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# ASsessing Clinical outcomes with microprocEssor kNee uTilization in a K2 population (ASCENT K2): randomized controlled trial results for above-knee prosthesis users over age 65

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## ABSTRACT

**Purpose:** To assess the effects of microprocessor knees (MPKs) versus non-microprocessor knees (NMPKs) among unilateral, above-the-knee prosthesis users classified as Medicare K2 ambulators over age 65.

**Materials and methods:** A two-arm, 12-month randomized controlled trial to compare MPKs (intervention) to standard-of-care NMPKs (control). Fear-of-falling avoidance behavior (FFABQ), falls and near-falls were assessed alongside additional measures of mobility, balance, and health-related quality-of-life (HR-QoL).

**Results:** A total of 107 individuals (MPK:  $n=54$ , age= $73.6\pm 0.8$  years, 47 diabetes/dysvascular etiology; NMPK:  $n=53$ , age= $73.7\pm 0.8$  years, 44 diabetes/dysvascular etiology) were enrolled. The MPK group reported significant improvement in activity avoidance due to fear of falling (FFABQ,  $p<0.001$ ), which was not seen in the NMPK group (FFABQ,  $p=0.104$ ). The MPK group also experienced significantly fewer falls ( $p=0.015$ ) and near-falls ( $p=0.001$ ) than the NMPK group. Results were also significantly favorable for mobility and HR-QoL for the MPK group and not the NMPK group.

**Conclusions:** MPKs result in lower levels of activity avoidance due to fear-of-falling, reduced falls and near-falls, and better HR-QoL as opposed to NMPKs. Expanded use of MPKs has the potential to enhance safety and HR-QoL among older prosthesis users with limited functional capabilities.

## ARTICLE HISTORY

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Accidental falls; quality of life; amputation; fear-of-Falling; medicare


## > IMPLICATIONS FOR REHABILITATION

- Individuals that have amputation above-the-knee and are considered limited community ambulators due to their lower functional ability experience fewer falls and near-falls with a microprocessor-controlled knee (MPK) compared to non-microprocessor knees (NMPK).
- Over a 12-month period, limited community ambulators with above-the-knee amputation categorized as Medicare K2 who were provided with a MPK maintained their quality of life, whereas individuals in an NMPK reported a significant decline.
- Limited community ambulators with above-the-knee amputation that were provided with an MPK had significant improvement in balance and walking ability (i.e., Timed-Up-and-Go and 10-meter walk test performance) that was not noted for those in an NMPK.

## Introduction

The advent of the microprocessor knee (MPK) brought multiple clinical benefits for individuals with above-knee amputation (AKA) [1–6]. Historically, an individual with AKA was rehabilitated through either a locked knee or an articulated knee. These knees, broadly classified today as non-microprocessor knees (NMPKs), employ different types of stance and swing control mechanisms but lack any sensors, signal

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processing, or technical means to make real-time adjustments to the user's gait. Articulated NMPKs can provide greater mobility and function compared to non-articulated knees, but rely on ground reaction forces, friction, and fluid for stability and versatility in walking and standing. MPKs, on the other hand, while still incorporating many of the same hardware elements as NMPKs, have a microprocessor and onboard sensors to read and react to changes in walking and standing for enhanced control of the knee, including stumble recovery in real time [7–12].

MPKs' ability to adapt to changes in walking and standing conditions has been associated with increased safety and physical function for users with AKA [3,13,14]. Prior studies have shown MPKs reduce falls and injurious falls, improve the ability to walk on uneven ground and slopes, reduce energy expenditure, and improve overall health-related quality-of-life (HR-QoL) and perceived satisfaction with health [1–3,5–7, 10,11, 13,15–31]. A recent clinical practice guideline noted that, relative to NMPKs, MPKs are indicated "to reduce stumbles, falls, and associated frustrations as well as the cognitive demands of ambulation" [14]. Additionally, the guideline noted MPKs are used "to increase confidence while walking, self-reported mobility, satisfaction, well-being, and quality of life," as well as "to increase self-selected walking speed, walking speed on uneven terrain, and metabolic efficiency during gait." [14] The current U.S. Departments of Veterans Affairs and Defense clinical practice guideline for rehabilitation of individuals with lower limb amputation also suggests, without regard for status as an existing prosthesis user, "offering [MPK] over [NMPK] for ambulation to reduce risk of falls and maximize patient satisfaction." [32]

Despite the documented benefits of MPKs compared to NMPKs, there has been limited use of MPKs among individuals classified as Medicare Functional Classification Level 2 (i.e., K2) with a few notable exceptions. K2 ambulators are commonly referred to simply as limited community ambulators [33]. Hafner and Smith [2] reported outcomes from eight limited community ambulators that wore an NMPK and a MPK in a nonrandomized crossover trial. While the K2 ambulators had fewer fall events (i.e. falls and near-falls) in the MPK, only three of the eight K2 participants were over 65 years old. Approximately 52% of individuals with lower limb amputations report having fallen in the past year—a rate significantly higher than the roughly 28% of adults over age 65 who report the same [34,35]. Individuals with AKA have about a 2.2x odds increase of falling due to amputation level [36]. Falls and near-falls are discussed within the current study, both separately and in combination, due to the known implications of falls as well as near-falls on individuals' fear of falling and activity avoidance [37]. The discussion of falls and near-falls in combination from hereon is simply referred to as fall events. A near-fall was defined as a loss of balance where you caught yourself or recovered your balance without landing on the ground, floor, or another object [38]. Activity avoidance due to fear of falling is the quantification of the effect that such fear has on activities and participation [39]. In addition to a reduction in fall events, there was an improvement in frustration and embarrassment related to falls. This suggests that the fear of falling may have an impact on avoiding activities. Kahle et al. [17] studied nine K2 ambulators along with 10 K3 ambulators. Results were not reported separately for K2 ambulators [20], but the entire group had a reduced number of fall events. The average age of the sample was 51 years, and only four individuals were over the age of 65. They did not investigate activity avoidance behavior associated with fear of falling. Possibly the most expansive work was performed by Kaufman et al. [6], which found a reduction of fall events in a cohort of 33 individuals. They did not measure fear of falling.

Fear of falling has been identified in the general population as the most significant predictor of avoidance of activities deemed critical to independence among older adults in the United States [37,40]. Avoidance of activities, especially those considered critical to independence, can potentially be even more devastating to longevity and vitality among the older population operating at what is already considered a lower functional level at K2.

