OBJECTIVE. Many people with chronic health conditions fail to take their medications as prescribed, resulting in declines in health and function. The purpose of this study was to perform a Phase I feasibility study to understand whether an integrated occupational therapy intervention could help people with chronic health conditions improve their adherence to medications.

METHOD. Using a small-N design, we report single-subject analyses of the medication adherence of 11 participants before and after either an occupational therapy intervention or a standard care intervention. We used a multiple baseline approach with intersubject replication and blinding.

RESULTS. The occupational therapy intervention was found to decrease performance variability and to increase medication adherence rates in some people with chronic conditions.

CONCLUSION. These findings suggest that an occupational therapy intervention can improve medication adherence in people with chronic health conditions. The intervention tested in this study is feasible and would benefit from further research.


Approximately 30%–50% of people on medication do not take their medications as prescribed (Osterberg & Blaschke, 2005). Hundreds of factors affect a person’s ability to take his or her medications as prescribed, including socioeconomic status, transportation, cultural beliefs, medication side effects, comorbid conditions, and so forth (Gadkari & McHorney, 2012; Vlasnik, Aliotta, & DeLor, 2005; World Health Organization, 2003). Few people maliciously fail to take their medications. A survey revealed that nonadherence is most often caused by forgetting, running out of medication, or being careless about the medication dosing schedule (Gadkari & McHorney, 2012). Poor health literacy can also inadvertently cause poor medication adherence (Zhang, Terry, & McHorney, 2014). In one study, almost half of low-income hospital patients were unable to understand the labels on their prescription bottles (Williams et al., 1995). Despite the reason, poor adherence to medications can cause poorer health outcomes, disability, hospitalizations, and higher rates of all-cause mortality (Davis, Edin, & Allen, 2010; Ho et al., 2006). People on medications need assistance in improving their performance on this daily occupation.

Unfortunately, current interventions for medication adherence have poor clinical utility. The Cochrane Review on the topic indicated that the strongest medication adherence interventions were tailored to the client; were delivered by allied health professionals; and included aspects of counseling (e.g., education, motivational interviewing, cognitive–behavioral therapy), daily treatment support, and support from peers or family (Nieuwlaat et al., 2014). Even the best interventions, however, were complex, costly, and not very effective (Nieuwlaat...
et al., 2014). Nieuwlaat et al. (2014) further criticized the literature for the lack of innovation. Few researchers have investigated assistive technology solutions, changes to the environment, or advocacy. New innovative interventions are needed to help people better manage their medications.

Occupational therapy practitioners have a role in helping clients better take their prescribed medications by developing “specific, individualized, concrete plans for integrating medication into daily routines” (Sanders & Van Oss, 2013, p. 97). Although rehabilitation of this instrumental activity of daily living is within the scope of practice for occupational therapy professionals, there is limited evidence guiding occupational therapy intervention in medication adherence (American Occupational Therapy Association, 2014; Leland, Elliott, O’Malley, & Murphy, 2012; Radomski, 2011; Sanders & Van Oss, 2013). Occupational therapy has been shown to improve performance in other daily living activities among people with chronic health conditions (Weaver, 2015; Wolf, Chuh, Floyd, McInnis, & Williams, 2014). In addition, occupational therapy intervention is highly compatible with the theoretical models for improving medication adherence. The Information–Motivation–Behavioral Skills (IMB) Model of Adherence suggests that medication adherence is affected by a person’s motivation, behavioral skills, and knowledge (Fisher, Fisher, Amico, & Harman, 2006). Factors in the IMB Model of Adherence are all responsive to occupational therapy intervention. Given the profession’s skill in treating occupational performance deficits and factors specified in the IMB Model of Adherence, we hypothesized that occupational therapy may be an effective medication management intervention.

Purpose

The purpose of this study was to understand the effectiveness of an occupational therapy intervention to promote medication adherence. Given the limited research in the area of occupational therapy and medication adherence, we began our investigation with a Phase I feasibility study. Feasibility studies are small, budget-constrained investigations that are the first in a line of research. In these studies, researchers investigate whether research ideas are worth pursuing (in larger, more costly investigations; Gitlin, 2013). In feasibility studies, researchers test many components of the research design and the intervention, including limited effectiveness (i.e., does the intervention demonstrate enough promise to warrant future research?; Bowen et al., 2009). This article is one of a series of studies in which the feasibility of an occupational therapy intervention for medication nonadherence is investigated. The specific purpose of this article is to report the feasibility study results of using a new occupational therapy intervention. Specifically, we posed two research questions: (1) Is an occupational therapy intervention for medication adherence feasible? (2) Does an integrated occupational therapy intervention appear to improve medication adherence in people with chronic health conditions? Answers to these questions will inform further work in this area.

