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A retrospective review of psychosocial outcomes following microprocessor knee prescription

Abstract

Study Design: Retrospective Analysis

Introduction: Microprocessor knees have been shown to improve gait biomechanics and to reduce the frequency of falls but evidence of their influence on psychosocial health is limited.

Objective: To evaluate the change in psychosocial outcome measures when prosthetic users change from a Non-Microprocessor controlled Prosthetic Knee (NMPK) to a Microprocessor-controlled Prosthetic Knee (MPK).

Methods: Using validated outcome measures, physical and psychological attributes of 26 MPK users were analysed using data collected at routine appointments. Baseline data were collected using NMPK limbs first then compared to data collected four weeks and six months following initial MPK fitting.

Results: A significant improvement of 13.7% in Reintegration to Normal Living Index (RNLI) scores was observed after six months ($p=0.001$). The PHQ-9 demonstrated a 64.6% significant reduction in the presence of depression-like symptoms after six months of MPK use ($p<0.001$), including four participants who previously scored highly enough to be diagnosed with major depressive disorder. Frequency of falls reduced significantly as well ($p<0.001$). Increases in self-selected walking speed were seen in both the 2 Minute Walk and 6 Minute Walk Tests.

Conclusions: Significant improvements were seen in all psychosocial outcome measures, indicating participants' psychosocial health improved with the prescription of an MPK despite a lack of clinically important improvements in parallel performance-based outcome measures.

Clinical Relevance: MPKs are well documented to reduce trips and falls which is corroborated by this research. However, the psychosocial benefits of MPKs are not documented extensively; this study provides evidence of an improvement in psychological wellbeing in this cohort**.**

Abstract Word Count: 214

Keywords: Rehabilitation of prostheses users, prosthetic outcome measures, biomechanics of prosthetic devices, rehabilitation of amputees, follow-up studies

Introduction

Psychological health is a major concern within the amputee population, with the prevalence of depression and depressive symptoms reportedly as high as 28%.[1,2] In the general population, mental health is a major cause of disability in England[3] with estimates of one in six adults suffering with a mental health problem at any one time. Therefore, mental health issues are much more common in amputees than in the general population, and there is a paucity of research in this area. To date, MPK research has focused on gait biomechanics and safety, but with mental health costing £6.5 billion to the UK Government in 2010/11 (most recent figures)[3] there is a need to understand the benefits that advanced technology may have for patients psychologically.

Convincing evidence of improved kinetic and kinematic parameters when using a Microprocessor-controlled Prosthetic Knee (MPK) compared to a Non-Microprocessor-controlled Prosthetic Knee (NMPK) already exists.[4-6] Reductions in the number of falls experienced and increased symmetry of gait have been the most prominent findings in these papers. Increased user satisfaction has also been reported in MPK users[7-9] which follows logically from reducing the frequency of adverse incidents. Novel research by Moller et al. demonstrates that NMPK users typically exhibit greater cortical brain activity than MPK users, suggesting that MPK users require less cognitive effort to walk.[10] Outcome measures specifically designed to study psychological health in the amputee population do exist in published literature, such as the Prosthesis Evaluation Questionnaire (PEQ) [11] and have been used to suggest preference for an MPK over NMPK limbs.[8]

In order to prescribe an MPK limb to a patient in England a trial must be carried out in accordance with guidelines set out in the Clinical Commissioning Policy from NHS England.[12] This policy has been in effect since December 2016. The policy requires improvements in patient function and participation in daily life to be demonstrated using an array of outcome measures before the new prosthesis can be prescribed. The authors were granted access to the existing database of these outcome measures for MPK users at one limb centre. Alongside the outcomes mandated by the policy, The Patient Health Questionnaire (PHQ-9)[13] was also included in this research as it was routinely recorded at the limb fitting centre and deemed relevant to the aims of this study.

Two hypotheses were formed to guide analysis: 1) Improvements would be seen across all outcome measures when comparing the NMPK measures to the MPK measures, and 2) Psychosocial health improvements would come with improved physical ability.