Thus, the purpose of this clinical trial was to evaluate the effects over 12 months of utilizing MPKs versus NMPKs on activity avoidance due to fear of falling and the frequency of fall events in older AKA prosthesis users age 65 or older classified as K2 limited community ambulators, as well as explore related outcomes assessing HR-QoL, mobility, and balance confidence. Outcomes were compared from baseline to follow-up at 12 months. Based on previous studies [2,6,17], it was hypothesized that use of an MPK would reduce activity avoidance due to fear of falling and decrease the frequency of fall events, and this would not be observed with use of an NMPK. Furthermore, while the primary

focus of this trial was on activity avoidance due to fear of falling and the frequency of fall events, additional outcomes were measured to capture the broader implications of these phenomena on health and functioning. For example, HR-QoL measures provide insight into the psychosocial impact of fear of falling, while physical mobility limitations are elucidated through both patient-reported measures and physical performance measures. Lastly, balance confidence, a key psychological factor linked to fear of falling, was included. Including these additional measures allows for a more comprehensive analysis of the factors that influence and are influenced by the primary outcomes. This context is critical given the limited evidence and thereby understanding of the population of K2 ambulators 65 and older.

## Methods

### *Trial design*

A randomized controlled trial with a two-arm parallel study design was conducted to evaluate the effects of MPKs versus NMPKs. Participants were allocated (1:1 ratio) into the intervention arm (MPK) or the control arm (NMPK) with follow-up at 12 months. The intervention arm had to use an MPK through 12-month period, while the control arm had to use the standard-of-care NMPK through 12-month period. This is the result of phase 1 (i.e., initial 12-month follow-up) of a longer ongoing trial monitoring the participants through 5 years. The Clinical Trial register includes additional timepoints (e.g. 3 and 5 years) that will be reported in a subsequent publication focused on longer-term outcomes as these observation periods close. The trial protocol was reviewed and approved through WCG Investigational Review Board (Protocol #OB-113) and registered on ClinicalTrials.gov (NCT04784429) on 3/2/2021 prior to initiating enrollment.

### *Participants*

Participants were recruited from across the United States to increase socioeconomic, demographic, and geographical representation. Inclusion criteria were: unilateral transfemoral or knee disarticulation amputation, use of an AKA prosthesis with a NMPK received four to 24 months prior to baseline assessment, able to speak English, 65 years of age or older at time of baseline assessment, a minimum socket comfort score of 6/10 [41], and classified as a K2 limited community ambulator. Receipt of the current NMPK prosthesis was limited to 24 months prior to ensure anyone randomized into the control arm was using an NMPK that was still within the minimum average [42] use lifetime of three years by the conclusion of the trial. Note all existing componentry were also checked for satisfactory function at time of enrollment. To be considered a K2 ambulator, potential participants had to meet three of the four following criteria: 1) classified as Medicare Functional Classification Level [43] K2 by their care provider, 2) an Amputee Mobility Predictor [33] score between 27 and 42, 3) a Houghton scale [44] score between 5 and 10, or 4) a Prosthetic Limb Users Survey of Mobility® (PLUS-M [45]) T-score less than 49.45 for those with an amputation due vascular disease/diabetes, or less than 36.75 for those whose amputation was not due to vascular disease or diabetes [46]. These three instruments have all been used to varying degrees to support K-level determination and subsequently served to reinforce K2 assignment. This initially restrictive criteria for K2 ensured all subjects were well within the spectrum of K2 with low possibility of becoming K3 even with different technologies used for their intervention. However, the criteria also slowed recruitment and is more restrictive than the standard of care provider classification used in clinical practice. Subsequently, once 80 individuals were enrolled, the K2 criteria were relaxed such that individuals were required to meet two out of the four criteria to be considered eligible for the trial. At the time of change, the clinical trial registry was updated to reflect accordingly.

Exclusion criteria were body mass greater than or equal to 125 kg (275 lbs), upper limb involvement, current or history of chronic residual limb breakdown, history of two or more socket adjustments/replacements in the past six months, amputation of the contralateral limb proximal to metatarsal heads, active malignancy, rapidly-declining health that resulted in reduced activity in the past six months, unable to provide informed consent, and unable or unwilling to follow study procedures. Individuals were verbally asked to confirm their willingness and ability to follow procedures.

## Protocol

Patients with AKA receiving prosthetic care at participating facilities were eligible for the trial. Facilities were eligible to participate if they worked with the study population and contacted the study team after receiving email invitations. Email invitations were sent to private prosthetic provider clinics from the vast network of providers from which the study team has contacts. Upon returning for follow-up care, eligible patients who received an AKA prosthesis with an NMPK in the last 4-24 months were informed of the study by their clinician. If patients expressed interest, screening questions, outcome measures (see *Endpoint Measures*), and the Amputee Mobility Predictor assessment were administered in private patient rooms by their clinician, who had been previously trained. Despite all outcome measures being routine measures commonly taught within the current curriculum for members of the rehabilitation care team, a member of the study team had a private session with each clinician to review measures for increased fidelity. If the individual qualified based on the clinical assessments, they were consented to and enrolled.

At the baseline session, participants were administered endpoint measures (see below). Administration of endpoint measures at any patient visit took no more than 90 min. Individuals were given ample time for rest between any performance measures. This was done prior to the intervention group being fitted with an MPK ensuring baseline status was a consistent condition across groups. Self-report measures were administered as a paper survey and performance measures were administered by a trained care provider (e.g. prosthetists, physical therapists, rehab physicians). Measures were entered into a digital database and subsequently monitored for input errors. Data monitoring was performed by an independent third-party. Participants were then randomized to the intervention or control arm. Participants assigned to the control arm were asked to continue use of the NMPK prescribed by their physician. Individuals returned 1–4 weeks later for the initiation of the 12-month observation period. Prior to start of the observation period, individuals must have completed baseline demographic data and outcomes data. While all individuals were provided the same 1–4 week period after baseline, this time period gave the necessary time for acquisition of the MPKs for the intervention group. Participants assigned to the intervention arm were asked to use a MPK (OttoBock Kenevo) with their existing socket and foot. The MPK was programmed, fit, and aligned by the participant's prosthetist. Components such as slides or rotators were utilized as needed to achieve appropriate alignment. The prosthetist provided basic training to ensure the participant could use the MPK safely and understood required maintenance before leaving the session. Additional therapists were not engaged to ensure that any effects from the study were related strictly to prosthetic intervention and not therapeutic intervention. The training covered basic use and maintenance (e.g. knee modes and functions, alerts and notifications, maintenance and charging, precautions surrounding driving and liquids), transitioning between positions (e.g. supported standing and sitting, kneeling, getting in and out of a car), standing in place (e.g. standing with knee locked, standing with "intuitive stance flexion"), level ground walking (e.g. walking at slow and normal speeds, varying stride lengths and cadence, small steps in confined spaces, walking backwards, turning, walking with aid such as a can or walker, turning, locking the knee, walking with a locked knee and without power), negotiating environmental obstacles (e.g. up and down curbs, stairs and slopes including step-over-step, uneven terrain), and managing unexpected situations (e.g. recovering from being bumped, changing directions, stumbling and recovered, stopping quickly).

