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BRIEF REPORTS

Effect of a Behavioral Self-Regulation Intervention on Patient Adherence in Hemodialysis

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The present study examined the efficacy of a behavioral intervention designed to increase adherence to fluid-intake restrictions among hemodialysis patients. Twenty intervention-group patients were compared with 20 matched control patients on an indicator of fluid-intake adherence at 3 time points. The Group × Time interaction was significant, indicating that patients in the 2 groups exhibited a differential pattern of change in fluid-intake adherence across the follow-up period. The intervention and control groups did not differ significantly in terms of adherence at the initial postintervention period but did differ at the 8-week follow-up. The observed group differences were, in part, due to a trend toward increasingly better adherence in the intervention group and poorer adherence in the control group across the follow-up period.

Key words: patient adherence, chronic illness, self-regulation, intervention

The failure of patients to follow prescribed treatment regimens is one of the most important problems facing health care today. Inadequate patient adherence poses a severe toll in terms of treatment failures, increased morbidity and mortality, and economic burden (Dunbar-Jacob & Schlenk, 2000). Although estimates of nonadherence vary across studies and clinical populations, reviews of the literature have suggested that between 20% and 80% of patients fail to follow medication regimens, make dietary or other lifestyle changes, or otherwise change their behavior as prescribed or recommended by their health care providers (Dunbar-Jacob & Schlenk, 2000; Turk & Meichenbaum, 1991).

Although many studies have been devoted to identifying factors that influence patient adherence (see reviews by Haynes, 1979; Kaplan & Simon, 1990), less empirical attention has been devoted to the design, implementation, and testing of interventions to improve adherence behavior. This is certainly true for studies involving end-stage renal disease (ESRD) patients receiving chronic hemodialysis treatment. In addition to undergoing frequent (three times weekly) and time-consuming (approximately 4 hours per session) dialysis treatments, patients receiving hemodialysis are required to follow a multifaceted behavioral regimen. For most patients, the most challenging aspect of the hemodialysis treatment regimen involves extreme restrictions placed on the amount of fluid that can be safely consumed (Christensen & Moran, 1998). Patients are generally instructed to ingest no more than 1 L of fluid per day because of the intermittent nature of the fluid-clearance accomplished by the periodic dialysis treatments. Failure to adhere to fluid-intake guidelines can result in fluid overload and is associated with congestive heart failure, hypertension, pulmonary edema, and shortened patient survival (Kimmel et al., 2000; Wolcott, Maida, Diamond, & Nissenson, 1986).

Despite the severe consequences of nonadherence in this population, studies have typically observed that between 30% and 60% of hemodialysis patients do not adhere to the fluid-intake regimen (Bame, Petersen, & Wray, 1993; Christensen, Moran, Lawton, Stallman, & Voigts, 1997; Friend, Hatchett, Schneider, & Wadhwa, 1997; Schneider, Friend, Whitaker, & Wadhwa, 1991). Modest evidence suggests that behavioral intervention strategies (e.g., instruction in self-monitoring, behavioral contracting, and positive reinforcement) may be associated with improved adherence among hemodialysis patients (Barnes, 1976; Carton & Schweitzer, 1996; Cummings, Becker, Kirscht, & Levin, 1981; Hart, 1979; Hegel, Ayllon, Thiel, & Oulton, 1992; Keane, Prue, & Collins, 1981). However, most past studies have been limited to very small samples ($N < 5$) or single-subject designs (see exception by Cummings et al., 1981).

The present study examined the efficacy of a group-administered behavioral self-regulation intervention designed by the

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authors to increase adherence to fluid-intake restrictions among hemodialysis patients. In past research, self-regulation or self-control–based interventions have been applied to a wide range of behavioral (e.g., weight loss, smoking cessation) and emotional (e.g., depression, anxiety) problems (Kanfer & Gaelick, 1986). Self-regulation theory espouses that successfully carrying out a target behavior is a function of three core self-regulatory stages or processes in which an individual must engage (Kanfer & Gaelick, 1986). These central regulatory processes include self-monitoring, self-evaluation, and self-reinforcement of the behavior. Although some past studies in this population have examined certain aspects of behavioral self-regulation in very small or single-subject samples, to our knowledge the present study represents the first examination of the effect of a multifaceted group-administered self-regulatory intervention on adherence among hemodialysis patients.