Methods

Outcome measures were recorded for all potential MPK limb candidates at the limb fitting centre in accordance with the prescription policy by the clinical team comprising of prosthetists and specialist amputee physiotherapists. The authors of this paper analysed the data separately from the clinical team and in retrospect. A short summary of the prescription process is given:

The NHS England MPK prescription policy is a set of guidelines and procedures that are applicable nationally. Potential participants are screened by the clinical team to check they meet the inclusion criteria outlined in the policy, namely: amputation involving destruction or loss of the knee joint, ability to walk utilising a free mechanical prosthetic knee with the potential or ability to vary cadence, ability to walk more than 50 yards on level ground, presents with a history of falls or co-existing medical condition that has a very high risk of injury due to a fall, and demonstration of adequate commitment, strength and balance to utilise the MPK unit. The limb fitting centre had added the criteria of wearing a prosthetic socket rated 7 or higher on the Socket Comfort Score.[14] A duplicate socket was then produced, and all participants were assessed using their normal NMPK prescription as the baseline measure before being fitted with the MPK. Each participant completed a 4-week acclimation period before the first review and then were reviewed again at six months.

All outcome measures were completed at each review. This included all mandatory measures from the prescription policy and any additional outcomes elected by preference of the prosthetic service. During the four-week acclimation period each participant attended one hour of physiotherapy per week. The data came from users who were provided with an Orion 3 MPK and Echelon prosthetic foot (Blatchford Ltd, Basingstoke UK): this was the preferred MPK prescription of the centre.

To date, the majority of MPK research has focused on alternative manufacturers of MPKs.[4,6,15,16] For this reason, temporospatial outcome measures have been included in this study to facilitate comparison with the populations in previously published literature. The Timed Up and Go (TUG) Test was omitted from analysis since one specific function of an MPK is to

slow down knee flexion when moving to sit down, and the TUG Test regards faster speeds as more positive. The outcome measures analysed are provided below:

Psychosocial outcome measures

I. The PHQ-9 questionnaire[17] has 9 questions resulting in a total score between 0-27 and was used to assess the severity of depression at each point. A score ≥10 can indicate major depressive disorder; therefore a lower score is considered more positive. The PHQ-9 has been proven to be sensitive to change over time[13,17,18] and is valid for use in the general outpatient population.[13]

II. The RNLI questionnaire measures how well-integrated to normal life the user feels and is validated for use with people with mobility limitations.[19,20] A score of 100% represents the participant feeling fully reintegrated to community living, and 0% represents no reintegration to community living. This is an important aspect of amputee rehabilitation as the aim of treatment is to facilitate normal daily life.

III. The PEQ investigates multiple aspects of perceived life and prosthesis quality and has been used extensively in the published literature. The PEQ was analysed in 9 subsets as described by Legro et al.[11] Each subset relates to a different aspect of the prosthesis allowing for more specific comparison to be made between different users/time points.

Physical performance measures

I. Self-reported patient diaries of trips and falls experienced over the four-week period leading up to each of the 3 appointments were completed.

II. The 2 Minute Walk Test (2MWT) as described by Brooks et al.[21] (2006) was conducted with verbal encouragement to ensure the participant achieved their best result.[22] For consistency for the participant, a version of the 6 Minute Walk Test (6MWT) based on Brooks' 2MWT method was used. All tests were carried out according to published protocol by a senior prosthetist or specialist amputee physiotherapist. These tests have previously been validated for use with amputees[23,24] and can be easily converted to a walking speed, allowing comparison with the existing literature.

One author accessed the database of MPK prosthesis users at the limb fitting centre and included patients who had completed the six-month review. Where individual data points were missing, the author manually searched the patient's paper records for the information. Statistical analysis was performed using SPSS 2018 v. 26. Approval for this analysis of patient information was provided by XXXX and XXXX. Patients had previously signed informed consent for their data to be used in future research.

Statistics:

ANOVA Tukey tests for multiple comparisons were used to understand the mean differences between the three time-points for normally distributed data, whilst Kruskal-Wallis was used for non-normally distributed data. Additionally, groups were split into two groups and t-tests were used to determine statistical differences between NMPK and MPK at each timepoint. When differences on the t-tests were observed, post-hoc Bonferroni adjustments were used to control for Type 1 error using a new significance level of 0.017 (99.98% C.I.). Similarly, Mann-Whitney (99.98% CI) were applied for non-normally distributed data. Clinical significance was measured against pre-existing published literature and expertise. For clarity, the measurement time points will be referred to as follows:

- NMPK – Measurement taken when participant was using their NMPK prosthesis and used as a baseline for comparison.
- MPK 4 weeks – Measurement taken 4 weeks after supply of the MPK prosthesis, at the end of the trial period.
- MPK 6 months – Measurement taken 6 months after the MPK prosthesis was supplied; at this point the MPK was no longer being trialled and had been the participant's daily prosthesis for approximately 21 weeks.

