Telephone Counseling and Home Telehealth Monitoring to Improve Medication Adherence: Results of a Pilot Trial Among Individuals With Multiple Sclerosis

Aaron P. Turner
VA Puget Sound Health Care System, Seattle, Washington, VA MS Center of Excellence West, Seattle, Washington, VA Center of Excellence in Substance Abuse Treatment and Education, Seattle, Washington, and University of Washington

Alicia P. Sloan
VA Puget Sound Health Care System, Seattle, Washington and VA MS Center of Excellence West, Seattle, Washington

Daniel R. Kivlahan
VA Puget Sound Health Care System, Seattle, Washington, VA Center of Excellence in Substance Abuse Treatment and Education, Seattle, Washington, and University of Washington

Jodie K. Haselkorn
VA Puget Sound Health Care System, Seattle, Washington, VA MS Center of Excellence West, Seattle, Washington, and University of Washington

Objective: To evaluate the impact upon medication adherence of brief telephone-based counseling using principles of motivational interviewing and telehealth home monitoring. Design: Randomized controlled pilot trial of 19 veterans with multiple sclerosis (MS) currently prescribed disease modifying therapy (DMT) who endorsed missing doses. Follow-up was conducted at 1, 3, and 6 months. Results: Participants in the intervention condition reported better adherence relative to controls at 6-month follow-up [M (SD) = 1.3 (2.1) vs. 8.2 (12.3) past month missed doses]. All participants in the intervention condition completed all 3 telephone counseling sessions and 90% or greater rated the program as highly successful. Conclusion: Brief telephone counseling represents a promising mechanism for improving medication adherence. The primary components, motivational interviewing and home telehealth monitoring, provided complementary mechanisms for initiating and sustaining behavior change over time. The intervention was well tolerated and provided an opportunity to extend access and reduce barriers to care by bringing it into the homes of participants.

Keywords: multiple sclerosis, medication adherence, motivational interviewing, self-management, telehealth

Impact and Implications
- Preliminary evidence suggests that brief telephone counseling based upon motivational interviewing is an effective means of promoting self-management and health behavior change.
- The flexibility of telephone-based counseling has considerable potential to extend the reach of psychological interventions outside of traditional practice settings.
- There is considerable opportunity to incorporate telephone-based counseling and self-management into both chronic illness management and rehabilitation care.

Introduction
Medication adherence represents a significant challenge to the efficacy and cost-effectiveness of health care. Problems with medication adherence are well documented in many common conditions, including hypertension, chronic obstructive pulmonary disease, depression, and diabetes. Existing literature suggests that typical rates of adherence are often as low as 50% (Haynes,
TELEPHONE COUNSELING TO IMPROVE MEDICATION ADHERENCE IN MS

McKibben, & Kanani, 1997; Haynes, Ackloo, Sahota, McDonald, & Yao, 2008; Haynes, McDonald, & Garg, 2002; R. B. Haynes, McKibben, & Kanani, 1996) significantly impacting the delivery of care as it was originally prescribed. Recognition of this fact has led many authors including the World Health Organization to argue that in coming years, increasing the effectiveness of adherence interventions may have a greater impact on long term health than improvements in specific medical treatments (Haynes et al., 2000; World Health Organization, 2003).

Individuals with multiple sclerosis (MS) face similar challenges to adherence. MS is a chronic degenerative demyelinating disorder of the central nervous system. It is associated with a host of disabling and sometimes unpredictable symptoms that may include sensory, motor, and balance impairment, fatigue, pain, cognitive impairment, and depression (Goodkin, 1992; Noseworthy, Lucchi-netti, Rodriguez, & Weinshenker, 2000; R. Williams et al., 2005). These symptoms often have a considerable impact upon quality of life (Aronson, 1997; Gottberg et al., 2006; Rao, Leo, Bernardin, & Unverzagt, 1991). Several medications effectively reduce acute exacerbation and disability associated with MS. Despite the wide availability of these disease modifying therapies (DMT), close to one half of individuals who begin an appropriate course of DMT discontinue use at some time (Fraser, Hadjimichael, & Vollmer, 2003; Hadjimichael & Vollmer, 1999) and less than two thirds remain on medication without a prescription lapse (Tremlett & Oger, 2003). Most recently, in a study of over 2,600 individuals with MS in 22 countries, participants reported adherence rates in the past month of 75% (Devonshire et al., 2011). Evidence suggests that psychosocial factors such as health beliefs, emotions, social support, and self-efficacy figure prominently in the initiation and maintenance of this important health behavior (Mohr, Boud-ewyn, Likosky, Levine, & Goodkin, 2001; Mohr, Cox, & Merluzzi, 2005; Mohr et al., 1997; Mohr et al., 1996; Siegel, Turner, & Haselkorn, 2008; Turner, Kivlahan, Sloan, & Haselkorn, 2007; Turner, Williams, Sloan, & Haselkorn, 2009).