Method

Participants

The protocol for the present study was approved by the University of Iowa Institutional Review Board for the protection of human research participants. Participants were recruited from six hemodialysis treatment centers, all affiliated with the University of Iowa Hospitals and Clinics Renal Dialysis Treatment Program. Hemodialysis centers are a highly social context, and patients at a given dialysis center typically have physically close, sustained, social contact with each other several times a week for years. As has been previously described (Hener, Weisenberg, & Har-Even, 1996), given the nature of the hemodialysis setting, diffusion of treatment across patients at a given center is a major impediment to utilizing a randomized control-group design. Thus, in the present quasiexperimental design, participants from three centers participated in the behavioral self-regulation groups while participants in the other three centers served as matched controls. Control participants were matched with intervention participants in terms of gender, diabetic status, average interdialysis weight gain at baseline, and age. These characteristics were selected given past evidence that they may be related to hemodialysis patient adherence (Christensen & Moran, 1998). To minimize the possibility of seasonal confounds in fluid-intake behavior, data were obtained from the intervention and control groups at approximately the same times of year, with four of the groups starting between April and July and two groups starting between October and January. A summary of participant characteristics according to group membership is provided in Table 1. The ethnic distribution of both groups was predominantly (90%) Caucasian. This distribution is very similar to the overall patient composition (87% Caucasian) of the University of Iowa dialysis units where the research was conducted. The intervention and control groups did not differ significantly on any of the clinical or demographic characteristics examined (all $ps > .10$).

Group participants were recruited through the distribution of flyers at the dialysis center inviting patients to participate in an "education and support group" designed to help them deal with problems faced on dialysis. Thirty-four patients initially consented to participate in the groups. Although an attempt was made to target the recruitment of patients with a history of problematic adherence, 5 participants had no history of objectively defined nonadherence (i.e., average interdialysis weight gains less than 2.0 kg at baseline). Data from these participants were not included in the analysis. In addition, 3 participants (8.8%) died, and 2 participants (5.9%) received transplants during the study period. Four additional participants (11.8%) failed to complete the study for unspecified reasons. Thus, the final sample included 20 participants in the intervention group. As specified above, 20 matched controls were identified at the other affiliated dialysis centers in the same geographical region. To obtain the 20 matched controls, 39 potential control patients were asked to complete background information forms and were informed that their medical records, including information related to fluid-intake adherence, would be reviewed over the next 8 weeks. The necessary data were abstracted from patient records over this period of time. Four control patients (10.3%) died and 2 (5.1%) received transplants during the study period. These 6 patients were not considered as potential matched controls.

Table 1
Patient Characteristics

Characteristic	Group	
	Intervention ($n = 20$)	Control ($n = 20$)
Age (years)		
M	53.65	56.47
SD	12.73	14.70
Years of education		
M	13.15	12.11
SD	2.39	2.47
Time on dialysis (months)		
M	84.06	75.47
SD	81.38	70.44
Baseline IWG		
M	3.18	3.14
SD	0.94	0.81
Men		
No.	9	9
%	45	45
Women		
No.	11	11
%	55	55
Diabetic status		
Diabetic		
No.	3	3
%	15	15
Nondiabetic		
No.	17	17
%	85	85
Cardiovascular disease		
Present		
No.	5	6
%	25	30
Absent		
No.	15	14
%	75	70
Albumin (gm/dL)		
M	3.88	3.83
SD	0.42	0.44
Creatinine (mg/dL)		
M	10.40	10.31
SD	2.60	3.00

Note. None of the between-groups differences on these variables approached significance (all $ps > .10$). IWG = interdialytic weight gain.

