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Willingness of older adults to participate in a randomized trial of conservative therapies for knee pain: A prospective preference assessment

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ABSTRACT

Background: In preparation for a trial of physical therapy (PT) for patients with degenerative meniscal tear and knee osteoarthritis, we conducted a prospective preference assessment – a methodology for estimating the proportion of eligible subjects who would participate in a hypothetical randomized trial.

Methods: We identified patients seeking care from the practices of five orthopedic surgeons. Patients completed a survey asking about their willingness to participate in a hypothetical trial, their treatment preferences, their knee pain, and demographic variables.

Results: We approached 201 eligible patients, of whom 67% (95% confidence interval [CI] 60%, 73%) completed questionnaires. Of these, 24% (95% CI 17%, 31%) were definitely and 39% (95% CI 31%, 47%) were probably willing to participate in the trial. Thirty-three percent (95% CI 23%, 43%) of subjects with no treatment preference were definitely willing to participate as compared to 9% (95% CI 1%, 17%) with treatment preference (p = .001). Patients with higher educational attainment also stated a greater willingness to participate than those with less education (p = .06). In multivariable logistic regression analysis, those with no treatment preferences had greater adjusted odds of stating they would definitely participate than those with a defined treatment preference (OR 5.2, 95% CI 1.7, 16.2), while subjects with an associate's degree or greater were more likely to state they would definitely participate than those with less education (OR 3.9, 95% CI 1.1, 14.1).

Conclusion: In this prospective preference assessment, 63% (95% CI 55%, 71%) of subjects with degenerative meniscal tear expressed willingness to participate in a trial of PT modalities. Individuals with no treatment preferences were more likely to state they would participate than were those with higher education. This methodology can help investigators estimate recruitment rates, anticipate generalizability of the trial sample and create strategies to facilitate enrollment.

1. Introduction

Clinical trials are essential for determining treatment efficacy, and the randomized controlled trial (RCT) is generally considered the gold standard for trial design. While RCTs provide high quality evidence [1], appropriate planning of enrollment strategies can be challenging, and slow enrollment can compromise a trial's timely completion [2,3]. Halpern (2002) suggests that researchers employ a pre-enrollment "prospective preference assessment" (PPA) to predict the number of patients that will need to be approached to reach enrollment goals and understand the characteristics of subjects interested in participating in the study [4]. With greater understanding of factors that impel patients to participate, investigators can devise strategies for timely enrollment of a sufficient and representative sample.

RCTs are especially useful when the results have the potential to influence clinical practice. Degenerative meniscal tear in the presence of knee osteoarthritis (OA) is a widespread and painful condition. Symptomatic knee OA affects over 15 million Americans [5]. Damage

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to the menisci is present in 70–90% of persons with symptomatic and radiographic OA, and clinicians frequently attribute symptoms of knee pain to degenerative meniscal damage [6]. In the past decade, five RCTs have compared physical therapy (PT) alone to arthroscopic partial meniscectomy followed by PT for participants with degenerative meniscal tear. Four of the trials found similar levels of pain relief and functional improvement in both arms [7–11]. These findings suggest that PT should be the first line of treatment for patients with degenerative meniscal tear and/or knee OA [12,13]. However, no current trial has rigorously studied whether outpatient PT is superior to exercises performed at home or whether the effect of PT is due, in part, to a placebo effect.

In preparation for a randomized control trial (RCT) comparing a home exercise program, in-person physical therapy (PT), and in-person topical treatments (that offer a placebo effect) for persons with degenerative meniscal tear, we conducted a PPA study. Our goals were to estimate the proportion of potentially eligible subjects who would be willing to participate in the trial and to identify factors associated with willingness to participate. Identification of demographic features of those who are and are not interested in participating would help investigators understand the generalizability of their sample and might be helpful in developing recruitment strategies to attract persons who are more reluctant to participate. Below, we describe the results of a PPA conducted in anticipation of this RCT comparing home exercise, PT, and a placebo PT intervention for degenerative meniscal tear in the presence of OA.

2. Methods

2.1. Sample

We recruited study participants from the outpatient practices of five orthopedic surgeons at a tertiary academic center in Boston, MA. Inclusion criteria consisted of knee pain for at least two weeks, age greater than 40 years, and English-speaking. Exclusion criteria consisted of evidence of bone-on-bone knee OA, inflammatory arthritis, locked knee, prior surgery on their index knee, attending more than four sessions of PT in the preceding year, dementia, residing in a nursing home, and current pregnancy.