Results

TABLE 1 ABOUT HERE

Patient demographics are shown in Table 1. 26 patients had completed the six-month review at the time of data collection. There were 4 females and 22 males, 25 transfemoral amputees and 1 person with knee disarticulation, and the majority of amputations were due to trauma (77%). On average, these prosthetic users had had their amputations for 29.5 years (range 8-55 years). Results from the outcome measures are presented in Table 2.

TABLE 2 ABOUT HERE

The mean number of falls were: 1 (±0.98) at NMPK baseline, 0 (±0.19) at MPK 4 weeks, and 0 (±0.19) at MPK 6 months. The number of falls was statistically significantly different (K-W, $p<0.001$; M-W, $p<0.001$) with the number of falls significantly greater for NMPK than at both MPK timepoints (Figure 1).

FIGURE 1 ABOUT HERE

Walking speeds derived from both timed walk tests are presented in Table 3. This was calculated by dividing the distance covered by the time of the test. No statistical difference was found between groups (ANOVA, $p=0.964$), however statistical significance was found when comparing between groups (NMPK and MPK) at the different timepoints (t-test, $p<0.001$).

TABLE 3 ABOUT HERE

PHQ-9: The mean PHQ-9 score when using NMPK prostheses was 5.27(±6.40); at MPK 4 weeks the mean was 1.31 (±2.67), and at MPK 6 months it was 1.89 (±2.89). A significant decrease was found in the depression scores when NMPK and MPK 4 weeks were tested ($W=838.00$, $p=0.003$). A statistically significant decrease was also found when comparing NMPK to MPK 6 months ($W=800.00$, $p=0.022$). There was no significant difference found between MPK 4 weeks and MPK 6 months (W-634.50, $p=0.843$).

As detailed in Figure. 2, of the 5 participants who could have been diagnosed with major depressive disorder when using their NMPK limb (PHQ-9 score ≥10), 4 scored below this cut-off after 4 weeks of MPK use. Only one participant continued to score above this cut-off score and had improved by 18.75%.

FIGURE 2 ABOUT HERE

RNLI:

The average score in the RNLI questionnaire when using an NMPK was 80.17% (±21.80). As shown in Fig. 3, after 4 weeks of MPK use this increased to 91.53% (±13.25), and at 6 months it was 92.73% (±10.04). Significant differences were found between NMPK and MPK 4 weeks ($W=562.00$, $p=0.010$, at 99.98% CI), and NMPK and MPK 6 months ($W=553.50$, $p=0.007$). No statistically significant mean difference was found between MPK 4 weeks and MPK 6 months ($W=685.00$, $p=0.474$).

FIGURE 3 ABOUT HERE

PEQ: For the purposes of this paper the authors focussed on 3 subsets of the PEQ: "appearance"; "social burden"; and "utility". In the "appearance" subset, significant improvement was found between NMPK and MPK 4 weeks (W=509.50, p=0.001 at 99.98% CI), and between NMPK and MPK 6 months (W=515.50, p=0.001), across all participants. No significant difference was found between the MPK measures (W=687.50, p=0.493). In the "social burden" subset (shown in Figure 4), significant differences were found in the mean scores between NMPK and both MPK time-points (W=515.50, p=0.001, and W=556.00, p=0.008, respectively). No significant mean difference was found between MPK measures (W=732.50, p=0.790). In the "utility" subset, significant improvements were found between NMPK and both MPK timepoints (W=484.50, p<0.001, and W=503.00, p<0.001, respectively). No significant difference was found between the two MPK measures (W=686.00, p=0.482).

FIGURE 4 ABOUT HERE

While detailed results are presented from the analyses of only three subsets, statistically significant improvements were seen in all PEQ subsets between NMPK and MPK measurements.

Discussion

This research sought to investigate if the introduction of an MPK influenced patient outcomes with a specific focus on psychosocial health. It builds on the previous research predominantly concerned with physical outcomes. Two hypotheses were tested. Firstly, if improvements would be seen in all outcome measures by replacing the NMPK limb with an MPK. This hypothesis holds true for this population as statistically significant improvements were seen in both physical and psychosocial outcomes. Secondly, the hypothesis presuming physical improvement would lead to psychosocial benefits needs to be examined further in subsequent research as the mental health benefits found in this study were disproportionate to the increases in physical performance. While statistical significance was seen, the clinical relevance of walking 6 metres further over the course of two minutes is negligible.