At the start of the observation period, participants returned for 1–4 training sessions where they were trained on the functionality of their assigned knee, either the MPK or NMPK. Training was provided to ensure participants could use their prostheses safely for daily activities. Sessions ideally began the same day to mitigate risk, but no later than within a week. The number of sessions varied based on participants' expressed comfort with the MPK or NMPK. It was not expected or required that all participants would demonstrate proficiency in all activities, as this was considered to differ from routine practice.

Participants were contacted by phone every two weeks over the 12-month trial period. They were provided with standardized definitions of falls and near-falls [47] and asked to report the number of each type of event experienced over the prior two weeks. Study personnel also inquired about any adverse events that may have occurred.

At the conclusion of the 12-month trial period, participants returned to the clinic for a final session where they were again administered all endpoint measures. Due to ethical considerations of withdrawing the intervention after an extended period of use, individuals assigned to the intervention arm were

permitted to keep the MPK if they withdrew from the study. They were not informed of this until they formally withdrew.

### **Randomization**

Allocation to each study arm was done through block randomization, using block sizes between four and eight to balance group size [48]. Randomization order was generated using Microsoft Excel (Redmond, WA) software. Assignment was concealed from clinic personnel and was not revealed until after the individual enrolled in the trial.

### **Blinding**

Blinding to study arm was not feasible for practical reasons. Participants assigned to the intervention arm were required to charge the MPK on a nightly basis to ensure the knee's functionality. NMPKs do not require charging.

### **Interventions**

Participants' prostheses were evaluated by a certified prosthetist at the time of enrollment. The prosthesis was serviced or adjusted, as needed, to ensure that all components were functioning as intended. The MPK was selected based on manufacturer recommended guidelines (Ottobock [49]). The original study design planned for all individuals walking slower than 0.8m/s, as measured by the 2-min walk test at their initial session, would receive the Ottobock Kenevo while those walking faster would receive the Ottobock C-Leg 4. All individuals received the Ottobock Kenevo based on slow baseline walking speed.

### **Endpoint measures**

The Fear of Falling Avoidance Behavior Questionnaire (FFABQ [39],) was the chosen outcome to measure the dependent variable (i.e. activity avoidance due to fear of falling). FFABQ has demonstrated high reliability and validity for the study demographics [39]. The FFABQ is a patient-reported outcome instrument that consists of 14 activities or participations. Each activity or participation is prefaced with the root statement, "Due to my fear of falling, I avoid...". There are five levels of agreement response options that are scored from 0 (i.e. "Completely disagree") to 4 (i.e. "Completely agree"). The total range of scores is from 0 indicating to no avoidance behavior due to fear of falling to a high of 56 indicating maximum avoidance behavior due to fear of falling and considered highly debilitating. Higher scores indicate increased avoidance of activities or participation due to fear of falling [39]. Secondary endpoint measures were the number of falls, near-falls, and total fall events over the 12-month observation period. A near-fall was defined as a loss of balance where you caught yourself or recovered your balance without landing on the ground, floor, or another object [38]. The EQ-5D-5L [50], Patient-Reported Outcomes Measurement Information System (PROMIS)-Preference Score (PROPr) [51], Consequences of Falling Questionnaire (CoFQ) [52], and Activities-Specific Balance Confidence Scale [53] were also measured. Lastly, mobility was measured through the Prosthetic Limb Users' Survey of Mobility (PLUS-M) [45], 10-meter walk test (10mWT) [54], Timed-Up-and-Go test (TUG) [55], and 2-min walk test (2MWT) [56].

### **Adverse event reporting**

At each follow-up call, in addition to collecting fall-related information, participants were also asked about any adverse events. A priori, the study team determined criteria for determining if adverse events were trial related (Table 1) and assigning a level of severity to each event (Table 2). Determination of relatedness (Table 1) was informed by World Health Organization protocols while severity (Table 2) was modified from the Common Terminology Criteria for Adverse Events [57,58].

**Table 1.** Related to study device.

Highly Probable	Follows a reasonable temporal sequence from receipt (or attempted receipt) of the device treatment or procedure
Probable	Follows a reasonable temporal sequence from receipt of the device treatment or procedure and the possibilities of factors other than the device treatment or procedure, such as underlying disease, concomitant drugs, or concurrent treatment can be excluded
Possible	Follows a reasonable temporal sequence from receipt of the device treatment or procedure and the possibility of device treatment or procedure involvement cannot be excluded. However, other factors such as underlying disease, concomitant medications, or concurrent treatment are presumable
Unlikely	Has an improbably temporal sequence from receipt of the device treatment or procedure, or it can reasonably explained by other factors, including underlying disease, concomitant medication, or concurrent treatment
Not Related	No temporal sequence from receipt of the device treatment or procedure, or it can be explained by other factors, including underlying disease, concomitant medication, or concurrent treatment

**Table 2.** Severity of event.

Mild	Usually transient, requiring no special treatment, does not interfere with the patient's daily activities.
Moderate	Low-level inconvenience or concern to the patient, may interfere with daily activities, usually resolved by simple therapeutic non-interventional methods.
Severe	Interruption in patient's daily activity requiring systemic drug therapy or other treatment.

## Analysis

Demographics and clinical characteristics were summarized through descriptive statistics for both groups.

