Study Title: Influence of Wearable Activity Monitors and Social Support on Physical Activity After Knee Replacement

Running Title: Fitbit and Social Support in Knee Replacement Patients & Buddies

Principal Investigator Name: Christine A. Pellegrini, PhD

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A. SPECIFIC AIMS

The current pilot study aims to gain preliminary data on the influence of wearables and social support on physical activity in total knee arthroplasty (TKA) patients following surgery. The specific aim for the study include:

1. To compare physical activity levels among TKA patients between Fitbit and Fitbit+Support over a 4 month period during the year following surgery.
2. To compare social support, fitbit acceptability, and adherence among TKA patients between Fitbit and Fitbit+Support after a 4 month period during the year following surgery

B. BACKGROUND AND SIGNIFICANCE

Patients undergoing TKA typically report improved health-related quality of life, increased physical function, and reduced pain.[1] Despite these improvements, physical activity levels remain unchanged, or only minimally increase from pre-operative levels, yet do not reach the same level of activity observed among healthy populations.[2,3] TKA patients often expect their activity levels and function to improve following surgery, but the majority of patients' activity levels 5 years post-operatively did not meet their pre-operative expectations.[4] Even though improvements are observed in pain and function, reasons for the maintenance of low levels of activity are unknown. Technology has the potential to increase physical activity levels in these patients, particularly as 81% of TKA patients in our recent study had a smartphone, and 40% were willing to wear a wrist-worn physical activity monitor. As the average age of TKA continues to decrease,[4] we anticipate that the percent of patients with a smartphone and willingness to wear an activity monitor will increase. In addition to technology, social support is associated with greater outcomes following TKA.[5] Thus, wearing a wrist-worn physical activity monitor and providing additional opportunities for social support via the technology may increase physical activity levels in these patients.

C. PRELIMINARY STUDIES

Twenty patients (11 pre-operative and 9 post-operative) between 47-79 years (55% male, 90% White, and 85% with a BMI ≥25 kg/m^2) completed a brief weight loss program preference questionnaire assessing preferred components of a weight loss program including social support. The most common sources of social support that patients reported as helpful while in a weight loss program were teaming up with another knee replacement patient (37%) and joining a program with a friend or family member (26%).[6]

Additionally, twenty patients completed qualitative interviews to examine the perceived social and environmental barriers and facilitators for healthy eating and activity before and after knee replacement. Healthy eating barriers included the availability of unhealthy food and attending social gatherings; facilitators included availability of healthy food, keeping unhealthy options "out of sight," and support from others. Weather was an activity barrier; facilitators included access to physical activity opportunities and support from others (Hoffman et al., under review)

D. RESEARCH DESIGN AND METHODS AND DATA ANALYSIS

Research Design. This is a pilot study in which participants who have recently had a knee replacement will be randomized to one of two conditions: (1) Fitbit or (2) Fitbit+Support. Participants will be recruited from multiple sources including social media (e.g., Twitter, online posts) and a local orthopedic group.

Screening. Participants and Buddy participants will be required to complete a brief screening online via RedCap. The screening will assess eligibility criteria and willingness to participate. Ineligible candidates will be notified via email within 1-2 business days. We will track reasons for exclusion, but we will not save personal information from ineligible candidates unless participants indicate they want to be contacted for future studies. Names and email addresses of participants interested in future studies will be kept separate from reason for exclusion. All screening data, with the exception of reasons for exclusion, will be destroyed after the final determination of eligibility has been made. Following the completion of the screener, eligible and interested participants will be invited to complete the informed consent process online.

Randomization. Participants will be randomized on a rolling basis to one of two conditions: (1) Fitbit or (2) Fitbit+Support. Participants will be randomized following the completion of the online consent, phone discussion answering any questions the participant may have, and completion of the baseline surveys.