The reduction in falls represents an important reason to advocate for the use of MPK prostheses and has been documented with multiple MPK prescriptions.[6-8 ,25] As shown in Figure 1, only 1 of the 27 participants reported a fall when using the MPK, compared to 17

who reported falling with their NMPK. The participant who reported one fall for each 4 week period with the MPK had reported 3 falls in the 4 weeks of NMPK use. Average walking speeds found here are comparable to those reported by Orendurff [26] and Kahle [25]. These results align the current study with the published literature for alternative MPKs.

Significant improvement was seen in the PHQ-9 between NMPK and both MPK time points, suggesting a reduction in the presence of depression-like symptoms in these lower limb amputees when changing to an MPK prosthesis. In all but one of the patients who scored 10 or above using the NMPK prosthesis, scores at MPK 4 weeks were then below this threshold and importantly did not relapse at MPK 6 months. This cut-off score of 10 has been shown to be acceptably specific and sensitive to identifying major depression,[27] therefore this is considered a clinically meaningful improvement in this patient group.

The RNLI measures integration in domains including comfort in social situations, personal relationships and the ability to carry out daily activities. The introduction of a new prosthesis demonstrated a significant increase in these users' perception of being able to integrate with society. The improvements in RNLI scores seen in this study when using an MPK are of interest as these patients were established prosthetic users who lived in the community for an average of 28.5 years. The improvements are above the 7% minimum clinically important difference reported by Mayo et al. [28] and it is possible that a ceiling effect was present particularly at the latter measurement time points.

The individual domain scores cannot be isolated for the RNLI but the PEQ subset "social burden" provides more of an insight into this area. Significantly higher scores were reported after the introduction of the MPK prosthesis and maintained six months later, again suggesting this type of prosthesis had a positive impact on the patients' lives. In the "utility" subset comparable results were found, and similar findings were seen again in the "appearance" subset. To date, the minimum detectable changes and clinically important differences for PEQ subsets have not been reported, nor have these values been reported for the PEQ as a whole. Research which was able to provide these values would potentially add weight to the findings of this study.

It is important to note that no statistically significant improvements were found with ANOVA in the timed-walk tests, however, when the data was treated as groups and t-tests were performed, statistically significance was found in between groups (Table 2), however, these do not necessarily imply clinically meaningful differences[21 ,23 ,29]. One plausible explanation

for this is that since these participants are established prosthetic users and are already ambulatory in a community setting; they have already achieved a desirable self-selected walking speed. The lack of clinically important differences does however suggest that these participants did not have any marked changes to their physical ability during the study period, thus increasing the likelihood of the new prosthesis being the cause of any differences in outcome measures.

All users attended physiotherapy once per week for the first four weeks. The effect this had on outcomes should not be overlooked when interpreting these results. It is difficult to isolate the effect of each treatment component on overall results in this study and it would be interesting to see a similar study conducted with an intervention group receiving four weeks of physiotherapy and continuing to use an NMPK. Notably, the lack of change in outcome measures between MPK 4 weeks and MPK 6 months would suggest that the new prosthesis was an important factor in the differences between NMPK and MPK measurements.

Finally, albeit statistically significant, the differences in results between interventions were relatively low and deserve further exploration on a greater sample size. A prospective trial with a larger sample size that controls for the effect of physiotherapy input for example, would be useful in gaining a clearer picture of the whole population. Nonetheless, 26 participants is a relatively large cohort for research of this kind in an amputee population.

The loss of a lower limb is a life-changing situation in which people are left to deal with a notable change in their quality of life and independence. This study adds to the existing evidence base for the use of an MPK compared to non-MPK knees to positively affect quality of life for above-knee amputees.

