Documentation Date: 6/30/2019

IRB: 00039439

NCT03988751

Feasibility Assessment of the Wake Forest Real-time Tracking System for Monitoring Patient Movement during Postoperative Recovery: Part 2

IRB 00039439

Principal Investigator: Clancy J. Clark, MD
Department of General Surgery
Section of Surgical Oncology
Wake Forest University School of Medicine
Medical Center Blvd
Winston-Salem, NC 27157
cjclark@wakehealth.edu
336-716-7207

Staff: Kathleen Cummins

Biostatistician: Fang-Chi Hsu, PhD
fhsu@wakehealth.edu

Participating Institution(s): Wake Forest University

Version Date: 6/30/2019

Confidential

Summary

The proposed study will investigate the feasibility of using the Wake Forest Real-time Location System (RTLS) in monitoring patient movement during their in-hospital postoperative recovery. The study will involve patients who have undergone surgery requiring inpatient admission to the 9CC surgical ward. Actual patient movement will be monitored during their postoperative recovery and compared with data recorded by the Wake Forest location system.

1.0 Introduction and Background

Early mobilization after surgery can decrease postoperative complications and length of stay. Recognizing these improved outcomes, current enhanced-recovery after surgery (ERAS) programs emphasize rapid mobilization during the postoperative period even on the day of surgery.(1–3) Unfortunately, patients face numerous real and perceived barriers to early mobilization including postoperative pain; multiple intravenous catheters; drains; lines, and staff resource limitations. Monitoring compliance with early mobilization programs rely on patient self-report, progress notes, and nursing documentation, all of which are unreliable. Our team has used accelerometers (Fitbit Zip and Kenz Lifecorder) to monitor postoperative movement after major gastrointestinal oncology surgery (CCCWFU 02114). Preliminary data from this study, demonstrates little to no movement by patients during their hospitalization. However, this may be an artifact of current accelerometer devices rather than lack of movement by patients.

In an era of the Internet of Things (IoT) and emerging technologies, we recognized a unique opportunity to use the existing real-time location system (RTLS) at Wake Forest Baptist Health to monitor patient movement during postoperative recovery.(4) The Wake Forest Office of Enterprise Visibility developed at program for the implementation of processes, supporting technologies, driving Service Excellence, Patient Safety and Satisfaction, Operational Excellence and Efficiency, and the Transformation of Healthcare Delivery (SPOT). The SPOT program installed the current real-time location system throughout Wake Forest Baptist Health initially to track high valued hospital assets. RTLS is a complex system of various tags and badges, platforms (Wi-Fi, Infrared, Ultrasound, and others), hardware infrastructure (readers & exciters) and other components (servers, middleware & end-user software).(5) The Wake Forest RTLS solution consists of specialized fixed location sensors receiving wireless signals from small ID badges or tags attached to equipment or persons. Tags transmit a unique identifier in real-time that enable tracking. The granularity of the RTLS program varies throughout the health system with room-level tracking capabilities in the wards of the Wake Forest Comprehensive Cancer Center.

The RTLS program at Wake Forest Baptist Health was introduced for asset tracking and not developed for monitoring patient movement. Therefore, the reliability of this system is unknown but has great potential for numerous quality improvement initiatives particularly focused on decreased postoperative complications and successful implementation of early recovery after surgery programs.

2.0 Objectives

The main objective of the proposed study is to investigate the feasibility of using the Wake Forest RTLS to monitor movement of hospitalized patients after surgery. Preliminary data from this prospective cohort study will help determine reliability, accuracy, sensitive and specificity of the RTLS system during the implementation of an in-patient postoperative exercise program.

3.0 Aims

3.1 Primary Aim

3.1.1 To demonstrate the feasibility of using the Wake Forest RTLS to track patient movement during the postoperative period.

