

Sensor Data-Driven Personalised Hip and Knee Replacement Rehabilitation Compared to Standard of Care, Pilot Randomized Trial

I McNamara

Norfolk and Norwich University Hospital

C. E Whitehouse

Norfolk and Norwich University Hospital

N Ward

Norfolk and Norwich University Hospital

D Hodgins

Dynamic Metrics Ltd

R Whalley

Dynamic Metrics Ltd

ABSTRACT

This pilot was to evaluate if GaitSmart, a sensor based digital health rehabilitation solution, could be administered in a clinical setting, and compare patient outcomes of GaitSmart directed rehabilitation with Standard of Care (SoC) for patients after lower limb arthroplasty. The intervention group were monitored 4 times, 3 weeks apart, with GaitSmart, starting at least 6 weeks after surgery and compared to a SoC group, treated in accordance with NICE Guidelines. Each group contained sub-groups comprised of 14 hip and 8 knee patients, total 44 participants. Gait speed increased by a clinically significant amount of 0.16 m/s in both hip and knee intervention groups, compared to 0.04m/s and -0.01m/s in the hip and knee SoC groups. Hip and knee intervention compared to hip and knee SoC; Total joint angles increased by 9.9° and 11.4° compared to 5.0° and 1.4, Utility Score of the EQ5D-5L increased 0.05 and 0.01 compared to 0.13 and 0.10 and the EQ5D-5L VAS score increased by 9 and 3.7 compared to 3.6 and 5.3. For the Oxford Hip Score, the intervention group increased by 3.5 and the SoC group by 6. For the Oxford Knee Score the intervention group increased by 7.4 and the SoC group by 4.3. Patients in the intervention and SoC groups increased confidence in walking 45% and 16% respectively. The study demonstrates the GaitSmart intervention programme can be administered in outpatients with high patient satisfaction and provides clinically meaningful results for the primary outcome gait speed.

Keywords: Gait, Rehabilitation, Hip, Knee, Care, Arthroplasty, OKS: Oxford Knee Score, OHS: Oxford Hip Score, SoC: Standard of Care, QoL: Quality of Life, THR: Total hip replacement, TKR: Total knee replacement, MDC: Mean Detectable Change, MCID: Minimal Clinically Important Differences

KEY MESSAGES REGARDING FEASIBILITY/HEADLINES

What uncertainties existed regarding the feasibility?

It was unclear whether a fully automated exercise rehabilitation programme could be delivered in outpatients and what the clinical efficacy of this would be in comparison to Standard of Care (SoC) provided by physiotherapists.

What are the key feasibility findings?

The key findings are that the automated digital health solution could be successfully delivered in outpatients. The hip and knee patients both responded well to the intervention and functional outcomes improved more than those provided with SoC.

What are the implications of the feasibility findings for the design of the main study?

The implication is that this digital health intervention programme could be incorporated in to a large multi-site study.

BACKGROUND

In the UK, success of surgery of total hip replacement (THR) or total knee replacement (TKR) is measured subjectively using the Oxford Hip Score (OHS) or Oxford Knee Score (OKS) respectively (1). A total of 97% of THR and 94% of TKR patients report a post operative improvement in their symptoms, however, only 69% of THR patients and 58.6% of TKR patients report an improvement in Quality of Life (QoL) (EQ-VAS) and 34% were not able to return to normal activities of daily living (2). In addition, approximately 50% of hip and knee patients have gait abnormalities one year post op (3, 4, 5, 6). Preoperatively, patients with arthritis exhibit gait alterations. Because patients are generally unaware of how their walking pattern has adapted, many continue with their abnormal pattern of joint loading and muscle usage (7). In the longer term, the lack of correction of gait abnormalities can lead to falls and pain in muscles or other joints (8, 9).

Post operative physiotherapy is perceived as being important for gait rehabilitation. Conventional physiotherapy focuses on the muscles around the replaced joint, thus different exercises are provided for THR and TKR patients. However, the provision of physiotherapy is variable, often short lived and doesn't capture objective data of a patient's walking ability.

To aid rehabilitation, NICE guidelines (10) recommend that patients after primary elective THR or TKR undertaking self-directed rehabilitation have a clear understanding of the goals of rehabilitation, and the importance of undertaking their prescribed exercises to achieve those goals. Home based or outpatient gait rehabilitation resulted in comparable outcomes (11) and it is accepted that a patient's incentive to carry out prescribed exercises is often low (12), one study quoted 47% of patients attended all prescribed sessions (13).

Patients failing to meet their rehabilitation goals at 6 weeks should be offered supervised outpatient rehabilitation (10). This will normally include gait assessment and re-education and a bespoke exercise programme. However, in the UK there is no standardised gait assessment post THR or TKR. Generally, assessment is undertaken visually, with known limitations and

lack of specificity (14). To support home based tele-rehabilitation a number of video and sensor-based solutions have recently been developed (15, 16, 17). These systems are designed to either support and encourage rehabilitation at home through the monitoring of exercises provided by a physiotherapist or collecting information using a brace fitted with markers to measure 3D knee kinematics. The information collected by such a device can be used by a physiotherapist to set appropriate exercises (17). Whilst this approach does use kinematic data the main limitations are that it does not include any measurement of the contralateral knee or either hip joint and it relies on a physiotherapist to set exercises based on the data. Advancements in robotic technology for gait rehabilitation is generally only offered to those with severe neurological conditions that affect their gait due to cost and complexity (18).

The issues with all of these techniques are that they require a physiotherapist to prescribe the exercises, which is resource limiting. The primary objective of this study was to determine the feasibility of using of the GaitSmart device for the collection of gait kinematic data and using this data to personalise exercise plans from Total Knee Arthroplasty and Total Hip Arthroplasty patients at various intervals from 6 weeks to 15 weeks follow-up post surgery and compare to the standard of care.

METHODS

The study was designed as a parallel group randomised control trial. Patients were recruited from Hospital A from the clinics of consultants who had performed hip or knee replacements, with surgery conducted at a single site. Outpatient physiotherapy was conducted in a single hospital. Patients and assessors were not blinded to the treatment allocation but the participants in the SoC group were blinded to their GaitSmart data.

Ethics Approval and Consent to Participate

The trial was conducted in compliance with the principles of the Declaration of Helsinki (1996), the principles of GCP and in accordance with all applicable regulatory guidance, including, but not limited to, the Research Governance Framework.

