Physical Activity in the Medical Workplace: A way to improve physical and mental well-being?

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Abstract
Many Americans do not meet the physical activity guidelines and the majority of Americans are overweight or obese. Decreased physical activity is not only associated with multiple chronic medical conditions, including obesity, but also with depressed mood, and other negative emotions. As many employed adults spend a great deal of time at work where we are predominantly sedentary, strategies to increase physical activity at work are being pursued to help improve the physical and mental health of Americans. This 17 week randomized controlled trial will investigate changes of occupational physical activity in three groups: those provided with a FitBit® but not able to monitor their activity level, and those provided with activity goals and individual physical activity challenges, and those who do not use a FitBit®. We hypothesize that providing awareness of occupational physical activity level as measured by an accelerometer (FitBit®) will increase occupational physical activity. In addition, we hypothesize that as measured by the SF-36® and perceived stress scale questionnaire measures of emotional health will also improve.

Specific Aims/Objectives

1. We hypothesize that utilizing a FitBit® to monitor activity level (i.e. Step count); will lead to increased occupational physical activity (OPA).

Background
Less than a third of American adults reach the CDC physical activity guidelines [2]. Many of our occupations are sedentary and lead to decreased time in physical activity [3, 4]. Being sedentary is associated with multiple adverse health outcomes, including obesity [5, 6]. In an effort to improve health, many workplaces and schools are attempting interventions to help increase occupational physical activity (OPA) [7].

In addition to general health benefits, participation in regular physical activity has been associated with decreased risk of depressive symptoms [8]. A review of school and workplace interventions to increase physical activity found that after the intervention there were improvements in self-esteem, self-efficacy, satisfaction and commitment while there were decreases in anger, difficulty concentrating, fatigue, stress and feelings of sadness and depression [7]. A variety of interventions have been tried in numerous settings, many using self-report or questionnaires of physical activity [7, 9]. Interventions utilizing pedometers and providing activity goals have been successful at increasing OPA at a multi country university study [9]. Correlations with the improvement in OPA with markers of physical and mental well-being were not performed [9].

Our goal with this study is to further investigate the efficacy of workplace interventions to improve physical activity as measured by an accelerometer (FitBit®). The FitBit® has been previously validated as a reliable step counter [10]. Our workplace includes many different occupations and we will investigate if participant knowledge of OPA level leads to improved OPA levels. Further, if there is an increase in OPA, is this associated with weight loss and with decreased feelings of sadness and depressive symptoms.

Project Design/Methods

<u>Study Subjects</u>

All employees within divisions of DOM will be eligible to participate in the present study. This will be a 17 week randomized controlled trial with a 4-week run-in phase, a 12 week randomized intervention phase, and a 1 week post intervention phase.

Inclusion criteria:

1. Be between 18 – 65 years of age
2. Be a Mayo Clinic employee at 0.75 FTE or more
3. Have not used an activity monitor within 2 weeks of study entry
4. Agrees not use any other activity monitor during study participation
5. Not be pregnant by subject self-report
6. Have a stable weight-defined as self-reported weight that has not changed more than 10% in the past 3 months
7. Not have any previous history of joint problems that limit free movement, as determined by the PI
8. Be able to participate fully in all aspects of the study
9. Have understood and signed study informed consent

Exclusion criteria:

1. Have a known history of any condition or factor judged by the investigator to preclude participation in the study or which might hinder adherence or skew data collection – such as a position where they predominantly provide transport as part of their job

Study Groups

We propose to recruit, consent and screen 270 subjects through IRB approved contact materials such as e-mail, phone call, flyers, and classified advertisements in order to randomize 135 to study. All subjects who respond will be pre-screened for inclusion and exclusion criteria via a telephone pre-screen. Those who meet criteria will be invited to a consent visit followed by a study screening visit. After consent and screening has taken place, subjects who meet all study entry criteria will be invited to participate in the study.

When a subject is found to be eligible for the study, they will be asked by the study staff to create a google email which will be used by the study to download their weekly fitbit data. Subjects will not have access to this google email password since they need to remain blinded to the fitbit data during the trial, but the email and password will be returned to them at the end of the study and they will be shown how to change their password so that it can remain confidential. They will also be informed that they will be able to keep the fitbit assigned to them once they complete all 17 weeks of the study. The google email is used by the study staff to download their weekly data in an online account and this is the outcome data needed for the study.

The first 20 subjects enrolled in the study will be asked to participate in an additional validation phase. For this validation phase of the subject will be asked to wear a FitBit® on both wrists and walk on a treadmill, located in the DAHLC, while the study coordinator records their steps manually using a clicking device. The subject will be asked to walk for 5 minutes at 0.9 MPH, followed by 5 minutes at 3.0 MPH and 5 minutes at 4.0 MPH. They will then be asked to continue on with the blinded run-in phase.

All eligible subjects will be invited to participate in 4-week run-in phase using the FitBit® while at work and be blinded to the FitBit® daily activity recording. This run-in phase will be used to collect baseline OPA data for each subject. During the run-in phase subjects will be provided with a FitBit® but will not be made aware of their OPA level. FitBit® accounts will be created and maintained by the study team. The FitBit® itself will have the displays covered so that it will not be available for the subject to read during the blinded phase(s). During this time subjects will be asked to wear their FitBit® while working and leave the FitBit® at their desk at the end of

each day. The FitBit® will be collected by study staff at the end of the subjects' workweek. During which time the coordinating staff will download the weekly data and recharge the devices. They will then return the devices to the subjects at the beginning of their work week. At the end of the 4-week run-in-phase (baseline) they will be randomized into one of the three 12 week intervention arms using a computer-driven random number generator created with the help of statistician. The groups to which they will be randomized will be:

1. **Group 1** (control group)- participants will be **blinded** to their OPA during the entire study (run-in and randomized intervention phases).
2. **Group 2** (intervention group)- This group will be able to access their FitBit® activity data by viewing the display, therefore they will be **unblinded** during the randomized intervention phase (and blinded during the run-in phase). Participants will be given a specific OPA target based on the results from the run-in phase. The principal investigator or one of the co-investigators will meet with the participants randomized into this intervention group. The investigator will meet with subjects within 1 week of the study visit (baseline and week 6). Based on the physical activity tracked during the baseline period, instructions will be provided to increase the OPA by 5 % a week as determined by their average OPA at their last study visit. If at the post 6 week study visit their OPA remains <5000 steps per day, we will encourage the same 5% per week increase in OPA. Various methods such as taking steps as much possible prior to taking elevators, lunch time walks, walking breaks, and walking meeting of non-patient related topics will be suggested. The daily FitBit OPA activity will be downloaded weekly by the study staff and a print out of the weekly activity will be placed in the subjects study files for use by the investigators during these feedback sessions with the subject.
3. **Group 3** (no FitBit® Group) – **No** FitBit® during the 12 week randomized intervention phase.

As in the run-in phase, subjects will be asked to wear their FitBit® while working and leave the FitBit® at their desk at the end of each day. The FitBit® will be collected by study staff at the end of the subjects workweek. During which time the coordinating staff will download the weekly data and recharge the devices. They will then return the devices to the subjects at the beginning of their work week.

All subjects will be contacted for a final study visit via the telephone at 1 week post the randomized intervention.

At baseline, and 6 weeks after they start the randomization intervention and at the end of the randomization phase (12 weeks) all study participants will be asked to complete the perceived stress scale, the SF 36 scale and be measured by the InBody 770®. In addition, subjects in group 2 will meet with one of the study investigators. OPA during the first 6 weeks of intervention period would be reviewed. For participants who have met the goal OPA, only feedback to continue the OPA would be provided. For participants who have not met the goal OPA, further instructions will be provided to improve the OPA.

Sample Size

A sample size of 42 in each group will have 80% power to detect a difference in the mean of 2.5% weight loss difference between a Group 1 and Group 2, or Group 1 and Group 3, or Group 2 and Group 3 assuming that the common standard deviation is 4.00 using a two group t-test with a 0.050 two sided significance level as shown below. Adding a control will not change the sample size required in each group since, there will only be a comparison between only two groups at a time.

Two group t-test of equal means (equal n's)

Column	1	2	3	4
Test significance level, α	0.050	0.050	0.050	0.050
1 or 2 sided test?	2	2	2	1
Group 1 mean, μ_1	2.500	2.500	2.500	2.500
Group 2 mean, μ_2	5.000	5.000	5.000	5.000
Difference in means, $\mu_1 - \mu_2$	-2.500	-2.500	-2.500	-2.500
Common standard deviation, σ	6.000	5.000	4.000	4.000
Effect size, $\delta = \lvert\mu_1 - \mu_2\rvert / \sigma$	0.417	0.500	0.625	0.625
Power (%)	80	80	80	80
n per group	92	64	42	33

From the research studies conducted at Mayo Clinic in the past, there is a 6 – 7% drop out rate in the recruitment. To account for this drop-out rate, we propose to include 45 subjects in each arm of the study. We acknowledge that achieving a 2.5 % change in body weight might not be clinically feasible.
We propose to run this study as pilot study to estimate the amount of weight loss, change in body fat percentage and improvement in satisfaction level. We propose to run a larger randomized controlled study using this as preliminary data.

Data Collection

All data will be collected by the Study coordinator or by an online RedCap survey emailed to the subject. After consent and screening is completed, Perceived stress scale questionnaire and SF-36®, height, weight and InBody 770® scan will be collected, followed by providing the participant with his/her FitBit® for the run-in-phase. After the 4-week run-in-phase is completed, subjects will come in for randomization to one of the groups described above.

FitBit® devices will be collected on a weekly basis to download activity levels and charge the devices. A FitBit® account will be created for each study participant by the research coordinator to allow us to track activity level while keeping all participants blinded during the run-in-phase and group 1 blinded during the randomized intervention phase . FitBit® display will be hidden from the wearer for Group 1. For Group 2, The online program will allow us to limit the information the FitBit® wearers see so that the FitBit® can be specific to the goals set by the investigators. We will repeat the perceived stress scale questionnaire, SF-36® and InBody 770® after 6 weeks in the intervention phase and at week 12 which is the end of the randomized intervention phase.

One week after the completion of the study, we will complete one phone visit with each of the subjects.

Subjects must wear the FitBit® at work for a minimum of 48 days out of the possible 60 days during the randomization phase.

Data Handling

To ensure the confidentially of the subjects participating in the present study; no names, social security numbers, hospital or clinic numbers will be included in the biostatistics databases. Names, addresses, telephone numbers, and any other information needed for recruitment, study involvement, and tracking will be obtained and maintained by the project personnel in a secured server with limited access. In addition, all study data (i.e. data collection forms as well as regulatory paperwork) will be maintained on a secure file server or in locked research data storage rooms to which only designated project staff will have access. All computer files and systems will be password protected and accessible by authorized personnel only. Data entry and transfer will be performed by the study staff after IRB approval.

Data Analysis

For our current study, participants need to complete the study with the requested data to be considered evaluable for the analysis. We will use a t-test to compare groups (from the eligible participants). A 2-sided p-value < 0.05 would be considered as statistically significant. If the data are highly skewed or non-normal, we will use the Wilcoxon Rank-Sum test to compare groups (nonparametric method).

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