Method

To understand the feasibility of an occupational therapy intervention for medication nonadherence, we implemented a small, two-group, experimental, blinded, randomized controlled trial (RCT) with single-subject data analysis. This approach allowed us to explore the methodology and to identify problems in the design of the research. In this study, we used single-subject design methodology to understand the effectiveness of the occupational therapy intervention to promote medication adherence.

Research Design

The research design for this study was created to examine an RCT approach with single-subject methodologies. We used a series of naturally occurring, intersubject, multiple-baseline, AB single-subject designs to understand the effects of the intervention over two phase changes. Single-subject components of this study were designed to meet the standards described by Kratochwill et al. (2010). This mixed research design procedure is depicted in Figure 1.

Participant Selection

We sought to recruit a diverse group of people with chronic health conditions and medication nonadherence. There were six inclusion criteria for this study. Participants (1) were ages 18 yr or older, (2) reported being diagnosed with a chronic health condition by a doctor, (3) lived independently in the community, (4) independently managed their medications, (5) had poor adherence to medications evidenced by a medication adherence screen, and (6) reported using a medication regimen of five or more pills a day. The medication regimen could include prescriptions and off-the-shelf medications recommended by a health care professional. The pills per day requirement helped to meet the needs of single-subject design and to identify people on complicated medication regimens. People with significant cognitive impairment (indicated by a score of 10 or more on the Short Blessed Test) and people unable to travel to the
university for research-related activities were excluded from the study (Katzman et al., 1983).

**Study Staff**

Research assistants conducted intervention and the data-collection procedures. The primary investigator (PI; Jaclyn Schwartz) trained the research assistants and implemented all enrollment and blinding procedures. The PI trained senior occupational therapy students to deliver all sessions using a detailed manual and series of protocols. Each research assistant completed approximately 6 hr of training and demonstrated competence through a series of written and practical-based exams before implementing the interventions with the research participants (Schwartz & Smith, 2015). Additionally, research assistants demonstrated good fidelity to the study protocols and good reliability with fellow research assistants in terms of intervention recommendations (Schwartz & Smith, 2015).

**Instrumentation**

Three types of data were collected. First, participants completed a demographics survey. Participants identified their race, gender, health insurance status, employment status, relationship status, and medical diagnoses. Second, participants completed a series of surveys and semistructured interviews describing their medication regimen and their habits, roles, and routines around medication management. Procedures and results of the survey and interview data are discussed elsewhere (Schwartz, 2015). Third, we taught participants how to monitor their daily medication adherence.
using a calendar. For the duration of the study, participants were asked to identify and record how many medications they consumed at the end of each day. This medication adherence calendar provided the single-subject data for this study.

**Intervention**

Participants were randomized to receive either the occupational therapy intervention or the standard care intervention.

**Treatment Intervention.** The occupational therapy intervention applied was a manualized approach named the Integrative Medication Self-Management (IMedS) intervention (Medication Management Research Project, 2014; Schwartz, 2015). The intended purpose of the IMedS intervention is to help people better take their medications as prescribed. An occupational therapist developed the IMedS intervention on the basis of theory, current practice, and best evidence (Schwartz, 2015). The IMedS intervention is a three-step process in which the interventionist (1) encourages research clients to reflect on past performance of medication management, (2) asks clients to set a medication management goal, and (3) helps clients generate strategies to reach their goal. During the personalized development of the intervention strategy, the interventionist uses skilled communication techniques (i.e., motivational interviewing) to help the client self-generate strategies across six topic areas: (1) altering the activity, (2) advocacy, (3) education, (4) assistive technology, (5) environmental modifications, and (6) securing timely refills. Although some of these approaches are standard in medication adherence interventions (i.e., education), several approaches are relatively novel to the field, particularly in combination (i.e., advocacy, assistive technology, environmental modifications). Interventionists were required to discuss all six types of strategies in some capacity, but the amount of time and specific strategy ideas were left to the interventionists’ clinical reasoning. This resulted in a personalized set of strategies tailored to the participant’s needs.

**Standard Care Intervention.** The standard care intervention was designed to contrast with the occupational therapy intervention and to simulate the standard of care. As with the intervention participants, interventionists told the standard care participants that taking medications as prescribed is important. However, instead of having a conversation about medications, the interventionist and the participant had an educational session that was based on the pamphlet Managing Your Medicines: Our Guide to Effective Medication Management (American Heart Association & American Stroke Association, 2013). During the standard care procedures, the interventionist was allowed to engage in active listening and discussion of the materials found in the pamphlet. The interventionist was prohibited from providing client-centered recommendations or using skilled therapeutic communication approaches. The pamphlet had many of the same intervention strategies recommended in the IMedS intervention, but the delivery of the information lacked the skilled approach used in the treatment intervention.

