NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation:

GID-MT575 GaitSmart rehabilitation exercise programme for gait and mobility issues

Supporting documentation – Committee papers

The enclosed documents were considered by the NICE medical technologies advisory committee (MTAC) when making their draft recommendations:

1. **Assessment report** – an independent report produced by an external assessment group (EAG) who have reviewed and critiqued the available evidence.
2. **Assessment report overview** – an overview produced by the NICE technical lead which highlights the key issues and uncertainties in the company's submission and assessment report.
3. **Scope of evaluation** – the framework for assessing the technology, taking into account how it works, its comparator(s), the relevant patient population(s), and its effect on clinical and system outcomes. The scope is based on the sponsor's case for adoption.
4. **Sponsor submission of evidence** – the evidence submitted to NICE by the notifying company.
5. **Expert questionnaires** – expert commentary gathered by the NICE team on the technology.
6. **EAG correspondence log** – a log of all correspondence between the external assessment group (EAG) and the company and/or experts during the course of the development of the assessment report.
7. **Company fact check comments** – the manufacturer's response following a factual accuracy check of the assessment report.

Please use the above links and bookmarks included in this PDF file to navigate to each of the above documents.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technologies guidance

MTG575 GaitSmart rehabilitation exercise programme for gait and mobility issues

External Assessment Group report

Produced by: CEDAR

Authors: Dr Susan O'Connell (Principal Healthcare Scientist)

Huey Yi Chong (Health Economist)

Simone Willis (Information Specialist)

Meg Kiseleva (Information Specialist)

Ayesha Rahim (Healthcare Scientist)

Megan Dale (Principal Healthcare Scientist)

Dr Rhys Morris (CEDAR Director)

Correspondence to: CEDAR, Cardiff Medicentre, Heath Park, Cardiff CF14 4UJ

Date completed: 30/06/2023

Contains confidential information: Yes, redacted

Number of attached appendices: 5

Purpose of the assessment report

The purpose of this External Assessment Group (EAG) report is to review and critically evaluate the company's clinical and economic evidence presented in the submission to support their case for adoption in the NHS. The report may also include additional analysis of the submitted evidence or new clinical and/or economic evidence. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Medical Technologies Advisory Committee when it is making decisions about the guidance.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

None

Acknowledgements

CEDAR wish to thank the following clinical experts for their contribution to the development of this report:

Prof. Alison McGregor, Professor of Musculoskeletal Biodynamics, Imperial College London

Andrea Sargeant, Senior Pathway Redesign Manager, NHS Norfolk and Waveny Integrated Care Board

Emma Brown, Innovation Lead, Bedfordshire, Luton and Milton Keynes ICS, Oxford Academic Health Science Network and Eastern Academic Health Science Network

Julien Owen, Consultant Trauma & Orthopaedic Surgeon, Cambridge University Hospitals NHS Trust

Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

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Abbreviations

Term	Definition
CI	Confidence interval
DHSC	Department of Health and Social Care
EAG	External Assessment Group
EFS	Edmonton Frailty Scale
FES-I	Falls Efficacy Scale International
GS	GaitSmart
ICOAP	Intermittent and Constant OsteoArthritis Pain
IQR	Interquartile range
KOOS	Knee Injury and Osteoarthritis Outcome Score
MAUDE	Manufacturer and User Facility Device Experience
MHRA	Medicines & Healthcare products Regulatory Agency
MTEP	Medical Technologies Evaluation Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICE CG	NICE clinical guideline
NICE MTG	NICE medical technology guidance
NICE QS	NICE quality standard
NRS	Numeric rating scale
OA	Osteoarthritis
OHS	Oxford hip score
OKS	Oxford knee score
OR	Odds ratio
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROMS	Patient Reported Outcome Measures
QUORUM	Quality of Reporting of Meta-analyses
RCT	Randomised controlled trial
RR	Risk ratio
SD	Standard deviation
THA	Total hip arthroplasty
TKA	Total knee arthroplasty
VAS	Visual analogue scale
Vs	Versus

Executive summary

GaitSmart (Dynamic Metrics Ltd.) is a sensor-based digital technology designed to measure lower limb movement. GaitSmart II and its predecessor GaitSmart I are class I CE marked devices. Sensors to be placed on either side of the body on the pelvis, thigh, calf as well on the base of the spine and objective measurements, taken while walking, identify any problems with gait. The integrated vGym app provides a personalised rehabilitation programme consisting of 6 exercises to help improve mobility. A colour coded report is produced which can be shared with the patient to help them understand their particular gait issues and what exercises they should do to improve them. There is limited evidence that patients like the report produced and found it helpful in understanding their condition and discussion with clinical experts supported this. Clinical experts also reported that the integrated exercise aspect was something they found very useful.

GaitSmart is intended for people who are ambulatory or partially ambulatory with gait and mobility issues and two specific populations were identified by the company as potentially being likely to benefit from use of GaitSmart. These are people referred for knee or hip replacement and people at risk of falling. The company states that the aim of the GaitSmart intervention is to reduce adverse effects such as falls and improve normal activities of daily living and quality of life through improving gait.

Clinical experts indicated that there is a lot of variability in the current care pathways, particularly for people at risk of falls, which makes it difficult to clearly define a standard care comparator for GaitSmart. Clinical experts did however note that they thought GaitSmart had the potential to improve outcomes for patients. One clinical expert noted that GaitSmart could be used by patients waiting for hip or knee surgery to prevent their condition from deteriorating while they wait. Clinical experts also considered that GaitSmart has a place in the community setting with a benefit being it is easy to use and can be used by a range of healthcare professionals. The experts noted that patients liked having the report with objective data and exercises provided.

The clinical evidence identified was limited in its applicability to the scope of the assessment. The evidence base included validation studies where GaitSmart measures were assessed against optical tracking systems and studies where the

diagnostic and prognostic potential of GaitSmart was investigated. A number of studies included a comparative element however there was little consistency, with comparators chosen ranging from comparisons with alternative gait assessment systems, comparisons with healthy populations, comparisons with alternative methods of diagnosis and pre and post intervention comparisons in the same patients. Patient reported outcomes measures (PROMs) were collected in a number of studies using validated tools however a range tools including Oxford hip and knee scores, KOOS scores, EQ-5D-5L and EQ-5D VAS scores, Edmonton Frail Scale (EFS) scores and Falls Efficacy Scale International (FES-I) scores were used.

