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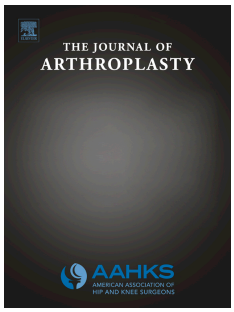

Feedback from Activity Trackers Improve Daily Step Count after Knee and Hip Arthroplasty: A Randomized Controlled Trial

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Feedback from Activity Trackers Improve Daily Step Count after Knee and Hip Arthroplasty: A Randomized Controlled Trial

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Abstract

BACKGROUND:

Commercial wrist worn activity monitors have the potential to accurately assess activity levels, and are being increasingly adopted in the general population. The aim of this study was to determine if feedback from a commercial activity monitor improves activity levels over the first 6 weeks after total hip (THA) or knee arthroplasty (TKA).

METHODS:

163 consecutive subjects undergoing primary TKA or THA were randomized into 2 groups. Subjects received an activity tracker with the step display obscured 2 weeks prior to surgery and completed patient reported outcome measures (PROMS). On day 1 after surgery participants were randomized to either the “Feedback Group” (FB) or the “Non Feedback Group” (NFB). The FB group were able to view their daily step count, and were given a daily step goal. Participants in the NFB group wore the device with the display obscured for 2 weeks after surgery, after which time they were also able to see their daily step count, but did not receive a formal step goal. The mean daily steps at 1, 2, 6 weeks, and 6 months were monitored. At 6 months after surgery subjects repeated PROMS and daily step count collection.

RESULTS:

Of the 163 subjects, 95 underwent THA and 68 underwent TKA. FB subjects had a significantly higher ($p<0.03$) mean daily step count by 43% in week 1, 33% in week 2, 21% in week 6, and 17% at 6 months, compared to NFB. FB subjects were 1.7 more likely to achieve a mean 7,000 steps per day than NFB subjects at 6 weeks after surgery ($p=0.02$). There was no significant difference between the groups in PROMS at 6 months. 91% of FB and 83% of NFB reported they were satisfied with the results of the surgery ($p=0.08$). At 6 months after surgery 70% of subjects had a greater mean daily step count compared to their preoperative level.

DISCUSSION AND CONCLUSION:

Subjects who received feedback from a commercial activity tracker with a daily step goal had significantly higher activity levels after hip and knee arthroplasty over 6 weeks and 6 months, compared to subjects who did not receive feedback in a randomized controlled trial. Commercial activity trackers may be a useful and effective adjunct after arthroplasty.

Keywords: Knee Arthroplasty, Hip Arthroplasty, Activity Tracker, Accelerometer, Patient Reported Outcomes, Steps.

Introduction

Mobility and physical activity are imperative to healthy aging. Evidence supports the positive benefits of regular physical activity with higher activity being associated with reduction in the risk of chronic disease and premature mortality[1, 2]. More recently associations like The Committee on Exercise and Cardiac Rehabilitation of the American Heart Association endorse regular physical activity and even classify it as a modifiable risk factor for prevention in cardiovascular disease and other chronic diseases, including diabetes mellitus, cancer, obesity, hypertension, bone and joint diseases, and depression[3].

After joint replacement surgery the aim should therefore not only be to improve pain and function, but also lead to improved activity. This activity should preferably meet the recommended daily activity levels as recommended by the WHO, US Centre for Disease Control and the National Heart Foundation of Australia [4] [5].

Historically, post-operative activity has been monitored by using participant completed subjective questionaries. [6, 7]. However, reports in literature have questioned the accuracy and validity of this form of assessment. It has been identified that in self-assessment of physical activity people tend to overestimate their level of activity by as much as 50%.[5] Verlaan et al. reported that up to 62% of the general population meet the activity intensity guidelines according to their self-assessment questionnaire whereas only 9.6% meet these same guidelines when defined from objective physical activity monitoring[8].

With the recent development of commercial-based accelerometers (activity trackers) the "subjective" error has been decreased and it has become easier to accurately measure daily activity level. It has also been identified that these activity trackers have a great potential to accurately assess activity level before and after joint arthroplasty[9]. These devices are largely used in the fitness industry as a motivational tool for those wanting to monitor and improve fitness. More importantly these devices have been shown to be a valid and reliable assessment tool for activity levels in normal participants[10], and participants after cardiac surgery[11].

