MobilWise: A worksite program for persons with chronic knee symptoms

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Introduction

An epidemic of arthritis-associated disability is expected in the US over the next 2 decades, largely fueled by the aging population and the tremendous surge in knee osteoarthritis (KOA) prevalence secondary to obesity and knee injury [1, 2]. Simultaneously, the average age of retirement is trending to 66 years and older for financial and other reasons [3]. Given that more than half of those with KOA are under 65 years of age, a large proportion of those suffering with knee symptoms will still be in the workforce [2, 4] as their symptoms intensify. Increasing physical activity (PA) levels is an evidence-based way to decrease both the severity of chronic knee symptoms and the risk of disabling consequences of knee OA, as well as other chronic diseases [5, 6].

Despite the known health benefits of PA in those with and at risk for knee OA and other chronic conditions, participation rates are low [7]. Between 2007 and 2014, 46% of all employed adults failed to meet U.S. recommendations for PA [8], resulting in increased employee health challenges and expenses [9]. Further, physical inactivity is noted as one of ten modifiable health risk factors collectively linked to more than one-fifth of employer-employee healthcare spending [10], and has been associated with absenteeism [11], decreased work productivity, and increased employee health challenges/expenses [9]. Employers have developed a stake in getting employees moving [12, 13]. Therefore, the purpose of this pilot study was to evaluate the effect of a worksite intervention (MobilWise) on PA behavior and its feasibility in employees with chronic knee symptoms working at a large health insurance firm in downtown Chicago.

Methods

Design:

A three-armed randomized controlled trial was designed to estimate the effect of a PA intervention, MobilWise (self-monitor + remotely-coached), compared to both a Fitbit Only (self-monitor only group, without remote coaching), and a wait-list control group on objectively-measured moderate to vigorous physical activity (MVPA).

This research protocol was approved by the Rush University institutional review board. All participants gave informed consent. Employees were recruited via customized website link, which was disseminated with the support of the company's central administration in corporate announcements. This website detailed the study requirements, then directed interested employees to an initial screening tool and online consent. The recruitment material messaging was tailored to attract employees with chronic knee symptoms who wanted to increase their physical activity. Inclusion criteria required that employees be $\geq$ 18 yrs., have chronic knee symptoms (pain, aching, or stiffness on most days of the last month), be able to ambulate at least 50 ft., speak and read English, have a BMI < 40 kg/m^2, and return at least 3 valid days (defined as 10 or more wear hours per day) of accelerometer monitored PA data. Potential subjects were excluded if a) PA was contraindicated by a comorbid condition, b) fibromyalgia or inflammatory arthritis was a primary diagnosis, c) total joint replacement surgery had taken place or was planned within the year, or d) subjects had a co-morbidity that was more functionally limiting than the knee symptoms (e.g. spinal stenosis, peripheral vascular disease or residual effects of stroke).

Potential subjects were additionally screened in person for uncontrolled hypertension (Systolic blood pressure >160, or Diastolic blood pressure >110), diabetes (HgA1c >9), and contraindications for increasing PA levels (Physical Activity Readiness Questionnaire [14]). Subjects were randomized to either MobilWise , Fitbit Only, or waitlist control group. Randomization was stratified based on current PA tracker ownership/use (yes/no) and meeting/not meeting PA recommendations of 150 minutes/week of MVPA. It was believed that

persons already using a personal fitness tracker would not stop wearing it if randomized to the waitlist control group, so they were only assigned to one of the two intervention groups.

Intervention:

Both the MobilWise and Fitbit Only intervention groups received PA trackers (Fitbit Flex) for self-monitoring, plus an education session on PA principles/safety, tracker use, and the expected synchronization protocol. Participants were required to synchronize their Fitbits with the Fitbit App at least twice weekly, which in turn sent data to the Fitabase® research data storage service. Both groups' trackers were observed for battery life and synchronization activity, but only the MobilWise group's PA data was observed and tracked by study personnel during the intervention period. The MobilWise group additionally received a goal-setting session with the coach at the beginning of the intervention, guided by the principles of supportive accountability theory [15] and motivational interviewing [16]. There after, MobilWise participants received weekly motivational interviewing-based coaching sessions by phone for 12 weeks. During these sessions, the MobilWise coach reviewed PA performance data with participants (visible via Fitabase®), examined potential barriers to progress toward PA goals as well as solutions with the participants, and set new goals. After the end of the 3-month intervention, there was an additional 3-month no-contact observation period. The waitlist control group received a similar intervention after the 6-month assessment.