For people at risk of falls, GaitSmart score improved in 76% of participants and gait speed increased in 80.5% of participants over the course of the study period (Rodgers 2020). Both of these measures were moderately correlated with measures of frailty and fear of falling suggesting that as gait parameters improved, risk of falling and fear of falling decreased. For people referred for hip or knee surgery, results [redacted]

Results from both the company's submitted rehabilitation model and the EAG base case indicate that GaitSmart is cost-saving, however this is dependent on the model of standard care. Economic modelling supports the company claims that where GaitSmart is delivered by trained healthcare assistants, it would lead to a reduction in staff time costs compared to most alternative standard care options. Both models are primarily driven by the costs of the intervention and comparator, with subsequent falls contributing less to the cost saving, over the 1-year time horizon modelled. The modelled number of falls is inferred from increased gait speed, rather than observed, in each model. The falls model has additional uncertainty due to greater variation in standard care and the lack of a comparator arm for the study data.

Overall, the EAG consider that GaitSmart could provide an additional option for both population groups with a number of places in the clinical pathway where it could potentially be of benefit.

1 Decision problem

The company has not proposed any variation to the decision problem outlined in the scope. The company has offered some clarification around the interventions, confirming that vGym is not a separate app. The EAG consider the clarification provided to be valid.

The company further offered some detailed justifications for the choice of outcomes in the scope, but did not propose any changes or variations (Table 1). The EAG notes that the additional detail provided by the company to explain choice of outcomes is informative and relevant. The EAG considers this information to warrant further discussion and it is therefore addressed in section 11.

Table 1 Proposed Variation to Scope

Decision problem	Scope	Proposed variation in company submission	EAG comment
Intervention	GaitSmart programme including 4 GaitSmart assessments and personalised rehabilitation via the vGym app	None	The company noted thre is no separate vGym app. The vGym exercises are integrated into a protocol chosen by the user. The EAG accepts the clarification

2 Overview of the technology

Developed by Dynamic Metrics Ltd., GaitSmart in a sensor-based digital technology designed to measure lower limb movement. GaitSmart II and its predecessor GaitSmart I are class I CE marked devices. Regulatory documents have been provided by the company and checked by the EAG. The company has informed the EAG that the notified body (BSI has been asked to commence the UKCA certification process.

The GaitSmart system comprises 8 sensors, charger cradle, power supply, power cable, wrist strap, pelvis pouch, pelvis extension strap, left and right thigh and calf straps, tablet, USB power outlet and USB tablet power cable, SIM slot removal tool and tablet and GaitSmart instructions for use, all stored in a carry case making the system portable. All components of the system are reusable.

GaitSmart I was a standalone (not cloud based) gait analysis system with no added exercise element. GaitSmart I was used until 2020 and studies published up to and including the IMI-APPROACH study used this version but it is no longer available. The current version of the technology, GaitSmart II, operates on a cloud-based system with fully automated personalised exercise plans if required. GaitSmart I and II perform the same calculations to obtain gait kinematic data however GaitSmart II has been automated to make it more suitable as a clinical tool. The accuracy for both versions is almost identical and therefore the EAG considers it is appropriate to use the evidence from GaitSmart I to inform this assessment.

[redacted]

The EAG noted that much of the published evidence reported using 4 or 6 sensors. The company clarified that in early studies, 4 sensors were used to measure knee joint and thigh and calf ROM. In 2014, this was extended to 6 sensors to include hip and knee joints and pelvis, thigh and calf

ROM. Additional sensor is provided as a spare. Once sensors are in place, the individual being assessed should walk normally for 10-15 metres in a straight line, turn and walk back. Objective measurements, taken while walking, identify any problems with gait. The test takes approximately 10 minutes and can be conducted by a healthcare assistant in a range of settings. Information from the sensors is processed automatically to produce a colour coded report to help understand gait issue and severity. The integrated vGym app provides a personalised rehabilitation programme consisting of 6 exercises to help improve mobility. The GaitSmart report can take between 1 and 20 minutes to process and is available to view either on the tablet or via an internet browser. The report uses a traffic light system to show results with green being normal movement, ambers being a moderate issue and red indicating a severe issue. As well as including results for individual gait factors, the report includes an overall GaitSmart Score which comprises all of the sagittal movement data to provide an overall assessment of strength and stability when walking.

Following initial assessment and allocation of exercise programme, individuals are expected to have an assessment every 4-6 weeks for a total of 4 assessments (inclusive of initial assessment) where gait changes will be monitored and exercises adjusted appropriately.

Innovative features of the technology noted by the company include:

- Fully automated process to identify a gait cycle from the sensor data and extract key gait kinematic features
- Presentation of the gait data using traffic light coding and scoring to aid understanding for clinicians and clients
- Calculation of muscle weakness from gait kinematic data
- Automated process to produce personalised exercise programme.

3 Clinical context

GaitSmart is intended for people who are ambulatory or partially ambulatory with gait and mobility issues. This assessment will focus on use of GaitSmart in two specific subgroups:

- People referred for knee or hip replacements
- People at risk of falling

For both cohorts, the aim of the GaitSmart intervention is to reduce adverse effects such as falls and improve normal activities of daily living and quality of life through improving gait. In this context, gait and gait changes are surrogate outcomes for outcomes such as function, pain and quality of life. The EAG queried the appropriateness of gait as a surrogate outcome and clinical experts confirmed that as gait assessment is used to identify problems and enables targeting of muscles that need strengthening, it is a suitable surrogate. For people at risk of falls, one expert noted that improving gait in this population can help improve quality of life as improving gait improves mobility and can enable people to be more independent. In relation to people referred for hip / knee replacements, one clinical expert reported that improving gait is the main purpose of doing surgery as this improves pain and function.

Clinical experts indicated that there is a lot of variability in the current care pathway which makes it difficult to clearly define a standard care comparator for GaitSmart. The EAG proposed a place in the current pathway for GaitSmart for each of the populations of interest and discussed them with clinical experts.

