Published in final edited form as:

Ann Behav Med. 2016 April ; 50(2): 167–176. doi:10.1007/s12160-015-9741-0.

Effect of a Behavioral Self-Regulation Intervention on Patient Adherence to Fluid Intake Restrictions in Hemodialysis: A Randomized Controlled Trial

M. Bryant Howren, PhD, MPH,

VA Iowa City Healthcare System & The University of Iowa

Quinn D. Kellerman, PhD,

VA Minneapolis Healthcare System

Stephen L. Hillis, PhD,

VA Iowa City Healthcare System & The University of Iowa

Jamie Cvengros, PhD,

Rush University Medical Center

William Lawton, MD,

The University of Iowa

Alan J. Christensen, PhD

The University of Iowa

Abstract

Objective: To evaluate the efficacy of a behavioral self-regulation intervention vs. active control condition using a parallel-group randomized clinical trial with a sample of center hemodialysis patients with chronic kidney disease.

Method: Participants were recruited from 8 hemodialysis treatment centers in the Midwest. Eligible patients were (a) fluid nonadherent as defined by an interdialytic weight gain > 2.5kg over a 4-week period, (b) > 18 years of age, (c) English-speaking without severe cognitive impairment, (d) treated with center-based hemodialysis for > 3 months, and (e) not living in a care facility in which meals were managed. Medical records were used to identify eligible patients. Patients were randomly assigned to either a behavioral self-regulation intervention or active control condition in which groups of 3–8 patients met for hour-long, weekly sessions for 7 weeks at their usual hemodialysis clinic. Primary analyses were intention-to-treat.

Results: Sixty-one patients were randomized to the intervention while 58 were assigned to the attention-placebo support and discussion control. Covariate-adjusted between-subjects analyses

Direct correspondence to: Alan J. Christensen, PhD, The University of Iowa, Department of Psychology, 11 Seashore Hall East, Iowa City, IA 52242, alan-christensen@uiowa.edu.

M. Bryant Howren, VA Iowa City Healthcare System and The University of Iowa, Department of Psychology. Alan J. Christensen, The University of Iowa, Departments of Psychology and Internal Medicine. Quinn D. Kellerman, VA Minneapolis Healthcare System. Stephen L. Hillis, VA Iowa City Healthcare System and The University of Iowa, Departments of Radiology and Biostatistics. Jamie Cvengros, Rush University Medical Center. William Lawton, The University of Iowa, Department of Internal Medicine.

ClinicalTrials.gov Identifier: NCT01066949

demonstrated no unique intervention effect for the primary outcome, interdialytic weight gain ($\beta = 0.13$, $p = .48$). Significant within-subjects improvement over time was observed for the intervention group ($\beta = -0.32$, $p = .014$).

Conclusions: The present study found that participation in a behavioral self-regulation intervention resulted in no unique intervention effect on a key indicator of adherence for those with severe chronic kidney disease. There was, however, modest within-subjects improvement in interdialytic weight gain for the intervention group which meshes with other evidence showing the utility of behavioral interventions in this patient population.

Keywords

patient adherence; chronic illness; self-regulation; intervention; randomized controlled trial

Patient adherence is as fundamental a component of effective healthcare as the treatment regimen itself. However, despite significant advances in biomedical science related to the treatment of disease, the failure of patients to follow prescribed treatment regimens remains pervasive. In addition to the enormous monetary cost, nonadherence has been linked to numerous deleterious outcomes, including patient and provider frustration, treatment failures, illness complications and relapse, mortality, and may compromise the establishment of empirically-based treatment guidelines (1,2).

In patients diagnosed with severe chronic kidney disease, a debilitating chronic illness often requiring life-sustaining renal replacement therapy, nonadherence is especially problematic. As part of a complex treatment program typically requiring lifelong hemodialysis and pharmacotherapy, patients must adhere to a multifaceted behavioral regimen, including fluid and dietary restrictions. Arguably the most challenging of these restrictions is the reduction of fluid consumption to approximately 1L per day or less (see (3)). Research suggests that 30 to 60 percent of patients fail to adhere to fluid intake recommendations (4–7), which is associated with uncomfortable and prolonged dialysis sessions as well as medical complications including pulmonary edema, hypertension, congestive heart failure, and increased risk of mortality (see (8)). Although the consequences of nonadherence in this patient population are well known, perhaps surprisingly, relatively few intervention trials have been conducted to date.

Increasing evidence suggests that behavioral intervention strategies—such as instruction in self-monitoring, behavioral contracting, and positive reinforcement—may improve adherence in this context (e.g., (9–20)). However, not only is research examining interventions targeting regimen adherence among hemodialysis patients more scarce than for most other chronic disease groups (e.g., diabetes, hypertension), this work is limited methodologically and often relies on very small sample sizes and nonrandomized designs ((8); see (21,22)). Thus, the design and evaluation of interventions to improve adherence is critically important in this chronic disease population.