Trial registration: HCRW, NCT04289025, Registered 23rd September 2020,
<https://clinicaltrials.gov/ct2/show/NCT04289025?term=NCT04289025&draw=2&rank=1>

Participants

As this was a pilot study, the original aim was to recruit 100 participants; 50 hip replacements and 50 knee replacements. Due to the COVID pandemic this number was revised down to 46 without constraint on the hip: knee patient ratio. As this was a pilot study this was considered acceptable to enable power calculations to be made for a full study (19).

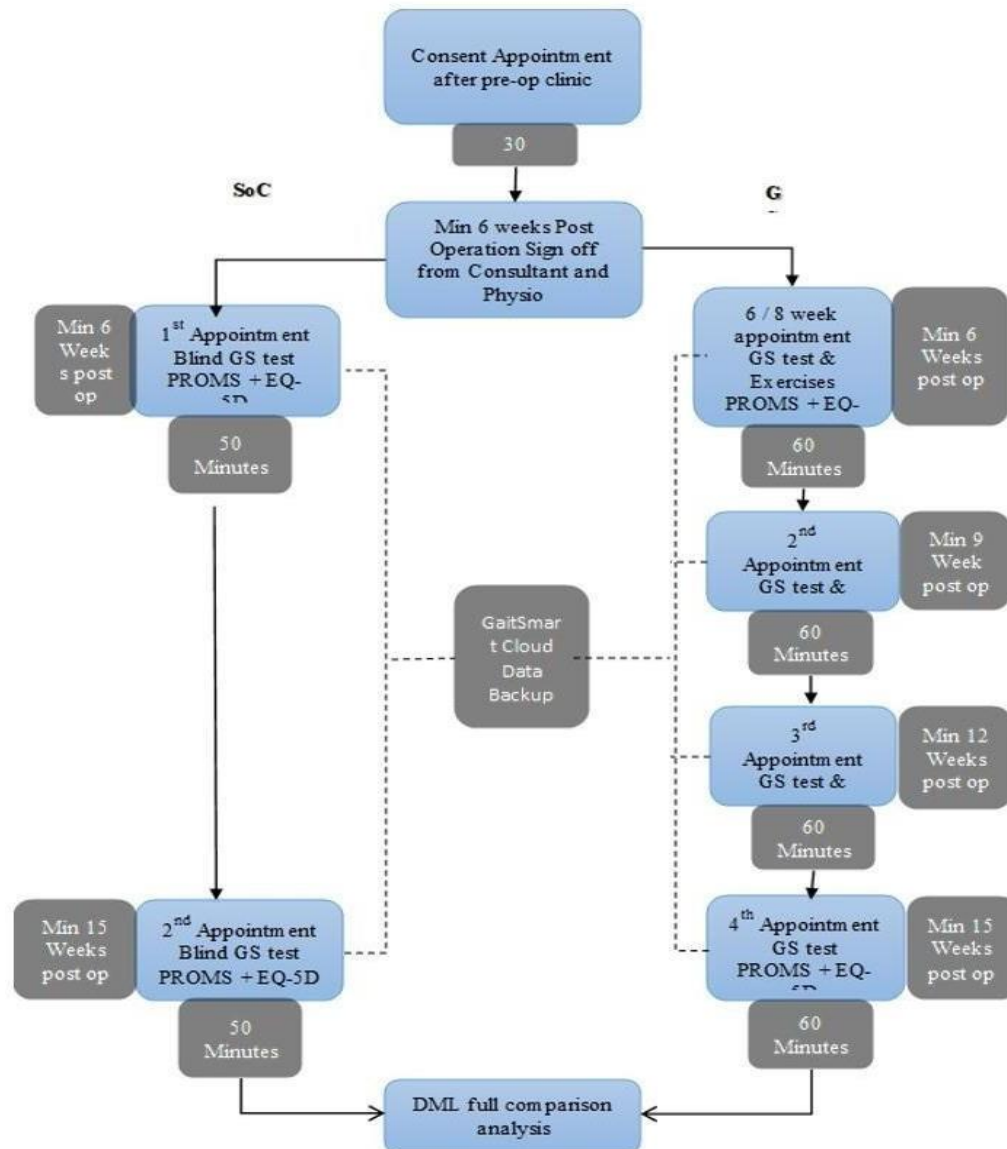


Figure 1: Protocol for Intervention and SoC groups

Patients were eligible if they had undergone either primary THR or TKR using standard implants and surgical techniques, received standard routine inpatient physiotherapy and then outpatient treatment until discharge from the physiotherapist up to 6 weeks post operatively. Patients were not excluded from the study if they; had previously received THR or TKR or had osteoarthritis in a native hip or knee joint. They were excluded if they had a pre-existing neurological condition that affected movement, or any constraint, such as catheters, or had moderate to severe pain in the contralateral limb.

The data collection timepoints and appointment protocol for the intervention and SoC groups are shown in Figure 1. All participants received routine NHS care. This included following a standard post-operative rehabilitation, of out-patient physiotherapy, centred on knee or hip strength and range of motion exercises, within the first six weeks after surgery.

Patients were randomised, by a computer-generated random sequence, into two groups: SoC and Intervention. Hospital A emailed the DML team with a pseudo-anonymised participant study identification number and whether the participant had had a hip or knee implant. After randomisation the DML team sent an email confirmation of the randomisation group to Hospital A. All GaitSmart tests were delivered by the research team. Training of the research team was undertaken by the equipment manufacturer.

Standard of Care Group (SoC):

The SoC group received postoperative rehabilitation in accordance with NICE QS 206 (20). All patients were given advice on self-directed rehabilitation. Those who had difficulties managing activities of daily living, ongoing functional impairment, or felt that they were not achieving their goals, were offered outpatient rehabilitation physiotherapy exercises in line with NICE guidance (10). The type of rehabilitation was not recorded for each patient.

Intervention Group:

The intervention group received an alternative gait rehabilitation programme based on a new scientific approach. The sensor data was used to calculate gait kinematic data. Mathematical analyses of the activation energies produced along with an automatic selection algorithm were used to recommend the exercises. Patients in the intervention group were provided with their GaitSmart report and with personalised exercises. The report included all gait kinematic variables but not gait speed, which was calculated. This was intentional as it may detract the patient's attention from improving gait kinematics.