The EAG proposed place for the inclusion of GaitSmart for people referred for hip or knee surgery in Figure 1**Error! Reference source not found.**. and people at risk of falls is outlined in Figure 2

People referred for knee or hip replacements

Referral for surgery should be considered for people who experience knee or hip joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life, and have been offered (non-surgical)

treatment options, or have symptoms that are not resolved by the core (non-surgical) treatment options. The company submission states that a GaitSmart assessment as part of pre-operative management will provide an exercise programme to enable individuals strengthen muscles in preparation for surgery. Clinical experts broadly agreed with the proposed pathway and provided some additional context.

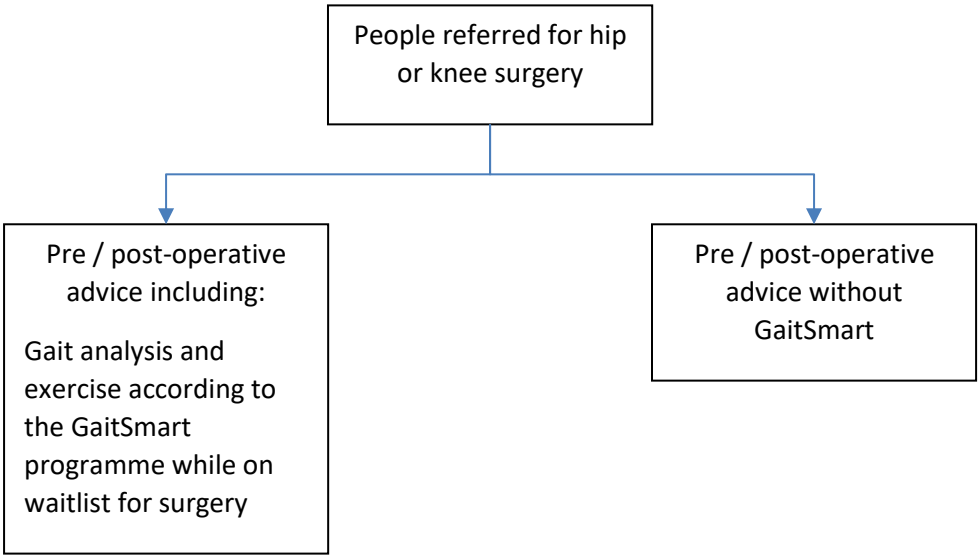


Figure 1: People referred for hip or knee surgery

People at risk of falling

People aged 65 and over have the highest risk of falling. 30% of people older than 65, and 50% of people older than 80, fall at least once a year (NICE CG161 Falls in older people: assessing risk and prevention). Falling can be distressing and cause pain, injury, and loss of mobility. People can lose confidence and, in some cases, lose their independence because of a fall.

People presenting for medical attention resulting from a fall, people reporting recurrent falls in the past year or people who demonstrate abnormalities of gait and / or balance should be offered a multifactorial falls risk assessment conducted by a healthcare profession with appropriate skills and experience. Assessment should normally be conducted in a specialist falls service. People reporting recurrent falls or assessed to be at risk of falls should be considered for individualised, multifactorial interventions. Part of the multifactorial risk

assessment includes a gait assessment and strength and balance training are recommended as part of the interventions.

The company submission states that for people at risk of falling, GaitSmart provides two functions in one assessment – an objective assessment of gait and an exercise programme as part of an individualised intervention – both of which are recommended in current NICE guidelines. Clinical experts broadly agreed with the proposed pathway with some caveats. One clinical expert stated that it can be difficult to get elderly people to come forward and that it might be better to target specific age-groups rather than relying on patients to identify risks of falling themselves. A second expert noted that there are many falls that go unreported as people do not always seek help after a fall. The EAG proposed pathways were based on GaitSmart intervention taking at least 12 weeks to complete (baseline assessment and 3 follow-up assessments around 3 weeks apart). One expert noted that it might be difficult for some practitioners to implement a 12-week programme of GaitSmart and that a 12-week intervention might be ambitious for current standard care with some services only commissioned to provide 6-week interventions. The EAG notes that the company has stated that there is flexibility in the number and frequency of assessments and if assessments are carried out at 3-week intervals, a full GaitSmart programme would be completed in 9 weeks.