Intervention Protocol

The intervention protocol was administered to groups of 4–6 participants meeting for hour-long weekly sessions for 7 weeks. A total of six groups were conducted, with two groups each being coadministered by one of three therapist dyads. Each participating therapist had master's- or doctoral-level training in clinical psychology, including previous behavior therapy experience. Session material utilized by therapists was highly structured and detailed across the seven sessions, and all participating therapists underwent multiple training sessions prior to the study.

A summary of the intervention protocol is provided in Table 2. Aspects of the protocol closely followed Kanfer's self-regulatory framework of self-monitoring, self-evaluation, and self-reinforcement of a target behavior (Kanfer & Gaelick, 1986). Illustrations of these behavioral principles, group discussions, and homework assignments (e.g., practice in self-monitoring, goal setting) were targeted to the issue of fluid-intake adherence. Sessions were generally highly therapist directed, although participants were regularly encouraged to share their experiences dealing with the dialysis regimen. A consistent attempt was made to focus all group discussion on self-regulatory principles as they related to treatment adherence. A more detailed summary of the intervention protocol is available on request from Alan J. Christensen.

Adherence Assessments

Adherence to the fluid-intake regimen was determined by computing the amount of weight a patient gained between dialysis treatment sessions. The values resulting from this computation (termed *interdialytic weight gain* [IWG]) are believed to be a valid reflection of the amount of fluid the hemodialysis patient ingests between sessions (Manley & Sweeney, 1986). IWGs greater than 2.5 kg are generally considered indicative of problematic adherence (Christensen & Moran, 1998). As seen in Table 1, baseline IWG values reflected clearly problematic fluid-intake adherence in both groups. At each assessment period, IWG values were averaged over six dialysis sessions (2 weeks). The baseline assessment (Time 1) comprised the 2 weeks immediately preceding the initial group session, Time 2 comprised the 2 weeks immediately following the final intervention session, and Time 3 comprised the 7th and 8th weeks postintervention.

Table 2
Summary of Self-Regulation Protocol

No.	Description
1.	Introduction and rationale for the self-regulation approach and its relation to the dialysis treatment regimen (Session 1).
2.	Brief review of how and why fluid-intake guidelines are established and the immediate and long-term effects of nonadherence (Session 1).
3.	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 (Session 2).
4.	Instruction in self-monitoring skills and began homework self-monitoring of daily fluid intake, mood, behavior, setting, and other antecedents. A daily diary method was used with entries made each time fluid was ingested (Session 3).
5.	Goal-setting discussion and patient goal setting for fluid intake between treatments. Homework assignment included each patient discussing goals with their renal care providers (Session 4).
6.	Establishing self-administered reinforcement strategies. Both covert reinforcers (e.g., positive self-evaluation) and overt reinforcers (e.g., engaging in pleasurable activities) were discussed. Homework assignment included identifying realistic and adaptive reinforcers (Session 5).
7.	Teaching stimulus control, self-instruction, and related behavioral coping skills to promote regulation of fluid intake (Session 6).
8.	Daily recording and evaluation of target behavior (i.e., fluid intake). Self-monitoring was reviewed and discussed during weekly group meetings (Sessions 3–7).
9.	Weekly self-evaluation of target behavior performance and interdialytic weight gain relative to goals. Patients' use of behavioral self-regulatory coping skills also reviewed and discussed during weekly group meetings. Any problems in meeting goals were discussed (Sessions 3–7).

Results

The primary analysis consisted of a 2 (group: intervention vs. control) $\times$ 3 (time: baseline, Time 2, Time 3) repeated measures analysis of variance with mean IWG values at each assessment period serving as a within-subject variable. The main effects for both Group, $F(1, 38) = 0.93$, $p > .30$, and Time $F(2, 37) = 0.10$, $p > .50$, were nonsignificant. However, the key Group $\times$ Time interaction was significant, $F(2, 76) = 3.72$, $p < .05$. This effect indicates that patients in the two groups exhibited a differential pattern of change in fluid-intake adherence across the follow-up period. The specific pattern of change in IWG values is illustrated graphically in Figure 1. As seen in Figure 1, intervention-group patients displayed a pattern of decreased IWG (improved adherence) over time whereas control patients displayed a pattern of increased IWG (poorer adherence) over time.[1]

To better understand the nature of the significant Group $\times$ Time interaction, a number of follow-up statistical comparisons were conducted. First, between-groups comparisons of IWG values in the intervention and control groups were conducted at each assessment period. As seen in Figure 1, at baseline, IWG values in the intervention and control groups were nearly identical, $t(38) = 0.19$, $p > .50$. In the 2 weeks following group completion (Time 2), the intervention ($M = 3.05$ kg) and control ($M = 3.30$ kg) groups did not significantly differ, $t(38) = 1.52$, $p > .10$. However, at the 8-week follow-up (Time 3), the intervention ($M = 2.88$ kg) and control ($M = 3.48$ kg) groups did differ significantly, with the intervention group exhibiting more favorable adherence, $t(38) = 3.65$, $p < .001$.[2]

Finally, IWG means within each group were compared. Differences between baseline and Time 2 IWG values were nonsignificant in both the intervention group, $t(19) = 0.73$, $p > .40$, and in the control group, $t(19) = .97$, $p > .30$. Differences between baseline ($M = 3.18$ kg) and Time 3 ($M = 2.88$) IWG values approached significance in the intervention group, $t(19) = 1.83$, $p = .08$, reflecting a trend toward improved adherence in this group. Differences between baseline ($M = 3.14$ kg) and Time 3 ($M = 3.48$) IWG values also approached significance in the control group, $t(19) = 2.05$, $p = .06$, reflecting a trend toward poorer adherence in the control group.

Discussion

The present study represents an early step toward the design and implementation of, and establishment of the effectiveness of, an adherence-enhancing intervention for the hemodialysis population. Change in adherence between the self-regulation intervention and

[1] Patients in each of the three control dialysis units showed some degree of decrease in adherence over the study period (mean increases in IWG ranged from .11 to .51 kg) across the three control units.

[2] Applying a full Bonferroni correction to the significance level of the six post hoc comparisons results in $p = .008$. The between-groups difference in IWG at the 8-week follow-up ($p < .001$) remains significant when subjected to this correction.

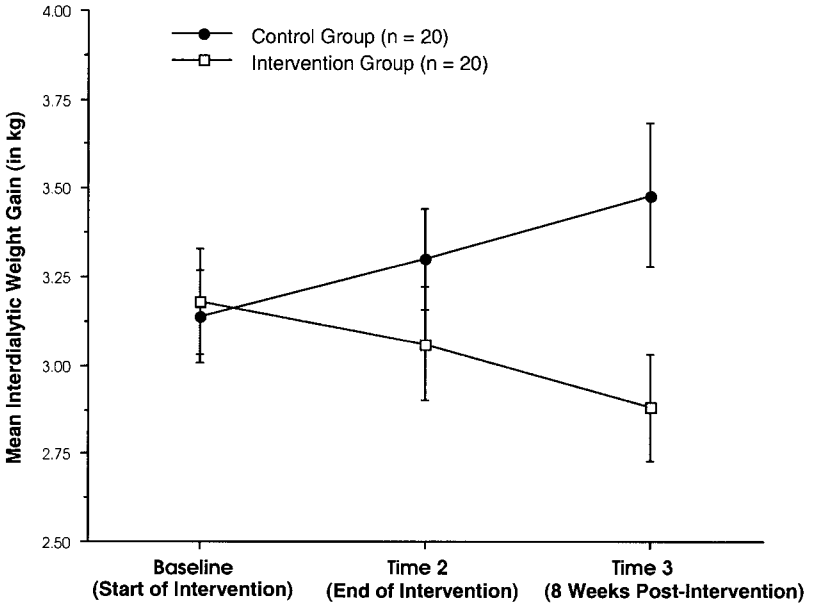

Figure 1. Change in interdialytic weight gain (IWG) values over time as a function of intervention status. Higher IWG values represent poorer patient adherence with the fluid-intake regimen.

matched-control conditions across the 8-week follow-up period was significantly different. However, follow-up statistical comparisons of group means revealed that group differences at the initial posttreatment assessment were not significant. Group differences at the initial posttreatment assessment were not significant. As expected, the group difference at the 8-week posttreatment assessment was significant. However, the group difference observed at follow-up was partly due to a trend toward worsening adherence among patients in the control group and partly due to the expected trend toward improving adherence in the intervention group.

