Title
"JointADventure: A Worksite Activity-Diet Intervention for Chronic Knee Pain – A Pilot Study"

Adrianna Borys, MPH, Pamela A Semanik, APN, PhD, Linda Ehrlich-Jones, PhD, RN, Christine Pellegrini, PhD, Julia Lee, PhD, MPH, and Rowland W Chang, MD, MPH

Abstract
Background: Rising prevalence of arthritis associated activity limitations resulting from knee osteoarthritis (KOA) is negatively impacting health care costs and quality of life in the US. Being physically active and attaining an ideal weight are two proven methods to improve symptoms and decrease the morbidity of those with osteoarthritis. We report the results of a pilot study that tests the feasibility/scalability of the JointADventure intervention, a workplace intervention utilizing motivational interviewing (MI) to promote healthy dietary and physical activity behaviors for those with or at risk for KOA.
Methods: Overweight/obese employees with chronic knee symptoms who did not meet 2008 CDC physical activity guidelines (n=38) were randomized to intervention (n=19) or wait-list control (n=19) groups. The intervention group received group and individual MI sessions focused on increasing physical activity and reducing caloric intake. Changes in objective physical activity (using accelerometers), weight, and self-reported pain and function [using the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC)] were reported after 3-months of follow-up.
Results: Group and individual session attendance from baseline to 3-months was 56% and 65%, respectively. At the 3-month follow-up, intervention participants had a mean increase in total physical activity of 10.8 minutes/day (95% CI: -15.6, 37.3) compared to a mean decrease of 4.1 minutes/day (95% CI: -38.7, 30.5) in the control group. Participants in the intervention group also achieved a mean weight loss of 1.9 kg (95% CI: -3.5, 0.4), while the mean weight of the control group did not change (95% CI: -1.2, 1.2). Mean WOMAC pain and function scores improved by 0.55 units (95% CI: -1.76, 0.67) and 1.64 units (95% CI: -5.93, 2.65) respectively in the intervention group. In the control participants, the mean pain score improved by only 0.08 units (95% CI: -1.95, 1.78) and the mean function score worsened by 3.06 points (95% CI: -2.42, 8.54).
Conclusions: Despite low session attendance, the JointADventure intervention showed promise in improving physical activity, weight loss, and pain and function outcomes in this small sample of overweight/obese employees with chronic knee symptoms. Further research focused on improving participant engagement is needed to enhance the scalability and public health impact of this intervention.

Trial Registration: *ClinicalTrials.gov Identifier: NCT01977872 – Registered November 7, 2013*

Key Words: Arthritis, physical activity, diet, chronic knee symptoms, worksite, accelerometer [pick 3-10 words]

Background

Symptomatic knee OA (KOA) affects an estimated 15 million Americans [1]. Arthritis associated activity limitations (AAAL) and pain translate to a heavy societal burden from health care costs, lost wages due to work absenteeism, and negative impacts on quality of life [2]. Additionally, indirect costs from work absenteeism also burden OA patients with a total loss of $10.3 billion each year [3].

Current non-surgical treatments for KOA are limited to prescribing increased physical activity, weight loss, or pharmacological treatments that address pain and stiffness before patients are considered for surgical interventions such as a total knee arthroplasty [4].

Two commonly targeted risk factors for KOA interventions are physical inactivity and excess weight [5-8]. Increasing physical activity has great potential for improving pain and function in patients with chronic knee symptoms [9]. Encouraging healthier physical activity behaviors at the population level could substantially reduce the burden of KOA since only 41% of patients with arthritis met 2008 US physical activity recommendations, significantly lower than the proportion of persons without arthritis [10]. In addition, nearly 25% of new development of knee pain can be attributed to overweight or obesity; thus weight reduction programs may aid in reducing KOA burden in the US population [11].

The Arthritis, Diet, and Activity Promotion Trial (ADAPT) and the Intensive Diet and Exercise for Arthritis (IDEA) trial demonstrated significantly improved pain and function scores and weight loss associated with diet and activity interventions for older adult patients with KOA. [7, 12]. These studies were carried out at academic settings using intensive, precisely scripted regimens, often utilizing resources that are not available in the community. In contrast to the interventions used in the ADAPT and IDEA trials, the present study focused on diet and lifestyle physical activity behavior changes in the workplace setting.