### Sample size determination

The targeted sample size ( $n=100$ ) was estimated through a power analysis using data from previously published research [1] that was similar having used a longitudinal design, MPK intervention, 12-month timeframe, and measured fear of falling as an outcome. Sample size was conservatively estimated as the ability to detect differences in fear of falling scores observed in a prior study ( $\mu_{MPK}=85.4$ ,  $\mu_{NMPK}=75.7$ ,  $SD_{MPK}=20.5$ ,  $SD_{NMPK}=28.7$ ,  $\rho=0.27$ ,  $\alpha=0.05$ ,  $\beta=0.80$ ). The estimated sample of 80 was increased to 100 to accommodate up to 20% attrition. Permission was obtained from the sponsor and Investigation Review Board to expand enrollment due to high interest in participation.

### Imputation of missing data

Data were reviewed and monitored by an external, third-party data monitor. All queries associated with data entry were subsequently resolved to satisfaction. In the instances of missing responses to questionnaires, k-Nearest Neighbors (kNN) imputation was used to fill missing data [59]. The kNN imputation algorithm was configured with  $k=5$  nearest neighbors to balance capturing the local structure of the data (i.e. preserving similarity among available data) and avoiding overfitting (i.e. relying too much on very close neighbors). Using  $k=5$  is a common practice in kNN imputation, providing a reasonable tradeoff between variance and bias in the imputed values [59].

To conduct an intention-to-treat (ITT) analysis, it was necessary to estimate outcomes of individuals that withdrew or were lost to follow-up. A multiple imputations approach was used to derive these participants' missing data. Five complete imputed datasets were generated and pooled for the ITT analysis. Multiple imputation addresses the uncertainty associated with any single imputation method by creating multiple complete datasets, each with imputed values. The subsequent ITT analyses of the multiple datasets were performed on a pooled dataset to provide a single set of estimates. The pooling process involved averaging the estimates (e.g. means) and adjusting the standard errors to reflect both within-imputation and between-imputation variability. All missing data imputation was performed using SPSS v20.0 (IBM, Armonk, NY).

### Intention-to-treat (ITT) and per-protocol (PP) analyses

ITT and PP analyses were both performed to provide a thorough examination of the intervention effects, accounting for both adherence to the protocol and the broader, inclusive perspective of ITT analysis. All outcomes with exception of fall events were assessed through dependent single-tailed t-tests comparing

differences from baseline to 12 months for the intervention (MPK) and control (NMPK) groups. The limitation of a baseline measure of fall events without extending the study to include an initial 12-month baseline observation period to collect fall data resulted in the decision to utilize independent t-tests to compare fall events across groups through the 12-month period. The alpha level for all analyses was set to 0.05. All statistical analyses were also performed using SPSS v20.0 (IBM, Armonk, NY).

The ITT analysis used pooled data from the five imputed datasets to compare changes through the observation period. All analyses again compared baseline to follow-up with exception of fall events, which compared directly across groups. Statistical testing methods were consistent with the PP analysis. Student's *t*-tests were implemented as they were appropriate to answer the aims. Assumptions of normality of data distribution were confirmed through observation of Q–Q plots.

## Results

A total of 107 individuals enrolled in the clinical trial (Table 3). Enrollment began with the initial participant June 2021 and closed with final participant in April 2022. Nine participants (8.4%) were lost to follow-up, while 11 (10.3%) died from unrelated causes over the course of the trial (CONSORT diagram, Figure 1). Additionally, six individuals (5.6%) in the control group obtained an MPK after starting the trial and were subsequently excluded from the PP analysis. In total, 81 participants completed the trial per protocol.

Of the 107 participants, 76 were male, 36 were non-white, and 91 had amputation etiology of diabetes/vascular disease (Table 4). All participants were over age 65 with an average age of  $73.6 \pm 0.8$  years and  $73.7 \pm 0.8$  years for MPK and NMPK, respectively. All but two individuals utilized an assistive device, with majority ( $n=86$ ) reporting use of a walker when ambulating with prosthesis (Table 4). In terms of comorbid health presentation (Table 5), a similar distribution of conditions was observed across the two groups. Arthritis, peripheral vascular, hypertension, hypercholesterolemia, type 2 diabetes, and obesity were the most prevalent comorbid conditions with each present in more than 40 participants. Average functional comorbidity index [60] for the sample was  $3.06 \pm 0.20$ .

With regards to baseline mobility (Table 6), 27 participants reported having walked with their prosthesis around places in their neighborhood beyond their own property or apartment building in the prior three days (15 MPK, 12 NMPK). Additionally, fewer than half of all participants reported walking with their prosthesis up ( $n=50$ ) or down ( $n=49$ ) more than 2 stairs in the prior 3 days.

### Endpoint measures

Overall results were similar for the ITT and PP analyses. ITT results are presented with the PP results included as supplemental material.

Participants in the MPK group showed greater improvements in the primary endpoint FFABQ (i.e. reduced activity avoidance due to fear of falling) than did those in the NMPK group compared to their

**Table 3.** Participant descriptives.

	MPK ( $n=54$ )		NMPK ( $n=53$ )	
	Mean	SE	Mean	SE
Age (years)	73.63	0.80	73.70	0.76
Height (cm)	172.93	1.43	172.19	1.46
Weight (kg)	76.53	2.03	76.22	2.48
Body Mass Index ( $\text{kg}/\text{m}^2$ )	28.51	0.76	28.56	0.88
Functional Comorbidity Index	3.94	0.35	4.34	0.31
Time Since Amputation (months)	28.14	8.75	55.04	21.43
Hours prosthesis wear per day	6.21	0.57	6.28	0.48
Reported hours walking with prosthesis per day	2.80	0.35	2.80	0.30
Socket Comfort Score (0–10)	7.74	0.19	7.72	0.19
Houghton Score	6.68	0.24	6.51	0.21
Amputee Mobility Predictor score (with prosthesis)	30.07	0.55	30.40	0.59
PLUS-M (v1.2)	42.28	1.05	42.21	0.87