GaitSmart

GaitSmart is a registered Class 1m Medical Device, where the accuracy of the sensor has been determined by the National Physical Laboratory (21) and the system has been compared against the reference standard optical gait lab data in measuring gait kinematics in THR and TKR patients (22, 23, 24). GaitSmart comprises seven sensor modules, custom elasticated straps, a tablet and a carrying case (see Figure 2).



Figure 2: GaitSmart system hardware

Gaitsmart Test Protocol:

To deliver the intervention, a 20 m quiet (discrete) straight corridor was used and patients wore flat or low-heeled shoes, with proper support, and were instructed to use the same footwear at each appointment, wherever possible. Elasticated straps were applied around the hips, with pockets at the base of the spine and just above the iliac crest, the thigh, just below the greater trochanter and the belly of the gastrocnemius muscle of the calf (see Figure 3).



Figure 3: Straps attached with sensors mounted

Control of the sensors was via the GaitSmart Smart App, which also provided instructions to the user, which included inserting the sensors in to pockets in the elasticated straps. Each patient walked up and down a 10-metre corridor at their self-selected speed. Once the evaluation was completed the sensors uploaded their data to the App via Bluetooth. Sensors were then returned to the Charger unit and the straps were removed.

Data was uploaded to the GaitSmart Cloud server via Wifi or 4-5g and the data analysis was performed automatically. Patients were presented with their report, in an easy-to-understand format, using scoring and colour coding to highlight gait deficiencies and simple text and photos to describe each exercise (Figure 4).

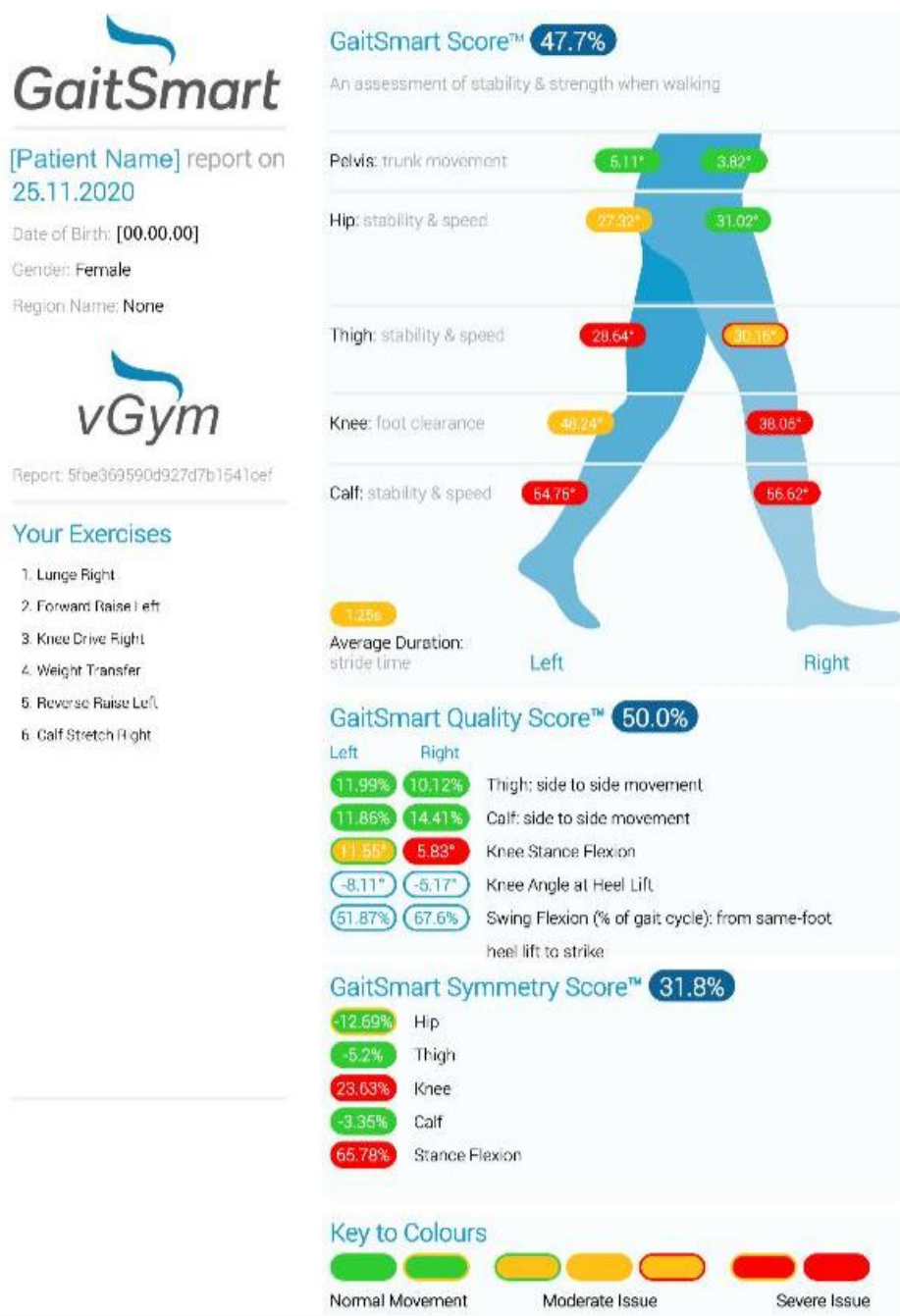


Figure 4: Example of report to patients Exercises

Many health groups in the UK publish online exercise booklets for hip and knee replacement surgery. In the UK these tend to be primarily stretching and ROM exercises, plus walking and stair climbing, and are considered as strength and balance exercises. The different exercises that could be offered for SoC are summarised in Table 1.

For the GaitSmart intervention programme, six exercises were automatically chosen from this list. The patient was advised to use support, if required.

