Cover letter

Title: Physical Activity Trackers to improve Blood Pressure (PAT-BP)

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1 BACKGROUND AND OVERVIEW OF CLINICAL STUDIES

Increasing physical activity levels may improve cardiovascular health and BP levels in young individuals, especially if such strategies promote healthy lifestyles. Physical activity is currently recommended for adults CV health, but physical activity levels are known to be low in populations with diabetes or chronic kidney disease.[5,6,7,8] One prior study of the use of pedometers (not associated with wireless technology or provider feedback) in children with CKD did not significantly improve physical activity levels.[9] Supervised walking appeared to provide some benefit in individuals with type II diabetes, but overall compliance was poor.[9,10] Interview of adolescents and young adults with chronic illnesses has shown preference for the use of electronic devices and online tools for disease management.[11,12] Thus, use of sophisticated electronic devices such as FitBits© (wireless pedometers worn on the wrist that sync with cell phones) may improve disease control by engaging young patients in self-monitoring of their own health and lifestyle behaviors. FitBits© have been previously validated in clinical studies for the accuracy of step count.[13]

PROTOCOL SYNOPSIS

TITLE	Physical Activity Trackers to Blood Pressure (PAT-BP)
SPONSOR	NIH
FUNDING ORGANIZATION	NHLBI
NUMBER OF SITES	1
RATIONALE	The rationale for this study is to determine whether use of physical activity trackers (Fitbits) helps improving patient self-awareness of their fitness level and enhance healthy lifestyle changes that may lead to lower blood pressure. The potential benefits (increased walking on a daily basis and awareness of own fitness level) outweigh the risks in this study (anxiety about step count, minimal risk of loss of confidentiality).
STUDY DESIGN	This is a pilot randomized controlled trial. We will recruit 75 adolescents and young adults at UCSF. Patients included for study will be between ages 8-30 receiving anti-hypertensive therapy at the time of recruitment or have elevated BP > 120 mm Hg or > 95th percentile for age/sex/height if < 18 years of age.[14,15] ***Study intervention***. Daily use of physical activity tracker coupled with biweekly provider telemonitoring and feedback (via secure email, phone call, or text) will be compared to usual care (daily use of physical activity tracker with biweekly feedback for the latter 6 months of the study). The study intervention will last 6 months for patients in the usual care group and 12 months for patients in the intervention group. Physical activity and data will be reviewed by telemonitoring on a biweekly basis by study personnel. Patients will receive feedback on their progress from study personnel via patient-preferred communication modalities (secure e-mail, phone call, or text) biweekly. If daily step count is below desired goal (as per age-appropriate references),[16] patients will be provided with ideas on how to increase physical activity level/step counts (e.g. parking further from their destination and walking, taking stairs instead of elevator).
OBJECTIVES	To determine feasibility of a randomized controlled trial testing to effect of physical activity trackers on blood pressure levels.
	To determine potential effect sizes from the use of physical activity trackers on change in blood pressure.
NUMBER OF SUBJECTS	75

SUBJECT SELECTION CRITERIA	Inclusion Criteria: Patients included for study will be • Male or female between ages 8-30 receiving anti-hypertensive therapy at the time of recruitment. Wewill target patients with DM, non-dialysis requiring CKD, or kidney transplant, but will not exclude patients with other etiologies of hypertension who are deemed eligible (such as fibromuscular dysplasia). • Only patients with phones compatible for wireless device data transmission will be eligible. Wireless sync between Fitbit monitors and online account (provided by Fitbit which securely stores step count) will be set-up in clinic, and only patients who consent to grant study personnel access to home monitoring data will be enrolled. • Written informed consent (and assent when applicable) obtained from subject or subject's legal representative and ability for subject to comply with the requirements of the study. Exclusion Criteria: We will exclude patients with a history of decompensated congestive heart failure, pregnancy, cognitive impairment (and therefore inability to self-manage disease), non-ambulatory patients who are unable to perform physical activity, patients with BP >180/110 mm Hg, prisoners, patients with any contraindication to use or wear of home activity tracker (such as allergy to activity tracker band), or presence of any co-morbidity that would preclude physical activity (such as moderate or severe cerebral palsy).
TEST PRODUCT, DOSE, AND ROUTE OF ADMINISTRATION	**1.1 Fitbit (to be worn on the wrist).** Up to 75 eligible patients will be randomly assigned to Fitbit or usual care treatment groups in a 2:1 ratio using a randomization scheme developed by the study data management provider. Due to the objectives of the study, the identity of test and control treatments will be known to investigators, patients.
CONTROL ARM	Usual care is defined as routine clinical care for the first 6 months of the study and wearing a Fitbit for the last 6 months of the study.

STATISTICS **Primary Analysis Plan**	The primary feasibility outcomes will be tallied using simple proportions and descriptive statistics. Chi-square and other tests will be used to characterize participants who did and did not enroll. To examine differences in clinical outcomes, intention-to-treat analysis will be performed. Change in mean office systolic BP between 3 and 12 months, compared across usual care vs. intervention arms will be evaluated using t-tests and mixed linear models with an interaction term between time and randomization arm to evaluate change in office BPs at various time intervals both between groups and within-subjects.

APPENDIX 1. EXAMPLE OF SCHEDULE OF STUDY VISITS

	VISIT 1 (Day/Week/Month #)[a]	VISIT 2 (Day/Week/Month #)[a]	VISIT 3 (Day/Week/Month #)[a]	VISIT 4 (Day/Week/Month #)[a]	VISIT 5 (Day/Week/Month #)
Informed Consent	X				
Medical History	X				
Complete Physical Exam	X				X
Abbreviated Physical Exam		X	X	X	
Height	X	X	X	X	X
Weight	X	X	X	X	X
Randomization	X				
Quality of Health Survey[b]	X		X		X
Initiate Subject Diary	X				
Subject Diary Review		X	X	X	X
Adverse Experiences	X	X	X	X	X

[a] ±2 day

[b] The Quality of Health Survey may be administered over the phone or email if needed.