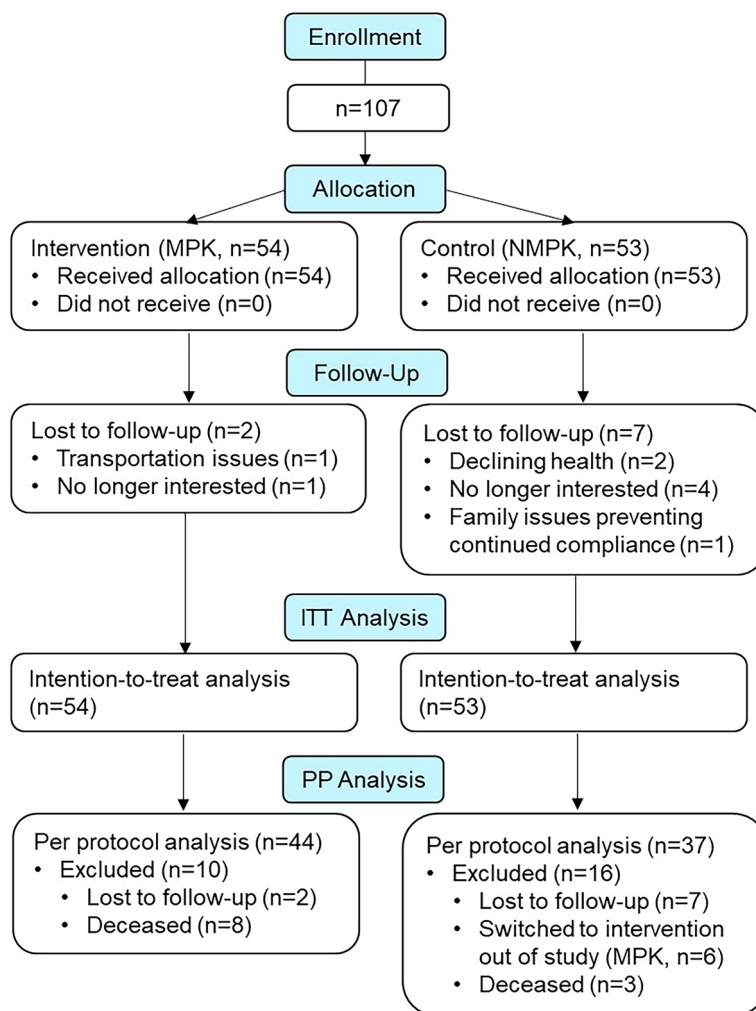


Figure 1. CONSORT diagram.

baseline (Figure 2). The MPK group reported baseline FFABQ of  $26.6 \pm 1.7$ , which improved to  $20.9 \pm 1.4$  at 12 months. This is in contrast to the NMPK group that reported baseline FFABQ of  $25.3 \pm 2.0$  and  $22.4 \pm 1.6$  at 12 months. Subsequently, FFABQ scores reported by the MPK group were significantly improved ( $5.7 \pm 1.9$  points,  $t(53)=2.98$ ,  $p=0.002$ ) at the end of the 12-month trial period while the changes to the FFABQ scores reported by the NMPK group were not significant ( $2.9 \pm 2.3$  points,  $t(52)=1.26$ ,  $p=0.106$ ).

Changes in secondary endpoints varied across the administered measures. For falls, near-falls and fall events, individuals in MPKs reported fewer falls, near-falls, and fall events after removal of outliers greater than three standard deviations from the mean. Compared to participants in the NMPK group, those in the MPK group experienced significantly fewer falls (MPK:  $1.3 \pm 0.2$  vs NMPK:  $2.7 \pm 0.6$ ,  $t(102)=2.12$ ,  $p=0.015$ ) and near-falls (MPK:  $1.7 \pm 0.4$  vs NMPK:  $5.7 \pm 1.1$ ,  $t(101)=3.43$ ,  $p<0.001$ ) over the trial period (Figure 3).

Subsequently, when combining into overall reported fall events, individuals in the MPK group experienced an overall significantly reduced number of fall events per person through the observation period compared to the NMPK group (MPK:  $2.7 \pm 0.4$  vs NMPK:  $8.3 \pm 1.5$ ,  $t(100)=3.54$ ,  $p<0.001$ ). There was no significant change in HR-QoL (as measured by EQ-5D-5L) in the MPK group; however, participants in the NMPK group reported significantly lower EQ-5D-5L scores at the 12-month endpoint than they did at baseline (Table 7). There were, however, no significant changes in either group in HR-QoL as measured by the PROMIS PROPr score over the trial period.

Participants in the MPK group exhibited greater reductions through the trial in perceived consequences of falling as their CoFQ scores were significantly lower at 12 months compared to baseline ( $2.21$

**Table 4.** Participant descriptives continued.

	MPK (n = 54)	NMPK (n = 53)
	Count	Count
Sex		
Male	40	36
Ethnicity		
Non-Hispanic Latino	36	41
Hispanic Latino	5	3
Not reported	13	9
Race		
White	34	37
Black or African American	16	15
Asian	0	1
Not reported	4	0
Assistive device		
None	0	2
Cane	7	6
Walker	42	44
Crutches	3	0
Forearm crutches	2	1
Amputation level		
Transfemoral	53	51
Knee disarticulation	1	2
Amputation etiology		
Diabetes/vascular disease	47	44
Trauma	2	2
Infection	4	4
Cancer	1	2
Congenital	0	1
Previous ipsilateral amputations		
1 Previous amputation	7	10
2 Previous amputations	1	0
Prior surgeries to restore blood flow to leg		
1 Previous surgery	9	7
2 Previous surgeries	7	4
3 Or more previous surgeries	12	16
Problems with non-amputated leg		
Yes	20	24
Problems with arm(s)		
Yes	18	10
Reduced sensation residual limb		
Yes	13	12
Hip replacement		
Amputated leg	7	1
Non-amputated leg	1	2
Knee replacement		
Yes	7	4
Vision impairment		
Yes, I wear glasses or contacts for reading	18	27
Yes, I wear glasses or contacts all the time	17	17
Yes, but I do not wear glasses or contacts	8	3
Cancer past 3 years		
Yes	2	3
Cancer prior to 3 years		
Yes	8	3
Difficulty sitting down		
Yes	5	3
Did not respond	2	0
Difficulty rising from a seated position		
Yes	8	9
Did not respond	1	0

points,  $p=0.045$ ). Conversely, participants in the NMPK group showed no differences in CoFQ scores over the trial period. Neither group experienced significant changes in perceived balance confidence or mobility over the trial period. However, the MPK group demonstrated significant improvements in mobility, as measured by all three of the performance-based tests (i.e. 10mWT speed, TUG time, and 2MWT distance were all significantly better ( $p \leq 0.001$ ) at 12 months relative to baseline). The NMPK group demonstrated a significant improvement in the 2MWT distance ( $p < 0.001$ ), but the 10mWT or TUG through the trial.

**Table 5.** Twelve-month self-report comorbid health (has a doctor told you that you have (or had) any of the following conditions in the past 12 months?), number of "yes" respondents.