Table 1: List of exercises that can be prescribed for both SoC and Intervention groups

No.	Exercise	THR	TKH
1	Lunges	x	x
2	Reverse lunges	x	x
3	Single leg balance (knee straight)	x	
4	Single leg balance (knee bent)		x
5	Knee extensor strengthening in standing		x
6	Standing with weight transfer	x	x
8	Marching on the spot	x	x
9	Single leg squat	x	x
10	Double leg squat	x	x
11	Hip abduction (1 leg standing)	x	x
12	Heel (calf) raise (unilateral)	x	x
13	Straight leg raises forward		x
14	Standing hamstring curls		x
15	Side stepping	x	
16	Straight leg raises reverse	x	
17	Unilateral pelvis raise	x	
18	Hip extension (bent knee)	x	
19	Hip flexion (bent knee)	x	x
20	Toe raises	x	
21	Heel to toe walking		x
22	Toe walking	x	
23	Heel walking	x	
24	Stand on toes	x	x
25	Quadriceps stretch	x	
26	Hamstring stretch		x
27	Calf stretches		x
28	Step up/ step down	x	x

Outcome Measures

Primary Outcome Measure:

The primary outcome measure was the change in the patient's gait. Gait speed is a universally recognised measure that predicts long term health outcomes, with established values for Mean Detectable Change (MDC) of 0.05m/s and minimally clinically significant change of 0.1m/s (25). There is also published evidence of the relationship between the risk of falls and speed (26, 27, 28, 29). Furthermore, gait kinematic data is associated with the risk of falls, where people at higher risk can be identified through kinematic data analysis (30, 31, 32, 33, 34, 35). G

Secondary Outcome Measures:

Secondary objective outcome measures included gait kinematic parameters and patient reported outcomes.

Gait Kinematic Parameters:

Gait kinematic data, particularly hip and knee range is used by optical gait labs to define gait deficiencies in THR and TKR patients (5, 24, 36). Total Joint angle is the combined range of motion through the gait cycle for the left and right hips and knees which provides a precise

metric of gait kinematics for THR and TKR patients. A quantifiable increase demonstrates an improvement in hip and/ or knee range of motion.

GaitSmart score; a proprietary value, which summarises the limb movement in the sagittal plane, in relation to a healthy, age matched, control reference (23). A perfect score of 100% is obtained when all parameters are in the normal healthy zone. Traffic light coding is used to identify how far each parameter deviates from normal. It is a proven method to empower and motivate patients in other healthcare applications, such as controlling blood pressure (37).

Patient Reported Outcome Questionnaires:

The Oxford Knee Score (OKS) and the Oxford Hip Score (OHS) were secondary outcome measures. These are a 12-question patient self-assessment of knee or hip function and pain (38) with values ranging from 0 (worst outcome) to 48 (best outcome).

The EQ-5D-5L is a two-part self-report questionnaire consisting of five domain questions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and a visual analogue scale of their overall health (VAS). Responses to the domain questions are profiled and mapped (38, 40, 41) to derive a single index utility value, which reflects quality of life according to the preferences of the general population of a country/region. The Utility index can range from below 0 (a state worse than death) to 1, the value for full health.

Clinical Context and Adverse Events

There were no adverse events.

Statistical Analysis

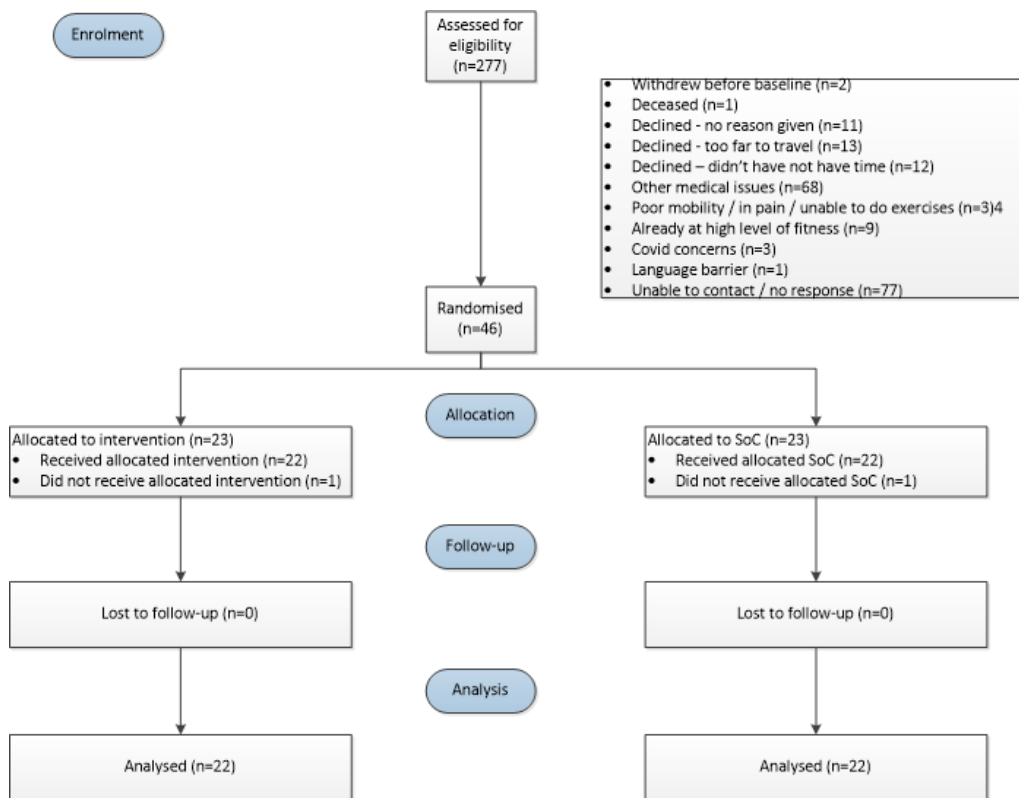
The hip and knee groups and the intervention and SoC groups were analysed separately. In accordance with good practice for pilot studies, the mean and 95% confidence levels and the p value were quoted using Excel, with the Data Analysis package installed (19). For all patients the following data was collected: Age, gender, height, weight, any conditions that affect mobility.

RESULTS

Participants were recruited between October 2020 and December 2021. Last follow-up visits were in February 2022 with some delayed visits due to COVID-19.

Flow of Participants Through the Trial

A total of 277 patients were screened, of which 46 were randomised.



Two patients with THR had to withdraw after their baseline test due to newly diagnosed medical conditions. There was no loss to follow up of the remaining 44 patients. All data was collected at all appointments, in accordance with the protocol. Due to Covid restrictions, six of the 44 patients had prolonged gaps between appointments. Thirty-nine exit questionnaires were completed, including 19 of the 24 who completed the protocol prior to the questionnaire being introduced and returned their form by post.