Addressing diet and physical activity behaviors in the workplace has potential advantages over the clinical or older adult settings. First, employed persons tend to be younger with less severe knee OA than clinical and older adult populations. Second, having milder knee symptoms, they may be more open to changing their diet and physical activity behavior, compared to persons with longstanding symptoms and maladaptive behavior. Finally, employers support wellness programs, since physical inactivity is noted as one of ten modifiable health risk factors collectively linked to more than one-fifth of employer-employee healthcare spending [13], and has been associated with absenteeism [14], decreased work productivity, and increased employee health challenges/expenses [15].

Therefore, the objective of this study was to pilot test JointADventure, a workplace intervention utilizing motivational interviewing in both individual and group sessions to promote healthy dietary and lifestyle physical activity behaviors in overweight/obese employees with chronic knee symptoms. Motivational interviewing is a counseling style promoting behavior change that has been shown to increase lifestyle physical activity for persons with other chronic illnesses [16-18] and is the basis for many behavior change treatments for obesity [19]. We sought to demonstrate the potential effectiveness and acceptability of the of the JointAdventure intervention as well as the feasibility for a larger JointAdventure trial. We hypothesized the JointADventure

intervention group would achieve greater weight loss, increase physical activity, and improve pain and function as compared to the wait list control group.

Methods

Study Population

Participants were recruited from an employee research registry of individuals with chronic knee symptoms at a large insurance company. Employees were contacted by a research assistant via telephone if they (1) reported pain, aching, or stiffness in the past 12 months or swelling in or around either or both knees on most days for at least one month, and (2) had a body mass index (BMI) between 25-40 kg/m^2 [20].

During the telephone interview, participants were further screened for demographic, clinical, functional, and logistical inclusion criteria (Table 1). Participants who met the telephone screening criteria were then invited to enroll in a 4 week run-in trial period that included a clinical visit to determine blood pressure and Hemoglobin A1c, total cholesterol and triglycerides levels, a one-week accelerometer-based physical activity assessment, and completing patient reported outcome questionnaires. Excluded were participants having HgA1c > 9, total cholesterol > 250mg/dl, systolic blood pressure > 160, diastolic blood pressure > 110, providing < 4 "valid" days of accelerometer data (see below), attained CDC physical activity guidelines (baseline accelerometer-measured moderate to vigorous physical activity greater than 150 minutes/week), or not completing questionnaires.

Institutional Review Board approval was obtained from Northwestern University Feinberg School of Medicine and all participants who met eligibility criteria and agreed to participate completed written informed consent prior to both the run in and the start of the trial.

All eligible participants completed radiographic imaging and were classified based on Kellgren-Lawrence (K-L) grade [21]. Randomization to either intervention or control was stratified by KOA status (presence, K-L grade ≥ 2 vs. absence, K-L grade = 0 or 1) and BMI status (overweight, BMI 25-30 kg/m^2 vs. obese, BMI ≥ 30 kg/m^2).

Wait List Control Group

All worksite employees enjoyed access to a wellness program consisting of an interactive, personalized webpage where employees were encouraged to complete a health risk self-assessment, financial incentives for participating in health screens, organized wellness-related events, and discounts to an onsite health club. The standard wellness benefits did not include any behavioral weight or physical activity programs. Following the completion of the 3 month assessment, participants randomized to the wait list control group were offered an intervention similar to JointADventure.

JointADventure Intervention

Participants randomized to JointADventure were given a weight loss goal of ≥ 7% of their baseline weight. To assist with weight loss, participants were provided with a calorie goal of 1200-1800 calories/day depending on body weight and a physical activity goal of 150 minutes of moderate intensity activity per week. This goal is consistent with physical activity recommendations for persons with arthritis [22]. Participants had access to an online program to self-monitor dietary intake and weight. Additionally, participants

received a physical activity tracker (pedometer/Fitbit Flex) to monitor their physical activity.

Each participant received three 30-60-minute individual sessions and six 1-hour group sessions during the 3-month intervention. The first individual session was conducted in-person. The remaining individual sessions were conducted via telephone. The Arthritis Comprehensive Treatment Assessment (ACTA) was used to assess facilitators and barriers to physical activity and diet alteration [23]. During each session, a Healthy Lifestyle Coach (HLC) (occupational therapist, exercise physiologist, or dietician) guided the participant to explore perceived barriers to altering physical activity and dietary behaviors, guiding them to overcome those barriers and focus on motivation to change their behaviors using MI. Through this collaborative effort, the HLC and participant created specific, measurable, attainable, relevant, and time-based (SMART) goals to guide the participant in between meeting dates.