The Present Study

Christensen and colleagues (23) previously conducted a pilot intervention based on Kanfer's self-regulatory framework of self-monitoring, self-evaluation, and self-reinforcement of a target behavior ((24); see also (25)). In that study, 20 hemodialysis patients took part in a multifaceted, group-administered behavioral intervention aimed at increasing adherence to fluid-intake restrictions. Results indicated a significant difference between intervention participants and 20 matched controls, with the former exhibiting more favorable adherence by 8-week follow-up. While promising, the pilot intervention utilized a non-randomized design and small sample size.

The present study represents the next step in this work in which a parallel-group randomized clinical trial with a larger—though still modest—sample of hemodialysis patients was conducted to evaluate the efficacy of this behavioral self-regulation intervention. The primary trial results are reported in this manuscript; no other results have yet been published from this study.

Methods

Participants & Protocol

Patient participants were recruited from 8 hemodialysis treatment centers in Eastern Iowa and Western Illinois. Because hemodialysis centers are a setting for treatment as well as social interaction, diffusion of treatment across patients at a given center is a major barrier to implementing a randomized design (see (26)). After careful consideration, random assignment was performed at the level of the dialysis treatment “shift.” Hemodialysis centers typically assign patients to a set shift schedule, three times per week, at the same time each session. This provides patients within a given shift considerable opportunity for social interaction—but little opportunity across shifts—thus alleviating concerns regarding treatment contamination as well as center-level differences in dialysis delivery that may be of concern.

To further increase our confidence in this assignment strategy, we gathered and compared a range of demographic (i.e., age, gender, marital status, occupational status) and clinical (i.e., years on dialysis/disease duration, diabetic status) characteristics by shift among all center hemodialysis patients at the University of Iowa Hospitals and Clinics, which was one of the larger study sites. All comparisons were non-significant, $ps > .10$. These preliminary data suggest that patients do not vary systematically between dialysis shifts and that random assignment at the shift level should avoid treatment contamination issues while not introducing other substantial confounds. Within each participating center ($N = 8$), shifts were randomly assigned in blocks of two to the intervention or control conditions, respectively, from which eligible patients were recruited.

Eligible patients were (a) fluid nonadherent as defined by an *interdialytic weight gain* $> 2.5\text{kg}$ over a 4-week period (see (27)), (b) > 18 years of age, (c) English-speaking with no severe cognitive impairment, (d) treated with center-based hemodialysis for > 3 months, and (e) not living in a care facility in which meals were managed. Medical records were used to

identify eligible patients who were then approached regarding potential participation by a research assistant during the patient's routine hemodialysis treatment session. The study was uniformly described to eligible patients in both study arms as involving an "education and support group" designed to help hemodialysis patients better manage the demands associated with hemodialysis treatment. Further, all eligible patients were told that the goal of the study was to determine how their participation affected their ability to manage the fluid-intake restrictions and other stressors associated with hemodialysis. The research assistant obtaining patient consent was not aware of which study arm a given shift had been assigned. Patients were paid \$100 for participation in this trial. All procedures were approved by The University of Iowa's IRB.

The intervention was administered to groups of 3–8 patients meeting for hour-long weekly sessions for 7 weeks at their usual hemodialysis clinic (see detailed summary in Table 2). Each session occurred just before or after the patient's regularly scheduled dialysis appointment in order to maximize participation and gauge the feasibility of conducting the intervention within clinic. All sessions were highly structured and led by Master's level or above clinicians with experience in behavior change techniques.

Key aspects of the intervention closely followed Kanfer's self-regulatory framework (24) of self-monitoring, self-evaluation, and self-reinforcement, which are considered critical behavioral skills that a patient must develop through active instruction, structured exercises, and repetition. As such, the intervention included illustrations of behavioral principles, group discussions, and homework assignments specific to fluid-intake adherence, with many opportunities for patient sharing present.

Patients assigned to the attention-placebo "support and discussion" control condition also met in groups of 3–8 participants at their usual hemodialysis clinic for hour-long weekly sessions for 7 weeks. Again, each session occurred just before or after the patient's regularly scheduled dialysis appointment. During each session, the group leader presented structured didactic material covering a topic related to living with chronic kidney disease and hemodialysis. Topics by week were as follows: a basic discussion about how hemodialysis treatment works, why patient behavior change (including fluid-intake restriction) is important to treatment success and quality of life, how the illness and treatment impact familial and other relationships, staying active on dialysis, patient-provider interaction in the dialysis setting, logistical issues related to dialysis (e.g., receiving treatment while traveling), and a closing session dedicated to review and discussion. In addition to participating in the same number and duration of weekly group sessions, as well as having the same degree of exposure to the group leaders and to the other patient participants, those in the support and discussion arm were also informed that their fluid-intake adherence was to be monitored during the study period because the material presented could positively impact their ability to manage their disease. This was done as a means of addressing differential expectancies across the trial arms.

To ensure appropriate treatment and control protocol fidelity, all group sessions—in both arms—were audiotaped and independently reviewed for protocol adherence by two research team members. During each session review, a detailed checklist was completed by both

research team members indicating whether the central components of each session were appropriately administered by the group leader. Cohen's (28) kappa statistic, used to assess interrater reliability, indicated an extremely high level of agreement; all values $> .90$.