Each week, a research assistant (RA) reviewed the clinic schedules of participating surgeons and assessed consecutive patient records using clinical schedule information and data from the electronic medical record. For every patient who met inclusion criteria and had no exclusions, the RA completed a screening form in a secure online database. In the clinic, the RA approached all study subjects deemed eligible after the screening process, reviewed their eligibility, and asked if they would be willing to complete a survey indicating their interest in a hypothetical trial. The RA described the trial as a hypothetical randomized study investigating different non-operative treatments for patients with knee pain, including: (1) PT with a trained physical therapist, (2) topical creams applied to the knee, and (3) education/instruction for therapeutic exercises to perform at home. Study materials the RA presented to patients were written in a manner that was thought to be appropriate for a participant with an 8th grade reading level. Training on how to present these materials and explain complex health topics with patients was minimal. Participants completing the survey were provided with a $10 gift card. We also asked each subject's treating physician to complete a form noting the participant's suspected diagnosis. We describe participants who completed a survey on their willingness to participate in the lager, hypothetical trial as “enrolled” in this pilot study report.

2.2. Data elements

Participants rated their willingness to participate in a hypothetical trial of non-operative physical therapy modalities using a five point Likert scale: definitely yes, probably yes, not sure, probably no, definitely no. Participants completed questionnaire items including information on whether or not they had a preferred intervention amongst the three intervention options offered:1) PT in clinic with a professional therapist, 2) topical creams applied to the knee, and 3) a home exercise program. We also evaluated patient willingness to undergo an MRI scan in Boston if it were required to participate in the trial. Other assessments included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain scale [14] (0 best, 100 worst), Knee injury and Osteoarthritis Outcomes Score (KOOS) Symptoms scale (0 worst, 100 best), and questions on demographics [15]. For this analysis, we specified race as white vs. non-white; ethnicity as Hispanic vs. non-Hispanic; and educational attainment as associate's degree or greater vs. some college, technical school training, or high school graduation.

2.3. Statistical analysis

We evaluated the association between participant willingness to enroll and demographics, clinical characteristics, and treatment preference. Willingness was categorized as “Willing” (definitely yes), “Probably” (probably yes) and “Unwilling” (not sure, probably no, definitely no). We summarized categorical variables as proportions and compared them across groups using a chi-squared test or the Freeman-Halton test, an extension of Fisher's exact test, where appropriate [16]. Continuous variables were presented as means or medians based on normality and compared using the Kruskal-Wallis test. Given that willingness to participate is ordinal, it was also assessed using the Cochran-Mantel-Haenszel statistic for categorical variables and the Jonckheere-Terpstra test for continuous variables [17]. We used logistic regression to evaluate the independent association between definite willingness to participate and baseline demographic and clinical characteristics. We considered in the regression model variables from the univariate analysis that were associated with willingness at a p-value criterion of ≤ 0.15. Candidate variables were eliminated individually using the Akaike information criterion (AIC). The Tables and Figures include the number of responses for each question. Notably, not every participant who completed a survey answered every survey query. Therefore, the total number of responses for each question varies for each variable. Missing data was minimal (less than 4%). We conducted all analysis using SAS version 9.4 (SAS Institute, Cary, NC).

3. Results

3.1. Enrollment and features of sample

Over seven months, we screened 705 patients with knee pain, of whom 134 (19%) ultimately enrolled in the pilot study (Fig. 1). We found 345 of the 705 to be ineligible during initial screening, most commonly due to previous knee surgery or prior attendance at more than four sessions of PT in the past year. Of the remaining 360, 159 were not approached in clinic due to scheduling conflict for the RA, observable exclusion (e.g. translator present, visibly pregnant), or failure to come to clinic. The RA spoke with the remaining 201 individuals; of these, 36 were found to be ineligible and 20 were not interested in completing the questionnaire. Of the 145 patients who agreed to be surveyed, 134 (92%) people completed the survey. Of the 134 responders, physician diagnoses were obtained for 114 (85%) participants (see Fig. 2).