Group sessions were scheduled during the workday lunch hour, lasting up to an hour. Participants met weekly for the first 4 weeks, bi-weekly for the second month, and then once for the final month. During the group meetings HLCs facilitated discussions between group members on topics related to nutrition, motivation and physical activity. Examples of topics covered included: portion control, eating out sensibly, healthy cooking tips, yoga demonstrations, problem solving, and stress management. Written materials summarizing session contents were provided at each session.

Sample Descriptors

Upon enrollment, self-reported demographic data (age, gender, race, marital status) were collected. BMI was calculated at the baseline visit using measured height and weight (kg/m^2) and classified into under/normal weight (BMI < 25 kg/m^2), overweight (BMI 25-30 kg/m^2) and obese (BMI ≥ 30 kg/m^2). Kellgren–Lawrence rating of baseline knee radiograph was used to classify KOA severity with scores ranging from grade 0 to grade 4 (the most severe) [24]. All knee radiographs were rated by a single reader.

Outcome measures

Objectively measured physical activity was monitored using a GT1M ActiGraph accelerometer, a small uniaxial accelerometer that measures vertical acceleration and deceleration [25]. Participants were given uniform scripted instructions to wear the unit on a belt at the natural waistline on the right hip in line with the right axilla during waking hours, except during water activities, for seven consecutive days prior to their baseline clinic visit as well as at each follow-up assessment. Participants were instructed to "do what they would normally do in a typical week." Accelerometer data were analytically filtered using validated methodology to identify nonwear periods (a period the monitor was potentially removed during the day) and days with sufficient wear time for valid analysis [26]. To provide reliable estimates, we restricted analyses to participants with at least 4 valid days of accelerometer monitoring [27]. Nonwear periods were defined as more than 90 minutes with zero activity counts (allowing for 2 consecutive interrupted minutes with counts < 100). A valid day of monitoring was defined as 10 or more wear hours in a 24-hour period, which was verified from accelerometer output. Accelerometers output an activity count, which is the weighted sum of the number of accelerations measured over one minute with the magnitude of the measured acceleration proportional to the weight. Physical activity measures were

summarized as average daily minutes of total physical activity (counts of ≥ 100 per minute which includes light, moderate, and vigorous intensity activity), and average daily minutes of moderate-vigorous physical activity (counts of ≥ 2020 counts per minute) [27].

Self-reported pain and function were measured using Likert versions of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain and Physical Function scales [28]. Test-retest reliability for the pain and physical function subscales have both been reported at 0.68 (Kendall's tau) [29]. Internal consistency scores (Cronbach's alpha) have been reported at 0.86 (pain subscale) and 0.95 (physical function). Moderately strong correlations have been noted between WOMAC scores (pain and physical function) and the SF 36 in arthritis populations [29]. The five pain and 17 physical function items are rated on an ordinal scale of 0 to 4, with lower scores indicating lower levels of symptoms or functional limitations. Summing the scores for each subscale item produces a WOMAC pain scale score of between 0 (best) and 20 (worst) and a WOMAC physical function score between 0 (best) and 68 (worst).

Weight was measured using standard protocols from the Coronary Artery Risk Development in Young Adults (CARDIA) epidemiology study [30].

All outcome assessments were done at baseline and 3-month follow-up by research assistants blinded to the participants' randomized group assignment.

Statistical Analysis

Participant data were analyzed as intention-to-treat. The mean change in the outcomes of interest from baseline to 3 months were compared between the intervention and control groups using 2-sided t-tests at a significance level of 0.05. Mean change and corresponding 95% confidence intervals (CI) from baseline to 3 months for intervention and control groups and the difference of treatment effect (i.e. mean difference of change between intervention and control groups) were estimated.

Multiple regression with generalized estimating equation methodology was used to compare the intervention and control groups. Included in the regression model were a time indicator (baseline and 3 months), a group indicator (intervention or control group), and their interaction term as covariates. The differences between intervention and control group improvement in the outcomes were examined by estimating the regression coefficients of the interaction between the group indicator and time. All analyses were performed with SAS v9.4 (Cary, NC).

Results:

524 employees enrolled in the registry, of which 221 met symptom and BMI criteria for the study. The telephone interview (Table 1) excluded 27, 72 could not be contacted, and 51 declined to participate, leaving 71 participants who were invited into the run-in trial.

At the end of the 4-week run-in trial, 33 participants were excluded: 6 were too active, 11 failed the medical screening, and 16 decided not to continue before randomization. This left 38 participants (54% of those in the run-in) who were randomized into the JointADventure intervention (n=19) or waitlist control (n=19) groups (Fig. 1).