3.2 Secondary Aims

3.2.1 To evaluate the accuracy of the RTLS to track distance and time traveled during a patient walk on the hospital ward.
3.2.2 To characterize daily movement (speed, steps, frequency, distance) of in-hospital post-surgery patients.
3.2.3 To evaluate patient perspective on in-hospital exercise programs.
3.2.4 To characterize provider perspective on in-hospital exercise programs, monitoring patient movement, and reporting patient movement.
3.2.5 To evaluate the accuracy of the RTLS to track patient movement at variable patterns of movement.
3.2.6 To evaluate patient tolerance of continuous verses interval exercise program.
3.2.7 To characterize subject readiness for discharge.

4.0 Study Population

The proposed study is a prospective, **observational** cohort study investigating the feasibility of using the Wake RTLS to monitor postoperative patient movement. All patients will be recruited from the surgical ward of the Wake Forest Baptist Health (9cc). All patients will have undergone elective surgical intervention with anticipated minimum of 24 hours hospitalization. We plan to enroll 40 patients.

All eligible subjects will be asked to participate in the study regardless of race, gender, age, or other characteristic except those outlined in the exclusion criteria below. Patients who meet inclusion criteria will be asked to participate in the study by the study team after permission obtained from the treating provider. If they agree, informed consent will be obtained by a study team member.

An additional cohort of providers care for patients on 9cc including nurses, nursing assistants, physicians, advanced practice providers, physical therapists, occupational therapists, students and residents will be asked to participate in the study. If they agree, informed consent will be obtained by a study team member. A maximum of 50 providers were be included in provider cohort.

Given feedback from providers and findings through analysis of RTLS, the study recognizes the need to confirm the validity of RTLS during various ambulatory patterns. This requires enrollment of an additional 22 patients. This additional cohort--**High Intensity Interval Training (HIIT) Cohort)**--will be randomly divided into two cohorts: Group 1, Continuous Ambulation (n = 12), and Group 2, Interval Ambulation (n =10).

4.1 Inclusion criteria -- Patient

4.1.1 Male or female patients between the ages of 18 and 90.
4.1.2 Admitted to 9cc.
4.1.3 Recovering from surgery.
4.1.4 Ability to understand and the willingness to sign an IRB-approved informed consent document.
4.1.5 Ability to understand and complete the study survey instruments in English.

4.2 Exclusion criteria -- Patient

4.2.1 Non-surgical patient.
4.2.2 Emergency surgical procedure.
4.2.3 Anticipated discharge less than 24 hours.
4.2.4 Unable to ambulate or ambulation not permitted by treating provider.
4.2.5 Unable to understand and complete the study survey instruments in English.

4.2.6 Post-operative complications that in the opinion of the study investigator would impair the ability of the patient to adhere to the study procedures.

4.3 Inclusion of women and minorities

Men and women of all races and ethnicities who meet the above-described eligibility criteria are eligible to participate in this study.

5.0 Methods

The proposed study will be completed on 9cc in Wake Forest Baptist Health. Study subjects will be recruited on 9cc in Wake Forest Baptist Health after approval from the treating physician. Recruitment, consent, and data collection will be completed in the privacy of the patient's room.

The nature, purpose, and risks of all procedures and protocols will be explained to each participant prior to obtaining written consent. All examiners are trained in the standardized conduction of all assessments before data collection. Standardized written instructions will be provided.

Subjects will not be recruited for the observational study cohort as this cohort is closed to enrollment.

Enrollment will be limited to the additional the expanded **HIIT Cohort (n= 22)**. Using random number generator, eligible patients will be randomized into two groups: Group 1, Continuous Ambulation (n = 12), and Group 2, Interval Ambulation (n =10). Assignment will be provided by the study coordinator. The study PI will be blinded to this randomization.

Provider participants will be enrolled if they are caring for patients on 9cc during the study period.

5.1a Study timeline (Observational Cohort)

	Initial Visit	Day 1	Day 2	Day 3
Informed Consent	X			
Medical Record Review	X			
Vital Signs	X	X	X	X
Walking Assessment		X	X	X
Fatigue Assessment		X	X	X
Pain Assessment		X	X	X
Walking Distance Measurement		X	X	X
Step/Pedometer Evaluation[1]		X	X	X

Distribution of SPOT Badge	X			
Physical Activity in Hospital Survey				X

[1] Patients will wear a Fitbit Zip™ and Kenz Lifecorder EX Accelerometer for pedometer evaluation.