In this study, we used commercial activity trackers to monitor and encourage higher activity levels in a series of participants before and after Total knee arthroplasty (TKA) or Total hip arthroplasty (THA). Our hypothesis was that subjects who received feedback of step count in the first 2 weeks after surgery would have higher mean daily step count over the first 6 weeks after TKA or THA. We also

examined whether this impacted participant satisfaction, participant reported outcome measures or 6 month activity level.

Materials and Methods:

This was a single center parallel group randomized controlled study with an equal allocation ratio. Eligible patients were all adults undergoing primary elective hip or knee arthroplasty under the care of one of the investigating surgeons between May 2016 and December 2016. Patients were required to provide written informed consent and were randomised to either control (NFB) or device feedback (FB) groups. Subjects with Rheumatoid Arthritis (RA) or other inflammatory disease, and those undergoing hip arthroplasty after an acute femoral fracture were excluded. Subjects who were not contactable within 2 weeks of their surgery were excluded.

Two weeks prior to surgery, subjects were contacted via telephone and invited to participate. All potential participants were informed the purpose of the study. Participants were emailed or posted the written Participant Information and Consent Form as approved by the Hospitals Human Research Ethics Committee. If the participant consented they received a Garmin Vivofit2 device for 2 weeks prior to their surgery. The Garmin Vivofit®2 uses a 3-axis MEMS accelerometer to estimate step count. This device has a long battery life of roughly 12 months and the retail cost is AUD$109. The device has been shown to be valid and reliable for assessment of step count [12-14].

The display on the Vívofit®2 device which indicates the number of steps per day was obscured in all participants in the preoperative period. On day 1 after arthroplasty, randomisation was performed. The randomisation was blocked in multitudes of 40 with a 1:1 allocation ratio. The random permutation list was generated from www.randomization.com. From this list a series of 40 numbered and sealed envelopes were created with the words “Feedback Group” or “No Feedback Group” generated in the order determined by the permutation list. When a participant was to be randomised the researcher obtained the next sequentially numbered envelope from a contact who was independent of the recruitment process for allocation consignment.

A researcher visited the subject on the first day after surgery and advised as to which group they had been allocated. If the subject was in the ‘Feedback Group’ the cover over the vivofit display was removed to make the step count visible and he or she was given a daily step goal as indicated in Table 1. Subjects were advised this goal should be considered a rough guide based on average activity level after arthroplasty, and may need to be adjusted in some circumstances for medical or lifestyle reasons. The weekly step goal was selected based on mean daily steps observed in a previous study of subjects with activity monitors after arthroplasty[15]. The goal of 7000 steps by week 6 was selected as this is the recommended daily step count for healthy older adults(>65)[16]

Participants in the "Non- Feedback Group" continued to wear the device with the display obscured for 2 weeks after surgery and were not given a daily step goal.

The mean daily steps from each group for the first 2 weeks was recorded and compared. After 2 weeks all participants were permitted to remove the cover over the display and see the step count. The non randomised group were not given the login or password required to sync the device and therefore could not access their data until after they were unblinded. All participants from both groups continued to wear their device until 6 weeks after surgery. Where possible the Garmin Vivofit2 device was synced to the subject's mobile device (phone or tablet) using the Garmin Connect mobile application. If the subject did not have a suitable mobile device, arrangements were made for the device to be synced at least every 3 weeks with the research unit's computers, either in person or via post. At 6 weeks after surgery participants returned the Garmin Vívofit®2 in person or via post. At 6 months after surgery subjects wore the Garmin Vívofit®2 again for a period of 3 weeks.

All subjects completed patient reported outcome questionnaires (PROMS) preoperatively and at 6 months after surgery. The questionnaire included the disease specific measure of the Knee injury and Osteoarthritis Outcome Score (KOOS) or Hip disability and Osteoarthritis Outcome Score (HOOS), and the general measure of the EuroQol-5D (EQ-5D): an instrument for measuring quality of life. At 6 months patients also completed the satisfaction component of the Knee Society Score, and graded their satisfaction with their outcome of surgery on a 5-point scale from very satisfied to very disappointed. They were also asked if they would have the same surgery again under the same circumstances (Yes/No/Unsure).