Adherence Assessments

The primary outcome, fluid-intake adherence, was assessed by computing each patient's mean interdialytic weight gain, a valid representation of fluid intake between dialysis sessions (29; see (18)). Patients with interdialytic weight gain values greater than 2.5kg are generally considered nonadherent (see (27)). Individual interdialytic weight gain values, abstracted from medical records, were averaged over 2 weeks (i.e., six dialysis sessions) at each assessment point. The baseline assessment (Time 0; T0) comprised the 2 weeks preceding intervention initiation, Time 1 (T1) comprised the 2 weeks immediately following the final intervention session, Time 2 (T2) comprised the 12th and 13th post-intervention weeks, and Time 3 (T3) comprised the 25th and 26th post-intervention weeks. Thus, defining time as the number of weeks after intervention initiation, the midpoint times for the 2-week assessment periods corresponding to times T0, T1, T2, and T3, are given by $t_0 = -1$, $t_1 = 8$, $t_2 = 20$, and $t_3 = 33$.

Statistical Analyses

The intervention and control groups were compared at baseline with respect to potential covariates, using the Wilcoxon rank-sum test for ordinal or continuous covariates and the chi-squared test for categorical covariates. Any significant covariates were included in the adjusted primary analysis.

The primary analysis consisted of the following steps. First, for each patient participant, we regressed the patient's four mean interdialytic weight gain values on the midpoint times corresponding to the 2-week assessments. The resulting slope estimates, one for each patient, are considered to be summary measures that describe the patients' interdialytic weight gain linear trends over time (or interdialytic weight gain linear rates of change). We note that we do not assume that each patient's data follow a simple linear regression, but simply use the slope as a summary measure of the patient's change over time. For example, a patient showing continuing improvement in interdialytic weight gain with each successive assessment period will have a large negative slope estimate, whereas a patient that shows little change or that initially shows considerable change (positive or negative), but whose interdialytic weight gain values return later to pre-intervention levels, will have a slope much closer to zero. We note that all patients had complete data in the sense that each had an interdialytic weight gain mean value for each of the four time points, as abstracted from medical records. The slope is an estimate of the average change in interdialytic weight gain per week. An estimate of the change over the 34-week period defined by the midpoints of the first and last 2-week assessment periods is given by $34 \times \text{slope}$.

Second, we compared the slope means between the intervention and control groups; a significant difference implies that one group has, on average, a faster linear rate of change than the other group. We also tested separately for each group if the slope mean differed from zero; a significant test result implies that the average linear rate of change is not zero.

These between-group and individual-group comparisons were performed using the same mixed ANOVA model. Both unadjusted and adjusted tests were performed using mixed ANOVA models that account for clustering within shift by including shift as a random factor in the model; the unadjusted model did not include any covariates, whereas the adjusted model included covariates for which there was a significant baseline difference between the treatment groups.

The following clinical and demographic variables were considered as potential covariates: age, diabetic status, education, gender, marital status, nutritional status, race/ethnicity, and time on dialysis. Both *intention-to-treat* and *as-treated* analyses were conducted (30,31). *Intention-to-treat* analyses included all patients who were randomized to intervention or control, according to the arm to which they were assigned, regardless of participation in group sessions; however, those patients withdrawing from the study or becoming ineligible prior to treatment initiation (see below) were excluded due to the inability to collect any outcomes data for analysis.

As-treated (a.k.a. *treatment received*) analyses involve the comparison of groups according to the actual treatment received (as opposed to that which was intended) and may be defined in relation to the degree of compliance with the protocol during the trial (32,33). For as-treated analyses, it was determined *a priori* to include those patients who remained in the study and completed a minimum of 4 of the 7 weekly group sessions in either study arm. All data were analyzed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) using alpha = .05.

Results

Eight hundred seventy-eight patients were screened for eligibility, 759 of which were excluded from further consideration (see Figure 1). Those excluded were either ineligible (n = 559), not interested (n = 185), could not be contacted (n = 9), or had a scheduling conflict (n = 6). Patients were determined ineligible for the following reasons: (a) patient did not meet a priori criterion of fluid nonadherence as defined by an interdialytic weight gain > 2.5kg over a 4-week period; (b) patient had been on dialysis for less than 3 months; (c) patient was severely cognitively impaired.

Ultimately, eleven shifts comprising 61 patients were randomized to the intervention while 11 shifts comprising 58 were assigned to the attention-placebo “support and discussion” control condition. Patient characteristics are displayed in Table 1, all of which are comparable to national epidemiological data reported for this population (34). Forty-one and 39 patients, respectively, in the intervention and control arms completed 4 or more group sessions while 8 and 11 participants in each respective arm completed 1–3 sessions. Twelve patients in the intervention arm and 8 patients in the control arm failed to complete any sessions for the following reasons: (a) no longer interested, (b) no show, (c) hospitalized, and (d) transferred to another dialysis clinic. Of note, those failing to complete any sessions for the above reasons did not differ significantly on any clinical or demographic characteristics, $ps > .40$.

Baseline comparisons.