5.1b Study timeline (HIIT Cohort)

	Initial Visit	Ambulatory Evaluation
Informed Consent	X	
Medical Record Review	X	
Vital Signs	X	X
Walking Assessment		X
Grip Assessment		X
Pedometer Evaluation[1]		X
Distribution of SPOT Badge[2]	na	
Patient Survey		X

[1] Patients will wear a Kenz Lifecorder EX Accelerometer for pedometer evaluation during walking assessment.
[2] SPOT badges are now worn by all inpatients at WFBH and no longer require badging specifically for this project.

5.2 Informed consent

Signed informed consent will be obtained from each subject. The informed consent process will follow the procedures of the WFU Institutional Review Board. The study team member will explain the purpose, methods and extent of the study to prospective participants. The potential participant is asked to read the informed consent form and ask questions. The form is written in simple, easy to understand language. We require study staff to review all of the key aspects of the study verbally with the potential participants. The staff will be provided with a structured checklist for this purpose. The study staff will question potential participants to ascertain whether s/he has understood the information. Potential participants who are illiterate or have impaired vision must have the consent read to them, followed by review of the checklist, opportunity for questions, and discussion. This process will take place in the patient's private room in 9cc of Wake Forest Baptist Health. For providers, the process will take place in the conference or workroom on 9cc of Wake Forest Baptist Health. A copy of the signed and dated consent form will be given to participants, and the original document will be placed in subjects' individual study files, which will be stored in a secure location. In compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Standards for Privacy of Individually Identifiable Health Information of the Department of Health and Human Services, we will access personal health information only after obtaining informed consent.

5.3 Pedometer and Step Data

The Fitbit Zip™ (Fitbit Inc., San Francisco, CA; www.fitbit.com) is a lightweight, portable pedometer device that contains a tri-axial accelerometer. The device is commercially available to consumers and is considered a recreational device. It is capable of tracking multiple measures of physical activity including steps and distance traveled. Tracking data is stored on the device for several weeks and is capable of being downloaded to a computer for analysis using USB or wireless connection. The accuracy of the Fitbit One™ and Fitbit Ultra™ have been independently validated.[15,16] The Fitbit device can be worn on various body locations (hip vs. pocket) and maintains a high level of accuracy.[16]

The Kenz Lifecorder EX Accelerometer is an accurate and reliable research grade activity monitor that, in addition to counting steps, calculates calories expended, monitors the intensity and duration of physical activity, computes basal metabolic rate (BMR) and stores 200 days of data. Each participant's height, weight, age, gender, as well as the time of day will be programmed into the device before given to the participant.

Each participant will wear the pedometer devices during their daily walk with research staff. Programming of the Fitbit Zip™ and Kenz Lifecorder EX Accelerometer will be performed by research staff.

The pedometer data will be stored in a secure, password-protected file behind the WFBH firewall.

5.4 Patient Medical Record Review

All participants will have medical records reviewed to determine specific details regarding their medical condition, diagnosis, co-morbidities, laboratory data (nutritional status), medications, social history, past operations, and operation. If barriers to successfully completing the study are identified, the participant may be dismissed from the study. Relevant clinical data will be collected and stored in RedCap.

5.5 SPOT/RTLS Badges and Data

All participants will wear a SPOT badge provided by the study team throughout the study period. Research staff will stress that participants should wear the pedometer during the study period. Participants will be asked to wear the activity monitors at all times except while bathing or showering. SPOT badge data is collected continuously by the SPOT team independent of the study team. This is standard procedures for Wake Forest Baptist Health. The study team will coordinate with the SPOT team to extract data specific for this study. The extracted data will be stored in secure, password-protect files behind the WFBH firewall using excel files.