The study was performed at the Mater Hospital, a private hospital located in Sydney, Australia at which over 2000 arthroplasty procedures are performed annually. The routine care of subjects undergoing arthroplasty was admission on day of surgery, 5-day postoperative stay in acute care orthopaedic ward, commencement of mobilization on Day 1 after surgery and twice daily physiotherapy sessions for 5 days. The vast majority of subjects then attend inpatient rehabilitation for a further 7-10 days, and outpatient sessions twice a week until 6 weeks from surgery.

The study was initially designed to recruit 300 participants. Prior to commencement of the study a series of 30 participants undergoing TKA wore a Garmin Activity monitor for 6 weeks after surgery. In this population the mean number of recorded steps per day was 6700 (standard deviation 3200) before surgery and 5700 at 6 weeks (standard deviation 2600). This data was used to determine the study sample size for the RCT design. Power calculations from (http://www.statisticalsolutions.net/)

determined that in order to detect a 25% variation in mean step count, with a power of 0.8 and a significance level of 0.05, 113 participants were required for each group. By over sampling an additional 37 participants in each group, we account for potential withdrawals and losses to follow-up. A single planned interim analysis of the primary outcome measures was performed 7 months after commencement of the study, after recruitment of over 200 subjects. A statistically significant difference between the Feedback and Non- Feedback Groups was evident on all primary outcome measures of 1, 2 and 6 week step count, therefore recruitment was ceased after enrollment of 202 subjects.

Statistical Methods

The primary endpoint of the study was the average daily step count as measured with the Garmin Vivofit device at 1 week, 2 weeks, 6 weeks after surgery. This was expressed as a percentage of the subject's preoperative step count. Secondary endpoints were 6-month PROMS and mean daily step count. Continuous variables such as mean step count and patient reported scores were compared between treatment groups with independent t-tests. Changes over time were assessed with paired t-tests. The magnitude of mean differences between treatment groups were assessed with Cohen's d. Difference in proportions of patients between treatment groups were assessed with the Chi test ($\chi 2$ test). Fisher's exact test was used for comparing proportions when the cell counts were less than 5. Risk ratios and 95% Confidence intervals were calculated for proportions as a risk estimate.

Results:

Between May 2016 and December 2016, 395 subjects underwent primary hip or knee arthroplasty under the care of the investigating surgeons. Participant flow is shown according to the CONSORT guidelines in Figure 1. 202 subjects met the eligibility criteria and were enrolled in the study, 9 were excluded as their surgery was cancelled or postponed and 30 patients were excluded as there was insufficient data for baseline step count. The final groups included 81 subjects in the Feedback Group and 82 subjects in the No Feedback Group.

Baseline demographic and clinical characteristics of the 2 groups are shown in Table 2. There were no significant differences between the feedback and no feedback group for any of the baseline variables or characteristics. Daily step count was recorded for each subject a mean of 36 of a possible 42 days in the first 6 weeks after surgery. Days missing step counts was either due to non-compliance with wearing the device, or difficulties with successfully syncing the device to retrieve step counts.

Mean daily step count for the 2 groups at 1- week, 2-week, 6- week and 6- months is shown in Table 3 and Figure 2. The feedback group had a significantly higher mean step count at all review points than the no feedback group. Cohen's d was 0.4-0.5, indicating a moderate effect size[17]. The mean difference between groups ranged from 6-20% between 1 week and 6 months after surgery. For the Feedback Group the mean daily step count increased from 7069 preoperatively to 8326 at 6 months after surgery (p=0.001). For the No Feedback Group the mean daily step count increased from 7748 preoperatively to 8467 at 6 months after surgery (p=0.001).

7000 steps per day is recommended as a suitable activity level for subjects over 65 years[16]. The proportion of subjects achieving a mean of 7000 or more steps each day is shown in Figure 3. Subjects is the Feedback Group were 1.7 (95CI% 1.2-2.6) more likely to be achieve a mean 7000 steps per day than subjects in the No Feedback group at 6 weeks after surgery (p=0.02).