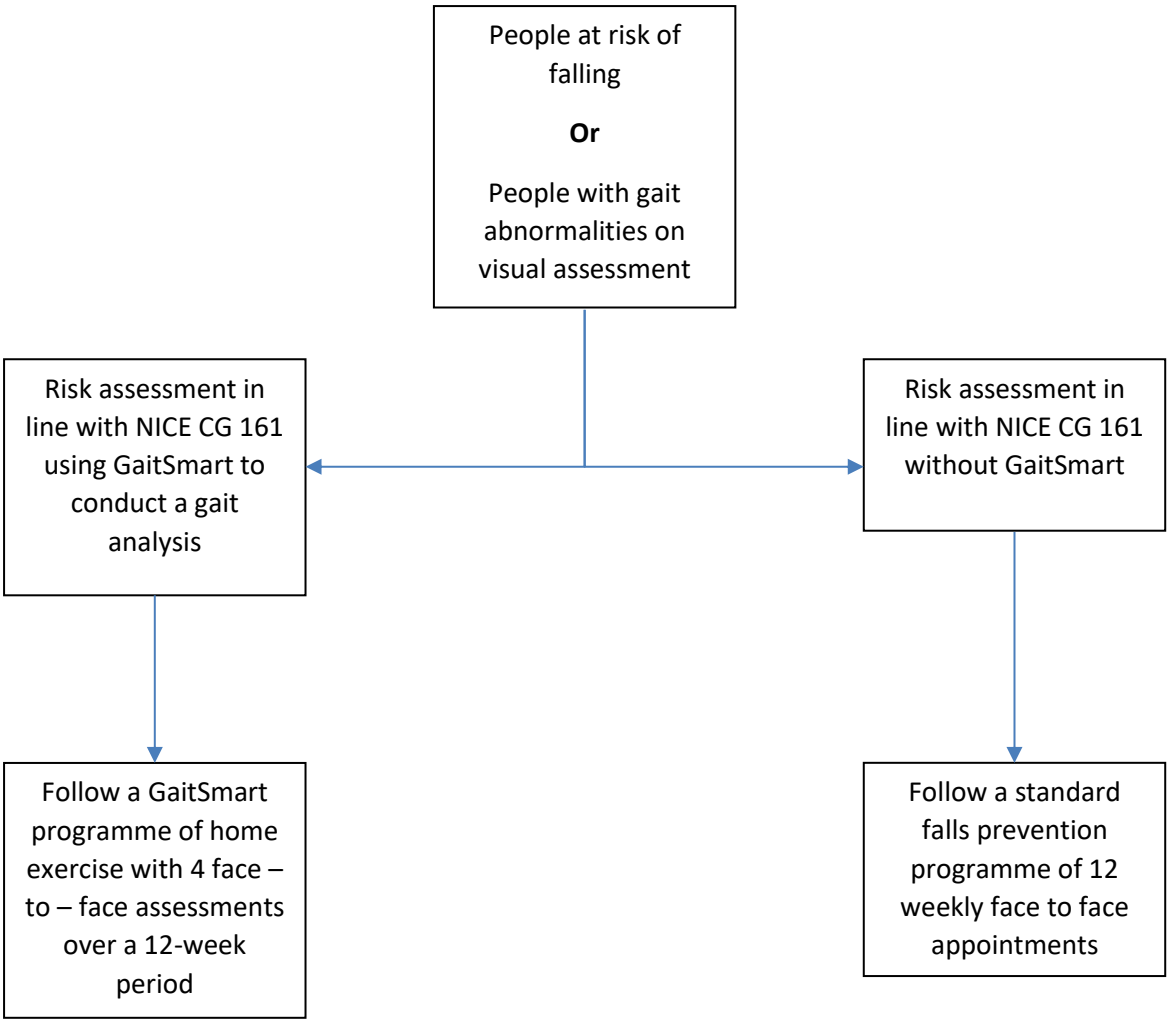


Figure 2: People at risk of falling

NICE guidance relevant to these patient populations is summarised in Table 2. No other relevant guidance was identified by the EAG. Clinical experts noted that there are best practice guides for hip and knee arthroplasty which the EAG reviewed. Both guides outline a clear practice for surgical approach and immediate post-operative management however they do not discuss exercise or gait assessments.

Table 2 Relevant Guidance

Guidance	Population	Recommendations
NICE NG226	People referred for knee or hip replacement	Consider referring people with hip, knee or shoulder osteoarthritis for joint replacement if: • their joint symptoms (such as pain, stiffness, reduced function or progressive joint deformity) are substantially impacting their quality of life and

Guidance	Population	Recommendations
		• non-surgical management (for example, therapeutic exercise, weight loss, pain relief) is ineffective or unsuitable. Use clinical assessment when deciding to refer someone for joint replacement, instead of systems that numerically score severity of disease. Do not exclude people with osteoarthritis from referral for joint replacement because of: • age • sex or gender • smoking • comorbidities • overweight or obesity, based on measurements such as body mass index (BMI). If discussing referral for joint replacement, explain to the person with osteoarthritis that the risks of joint replacement can vary depending on the factors listed in previous recommendation
NICE MTG76	People referred for knee or hip replacement	AposHealth is recommended as a cost-saving option to manage knee osteoarthritis in adults only if: • non-surgical standard care has not worked well enough and • their condition meets the referral criteria for total knee replacement surgery but they do not want surgery and • data is collected on the person's quality of life, health resource use and if they have knee replacement surgery in the long term. Further research is recommended on AposHealth for: • people with knee osteoarthritis that meets the referral criteria for total knee replacement surgery but who cannot have surgery because it would be unsafe • people whose condition does not meet the referral criteria for total knee replacement surgery.
NICE CG161	People at risk of falls	**Case/risk identification** Older people in contact with healthcare professionals should be asked routinely whether they have fallen in the past year and asked about the frequency, context and characteristics of the fall/s. [2004] Older people reporting a fall or considered at risk of falling should be observed for balance and gait deficits and considered for their ability to benefit from interventions to improve strength and balance. **Multifactorial falls risk assessment** Older people who present for medical attention because of a fall, or report recurrent falls in the past year, or

Guidance	Population	Recommendations
		demonstrate abnormalities of gait and/or balance should be offered a multifactorial falls risk assessment. This assessment should be performed by a healthcare professional with appropriate skills and experience, normally in the setting of a specialist falls service. This assessment should be part of an individualised, multifactorial intervention. Multifactorial assessment may include the following: • identification of falls history • assessment of gait, balance and mobility, and muscle weakness • assessment of osteoporosis risk • assessment of the older person's perceived functional ability and fear relating to falling • assessment of visual impairment • assessment of cognitive impairment and neurological examination • assessment of urinary incontinence • assessment of home hazards • cardiovascular examination and medication review. **Multifactorial interventions** All older people with recurrent falls or assessed as being at increased risk of falling should be considered for an individualised multifactorial intervention. In successful multifactorial intervention programmes the following specific components are common (against a background of the general diagnosis and management of causes and recognised risk factors): strength and balance training • home hazard assessment and intervention • vision assessment and referral • medication review with modification/withdrawal. Following treatment for an injurious fall, older people should be offered a multidisciplinary assessment to identify and address future risk and individualised intervention aimed at promoting independence and improving physical and psychological function. **Strength and balance training** Strength and balance training is recommended. Those most likely to benefit are older people living in the community with a history of recurrent falls and/or balance and gait deficit. A muscle-strengthening and balance programme should be offered. This should be individually prescribed and monitored by an appropriately trained professional. **Exercise in extended care settings**

Guidance	Population	Recommendations
		Multifactorial interventions with an exercise component are recommended for older people in extended care settings who are at risk of falling.

Special considerations, including issues related to equality

The technology should not be used on bare skin and suitable footwear (closed shoes with a low heel) are required. Belts with metallic buckles should be removed and items such as phones or wallets should be removed from pockets as they may affect readings.

