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The Association Between Medication Usage and Dropout Status Among Participants of an Exercise Study for People With Osteoarthritis

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Background and Purpose. Little is known about predictors of dropout status in exercise studies for people with osteoarthritis. Losses to follow-up can pose serious threats to study validity. The purpose of this study was to assess the ability of arthritis medication usage the month prior to enrollment to predict dropout status among participants in an exercise study for people with osteoarthritis. Subjects and Methods. Men and women who participated in an exercise study for people with osteoarthritis (N=143) were followed. Participants who completed 24+ months of the exercise program were considered retained, whereas individuals who withdrew prior to 24 months were considered dropouts. Results. Of the 143 participants analyzed, 78 (55%) completed 24+ months of the exercise program and 65 (45%) dropped out. Among those who reported arthritis medication usage, 54% were lost to follow-up. The group reporting no usage of arthritis medication had a 20% dropout rate (odds ratio=3.5, 95% confidence interval=1.6–7.6). The final adjusted model controlling for baseline health status, body mass index, and the interaction between baseline health status and body mass index indicated that those individuals who reported arthritis medication usage were more than 4 times more likely to drop out than were those who reported no arthritis medication usage (odds ratio=4.5, 95% confidence interval=1.8–11.4). Discussion and Conclusion. The results showed that self-reported arthritis medication usage the month prior to study enrollment was associated with subsequent dropout status among this group of exercisers with osteoarthritis. Further identification of baseline characteristics predictive of participant dropout status may benefit future exercise studies. A priori knowledge of "at-risk" exercise study participants will afford the opportunity for the timely allocation of appropriate resources aimed at reducing losses to follow-up. [Wilder FV, Barrett JP Jr. The association between medication usage and dropout status among participants of an exercise study for people with osteoarthritis. *Phys Ther.* 2005;85:142–149.]

Key Words: *Dropout, Exercise, Methodology, Osteoarthritis, Retention.*

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xercise is heralded as an effective prevention technique for numerous health conditions, including arthritis.[1,2] We are currently investigating the influence of exercise among a group of men and women (mean age=72 years, SD=7) with radiologically confirmed osteoarthritis (OA). Increasingly, health care providers are recommending exercise for people with OA. Given that exercise requires a long-term commitment, commensurately long-term, prospective studies examining the effects of exercise among people with OA are warranted. Because substantial resources are required to conduct such investigations, every effort should be made to safeguard the validity of the findings. Following a group of elderly subjects presents unique challenges to investigators, specifically, participant attrition, which may affect the validity of the data. This information is useful for a priori power calculations. If an investigator assumes that a percentage of a group will drop out (eg, 15%), he or she can increase the projected sample size, thus maintaining a given level of statistical power. Selective attrition can yield decreased heterogeneity and impose a restricted generalizability of study findings. To avoid these problems, identification of the factors that increase the likelihood of participant dropout is vital.[3] A priori knowledge of participants' characteristics that increase the risk of dropout, we believe, will enable the timely allocation of appropriate resources aimed at enhancing retention.

Dropout predictors have received well-deserved attention among exercisers participating in cardiac rehabilitation programs,[4–6] as well as in the mental health arena.[7] These studies have evaluated characteristics such as family and lifestyle factors, perception of program participation, and convenience of program participation (eg, time of day participants are scheduled to exercise). Research indicates that exercise dropouts have lower levels of education, more baseline health problems, and lower baseline self-ratings of health.[8] There is a dearth of published information characterizing factors predictive of study dropout among older people in arthritis exercise programs.[3] PubMed, developed at the National Library of Medicine, is a text-based search system for most databases of medical literature, including MEDLINE.[9] A search of PubMed for publications addressing determinants of dropout status among participants in an arthritis exercise program produced no results. The following text string was searched: arthritis AND (dropout OR attrition OR retention) AND (exercise OR physical activity OR run* OR iso* OR train*). Asterisks are used to truncate search terms to account for variations in the term (eg, train, training).

Although similar methodological studies have been conducted in other groups, a 2000 study noted a need for additional studies to broaden our understanding of dropout predictors in older subjects.[3] Our study group had baseline ages that varied from 49 to 90 years, presenting an opportunity to further examine an older group of individuals. Additionally, the length of follow-up time for our exercise study affords the ability to identify dropout characteristics for a time period that corresponds with longer-term studies that are needed to further investigate the relationship between exercise and older people with OA.

We suggest that a priori knowledge of participants' baseline information in 3 categories will assist in the design of enhanced retention strategies. These information categories are: (1) demographics (2) clinical features, and (3) the complexity of medical regimen and the severity of disease and symptoms. Falling into the latter category, the purpose of our study was to assess the ability of arthritis medication usage to predict study dropout. We hypothesized that subjects who used arthritis medication at baseline would experience a greater percentage of dropout than subjects who did not use arthritis medication. Use of medication for the condition being studied provides a measure of the participant's perceived severity of symptoms or illness that is easy and inexpensive to collect, thus making it a useful possible predictor for a wide variety of studies in any number of settings.

Methods

The Clearwater Exercise Study (CES), which was initiated in 1998 by The Arthritis Research Institute of

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America Inc, was designed to evaluate the impact of a regular exercise regimen among people with OA.[10] The CES is an ongoing, community-based study with participants who are recruited by various methods, including newspaper articles and bulletins of community organizations. This nonrandomized, prospective study collects data, including demographics, radiological information, measurements of range of motion, and functional assessment information. The CES is designed to prospectively follow participants to evaluate the physical and radiographic effects of exercise among people with OA. Institutional review board approval is obtained prior to participation in the study. All participants provide written approval from their health care provider and sign an informed consent statement.

The CES is a dynamic cohort with individuals enrolling at different time points. The study is primarily concerned with the long-term effects of exercise among people with OA. Consequently, participants are asked to complete at least 24 months of the exercise program. Study inclusion criteria dictate that CES participants have evidence of radiological OA (grades 2+) at the knees, hands (second distal interphalangeal, third proximal interphalangeal, and first carpometacarpal joints), feet (first metatarsophalangeal joint), or cervical spine joints. Each knee radiograph is graded 0 to 4 for OA by the ordinal criteria of the Kellgren and Lawrence scale: 0=absent, 1=questionable osteophytes and no joint space narrowing, 2=definite osteophytes with possible joint space narrowing, 3=definite joint space narrowing with moderate multiple osteophytes and some sclerosis, and 4=severe joint space narrowing with cysts, osteophytes, and sclerosis present.[11] Participants are eligible if they have one, or multiple, sites with OA. For the current study, all participants were evaluated in the same manner, regardless of the number of OA sites. Study exclusion criteria include: individuals younger than 40 years of age, no radiographic evidence of OA at the aforementioned sites, unable to attend 3 times per week, and inability to participate in the specified exercise routine (eg, using a wheelchair, unable to receive physicians' approval).

Procedure

Prior to enrollment, radiographs were obtained on all participants at the aforementioned sites and all participants underwent a physical examination and completed the Arthritis Impact Measurement Scales 2 (AIMS2) questionnaire.[12] The AIMS2 instrument is a 78-item questionnaire designed to measure a range of health status components in a multidimensional fashion. The first 57 items are broken down into 12 scales: mobility level, walking and bending, hand and finger function, arm function, self-care tasks, household tasks, social activity, support from family and friends, arthritis pain,

work, level of tension, and mood. Meenan et al[13] reported internal consistency coefficients of .74 to .96 for the 12 scales of the AIMS2 for their subjects with OA. Test-retest reliability was .78 to .94.[13] The physical examination conducted by a registered nurse included measurements of height, weight, and blood pressure and numerous measurements of range of motion (eg, right knee extension and flexion). Height was measured in inches, and weight was recorded in pounds. Height and weight measurements were taken with the participants wearing indoor clothing and no shoes. Both values were recorded as integers, rounding up from greater than half a unit. Waist and hip circumference were measured in inches and similarly rounded. Systolic and diastolic blood pressure were measured once with a sphygmomanometer while the participants were in a sitting position. Measurements of systolic and diastolic blood pressure were recorded to the nearest millimeter. A goniometer, a gravity inclinometer, a mechanic caliper, a dynamometer, and a surface temperature scanner were used for joint motion evaluation. The measurements were taken by a registered nurse who was with the institute for the duration of the CES.

Study participants followed a structured exercise routine, performed 3 times per week at the institute. The goal of the program was to increase flexibility, muscle force, and endurance. Exercise sessions were supervised by a certified fitness trainer. The 25- to 30-minute routine included 3 components. A 5- to 7-minute aerobic warm-up period started the session, with participants selecting either a treadmill* or a stationary bicycle (Monark Ergomedic model 818E†). The aerobic warm-up was followed immediately by a weight-resistance routine. The routine was individualized by adjusting the amount of weight for each participant. The number of sets and repetitions were consistent for each study participant and progressed over time. The number of sets and repetitions for weeks 1 through 4 were 2×10, 2×15, 3×10, and 3×15, respectively (eg, 2 sets of 10 repetitions each=2×10). Subsequently, this pattern of sets and repetitions was repeated every 4 weeks. The machines used were: a leg press,‡ a hip extension and flexion instrument (Muscle Master§), a freestanding handgrip device,‖ and a universal gym.§ A 3-minute aerobic cooldown on either the stationary bicycle or treadmill completed the exercise session.

The outcome measure of the current study was dropout status (yes/no). To allow for a full 24 months of participation, we included only participants who entered

Table 1.
Descriptive Baseline Characteristics Among Exercise Study Participants by Dropout Status[a]

	All Participants (n=143)		Retained (n=78)		Dropouts (n=65)	
	n	%	n	%	n	%
Arthritis medication (yes)	108	76	50	64	58	89
Female	109	76	58	74	51	78
Married	81	57	46	59	35	54
Baseline health (excellent/good)	117	82	66	85	51	78
Knee osteoarthritis (yes)	54	38	29	37	25	38
Hand osteoarthritis (yes)	118	83	67	86	51	78
Foot osteoarthritis (yes)	48	34	20	26	28	43
Cervical spine osteoarthritis (yes)	88	62	47	60	41	63

	All participants (n=143)			Retained (n=78)			Dropouts (n=65)		
	$\overline{X}$	SD	Range	$\overline{X}$	SD	Range	$\overline{X}$	SD	Range
Age (y): total	72	7.0	49–90	72	6.5	54–85	71	7.6	49–90
Age (y): women	71	6.9	54–90	71	7.3	57–90	71	6.6	54–85
Age (y): men	73	7.3	49–84	71	8.9	49–80	74	5.8	62–84
Body mass index	27.5	4.5	18–40	27.6	4.5	18–39	27.4	4.7	20–40
Follow-up time (no. of months)	17.1	8.6	1–24	24	0	24–24	8.8	6.1	1.2–22.8

[a] Dropout status categories: retained=24+ months of study participation; dropouts=24 months or less of study participation.

the CES before August 2001. Study participants who completed 24 months or more of the exercise regimen were retained. Individuals who withdrew prior to completing 24 months of the exercise regimen were considered dropouts. A literature review revealed that studies examining the effects of exercise among people with OA currently use designs that use lengthier periods of follow-up (eg, 24 months) than were once used.[14–17]

The primary variable of interest in this study was arthritis medication usage (yes/no). Participants answered the following baseline question from the AIMS2 questionnaire, "During the past month, how often have you had to take medication for your arthritis?" The 5 response choices were: "all days," "most days," "some days," "few days," and "no days." We collapsed these 5 responses into 2 categories: yes/no. "All days," "most days," "some days," and "few days" were categorized as "yes" for arthritis medication usage. "No days" was categorized as "no" for arthritis medication usage.

Participants
Among the 156 study participants, 8 subjects had not been enrolled for at least 24 months and their data were eliminated from the data analysis. Of the remaining 148 participants, 5 subjects (3.4%) were missing baseline information about arthritis medication usage. These 5 subjects were similar to the 143 subjects whose data were retained in the data analysis with regard to baseline characteristics such as age, body mass index (BMI), and sex. Additionally, 3 of the 5 subjects were eventually classified as study dropouts. However, only 1 of the 5 subjects (20%) was married compared with 57% of the

subjects whose data were retained in the data analysis. A total of 143 participants were included in this analysis. We attempted to minimize attrition by providing an overview of our exercise program prior to study consent, providing ample opportunity to ask questions and gain the information needed about the CES, selecting a workout time well-suited to individual schedules, and instituting a telephone call to inquire about the subject's well-being in the event that a participant missed a scheduled appointment.

Table 1 displays descriptive frequencies (and percentages) for all participants and by dropout status. The majority of participants reported use of arthritis medication (76%), were female (76%), indicated they were in "excellent or good" health (82%), and were married (57%). The percentage of people with radiographically confirmed OA at the knees, hands, feet, and cervical spine were 38%, 83%, 34%, and 62%, respectively. The average length of follow-up time was 17 months. Of the 143 participants, 78 subjects (55%) completed 24+ months and 65 subjects (45%) dropped out. Among those who reported arthritis medication usage, 54% were study dropouts. Twenty percent of subjects reporting no usage of arthritis medication were study dropouts (Figure).

Data Analysis
We used the Mantel-Haenszel chi-square test statistic[18] to examine the association between arthritis medication usage and dropout status. Because no studies have conducted an in-depth examination of dropout factors among older exercisers with OA, basic demographic
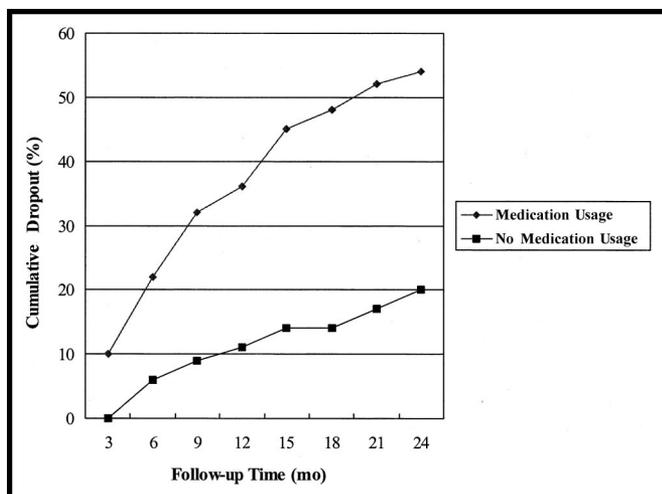
Figure.
Cumulative dropout percentages by arthritis medication usage 1 month prior to study enrollment.

variables were assessed a priori for possible confounding. The Student t test was used to quantify the statistical significance between the relationship of the continuous variables age and BMI (recorded as weight divided by height squared).[19] A Cox proportional hazard model was used to quantify the relationship between arthritis medication usage and study dropout status because participants were observed for unequal lengths of time,[20] while simultaneously controlling for the influence of exogenous factors.[15] The exponentiated β coefficients were used to calculate the point estimates (hazard ratios) for the final predictive models. We used Statistical Analysis Software (SAS), version 8.12,[#] specifically PROC PHREG.[21] Continuous covariates in the analytic analyses (age and BMI) were kept as continuous variables. We used Cox modeling for unadjusted analyses, with arthritis medication usage as the only independent variable in the model. All point estimates reported are hazard ratios. Although many factors need to be examined for their influence on study dropout among exercisers, the current study had the statistical power to examine one predictor (medication usage). A 2-group continuity-corrected test with a 2-sided significance level of .05 will have over 90% power to detect a difference between a group 1 proportion of 0.54 and a group 2 proportion of 0.20 when sample sizes are 108 and 35, respectively. This power calculation was conducted specific to this data set using nQuery software.[**,22]

Results

Unadjusted analyses examined the relationship between arthritis medication usage and dropout status. Individuals who reported taking arthritis medication were 3.5

times more likely to drop out than individuals who reported no arthritis medication usage (risk ratio [RR]=3.5, 95% confidence interval [CI]=1.6–7.6). This association remained statistically significant after stratifying for sex (women: RR=3.0, 95% CI=1.3–7.0; men: RR=4.9, 95% CI=1.1–15.6). Further analyses were conducted to quantify the relationship between arthritis medication usage and dropout status while controlling for the influence of other factors such as sex, baseline age, and BMI. The final adjusted model controlled for BMI, baseline health status, and the interaction between baseline health status and BMI (Tab. 2). Baseline health status influenced the relationship between arthritis medication usage and dropout status. The final adjusted model revealed that individuals who reported arthritis medication usage were 4.5 times more likely to drop out than were those who reported no arthritis medication usage (RR=4.5, 95% CI=1.8–11.4).

Discussion and Conclusions

The CES provided an opportunity to examine the influence of baseline characteristics and subsequent dropout status among elderly people with OA. Participants' ages varied from 49 to 90 years. Six percent were less than 60 years of age, 29% were 60 to 69 years of age, and 65% were 70 years of age and older. The time periods evaluated were less than 24 months and 24 months or longer. In this study, we investigated the influence of exercise among older people with OA and examined predictors of dropout status over a relatively lengthy study period. Our data demonstrated that dropouts differed from retained participants with respect to self-reported arthritis medication usage the month prior to study enrollment. These findings were maintained in sex-stratified analyses. The influence of age, sex, and BMI did not change the direction of the association or make the results nonsignificant. The final model that was fitted to these data predicted study dropout by baseline arthritis medication usage, while controlling for baseline health status, BMI, and the interaction between baseline health status and BMI.

Published studies evaluating predictors of dropout status have not examined the influence of medication usage. However, a review of the literature has identified baseline medical issues as a predictor of study dropout. In a 1999 study, Colangelo and colleagues[23] examined predictors of dropout status in a 12-month follow-up study of patients with head and neck cancer. Their findings, although not specific to baseline medication usage, indicated that 50% of the study dropout rate was accounted for by "baseline medical reasons," 23% by administrative reasons, and 27% by nonspecific reasons. If we speculate that baseline medication usage is an indicator of disease severity, these data indirectly support our current findings.

Table 2.
Adjusted Associations Between Arthritis Medication Usage and Dropout Status While Controlling for the Influence of Other Factors[a]

	RR[b]	95% CI[c]
Medication usage	3.5*	1.6–7.6
Medication usage + sex	3.4*	1.6–7.5
Medication usage + age	3.4*	1.6–7.5
Medication usage + BMI[d]	3.5*	1.6–7.8
Medication usage + marital status	3.5*	1.6–7.6
Medication usage + current health	4.5*	1.8–11.3
Medication usage + knee osteoarthritis	3.6**	1.6–8.0
Medication usage + sex + age + BMI	3.5*	1.6–7.7
Medication usage + baseline health status + BMI	4.5**	1.8–11.4
Medication usage + baseline health status + BMI + (baseline health status × BMI)	4.5**	1.8–11.4

[a] Reference category: retained (24+ months of study participation), as compared with dropouts (24 months or less of study participation). *$P<.005$. **$P<.001$.
[b] RR=risk ratio.
[c] CI=confidence interval.
[d] BMI=body mass index.

Although study dropout in OA exercise programs has received little attention in the published literature, some studies have addressed attrition in other groups of exercisers. A 2003 study examined the influence of a home-based or center-based exercise program on participant dropout among a group of 40- to 65-year-old women.[24] The authors noted that the center-based group had higher retention (97%) than the home-based group (87%) at 6 months ($P<.05$). Sources of attrition in a church-based exercise program for 123 older African Americans were examined in a 2000 study.[8] Within the first 4 months, 43% of the participants had dropped out. Compared with those who did not drop out, dropouts had lower levels of education and lower baseline self-ratings of health. If arthritis medication usage is viewed as a rudimentary, surrogate marker of baseline health status among exercisers with OA, our findings complemented the results of this study.[8]

Psychosocial factors predicting treatment dropout were identified in a 2002 randomized trial of exercise therapy and pharmacotherapy for major depression.[7] Men and women (n=156), aged 50 years and older, who were diagnosed with major depressive disorder were assigned to a 16-week program of aerobic exercise, medication, or a combination of exercise and medication. Thirty-two patients (21%) were dropouts. Baseline levels of self-reported anxiety and life satisfaction were the best predictors of patient dropout status for all 3 interventions. Schmidt and colleagues[3] examined factors that may have been predictors of dropout status in their 18-month, randomized trial. They examined an exercise intervention aimed at improving physical function in frail older people (n=155). At 3 months, 31 (20%) of the subjects had dropped out. Compared with retained subjects, the dropout group had more baseline health problems (23% versus 5%, $P<.01$), worse self-perceived physical health (35 versus 41 on a scale of 0–100, $P<.01$), and slower usual gait speed (0.84 versus 0.99 m/s, $P<.001$) and walked a shorter distance over 6 minutes (268 versus 350 m, $P<.001$). The findings of this study support the notion that baseline health status may play a predictive role in study dropout.

Independent of its purported relationship to health status, we suggest that arthritis medication usage may be related to dropout status through an additional venue. People taking arthritis medication may be seeking short-term relief from OA-related symptoms. If this group expects exercise to be another "quick fix" for OA-related symptoms, and subsequently exercise decreases, we may speculate that people who have this expectation would be more likely to drop out than would others.[25] Arthritis medication usage may, indeed, be a surrogate, albeit crude, measure of discomfort experienced by a study participant at baseline. If the participant perceives that exercise exacerbates symptoms, we might expect this group to experience higher losses to follow-up. Specific retention techniques for study participants can include several approaches. The awarding of a personalized appreciation certificate at specific time intervals (eg, every 4 weeks) reinforces a participant's valued role. The creation of a social atmosphere through a rapport with the exercise instructor may be an incentive for many subjects to continue their participation in the study (eg, the exercise instructor might inquire when the participant's grandchildren are due to visit). Additionally, displaying a bulletin board with postcards and photos from participants' travels may offer a sense of group membership, thus enhancing retention.

A well-designed exercise intervention necessitates a meticulous plan, methodical organization, adequate personnel time, and sometimes large capital outlays for equipment. Lack of attention to those study subjects who may be likely to drop out could be a costly mistake. We believe that proper allocation of study resources includes the identification of those individuals and implementation of the commensurate retention techniques needed to reduce dropout. Reduced statistical power can be a concern for studies experiencing significant dropout. However, the greater threat from selective attrition is that the remaining subjects may have a narrower range of study outcome values (eg, percentage experiencing OA progression). This results in a reduced ability to generalize study findings. Differences in char-

acteristics between retained subjects and dropouts can introduce bias into a study. The factor that is differentially distributed between retained and lost individuals must be related to the study outcome for such differences to be of concern for study validity.[26] Our findings are limited by their inability to fully characterize arthritis medication usage. Knowledge of the medication's type, dosage, and exact frequency of use during the month prior to study entry may have more specifically identified a predictor of study dropout. Additionally, generalizability of our current findings is limited to people aged 49 years and older.

As a hypothetical example, suppose that an exercise intervention is designed to evaluate changes in participants' symptoms of OA. The investigator notes from the published literature that factors "A," "B," and "C" have been demonstrated to be related to exercise study dropout. Yet factor "B" is suggested as the only noted predictor related to symptoms of OA, the study's outcome. In this hypothetical example, limited resources could be best used by designing study retention efforts aimed specifically at those participants with factor "B."

Research is needed to identify techniques to reduce attrition among older exercisers with OA without introducing bias. Studies of exercise interventions in older adults with OA are becoming increasingly popular[15,17,27–30] and would benefit greatly from a priori knowledge of the characteristics that increase the risk of dropout among this group. The use of arthritis medication during the last month prior to enrollment proved to be a useful, easily acquired, and inexpensive technique for predicting dropout status. Additional methodological studies examining baseline predictors of dropout status may provide greater clarity on the factors affecting dropout status.

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