The patient reported outcome scores reported at 6 months for the 2 groups is shown in Table 4. There was no significant difference between the 2 groups for patient reported outcome scores at 6 months after surgery.

Patient satisfaction with the outcome was assessed at 6 months and the results are shown in Table 5. There was a trend (p=0.089) towards higher proportion of satisfied or very satisfied subjects in the Feedback Group, compared to the No Feedback Group.

30 day readmission was monitored for all subjects. One patient in the feedback group was readmitted with a post operative wound dehiscence at 17 days postoperatively and underwent debridement of the surgical wound and administration of intravenous antibiotics for 5 days. Tissue culture returned staphylococcus epidermidis. No further treatment was necessary. One patient in the non feedback group was readmitted after 28 days for investigation of pyrexia of unknown origin for investigation. No treatment required.

Discussion

Subjects who received feedback from a commercial activity tracker with a daily step goal had significantly higher activity levels after hip and knee arthroplasty at all measured time points over 6 months, compared to subjects who did not receive feedback. Feedback from activity trackers was found to be an effective tool to increase early mobilization with subjects motivated to “achieve their daily goal”.

This study is the first to report the positive effect of the use of activity monitors after knee and hip arthroplasty. Our results indicated that in the feedback group the patients receiving a daily goal and daily feedback in the first two weeks after surgery led to increased activity in the acute phase, increased activity at 6 months, and a trend to improved higher patient satisfaction at 6 months ($p=0.09$). The Feedback Group had significantly higher activity than the Non- Feedback Group by 45% at one week, 34% at two-weeks, 26% at six weeks and then finally the 17% at six-month mark. With the evident benefits of physical activity to healthy aging, especially after surgery, this increased activity can be considered a positive effect for a successful surgery.

The success following joint replacement surgery can be measured by a variety of parameters. It is important to aim to improve pain and function, but also physical activity. Physical activity includes an improvement in mobility which can be measured by daily step count. However, until now a reliable objective measure of improved step count following arthroplasty has not been reported. The World Health Organisation (WHO), US Centre for Disease Control and the National Heart Foundation of Australia have released a list of recommendations of daily activity or step count to improve an

individuals' health and reduce the risk of disease. According to their recommendations the average individual needs to take 10,000 steps a day to improve their health and reduce the risk of disease.[18-20] It is further specified that the recommended daily step count for healthy older adults(>65) is 7,000-10,000 [21]. The proportion of subjects taking 7000 steps or more increased from 50% prior to surgery to 70% at 6 months after surgery. The mean daily step count at 6 months was increased compared to preoperative status in 66% of subjects. Even though a value of 10,000 steps/day currently is promoted as a target for obtaining health benefits the increase seen in these patients after arthroplasty can be seen as a step in the right direction towards improving their health outcomes.

It should be noted that the group were differentiated by the presence or absence of feedback from the activity monitor only for the first 2 weeks after surgery. After this time both groups were able to see their daily step count on the device, but only the Feedback Group were encouraged to use the weekly step goals (see Table 1). It is interesting that the positive effect of the early feedback from the device and the use a goal had a positive effect over the full 6 months of the study. We hypothesise that the early feedback was a powerful and persisting motivator for subjects to be aware of their activity level over the long term.

With the recent rise in technological based assessment tools it is important for the orthopaedic fraternity to stay up to date [22] According to the World Health Organization (WHO) physical activity should be assessed by its four components: frequency, intensity, time, as well as type of activity (abbreviated as FITT). Modern commercially available activity trackers have the ability to monitor all of the FITT components. Physical performance is used as an assessment tool of patient recovery, rehabilitation, and clinical progress postoperatively. It is therefore important to be able to measure this accurately. The devices used in this study did not include a heart rate monitor to assess intensity, rather we deliberately focused on the daily step count, as it is our opinion that in the older population group, simpler goals may just be more appropriate. There are different forms of activity monitors with increasing levels of complexity and accuracy but ultimately just a basic, accurate activity monitor proved to be valuable in the rehabilitation of the post joint replacement patients.