People who have difficulty accessing or using a device for the GaitSmart report and vGym exercise programme may be excluded from using this technology. Additional support and resources may be needed for people unfamiliar with digital technologies or who do not have access to smart devices. The company states these reports can be printed and paper copies provided to individuals.

The company states the technology can be used by people of any age, ethnicity or gender and by people who use a walking aid provided they can complete a 10-metre walk test. For people with cognitive impairment, prompts to do their exercises may be required but as there is no strict protocol for when exercises should be performed, this can be planned around when support is available. People with visual impairment may find the 10-metre walk test and exercises difficult.

Age, sex, disability and race are protected characteristics under the Equalities Act.

4 Clinical evidence selection

4.1 *Evidence search strategy and study selection*

The company conducted searches in one database for both clinical and economic evidence, which encompassed the key components of the decision problem. The company study selection was made using the following inclusion criteria:

- People aged 65 or older that are at risk of falling
- People referred for knee or hip surgery (pre-operative and post-operative management)
- Gait kinematic data measured or exercise rehabilitation prescribed

The EAG considered that inclusion of records related to “Gait kinematic data” may be too broad for the decision problem. The company identified a total of 648 studies, however, the number of duplicate records was not reported. The company did not search clinical trial registers or conduct searches for adverse events. It was noted that the search terms used by the company included free text terms but not indexed terms. Additionally, it was noted that the free text terms used were broad rather than specific and truncation was not used e.g., using “Joint Replacement” rather than “knee adj3 replace*”. This means the company searches may have failed to identify records that contained “knee replacement”. As only one database had been searched by the company and some key concepts had not been adequately captured by the search terms, the EAG were not confident that all relevant literature had been identified and therefore conducted their own systematic searches. Details of the company and EAG searches are provided in Appendix A: Clinical and economic evidence identification.

The EAG literature searches identified a total of 596 records. All published evidence included in the company submission was identified through EAG searches. The company provided an additional manuscript which has been submitted for publication in a peer-reviewed journal, giving a total of 597 records. In addition, the company provided details of 8 potentially relevant, unpublished studies giving a total of 605 records to screen at title and abstract stage. Two EAG researchers screened the 605 records in accordance with the scope; 537 were excluded as they did not meet the scope, leaving 68 records for screening against the criteria of the decision problem. There were no disagreements on inclusion and exclusion of records. 48 publications were excluded, leaving 20 publications for inclusion.

4.2 *Included and excluded studies*

The EAG has included 8 published studies (reported in 14 publications). The company also provided details for 4 unpublished reports covering 3 studies. Of these publications, 8 were full-texts, 4 were unpublished manuscripts, 4 were abstracts associated with the included full-texts, 1 was a thesis associated with an included full-text and 1 was an additional abstract.

This is broadly consistent with the evidence included in the company submission. The company submission also included a PhD thesis (Walters, 2018) and an additional validation study (Heaps 2019) both of which were excluded by the EAG. The EAG excluded Heaps 2019 as it is a PowerPoint presentation describing a laboratory-based validation study. Walters 2018 was excluded because although it is a study investigating whether task orientated rehabilitation can improve knee function and satisfaction in patients undergoing knee replacement surgery, the company noted that the intervention programme in the study was not aligned with the GaitSmart programme as it focuses only on knee flexion on load. The EAG considered therefore that there would be limited value to the information provided by this thesis to warrant detailed data extraction and appraisal. Briefly, results indicated that stride duration significantly predicted Oxford knee scores in 76 patients with higher scores observed in patients with shorter stride duration. In a subset of 21 patients, Oxford knee scores were significantly higher following a task orientated rehabilitation and stride duration, sagittal range of motion and knee flexion in stance also increased in both limbs.

In total, the EAG has included 11 studies (reported in 18 publications) for the clinical evidence, details of which are described in Table 3.

Table 3: Included Studies

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Care City Pilot (Unpublished) **Location**: [redacted] **Duration**: [redacted] **Aims:** [redacted]	**Design:** Before and after study **Intervention:** GaitSmart gait analysis and exercise programme **Green:** meets scope	**Participants:** n=[redacted] (no inclusion / exclusion details but appears to be people at risk of falls). [redacted] [redacted] **Setting:** [redacted] **Green:** meets scope	[redacted] [redacted] **Green:** meets scope	• Study design not defined, allocated by EAG • Short report of a pilot study • Limited details on methods provided

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
[redacted] **Green:** meets scope				
Hanley (2016) – Abstract only **Location:** Not reported **Duration:** Not reported **Aim:** To quantify post-operative gait abnormalities following THA **Green:** meets scope	**Design:** Case series **Intervention:** 3-D gait analysis using a portable system with Inertial Measurement Units (IMUs) **Amber:** partially meets scope, exercise component of GaitSmart not included	**Participants**: N=55 patients with moarthrodial hip arthrosis **Exclusions:** Patients with medical co-morbidity or other conditions affecting their gait N=92 healthy participants assessed for comparison **Setting:** Outpatients **Green:** meets scope	Measurements taken pre-operatively and one-year post operatively • Movement in the sagittal plane of the ipsilateral and contralateral hips • Knee movement **Green:** meets scope	• Study described as case series • Abstract only, not related to any of the full text publications • Not stated that GaitSmart is the technology used but abstract provided by company

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Hodgins (2015) **Location:** UK **Duration:** Not Reported **Aim:** To determine how gait parameters of a healthy older population compare with those of an older population with gait and balance issues and to explore the possibility of using objective data to support a personalised exercise programme to help prevent falls **Green:** meets scope	**Design:** Case Series Study **Intervention:** GaitSmart assessment with personalised exercises Multiple assessments over a 2-year period however it is somewhat unclear as to how often assessments were conducted – seems to be ~10-week intervals **Green:** meets scope	**Participants:** N=11 older people (mean age 78 years) with walking and balance problems (balance class) N=18 older people (mean age 70 years) with no walking / balance problems were used to obtain reference gait parameters (reference group) **Exclusions:** Previous surgery on lower limbs; had a neuromuscular condition that might affect gait; current back pain; were not able to walk 10 metres without a walking aid; could not give informed consent – apart from informed consent, exclusions applied only to the reference group as the balance class included individuals who had suffered a stroke,	Gait pattern which was used to calculate • Knee ROM • Symmetry between left and right knees The lower limit was 1 standard deviation from the reference group **Green:** meets scope	• Study design not defined, allocated by EAG • 4 IMUs, each containing 3 orthogonal gyroscopes and 3 orthogonal accelerometers • Unclear but assumed that reference group were measured only once for reference purposes • Advice on exercise was provided based on evidence from the GaitSmart assessment