There is increasing recognition that chronic illness management should be viewed as a collaborative process and that coordinated approaches to problems such as medication adherence improve outcomes (Bodenheimer, Wagner, & Grumbach, 2002a, 2002b; Clark & Gong, 2000; Wagner, 2000; Wagner, Austin, & Von Korff, 1996). Individuals with MS and their providers must work together to define problems, engage in solutions, and monitor and respond to changes in physical and mental health (Von Korff, Gruman, Schaefer, Curry, & Wagner, 1997). These illness management skills require self-direction, motivation, and self-efficacy, but also can be learned over time. Interventions should provide a variety of self-management training strategies, and management should include sustained follow-up (Clark & Gong, 2000; Von Korff et al., 1997). Although providers play an essential role in the recommendation to initiate therapies, ultimately the success of self-management strategies such as medication adherence will depend upon the actions of persons with the disease and the ability of health care providers to support and sustain their behavior change.

One form of intervention that is particularly promising for facilitating chronic illness care and promoting self-management behaviors such as medication adherence is motivational interviewing. Motivational interviewing is a “person-centered form of guiding to elicit and strengthen motivation for change.”(Miller & Rollnick, 2009) Motivational interviewing encourages behavior change by contrasting current behavior (such as poor medication adherence) to desired goals and values (such as good self care, health, and quality of life), while simultaneously providing empathy and promoting self-efficacy in a manner that is supportive, evocative, and collaborative (Miller & Rollnick, 2002). It is informed by the transtheoretical model that recognizes individuals are often ambivalent about changing behavior, and may be in different stages of willingness to do so (Prochaska & DiClemente, 1983). As a result, the content of counseling is titrated to a person’s readiness to change and implemented with the goal of minimizing resistance and maximizing engagement. Motivational interviewing is often used in conjunction with other self-management behavioral strategies, such as targeted goal setting and problem solving and has been shown to improve medication adherence in a variety of contexts including treatment for asthma (Halterman et al., 2011), hypertension (Ogedegbe et al., 2008), alcohol dependence (Heffner et al., 2010; Reid, Teesson, Sanni-bale, Matsuda, & Haber, 2005), and HIV (Dilorio et al., 2008; Ingersoll et al., 2011), though in most cases evidence has been preliminary.

Motivational interviewing and self-management support are well suited to delivery by telephone and home telehealth monitoring. Interventions using these modalities are consistently well tolerated, effective across a variety of chronic illnesses (Bell et al., 2003; Bell et al., 2005; Bombardier et al., 2009; Bombardier et al., 2008; Bombardier et al., 2013; Dellifraire & Dansky, 2008; Pare, Jaana, & Sicotte, 2007; Pare, Moqadem, Pineau, & St-Hilaire, 2010), and provide important opportunities to deliver care to those who may not otherwise receive it (Hatzakis, Haselkorn, Williams, Turner, & Nichol, 2003). Several studies have used telephone-based motivational interviewing as an adjunct to in-person sessions to improve medication adherence in asthma (Halterman et al., 2011) and HIV (Dilorio et al., 2008).

Only one educational program to date has used telephone-based intervention to improve medication adherence among individuals with MS (Stockl et al., 2010). It did not specifically target adherence, but rather provided monthly calls, provided by nurses and pharmacists, on 12 MS-related topics, one of which was adherence. The program included goal setting but was also largely didactic in nature.