Word Count: 2867

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Table 1 patient demographics

Patient	Gender	Age (years)	Time from amputation (years)	Cause of amputation	Level of amputation	K level	NMPK (used prior to baseline MPK measure)
1	F	64	55	Trauma	TF	3	Smart IP
2	F	62	36	Neoplasm	TF	3	Smart IP
3	M	65	48	Trauma	TF	3	ESK
4	M	53	12	Trauma	TF	3	Smart IP
5	M	55	37	Trauma	TF	3	Smart IP
6	M	61	45	Neoplasm	TF	3	IP+
7	F	33	17	Congenital	KD	3	Total Knee
8	M	61	43	Trauma	TF	3	ESK
9	M	31	15	Neoplasm	TF	3	Mercury
10	M	47	23	Trauma	TF	3	IP+
11	M	56	39	Trauma	TF	3	Smart IP
12	M	48	14	Trauma	TF	3	Mercury
13	M	45	8	Vascular	TF	3	ESK CaTech
14	M	60	43	Trauma	TF	2	Smart IP
15	M	65	48	Trauma	TF	3	ESK
16	M	41	12	Trauma	TF	2	ESK PSPC
17	M	36	14	Trauma	TF	3	Mercury
18	M	70	11	Trauma	TF	3	ESK PSPC
19	M	54	37	Trauma	TF	3	Smart IP
20	M	72	9	Trauma	TF	3	ESK PSPC
21	M	32	13	Congenital	TF	3	KX06
22	M	67	48	Trauma	TF	3	Smart IP
23	M	69	15	Trauma	TF	3	ESK PSPC HOKL
24	M	61	40	Trauma	TF	3	Smart IP
25	M	56	33	Trauma	TF	3	ESK PSPC
26	M	71	52	Trauma	TF	3	Smart IP
Total	*3F, 23M*	*55.19, Range: [31,72]*	*29.50, Range: [8,55]*	*Trauma:20, Vascular: 1, Neoplasm:3, Congenital:2*	*TF:25, KD:1*	*Level 2: 2; Level 3: 25.*	

(Table 2_Mean_Participant_Outcomes)

Outcome measure		**NMPK** (mean ± SD)	**MPK (4 weeks)** (mean ± SD)	**MPK (6 months)** (mean ± SD)
Falls		(1 ± 0.98)	(0 ± 0.19)*	(0 ± 0.19)*
2MWT [m]		(125 ± 25)	(133 ± 21)*	(131 ± 22)*
6MWT [m]		(362 ± 74)	(391 ± 67)*	(385 ± 69)*
PHQ-9		(5 ± 6)	(1 ± 3)*	(2 ± 3)*
RNLI		(80 ± 21)	(92 ± 13)*	(93 ± 10)*
PEQ	Ambulation	(50 ± 21)	(86 ± 13)*	(85 ± 16)*
	Appearance	(67 ± 24)	(86 ± 14)*	(86 ± 14)*
	Frustration	(52 ± 34)	(87 ± 17)*	(83 ± 22)*
	Perceived Response	(85 ± 18)	(95 ±7)*	(93 ± 8)*
	Residual Limb Health	(71 ± 27)	(88 ± 11)*	(84 ± 12)*
	Social Burden	(72 ± 25)	(93 ± 8)*	(88 ± 16)*
	Sounds	(61 ± 31)	(82 ± 20)*	(86 ± 25)*
	Utility	(66 ± 22)	(85 ± 11)*	(85 ± 12)*
	Wellbeing	(63 ± 26)	(91 ± 10)*	(89 ± 11)*

* Denotes statistical significance when compared to the NMPK intervention (t-tests, $p<0.001$).

Table 3: Converted TWT distances to average walking speeds

	Average walking speed at each time point		
	NMPK	MPK 4 weeks	MPK 6 months
2MWT	1.064 ms^{-1} (±0.174)	1.125 ms^{-1}(±0.154)	1.114 ms^{-1}(±0.164)
6MWT	1.030ms^{-1}(±0.167)	1.102ms^{-1}(±0.168)	1.022ms^{-1}(±0.169)

Table captions

Table 1. Patients demographics (age, gender) and time (in years) from amputation; cause and level of amputation; K level; and type of NMPK used when recruited for the trial.