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
		had a brain tumour and had a lower limb prosthesis **Setting:** Community (weekly balance class) **Green:** meets scope		
IMI-APPROACH Study Jansen 2023 (poster) Van Helvoort 2022 (full publication) Van Helvoort 2021a (full publication) Van Helvoort 2021b (abstract) Hodgins 2019 (abstract)	**Design:** Diagnostic Study **Intervention:** GaitSmart assessment at baseline and six-month follow-up **Comparators:** Radiographic assessments, KOOS, SF-36, 30sec chair stand test, 40m self-paced walk test	**Participants:** N=297 people with knee OA • age; 66.5±7.1 • female; 230 (77%), • BMI; 28.1±5.3 An index knee was chosen based on American College of Rheumatology clinical criteria. If equal between both knees, the most painful knee was chosen as the index knee	*Reported in Van Helvoort 2021a* • ROM for both knees in swing and stance • ROM for both hips and both calves • Differences between both legs • Average stride duration, calculated speed and stride length	• Study design listed as a prospective cohort study but allocated diagnostic by EAG due to purpose and outcomes • IMI-APPROACH is a consortium that brings together a multidisciplinary group of stakeholders that will set up a broad database of OA patients as well as a longitudinal

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Location: Multicentre, European **Duration:** January 2018 to April 2019 **Aim:** To assess underlying domains measured by GaitSmart parameters and determine whether these are additional to established OA markers including PROMs and radiographic parameters and to evaluate the validity and responsiveness of GaitSmart motion analysis as a function measurement in knee OA		**Exclusions:** None reported **Setting:** Not reported	• Radiographic knee osteoarthritis • Pain and function (KOOS, and ICOAP to assess pain in the MAK; NRS for both knees) • Relationship between individual GaitSmart parameters and conventional parameters • Relationship with presence and severity of radiographic knee OA *Reported in Van Helvoort 2022* • Relation between GaitSmart and common outcome measures for function	cohort based on innovative stratification methods to identify different OA phenotypes • Results and methods from full text publications only • Principal component analysis of GaitSmart parameters identified 5 underlying domains relating to ○ ROM in hips ○ ROM in knees and calves ○ Differences in either ROM of knees and calves in swing phase ○ Differences in ROM in hips

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
			• Differentiation between two groups with different general health status • Change in function at 6 months	○ Differences in ROM in knees during stance When added to the PCA, PROMS and radiographic parameters each formed an additional component suggesting that the parameters measure different domains of a patient's disease
McCarthy (2013) **Location:** Israel / UK **Duration:** Not Reported **Aim:** To examine difference in gait profile between patients	**Design:** Diagnostic Accuracy Study **Intervention:** GaitWalk	**Participants:** N=44 participants total N=23 participants with medial compartment knee OA. • Mean age 65.1 years (SD 7.7) • Mean BMI 28.7 (SD 3.7) • 14 females / 9 males	ROM of the knee flexion angle in swing and stance over a stride **Green:** meets scope	• Study design listed as a case series study but allocated diagnostic by EAG due to purpose and outcomes. EAG accept case series could also apply.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
with knee OA and healthy controls and to create motion characteristics that will differentiate them Amber: partially meets scope, GaitSmart assessment being used in a diagnostic capacity	**Comparator:** Comparison between patients with knee OA and healthy controls Amber: partially meets scope, comparison not within the scope and no exercise component	• 15 with bilateral knee OA / 9 with unilateral knee OA • Average symptom duration was 12.3±6.5 months (6-24 months) **Inclusions:** patients suffering from symptomatic knee OA, according to ACR clinical criteria, at the medial compartment for at least 6 months **Exclusions:** Acute septic arthritis; inflammatory arthritis; corticosteroid injection within 3 months of study; avascular necrosis of the knee; history of knee buckling or recent knee injury; joint replacement; neuropathic arthropathy; history of pathological osteoporotic fracture; symptomatic degenerative arthritis in lower limb joints other than knees		• Technology named is GaitWalk. The EAG confirmed with the company that this is an older name for the GaitSmart technology • Possible typographical error relating to number of participants with bilateral knee OA • 4 sensors used • For patients with unilateral OA, data for the OA limb was included with data for participants with bilateral OA. Data for the

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
		N=21 healthy controls • Mean age 71.3 (SD 6.1) • 17 females / 4 males • Mean BMI 25.5 (SD 2.9) **Setting:** Unclear but likely community. Participants recruited from AposTherapy centre, Israel. Controls recruited from staff and volunteers at the Royal National Orthopaedic Hospital, London, UK **Green:** meets scope		unaffected limb was analysed separately
Monda (2015) **Location:** UK **Duration:** Not Reported	**Design:** Case Series Study **Intervention:** GaitSmart (compared with an	**Participants:** n=9 adults in the pilot study comparison between GaitSmart (n=4) and an optoelectronic gait system (n=5) N=136 participants (mean age 53.8 years (18-97 years)) recruited from staff	• Stride duration • Knee ROM • Knee stance • Thigh ROM • Shank ROM	• Study design not defined, allocated by EAG • While the study does not meet the scope specifically, the validation