Overall, respondents were predominantly female (66%) and white (82%), and most (77%) had at least an associate's degree. The average age was 63 years (standard deviation [SD] 11) and median body mass index (BMI) was 27.3 kg/m^2 (25th, 75th percentile 27.3, 31.8). The median KOOS Symptoms score was 50 (25th, 75th percentiles 40, 60), and the median WOMAC Pain was 40 (25th, 75th percentile 25, 60). Approximately 65% of subjects reported they had no preference

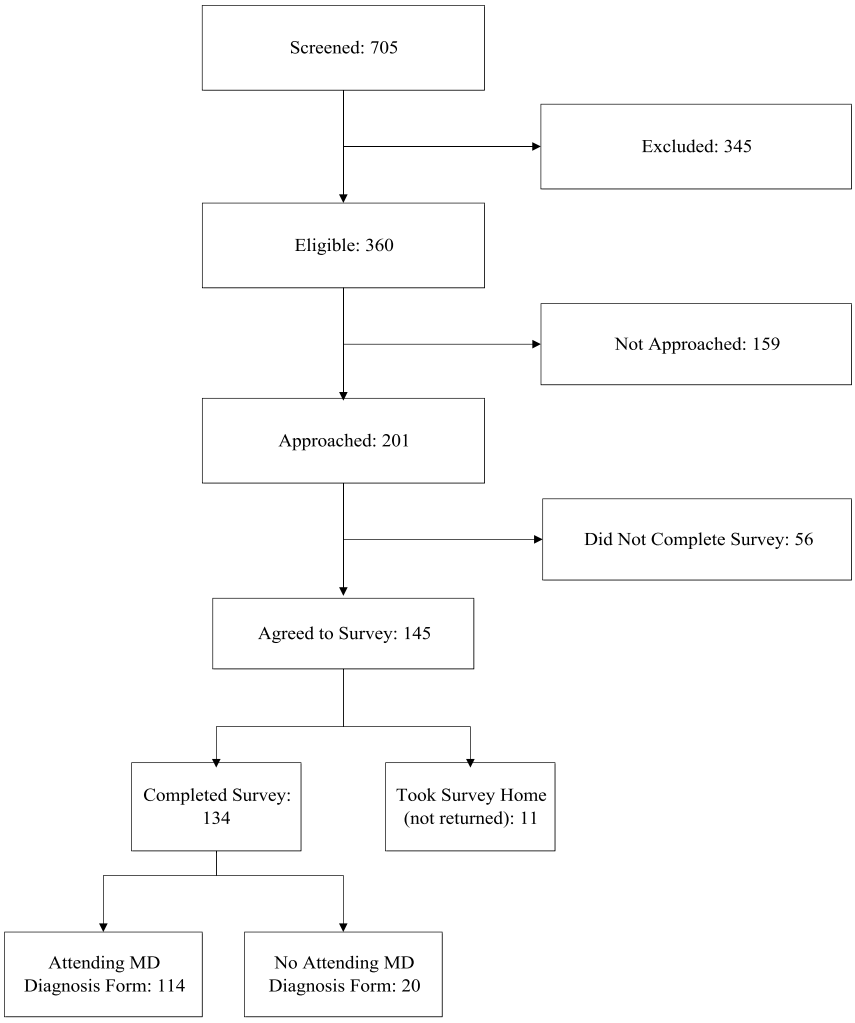

Fig. 1. Patient screening and enrollment diagram.

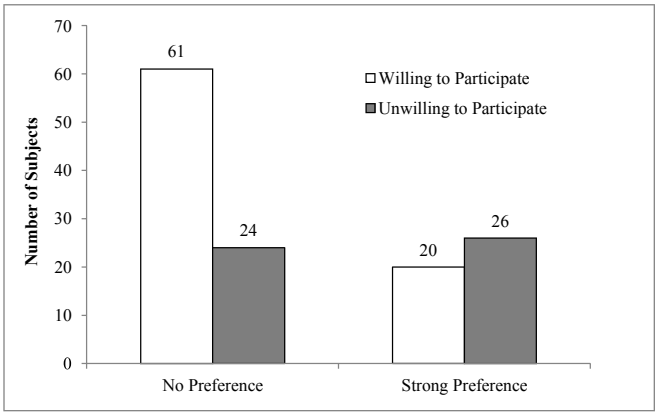

Fig. 2. Willingness to participate stratified by preference for treatment.

between the three treatment strategies mentioned.

Additionally, 84% of participants said they would be willing to undergo an MRI scan in a Boston-based clinic if it were required for participation. Of 114 patients for whom physicians noted a diagnosis, 38% had a primary diagnosis that included meniscal tear (meniscal tear alone or meniscal tear and OA).