**Procedures**

The participants had four interactions with the research team: a phone screen, baseline evaluation session, intervention, and follow-up evaluation. Participants were compensated with a $20 gift card at the conclusion of each face-to-face interaction, for a total of $60 for participants completing the study. All procedures were reviewed and approved by the institutional review board at the University of Wisconsin–Milwaukee.

**Recruitment and Phone Screen.** Participants were recruited through paper and electronic flyers posted throughout the community and on email lists for groups serving people with chronic health conditions in early fall 2014. Interested individuals called the research team to participate in a phone screen. Potential participants were asked a series of questions pertaining to the inclusion and exclusion criteria and were screened with the Short Blessed Test and medication adherence screener. People who passed the phone screen were invited to schedule a baseline evaluation appointment.

**Baseline Data Collection.** During the baseline data collection session, each participant reviewed and signed the informed consent, completed the assessment battery, and learned how to complete the medication calendar. The session took approximately 1 hr and occurred either at the participant’s home or in a shared lab space at the university. Because baseline data collection occurred before randomization, both the evaluator and the participant were blind to condition at baseline.

**Randomization.** After the baseline evaluation, participants were adaptively randomized to the intervention or standard care condition. Using the protocol described by Smoak and Lin (2001), we accounted for the participants’ age, gender, and extent of medication nonadherence through the randomization process.

**Intervention.** The intervention was scheduled 2 wk after the baseline evaluation. All interventions occurred in a shared lab space at the university. As randomized, study participants received either the occupational therapy intervention or the standard care educational session. Both the treatment and standard care conditions lasted approximately 30 min. Participants were blinded to their
assignment. Although the interventionists were unable to be blinded, the interventionists’ fidelity to the protocol was monitored via video evaluation.

**Follow-Up Data Collection.** Participants were scheduled for follow-up 1 mo after intervention. Participants met with a new research assistant who was blinded to their treatment condition. During the follow-up visit, the participant turned in his or her medication calendar.

**Data Analysis**

At the conclusion of the study, the researcher collected the medication calendar and calculated the percentage of adherence for each study day. Percentage of adherence was calculated as the ratio of the number of pills actually consumed to the number of pills prescribed for daily consumption. A score of 100% indicated that the client took all of his or her prescribed pills for that day. Scores greater than 100% indicated that the client took more pills than prescribed, and scores less than 100% indicated that the client took fewer pills than prescribed. The research suggests that people on medication must take a minimum of 80%–95% of their medications to benefit from intervention (Osterberg & Blaschke, 2005). The medication calendar provided the researchers with the participant’s daily medication adherence over the course of the approximate 2-wk baseline and 4-wk intervention phase. The participant’s daily percentage of adherence was the dependent variable used for the single-subject analyses.

Single-subject data were analyzed visually and with simulation modeling analysis (SMA). SMA is a statistical approach that is designed for analyzing short streams of single-subject data (Borckardt & Nash, 2014). Briefly, SMA calculates the autocorrelation coefficient between the phase and the observed data. Then the procedure creates 5,000 random-normal data streams with the same autocorrelation coefficient and number of observations. Finally, using the generated data, the procedure calculates an empirical p value. Therefore, SMA answers the question, “How likely is it for a completely random data stream of the same length and same amount of autocorrelation to demonstrate correlation with the phase as large as the observed data?” (Borckardt & Nash, 2014, p. 496).

We visually analyzed the single-subject data using the methods described by Kratochwill et al. (2010) for changes in level, slope, variability, immediacy of the effect, overlap, and consistency of data patterns across similar phases. Although visual analysis is informative, it is also associated with poor reliability and an increase in the Type I error rate (Ottenbacher, 1986). Therefore, we also used SMA to determine the statistical significance of changes to slope and level (Borckardt et al., 2008). We completed the SMA procedure for each participant’s data using the freely available software SMA 9.9.28 for Mac (Clinical Research Solutions, Knoxville, TN).

**Results**

**Participants**

Thirty-four participants were screened for the study. Twenty-three participants were admitted to the study, and 11 participants were rejected because they failed to meet the inclusion criteria. Two people withdrew from the study before the baseline evaluation.