Outcome Measures:

The primary outcome measure was weekly MVPA minutes, as measured by accelerometer (ActiGraph GT3x+). 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 at baseline, immediately

following the intervention (3-months) and after a 3-month observation period (6-months). 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 [17]. To provide reliable estimates, we restricted analyses to participants with at least three valid days of accelerometer monitoring [18]. Nonwear periods were defined as more than 90 minutes with zero activity counts, allowing for 2 minutes of interruption with 30-minutes upstream and downstream screening for artificial movement. A valid day of monitoring was defined as 10 or more wear hours in a 24-hour period. Physical activity measures were summarized as average weekly minutes of moderate-vigorous physical activity (counts of ≥2020 counts per minute) [19].

Enrollment rate was calculated by dividing the number of employees responding to the initial screening tool by the number of consents obtained. Retention rates were calculated by dividing the number of participants completing the protocol by the number of persons initially enrolled. Fitbit wear and synchronization adherence were calculated by tracking the percentage of participants who synchronized their Fitbits the required number of times.

Analysis:

To evaluate the effect on MVPA behavior of both intervention and control groups over time, we used quantile regression to model change in median weekly MVPA minutes. Bootstrapping methods were applied to take into account repeated measures (i.e. baseline-to-3 month change, baseline-to-6 month change). The model included indicator variable for time, group membership (control and two intervention groups) and their interaction as covariates. Median weekly MVPA minutes and 95% confidence intervals (CI) are reported. To examine the impact of previous tracker experience, we conducted similar quantile regression models by

using indicators to represent 5 groups: three *No Previous PA Tracker* groups (MobilWise, Fitbit only, and Wait list control), and two *Previous PA Tracker* groups (MobilWise and Fitbit only).

All statistical analyses were conducted using Stata/SE 13.1 (StataCorp LLC, College Station, TX) and SAS version 9.4 (SAS Institute, Cary, NC).

Results:

Subjects: Fifty-eight participants were randomized to treatment arms: MobilWise (n=20), Fitbit Only (n=21) , and Waitlist Control (n=17). At baseline, participants were 72% female, 57% Caucasian, with mean age 50.4 years (SD=9.1), and mean BMI 32.8 kg/m^2 (SD= 7.2). There were no significant differences among the groups in age, gender, race/ethnicity, or BMI. Fifty participants provided data at the 3-month follow-up and forty-eight participants provided data at the 6-month follow-up.

Feasibility: We assessed the feasibility of conducting a larger RCT by tracking enrollment, which showed that 63% of those screened via web tool signed a consent to participate. Retention rates by group were 95% (MobilWise) and 80% for both the Fitbit Only and waitlist control groups. Study completers (n=48) versus non-completers (n=10) were similar in age, gender, and BMI. Of the 36 persons participating in the MobilWise and Fitbit Only groups, 93% synchronized their study monitor as directed per the protocol on the Fitabase® data storage system. For those participating in MobilWise, 100% completed weekly coaching encounters during weeks 2-12.

Main Outcome: Both intervention groups experienced gains in baseline-to-3- month median weekly MVPA at the end of the formal 3-month intervention [MobilWise: 19 minutes/week (95%CI: -49.7, 87.7); Fitbit Only: 31.3 minutes/week (95%CI: -4.4, 66.9)], while the control group decreased MVPA activity: -17 minutes/week (95%CI: -39.2, 5.2).

At post-intervention follow-up, the MobilWise baseline-to-6-month median gain in MVPA was attenuated to 8 minutes/week (95%CI: -51.4, 67.4), while the Fitbit Only group baseline-to-

6-month median MVPA change was -12.5 minutes/week (95%CI: -62.5, 37.5). The waitlist control group baseline-to-6 month median MVPA was diminished [-15 minutes/week (-52.1, 22.1)] (Table 1).

Results were further stratified by group membership, based on participants' previous tracker experience. Those in the two intervention groups with no previous tracker experience showed baseline-to-3-month median increases in MVPA [MobilWise: 50.7 minutes/week (95%CI: -24.4, 125.7); Fitbit Only: 31.3 minutes/week (95%CI: -109.0, 171.5)], and baseline-to-6 month median increases [MobilWise: 38.0 minutes/week (95%CI: -15.6, 91.6); Fitbit Only: 21.0 minutes/week (95%CI: -44.0, 86.0)]. However, those who previously owned trackers showed less median improvement in baseline-to-3-month MVPA [MobilWise: 19.0 minutes/week (95%CI: -85.6, 123.6); Fitbit Only: 5.0 minutes/week (95%CI: -41.2, 51.2)], and decreased median baseline-to-6 month MVPA [MobilWise: -36.8 minutes/week (95%CI: -127.1, 53.4); Fitbit Only: -50.0 minutes/week (95%CI: -102.4, 2.4)] (Table 2).