The intervention and control groups did not differ significantly on any clinical characteristics, p s > .25. Only for the variable education was there a significant difference; as a result, level of education (< high school, high school, > high school) was the only covariate included in the adjusted analysis models. Additionally, comparisons of patients by dialysis shift and center, respectively, indicated no significant differences on any clinical or demographic characteristics, p s > .30. A comparison of those patients completing 4 (vs. fewer than 4) group sessions also revealed no significant differences on any clinical or demographic characteristics, p s > .30. Finally, the possibility that change in adherence differed by group leader and time on dialysis, respectively, was also investigated. No such effects were found.

Descriptive statistics.

Descriptive statistics for the interdialytic weight gain outcome at each of the four time points are presented in Table 3 for both the intention-to-treat (Participants = “All participants”) and the as-treated analyses (Participants = “4 sessions”). The “Weeks” column is the midpoint of the assessment period, with Weeks = 0 indicating the start of the intervention. Figures 2 and 3 present plots of the interdialytic weight gain means for the intervention and control groups at each assessment time point for the intention-to-treat and as-treated groups, respectively.

Table 4 presents descriptive statistics for the slopes for each group. Here we see for both subsets of participants that the improvement in the intervention group was greater by roughly a factor of two or more than within the control group (−0.0082 vs. −0.0032 for all participants; −0.0120 vs. −0.0066 for those with 4 sessions).

Primary analysis.

Table 5 presents the unadjusted and adjusted analyses, respectively, of the participant-specific slopes. Let β denote the estimate for the change in interdialytic weight gain over 34 weeks and “diff_34” denote the estimate of the control-minus-intervention difference in the 34-week change. For the unadjusted analysis, the between-group analyses were not significant for either subset (all participants: diff_34 = 0.17, p = .35; those with 4 sessions: diff_34 = 0.18, p = 0.39), indicating no unique intervention effect.

There was statistically significant improvement within the intervention group for each subset (all participants: β = −0.28, p = .023; those with 4 sessions: β = −0.41, p = 0.007). In contrast, there was not statistically significant improvement within the control group for either subset (all participants: β = −0.11, p = .39; those with 4 sessions: β = −0.22, p = 0.14). The variance component estimate for shift (not shown in Table 5) was zero, resulting in an intra-shift correlation coefficient estimate of zero; for this reason, estimates of change in Table 5 are the same as in Table 4.

Results are similar for the adjusted analysis (i.e., for education). For this analysis, the change estimates in the table are an average of the estimates specific to the three levels of education. Letting β and diff_34 be defined as above, the between-group analyses were not significant

for either subset (all participants: $\text{diff} = 0.13$, $p = .48$; those with 4 sessions: $\text{diff} = 0.11$, $p = 0.63$).

There was statistically significant improvement within the intervention group for each subset (all participants: $\beta = -0.32$, $p = .014$; those with 4 sessions: $\beta = -0.42$, $p = 0.007$). In contrast, there was not statistically significant improvement within the control group for either subset (all participants: $\beta = -0.19$, $p = .16$; those with 4 sessions: $\beta = -0.31$, $p = 0.08$). The variance component estimate for shift was zero, resulting in an intra-shift correlation coefficient estimate of zero.

As detailed above, interdialytic weight gain was computed by averaging values over 2 weeks (i.e., six dialysis sessions) at each assessment point. This includes the longer, weekend interval in which patients go an extra day between dialysis sessions. Because of this variation, we ran additional analyses excluding the longer interval, instead computing interdialytic weight gain using only values from mid-week dialysis sessions (i.e., four dialysis sessions). These results (not reported) mirrored those described above—that is, we found no unique intervention effect, but did see some improvement over time in the intervention group, but not control group.

Discussion

The present study found that participation in a behavioral self-regulation intervention resulted in no unique intervention effect (i.e., both between-subjects intention-to-treat and as-treated analyses were nonsignificant when compared against the active control) on a key indicator of adherence for those with severe chronic kidney disease. There was, however, modest within-subjects improvement in interdialytic weight gain for the intervention group which meshes with other evidence showing the utility of behavioral interventions in this patient population (e.g., (9–16)).

Despite this improvement in interdialytic weight gain, it is noteworthy that the intervention group remained clinically nonadherent, making only modest progress over the intervention period; that said, even modest improvement can be meaningful given the negative outcomes associated with poor adherence to fluid intake recommendations between dialysis sessions (e.g., (35–37); see also (3,8)). Moreover, the clinical importance of interdialytic weight gain exists on a continuum, and while a 2.5kg threshold has often been used to reflect problematic adherence (18), any threshold is somewhat arbitrary. The crucial point clinically is that higher interdialytic weight gain reflects less successful adherence to the extreme fluid intake restrictions patients face. The threshold itself is not necessarily the key to optimal outcomes; rather, notable reduction of interdialytic weight gain over time is typically associated with better outcomes (see (20)). Of course, the control condition also experienced some improvement suggesting that perhaps didactic instruction covering a broad array of topics relevant for those on hemodialysis maybe sufficient to achieve behavioral adjustment. More investigation into this possibility is needed.