1. **Fitbit.** Participants randomized to Fitbit will be mailed a Fitbit and encouraged to wear it over the next 4 months. The Fitbit captures data related to physical activity including the number of steps taken, minutes and intensity of activity, distance traveled, calories burned, sedentary time, and sleep (if participants choose to wear it while sleeping). We will ask participants to allow study staff access to any of the diet, activity, and weight information recorded on Fitbit via Fitabase, which is a secure service that facilitate access to the data; however we will not provide any intervention or coaching relating to diet, activity, or weight loss.

2. **Fitbit+Support.** Participants randomized to Fitbit+Support will be provided with a link to join the study to send to their Buddy. The link will direct the Buddy to the screener and consent form. Once the Buddy completes the screener, consent process and baseline surveys, a Fitbit will be mailed to both the participant and Buddy. Both participant and Buddy will be asked to "Friend" each other on Fitbit and encouraged to wear the monitor over the next 4 months. Becoming "Friends" on Fitbit allows them to see each others average step count for the past 7 days. Additionally, participants can compete in various challenges against each other such as the Workweek Hustle (who can take the most steps Monday-Friday) or Goal Day (who can reach their personal goal each day). Similar to the Fitbit only condition, we will ask participants and participant buddies to allow study staff access to any of the diet, activity, and weight information recorded on Fitbit via Fitabase. Also, we will not provide any intervention or coaching relating to diet, activity, or weight loss to participants or participant buddies in the Fitbit+Support condition.

Outcomes. Outcomes across both participants and participant buddies will be examined over the 4 month period. Participants will be asked to complete baseline surveys (demographics, social support, brief medical history) which should take approximately 10 minutes to

complete. Additionally, participants will be asked to complete a short survey (approximately 10 minutes) at the end of their 4 months to evaluate social support and acceptability of the Fitbit. Surveys will be administered using RedCap. All participants will be able to keep their Fitbit at the end of the study.

Table 1. Data Collection

	Baseline	**Continuous During 4 Months**	**4 Months**
Fitbit	- Participant Demographics - Social Support & Exercise Survey (SSES) - Inventory of Socially Supportive Behaviors (ISSB) - Knee Injury and Osteoarthritis Outcome Score (KOOS)	- Minutes of sedentary, light-, & moderate/vigorous activity -% of days Fitbit was worn	- KOOS - SSES - ISSB - Fitbit Survey - Health & Injury/Illness Report
Fitbit+Support	- Participant Demographics - Buddy Information Form - SSES – modified for Buddy - ISSB - KOOS	- Minutes of sedentary, light-, & moderate/vigorous activity -% of days Fitbit was worn	- KOOS - SSES – modified for Buddy - ISSB - Fitbit Survey - Health & Injury/Illness Report
Buddies	- Buddy Demographics - SSES – modified for Buddy - ISSB	- Minutes of sedentary, light-, & moderate/vigorous activity -% of days Fitbit was worn	- SSES – modified for Buddy - ISSB - Fitbit Survey - Health & Injury/Illness Report

1. **Physical activity** and **sleep** will be obtained from the Fitbit via Fitabase. Specifically, steps counted and time spent in sedentary, light, and moderate-to-vigorous intensity activity will be examined over the 4 months. Additionally, if worn overnight, time spent sleeping will be examined. We will control for 1) knee symptoms, obtained from the Knee Injury and Osteoarthritis Outcome Score (KOOS), 2) injuries/illness reported in the Health & Injury/Illness Report, and 3) changes in weight.

2. **Social support** will be assessed at baseline and 4 months using the Inventory of Socially Supportive Behaviors (ISSB) Short form (Barrera, 1981) and Social Support & Exercise Survey (SSES) (Sallis, 1986). The ISSB is a 19-item self-report measure that was designed to assess how often individuals received various forms of social support. The SSES is a 13-item survey that assess the level of support individuals felt they were receiving from family and friends relating to physical activity. Those randomized to

the Fitbit+Support and Buddies will be asked to also rate their support from their Buddy or TKA participant.