Table 2. Mean and SD for all completed outcome measures by time point

Table 3. Average walking speeds by time point

FIGURES

Figure 1

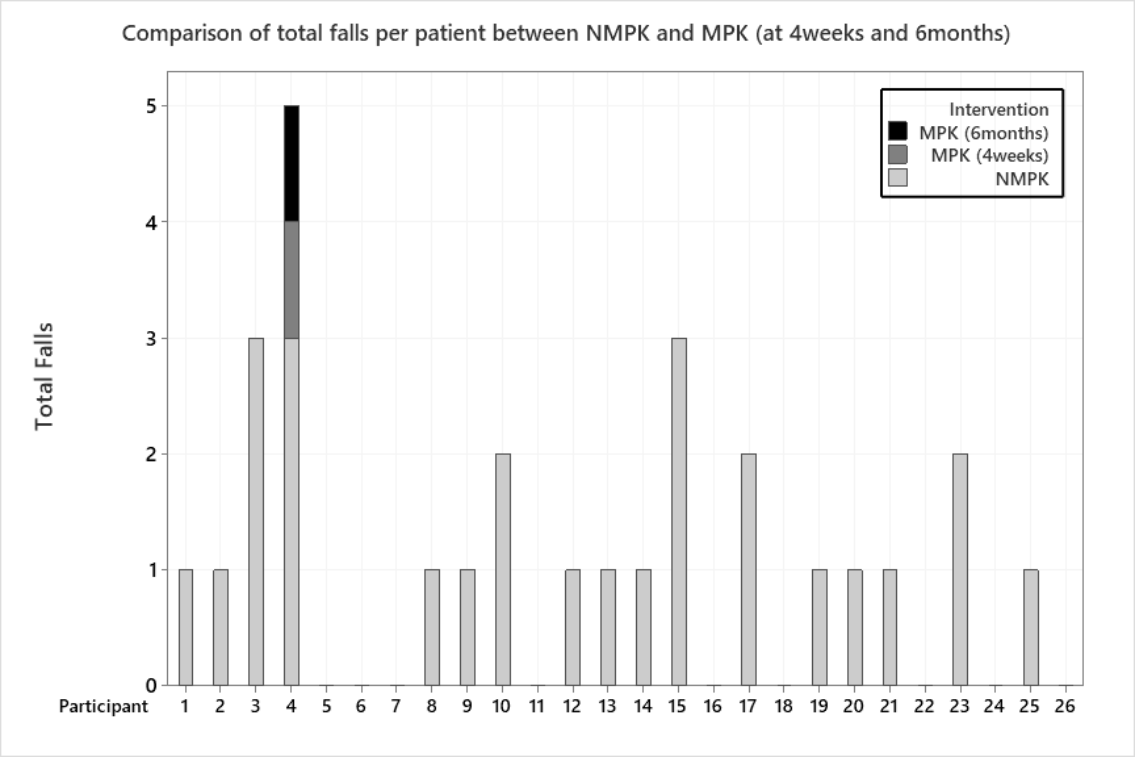

Figure 2

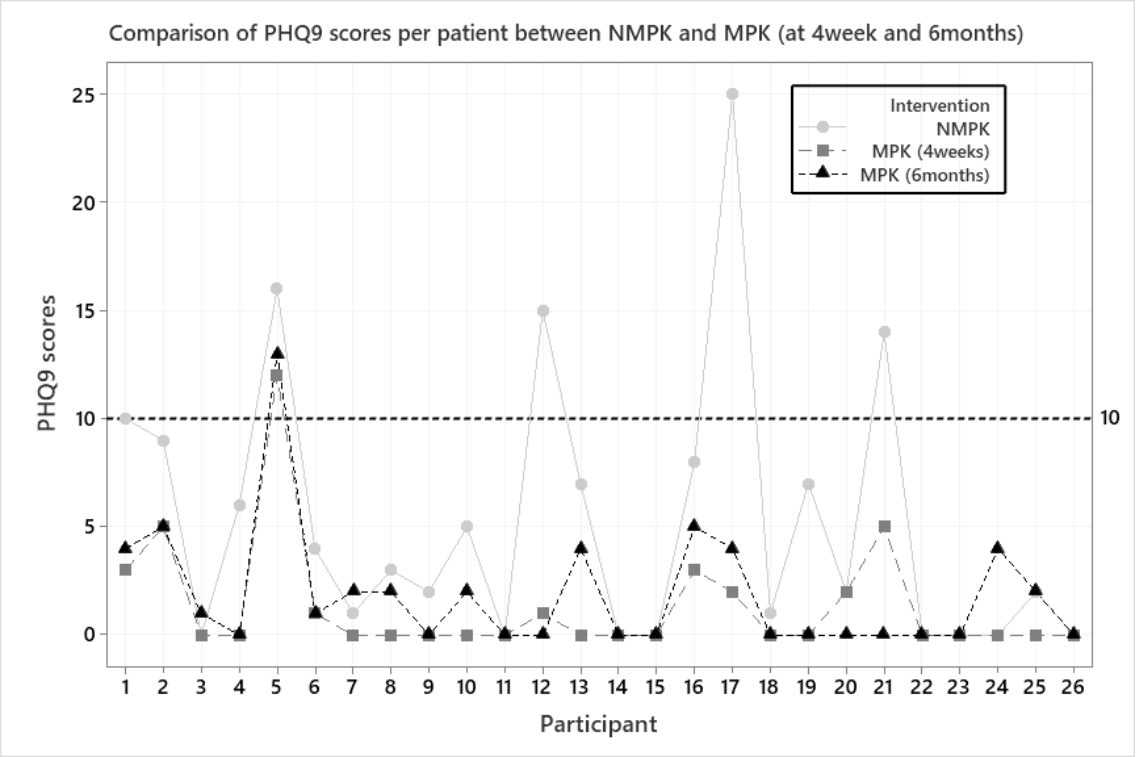
Comparison of PHQ9 scores per patient between NMPK and MPK (at 4week and 6months)
PHQ9 scores
Participant
Intervention
NMPK
MPK (4weeks)
MPK (6months)
10