3.2. Willingness to participate

Of the 705 patients screened, 134 (19%) enrolled and completed questionnaires. Of these enrolled subjects, 63% (95% CI 55%, 71%) expressed a willingness to participate in the study. Specifically, 24% (95% CI 17%, 31%) said they were definitely willing to participate, 39% (95% CI 31%, 47%) said they were probably willing to participate, and 37% (95% CI 29%, 46%) were undecided, probably not, or definitely not willing to participate in the hypothetical RCT. Of the original 705 screened patients, 12% (95% CI 10%, 14%) were either definitely or probably interested in participating in this hypothetical trail of non-operative PT modalities.

Among subjects with no preference for a particular treatment, 33% stated they would definitely participate, 39% stated they would probably participate, and 28% were unsure or unwilling to participate (Table 1). For subjects who did prefer a specific treatment, such as topical creams applied to the knee or in-clinic PT, 9% said they would definitely participate, 35% said they would probably participate, and 57% were unsure or unwilling to participate ($p = .001$).

Neither age nor sex had a meaningful association with participant willingness to participate in the hypothetical RCT (Table 1). Identifying as non-white was associated with a numerically greater likelihood of being unwilling to participate in the hypothetical trail, although this observation did not reach statistical significance ($p = .18$). Higher educational attainment and lower BMI were also associated with a greater stated willingness to participate, although neither of these conclusions was found to be statistically significant ($p = .06$ and $p = .14$, respectively). Participants who stated a willingness to come to Boston for an MRI were more likely to state a willingness to participate ($p < .001$).

Table 1
The association between baseline demographic and clinical characteristics and willingness to participate.[a]

Baseline Characteristics	Definitely Participate N = 32		Probably Participate N = 52		Not Participate N = 50		*P-value*
	N	% or Mean (SD)/Median (25th, 75th %)	N	% or Mean (SD)/Median (25th, 75th %)	N	% or Mean (SD)/Median (25th, 75th %)	
Age (years), Mean	32	64.1 (9.8)	52	61.7 (9.7)	50	64.1 (11.8)	0.33
Female							
No	8	17.8	19	42.2	18	40.0	0.50
Yes	24	27.0	33	37.1	32	36.0	
Body Mass Index (kg/m^2), Median	32	26.3 (23.5, 30.7)	52	27.0 (24.0, 30.1)	49	29.9 (25.1, 33.5)	0.14
White race							
No	4	16.7	7	29.2	13	54.2	0.18
Yes	28	25.7	44	40.4	37	33.9	
Hispanic							
No	31	24.2	49	38.3	48	37.5	0.98
Yes	1	20.0	2	40.0	2	40.0	
Education							
High school or technical school	3	9.7	12	38.7	16	51.6	0.06
Associate's degree or greater	29	28.2	40	38.8	34	33.0	
Willingness to come for an MRI							
No	2	10.0	2	10.0	16	80.0	< 0.001
Yes	29	26.6	49	45.0	31	28.4	
Treatment preference							
No specific preference	28	32.9	33	38.8	24	28.2	0.001
Had a specific preference	4	8.7	16	34.8	26	56.5	
WOMAC Pain, Median	32	45 (25, 60)	52	35 (25, 47.5)	48	50 (32.5, 65)	0.01
KOOS Symptoms, Median	32	50 (40, 60)	52	52.5 (45, 65)	50	50 (40, 55)	0.17
Exercise Frequency in past week							
0 times	14	22.2	25	39.7	24	38.1	0.99
1 to 3 times	11	25.0	17	38.6	16	36.4	
≥4 times	6	23.1	10	38.5	10	38.5	
Primary Diagnosis[b]							
OA only	12	27.9	14	32.6	17	39.5	0.77
Symptomatic meniscal tear	4	16.7	11	45.8	9	37.5	
Symptomatic meniscal tear & OA	4	21.1	8	42.1	7	36.8	
Other	8	28.6	13	46.4	7	25.0	

[a] Not Participate includes undecided, probably not willing to participate, and definitely not willing to participate.
[b] Primary diagnosis of OA includes both tricompartmental and patellofemoral OA. Other diagnoses include: Symptomatic ligament tear, Patellofemoral syndrome, Rheumatoid arthritis, Gastrocnemius strain, Trochlear contusion, Lateral condyle defect, Tibial tubercle bursitis, Osteonecrosis, Pes anserine bursitis, Patellofemoral bursitis, Insufficiency fracture, Cellulitis, Spinal stenosis, Gait issues, Ruptured Baker's cyst, and Knee strain.

In the multivariable logistic regression analysis, those with no treatment preferences had greater odds of stating they would definitely participate than those with a defined treatment preference (OR 5.2, 95% CI 1.7, 16.2). Those with an associate's degree or greater had higher odds of stating that they would definitely participate in a trial compared to participants with some technical school or high school education only (OR 3.9, 95% CI 1.1, 14.1).