Patient satisfaction is the ultimate indicator of successful surgery. At 6 months after surgery, 91% of subjects in the Feedback Group reported they were satisfied or very satisfied with the outcome of the surgery, compared to 83% of the subjects in the No Feedback Group (p=0.089). While this trend is encouraging, it was not reflected in the other patient reported outcomes at 6 months, with no

significant difference observed between the groups for the disease specific KOOS/HOOS sub scores ($p>0.65$), or the EQ5D general health measure ($p>0.17$).

In 2001 a group of surgeons from Europe coined the term “ERAS”. Enhanced recovery after surgery. Their research has highlighted the focus on quality of post-operative recovery and rested on several factors: a multimodal team approach, preoperative counselling, standardized analgesic and anaesthetic protocols, optimization of nutrition and early mobilization. Paying attention to these elements they stated: “Enhanced Recovery After Surgery practices improve the opportunity for rapid, uncomplicated recovery after surgery with both short- and long-term benefits for patients while improving quality and saving money” [23] With the focus on early mobilization in joint replacement surgery it has historically been difficult to monitor post-operative mobility with an objective scoring system or scale that accurately identified the patients level of activity. We believe the use of activity monitors can potentially lead to improved monitoring and ultimately improved activity outcomes. Activity monitors have been enthusiastically adopted by the younger populations. A recent commercial consumer reports of 1000 respondents suggest that over 50% of 18-64 year olds own at least one wearable device, and report health as the primary motivation for purchase[24]. It is likely that this technology will be used with increasing frequency in the arthroplasty population of the future.

Subjects in this study stayed in acute care hospital for a mean of 5 days after arthroplasty surgery. The most common practice was that they then attended inpatient rehabilitation for a further week. This practice is considerably slower than the usual care after arthroplasty seen in majority of other centres. This limits the generalisabilty of our findings. However it is plausible that the benefit of receiving feedback from an activity monitor is relevant to populations of both slow stream and fast stream rehabilitated protocols.

We identified some limitations to our study. We question the accuracy of these activity trackers at low speeds. The devices make an estimate of daily step count using a combination of motion sensors, including an accelerometer, which then use an algorithm to estimate step count. It is the algorithm that allows the device to differentiate between simple movements of the arm and walking. It can be expected that the algorithms are based on ‘normal’ walking speeds and so lack the sensitivity to accurately measure very slow speed walking, or movement patterns that are complicated by use of walking aids, such as crutches or walking frames. This is especially a concern in the first days after surgery when activity levels are expected to be at a slower rate. [25-27]. This potential error would affect both groups in this study equally so should not have unevenly biased

our early results. Regardless we advocate that these devices are probably better used after the first week from surgery when walking patterns are starting to normalise. Additionally, we lost a number of patients in our follow up either due to failure of device or information loss. We contributed this to possible hardware or user failure. Overall the activity monitors were well tolerated by subjects but for some elderly there were challenges with successfully managing the technology. Certainly, setting up the devices correctly required some form of assistance in a significant proportion of these subjects. This is likely to become less of an issue over time as the younger populations are vastly more familiar and comfortable with using modern technologies. Lastly during our exclusion process, 30 patients had to be excluded due to late arrival or delivery of their devices (more than 1-week post op). Despite these difficulties we achieved a more than 90% of successful data retrieval of the study cohort, and remained suitably powered for detecting differences in step counts between the groups.

Conclusion:

In a randomized controlled trial subjects who received feedback from a commercial activity tracker with a daily step goal had significantly higher activity levels after hip and knee arthroplasty over 6 months, compared to subjects who did not receive feedback. Commercial, non-invasive, light weight, low cost accelerometers may be a useful and effective adjunct to treatment after arthroplasty.

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Tables

Table 1: Daily Step Goal given to subject in the Feedback Group

Post op Day	Daily Step Goal
Day 1	No goal
Day 2	500
Day 3	1000
Day 4	1500
Day 5 to 7	2000
Week 2	3000
Week 3	4000
Week 4	5000
Week 5	6000
Week 6	7000

382 Table 2: Baseline demographic and clinical characteristics of the Feedback and No Feedback Group.

		FEEDBACK GROUP (N=81)	NO FEEDBACK GROUP (N=82)	p
OP TYPE	THR	52 (64%)	43 (53%)	0.128
	TKR	29 (36%)	39 (48%)	
GENDER	MALE	45 (56%)	36 (44%)	0.137
SIDE	RIGHT	48 (59%)	53 (65%)	0.480
AGE		67 (9)	66 (9)	0.289
BMI		27.8 (4.5)	28.2 (4.1)	0.951
PREOP MEAN DAILY STEP COUNT		6953	7655	0.146
PREOP PATIENT REPORTED SCORES				
KOOS	SYMPTOMS	45 (18)	45 (18)	0.849
	PAIN	47(16)	45 (19)	0.443
	FUNCTION	50 (18)	51 (21)	0.794
	QOL	30 (19)	33 (18)	0.335
EQ5D	MOBILITY	2.8 (0.9)	2.7 (0.9)	0.461
	SELF CARE	1.5 (0.8)	1.4 (0.8)	0.426
	USUAL ACTIVTIES	2.6 (1.0)	2.4 (0.9)	0.201
	PAIN	3.2 (0.9)	3.3 (0.6)	0.591
	ANXIETY/DEPRESSION	1.6 (0.9)	1.6 (0.8)	0.677
	GENERAL HEALTH	71 (18)	72 (16)	0.786

383 • Data shown are means (SD = Standard Deviation) or numbers (%)

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385 Table 3: Mean daily step count expressed at percentage of preoperative step count for the
386 Feedback and No Feedback Group

Mean Daily Step Count	Feedback Group (n=81)	No Feedback Group (n=82)	P value	Ratio	Mean Difference	95% CI for the mean difference	Cohen's d
1 week	20%	14%	0.002	1.43	6%	2-10%	0.5
2 week	44%	33%	0.001	1.33	11%	5-18%	0.5
6 week	103%	85%	0.005	1.21	18%	6-31%	0.5
6 month	137%	117%	0.030	1.17	20%	2-38%	0.4

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389 Table 4: Patient reported outcome scores for the 2 groups at 6 months

PATIENT REPORTED SCORES		FEEDBACK GROUP (N=80)	NO FEEDBACK GROUP (N=82)	p
KOOS MEAN (SD)	SYMPTOMS/100	75.6 (21.2)	75.1 (19.2)	0.886
	PAIN/100	86.0 (13.8)	85.4 (15.3)	0.801
	FUNCTION/100	87.3 (10.2)	86.4 (13.7)	0.651
	QOL/100	75.5 (17.2)	74.8 (20.0)	0.812
EQ5D MEAN (SD)	MOBILITY/5	1.5 (0.8)	1.3 (0.7)	0.176
	SELF CARE/5	1.1 (0.6)	1.1 (0.3)	0.434
	USUAL ACTIVTIES/5	1.5 (0.8)	1.4 (0.6)	0.435
	PAIN/5	1.7 (0.8)	1.8 (0.7)	0.836
	ANXIETY/DEPRESSION/5	1.2 (0.6)	1.3 (0.6)	0.529
	GENERAL HEALTH/10	7.8 (1.9)	8.2 (1.6)	0.160

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394 Table 5: Patient Reported Satisfaction for the 2 groups at 6 months

SATISFACTION AT 6 MONTHS	FEEDBACK GROUP (N=80)	NO FEEDBACK GROUP (N=82)	P	RISK RATIO	95% CI
SATISFIED OR VERY SATISFIED, N (%)	73 (91%)	68 (83%)	0.089	1.10	1.0-1.2
SAME SURGERY AGAIN, N (%)	78 (98%)	77 (94%)	0.230	1.04	1.0-1.1
KNEE SOCIETY SATISFACTION SCORE, MEAN /40	34.1	33.6	0.691		
KNEE SOCIETY EXPECTATION, SCORE/15	10.4 (3.3)	9.9 (2.9)	0.308		