The active control condition may have played a role in the nonsignificant treatment (vs. control) effect reported here and deserves further discussion. The active control condition

was deemed necessary to ensure that a potential treatment effect occurred as a function of the self-regulatory components of the intervention and not simply additional education and behavioral contact. Yet in typical dialysis settings, no such education or behavioral contact is provided in addition to usual care. Thus, in effect, both arms were administered an intervention aimed at reducing fluid intake (although to differing degrees and with differing theoretical foci) and both arms were explicitly told that fluid intake adherence was to be monitored over the course of the program. Consequently, the present intervention must be viewed in relation to the control condition employed in this trial (see (38)).

Shared, nonspecific therapeutic factors across groups also may have played a role in the results reported here. Nonspecific, or common, therapeutic factors are those shared by different therapies (and modes of administration) which contribute to patient improvement. These factors may take many forms, including those related to the patient, the therapist, the approach, or an interaction of these (39). In the present study, several such factors may have influenced the outcome. For example, because both the intervention and control protocols involved didactic instruction with some degree of content overlap (an issue not exclusive of that discussed in the previous paragraph), there may have been improved behavioral adjustment in both groups simply through better understanding of the importance of adherence and its impact on treatment duration and success. In addition, group cohesion—known to affect retention and participation—may have increased with each session as participants in both groups were encouraged to share experiences related to the management of the disease. Patient outcome expectancies also are relevant, not only because of the content delivered in each arm, but because of the novelty of this adjunctive intervention relative to the typical patient experience in clinic, which most often contains no additional treatment or education aimed at improving dialysis outcomes.

Individual difference characteristics such as distress tolerance must be considered in light of the present results. The ability of patients to withstand physical and/or psychological discomfort (i.e., distress tolerance; see (40)) has been the focus of considerable research in the context of psychopathology (see (40,41)), but also has received attention in behavioral medicine (e.g., (42–44)). Patients with low distress tolerance may be more likely to maladaptively respond to an aversive experience and have trouble focusing attention away from the negative feelings accompanying the experience, both of which would ostensibly impact self-regulation. In the present study more specifically, distress tolerance may be related to one's strength in resisting the temptation to consume (excess) fluid when otherwise recommended, such as between regular meal times or in social settings. We did not measure this construct and thus have no information about its moderating influence, but future research should include these and other measures known to impact fluid intake in this population (e.g., illness representations; (45)), which may help to describe patients at greatest risk for nonadherent behavior.

This study has several strengths—including the randomized design, a relatively large sample of patients on hemodialysis, the collection of an objective clinical marker of adherence as the primary outcome, and its strong theoretical basis and multifaceted approach—but is not without limitations. First, patients were drawn from a concentrated area in Eastern Iowa and Western Illinois, making generalizability an issue. Despite this limited area, it is notable that

minority individuals were recruited in greater number than are typically found in this region of the US and, overall, this sample compares quite favorably to that reported nationally (34). Second, we excluded non-English speaking patients which elicits similar concerns regarding generalizability. Third, although the employment of a 6-month follow-up period is relatively standard, we have no information about the longer-term effectiveness of the intervention, which is a limitation of many behavioral trials. Fourth, we did not collect information regarding patient expectancies or motivation, which would be useful in determining the extent to which such factors played a role in the nonsignificant treatment effect reported here. Future research should also examine psychosocial characteristics such as depressive symptomatology and social support, and alternative modes of delivery, as possible moderators of intervention efficacy. Finally, the present design does not allow more than speculation as to the key “ingredients” of the self-regulatory intervention and issues related to dosing and implementation (see (46)).

In conclusion, this randomized clinical trial extends previous work done in this patient population by testing a theory-based, multimodal behavioral intervention in patients undergoing hemodialysis. Although there was no significant treatment effect, future research is warranted to address some of the limitations noted above, especially delineation of the most effective components of this intervention, and whether adaptation may prove useful in this and other chronic disease populations.

Acknowledgments

Preparation of this article was supported in part by NIDDK grant R01DK072325 awarded to Alan J. Christensen. The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

References

1. Christensen AJ. Patient adherence to medical treatment regimens: Bridging the gap between behavioral science and biomedicine. Yale University Press: New Haven, CT, 2004.
2. Howren MB, Van Liew JR, Christensen AJ. Advances in patient adherence to medical treatment regimens: The emerging role of technology in adherence monitoring and management. *Soc Pers Psychol Compass—Health Series* 2013; 7:427–443.
3. Denhaerynck K, Manhaeve D, Dobbels F, et al. Prevalence and consequences of nonadherence to hemodialysis regimens. *Am J Critical Care* 2007; 16:222–235. [PubMed: 17460313]
4. Bame SI, Petersen N, Wray NP. Variation in hemodialysis patient compliance according to demographic characteristics. *Soc Sci Med* 1993; 37:1035–1043. [PubMed: 8235736]
5. Christensen AJ, Moran PJ, Lawton WJ, et al. Monitoring attentional style and medical regimen adherence in hemodialysis patients. *Health Psychol* 1997; 16:256–262. [PubMed: 9152704]
6. Friend R, Hatchett L, Schneider MS, et al. A comparison of attributions, health beliefs, and negative emotions as predictors of fluid adherence in renal dialysis patients: A prospective analysis. *Annals Behav Med* 1997; 19:344–347.
7. Schneider MS, Friend R, Whitaker P, et al. Fluid noncompliance and symptomatology in end-stage renal disease: Cognitive and emotional variables. *Health Psychol* 1991; 10:209–215. [PubMed: 1879393]
8. Christensen AJ, Ehlers SL. Psychological factors in end-stage renal disease: An emerging context for behavioral medicine research. *J Consul Clin Psychol* 2002; 70:712–724.
9. Barnes MR. Token economy control of fluid overload in a patient receiving hemodialysis. *J Behav Therapy Exp Psychiatry* 1976; 7:305–306.