4. Discussion

In this pilot study assessing willingness to participate in a hypothetical randomized trial evaluating non-operative therapies for degenerative meniscal tear, we surveyed 134 individuals and found that 24% were definitely willing and 39% were probably willing to participate in the hypothetical trial.

Twelve percent of the initial 705 subjects screened were willing to participate. Of the 134 subjects enrolled, those with no specific treatment preferences and those with higher educational attainment were more likely to state a definite willingness to participate.

Our study agrees with the findings of Creel et al. which emphasize the importance of patient treatment preferences as a key factor influencing patient enrollment and, eventually, study outcomes [18]. Patient expectations have been shown to influence intervention efficacy in other trials assessing therapies for neck and joint pain [19–21]. Comparing our trial to other PPA studies, the proportion of subjects who stated they would enroll in our trial is higher than the proportion of a similar cohort willing to participate in a previous RCT comparing surgery to PT for patients with degenerative meniscal tear and OA. In this PPA assessing interest in a surgery and PT trial, 46% of potential subjects said they were probably or definitely willing to participate and 22% were definitely willing to participate [18]. Twenty-six percent actually enrolled [8]. In our current PPA, 63% of subjects were probably or definitely willing to participate and 24% were definitely willing to participate. The larger number of subjects probably or definitely willing to participate in the hypothetical trial of non-operative treatments compared to the surgical trial likely reflects greater reluctance of patients to be randomized to surgery, an irrevocable treatment with nontrivial risks.

Educational attainment also had a meaningful effect on patient willingness to enroll in the trial. Other studies have similarly documented greater participation rates among potential subjects with more education, a variable associated with increased health literacy [22–25]. In addition, hypothetical preference assessment and randomization are somewhat abstract concepts and may have been alienating to those with less education. Whether subjects with lower educational attainment would be more comfortable enrolling in RCTs if they received careful explanation of the process of randomization is worthy of study, as selective non-participation by those with less education would reduce generalizability. Some factors associated with willingness at levels of significance less than 0.15, such as body mass index, were not independently associated with willingness in the multivariate analysis and should not be construed as risk factors or non-participation.

Our observations are limited by the relatively few primary diagnoses of meniscal tear. This issue may be mitigated by overlapping etiologies of OA and degenerative meniscal tear [26] and the fact that PT is the recommended first-line treatment for both diseases [13,27]. In

addition, the study sample recruited for our pilot survey was well-educated and predominantly female; reflecting the demographics of the Boston area [28] as well as the gender distribution of OA disease burden [29]. We also acknowledge that our sample size was relatively small. We provide 95% confidence intervals to depict the precision around our estimates of participation. Finally, we acknowledge that the p value we chose for entry into the model, 0.15, risks a false positive finding. With a modest size sample, we were concerned that a more stringent level would preclude potentially important variables from entering the model. The multivariable model included two independent correlates of willingness (treatment preference and education) that achieve a more traditional level of statistical significance in the model ($p < .05$ for each).

In conclusion, we found 24% of potentially eligible subjects definitely willing and 39% of subjects probably willing to participate in a trial of non-operative therapies for knee pain. Therefore 63% of all enrolled subjects and 12% of the 705 patients initially screened were interested in participating in the trial. Patients with more education and those without treatment preferences were more likely to state that they would participate in the trial. These findings illuminate the influence of patient preference and education on patient participation in studies and may help investigators plan RCTs. Specifically, the outcomes of our study underscore the importance of training research staff to present participants evidence clarifying that treatment arms in RCTs have similar (or uncertain) effectiveness. Training on how to present the trial to persons with low health literacy may be an important factor in recruiting a more diverse and representative trial sample. This evidence-based presentation of effectiveness may modify patient preferences constructed on inaccurate or incomplete information. Extra efforts may be required to enroll subjects with lower levels of education. Such efforts could both facilitate study enrollment and improve generalizability of study results.

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Competing interest statement

Dr. Katz is President-Elect of the Osteoarthritis Research Society International (OARSI). Drs. Katz and Losina are Deputy Editors for Methodology and Biostatistics for the *Journal of Bone and Joint Surgery*. The authors report no other competing interests.

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Collection and assembly of data: Kerman.

Analysis and interpretation of the data: Kerman, Deshpande, Selzer, Losina, Katz Statistical expertise: Selzer, Katz, Drafting of the article: Kerman.

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