TABLE 1. Median change in weekly MVPA minutes from baseline (95% CI)*

		MobilWise (n=19 participants)	**Fitbit only (n=17 participants)**	**Wait list control (n=14 participants)**
Baseline-to-3 month change at end of formal coaching	Median (95% CI) **	19 (-49.7, 87.7)	31.3 (-4.4, 66.9)	-17.0 (-39.2, 5.2)
Baseline-to-6 month change	Median (95% CI) **	8.0 (-51.4, 67.4)	-12.5 (-62.5, 37.5)	-15.0 (-52.1, 22.1)

*50 participants at baseline and 3-month follow-up, 48 participants at 6-month follow-up

** Medians and 95% CI's are based on median quantile regression models; (+) in change indicates increased weekly MVPA minutes from baseline, (-) in change indicate decreased weekly MVPA minutes

TABLE 2. Median change in weekly MVPA minutes from baseline (95% CI) by previous fitness tracker ownership*

		No Previous PA Tracker			Previous PA Tracker	
		MobilWise (n=6 participants)	**Fitbit only (n=7 participants)**	**Wait list control (n=14 participants)**	**MobilWise (n=13 participants)**	**Fitbit only (n=10 participants)**
Baseline-to-3 month change at end of formal coaching	Median (95% CI)**	50.7 (-24.4, 125.7)	31.3 (-109.0, 171.5)	-17.0 (-39.3, 5.3)	19 (-85.6, 123.6)	5.0 (-41.2, 51.2)
Baseline-to-6 month change	Median (95% CI)**	38.0 (-15.6, 91.6)	21.0 (-44.0, 86.0)	-15.0 (-50.7, 20.7)	-36.8 (-127.1, 53.4)	-50.0 (-102.4, 2.4)

*50 participants at baseline and 3-month follow-up, 48 participants at 6-month follow-up

** Medians and 95% CI's are based on median quantile regression models; (+) in change indicates increased weekly MVPA minutes from baseline, (-) in change indicate decreased weekly MVPA minutes

Discussion

This pilot study is the first to our knowledge to use Fitbits in a workplace PA intervention targeting persons with knee OA symptoms. With the corporate leadership engagement and support demonstrated in this pilot, the feasibility of conducting a larger RCT was supported by the ease of enrollment using web-based corporate communications already in place, high

adherence to coaching calls, and retention rates, which ranged between 80 and 95%. The intervention groups (MobilWise and Fitbit Only) increased their MVPA at three months, however, unexpectedly, only those who had not had a fitness tracker previously showed improvements in MVPA at six months. MobilWise was beneficial in persons both with and without previous PA tracker experience, while the positive impact of the Fitbit Only intervention seemed limited to persons without previous tracker experience. Since it is estimated that 27% of adults use wearable fitness technology [20], future PA intervention studies may need to keep tracker ownership/use history in mind, as it appears to play a role in PA outcomes.

Improvements in PA in this study were most apparent after the 3-month intervention period, with median weekly MVPA minutes increased by 19 to 31 minutes for the MobilWise and Fitbit Only groups respectively. Other PA promotion interventions with similar methodology (Fitbit + goal setting/other prompts or incentives) or similar populations, but varying in length from 10 weeks to 6 months, reported comparable modest or greater increases in MVPA, ranging from 37-115 min/week [21-25]. Although some studies have suggested that Fitbit alone may be beneficial [26, 27], results have been mixed [22]. Further research is needed to determine the optimal combination of behavior change strategies and technology to increase physical activity in those with knee OA symptoms.

The effects of the MobilWise intervention were moderately well sustained at the 6-month post-intervention follow-up in this group, with median MVPA gains attenuated to 8 min/week. These results are consistent with previous PA interventions demonstrating that removal of intervention supports may be associated with PA behavior that drifts back towards baseline levels [28]. It is also possible that PA intervention habituation (decrease in response to a stimulus after repeated stimulus exposure over time) was occurring. The introduction of a new and different intervention feature may be necessary once the novelty of the previous intervention has worn off. A stepped-approach that involves introducing new or additional

behavioral strategies throughout the intervention has shown promising results in other PA interventions and populations [29].

Despite the small sample size, the strengths of our study included the acceptability/usage of Fitbits, good retention rates, and high adherence to the coaching calls in this employee population. The workplace community seems to be an ideal venue to attract and retain participants with chronic knee symptoms who wish to make positive lifestyle changes that may lower their risk of future knee osteoarthritis development.

Conclusion

In a large urban company, this pilot randomized controlled trial demonstrated the feasibility and beneficial effect of a 3-month PA intervention, MobilWise (Fitbit + remote coaching), compared to both a Fitbit Only (without remote coaching), and a wait-list control group on objectively-measured MVPA in employees with chronic knee symptoms. Both technology-based PA interventions were beneficial for employees, compared to waitlist controls to increase baseline to 3-month MVPA.

• **Key words and indexing key words 2344 words**

Key Words: Physical activity, Accelerometer, Fitbit, Osteoarthritis, Employees

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