10. Carton JS, Schweitzer JB. Use of a token economy to increase compliance during hemodialysis. *J Applied Behav Analysis*, 1996; 29:111–113.
11. Hart R Utilization of token economy within a chronic dialysis unit. *J Consul Clin Psychol* 1979; 47:646–648.
12. Hegel MT, Ayllon T, Thiel G, et al. Improving adherence to fluid-restrictions in male hemodialysis patients: A comparison of cognitive and behavioral approaches. *Health Psychol* 1992; 11:324–330. [PubMed: 1425550]
13. Keane TM, Prue DM, Collins FL. Behavioral contracting to improve dietary compliance in chronic renal dialysis patients. *J Behav Ther Exp Psychiatry* 1981; 12:63–67. [PubMed: 7251883]
14. Mosley TH, Eisen AR, Bruce BK, Brantley PJ, & Cocke TB (1993). Contingent social reinforcement for fluid compliance in a hemodialysis patient. *J BehavTher Exp Psychiatry* 1993; 1:77–81.
15. Sharp J, Wild MR, Gumley AI, et al. A cognitive behavioral group approach to enhance adherence to hemodialysis fluid restrictions: A randomized controlled trial. *Am J Kidney Dis* 2005; 45:1046–1057. [PubMed: 15957134]
16. Tsay SL. Self-efficacy training for patients with end-stage renal disease. *J Adv Nurs* 2003; 43:370–375. [PubMed: 12887355]
17. Bonner A, Havas K, Douglas C, et al. Self-management programmes in stages 1–4 chronic kidney disease: A literature review. *J Renal Care* 2014; 40:194–204.
18. Clark S, Farrington K, Chilcot J. Nonadherence in dialysis patients: Prevalence, measurement, outcome, and psychological determinants. *Sem Dialysis* 2014; 27:42–49.
19. Kaptein AA, van Dijk S, Broadbent E, et al. Behavioural research in patients with end-stage renal disease: A review and research agenda. *Patient Educ Counseling* 2010; 81:23–29.
20. Sharp J, Wild MR, Gumley AI. A systematic review of psychological interventions for the treatment of nonadherence to fluid-intake restrictions in people receiving hemodialysis. *Am J Kidney Dis* 2005; 45:15–27. [PubMed: 15696440]
21. Matteson ML, Russell C. Interventions to improve hemodialysis adherence: A systematic review of randomized-controlled trials. *Hemodialysis Int* 2010; 14:370–382.
22. Welch JL, Thomas-Hawkins C. Psycho-educational strategies to promote fluid adherence in adult hemodialysis patients: A review of intervention studies. *Int J Nurs Studies* 2005; 42:597–608.
23. Christensen AJ, Moran PJ, Wiebe JS, et al. Effect of a behavioral self-regulation intervention on patient in hemodialysis. *Health Psychol* 2002; 21:393–397. [PubMed: 12090682]
24. Kanfer FH, Gaelick L. Self-management methods, in *Helping People Change* (3rd ed.), eds, Kanfer F, Goldstein A. Pergamon Press: New York 1986, pp. 283–345.
25. Maes S, Karoly P. Self-regulation assessment and intervention in physical health and illness: A review. *Applied psychol: Int rev* 2005; 54:267–299.
26. Hener T, Weisenberg M, Har-Even D. (1996). Supportive versus cognitive-behavioral intervention programs in achieving adjustment to home peritoneal kidney dialysis. *J Consul Clin Psychol* 1996; 64:731–741.
27. Christensen AJ, Raichle K. End-stage renal disease, in *Chronic Physical Disorders: Behavioral Medicine's Perspective*, eds, Christensen AJ, Anotoni MH. Blackwell Publishers Ltd.: Malden, MA, 2002, pp. 220–243.
28. Cohen J A coefficient of agreement for nominal scales. *Educ Psychol Measurement* 1960; 20:37–46.
29. Kaplan De-Nour A, Czaczkes JW. Personality factors in chronic hemodialysis patients causing noncompliance with medical regimen. *Psychosom Med* 1972; 34:333–344. [PubMed: 5074959]
30. Friedman LM, Furberg CD, DeMets DL. *Fundamentals of Clinical Trials*. Springer: New York, 2010.
31. Piantadosi S *Clinical trials: A methodologic perspective*. Wiley-Interscience: Hoboken, NJ, 2005.
32. Ellenberg JH. Intent-to-treat analysis versus as-treated analysis. *Drug Inform J* 1996; 30:535–544.
33. Miladinovic B, Kumar A, Hozo I, et al. Instrumental variable meta-analysis of individual patient data: Application to adjust for treatment non-compliance. *BMC Med Res Methodol* 2011; 11:55. [PubMed: 21510899]

