistent with