Autonomous Regulation and Long-Term Medication Adherence in Adult Outpatients

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Self-determination theory was applied to explore the motivational basis of adherence to long-term medication prescriptions. Adult outpatients with various diagnoses who had been on a medication for at least 1 month and expected to continue (a) completed questionnaires that assessed their autonomous regulation, other motivation variables, and perceptions of their physicians' support of their autonomy by hearing their concerns and offering choice; (b) provided subjective ratings of their adherence and a 2-day retrospective pill count during an interview with a clinical psychologist; and (c) provided a 14-day prospective pill count during a subsequent, brief telephone survey. LISREL analyses supported the self-determination model for adherence by confirming that patients' autonomous motivation for adherence did mediate the relation between patients' perceptions of their physicians' autonomy support and their own medication adherence.

Key words: medication adherence, patient autonomous motivation, physician autonomy support, self-determination theory

Patients' nonadherence to medical regimens is a monumental problem for health care (Horwitz & Horwitz, 1993). Evidence suggests that patients take an average of about 50% of their prescribed medication (Haynes, McKibbon, & Kanani, 1996; Rudd et al., 1988; Sackett & Snow, 1979) and that half of all patients on prescribed medications of 2 weeks or longer take less than the amount necessary for effective results (Dwyer, Levy, & Menander, 1986; Epstein & Cluss, 1982). This nonadherence reduces treatment benefits (Gordis, 1979), biases clinician and researcher assessment of the efficacy of treatments (Haynes & Dantes, 1987; Roth, 1987), and leads to the unnecessary prescription of higher doses or stronger drugs (Norell, 1980).

Many studies have explored adherence, although few have been guided by theories of behavior regulation (Becker & Maiman, 1975; Caplan, Robinson, French, Caldwell, & Shinn, 1976; DiMatteo & DiNicola, 1982; Epstein & Cluss, 1982), so there is little empirical basis for improving adherence (Haynes et al., 1996). The present cross-sectional study tested the application of self-determination theory (Deci & Ryan, 1985, 1991) to long-term medication adherence.

Self-Determination Theory

This theory distinguishes between autonomous and controlled behavior regulation. Behaviors are autonomous to the extent that people experience a true sense of volition and choice and act because of the personal importance of the behavior. By contrast, behaviors are controlled to the extent that people perform them because they feel pressured, either by external or intrapsychic forces.

Autonomous regulation is assessed by the Treatment Self-Regulation Questionnaire (TSRQ). Previous research using this questionnaire found autonomous regulation to be positively associated with active participation in an alcohol treatment program (Ryan, Plant, & O'Malley, 1995), long-
prescription medication, as pill, tablet, or capsule, for the past month and expected to continue for another month. Participants ranged in age from 37 to 65 years ($M = 56.3$ years; men were slightly older than women: $M = 58.0$ vs. $55.7$, $ns$). The mean years of education was $16.1$ ($SD = 1.98$), with no differences between men and women.

Participants were recruited by telephone from a list 438 individuals in the Subject Register of the Duke Center for the Study of Aging and Human Development. Of those, 103 could not be reached (they had moved or changed telephone numbers), and 149 did not meet inclusion criteria (they did not take a medication or did not have a physician). Of the remaining 186, 60 chose not to participate, whereas $126 (67.7\%)$ agreed to participate and gave informed consent. Participants did not differ from nonparticipants in age, but they did differ in gender. Seventy-five percent of participants were women, whereas only $54\%$ of the nonparticipants were women, $\chi^2(1, N = 186) = 7.93, p < .01$.

The 126 participants agreed to be interviewed and to bring their medications in the original bottles. They were assured that their responses would not be given to their health care providers. All of the 126 completed the study, and each was paid $5 and reimbursed for parking.

**Procedure**

A clinical psychologist conducted a structured interview with each patient that lasted about 1 hour and concerned the patient's health status, medication regimen, relationship with his or her physician, and adherence. A pill count was performed to provide the baseline for a 14-day prospective pill count, and participants completed a questionnaire concerning demographics, perceived health, perceived barriers, health locus of control, and relevant constructs from self-determination theory. Only those pills prescribed by the primary physician for the patient's primary health concern were included in the analyses. At the end of the session, the interviewer asked for permission to make a follow-up telephone contact in approximately 2 weeks to gather some additional information.

Approximately 2 weeks later, the interviewer made the telephone contact and, after inquiring about any changes in medications, asked the participant to do a pill count for each medication. Participants were not aware that this would be asked, and many expressed surprise. After the call, participants were sent a letter that fully explained the purposes of the study.

**Measures**

**Demographics and health status.** Eight items, each measuring a separate variable, were used. Six requested factual information, including age, gender, education, number of medications, number of doses, duration of treatment, and their perceptions of their current health and illness severity.

**Health perceptions and expectancies.** The Perceived Barriers Survey has 46 items about barriers to medication adherence, which were assembled from previously used measures (Glasgow et al., 1986; Schafer, Glasgow, McCaul, & Drehn, 1983). Participants
The Multidimensional Health Locus of Control Scale (Wallston, 1988) consists of 24 items rated on 6-point Likert scales. Eight items per subscale tap three potential perceived loci of control: internal (IHLOC), powerful others (PHLOC), and chance (CHLOC). Subscale scores are the sum of the subscale items. Form C was designed for individuals with existing health conditions. The actual items, along with reliability and validity data, are presented by Wallston (1988, 1991). Alpha reliabilities in this study were .85 (IHLOC), .75 (PHLOC), and .72 (CHLOC).

Self-determination theory. The TSRQ was designed to assess autonomous and controlled reasons (or motivations) for taking medications, adapted from previous self-regulation questionnaires (Ryan & Connell, 1989). A sample item from the autonomous subscale (three items, α = .69) is “Improving my health is something that I am doing by my own choice.” The controlled variable (three items, α = .55) is represented by “I will feel ashamed if I can’t make significant improvement in my health condition.” The autonomous and controlled variables were the sums of relevant items, answered on 6-point Likert scales. Because the TSRQ reliabilities were low, we revised the scale in subsequent studies and obtained subscale α values of .81 and .84, respectively (Williams, Freedman, & Deci, 1996).

The Health Care Climate Questionnaire (HCCQ) assesses patients' perceptions of their physicians' autonomy support. Alpha for the HCCQ was .96; however, because LISREL ideally uses three or four indicators for a latent variable, four HCCQ items were selected as most representative of the construct (α = .82). A sample item is “My doctor listens to how I would like to do things.” The sum of the four items was highly correlated with the full HCCQ (r = .91 p < .001).

The HCCQ and TSRQ have been validated in studies of weight loss (Williams, Grow, et al., 1996), smoking cessation (Williams & Deci, 1996b), and glucose control (Williams, Freedman, et al., 1996).

Adherence. Three self-reported indicators of adherence were used to form a composite measure for regression analyses and a latent variable for LISREL analyses. The first two were taken during the interview. After acknowledging that “people find it difficult to always take their medicine exactly as prescribed,” the interviewer said, “Please think back over the last 2 full days and try to recall which pills you actually took and when. I’m interested in the pills you took exactly as prescribed, ones you took late or early, ones you forgot to take or decided not to take, extra pills you took, and so on. Let’s start with yesterday.” After clarifying any uncertainties for each relevant medication, the number of pills taken as prescribed was divided by the number prescribed. This method is consistent with current standards for pill counts (Stephenson et al., 1993). To obtain the second indicator, the interviewer stated, “I’d like you to estimate for me the percentage of your medication dosages that you take exactly as prescribed; that is not early or late, not forgotten or omitted, but taken in the amount and at the time prescribed. Just give me a number between 0% and 100%.”

To obtain the third indicator of adherence, at the interview a baseline count of the pills in each patient’s pill bottles was done. About 2 weeks later, each patient was telephoned and asked to count the pills in the bottles. The number of pills taken was calculated and divided by the number that should have been taken after adjusting for prescription changes made during the 2 weeks. The α reliability across these three indicators of adherence was .79. Therefore, a composite (self-report/pill count) adherence variable was formed by averaging the three indicators. Logistic regression requires a dichotomous dependent variable, so we dichotomized the adherence composite for those analyses and used it as a continuous variable for others. For the dichotomy, patients whose average composite adherence was 80% or more were considered to be adherent, and the remainder were considered to be nonadherent. The 80% cutoff, although arbitrary, was selected because studies of various illnesses such as hypertension indicate that an 80% adherence rate was sufficient for therapeutic benefit (e.g., Sackett, 1977; Sackett, Haynes, & Tugwell, 1985).

Analyses

Correlations, logistic regressions, and structural equation modeling tested the hypotheses. In the logistic regressions, we entered demographic variables first and then entered psychological variables that had significantly correlated with the composite adherence variable. This analysis is reported because, within the medical literature, it is considered clinically important to perform analyses using a dichotomous variable, selected on the basis of clinical benefit. Further, if the regression analysis determines that no variable in the study accounted for significant independent variance in adherence over and above that explained by autonomous regulation, we would be justified in testing the self-determination model of medication adherence using only variables from the theory.

LISREL VIII was used to test the self-determination model (Jöreskog & Sörbom, 1993). We hypothesized that the effect of the latent variable perceived autonomy support on the latent variable adherence would be mediated by the latent variable autonomous regulation.

In LISREL analyses one begins by assessing the relation between latent variables and their indicators (Anderson & Gerbing, 1988). To make this assessment, we performed confirmatory factor analyses. Then one tests hypotheses about the relations among the latent variables (Jöreskog & Sörbom, 1993). For this, we first tested whether the structural model consisting of three latent variables—autonomous regulation, which was theorized to mediate between perceived autonomy support and adherence—fit the data. Then we tested two alternative models to ascertain whether the relation between perceived autonomy support and adherence would be significant and would decrease when autonomous regulation was added to the model as a mediator (Hoyle & Smith, 1994). If it did, the hypothesized model would fulfill Baron and Kenny's (1986) criteria for mediation.

Maximum likelihood estimation was used to generate the standardized parameter estimates because it is robust in dealing with data that deviate from multinormality (Huba & Harlow, 1987). To determine the fit of the models to the observed data, we used the chi-square statistic (Bollen, 1989), the nonnormed fit index (NNFI; Tucker & Lewis, 1973), and the root-mean-square error of approximation (RMSEA) (Steiger, 1990). A chi-square that is not significant (i.e., p > .05) indicates a good fit because the model does not differ significantly from the data (Bollen, 1989). An NNFI with a value above .90 and close to 1.00 indicates a good fit (Bollen, 1989), an RMSEA of 0.05 to 0.08 indicates a good fit, and an RMSEA of less than 0.05 represents an excellent fit (Browne & Cudeck, 1993).

Results

Preliminary Analyses

The sample varied in terms of primary diagnosis: hypertension (23%), menopausal symptoms (21%), and hyperthy-
roidism (8%); the remainder had one of 28 other diagnoses (e.g., arthritis and seizure disorder), each accounting for fewer than 6% of the patients.

Participants rated themselves as relatively healthy ($M = 4.68$, $SD = 1.14$, on a 6-point scale), and severity of primary health problem was rated as low ($M = 2.42$, $SD = 1.43$). They reported taking an average of 1.36 medications ($SD = 0.76$, range = 1-10), and an average of 1.40 doses of study medications per day ($SD = .69$). The mean duration of treatment of the primary illness was 6.5 years ($SD = 6.9$ years). Table 1 reports the means, standard deviations, and ranges of all variables.

**Correlation and Logistic Regression Analyses**

As shown in Table 2, no demographic or health status variable was significantly related to composite adherence, although severity of illness was marginally negatively related, which is the opposite direction from what would typically be predicted. Further, the health locus of control variables were not significantly related to composite adherence. Perceived barriers was negatively correlated with composite adherence, $r(125) = -.19$, $p < .04$, as predicted by the health belief model. Although this correlation would not be considered significant using the Bonferroni procedure, that procedure is not necessary for relations that were specifically predicted based on theory and past research (Rosenthal & Rosnow, 1991). Further, perceived autonomy support was positively correlated with composite adherence, and autonomous regulation was negatively correlated with composite adherence, all as predicted by self-determination theory. Thus, these variables were all included in the regression analyses.

**LISREL Analyses**

The structural equation model includes three latent variables (Figure 1). We used four items from the HCCQ as indicators of the latent variable perceived autonomy support, whereas the latent variables autonomous regulation and adherence each had three indicators. We performed the confirmatory factor analysis, setting the first construct loading for each latent variable at 1.00. The factor loadings for the measurement model were substantial and significant ($p < .001$). The completely standardized lambda, and lambda, coefficients are shown in Figure 1. The overall measures of fit for the model, $\chi^2(32, N = 126) = 38.9$, $ns$, NNFI = .98, and RMSEA = .04, were all very good. Because the measurement model fit well, the full model was tested.

To represent the self-determination model of adherence, perceived autonomy support was specified to predict autonomous regulation and autonomous regulation to predict medication adherence. Again, the overall fit of the model was good, $\chi^2(33, N = 126) = 40.8$, $ns$, NNFI = .98; RMSEA = .04. LISREL also allows testing of the individual direct and indirect relationships between variables, and perceived autonomy support significantly predicted autonomous regulation directly (parameter estimate = .37, $p < .001$) and adherence indirectly (parameter estimate = .29, $p < .001$). Autonomous regulation directly predicted adherence (parameter estimate = .78, $p < .001$). Thus, the self-determination model of adherence fit the data well.

To test whether autonomous regulation mediates the relation of perceived autonomy support on adherence, two alternative models were specified. The first model involved perceived autonomy support directly predicting adherence, with autonomous regulation left out. Results showed perceived autonomy support to be a significant, direct predictor of adherence (parameter estimate = .21, $p < .05$). The second model specified perceived autonomy support to predict both autonomous regulation and adherence directly and autonomous regulation to predict adherence directly. Results showed that autonomy support did not directly predict adherence in this model (parameter estimate = -.15, $ns$). Thus, the mediational hypothesis was confirmed.
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Discussion

This study tested the prediction that the variables of self-determination theory would relate to self-reported adherence to long-term medication prescriptions. Autonomous regulation of behavior was hypothesized to be a unique psychological predictor of adherence beyond any variance accounted for by demographics, health status, or health expectancies. In fact, autonomous regulation accounted for 68% of the variance in composite (self-report/pill count) adherence in the LISREL model and was the only variable that had a significant partial correlation with adherence in the more conservative and clinically relevant logistic regression model. These results thus indicate that autonomous self-regulation is strongly related to self-reports of adherence and pill counts.

Not only was autonomous regulation shown to be related to adherence, but, perhaps more importantly, perceived autonomy support was found to be associated with adherence, and its effects were mediated through autonomous regulation. Previous research has demonstrated that regulation becomes more autonomous when parents, educators, health care providers, and treatment programs are autonomy supportive (Curry, Wagner, & Grothaus, 1991; Deci et al., 1994; Williams & Deci, 1996b; Williams, Grow, et al., 1996). This is important because of its implications for much-needed interventions to improve adherence (Haynes et al., 1996). It suggests that interventions should focus on supporting patients' autonomy to enhance autonomous regulation, which in turn would be expected to improve adherence. The present study was, of course, cross-sectional, so further research is needed to confirm the causal nature of the relationship, but the LISREL results in this study are encouraging.

Perceived Barriers and Other Variables

We also assessed perceived barriers from the health belief model (Janz & Becker, 1984) and health locus of control (Wallston, 1988), because these measures had been used in previous studies of adherence. Perceived barriers correlated significantly with adherence, thus providing further evidence that it is related to adherence. However, perceived barriers was not significant in the logistic regression model with autonomous regulation, suggesting that autonomy mediates the relation between perceived barriers and adherence. Given that autonomous regulation was negatively correlated with perceived barriers, the results suggest that individuals who are more autonomously self-regulating tend to perceive fewer barriers to adherence. Further, perceived autonomy support was negatively correlated with perceived barriers, suggesting that people who feel autonomy support from their physicians perceive fewer barriers. Again, the cross-sectional nature of this study precludes making causal inference.

Although none of the demographic, health status, or health locus of control variables was significantly correlated with adherence, we would not conclude that the constructs are wholly unrelated to adherence because this is only a
single, cross-sectional study. Nonetheless, the fact that the correlation of autonomous regulation with adherence was so strong, relative to the correlations of demographic, health status, and health locus of control variables with adherence, gives us greater confidence that the autonomous regulation construct may have considerable utility for predicting adherence.

Limitations of the Study

This study has several limitations. We already mentioned that it is cross-sectional. Thus, the results are consistent with, but do not confirm, the hypothesis that autonomy support and autonomous regulation cause participants to take their medications as prescribed. Second, adherence was assessed with three self-reports. There has been considerable debate about the validity of self-reports and pill counts to reflect actual pill-taking behavior (e.g., Rudd et al., 1988; Stephenson et al., 1993), and it is clear that self-reports of both adherence and pill taking are subject to distortion. However, it also seems clear that the reliability and validity of these indicators are greater when the number of daily doses is low (Cramer, Mattson, Prevey, Scheyer, & Ouellette, 1989), the time frame is relatively short (Rudd et al., 1988), there are multiple indicators, and the information is obtained from interviews rather than questionnaires.

In our sample, the average dosage was only 1.4 per day, the pill counts were for relatively short periods (2 days and 14 days), and the three measures of adherence were obtained from two direct contacts, thus increasing the likelihood that the composite adherence measure was reliable and valid. Furthermore, the strong relation between autonomous regulation and adherence, combined with the previously established relations between autonomous regulation and various health behaviors and outcomes, including actual attendance in alcohol rehabilitation and weight loss programs (Ryan et al., 1995; Williams, Grow, et al., 1996), carbon monoxide–validated reports of smoking cessation (Williams & Deci, 1996b), and diabetics' glucose control measured by HbA1c (Williams, Freedman, & Deci, 1996), also increase the likelihood that the composite measure of adherence was reliable and valid.

A third limitation is the sample itself, which was not representative of the general population because of the high educational level and high reported adherence. Thus, generalizing the results requires replication with other samples. Further, the fact that only 68% of eligible patients participated raises the possibility that patients in the sample were the most highly motivated. Although that is nonoptimal, it is unlikely that it inflated the results because, if the range on autonomous regulation were restricted, it would weaken rather than strengthen these results.

Implications and Conclusions

In summary, in accord with self-determination theory, this study provides initial evidence that patients' adherence to long-term prescriptions is strongly associated with autonomous motivation. Further, in this study, as in several previous studies, autonomous motivation was found to relate to perceptions of the physicians' autonomy support. If these findings are replicated, they will suggest that autonomy support should be an important variable to consider in interventions aimed at improving adherence to medical regimens.

More specifically, if, when relating to patients about issues of chronic care and prevention, physicians encourage and support initiative, acknowledge feelings, minimize pressure to behave, offer choice about treatment regimens, and provide meaningful rationales for suggested behaviors, they may be able to facilitate more autonomous motivation in the patients (Deci et al., 1994). Fortunately, research has indicated that medical students can be trained to behave in these autonomy supportive ways (Williams & Deci, 1996a), so it may be time for medical school curricula to begin...
considering this important set of interpersonal skills, which has now been linked to a variety of health care outcomes.

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