Traditional Home Health Physical Therapy Versus a Smartphone App for Patients Recovering from Total Knee Arthroplasty During the Home-bound Portion of Recovery: Study Protocol for a Randomized Controlled Trial

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Study Design

Prospective randomized controlled trial comparing traditional home health care physical therapy to physical therapy provided via a smartphone app for patients recovering from total knee arthroplasty (TKA)

Background

As of 2013, it was estimated that 4.0 million individuals in the U.S. were living with a TKA, representing 4.2% of the population fifty years of age or older (8). As of 2010, there were 81,489,445 people aged 45 to 64 in the U.S. (4), with a rate of 39.5 total knee arthroplasties per year per 10,000 individuals in that age group (3). Therefore, approximately 322,000 TKAs were performed in 2010 for those aged 45 to 64. A 2010 study from The Centers for Disease Control and Prevention found the average cost of home health care following TKA to be $3,709 per episode of care per patient (5). This results in nearly $1.2 billion dollars in U.S. healthcare spending in 2010 for home care following TKA for those aged 45 to 64. The reason for the high cost of home health care may be the state regulations governing home health care agencies. The Louisiana Department of Health and Hospitals states that 'skilled home health care,' found under the definition of 'home health agency' in the official Louisiana Home Health State Regulations, is to include skilled nursing and at least one of the following services: physical therapy, occupational therapy, speech therapy, medical social services, or home health aide services (9). These regulations place pressure, whether conscious or subconscious, on the home health agency to over utilize skilled nursing services for those patients aged 45 to 64 recovering from TKA. Skilled nursing home health care services for this particular patient population usually involves managing the patient's medications and providing wound care services. A cohort study by Bleijenberg et al published in the Journal of the American Geriatric Society in 2017 found that only 10.3% of adults aged 65 to 69, which is above the age cutoff for this prospective study, had difficulty with managing their medications (10). Also, in the author's clinical experience, it is rare for an orthopedic surgeon to allow any other clinician to manage post-operative dressing changes except those clinicians under the surgeon's direct supervision; though further research in this area would be helpful. Furthermore, utilization of TKA, and the home care cost associated with recovery from TKA, is on the rise. As of 2009, the number of primary TKAs performed annually in the U.S. among all age groups exceeded 620,000 procedures, which is more than doubled when compared to the previous decade (7). Smartphones and other technologies may provide a solution to the rising costs of home health care following TKA for those aged

45 to 64. Over the past decade, the smartphone has become an integral part of most people's lives. The latest Pew Research Data from February 2018 shows that 73% of individuals aged 50 to 64 own a smartphone (8). Smartphones would allow the patient to have direct multimedia access to a prescriptive exercise program designed by a licensed Physical Therapist without an in-person home visit, as well as to have communication directly with their Physical Therapist through secure in-app messaging or e-mail. The patient would benefit by having reduced intrusion in their home environment, convenient access to their Physical Therapist and their Physical Therapist's plan of care, and financial savings due to the elimination of home health care services following TKA. The Physical Therapist would benefit from the ability to quickly interact with the patient to mitigate any adverse events and to efficiently assist a greater number of patients compared to traditional home-based physical therapy. Third-party payors would benefit from drastically reduced home care costs for those recovering from TKA.

Objectives

The primary objective will be to determine the efficacy of the app for those recovering from TKA compared to traditional home care during the home bound portion of the patient's recovery from TKA by comparing ROM improvement outcomes between the intervention group and the control, as well as measuring the subjective improvement in functional outcomes for the intervention group by using the Short MAC. A secondary objective of the study is to determine the relationship between the intervention participants' self-reported frequency of engagement with the app and their qualitative and quantitative outcomes, otherwise known as the dose-response.

Methods

The intervention group for this study are those who will utilize the smartphone app to complete the home-based portion of physical therapy following TKA. The control group are those who have completed traditional home health physical therapy following TKA. Inclusion criteria for the study consists of participants aged 45 to 64, the participant will have undergone unilateral TKA, and the participant should be discharged directly to home from the hospital. Participant's data from the intervention group will be excluded from the study if they do not engage with the app within 24 hours of discharge from the hospital, if the participant neglects to engage with the app over any 24-hour period during the study, or if the participant is readmitted to the hospital at any point during the home bound portion of their recovery.

Subjective outcomes for the participants in the intervention group will be assessed by the Short MAC and objective outcomes will be assessed by measuring total knee ROM improvement. The intervention participants' self-reported frequency of app usage will be compared to the participants' outcomes to determine the dose-response of the app. The Short MAC has been previously shown to be a reliable, valid, and responsive indicator of qualitative improvement in a patient's functional status post-TKA and total hip arthroplasty (THA) by Whitehouse et al (1). Minimum important change for Short MAC has been found to be 7.9 points for small change, 8.4 points for medium change, and 12.1 points for large change (2). The total knee ROM

improvement in the treatment group will be compared against a control group of patients who have completed traditional home care from a variety of physical therapists following TKA.

The primary hypothesis is that the intervention group will show a statistically equal outcome to the control group, demonstrating the efficacy of a low-cost alternative to traditional home care. The null hypothesis is that the research group will not show a statistically equal outcome to the control group. The first alternative hypothesis is that the intervention group will show a statistically significant improvement over the control group. The second alternative hypothesis is that the control group will show a statistically significant improvement over the intervention group.

Data for the control group will be taken from approximately 30 individuals aged 45 to 64 that have previously completed traditional home health physical therapy care from a variety of physical therapists following TKA. Data for the intervention group will be taken within 48 hours of being discharged from the hospital from approximately 30 participants who agree to use the smartphone app to complete the home-based physical therapy portion of their recovery from TKA. Intervention group participants will complete an introductory meeting with the physical therapist in-person to onboard the patient to the app and perform the initial data collection. Participants in the intervention group will be encouraged to engage with the app 3 to 5 times per day as able. The intervention participant will have the ability to communicate any questions or concerns to the Physical Therapist via e-mail or phone call throughout the homebound portion of their recovery. For safety monitoring, a physical therapist will contact the intervention group participant via phone or e-mail every 24 to 48 hours to ensure no adverse events have occurred. A final in-person meeting will occur between the Physical Therapist and the participant at the conclusion of the homebound portion of the participants' recovery for the purpose of final data collection. A two-tailed t-test for two independent groups will be used to compare the means for total ROM improvement between the intervention group and the control group. Data from the Short MAC will be used to describe the overall subjective effect of the intervention on the patient's functional abilities. The relationship between the Participants self-reported frequency of app usage and their combined subjective and objective outcomes will be used to understand the dose-response of the app. Information about dose-response will be integral in establishing guidelines regarding frequency of app usage for optimal results.

Conclusion

Traditional home health care for individuals recovering from unilateral TKA is expensive and provides a higher level of service than most individuals, aged 45 to 64, require. Use of smartphone technology has the potential to drive down costs while maintaining outcomes for this patient population. The proposed randomized controlled trial would determine the efficacy and proper dose-response of a smartphone app to reduce costs and maintain outcomes for the desired patient population compared to traditional home care.

Citations

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