Baseline characteristics of the 38 participants are reported in Table 2. Overall, participants average age was 53 years (ranged 37-63 years) and average BMI was 34.7 kg/m^2 (range 25-44). Participants were primarily female (71%), white (53%), and 24% of the participants did not have radiographic knee OA defined as K-L grade ≥ 2. There were no significant differences between JointADventure and waitlist control groups in demographic characteristics at baseline (Table 1). A total of 29 randomized participants (76%) completed the 3-month assessment, with no difference in attrition between groups and no baseline characteristic differences between those who did vs those who did not complete the 3-month assessment.

At 3 months, JointADventure participants increased their total physical activity an average of 10.84 minutes/day (95% CI: -15.63, 37.3) compared to a mean decrease of 4.09 minutes/day (95% CI: -38.71, 30.54) in the control group. Mean daily minutes of moderate-vigorous physical activity also increased by 4.02 min/day (95% CI: -4.19, 12.23) in JointADventure and decreased by 1.21 min/day (95% CI: -8.59, 6.17) in the control group. Participants in JointADventure experienced a mean weight loss of 1.9 kg (95% CI: -3.5, 0.4), while the mean weight of the control group did not change (0 kg, 95% CI: -1.2, 1.2). Mean WOMAC pain and function scores improved by 0.55 units (95% CI: -1.76, 0.67) and 1.64 units (95% CI: -5.93, 2.65) respectively in the intervention group. In the control participants, the mean pain score improved by only 0.08 units (95% CI: -1.95, 1.78) and the mean function score worsened by 3.06 points (95% CI: -2.42, 8.54) (Table 3).

Overall group and individual session attendance for those in JointADventure was 56% and 65%, respectively. No intervention-related adverse events were reported.

Discussion

The aims of this pilot study were to demonstrate the feasibility and potential effectiveness of the JointADventure intervention in an employee population with chronic knee symptoms. The trial randomized approximately 21% of employees who met all eligibility criteria for the study and 76% of randomized participants completed the 3-month assessment. The MI-based JointADventure intervention resulted in improvements in objectively-measured physical activity, weight, and self-reported pain and physical function outcomes at 3 months. Despite some challenges with session adherence (56-65%), the JointADventure intervention shows some potential to improve health outcomes in employees with chronic knee symptoms.

While the improvement in mean daily total physical activity (about 11 minutes/day) and mean moderate/vigorous physical activity (more than 4 min/day) were substantial, the magnitudes of improvement in weight (about 2 kg), pain (0.55 WOMAC pain units), and function (1.64 WOMAC function units) were small. In comparison, Messier reported mean improvements in weight of 8.7 kg and 4.6 units and 16.5 units of improvement in WOMAC pain and function scores respectively at 6 months of follow-up for those receiving the more intensive IDEA trial's diet/exercise intervention.[12] Possible explanations for smaller changes in JointADventure include it being a shorter and less intensive intervention and its physical activity component promoted lifestyle changes as opposed to participating in a prescribed exercise program. Additionally, it was conducted in the worksite, which may have different challenges than interventions

either done at home or in a clinic. The JointADventure study population was also different from the IDEA trial. The mean age of our trial's participants was 53, and a mean K/L grade of 2.2 with more than half either having no radiographic OA (K/L grade 0 or 1) or mild OA (K/L grade 2) whereas the IDEA trial participants had a mean age 66 and a mean K/L grade of 2.6.

Worksite interventions for persons with chronic knee symptoms are understudied. A study that tested a workplace exercise intervention prior to work hours conducted among older (>50 years) working age adults with osteoarthritis did result in reduced pain [31], but function and weight loss outcomes were not reported. In contrast, our JointADventure intervention was designed to focus on lifestyle physical activity (not prescribed exercise) and achieving weight loss goals through MI to encourage sustained behavior change. More work is needed to better understand how to effectively target lifestyle PA within the worksite among those with knee symptoms and sustain changes long-term.

A key obstacle for JointADventure and the other worksite behavioral interventions was session adherence over the 3 months. Group session attendance was 56% and the individual session's attendance was 65%. Other worksite studies focused on improving general health have also shown trends of low participation rates[32, 33]. Challenges with in-person session adherence at the workplace may be related to management support, work demands, and ability to work remotely. Further research focused on improving participant engagement is needed to enhance the scalability of this worksite intervention, perhaps with increased reliance on technology to allow for more time-efficient virtual or phone sessions that could occur outside of work hours.