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Figures

Figure 1: Participant Flow according to CONSORT guidelines

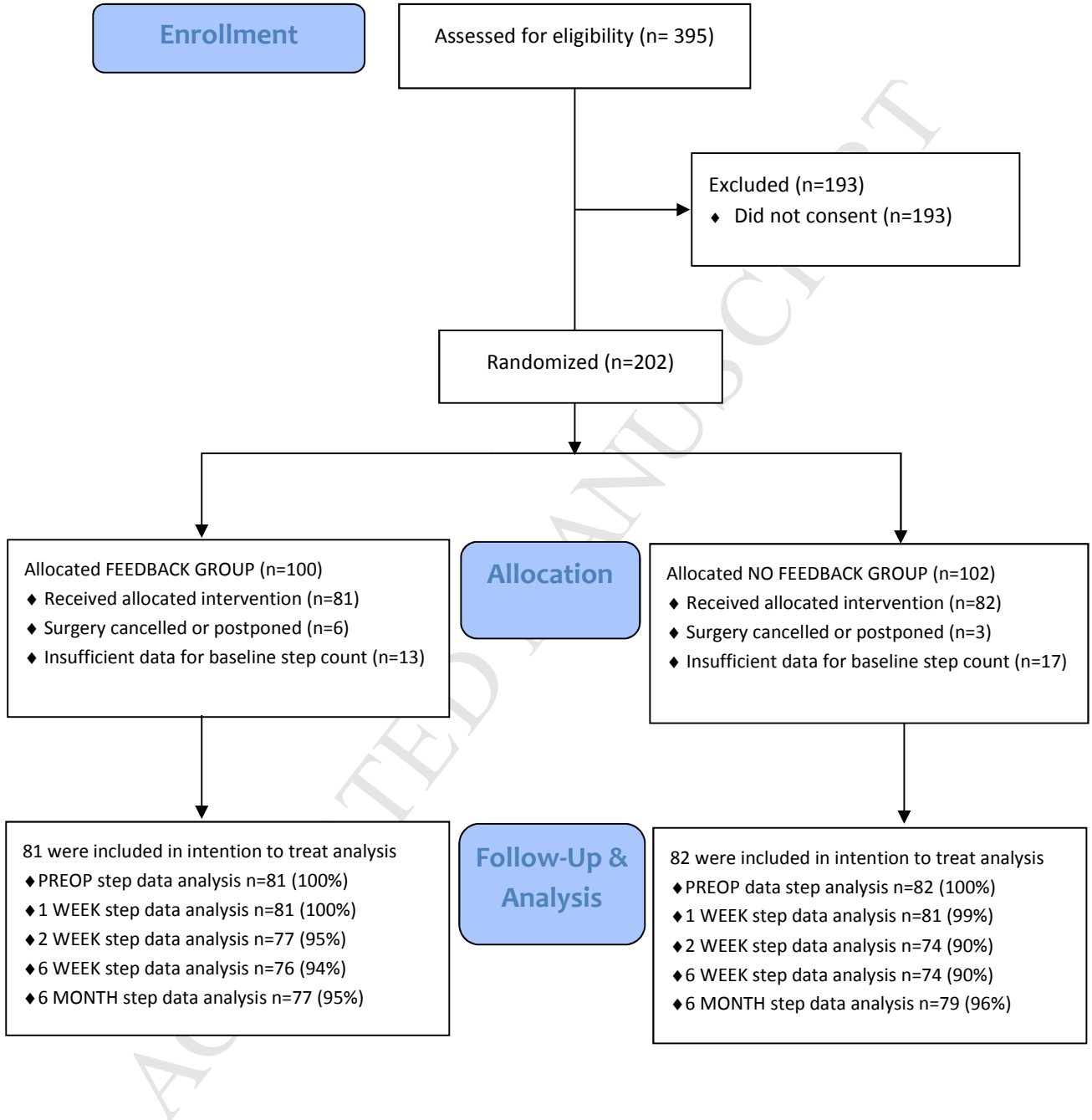


Figure 2: Mean Step Count as a Percentage of Preoperative Steps in the Feedback and No Feedback Group over Time