34. U.S. Renal Data System, USRDS 2014 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.
35. Leggat JE, Orzol SM, Hulbert-Shearon TE, et al. Noncompliance in hemodialysis: Predictors and survival analysis. *Am J Kidney Diseases* 1998; 32:139–145. [PubMed: 9669435]
36. Saran R, Bragg-Gresham JL, Rayner HC, et al. Nonadherence in hemodialysis: Associations with mortality, hospitalization, and practice patterns in the DOPPS. *Kidney International* 2003; 64: 254–262. [PubMed: 12787417]
37. Szczech LA, Reddan DN, Klassen PS, et al. Interactions between dialysis-related volume exposures, nutritional surrogates and mortality among ESRD patients. *Nephrology, Dialysis, Transplantation* 2003; 18:1585–1591.
38. Mohr DC, Spring B, Freedland KE, et al. The selection and design of control conditions for randomized controlled trials of psychological interventions. *Psychother Psychosom* 2009; 78:275–284. [PubMed: 19602916]
39. Bloch S, Crouch E, Reibstein J. Therapeutic factors in group psychotherapy. *Arch Gen Psychiatry* 1981; 38:519–526. [PubMed: 7235852]
40. Zvolensky MJ, Vujanovic AA, Bernstein A, et al. Distress tolerance: Theory, measurement, and relations to psychopathology. *Current Dir Psychol Sci* 2010; 19:406–410.
41. Leyro TM, Zvolensky MJ, Bernstein A. Distress tolerance and psychopathological symptoms and disorders: A review of the empirical literature among adults. *Psychol Bulletin* 2010; 136:576–600.
42. Brown RA, Lejuez CW, Strong DR, et al. A prospective examination of distress tolerance and early smoking lapse in adult self-quitters. *Nicotine Tobacco Res* 2009; 11:493–502.
43. Lillis J, Hayes SC, Bunting K, et al. Teaching acceptance and mindfulness to improve the lives of the obese: A preliminary test of a theoretical model. *Annals Behav Med* 2009; 37:58–69.
44. O’Cleirigh C, Ironson G, Smits JAJ. Does distress tolerance moderate the impact of major life events on psychosocial variables and behaviors important in the management of HIV. *Behav Ther* 2007; 38:314–323.
45. Chilcot J, Wellsted D, Farrington K. Illness representations are associated with fluid nonadherence among hemodialysis patients. *J Psychosomatic Res* 2010; 68:203–212.
46. Collins LM, Murphy SA, Nair VN, et al. A strategy for optimizing and evaluating behavioral interventions. *Annals Behav Med* 2005;30:65–73.

Public Health Significance Statement:

This study suggests that participation in a behavioral self-management intervention may provide some benefits for chronic kidney disease patients undergoing hemodialysis.

Figure 1. Patient participant flow through screening, enrollment, and analysis; IWG = interdialytic weight gain.

Figure 2.

Mean interdialytic weight gain (IWG) values in kilograms over time by group status. Higher IWG values indicate poorer patient adherence. Intention-to-treat analyses.

Figure 3.

Mean interdialytic weight gain (IWG) values in kilograms over time by group status. Higher IWG values indicate poorer patient adherence. As-treated analyses.

Table 1**Patient Participant Characteristics**

Characteristic	Group	
	Intervention (<i>n</i> = 61)	Control (<i>n</i> = 58)
Age (years)		
<i>Mean (SD)</i>	55.9 (12.7)	58.2 (10.4)
Sex (% male)	63.0	68.8
Race/Ethnicity (%)		
Caucasian	63.9	67.2
African-American	31.1	24.1
Hispanic/Latino	1.6	8.6
Not reported	1.6	---
Education (years)		
<i>Mean (SD)</i>	12.4 (2.7)	13.4 (2.6)
Marital status (%)		
Married	31.1	36.2
Divorced/Separated	26.3	19.0
Widowed	13.1	6.9
Never married	9.8	17.2
Missing/Not reported	19.7	20.7
Time on dialysis (months)		
<i>Mean (SD)</i>	50.4 (46.1)	58.5 (68.5)
Baseline IWG (kg)		
<i>Mean (SD)</i>	3.9 (1.1)	3.9 (1.3)
Diabetic status (% diabetic)	44.3	53.4
Sessions completed		
4 or more	41 (67.2%)	39 (67.2%)
1–3	8 (13.1%)	11 (19.0%)
0	12 (19.6%)	8 (13.8%)

Note. IWG = interdialytic weight gain; kg = kilograms. The intervention and control groups did not differ significantly on any clinical or demographic characteristics, $p > .25$.