Limitations of this study include a small sample size, the possibility of migration bias due to participant dropout and missing data, and the lack of generalizability due to the single site nature of the trial. Study strengths include its unique attention to employees with chronic knee symptom and a worksite intervention that focused on lifestyle physical activity and incorporated motivational interviewing principles.

Conclusion

While the delivery of the JointADventure intervention led to suboptimal adherence due to time conflicts with work, this MI-based intervention was moderately successful at increasing physical activity levels, reducing weight, and improving pain and function in employees with overweight/obesity and with or at risk for KOA. Further research on similar but more flexible and efficient MI-based intervention may eventually yield a scalable worksite program that improves physical activity and dietary behaviors as well as pain and functional outcomes.

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Tables and Figures:

Table 1. JointADventure study telephone interview criteria for persons already enrolled in chronic knee pain research registry

Age > 18
No diagnosis of primary fibromyalgia
No co-morbidity more functionally limiting than knee OA
Ability to walk at least 50 feet at a time
Ability to read and speak English
No comorbid condition that contraindicated a physical activity or dietary intervention
No total joint replacement surgery within 1 year and no plans for total joint replacement in the next 12 months
No plans to relocate away from the Chicago-land area in the next 12 months
Not being on a special diet that was inconsistent with the DASH diet
Not already being involved in a weight loss program within the past 3 months

Table 2. Baseline characteristics of randomized participants.

	All N=38	Intervention N=19	Control N=19
Gender, N (%)			
Female	27 (71.1%)	13 (68.4%)	14 (73.7%)
Age, mean (SD)	52.9 (7.3)	53.6 (7.3)	53.1 (7.5)
Race, N (%)			
White	20 (52.6%)	13 (68.4%)	7 (36.8%)
Marital Status, N (%)			
Married	21(55.26%)	10 (52.6%)	11 (57.9%)
K-L Grade, N (%) (K-L grade of worse knee)			
0-1	9 (23.7%)	5 (26.3%)	4 (21.1%)
2	13 (34.2%)	6 (31.6%)	7 (36.8%)
3	9 (23.7%)	4 (21.1%)	5 (26.3%)
4	7 (18.4%)	4 (21.1%)	3 (15.8%)
BMI, mean (SD), kg/m^2	34.7 (6.1)	35.3 (6.4)	34.0 (5.8)
Weight, mean (SD), kg	97.2 (16.9)	100.2 (18.1)	93.0 (14.5)

Baseline characteristics of the randomized participants overall and in their respective group, presented as N (percentage) or mean (standard deviation). Abbreviation: BMI, Body Mass Index; K-L, Kellgren-Lawrence. Age of all participants ranged from 37 to 63. BMI ranged from 25 to 44.

Table 3. Baseline, 3 month follow-up, and changes in outcome measures

	Baseline		3M Follow-up		Change from baseline to 3M		
	Intervention N=19	**Control N=19**	**Intervention N=14**	**Control N=14**	**Intervention N=14**	**Control N=14**	**Int-Ctrl Treatment effect**
	Mean (SD)				**Mean change (95% CI)**		**Difference of Change (95% CI)**
Total physical activity (minutes/day)	257.57 (54.17) N=19	265.96 (53.38) N=19	271.30 (56.39) N=14	261.44 (72.96) N=14	10.84 (-15.63, 37.3) N=14	-4.09 (-38.71, 30.54) N=14	14.92 (-26.54, 56.39)
Moderate-vigorous physical activity (minutes/day)	22.47 (14.13) N=19	21.41 (13.84) N=19	27.75 (21.07) N=14	19.28 (16.54) N=14	4.02 (-4.19, 12.23) N=14	-1.21 (-8.59, 6.17) N=14	5.23 (-5.28, 15.74)
Weight (kg)	100.9 (19.2) N=19	93.7 (15.3) N=19	98.9 (18.9) N=18	93.7 (15.3) N=14	-1.9 (-3.5, 0.4) N=14	0 (-1.2, 1.2) N=14	-2 (-3.8, 0.1)
WOMAC Pain	4.45 (2.11) N=18	5.17 (3.27) N=18	3.91 (2.95) N=11	5.08 (3.6)0 N=12	-0.55 (-1.76, 0.67) N=11	-0.08 (-1.95, 1.78) N=12	-0.46 (-2.60, 1.68)
WOMAC Function	12.38 (6.53) N=18	13.23 (9.38) N=18	10.74 (7.04) N=11	16.3 (10.77) N=12	-1.64 (-5.93, 2.65) N=11	3.06 (-2.42, 8.54) N=12	-4.70 (-11.33, 1.93)

Figure 1. Consort diagram of enrollment process.