Participant Characteristics

There were no discernible baseline differences between the groups. (Table 2). Gait kinematics do not change with gender or age up to the age of 80 (23)A summary of key characteristics for all participants is provided in Table 2.

Table 2 Patient characteristics

	SoC		Intervention	
	Hip	Knee	Hip	Knee
No:	14	8	14	8
Average Age (SD)	72.9 (10.12)	71.9 (8.82)	66.2 (11.8)	69.1 (9.39)
Gender (% male)	36	75	50	50
Av Height (m)	1.65	1.71	1.67	1.68
Av Weight (kg) start	77.0	88.2	88.7	86.3
Av No: joint replacements per patient, including current operation	1.4	1.9	1.4	1.6
Av No: arthritic joints patient has post op	0.43	0.38	0.29	0.50

Av No days after surgery before start of programme	112.9	102.4	98.5	80.1
No: Exit questionnaires	12	7	13	7

Primary Outcome Comparison-Baseline To 9 Weeks Post Intervention

The average baseline walking speed for the hip patients was 0.84 m/s. For the knee patients it was slightly higher at 0.93 m/s for the SoC group and 0.88 m/s for the intervention group.

Walking speed increased by an average of 0.16 m/s for both hip and knee patients in the intervention group, above the Mean Detectable Change (MDC) of 0.05m/s and minimally clinically significant change of 0.1m/s. For the SoC group the hip patients had a slight increase of 0.04m/s, whereas the knee patients reduced their speed by 0.1m/s. Neither SoC group met the MDC value. No group changes were statistically significant.

Table 3: Primary Outcome - Gait speed at the start and end of the trial

		Gait Speed (m/s)					
		Hip and Knee		Hip		Knee	
		Control	Intervention	Control	Intervention	Control	Intervention
Start	av	0.87	0.85	0.84	0.84	0.93	0.88
	95% conf	0.78-0.96	0.74-0.97	0.74-0.93	0.68-0.99	0.76-1.10	0.73-1.03
End	av	0.89	1.02	0.88	1	0.92	1.04
	95% conf	0.82-0.97	0.91-1.12	0.78-0.98	0.84-1.16	0.79-1.05	0.94-1.15
p value		0.682	0.045	0.527	0.165	0.918	0.103

Secondary Outcome Comparisons – Baseline To 9 Weeks Post Intervention

GaitSmart Score and Total Joint Angle:

The GaitSmart Score increased by 11% and 14.5% for the hip and knee intervention groups respectively. For the SoC hip and knee groups it was 6% and 2% respectively. None were statistically significant.

Table 4: GaitSmart Score at the start and end of the trial

		GaitSmart Score (%)					
		Hip and Knee		Hip		Knee	
		Control	Intervention	Control	Intervention	Control	Intervention
Start	av	69.3	68	70.9	67.7	66.5	68.5
	95% conf	59.2-79.5	57.8-78.2	58.8-83.1	54.3-81.0	47.4-85.5	51.7-85.2
End	av	73.9	80.5	76.8	78.8	68.9	83.2
	95% conf	63.5-84.4	72.5-88.5	65.9-87.7	67.4-90.5	46.6-91.3	73.9-92.6
p value		0.538	0.065	0.489	0.222	0.871	0.154

The total joint range increased by 10° and 11.5° for the hip and knee intervention groups respectively. For the SoC hip and knee groups it was 5° and 1.5° respectively. None were statistically significant. However, a reduction in hip and knee angles is associated with fallers in older adults (8).

Table 5: Total Joint Angle at the start and end of the trial (P value in bold if p<0.05)

		Total Joint angle (°)					
		Hip and Knee		Hip		Knee	
		SoC	Intervention	SoC	Intervention	SoC	Intervention
Start	av	172.4	171.7	176.3	173.6	165.5	168.4
95% conf		161.8-182.9	162.9-180.6	164.9-187.8	161.4-185.5	144.3-186.7	155.9-180.9
End	av	176	182.2	181.3	183.5	166.9	179.8
95% conf		165.5-186.6	172.7-191.6	170.1-192.5	169.8-197.3	145.8-188.0	168.9-190.6
p value		0.634	0.121	0.551	0.299	0.928	0.199

Patient-Reported Outcome Questionnaires:

EQ5D-5L utility index increased by 0.05 and 0.01 for the hip and knee intervention groups respectively. For the SoC hip and knee groups it increased by 0.13 and 0.10 respectively. Both the SoC hip and knee groups exceeded the Minimal Clinically Important Difference (MCID) of 0.07 (42). The control hip group change was statistically significant (p=0.016). EQ5D-5L VAS increased by 9 and 3.7 for the hip and knee intervention groups respectively and the hip group exceeded the MCID of 5.35 (43). For the SoC hip and knee groups it was 3.6 and 5.3 respectively, both below the MCID value. The intervention hip group change was statistically significant (p=0.036).

Table 6: Change in Index using EQ5D-5L

		EQ5D Index score					
		Hip and Knee		Hip		Knee	
		SoC	Intervention	SoC	Intervention	SoC	Intervention
Start	av	0.71	0.77	0.73	0.80	0.68	0.73
95% conf		0.66-0.77	0.72-0.83	0.67-0.80	0.72-0.88	0.57-0.78	0.64-0.82
End	av	0.83	0.81	0.86	0.85	0.78	0.74
95% conf		0.77-0.89	0.73-0.89	0.79-0.99	0.78-0.92	0.66-0.90	0.57-0.91
p value		0.010	0.470	0.016	0.368	0.240	0.897

Table 7: Change in VAS using EQ5D-5L

		EQ5D VAS					
		Hip and Knee		Hip		Knee	
		SoC	Intervention	SoC	Intervention	SoC	Intervention
Start	av	79.6	79.1	78.2	80.7	81.9	76.3
95% conf		75.6-83.5	73.9-84.3	73.2-83.2	73.7-87.7	75.2-88.5	68.7-83.8
End	av	83.8	86.2	81.8	89.7	87.2	80
95% conf		78.2-89.3	81.1-91.2	73.7-89.8	85.9-93.5	81.5-93.0	68.6-91.4
p value		0.232	0.062	0.467	0.036	0.251	0.600

Oxford Hip and Knee Score:

The data for the Oxford Hip or Knee Score at the start and end of the trial for all patients in provided in Table 8.