3. **Fitbit Acceptability & Engagement.** A brief 21-item survey will be completed at 4 months to assess the acceptability of the Fitbit activity monitor as well as how often participants used various features on Fitbit. Additionally, engagement with the Fitbit will be examined by determining the percentage of days over the 4 month period of time that the Fitbit was worn. Also, while not encouraged to record their diet, we will examine the amount of days participants record their dietary intake in Fitbit, as it may be an additional motivating factor to continue use the Fitbit.

Data Analyses. Basic demographic and baseline variables will be described for both the TKA patients and buddies. For the primary analysis, independent samples t tests will be conducted to compare physical activity levels between TKA patients randomized to Fitbit and Fitbit+Support at 4 months. Specifically, we aim to examine steps/day and moderate/vigorous intensity activity obtained from the Fitbit. We will also examine differences in 4 month social support, Fitbit acceptability, and adherence to Fitbit over 4 months.

E. PROTECTION OF HUMAN SUBJECTS

1. TARGET POPULATION:

We will aim to recruit 40 patients that have had a knee replacement within the last 12 months, of which 20 of these TKA patients will be recruited with a "buddy."

TKA Patients. Patients must: (1) have had a knee replacement in the last 12 months; (2) have a computer or smartphone/tablet compatible with Fitbit, (3) be English speaking, (4) willing to wear the Fitbit for 4 months, and (5) have a "buddy" willing to participate. TKA participants will be excluded if they have another knee replacement scheduled within the next 4 months.

Buddies. Patient buddies must: (1) have a computer or smartphone/tablet compatible with Fitbit, (2) be English speaking, and (3) willing to wear the Fitbit for 4 months.

2. RECRUITMENT PLANS:

We will target recruitment channels including: 1) promotions in publications with low or no advertising cost (i.e., Craig's List); 2) electronic and social media recruitment blurbs (i.e., Facebook, Twitter, website, email newsletter, electronic billboard, etc.); 3) relevant websites or blogs related to knee replacement that we will solicit to "post" current approved ads on their sites; 4) word of mouth; 5) posting flyers around USC campus area and local Columbia businesses and health centers; and 6) emails to TKA patients from previous studies who expressed interest in participating in future trials. All recruitment material will list study eligibility criteria and requirements and include a phone number, email address, and website where participants can reach staff if they have any general questions regarding study participation.

Additionally, patients will be recruited from local orthopedic centers. Surgeons and staff may identify potentially eligible participants and direct them to the website or to talk to research staff for more information about the study.

3. EXISTING DATA/SAMPLES:

Not applicable

4. CONSENT/ASSENT:
Informed consent will be obtained before entry into the study from all participants and buddy participants online via RedCap. Full disclosure will be made of the nature and potential risks of participating in the study. We estimate it will take approximately 5 minutes to read the online consent process. Prior to starting, all participants and buddy participants will be asked if they have any questions about their participation to ensure they understand the procedures.
The online consent form has been developed according to the requirements of the University of South Carolina Institutional Review Board.

A copy of all signed IRB-approved online consent forms will be saved.

5. POTENTIAL RISKS:
The risks of participating in this study are minimal. Participants may experience: 1) skin irritation from the Fitbit, 2) muscle soreness or pain if they increase their physical activity levels; 3) an injury as a result of their physical activity. Skin irritations from wearing the Fitbit have been reported in the press; however to date, we have not had any previous participants have any issues. In the event a participant experiences skin irritation, we will encourage him/her to not wear it until the rash goes away. Also, while we will not give participants physical activity goals or even encourage them to increase their activity, there is a chance that wearing the monitor may motivate them to increase their activity. Participants are encouraged to stop exercising immediately if at any time they are injured or are encouraged to stop engaging in physical activity from their physical therapist/physician/medical professional.

6. POTENTIAL BENEFITS:
Participants may or may not experience any benefits from participating in this study. If participants modify activity behaviors, they may be experience positive changes to health and mood. Additionally, this research may help us understand if social support can help to increase activity in TKA patients.