Twenty-one participants received the baseline evaluation and were instructed to keep a medication calendar. After the baseline evaluation, 2 participants dropped out of the study. Eight participants had perfect medication adherence for all 6 wk of the study. These perfect adherers were removed from the single-subject analyses because they did not demonstrate occupational performance deficits in medication management.

Eleven participants with true medication nonadherence completed the study. Seven participants were assigned to the standard care condition, and 4 participants were assigned to the IMedS intervention condition. Eight male participants had been recruited into the study; 2 dropped out and 6 demonstrated perfect medication adherence, resulting in a sample of 100% women for the single-subject portion of the study. The participants had a diverse age range of 23–79 yr, but on average, participants were older with a mean age of 53 yr (standard deviation [SD] = 20). Participants were mostly White and lived alone. All of the participants had health insurance. On average, participants had four chronic health conditions (SD = 2) and took 10 medications a day (SD = 4). Participants in the treatment group were diagnosed with a variety of health conditions, including osteoporosis, arthritis, heart disease, anxiety, depression, HIV, and diabetes. Participants in the standard care group also demonstrated a variety of health conditions, including arthritis, heart disease, anxiety, depression, asthma, diabetes, chronic obstructive pulmonary disease, attention deficit disorder, and conditions related to postcancer. Table 1 identifies participant demographics by group.

Both baseline and intervention phases were incorporated within an approximate 6-wk duration for the study. For the standard care group, the baseline phase lasted an average of 15 days (SD = 10), and the intervention lasted an average of 29 days (SD = 9). For the occupational therapy intervention group, the baseline...
phase lasted an average of 17 days ($SD = 7$), and the intervention lasted an average of 26 days ($SD = 9$).

**Standard Care Effectiveness**

Seven participants received the pamphlet-based education session for medication adherence. Figure 2 demonstrates the single-subject data for each person in the standard care group. Most participants ($n = 6; 86\%$) were not able to significantly improve their medication adherence. SMA revealed that Participant K had a significant change in slope ($r_{\text{slope}} = -0.48, p = .004$) but not level ($r_{\text{level}} = .13, p = .48$). Although Participant K’s percentage of adherence increased, she continued to demonstrate variability in performance. Participant F reported two lapses in medication adherence at baseline and had no lapses in the intervention phase. The change, however, was not statistically significant. The remaining 5 participants demonstrated no improvements in level, trend, and variability after receiving the educational session. The adherence patterns of Participants E, G, and J persisted into the intervention phase, whereas Participants B and H seemed to have worse medication adherence after the educational session.

**Treatment Effectiveness**

Four participants received the IMedS intervention. Figure 3 demonstrates the single-subject data for each person in the occupational therapy intervention group. Half of the participants ($n = 2$) significantly improved their medication adherence at follow-up and maintained improvements for approximately 4 wk. SMA revealed that Participant A had a significant change in slope ($r_{\text{slope}} = .29, p = .05$) and level ($r_{\text{level}} = -0.40, p = .01$). Participant I had a significant change in level ($r_{\text{level}} = .52, p = .01$) alone. Visual analysis of Participants A and I indicated that the IMedS intervention decreased both under- and overdosing of medication (decreasing variability) and was able to stabilize medication adherence at an optimal level. Participant E’s adherence data visually portrayed improvements in trend and level and decreases in variability, but changes did not meet the threshold for statistical significance. Data for Participants A, D, and I indicated that the intervention began to work immediately and that effects persisted for the observed period (about 4 wk). Participant C’s nonadherence persisted at the same frequency and extent even after intervention, indicating that the intervention was not effective for her.

**Discussion**

The purpose of this small feasibility study was twofold. First, we wanted to determine the feasibility of an occupational therapy medication adherence intervention. Second, we sought to identify the effectiveness of the intervention to determine whether it warranted future research. We accomplished both objectives.

**Intervention Outcomes**

Most participants ($n = 3; 75\%$) in the occupational therapy group seemed to benefit from the intervention. Occupational therapy significantly improved the medication adherence of 2 participants, and 1 participant demonstrated improvement (but the extent of change...
failed to meet statistical significance. Participants in the standard care group demonstrated fewer changes. Most participants either continued their pattern of nonadherence \( (n = 3; 43\%) \) or had worse adherence at follow-up \( (n = 2; 29\%) \). Two participants \( (29\%) \) did demonstrate positive change after the educational session, but only 1 participant

Figure 2. Single-subject data for participants receiving the standard care intervention.

Note. The vertical black line indicates the day of the standard care intervention. Participants are grouped by simulation modeling analysis results. Letters at the top of each graph refer to individual participants.
experienced enough change to reach statistical significance. Together, the results suggest that medication adherence can be responsive to occupational therapy intervention, and that occupational therapy may positively affect a higher percentage of participants than standard care. More research is needed to better identify when, how, where, and with whom the intervention is most effective.