5.6 Walking Assessment and Physical Activity Survey (Observational Cohort)

All participants will receive a visit by a study team member each day for maximum of 3 days. If discharge is less than 24 hours after enrollment, the participant will be excluded from study. Study participants will be invited by a study team member to join them on a walk. Time, distance, and duration will be determined by the patient. If nursing staff or treating provider determines that walking is not safe or inappropriate, walk will not be performed and rationale documented. If patient declines to walk, rationale will be documented. For all patients who decline, a second visit by a study team member will occur later in the day. Participants will be encouraged to walk by study team members emphasizing the importance of walking after surgery. Each participant will complete a pre- and post-walk assessment including measurement of pain and fatigue. Pre- and post-walk vital signs will be recorded. Participants will also be asked to report number of walks completed in the last 24 hours along with distance traveled. At completion of walk, the study team will record exact time of walk, distance, and duration. At conclusion of walk assessment, the patient will complete a physical activity in hospital survey. Survey data will be collected in the subject's private room.

5.7 HIIT Cohort

5.7.1 Physical Activity Survey

Prior to the ambulatory session, the subject will receive information regarding the type of exercise they will be engaging in (continuous or HIIT). The subject will also complete a questionnaire regarding their current level of physical fitness to determine his/her qualitative baseline.

5.7.2 Vital signs

The subject's heart rate, blood pressure, pulse, and respiratory rate will be collected before and after each ambulatory session.

5.7.3 Grip Strength

Grip strength will be measured as a baseline. Two trials will be measured and then averaged together for the right and left arm. This will provide a baseline objective measure of subject frailty.

5.7.4 Ambulatory Session

Each subject perform one ambulatory session during the study. This will include walking 40 meters. Gait speed will be calculated using the speed

in which the subject walked 40 meters. Alternative exercise (hand bike) will be provided if subject declines ambulation or unable to ambulate out of their room. Demonstration of the hand bike will be provided by the study team member and subjects will be allowed to practice with the bike prior to exercise session. For subjects unable to perform the ambulatory session, a study team member will return on a subsequent hospital day to complete this portion of the study. If patient unable to perform the ambulatory session during their hospitalization or during the study period, the reason will be documented.

1. Walking Continuous Training (Group 1): The total distance will be 40 meters. Study team members will walk, support, and coach the subject to walk as slow as he/she wants.
2. Walking Interval Training (Group 2): The subject will walk a total distance of 40 meters. This distance will be divided into four intervals of 10 meters to equal the same measured distance as the continuous group. The subject will receive two minutes of rest between each interval and will be supported and coached to walk as fast as they can.
3. Hand Bike Continuous Training (Group 1, alternative option until able to participate in ambulatory session): The subject will be asked to bike for 5 minutes continuously with coaching "go as slow as you want."
4. Hand Bike Interval Training (Group 2, alternative option until able to participate in ambulatory session): The subject will be asked to bike in 10 second intervals ("as fast as they want to go") and rest for 50 seconds for five rounds (i.e. every minute on the minute (EMOM).

5.7.5 Perceived Exertion

Subject perceived exertion will be evaluated at the beginning, at 20 meters, and at the end of the ambulatory session using a standard RPE scale.

5.7.6 Gait Speed

Gait speed (meters/second) will be calculated at the end of each session based on distance traveled over time.

5.8 Provider Physical Activity Survey

All provider participants will complete a physical activity survey and repeat the survey after 30 days of providing care for patients on 9cc. During the study period, patient mobility data will be available to providers.

6.0 Outcome Measures

6.1 Primary Outcome: Determine if the SPOT system can detect movement in and out of a patient's room.

6.2 Secondary Outcomes:

- 6.2.1 Characterize patterns of patient movement after surgery.
- 6.2.2 Characterize number of times of patient exits a room per day after surgery.
- 6.2.3 Characterize distances traveled per time out of room per day after surgery.
- 6.2.4 Characterize patient opinion regarding exercise after surgery.
- 6.2.5 Characterize provider opinion regarding in-hospital exercise programs, monitoring patient movement, and reporting patient movement.
- 6.2.6 Determine if the SPOT system can detect movement when a patient varies their ambulatory behavior.
- 6.2.7 Characterize patient's ability to tolerate various ambulatory intensities after surgery.
- 6.2.8 Describe patient readiness for discharge.