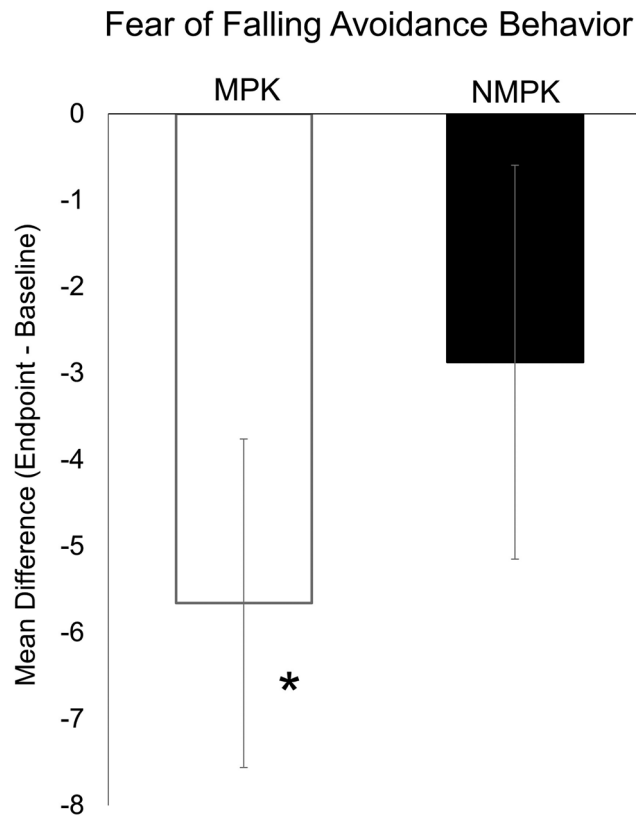
	MPK (n=54)	NMPK (n=53)
Hypertension	36	34
Hypercholesterolemia	19	26
Peripheral vascular disease	23	21
Obesity (Body Mass Index > 30)	24	19
Diabetes—Type 2	16	26
Arthritis (rheumatoid or osteoarthritis)	19	21
Visual impairment (e.g. cataracts, glaucoma, macular degeneration)	11	13
Hearing impairment (very hard of hearing, even with hearing aids)	8	12
Upper gastrointestinal disease (e.g. ulcer/hernia/reflux)	10	9
Coronary artery disease	8	11
Chronic obstructive pulmonary disease or acute respiratory distress syndrome	4	11
Degenerative disk disease (e.g. back disease, spinal stenosis, or severe chronic back pain)	7	6
Depression	6	7
Anxiety/panic disorder	3	8
Kidney disease	5	4
Osteoporosis	4	5
Bypass surgery in non-amputated leg	4	5
Digestive problems (e.g. colitis or gallbladder disease)	4	4
Asthma	4	3
Emphysema	4	3
Stroke	4	1
Congestive heart failure	3	2
Diabetes—Type 1	2	3
Myocardial Infarct	4	0
Liver cirrhosis	2	1
Transient ischemic attack	1	2
Angina (or severe chest pain)	1	1
HIV illness or AIDS	1	0
Chronic bronchitis	0	1
End stage renal disease	0	1
Neurological disease (e.g. multiple sclerosis, Parkinson's)	1	0

**Table 6.** Baseline mobility.

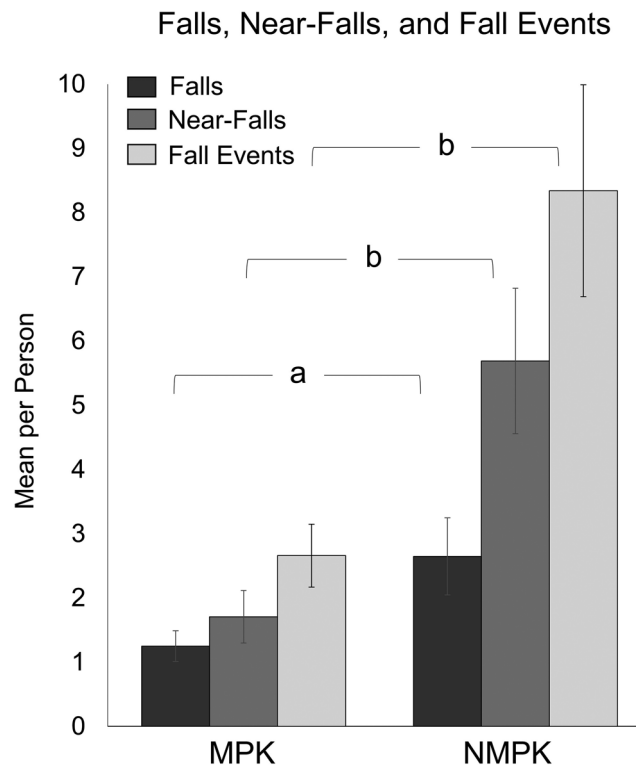
During the past 3 days, have you walked with your prosthesis...	Number of "yes" respondents	
	MPK (n=54)	NMPK (n=53)
To other rooms of your home besides the room where you sleep?	46	49
To an area immediately outside your home such as your porch, deck or patio, hallway of an apartment building, or garage?	39	46
To an area outside your home such as a yard, courtyard, driveway, or parking lot?	38	40
Around places in your immediate neighborhood that are beyond your own property or apartment building?	15	12
Around places outside your immediate neighborhood that are still within your town or community?	27	18
More than 100 yards (about the length of walking from front of a large department store to the back of the department store) in a single bout of walking?	21	21
More than 300 yards (about the length of a large department store parking lot and to the back of the department store) in a single bout of walking?	7	8
More than 600 yards (about the length from the end of a large department store parking lot and to the back of the department store, and then back to the end of the parking lot) in a single bout of walking?	2	4
Up more than 2 stairs?	24	26
Up more than 6 stairs?	13	14
Up at least 1 flight of stairs (12 stairs)?	7	11
Down more than 2 stairs?	24	25
Down more than 6 stairs?	14	12
Down at least 1 flight of stairs (12 stairs)?	7	10

### Adverse events

In total, 129 adverse events were reported over the trial period (Table 8). Four were deemed "highly probable" to be related to the intervention. Of these four events, two had an impact on patient health while two were associated with negatively impacting participant's activities of daily living due to MPK malfunction. Further, one of the four events was classified as "severe." This was noted to be due to participant reportedly not utilizing knee function correctly and falling.