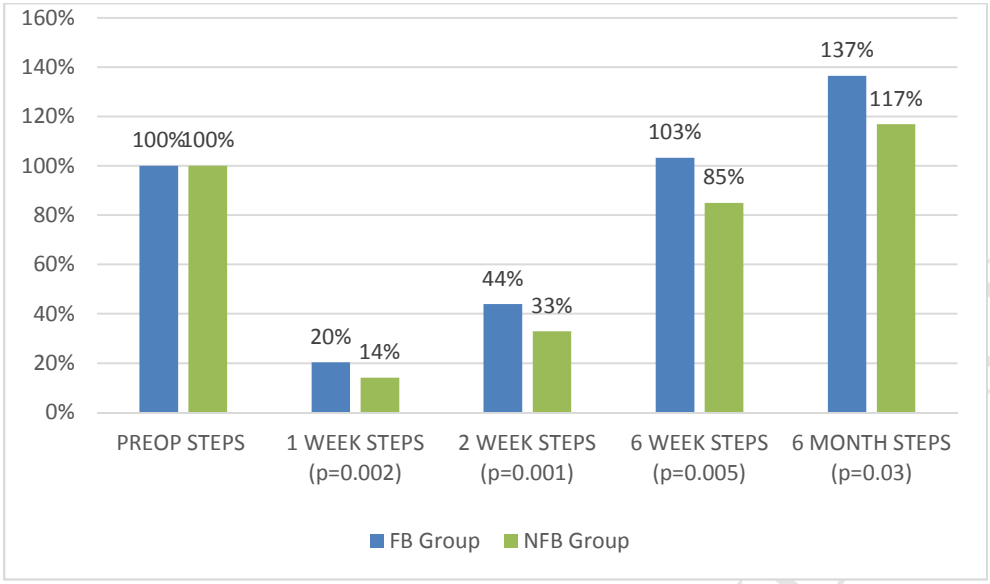
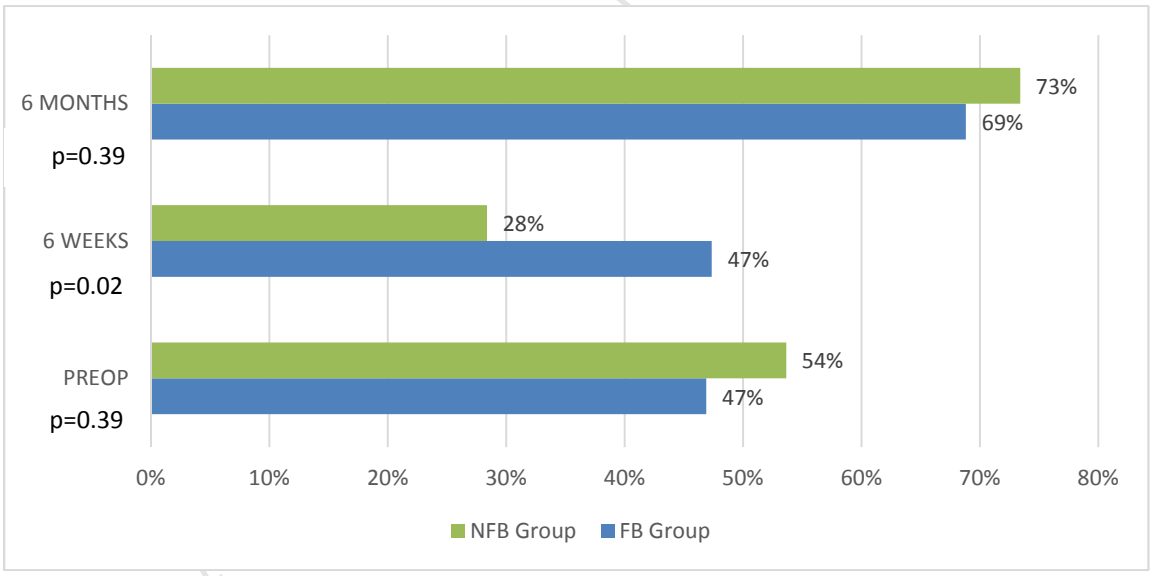


Figure 3: Proportion of Subjects in the Feedback and No Feedback Group taking a mean 7000 or more steps each day over time



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