Table 8: Change in Oxford Hip and Knee Score (P value in bold if <0.05).

		OHS		OKS	
		Control	Intervention	Control	Intervention
Start	av	37.6	39.9	34.8	30.6
95% conf		33.0-42.3	36.0-41.8	31.9-37.6	26.2-35.0
End	av	43.6	43.4	39.1	38
95% conf		41.4-45.7	40.9-45.9	35.4-42.8	35.7-40.3
p value		0.037	0.151	0.251	0.011

The changes in Oxford Hip Score for the intervention and SoC groups were 3.5 and 5.9 respectively. Only the SoC was statistically significant ($p=0.037$) and above the threshold of 5 points for minimal important difference (44).

For the Oxford Knee Score, the changes for the intervention groups and SoC were 7.4 and 4.3 respectively. Only the intervention group showed a change that was statistically significant ($p=0.011$) and above the minimal important difference of 5 points (44, 45).

Patient Feedback:

All patients undertaking the GaitSmart intervention found the GaitSmart report useful and would recommend it to a friend undergoing hip or knee replacement.

When asked which aspects of the report they found useful, allowing for as many options they felt were appropriate, 90% chose the GaitSmart Score.

This data is summarised in Table 9.

Table 9: Report preferences for the intervention group

	Overall report (%)	GS Score (%)	Traffic lights (%)	Values (%)
Intervention	100	90	70	65

Both the SoC and intervention group were asked if their confidence in walking had altered by the end of the programme and whether they performed rehabilitation exercises between visits and the findings are presented in Table 10.

Table 10: Change in walking confidence for SoC and intervention group

	Reported walking confidence (%)				% Exercised between sessions
	Significantly increase	Increased	Stayed the same	Decreased	
SoC	16	42	42	0	84
Intervention	45	30	25	0	100

Forty five percent of the intervention group reported that their confidence in walking significantly increased compared with 16 % in the SoC group. All the intervention group reported that they had performed rehabilitation exercises, compared to 84% of the SoC group.

DISCUSSION

The findings of this study support the hypothesis that the GaitSmart device improves gait speed, compared to standard of care, after discharge from standard post op rehabilitation.

The primary outcome measure was gait speed, as this is a universally recognised outcome metric for gait rehabilitation, and evidence exists showing how this relates to mortality, cardiovascular disease and cancer (46). In this study the hip and knee intervention groups both increased gait speed by 0.16m/s, which were clinically meaningful changes (25) and took the average values for both hip and knee patients to above 1m/s. The control groups however, showed minimal changes of 0.04m/s and -0.01m/s and lower final speed values of 0.88m/s and 0.92m/s respectively for the hip and knee groups.

The two other objective secondary outcome measures, GaitSmart Score and change in total joint angle range, showed a trend for a greater improvement for the intervention groups compared to the SoC groups, although none were significantly different for this small cohort. Hip and knee angle range is related to falls (8) and all groups were below that of a healthy reference of 202° at baseline (23). The increase in total joint angle for the hip and knee intervention groups were 9.9° and 11.4° respectively, compared to 5.0° and 1.4° for the SoC groups. These changes correspond with the increase in gait speed and provide an objective way of identifying gait changes.

The patient reported outcome measures of EQ5D-5L Function and VAS, and the OHS and OKS showed variations across the groups. The EQ5D-5L Function Index showed greater improvement with the SoC hip and knee groups compared to the intervention groups, with the hip groups change statistically significant. However, for the EQ5D-5L VAS, the hip intervention group was the only one that showed a statistically significant increase. It is recognised that the EQ5D-5L questionnaire covers all health aspects and not just mobility. The fact that the study ran during Covid may have affected some individuals more than others, for example regarding anxiety. The single question regarding confidence in walking, Table 9, highlights this, with the intervention group showing greater improvements than the SoC group.

For the OHS, in both groups, the baseline values were already indicative of a very satisfied hip patient. As such there were small changes in both groups with the SoC group exceeding the MCID. For the OKS, the intervention group commenced as a satisfied knee patient and concluded as a very satisfied patient and exceeded the MCID. By comparison the SoC group commenced between satisfied and very satisfied and completed as very satisfied. As knee replacement patients experience greater dissatisfaction post operatively, it is unsurprising that there are greater potential gains to be made with an intervention, and encouraging that GaitSmart can address some of the dissatisfaction in a clinically significant manner. Overall, there was poor correlation between the objective gait data, and both the patient reported outcome measures. There were also poor correlations between the OHS/ OKS and the EQ5D5L. This poor correlation was also observed in another study comparing gait parameters and WOMAC as a patient reported outcome (47). Their conclusion was the gait parameters are more sensitive than the WOMAC score. The patients in the intervention group all found the GaitSmart report useful, but there was no specific feature which all patients found beneficial to them. The most popular was the GaitSmart Score at 90%, followed by traffic lights at 70% and the specific values at 65%. The inclusion of all of these values meant patients could choose which to focus

on. Ninety five percent found the exercises useful and 100% would recommend the programme to friends.

A potential limitation of the study is that it ran throughout the Covid Pandemic. Whilst this is also a strength in that it demonstrated that the GaitSmart Intervention programme can run very effectively in an outpatient clinic, the disruption due to Covid, meant that many patients were not able to start the programme at 6 weeks after surgery. The SoC group started on average 104.5 days after surgery and the intervention group 92.5 days after surgery. Whilst all patients in the intervention group received the intervention programme as planned, some in the SoC group, who should have received further physiotherapy found it was not accessible. Both groups were also small, with 14 hip and 8 knee patients in both the intervention and SoC groups.

SUMMARY

This pilot study has shown that the GaitSmart intervention programme can be delivered in an outpatient department by a health care assistant. The findings suggest that the intervention programme has a greater impact on the patient's gait, compared to SoC, whilst patient reported outcomes varied between groups. This presents a feasible method of offering a rehabilitation intervention in an outpatient setting to improve patient outcomes. This pilot demonstrated positive results, with no amendments proposed to the protocol, for progression to future trials intended to extend site coverage.

ACKNOWLEDGEMENTS

R Markwell supported the ethical submissions.