Figure 3

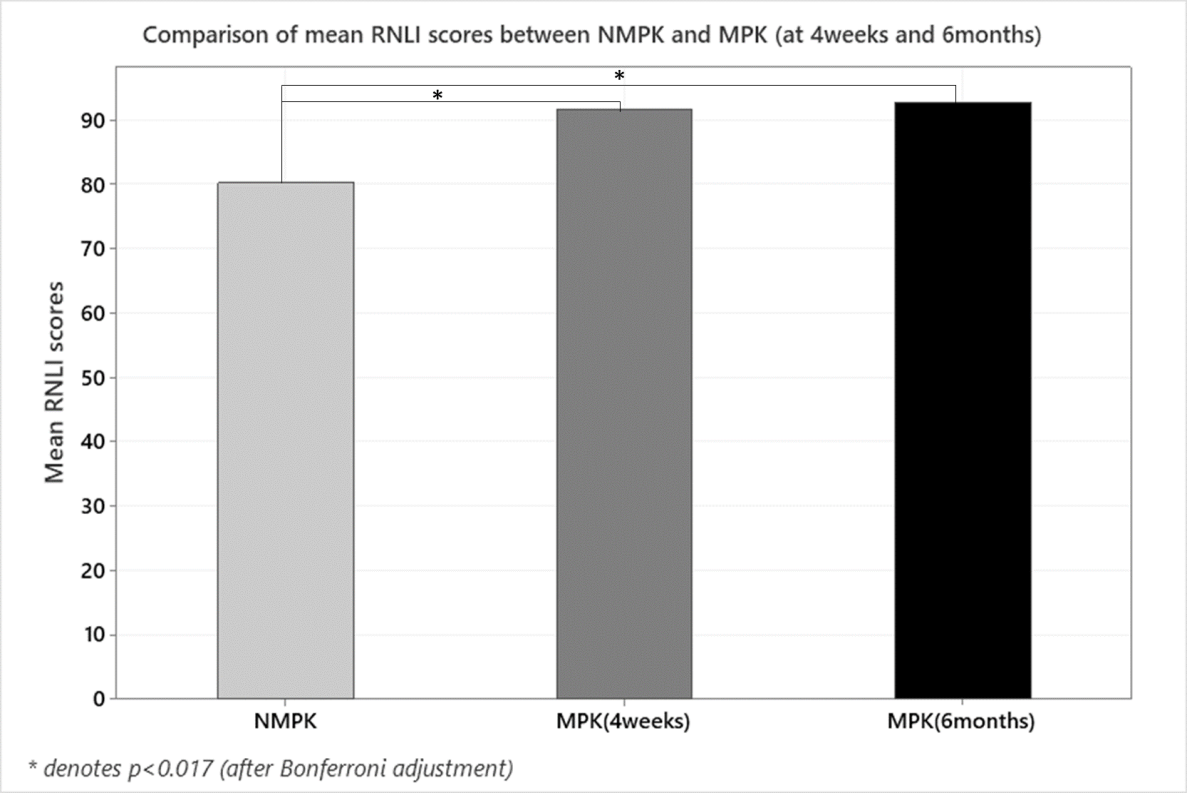
Comparison of mean RNLI scores between NMPK and MPK (at 4weeks and 6months)
Mean RNLI scores
0
10
20
30
40
50
60
70
80
90
*
*
NMPK
MPK(4weeks)
MPK(6months)
* denotes p<0.017 (after Bonferroni adjustment)