Table 2**Summary of Self-Regulation Protocol**

Session	Description
(1)	Introduction and rationale for the self-regulation approach and its relation to the dialysis treatment regimen. Brief review of how and why fluid-intake guidelines are established and the immediate and long-term effects of nonadherence.
(2)	An overview of the association between self-regulatory processes (i.e., self-monitoring, self-evaluation, self-reinforcement) and behavior. Examples of this overview include the effect of self-monitoring on enhancing awareness and perceived control over behavior and the association between reinforcement contingencies and the likelihood of repeating a behavior in the future.
(3)	Self-monitoring is reviewed/discussed. Instruction in self-monitoring skills and begin homework consisting of self-monitoring of daily fluid intake, mood, behavior, setting, and other antecedents. Daily recording and evaluation of target behavior (i.e., fluid-intake) begins. Weekly self-evaluation of target behavior performance and interdialytic weight gain relative to goals begins. Patients' use of behavioral self-regulatory coping skills also reviewed/discussed. Any problems in meeting goals are discussed.
(4)	Goal-setting discussion and patient goal-setting for fluid-intake between treatments. Homework assignments include each patient discussing goals with their renal care providers as well as continued self-monitoring of fluid-intake.
(5)	Establishing self-administered reinforcement strategies. Both covert reinforcers (e.g., positive self-evaluation) and overt reinforcers (e.g., engaging in pleasurable activities) are discussed. Homework assignments include identifying realistic and adaptive reinforcers as well as continued self-monitoring of fluid-intake.
(6)	Teaching behavioral stimulus-control (e.g., removing drinking-related cues from the table; constraining drinking to a single, modest-sized fluid container that must be refilled/reused), self-instruction (e.g., use of cues/reminders in the home environment to promote fluid-adherence), and related behavioral coping skills to promote regulation of fluid-intake and appropriate corrective responses for fluid-intake behavior as well as continued self-monitoring of fluid-intake.
(7)	Review/evaluation of group experience. Discussion of relapse prevention strategies (i.e., how to respond to and prevent "backsliding" of fluid-intake behavior using tools gained in group sessions). Group close.

Table 3

Descriptive statistics for interdialytic weight gain

Participants	Time (T0, T1, T2, T3)	Treatment condition	N Obs	Mean	Min	Max	SD	Weeks
All participants	0	C	58	3.93	1.30	7.50	1.28	−1
	0	I	61	3.89	2.45	7.77	1.06	−1
	1	C	58	3.75	0.95	7.52	1.42	8
	1	I	61	3.73	1.78	7.55	1.08	8
	2	C	58	3.73	1.28	8.12	1.47	20
	2	I	61	3.66	1.17	6.98	1.12	20
	3	C	58	3.80	1.30	7.02	1.16	33
	3	I	61	3.60	0.46	7.43	1.18	33
4 Sessions	0	C	39	4.21	2.50	7.50	1.37	−1
	0	I	41	3.93	2.45	7.77	1.09	−1
	1	C	39	4.05	2.07	7.52	1.45	8
	1	I	41	3.61	1.78	5.52	0.98	8
	2	C	39	4.03	1.28	8.12	1.60	20
	2	I	41	3.52	1.17	6.24	1.10	20
	3	C	39	3.96	1.80	7.02	1.23	33
	3	I	41	3.48	0.46	5.82	1.18	33

Note. C = control group; I = intervention group; interdialytic weight gain reported in kilograms; SD = standard deviation.

Table 4

Descriptive statistics for participant-specific slope estimates

Participants	Group	N	Mean	Median	Minimum	Maximum	SD
All participants	Control	58	-0.0032	-0.0007	-0.0795	0.0608	0.0282
	Intervention	61	-0.0082	-0.0071	-0.0775	0.0608	0.0293
4 sessions	Control	39	-0.0066	-0.0040	-0.0795	0.0608	0.0283
	Intervention	41	-0.0120	-0.0061	-0.0775	0.0582	0.0273

Note. SD = standard deviation.

Table 5

Unadjusted & adjusted analyses of participant-specific slope estimates

Participants	Effect	Change/wk	Change/34 wks	p-value	Sig
Unadjusted					
All participants	Control	−0.0032	−0.11	0.3933	
	Intervention	−0.0082	−0.28	0.0272	*
	Diff (Cont - Int)	0.0050	0.17	0.3450	
4 sessions	Control	−0.0066	−0.22	0.1436	
	Intervention	−0.0120	−0.41	0.0073	*
	Diff (Cont - Int)	0.0054	0.18	0.3889	
Adjusted					
All participants	Control	−0.0055	−0.19	0.1649	
	Intervention	−0.0093	−0.32	0.0144	*
	Diff (Cont - Int)	0.0038	0.13	0.4836	
4 sessions	Control	−0.0091	−0.31	0.0813	
	Intervention	−0.0124	−0.42	0.0065	*
	Diff (Cont - Int)	0.0033	0.11	0.6279	

Note. For the unadjusted panel (top), change/wk is the estimate of the mean slope computed from a mixed two-factor (group × shift) ANOVA model where the outcome is the participant-specific slope (from regressing interdialytic weight gain on time in weeks) and shift is a random factor. For the adjusted panel (bottom), change/wk is the estimate of the mean slope computed from a mixed three-factor (group × education × shift) ANOVA model where the outcome is the participant-specific slope (from regressing interdialytic weight gain on time in weeks) and shift is a random factor. Change/34 weeks = 34(change/wk) and represents the estimated change from 1 week pre-intervention to 33 weeks after beginning the intervention. Education is categorized as < high school, high school, and > high school. All results account for within-shift correlation. Sig = “*” if p-value < .05. Diff = control-minus-intervention difference in change estimates.