**Figure 2.** Participants in the microprocessor knee (MPK) group demonstrated a significantly decreased (i.e. improved) score on the fear of falling avoidance behavior questionnaire (FFABQ), while the non-microprocessor knee group (NMPK) demonstrated no significant changes over the 12-month trial period. \* $p < 0.05$



**Figure 3.** Participants in the microprocessor knee (MPK) group reported significantly fewer falls, near-falls, and total fall events per person over the 12-month study period compared to those in the non-microprocessor knee (NMPK) group. <sup>a</sup> $p = 0.015$ ; <sup>b</sup> $p < 0.001$

Table 7. Results for MPK and NMPK through 12-month observation period.

	MPK										NMPK																	
	Endpoint					Baseline					Mean Diff	SE	t-stat	p-value: End vs BL	Endpoint					Baseline					Mean Diff	SE	t-stat	p-value: End vs BL
	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE					Mean	SE	Mean	SE	Mean	SE	Mean	SE						
EQ-5D-5L	0.710	0.037	0.702	0.028	0.008	0.041	0.20	0.420	0.646	0.047	0.738	0.023	-0.092	0.044	2.09	0.021	0.420	0.047	0.738	0.023	-0.092	0.044	2.09	0.021				
Health-Related Quality of Life PROPr score	0.325	0.033	0.320	0.024	0.005	0.039	0.13	0.449	0.340	0.032	0.327	0.027	0.013	0.031	0.42	0.337	0.449	0.032	0.327	0.027	0.013	0.031	0.42	0.337				
Consequences of Falling	25.8	1.0	28.0	1.0	-2.2	1.3	1.70	0.045	25.9	1.1	25.9	0.8	0.0	1.1	0.00	0.500	0.045	1.1	25.9	0.8	0.0	1.1	0.00	0.500				
Activities-Specific Balance Confidence	30.4	1.7	28.6	1.7	1.8	1.7	1.03	0.151	28.1	1.6	28.0	1.3	0.2	1.4	0.13	0.447	0.151	1.6	28.0	1.3	0.2	1.4	0.13	0.447				
Prosthetic Limb Users' Survey of Mobility (v3)	43.7	1.2	42.4	1.0	1.3	1.4	0.96	0.170	43.1	1.1	42.8	0.9	0.3	1.3	0.20	0.422	0.170	1.1	42.8	0.9	0.3	1.3	0.20	0.422				
10 m Walk Test (m/s)	0.42	0.03	0.34	0.02	0.08	0.03	1.99	0.001	0.41	0.03	0.40	0.03	0.01	0.03	1.13	0.327	0.001	0.03	0.40	0.03	0.01	0.03	1.13	0.327				
Timed-Up and Go Test (s)	40.5	3.3	50.7	4.5	-10.1	3.3	3.07	0.001	38.3	2.3	38.7	3.3	-0.5	3.1	0.15	0.441	0.001	2.3	38.7	3.3	-0.5	3.1	0.15	0.441				
2 min Walk Test (m)	37.51	2.01	26.81	2.03	10.71	1.97	5.45	<0.001	36.64	1.92	28.76	2.02	7.88	1.84	4.30	<0.001	<0.001	1.92	28.76	2.02	7.88	1.84	4.30	<0.001				

Shading is used to denote significant p-values given large volume.

**Table 8.** Adverse events.

	MPK		NMPK		Total	
	Events	Persons	Events	Persons	Events	Persons
Adverse events						
Mild	7	6	8	7	15	13
Moderate	27	18	24	14	51	32
Severe	35	19	28	17	63	36
Study device related						
Not related	57	26	55	27	112	53
Unlikely	6	4	1	1	7	5
Possible	1	1	3	3	4	4
Probable	1	1	1	1	2	2
*Highly probable	4	4	0	0	4	4

\*Notes to describe the four Highly Probable events that occurred in total were noted as follows (Mild = 1 event, Moderate = 2 events, Severe = 1 event).

Event 1 (Mild): Difficulty initiating flexion with MPK in stand-to-sit, training required.

Event 2 (Moderate): MPK knee cap fell off, knee had to be sent to manufacturer for service.

Event 3 (Moderate): Patient developed blister on residual limb.

Event 4 (Severe): Participant fell and fractured hip and pelvis.

## Discussion

MPKs have been available for nearly three decades but primarily utilized in higher activity patients classified as K3 or higher. However, there is a growing body of evidence published over the prior two decades that has demonstrated the potential clinical benefits to use of MPKs among patients with lower function such as Medicare Functional Classification Level K2 [3,13,20]. The current trial sought to quantify the benefits of MPK use among older users (i.e. those over 65 years of age) over a 12-month period across the domains of fear of falling activity avoidance, frequency of fall events, HR-QoL, mobility, and balance confidence. The randomization process was effective, resulting in two similar groups at baseline. Overall, results of the current trial demonstrated older users experience improvements related to activity avoidance due to fear of falling and also frequency of fall events. Individuals also sustained their HR-QoL through the 12-month period while those in the NMPK experienced significant decline.

The current trial expands upon the existing body of literature in several notable ways. First, this trial targeted participants over the age of 65, a population that has been understudied in the existing prosthetics literature. It is critical to understand clinical outcomes in prosthesis users over 65 due to higher prevalence of health issues associated with aging and, for individuals in the United States, differences commonly seen related to insurance coverage.

Prior studies of limited community ambulators demonstrated that participants often experienced better health outcomes, like fewer falls, when using a MPK as compared to when they used an NMPK [2,6,26]. However, as these studies involved individuals as young as 33 [2], 43 [26], and 55 [6], it was possible that inclusion of younger users may have influenced the results. Limiting enrollment to those over 65 in the current trial mitigated the potential for younger individuals to affect the findings. Consistent with findings from these earlier studies, participants in the MPK arm of the current trial experienced a number of clinical improvements, including a reduction in reported activity avoidance due to fear of falling, reduced falls and near-falls, and a sustained HR-QoL. They also demonstrated improved functional capabilities over the course of the trial. Participants in the NMPK arm, however, reported and demonstrated very few improvements over the 12-month trial period. These results suggest that the benefits of MPKs are not limited to just younger limited community ambulators but also extend to those aged 65 and older. As such, there is need for strong consideration of revision to current policies within the US and other countries that are restrictive in terms of access to MPKs for individuals aged 65 and older to ensure these individuals can experience the clinical benefits noted in the current trial.