It is not clear why the treatment effect appeared to strengthen in the 8 weeks following completion of the intervention. Previous behavioral intervention studies in this population involving single-subject designs and very small samples have reported that maintenance of adherence changes over a 2–6-month period is quite high (Hegel et al., 1992; Mosley, Eisen, Bruce, Brantley, & Cocke, 1993). However, earlier studies did not observe this apparent strengthening of the adherence effect over time. An additional follow-up period would have been useful to evaluate the stability and the longer term trajectory of the level of adherence in both the treatment and control groups.

Given the highly integrated nature of the typical hemodialysis unit and the frequent and prolonged interaction between patients, a randomized control group design did not appear feasible. Although the control group was successfully matched on a number of key clinical and demographic characteristics, without random assignment we cannot rule out the possibility that some unrecognized difference between the control and intervention groups influenced our results. For example, it is possible that the decrease over time in nonadherence in the intervention group simply reflected a regression to the mean phenomenon rather than an intervention effect. However, we believe the fact that the matched control group exhibited a nearly identical level of nonadherence at baseline and clearly did not show any regression over time (adherence actually worsened somewhat in this group) makes the regression interpretation less likely.

As has often been argued in the broader psychological intervention outcome literature, we cannot rule out the possibility that the changes in adherence we observed were due to nonspecific or "placebo" effects of group participation rather than the specific or unique aspects of the self-regulation protocol. One strategy for addressing this issue in future work is to use an attention placebo control condition rather than relying solely on a no-treatment control as was the case in the present study. Some have argued that a comparative design involving two previously established active treatments provides an even more effective alternative (for a discussion of this issue, see Parloff, 1986).

Although the between-groups difference in adherence at the 8-week assessment was statistically significant, the mean level of fluid intake adherence (mean IWG = 2.88 kg) in the intervention group still fell in the clinically problematic range. Although the association between degree of nonadherence to fluid restrictions and the risk of complications and death is believed to be linear in nature (e.g., Kimmel et al., 2000), the fact that the intervention group still displayed generally poor adherence at follow-up might be interpreted as evidence that the clinical significance of the effect was limited. Although studies involving ESRD patients have generally not explicitly evaluated the clinical significance of an intervention effect, it is important for future intervention research to explicitly incorporate some examination of clinical significance into research designs (see Kendall, Marrs-Garcia, Nath, & Sheldrick, 1999).

The ethnic diversity of the sample was limited because 90% of participants were Caucasian. Although this mirrors the ethnic distribution of the population of hemodialysis patients in the units and geographical region where the research was conducted, it is an underrepresentation of the ethnic diversity of the broader population of hemodialysis patients in the United States (U.S. Renal Data

System, 2000). Finally, limited statistical power because of the modest sample size in the present study ($N = 40$) may have played a role in limiting the significance of some of the statistical comparisons conducted. A post hoc power analysis revealed that on the basis of the mean, between-groups comparison effect size observed in the present study ($d = .47$), an n of approximately 65 would be needed to obtain statistical power at the recommended .80 level (Cohen, 1988).

These limitations notwithstanding, we believe the present study reflects an early but important step toward the design and implementation of a potentially effective strategy for improving adherence among patients undergoing hemodialysis. The study extends previous efforts by testing the effect of a theory-based, group-administered, and multifaceted behavioral intervention in a moderately sized sample of nonadherent hemodialysis patients. Further research is also needed to address the limitations of our effort as well as to determine whether an analogous group-delivered self-regulatory approach might prove useful in facilitating adherence among patients facing other chronic medical treatment regimens.

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