The occupational therapy intervention also demonstrated large effect sizes with these participants. For example, Participant A’s medication adherence at baseline ranged from 71% to 171%. After intervention, her adherence stabilized at 100% for the length of the intervention phase. Similar results were found for Participant I. Conversely, in the standard care group, Participant K’s adherence only improved by about 10%, and she continued to demonstrate large performance variability into the intervention phase. These findings suggest that occupational therapy intervention may have a larger effect size and may produce more consistent results than standard care. This is one of the first findings that support occupational therapy as an effective intervention for medication nonadherence. Additional study of this occupational therapy intervention to promote medication adherence seems highly warranted.

Feasibility, Limitations, and Future Directions
The purpose of this study was to understand the feasibility of an occupational therapy intervention for medication nonadherence. This objective has been accomplished; however, the data do not yet support generalization of these techniques to the clinic. In this article, we describe the experiences of a nonrandom sample of 11 people with chronic health conditions. Recruitment resulted in a biased sample of mostly White, female, and older adult participants. Future research is needed to determine the effectiveness of the intervention with a larger and more representative sample. In subsequent research, investigators should invoke new strategies to recruit a more diverse sample, such as using an advisory board or requesting people of diverse backgrounds to review the recruitment materials.

The uneven group sizes and the number of participants who withdrew or were found to be ineligible for the study also pose a limitation. Despite recruiting 23 participants, only 11 participants were appropriate for the
The medication diaries also presented a measurement limitation. To attain the needed single-subject data, we had three options: direct observation, electronic monitoring, and diaries. Direct observation was deemed too labor intensive and invasive for a feasibility study on medication adherence. Electronic monitoring was another option but presented three problems. First, monitoring systems are very expensive. Second, electronic monitoring does not indicate how much medication was actually consumed, just that the container was opened. Third, electronic monitoring requires participants to use special medication containers. This disrupts the participant’s ability to use pillboxes, and assistive technology was a major component of the occupational therapy intervention. Although self-report measures, such as diaries, can be biased by inaccurate participant recall or by social desirability, diaries were the best available option (Ho, Bryson, & Rumsfeld, 2009). Pill counts were conducted at baseline and follow-up to collaborate the diaries. Unfortunately, most participants engaged in behaviors that caused the pill count to be inaccurate, such as using old medication bottles or combining two medication bottles after a refill. A review of the literature, however, indicates that diaries demonstrate moderate-to-high concordance with electronic monitoring (Garber, Nau, Erickson, Aikens, & Lawrence, 2004). In future studies, researchers should investigate more reliable measures of medication adherence, including momentary time sampling or new methods of electronic monitoring.

Despite the limitations, the study methodology included several measures to optimize its integrity. The standard care condition was tested over seven phase changes, and the treatment condition was tested over four phase changes. The immediacy of the change in the data in the treatment group, the lack of change in the standard care group, and the consistency of data patterns across people within groups all consistently corroborate that differences in medication adherence rates were most likely due to the intervention as opposed to some unobserved phenomenon. Moreover, the blinding of the research participants, the randomization of participants to treatment conditions, and the presence of a standard care group served to improve the internal validity of the study.

**Implications for Occupational Therapy Practice**

This study has two implications for occupational therapy practice:

- These finding support the research of Sanders and Van Oss (2013) in indicating that occupational therapy practitioners can play a role on the medication adherence team. Occupational therapy has the potential to improve medication adherence in people with chronic health conditions.
- The IMedS approach is a manualized occupational therapy intervention. This feasibility study reinforces the findings of Blanche, Fogelberg, Diaz, Carlson, and Clark (2011) and supports the effectiveness of manualized occupational therapy interventions.

**Conclusion**

Although occupational therapy practitioners are widely considered experts in occupational performance, the profession has been absent from the research around the occupation of medication management. On the basis of the profession’s expertise and the IMB Model of Adherence, we anticipated that occupational therapy could improve medication nonadherence. Little research, however, supported therapists in this role. In this Phase I feasibility study, we tested the relationship between occupational therapy intervention and the medication adherence rates of people with chronic health conditions. We found that medication adherence can be receptive to occupational therapy intervention and that it is feasible to conduct research in which occupational therapy intervention is tested. Medication management is a critical life skill for people with chronic health conditions, and occupational therapy practitioners have a role on the medication team. In future research, investigators must test occupational therapy interventions, such as the IMedS intervention, to encourage clinical implementation of evidence-based occupational therapy interventions. ▲
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