7. CONFIDENTIALITY
All of participants data will be deidentified, including the data obtained from Fitabase. Only study team members will have access to participant information and study data. Surveys will be completed electronically on RedCap. All survey data will be examined by study staff to ensure completion. Additionally, data (physical activity, sleep, and diet) will be obtained from Fitbit via Fitabase. The Fitbit app or website collects various information for their own use which we will be unable to control (Fitbit collects device information, battery level, IP address, height, weight, gender, and date of birth (to estimate energy expenditure), friends connected with within the app, purchases made from the Fitbit online store, and if connecting to social media, basic information from your social media account). Additionally, Fitbit and Fitabase will ask users to log in with a name and email address. Participants will have the option to use either their own personal email address (which makes it easier to use following the completion of the trial and more naturally replicate real-world Fitbit use) or can be provided with a confidential study name and email address. Any data downloaded from Fitabase will be coded with an ID and de-identified. All data will be uploaded from these secure sites by study personnel and saved on the department server. These data are stored behind an encrypted

firewall, and automatically backed up. Any paper data will be de-identified, and kept in the laboratory in a locked suite and cabinet. The legend for the codes will be stored in the laboratory in a locked cabinet on-site in access-controlled laboratory. All data will be stored at least 7 years after the completion of the study. All baseline data will be assessed for completion prior to randomization. Once randomized, Fitbit data will be examined regularly via Fitbit to ensure there are not any technological issues. During the 4 month study period, the only data that will be visible to study team members are related to physical activity, sleep, and diet. As we will not be able to determine any safety related issues from this data during the study, we will assess any injuries/illnesses that were experienced during the study period at the end of the 4 months.

8. COMPENSATION:

Participants will be provided with a Fitbit and allowed to keep it following the completion of the 4 month study. Participants who withdrawal will also be able to keep the Fitbit.

9. WITHDRAWAL:

Participants will be informed they can leave the research at any time without penalty. If a participant decides to withdraw, no more information will be collected. If a participant decides to withdraw and is in the Fitbit+Support group, the buddy can remain in the study. The same is true if a buddy decides to withdraw. Participants who withdraw from the study will be able to keep the Fitbit.

Any data collected during your participation in this research study prior to the date the participant chooses to withdraw consent may continue to be used by the investigators for the purposes described above.

Choosing not to be in the study will not result in any penalty or loss of benefit to which participants are entitled. Specifically, the choice not to be in this study will not negatively affect a participant's right to any present of future medical treatment or his/her present or future employment (for employees at USC or its affiliates).

F. REFERENCES/LITERATURE CITATIONS

1. HAWKER G, WRIGHT J, COYTE P, et al. Health-Related Quality of Life after Knee Replacement. Results of the Knee Replacement Patient Outcomes Research Team Study*. *The Journal of Bone & Joint Surgery.* 1998;80(2):163-173.
2. Harding P, Holland AE, Delany C, Hinman RS. Do activity levels increase after total hip and knee arthroplasty? *Clin Orthop Relat Res.* 2014;472.
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4. Nilsdotter AK, Toksvig-Larsen S, Roos EM. Knee arthroplasty: are patients' expectations fulfilled? A prospective study of pain and function in 102 patients with 5-year follow-up. *Acta orthopaedica.* 2009;80(1):55-61.
5. Waimann CA, Fernandez-Mazarambroz RJ, Cantor SB, et al. Effect of Body Mass Index and Psychosocial Traits on Total Knee Replacement Costs in Patients with Osteoarthritis. *J Rheumatol.* 2016;43(8):1600-1606.

6. Pellegrini CA, Ledford G, Hoffman SA, Chang RW, Cameron KA. Preferences and motivation for weight loss among knee replacement patients: implications for a patient-centered weight loss intervention. *BMC Musculoskelet Disord.* 2017;18(1):327.