References

1. NHS Digital. Finalised Patient Reported Outcome Measures (PROMS) in England, for Hip and Knee Replacement Procedures (April 2020-March 2021)
2. Wylde, V., et al. "Patient-reported outcomes after fixed-versus mobile-bearing total knee replacement: a multi-centre randomised controlled trial using the Kinemax total knee replacement." *The Journal of bone and joint surgery. British volume* 90.9 (2008): 1172-1179.
3. Blixt S. Patient-reported Mobility Problems after Total Hip Arthroplasty. Gothenburg University <https://gupea.ub.gu.se/handle/2077/45217> 2017
4. Hanly RJ et al. Outpatient 3-D gait analysis one year after THA using a portable IMU system: bone joint j jun 2016, 98-b (supp 11) 1
5. Levinger P, Menz HB, Morrow HD, Perrot MA, Bartlett JR et al. Knee biomechanics early after replacement surgery predict abnormal gait patterns 12 months post operatively. *Journal of Orthopaedic Research* 2012 371-376
6. Rahman J, Tang Q, Monda M, Miles J, McCarthy I. Gait assessment as a functional outcome measure in total knee arthroplasty: a cross sectional study. *BMC Musculoskeletal Disorders* 2015 16:66
7. Shakoor, N., Block, J. A., Shott, S., and Case, J. P. (2002). Nonrandom evolution of end- stage osteoarthritis of the lower limbs. *Arthritis Rheum.* 46, 3185–3189. doi: 10.1002/art.10649
8. Kerrigan, D. C., Lee, L. W., Collins, J. J., Riley, P. O., & Lipsitz, L. A. (2001). Reduced hip extension during walking: healthy elderly and fallers versus young adults. *Archives of physical medicine and rehabilitation,*

- 82(1), 26-30.
9. Chen KH, Chen PC, Liu KC, Chan CT. Wearable sensor-based rehabilitation exercise assessment for knee osteoarthritis. *Sensors*. 2015 Feb 12;15(2):4193-211.
 10. NICE guideline NG 157 Joint replacement (primary): hip, knee and shoulder. Published 04 June 2020 <https://www.nice.org.uk/guidance/ng157>
 11. Barker KL, Room J, Knight R, et al. Home-based rehabilitation programme compared with traditional physiotherapy for patients at risk of poor outcome after knee arthroplasty: the CORKA randomised controlled trial. *BMJ Open* 2021;11: e052598. doi:10.1136/ bmjopen-2021- 052598
 12. McLean SM, Burton M, Bradley L, Littlewood C. Interventions for enhancing adherence with physiotherapy: a systematic review. *Man Ther* 2010; 15: 514 -521.
 13. Artz L E, Marques N, Sanderson E, Lewis E, Murray K, Parwez J, Bertram T, Beswick W, Burston A, Gooberman-Hill A, Rachael, Blom, A and Wylde, V. Effect of group-based outpatient physiotherapy on function after total knee replacement: The ARENA randomised controlled trial. *Arthritis Care and Research*, 72 (6) 2020. pp. 768-777
 14. Toro B, Nester CJ, Farren PC. The status of gait assessment among physiotherapists in the United Kingdom. *Arch Phys Med Rehabil*. 2003 Dec;84(12):1878-84. doi: 10.1016/s0003- 9993(03)00482-9. PMID: 14669198.
 15. Ianculescu, M., Andrei, B. and Alexandru, A. A smart assistance solution for remotely monitoring the orthopaedic rehabilitation process using wearable technology: Re. flex system. *Studies in Informatics and Control*, 201928(3), pp.317-326.
 16. Bahadori S, Immins T, Wainwright TW. A review of wearable motion tracking systems used in rehabilitation following hip and knee replacement. *Journal of rehabilitation and assistive technologies engineering*. 2018 Apr; 5:2055668318771816.
 17. Cagnin A, Choinière M, Bureau N, Durand M, Mezghani N, Gaudreault N & Hagemester N (2019): A multi-arm cluster randomized clinical trial of the use of knee kinesiology in the management of osteoarthritis patients in a primary care setting, *Postgraduate Medicine*, DOI: 10.1080/00325481.2019.1665457
 18. Mikolajczyk T, Ciobanu I, Badea DI, Iliescu A, Pizzamiglio S, Schauer T, Seel T, Seiciu PL, Turner DL, Berteanu M. Advanced technology for gait rehabilitation: An overview. *Advances in Mechanical Engineering*. 2018 Jul;10(7):1687814018783627.
 19. Lancaster, G.A., Dodd, S. and Williamson, P.R., (2004). Design and analysis of pilot studies: recommendations for good practice. *Journal of evaluation in clinical practice*, 10(2), pp.307-312.
 20. NICE Quality standard QS206 Joint replacement (primary): hip, knee and shoulder. Published 29th March 2022 <https://www.nice.org.uk/guidance/qs206> Heaps 2019...
 21. Heaps J. Inertial Measurement Unit Characterisation for Gait Analysis. 3DMC 2019 Here East, London 5 –7 November 2019
 22. McCarthy, I., Hodgins, D., Mor, A. et al. Analysis of knee flexion characteristics and how they alter with the onset of knee osteoarthritis: a case control study. *BMC Musculoskelet Disord* 14, 169 (2013). <https://doi.org/10.1186/1471-2474-14-169>
 23. Monda M et al. Use of Inertial Measurement Units to Assess Age-Related Changes in Gait Kinematics in an Active Population. *Journal of Aging and Physical Activity*, 23: 18-23. 2015