7.0 Analytic Plan

7.1 Sample size

40 subjects will be included in initial observational study. Preliminary tests of SPOT badges indicate sensitivity and specificity nearly 100% using controlled movements on 9cc. Assuming type I error of 0.05, a two-sided test, 20 subjects, the sensitivity or specificity under the null equal to 0, and prevalence of 0.3, we have more than 90% power to detect the sensitivity of specificity under the alternative hypothesis equal to 0.9. If we use a range of prevalence from 0.1 to 0.9, we still have more than 90% power. However, the positioning of SPOT badge may decrease the sensitivity and specificity of the movement readings. Review of preliminary survey data indicates significant variability in response indicating need for expansion of sample size for secondary study objectives. With 40 subjects being recruited, we will be sure to have enough power to demonstrate the feasibility of this study and provide appropriate confidence intervals for future studies.

For provider participants, a maximum of 50 respondents will be included in the study. Based on staffing, resource demands, and learner rotations, the exact number of respondents available may be lower than 50 respondents. With 50 subjects being recruited, we will be sure to have

enough power to demonstrate the feasibility of exercise and patient mobility monitoring programs. This number will also provide appropriate confidence intervals for future studies.

For the additional HITT cohort, we will enroll a maximum of 22 subjects. This sample size will have sufficient power to demonstrate the feasibility of this study and provide appropriate confidence intervals for future studies.

In total, targeted study enrollment will be 62 patients and 50 providers.

7.2 Feasibility analysis and statistics.

The study team will also capture information from this pilot study that will be used to improve the efficiency of larger studies. We will evaluate the capabilities of the SPOT system to monitor patient movement. Feasible study will be defined as more than 80% of badges assigned to the observational study participants will detect movement in and out a room. All data will be descriptive in nature and will focus on patterns of movement and presence or absence of data. Summary statistics such as means and standard deviations will be calculated for continuous measures and counts and percentages will be calculated for discrete measures. Agreement statistics, including kappa statistics, sensitivity, and specify, will be calculated. Changes of pre- and post- vital signs will be calculated and graphical display will be performed to show the changes over time. The correlation between walking distance as well as pain and fatigue will be calculated each day. Mixed effects models will be used to study the association over time. Since the sample size is small, we are aware that the models may not be stable. Thus, descriptive analysis will be our primary analysis.

The additional HITT study cohort will enable validation of SPOT system to capture out of room events under various ambulatory patterns. This will build on the current cohort that validated simple in and out of room events. Feasible study will be defined as more than 80% of badges assigned to participants detect movement in and out a room during continuous and interval movement patterns.

7.3 Data management

Clinical Data Collection Form	REDCap
Tag Tracking Data	Excel

8.0 Potential Risks

8.1 Wearable SPOT badges and activity monitors

We are currently not aware of any risks associated with activity monitors, including the Fitbit, Kenz Lifecorder, or SPOT badges. Pedometers are available to the public without restrictions and SPOT badges are deployed throughout WFBH and worn by medical staff. Data collected on the pedometers are stored on the device and retrievable only by staff team members. Downloaded data will be stored using a secure server in WFBH. Data collected by the SPOT badge is stored electronically on a secure served managed by WFBH SPOT team. If the SPOT badge was to be lost by a participant, no data is retrievable from the device.

8.2 Walk Assessment

There is a risk of the participant losing their balance and falling associated with the walking after surgery. In rare instances, persons could experience leg or chest pain, heart palpitations, shortness of breath. In very rare situations exercise can result in heart attack or sudden death. We will minimize this risk by: (1) safely escorting participants to chairs located along the walking course should they become unsteady; (2) following them at a close distance; and, (3) being at their side should they need assistance. There is a risk that participants may experience muscle soreness or discomfort as a result of physical activity. However, walking is regarded as an important component of postoperative recovery.