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Aim: To investigate whether IMUs attached to lower limb segments could provide useful information about kinematics of limb segment movement in gait in an active population **Red**: Does not meet scope, validation study in a healthy population, no exercise component	optoelectronic gait system for the pilot study) **Amber**: partially meets scope, intervention is GaitSmart but used in a healthy population	and volunteers at UCL Institute of Orthopaedics and Musculoskeletal Science, members of local sports clubs and attendees of exercise classes at a day centre **Exclusions:** Previous surgery on lower limbs; neuromuscular condition that might affect gait; current back pain; not able to walk 10m; unable to provide informed consent **Setting:** Community **Red**: Does not meet scope, validation study in a healthy population	Results reported by age group • <30 • 30-39 • 40-49 • 50-59 • 60-69 • 70-79 • >80 **Green:** meets scope	of GaitSmart measurements against an optoelectronic gait system provides useful information about the reliability of GaitSmart measurements • No exercise component being assessed • Unclear how many participants were included in the comparison with optoelectronic system (text implies 9 total, 4 with GaitSmart and 5 with optoelectronic system)

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
NHS Glasgow Falls Clinic Final Report (unpublished) **Location:** [redacted] **Duration:** [redacted] **Aim:** [redacted] **Green:** meets scope	**Design:** Before and after study **Intervention:** [redacted] **Green:** meets scope	**Participants:** Target number for the trial was 100. [redacted] **Inclusion**: [redacted] **Exclusions**: [redacted]	• [redacted] **Green:** meets scope	• Study design not defined, allocated by EAG • [redacted]

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
		Setting: [redacted] **Green:** meets scope		
Norfolk and Norwich University Hospital (NNUH) McNamara (unpublished) Ward (unpublished) **Location:** [redacted] **Duration:** [redacted] **Aim:** [redacted]	**Design:** [redacted] **Intervention:** [redacted] **Comparator:** [redacted] **Green:** meets scope	**Participants:** [redacted]	**Reported in McNamara** **Primary Outcome** [redacted]**Secondary Outcomes** • [redacted] **Reported in Ward**	• Study design stated RCT – EAG agree. The sub-study by Ward et al is a case report study • Within group comparisons before and after surgery, no between group comparisons

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
[redacted] **Green:** meets scope		**Exclusions:** [redacted] **Setting:** [redacted] **Green:** meets scope	• Patient experience with using the technology **Green:** meets scope	
Rahman (2015) **Location**: UK **Duration:** Not Reported **Aim**: To evaluate the use of IMUs in pre and post - operative outpatients' clinics for patients with TKA **Amber**: partially meets scope, no exercise component being assessed	**Design:** Cross Sectional Study **Intervention**: GaitSmart gait assessment **Green:** meets scope	**Participants**: N=74 people aged between 40 and 80 years who have undergone knee replacement within the previous year or who are waiting for knee replacement. All participants had a radiological diagnosis of knee OA • Mean age: 66.9 (SD 10.7) • Male to female ratio 32:42 • Mean BMI: 29.9 (SD 4.7) N=29 age / gender matched controls for comparison	• Knee ROM during swing and stance phases • Overall thigh sagittal ROM • Overall shank sagittal ROM • Difference in timing between the two peaks of thigh sagittal angle • Stride duration • Passive ROM	• Study described as cross sectional, EAG agree • Motion sensors (IMUs) containing 3 orthogonal gyroscopes and 3 orthogonal accelerometers • Caution in interpreting the results from this study as the measurements are not matched (i.e. different patients in the before and after groups) therefore

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
		• Mean BMI 26.1 (SD (3.8) **Exclusions**: walking with a stick / frame; post-operative complications (e.g. active infection / DVT); neuromuscular conditions that could alter gait **Setting**: Outpatient clinics at a single hospital **Green:** meets scope	• Oxford Knee scores (pre-operatively and at 52 weeks) Outcomes were compared for 4 patient groups: • Pre-operative (n=29) • 8 weeks post-operative (n=17) • 52 weeks post-operative (n=28) • Healthy controls (n=29) **Green:** meets scope	results do not represent a change in outcomes, rather a difference in outcomes • People did not have gait measurements taken before and after surgery. There was one group of people in the 'before surgery' assessment and a different group of people in the 'after surgery' assessment so not clear that this study can indicate whether people have not improved their gait post-surgery • Authors conclude that there is potential to identify patients who may benefit

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
				from additional rehabilitation but it is unclear whether there are specific gait criteria which would indicate a need for additional rehabilitation • Thigh, shank and knee sagittal angles, coronal angles and temporal descriptors of gait were measured and a number of discrete parameters were selected for detailed analysis however it is not clear how / why these specific parameters were selected

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Rodgers (2020) **Location:** UK **Duration:** Not Reported **Aim:** To determine whether a digital health solution based on gait kinematics monitoring could be as effective or more effective than current physiotherapy led programmes in reversing frailty **Green:** meets scope	**Design:** Before and After Study **Intervention:** GaitSmart gait assessment and personalised exercise programme 4 tests performed with an average of 3 weeks between each test (~10 weeks total) **Green:** meets scope	**Participants:** N=121 people who suffered an injurious fall and were under the care of a community hospital; people could use any / no walking aid and could be anywhere on the frailty spectrum (n=169 recruited) **Exclusions:** People who suffered from severe dementia or a neurological condition that affects walking; people who were unable to perform gentle exercise / were immobile **Setting:** Community Hospital **Green:** meets scope	• Change in frailty score • Change in fear of falling score • Gait Score (%) • Speed (m/s) - assumed to be metres per second as not defined in the manuscript • Correlation between gait score and speed (compared to FES-I and EFS) before and after intervention (measured using Pearson correlation) **Green:** meets scope	• Described as a quality improvement study. Designated a before and after study by EAG • Details of ethical approvals / consent not reported in publication • 6 sensor modules (IMUs) each containing 3 orthogonal gyroscopes and 3 orthogonal accelerometers • Frailty determined using the Edmonton Frail Scale (EFS); Fear of falling measured using the short

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
				form Falls Efficacy Scale International (FES-I) • Exercise programme based on the Otago exercise program or NHS published exercises and excluded exercises from sitting / lying • Unclear how the mean scores related to the use of walking aids are calculated. Appears to be that a score is assigned to a participant based on type of walking aid (none, walking stick(s), walker, frame) and the mean calculated from the total