Figure 4

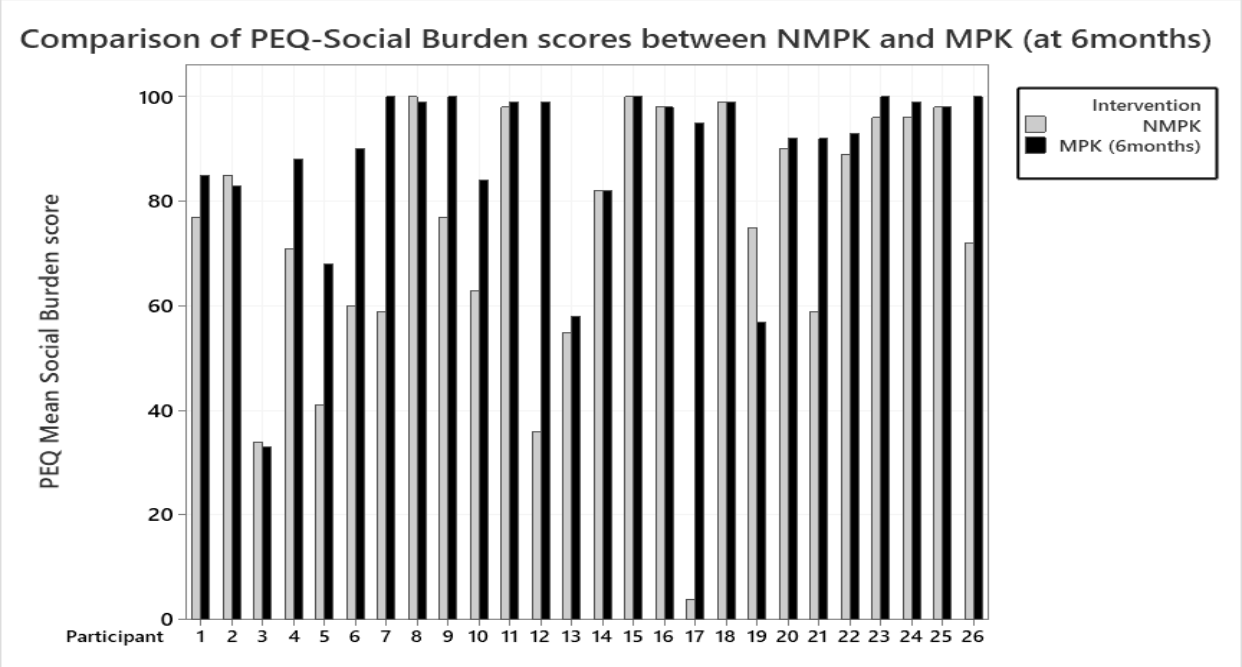
Comparison of PEQ-Social Burden scores between NMPK and MPK (at 6months)
PEQ Mean Social Burden score
0
20
40
60
80
100
Participant
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26
Intervention
NMPK
MPK (6months)

Figure Captions

Fig. 1 – Comparison of the total falls per patient between NMPK and MPK at 4weeks and NMPK and MPK at 6months. There was a 94% decrease in the number of people falling using MPKs (regardless of the timepoint) when compared to NMPKs. Only 1 of the 26 patients reported to fall when using the new MPK prescription at both 4weeks and 6 months, compared to 17 patients who reported falling with their NMPK

Fig. 2 – Comparison of PHQ9 scores per patient between the three interventions: NMPL, MPK at 4weeks and MPK at 6months. From the 26 patients, 5 would have been diagnosed with a major depressive disorder when using their NMPK prescription (as shown by the Threshold for depression diagnosis dotted line ≥10). From those ones, four scored below this threshold after 4 weeks of MPK use whilst one patient continued to score above it, however, a score improvement of 18.75% can be appreciated.

Fig. 3 – Comparison of the mean RNLI scores between interventions. When using an NMPK, the RNLI was 80.17% (±21.45), after 4 weeks of MPK use the average score was 91.53% (±13.25), and at 6 months it was 92.73% (±10.04). Significant mean differences were found between NMPK and MPK 4 weeks, and NMPK and MPK 6 months (* denotes $p=0.001$). No statistically significant mean difference was found between MPK 4 weeks and MPK 6 months. Error bars denote standard error.

Fig. 4 – Comparison of PEQ scores for the Social Burden subset between NMPK and MPK at 6months. Statistically significant mean differences were found between these two interventions ($W=245.5$, $p<0.001$).