The current trial was also novel in that the K2 inclusion criteria resulted in recruitment of “low K2 patients,” or patients with relatively low functional abilities. For example, fewer than half of the participants had walked more than 100 yards on their prosthesis or up or down more than two stairs in the 3 days prior to enrollment [61]. Prior studies likely included patients with higher levels of rehabilitation potential as several participants classified as K2 limited community ambulators at the beginning of these studies were reclassified as K3 unlimited community ambulators by the end of the clinical trial [6,13,17].

This was not the case for participants in the current trial. Rather, in patients that were low K2 functional level, clinical benefits were demonstrated. This finding challenges some misperceptions about the typical presentation of those classified as Medicare Functional Classification Level K2. Furthermore, it highlights that advancement to a Medicare Functional Classification Level K3 classification should not be the benchmark for a successful outcome for K2 ambulators being fit with an MPK.

One of the more interesting findings from the current trial was the difference in HR-QoL changes reported by the groups. While the MPK group, as a whole reported no significant changes in HR-QoL over the trial period, the NMPK group reported a significant drop of about 0.09 in the EQ-5D. This drop of 0.09 is consistent with the EQ-5D difference of 0.09 between MPK and NMPK similarly reported in both Gerzeli et al. [62] and Cutti et al. [50] As noted in these prior studies, this significant difference denotes individuals with a NMPK had a 9% drop in their utility which equates to approximately 33 days of perfect health over a 12-month period. This magnitude of change for an elderly individual should be considered clinically significant- how many individuals average age 72 would not value being given slightly more than a month of perfect health. It is worth noting that the PROMIS-PROPr did not demonstrate significant change. This may be reflective of the EQ-5D potentially being more sensitive due to alignment with its original design intent. Conversely, PROPr was designed secondarily representing an amalgamation of multiple instruments developed separately within the PROMIS system.

While HR-QoL is a multidimensional construct, the literature has well established the link between both falling and fear of falling with diminished HR-QoL [37,63–65]. Evidence further notes that near-falls, or stumbles, can negatively impact HR-QoL and lead to reduced activity levels [37]. There is also evidence that links walking speed to HR-QoL [66,67]. Subsequently, the decline in HR-QoL reported by the NMPK group in the current trial is likely due to increased fall events, greater activity avoidance due to fear of falling, and slower walking times.

It should be noted that the current trial was conducted largely in the wake of the COVID-19 pandemic. Subsequently, most adverse events reported by trial participants were related to fevers and coughs consistent with symptoms of COVID-19. Perhaps most of note was the “severe” adverse event with the participant suffering a fall and hip and pelvic fracture. The person with above-knee amputation recovered from their injury and resumed walking. The person also continued to report favorability toward the MPK. However, this demonstrates the reality that patients in MPKs can still fall [18]. This event highlights the potential the need for increased training and access to therapy for individuals with MPKs to maximize benefit opportunity. Unfortunately, not all patients are provided therapy with their prosthesis. For consistency with current clinical standards, the current trial did not include any therapy or skill-based training. Instead, participants received competency-based training whereby they were required to demonstrate either physically or verbally an understanding of the knee functionality. Subsequently, the benefits measured may be attributed to only the MPK intervention. There is likely opportunity for additional or greater benefits with complementary skill-based training or therapy.

The current trial has several limitations worth noting. First, participants were enrolled across multiple care facilities across the United States. As such, there may have been variations in practitioner experience and prosthetic fitting practices that could have affected the trial results. This does however extend the ecological validity of the results. Furthermore, while randomized controlled trials are the gold standard for assessing intervention efficacy, they have several limitations. The strict inclusion and exclusion criteria implemented may limit the generalizability of the findings to broader populations. Additionally, the two arm study design resulted in withholding potentially beneficial intervention from participants. This may have contributed to participants in the control group choosing to break protocol and acquire MPKs outside of the trial design, which negatively impacted the internal validity of the trial. The ITT analysis, although valuable for preserving the benefits of randomization by including all participants in their originally assigned groups, regardless of adherence, also presents challenges. Dropouts and noncompliance may have diluted the treatment effect, resulting in a potentially conservative estimate of efficacy. Furthermore, follow-up for falls occurred every two weeks. It is unknown what is the best frequency for fall recall, which also must be weighed against excessive contact with participants which can inherently impact their daily routine and lives, an effect commonly referred to

as the Hawthorne effect. It is possible that more time between calls could yield similar results related to fall recall while lessening the potential for influencing participants' routines. Additionally, the original study design allowed for individuals to receive a C-Leg if they ambulated  $>0.8\text{m/s}$  at enrollment. Given that none of the enrolled individuals exceeded this walking speed, the clinical community should give further consideration to whether an individual that walks  $>0.8\text{m/s}$  is a K2 ambulator versus the more likely classification of K3. Another limitation is the use of independent *t*-tests for fall events. While we were able to utilize dependent *t*-tests to compare how each group changed with exposure to either the intervention or the control, and thereby minimize the impact of potential confounders, it was not possible to compare to a baseline measure of fall events without implementing an initial 12-month observation period with similar two-week follow-up calls. It was felt such an additional baseline 12-month observation period would overly impact study feasibility. Also, our study through its comprehensive design made it possible to conclude the significant changes in HR-QoL and FFABQ resultant from an MPK are also clinically meaningful, coinciding with the significant reduction in falls and near-falls. Further work would be valuable to extend the understanding on how these changes align with other clinically important changes.

## Conclusion

The clinical trial demonstrated that MPKs significantly improve clinical outcomes for older adults with above-knee amputations classified as limited community ambulators. Participants using MPKs reported lower levels of activity avoidance due to fear of falling and experienced a notable reduction in the number of falls, near-falls, and combined fall events compared to those using NMPKs. While the MPK group maintained HR-QoL through the trial, the NMPK group experienced a significant decline, highlighting the potential for MPKs to sustain or enhance HR-QoL in this population. Despite limitations, the results of this clinical trial confirm that benefits of MPKs reported among younger limited community ambulators also extend to older, less functional individuals with above-knee amputations. Findings from this randomized controlled trial also suggest that wider adoption of MPKs could enhance safety and HR-QoL in this rather impaired clinical population.

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## Disclosure statement

The following authors report there are no competing interests to declare: SW, BH, AS, DE. RL and AK are employed by Ottobock who is the manufacturer of the intervention microprocessor knee (MPK). Potential conflict of interest was mitigated by removing RL and AK from data analysis and use of a third-party data monitor.

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