24. Zügner R et al. Validation of Inertial Measurement Units with Optical tracking system in patients operated with Total Hip Arthroplasty. *BMC Musculoskeletal Disorders* 2019
25. Abellan van kan, G et al. Gait speed at usual pace as a predictor of adverse outcomes in community-dwelling older people an international academy on nutrition and aging (iana) Task force. *The Journal of Nutrition, Health & Aging*© Volume 13, Number 10, 2009
26. Callisaya ML, Blizzard L, McGinley JL, Srikanth VK. Risk of falls in older people during fast-walking--the TASCOG study. *Gait Posture*. 2012 Jul;36(3):510-5. doi: 10.1016/j.gaitpost.2012.05.003. Epub 2012 Jun 8. PMID: 22682610.
27. Oliveira CF, Vieira ER, Machado Sousa FM, Vilas-Boas JP. Kinematic Changes during Prolonged Fast-Walking in Old and Young Adults. *Front Med (Lausanne)*. 2017 Nov 23; 4:207. doi: 10.3389/fmed.2017.00207. PMID: 29218309; PMCID: PMC5703830.
28. Schulz BW. A new measure of trip risk integrating minimum foot clearance and dynamic stability across the swing phase of gait. *J Biomech*. 2017 Apr 11; 55:107-112. doi: 10.1016/j.jbiomech.2017.02.024. Epub 2017 Feb 27. PMID: 28302314; PMCID: PMC5473159.
29. Mademli L, Arampatzis A. Lower safety factor for old adults during walking at preferred velocity. *Age (Dordr)*. 2014 Jun;36(3):9636. doi: 10.1007/s11357-014-9636-1. Epub 2014 Mar 9. PMID: 24609821; PMCID: PMC4082586. Marques et al. 2017...
30. Marques NR, Dos Santos APML, Camilo GF, Cardoso BC, Brando ND, Hoffman J, Navega MT, de Abreu DCCL. Effect of different residential settings on gait kinematic parameters in older adults with cognitive impairment. *Hum Mov Sci*. 2021 Feb; 75:102747. doi: 10.1016/j.humov.2020.102747. Epub 2020 Dec 19. PMID: 33348290.
31. Marques NR, Hallal CZ, Spinoso DH, Morcelli MH, Crozara LF, Gonçalves M. Applying different mathematical variability methods to identify older fallers and non-fallers using gait variability data. *Aging Clin Exp Res*. 2017 Jun;29(3):473-481. doi: 10.1007/s40520-016-0592-8. Epub 2016 Jun 2. PMID: 27256077.
32. Marques NR, Spinoso DH, Cardoso BC, Moreno VC, Kuroda MH, Navega MT. Is it possible to predict falls in older adults using gait kinematics? *Clin Biomech (Bristol, Avon)*. 2018 Nov; 59:15-18. doi: 10.1016/j.clinbiomech.2018.08.006. Epub 2018 Aug 11. PMID: 30114546.
33. Martinez M, De Leon PL, Keeley D. Bayesian classification of falls risk. *Gait Posture*. 2019 Jan; 67:99-103. doi: 10.1016/j.gaitpost.2018.09.028. Epub 2018 Oct 1. PMID: 30312848.
34. Porta S, Martínez A, Millor N, Gómez M, Izquierdo M. Relevance of sex, age and gait kinematics when predicting fall-risk and mortality in older adults. *J Biomech*. 2020 May 22; 105:109723. doi: 10.1016/j.jbiomech.2020.109723. Epub 2020 Feb 28. PMID: 32151381.
35. Smith TO, Clarke C, Dainty JR, Watts L, Yates M, Pomeroy VM, Stanmore E, O'Neill TW, Macgregor AJ. Clinical and biomechanical factors associated with falls and rheumatoid arthritis: baseline cohort with longitudinal nested case-control study. *Rheumatology (Oxford)*. 2022 Feb 2;61(2):679-687. doi: 10.1093/rheumatology/keab388. Erratum in: *Rheumatology (Oxford)*. 2023 Feb 03; PMID: 33905483; PMCID: PMC8824410.
36. Astephen, J.L., Deluzio, K.J., Caldwell, G.E. and Dunbar, M.J., 2008. Biomechanical changes at the hip, knee, and ankle joints during gait are associated with knee osteoarthritis severity. *Journal of orthopaedic research*, 26(3), pp.332-341.
37. Chmiel C, Senn O, Rosemann T, Del Prete V, Steurer-Stey C. CoCo trial: Color-coded blood pressure Control, a randomized controlled study. *Patient Prefer Adherence*. 2014; 8:1383- 1392. Published 2014 Oct 16.

doi:10.2147/PPA.S68213

38. Pynsent PB, Adams DJ, Disney SP. The Oxford hip and knee outcome questionnaires for arthroplasty. *J Bone Joint Surg Br*. 2005;87-B (2):241-248. doi:10.1302/0301-620X.87B2.15095
39. Hernández Alava M, Pudney S. (2017) Econometric modelling of multiple self-reports of health states: The switch from EQ-5D-3L to EQ-5D-5L in evaluating drug therapies for rheumatoid arthritis. *Journal of Health Economics*, 55:139-152
40. Hernandez Alava, M., Pudney, S., and Wailoo, A. (2020) Estimating the relationship between EQ-5D-5L and EQ-5D-3L: results from an English Population Study. Policy Research Unit in Economic Evaluation of Health and Care Interventions. Universities of Sheffield and York. Report 063
41. NICE health technology evaluations: the manual Process and methods (PMG36) Published: 31 January 2022
42. Wainwright, Thomas W., et al. "A cycling and education intervention for the treatment of hip osteoarthritis: A quality improvement replication programme." *SAGE Open Medicine* 8 (2020): 2050312120946522.
43. Hu et al. Responsiveness and minimal clinically important difference of the EQ 5D 5L in cervical intraepithelial neoplasia: a longitudinal study. *Health and Quality of Life Outcomes* 2020
44. Beard D et al. Meaningful changes for the Oxford hip and knee scores after joint replacement surgery *J Clin Epidemiol*. 2015 Jan; 68(1): 73–79. doi: 10.1016/j.jclinepi.2014.08.009: 10.1016/j.jclinepi.2014.08.009
45. Martin-Fernandez J, Gray-Laymon P, Molina-Siguero A, et al. Cross-cultural adaptation and validation of the Spanish version of the Oxford Hip Score in patients with hip osteoarthritis. *BMC Musculoskelet Disord* 2017; 18: 205.
46. Veronese, N., Stubbs, B., Volpato, S., Zuliani, G., Maggi, S., Cesari, M., ... & Cereda, E. (2018). Association between gait speed with mortality, cardiovascular disease and cancer: a systematic review and meta-analysis of prospective cohort studies. *Journal of the American Medical Directors Association*, 19(11), 981-988.
47. Bolink SA, Lenguerrand E, Brunton LR, Wylde V, Gooberman-Hill R, Heyligers IC, Blom AW, Grimm B. Assessment of physical function following total hip arthroplasty: Inertial sensor-based gait analysis is supplementary to patient-reported outcome measures. *Clin Biomech (Bristol, Avon)*. 2016 Feb; 32:171-9. doi: 10.1016/j.clinbiomech.2015.11.014. Epub 2015 Dec 7. PMID: 26706048