The purpose of the current study was to investigate the feasibility and efficacy of a brief intervention combining telephone counseling based upon principles of motivational interviewing and home telehealth monitoring to improve adherence to DMT for people with MS. The intent was to create a counseling-based intervention that was brief in duration, focused on a specific goal, and flexible so that it could be adapted to the differing needs of participants. If successful, it could stand alone or serve as a component of a larger self-management intervention.

Methods

Design

This study is a randomized controlled pilot trial of a brief intervention combining telephone counseling and home telehealth monitoring to improve adherence to MS disease modifying therapies (DMT). The primary outcome, adherence, was examined at
baseline prior to randomization, and then at 1, 3, and 6 months (following the telephone counseling but during ongoing home telehealth monitoring). Participants received either the telephone-based counseling intervention or care as usual.

Participants

Participants were recruited from veterans receiving outpatient services for MS at a VA regional medical center as part of a larger project examining DMT adherence in MS. Inclusion criteria for the original study included a diagnosis of MS, current use of one of four injectable DMTs to slow disease progression available at the time of the intervention (interferon beta-1a [Avonex], interferon beta-1a [Rebif], interferon beta-1b [Betaseron], or glatiramer acetate [Copaxone]), and active participation in medication administration. Individuals who received their injections primarily from an injection clinic nurse or a caregiver were excluded. The study consisted of two parts. Participants of the original study were first enrolled into a longitudinal cohort by a coordinator during a regularly scheduled clinic visit, or in response to a mailing. Medication adherence of individuals participating in the original study was obtained during monthly follow-up assessments for a period of 6 months. Individuals who endorsed difficulties with adherence (missed doses during the study period) were invited to participate in the intervention trial after the completion of this 6-month period.

Of 89 original participants, 36 individuals were alive, still taking DMT medication, and reported missing doses during the original study. Of the 36, 19 (52.8%) enrolled in the brief intervention trial. Among those who did not enroll, five (13.9%) declined and 11 (30.6%) were not available or did not respond to enrollment queries within the recruitment time frame. One individual consented, but then moved out of state prior to completion of baseline (please see Figure 1). All 19 individuals who were enrolled in the trial completed the entire study; no individuals dropped out or were lost to follow-up. All 19 individuals were active users of DMTs during the entire study period. No individual switched to a different DMT during the study period.

Procedure

As part of the original study, potential participants’ medical records were prescreened to confirm that they were currently taking a DMT. Additional screening was conducted to verify that the individual was primarily responsible for administering his or
her own DMT, and that there was a telephone number where the person could be reached.

For this study, individuals were approached by the study coordinator and asked if they would be willing to participate in a study examining a brief telephone-based intervention to improve adherence. Participants were required to meet criteria for Veterans Health Administration (VHA) home telehealth programs and be willing to agree to the installation of a brief telehealth home monitor in their primary residence.

Participants completed a telephone interview that included questionnaires addressing adherence behavior over the past month including DMT missed doses, adherence self-efficacy, and side effects and reasons for missed doses. Baseline demographic information (e.g., age, gender, education) and disease information (e.g., years with MS, mobility disability, fatigue, depression, cognitive functioning) were obtained from information obtained in the original study.

Following completion of baseline, individuals were individually randomized via computer algorithm to the intervention or the control condition. Prior to assignment, treatment condition was unknown to the project coordinator to ensure concealment of allocation.

Individuals assigned to the treatment condition participated in a combination of brief telephone counseling and home telehealth monitoring to promote improved DMT adherence. The telephone sessions were scheduled at a time and place of the participant’s choosing (usually the veteran’s home and at various times of the day and evening). Individuals assigned to the control condition received treatment as usual and were offered telephone counseling and monitoring only after the completion of the final follow-up time point (waitlist control). All participants completed follow-up telephone interviews at Months 1, 3, and 6. Treatment condition was concealed from the telephone interviewer for all outcome measures.

The original sample was good (α = .90). Depression was measured using the nine-item depression module from the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a brief screening instrument designed to identify depressive symptoms consistent with criteria of the Diagnostic and Statistical Manual for Mental Disorders, 4th ed. (American Psychiatric Association, 1994). Participants rate the degree to which they experienced each of 9 symptoms of depression over the last 2 weeks from 0 (not at all) to 3 (nearly every day). The PHQ-9 has shown utility in estimating the level of depressive severity in medical patients using the sum of scores on each of the 9 items (Spitzer, Kroenke, & Williams, 1999). Internal consistency in the current sample was good (α = .88).

Cognitive functioning was measured using a series of brief screening measures administered during the telephone interview. Verbal memory was examined using the short delay recall task from the Screening Examination for Cognitive Impairment (Beatty et al., 1995). Attention was examined using the digit span task from the Wechsler Adult Intelligence Scale–III (Wechsler, 1997). Verbal fluency/executive functioning was examined using the Controlled Oral Word Association Task (FAS version; Strauss, Sherman, & Spreen, 2006). All three measures have been used extensively and have well established psychometric properties (Beatty et al., 1995; Strauss et al., 2006; Wechsler, 1997). The use of telephone-based cognitive assessment has been used in multiple trials of psychotherapy interventions in individuals with MS (Mohr, Hart et al., 2005) and telephone administration of functionally similar measures have been shown to be valid and reliable in other samples (Debane et al., 1997; Unverzagt et al., 2007).

Medication Information

Adherence to DMT medications was assessed with a single self-report question adapted from HIV adherence literature.(Stone, 2001) Participants were asked, “People often have difficulty taking their medications for one reason or another. How many times have you missed taking your DMT in the past month?”. DMT medications are taken at different frequencies ranging from once per week (interferon beta-1a [Avonex]) to once per day (glatiramer acetate). As a result, it was necessary to create a common metric for missed doses across medications. Standard weightings corresponding to a 30-day month were computed for each medication. A missed dose of once per week interferon beta-1a (Avonex) was given a weight of 7.5 such that total nonadherence (4 doses) × 7.5 = 30. A missed dose of daily glatiramer acetate was given a weight of 1 such that
total nonadherence (30 doses) \( \times 1 = 30 \) as well. Self-report of adherence to DMT has been shown to be very highly correlated with multiple measurement modalities including medication diaries and Medication Event Monitoring System data (Bruce, Hancock, & Lynch, 2010). This specific missed dose measure is highly correlated with other self-reported indicators of adherence and the cross-medication missed dose common metric has been used in previous literature on adherence to DMT in MS (Siegel et al., 2008; Turner et al., 2007; Turner et al., 2009).

Current DMT type was extracted from participants’ medical records. Because of limited sample size, DMT type was dichotomized for analyses to reflect the use of an interferon based medication (interferon beta-1a [Avonex], interferon beta-1a [Rebif], interferon beta-1b [Betaseron]), or glatiramer acetate (Copaxone).

Length of time on current DMT medication was obtained from a single item query in the interview. Side effects of current DMT medication were measured using a six-item scale created for this study. Item selection was based upon published information regarding frequent side effects of DMT medications and included items such as “injection pain, red spot or rash at injection site,” “flu-like symptoms (increased fatigue, fever, chills, sweating, muscle aches),” and “shortness of breath, strong heartbeat, chest pain, flushing.” Participants were asked to rate the frequency of occurrence of side effects with response options ranging from 1 (never) to 5 (always).

Adherence self-efficacy was measured using a single-uuid item adapted from previous research on medication adherence in MS (Mohr et al., 2001; Mohr, Cox, Epstein, & Boudewyn, 2002). The item asks participants “How confident are you that you will be taking your prescribed DMT one month from now?” with response options ranging from 1 (not at all) to 5 (extremely).

Treatment acceptability was measured using the four credibility items adapted from the Reaction to Treatment Questionnaire (Holt & Heimberg, 1990). The items ask participants to rate confidence the program would help with adherence, the success of the program, confidence in recommending the program to a friend, and how logical the program was using a Likert-type scale ranging from 1 to 10. For purposes of this study, responses were dichotomized and scores of 7 out of 10 or higher were considered positive (confident, successful, recommended, logical).

**Intervention**

The treatment intervention consisted of two primary components: telephone counseling and home-based telehealth monitoring. Telephone counseling was based upon principles of motivational interviewing and was intended to increase motivation and confidence in medication adherence. Telehealth monitoring was based upon principles of self-management and intended to support sustained medication adherence over time.

**Telephone Counseling**

Telephone counseling consisted of three sessions. Session 1 included the following components: (a) a discussion with the participant about his or her experiences coping with the challenges of MS, as well as hopes for life with the illness over time; (b) identification of participants’ perceptions of the pros and cons for DMT use; (c) personalized graphic feedback summarizing the scientific evidence supporting the benefits of the specific medication taken by each participant (delayed progression of disability, reduced proliferation of MRI lesions, sustained cognitive ability) and individual performance on a brief cognitive screening battery; and (d) a review of each participants’ recent missed doses and medication adherence. The overall purpose of the early session components was to facilitate readiness to change by increasing the salience of adherence benefits and developing discrepancies between actual behavior (missed doses) and desired behavior (effective self-care that promoted health and well being with chronic illness). At the end of Session 1, when appropriate, participants created a change plan that identified desired improvements in medication adherence, personal reasons to reduce missed doses, specific steps to make these changes, and ways to elicit support and reduce barriers. The purpose of this final exercise was to elicit and articulate commitment to medication adherence as well as begin the process of problem solving sustained adherence.

Session 2 consisted primarily of skills training. The counselor and participants reviewed strategies for reducing medication side effects, rotating injections, interacting with providers and pharmacies, and creating a sustainable medication schedule. Participants were asked to identify personal high-risk situations that increased the likelihood of a missed dose, engage in a behavioral chain analysis of a recent missed dose, and problem solving coping strategies to intervene at various points along the path of the circumstances leading to a missed dose. Session 2 also included an orientation to the telehealth home monitor, including set-up and introduction to functions.

Session 3 was a booster session. The counselor engaged in problem solving around missed doses, adherence skills, additional motivational interviewing, and trouble-shooting difficulties with home telehealth monitors depending upon the needs of individual participants. Each of the three sessions ranged from 45 to 75 min in length.

**Telehealth Home Monitoring**

Between telephone counseling Sessions 2 and 3, each participant received a home monitoring unit that connected to ordinary telephone lines that could deliver customized text messages using store and forward technology. Monitors were programmed to participants’ individual medication administration schedules and provided reminder alarms if desired. Participants were asked after every programmed dose interval, “Did you take your DMT dose as prescribed?” Individuals who answered yes received encouraging statements. Individuals who answered no received a follow up question examining why the dose was missed. All responses were transmitted to the project coordinator who viewed responses via a web-based graphical interface that was color coded to allow quick daily review of all study participants (green = adherent, red = not adherent, blue = did not respond when expected to do so). Individuals who were nonadherent, or did not respond to the question when expected to do so, received a follow-up telephone call for additional counseling and problem solving as necessary. This process allowed for flexible follow-up of participants that could be titrated to their specific needs.
Intervention Training and Treatment Fidelity

Treatment fidelity is the extent to which an intervention is delivered as intended. The study therapist (Alicia P. Sloan) received training from the study principal investigator who has significant experience with motivational interviewing. The therapist also participated in an additional multiday training in motivational interviewing conducted by an independent motivational interviewing trainer. Prior to study initiation, the study therapist participated in experiential and role play exercises as well as case-consultation exercises utilizing core MI skills, and also completed training cases. All telephone counseling sessions were audio taped. Immediately following each session, the study therapist completed a fidelity checklist of behaviors consistent with the spirit of motivational interviewing (e.g., open ended questions, affirmation, reflection, summary) and inconsistent with motivational interviewing (e.g., closed questions, arguing, giving advice without permission). Overall ratings of counselor style were obtained in the areas of warmth, understanding, and egalitarianism, as was an overall rating of participant resistance. During the course of the study, the study therapist participated in supervision with the principal investigator in which recorded intervention sessions were reviewed in detail, including a focus on the behavioral and style ratings previously mentioned. Supervision meetings were held weekly and tapered to biweekly over the course of the study.

Data Analytic Strategy

Our primary aim was to test the hypothesis that participation in a brief telephone-based intervention in combination with home telehealth-monitoring would improve adherence to DMT compared to a treatment as usual control group. We first examined the adequacy of randomization by comparing baseline differences in demographic, disease, and medication-related variables. Means and frequencies for continuous and categorical variables were compared using t tests and chi-square tests, respectively. To test our primary aim, we conducted three separate analysis of covariance (ANCOVA) analyses (one for each of our three follow-up time points). We compared differences in adherence to DMT in the control and intervention conditions at each time point adjusting for baseline adherence. This particular strategy was selected because of its favorable ability to detect group differences (Vickers, 2001). All participants completed the entire study and completed all assessment time points (except one participant at Month 3). For this reason, individuals were considered “analyzed as randomized” and results were considered based upon an intent-to-treat sample. No additional completers subanalyses were conducted (in a follow-up analysis, imputing the one missing data element by carrying the last observation forward did not alter the overall significance of the results).

Results

Sample Characteristics at Baseline

Participants were largely male (84.2%), Caucasian (84.2%), and married (57.9%), with a mean age of 52.4 (SD = 7.4) years and a mean education level of 15.0 (SD = 2.2) years. Overall, the sample population was highly representative of the larger population of VHA veterans with MS (Vollmer, Hadjimichael, Preiningerova, Ni, & Buenconsejo, 2002).

Participants reported they had been diagnosed with MS for a mean of 14.1 (SD = 10.2) years and reported moderate levels of MS disease severity for Performance Scale Mobility Subscale, M (SD) = 3.0 (1.8) and Performance Scale Hand Function Subscale, M (SD) = 1.7 (1.5). They reported taking their current DMT medication for a mean of 2.6 (SD = 2.7) years. All four injectable medications available at the time of the study were represented in the sample with 15.8% taking interferon beta-1a (Avonex), 10.5% taking interferon beta-1a (Rebif), 31.6% taking interferon beta-1b (Betaseron), and 42.1% taking glatiramer acetate (Copaxone). No participant changed DMT during the study period.

Adequacy of Randomization

Twelve individuals were assigned to the intervention condition and 7 individuals to the control condition. To examine randomization adequacy we compared the intervention and control conditions at baseline on demographics, disease-related variables, and medication-related variables. There were no significant differences between groups for any of these variables (see Tables 1 and 2).

Intervention Integrity

All participants in the intervention condition received mailed graphic feedback and participated in all three telephone counseling sessions. All participants were successful in enrolling in VA telehealth, installing telehealth monitors in their homes, and making use of the home telemonitoring question set. In addition to the prescribed telephone counseling sessions, during the study period, the study therapist provided an average of 11.2 additional telephone follow-up attempts resulting in an average of 4.0 support telephone calls for each participant (range 1 to 9) over 6 months. The average call duration was 9.3 min (range 2 to 60) and the average total time in calls per participant was 44.2 min (range 5 to 125). The primary reason for calls was to follow-up about missing data when telehealth monitors did not transmit data accurately within the expected timeframe.

Primary Outcome: Medication Adherence

Following the brief telephone-based counseling, and during ongoing telehealth home monitoring, participants in the intervention condition reported missing fewer doses of DMT in the prior month compared to the control group at all time points including 1-month follow-up, M (SD) = 3.9 (8.4) versus 7.3 (11.5); 3-month follow-up, M (SD) = 0.8 (1.0) versus 5.7 (12.0); and 6-month follow-up, M (SD) = 1.3 (2.1) versus 8.2 (12.1) (see Figure 2). These differences corresponded to moderate effect sizes for follow-up at 1 month (d = .4), and large effect sizes for 3 months (d = .7) and 6 months (d = .9). Using ANCOVA to examine differences in adherence by treatment condition adjusting for baseline adherence, the effect of treatment condition was not significant at 1 month, F(1, 16) = .67, p < .40; approached significance at 3 months, F(1, 15) = 1.77, p < .20; and was significant at 6 months, F(1, 16) = 4.79, p < .05. Overall, differences between the intervention and control arms were consistent and large, but significance was limited in part by small baseline differences favoring
the intervention condition, $M (SD) = 5.2 (8.9)$ versus $M (SD) = 6.9 (11.8)$, and more notably by the study’s small sample size. Differences between the intervention and control condition increased over time (see Figure 2).

Secondary Outcome: Adherence Self-Efficacy

Adherence self-efficacy improved in the intervention condition relative to the control condition. However, using ANCOVA controlling for baseline values, these results only approached statistical significance, for example, at 6-month follow-up, $M (SD) = 5.00 (0.01)$ versus $4.29 (1.50)$, $F(1, 16) = 2.87$, $p = .10$.

Treatment Acceptability

On the reaction to treatment questionnaire, 91.6% of participants viewed the intervention as logical and 91.6% stated that they were confident the program would help them maintain improved adherence. One hundred percent of participants rated the program as highly successful and 100% said they would recommend the program to a friend.

Satisfaction With Home Telehealth Monitoring Data

Overall, home telehealth monitoring was well tolerated: 83.3% of participants were “quite a bit” or “extremely” satisfied with home telehealth monitoring, 100% “agreed” or “strongly agreed” that the monitor was useful as a medication reminder, and 91.6% “agreed” or “strongly agreed” the monitor was easy to use.
Discussion

Results of this pilot trial provide preliminary evidence that brief telephone counseling combined with telehealth home monitoring improves adherence to DMT among individuals with MS. By 6-month follow-up, individuals in the intervention group had improved their past month adherence by an average of 6.9 standardized doses. Individuals participating in counseling and monitoring were essentially adherent with their medication one week per month more than individuals in the treatment as usual control condition. Two-thirds of intervention condition participants reported missing one dose or less.

Findings from this study confirm the feasibility and acceptability of telephone-based motivational interviewing to encourage health promotion, and specifically demonstrate its value in supporting medication adherence among individuals identifying improved adherence as a goal. This is consistent with much if not all of the limited available literature (Cook, Emiliozzi, & McCabe, 2007; Cook, Emiliozzi, Waters, & El Hajj, 2008; Cook, McCabe, Emiliozzi, & Pointer, 2009; Diiorio et al., 2008; Halterman et al., 2011; Solomon et al., 2012; A. Williams, Manias, Walker, & Gorelik, 2012) and is promising for a number of reasons. First, there is increasing evidence that sustained adherence to DMT is a threat to feasibility appeared to be that home monitors would use. All study participants completed all three telephone counsel- recommendations were essentially adherent with their medication one week per month more than individuals in the treatment as usual control condition. Two-thirds of intervention condition participants reported missing one dose or less.

Findings from this study confirm the feasibility and acceptability of telephone-based motivational interviewing to encourage health promotion, and specifically demonstrate its value in supporting medication adherence among individuals identifying improved adherence as a goal. This is consistent with much if not all of the limited available literature (Cook, Emiliozzi, & McCabe, 2007; Cook, Emiliozzi, Waters, & El Hajj, 2008; Cook, McCabe, Emiliozzi, & Pointer, 2009; Diiorio et al., 2008; Halterman et al., 2011; Solomon et al., 2012; A. Williams, Manias, Walker, & Gorelik, 2012) and is promising for a number of reasons. First, there is increasing evidence that sustained adherence to DMT is associated with better health outcomes for individuals with MS including reduced relapses and fewer hospitalizations (Steinberg, Faris, Chang, Chan, & Tankersley, 2010; Tan, Cai, Agarwal, Stephenson, & Kamat, 2011), suggesting a favorable cost/benefit ratio for a psychosocial intervention that typically involved three provider encounters and an average of 44 min of follow-up over 6 months. Second, telephone administration of the counseling intervention improves access to care by reducing the need for appointments, travel, and physical space within a medical facility. This is consistent with the philosophy of rehabilitation to match treatment with the abilities and limitations of the person served and the vision of the VHA to make the home and local community into the preferred place of care whenever possible and practicable (Department of Veterans Affairs, 2013).

It is not uncommon for the effects of treatment interventions such as motivational interviewing to decrease over time. The maintenance of gains over time in this study well past the period of initial counseling in the first month suggest that telehealth home monitoring provided additional value to participants and supported the ongoing practice of self-management to sustain behavior change. Home monitoring, when appropriately implemented (i.e., goals are specific, measurable, achievable, and timely follow-up is available) is also extremely promising as it allows for flexible care that can be scaled up or down to the needs of a specific individual. It also allowed for the efficient delivery of care, as individuals who were doing well continued to receive close monitoring without unneeded additional visits. On the other hand, individuals who experienced an adherence lapse could be identified quickly for additional support.

Overall, the intervention was both well accepted and feasible with all participants considering it to be successful and willing to recommend it to a friend. Over 80% were satisfied with the home telehealth monitors and over 90% found them useful and easy to use. All study participants completed all three telephone counseling sessions and successfully used home monitoring. The primary threat to feasibility appeared to be that home monitors would occasionally malfunction and that each successful telephone contact required approximately three attempts, even when the study therapist had invested considerable energy establishing the best times to contact participants.

This study has several limitations worthy of mention. Most immediate is the small sample size, which detracts from the ability of randomization to provide equal allocation of known and unknown influences upon the primary outcome, to all study conditions. Compounding this, small sample size also increases the likelihood, as seen in this trial, that pure randomization will lead to unequal allocation of participants to conditions. I had randomization to the intervention condition). This phenomenon also increases the likelihood of unequal allocation of variables that may influence our adherence outcome and places additional burden on the examination of baseline differences in treatment groups. Also, our sample was limited to veterans with MS, who are typically older, male, and more disabled (Vollmer et al., 2002). The adherence variable used in this study was based upon self-report, which may be subject to bias because of social desirability or errors in recall, although as previously noted self-report of DMT adherence is highly correlated with other adherence measurement modalities (Bruce, Hancock et al., 2010), and there is no reason to suspect differential bias in the report of adherence between our randomized treatment arms given that follow-up assessment was independent of the intervention staff and blinded to condition. There was a small baseline difference in adherence favoring the intervention condition (d < .2), though baseline values were controlled in our ANCOVA model. It is also possible that limited sample size masked important pretreatment demographic differences between treatment arms, though the majority of current literature has typically failed to find consistent associations between demographic variables and DMT adherence (Turner et al., 2007) and medication adherence more generally (Haynes et al., 2002). In instances in our study where there was a difference (though still small and still nonsignificant) between conditions that has been shown in prior studies to be related to adherence (such as depression and verbal recall) (Bruce, Bruce, Hancock, & Lynch, 2010) differences favored the control condition. Although the difference, again, was not significant, there was also a higher proportion of individuals on medications taken less frequently in the intervention condition. To alleviate the concern the behavior of taking medication weekly versus taking medication daily was qualitatively different and may have differed in the treatment arms, we created a “possible dose” variable based on the specific medication of each participant. There was no significant difference between the conditions in the number of doses that could potentially be missed. Since the completion of this study, new oral disease-modifying therapies that do not require injection have been introduced to market and several others are in development. It is not clear that results of this study will translate to these noninjectable medications, although in the largest available survey, the two most common reasons for missing doses—forgetting’ and being ‘tired of taking a medication—are likely universal (Devonshire et al., 2011).

This study also has considerable strengths worth briefly reviewing. It is a randomized, controlled pilot trial. Threats to validity were minimized by concealment of treatment allocation and blinding of outcome assessment. There was no attrition in either study arm and all participants received the full prescribed intervention.
(three counseling sessions and participation in home telemonitoring). Results were analyzed as randomized and can be considered to be based upon an intent-to-treat sample. Treatment fidelity was monitored throughout the course of the study. The 6-month study duration provided adequate time to examine short-term intervention efficacy. Stakeholder (participant) feedback was elicited and was overwhelmingly positive.

The next logical step would be to establish the efficacy of this intervention in a larger definitive trial that would provide better power and could establish more definitively the generalizability of our findings as well as better alleviate concerns of baseline differences in treatment conditions inherent in small trials. Such a study would include newer classes of oral DMT medications and would allow for examination of individual and medication-related factors that may moderate treatment outcome. Future studies would also benefit from more extensive evaluation of the fidelity of the intervention by an outside rater and the ability to examine individual components of treatment (e.g., counseling vs. counseling with additional monitoring).

References


of Systematic Reviews, (2). CD000011. doi:10.1002/14651858.CD000011.pub3