9.0 Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. No patient identifying information will be collected or stored. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

10.0 Data Safety and Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

11.0 Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

1. Hughes MJ, McNally S, Wigmore SJ. Enhanced recovery following liver surgery: a systematic review and meta-analysis. *HPB (Oxford)* 2014:699–706.
2. Kehlet H, Slim K. The future of fast-track surgery. *Br J Surg* 2012.
3. Bradshaw BG, Liu SS, Thirlby RC. Standardized perioperative care protocols and reduced length of stay after colon surgery. *J Am Coll Surg* 1998;186:501–6.
4. Chui M, Loffler M, Roberts R. (2016). Internet of Things (IoT). [WWW document]. URL http://www.mckinsey.com/industries/high-tech/our-insights/the-internet-of-things
5. Centrak. (2016). Centrak RTLS Introduction. [WWW document]. URL http://www.centrak.com/intro-to-rtls/
6. Hannan AL, Hing W, Simas V, et al. High-intensity interval training versus moderate-intensity continuous training within cardiac rehabilitation: a systematic review and meta-analysis. *Open Access J Sports Med*. 2018;9:1-17. Published 2018 Jan 26. doi:10.2147/OAJSM.S150596
7. Gibala MJ, Little JP, Macdonald MJ, Hawley JA. Physiological adaptations to low-volume, high-intensity interval training in health and disease. *J Physiol*. 2012;590(5):1077-84.
8. Kupst, M.J., Butt, Z., Stoney, C.M., Griffith, J.W., Salsman, J.M., Folkman, S., & Cella, D. (2015). Assessment of Stress and Self-Efficacy for the NIH Toolbox for Neurological and Behavioral Function. Anxiety, Stress and Coping, 28(5), 531-544.
9. Asano, M, Miller, WC. Eng JJ. Development and psychometric properties of the ambulatory self-confidence questionnaire. *Gerontology*. 2007;53(6):373-81. Epub 2007 Jun 29.
10. Jones, D., Musselman, R., Pearsall, E. et al. "Ready to Go Home? Patients' Experiences of the Discharge Process in an Enhanced Recovery After Surgery (ERAS) Program for Colorectal Surgery." *J Gastrointest Surg* (2017) 21: 1865.
11. Reeve, Thomas E. et al. "Grip strength measurement for frailty assessment in patients with vascular disease and associations with comorbidity, cardiac risk, and sarcopenia." *Journal of Vascular Surgery*, vol. 67: Issue 5 :1512 - 1520
12. Fulk GD, Combs S a, Danks K a, Nirider CD, Raja B, Reisman DS. Accuracy of 2 activity monitors in detecting steps in people with stroke and traumatic brain injury. *Phys Ther* 2014;94:222–9.
13. Takacs J, Pollock CL, Guenther JR, Bahar M, Napier C, Hunt M a. Validation of the Fitbit One activity monitor device during treadmill walking. *J Sci Med Sport* 2013:1–5.
14. Mammen, G., Gardiner, S., Senthinathan, A., McClemont, L., Stone, M., & Faulkner, G. (2012). Is this Bit Fit? Measuring the Quality of the Fitbit Step-Counter. *The Health & Fitness Journal of Canada*, *5*(4), 30-39. https://doi.org/10.14288/hfjc.v5i4.144
15. Guralnik JM, Simonsick EM, Ferrucci L, *et al.* A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol* 1994;49:M85–94.
16. Guralnik JM, Ferrucci L, Pieper CF, *et al.* Lower extremity function and subsequent disability: consistency across studies, predictive models, and value of gait speed alone compared with the short physical performance battery. *J Gerontol A Biol Sci Med Sci*

2000;55:M221–31.

17. Simonsick EM, Montgomery PS, Newman AB, Bauer DC, Harris T. Measuring fitness in healthy older adults: the Health ABC Long Distance Corridor Walk. *J Am Geriatr Soc* 2001;49:1544–8.
18. Vestergaard S, Patel K V, Bandinelli S, Ferrucci L, Guralnik JM. Characteristics of 400-meter walk test performance and subsequent mortality in older adults. *Rejuvenation Res* 2009;12:177–84.
19. Tudor-Locke C, Burkett L, Reis JP, Ainsworth BE, Macera CA, Wilson DK. How many days of pedometer monitoring predict weekly physical activity in adults? *Prev Med (Baltim)* 2005;40:293–8.
20. Middleton, Addie et al. “Walking speed: the functional vital sign.” *Journal of aging and physical activity* vol. 23,2 (2015): 314-22.