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
				• Authors state that the study shows superior results to conventional approach but as there is no comparator, it is unclear how this conclusion has been reached. Study shows improvements in measured outcomes following GaitSmart programme
Zügner 2019 Mohaddes 2016 (abstract) Blixt 2016 (thesis) **Location:** Sweden	**Design:** Diagnostic Accuracy Study **Intervention:** GaitSmart **Comparator:** Optical tracking system (12	**Participants:** N=50 participants • Mean age: 71 year (51-80) • BMI: 28.7 (20-44) • N=25 patients who underwent THA and reported mobility problems 1 year post-operatively • N=25 patients who reported no mobility problems	• Pelvic tilt • Range of knee flexion-extension • Range of hip flexion-extension **Green:** meets scope	• Study design not defined but allocated diagnostic by EAG due to purpose and outcomes • While the study does not meet the scope specifically, the validation

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Duration: 2011-2013 **Aim:** To evaluate the accuracy of inertial measurement units (IMU) compared with an optical tracking system (OTS) to record pelvic tilt, hip and knee flexion in patients who had undergone THA **Amber**: partially meets scope, validation study, no exercise component	camera motion capture system) **Amber**: partially meets scope, intervention is GaitSmart but comparator is optical tracking system	• Participants identified using post-operative EQ-5D • 1 participant was excluded due to technical problems but not clear which group participant was in **Green:** meets scope		of GaitSmart measurements against an optical tracking system may provide useful information on the accuracy of GaitSmart measurements in people who have undergone THA • 6 IMU sensors used • Limited applicability to the scope but shows reliability of GaitSmart measures compared with a 'gold standard' gait analysis method

Abbreviations: ACR, American College of Rheumatology; GS, GaitSmart; ICOAP, Intermittent and Constant OsteoArthritis Pain; IMI-APPROACH, Innovative Medicines Initiative—Applied Public-Private Research enabling OsteoArthritis Clinical Headway; IMU, Inertial measurement units; KOOS, Knee

injury and Osteoarthritis Outcome Score; MAK, most affected knee; NRS, numeric rating scale; OA, osteoarthritis; OHS, Oxford hip score; OKS, Oxford knee score; SoC, standard of care; THA, total hip arthroplasty; TKA, total knee arthroplasty.

5 Clinical evidence review

5.1 *Overview of methodologies of all included studies*

Study design was poorly reported across all included studies and there was a high degree of variability in the study purpose, methods and analysis approaches. Guided by an algorithm for study design selection (Hartling 2010) and considering additional factors such as study aims, population and recruitment approaches, type of analysis and outcomes reported, the EAG assigned a design to each included study (Table 3).

Study populations varied both in size and inclusion criteria. Sample size ranged from 29 participants (Hodgins 2015) to 297 participants (IMI-APPROACH). In total, 6 studies included people with hip or knee osteoarthritis (IMI-APPROACH, McCarthy 2013, Glasgow Falls Clinic Report, NNUH RCT, Rahman 2015, Zugner 2019) and 4 studies included people at risk of falls (Care City Pilot report, Hanley 2016, Hodgins 2015, Rodgers 2020) though it should be noted that in one study, the population was defined as people with balance and mobility problems (Hodgins 2015). In one study, only a healthy population was included (Monda 2015).

A number of studies included a comparative element however there was little consistency, with comparators chosen ranging from comparisons with alternative gait assessment systems, comparisons with healthy populations, comparisons with alternative methods of diagnosis and pre and post intervention comparisons in the same patients.

Patient reported outcomes measures (PROMs) were collected in a number of studies using validated tools however a range tools including Oxford hip and knee scores, KOOS scores, EQ-5D-5L and EQ-5D VAS scores, Edmonton Frail Scale (EFS) scores and Falls Efficacy Scale International (FES-I) scores were used.

The published literature includes validation studies in which GaitSmart technology is compared against alternative gait assessment methods or studies where the diagnostic potential of GaitSmart is assessed. Unpublished

studies provided by the company provided evidence that may be more directly relevant to the decision problem in that they used GaitSmart in line with the scope, reporting on gait outcomes and PROMs.

The EAG note that although validation studies may not be directly relevant to the decision problem, they provide an indication of the accuracy of the GaitSmart technology in measuring gait parameters thus may support the use of GaitSmart technology as an alternative to visual gait assessment.

5.2 *Critical appraisal of studies and review of company's critical appraisal*

The company submission did not include a critical appraisal of the included publications. The EAG critically appraised each of the included publications using recognised critical appraisal checklist. Choice of appropriate checklist was made difficult by the fact that many publications did not have a clearly described study design and reporting of methods in the publications lacked detail. The EAG used the JBI critical appraisal checklist appropriate for the study design assigned to each study (Barker 2023, Campbell 2020, Moola 2020, Munn 2020). The choice of appraisal checklist was made by one reviewer and checked by a second reviewer with any discrepancies discussed and a final decision agreed. A rationale for the choice of study design and checklist used for each study is provided in Appendix B. Abstracts were not critically appraised due to a lack of detail.

There was 1 randomised trial (McNamara, unpublished), 4 publications with a diagnostic study design (McCarthy 2013, van Helvoort 2021a, van Helvoort 2022, Zügner 2019), 1 publication with a cross sectional study design (Rahman 2015), 1 case report (Ward, unpublished) and 4 publications that comprised a mix of before and after study design and case series study design (Care City Pilot, unpublished, Hodgins 2015, Monda 2015, NHS Glasgow Falls Clinic Report unpublished and Rodgers 2020). These were assessed using the case series studies checklist.

The EAG consider the overall quality of the included studies to be low due to a number of factors including

- poor reporting of study designs and recruitment methods. One published study (Rodgers 2020) did not report information on consent or ethics for the study
- unclear study aims and analysis methods which make results difficult to interpret
- lack of appropriate comparator groups
- incomplete reporting of factors such as participant demographics
- lack of blinding, in particular diagnostic accuracy studies did not avoid a case-control design which meant that participant diagnosis was known prior to study inclusion

Considering the population group people undergoing hip or knee replacements, one unpublished randomised trial (McNamara) is the closest match to the scope though it should be noted that gait analysis was done using GaitSmart in both arms. The study was considered to be medium risk of bias based on the information reported. The EAG noted that there was no treatment blinding although participants in the standard care arm were blinded to their GaitSmart assessment results.

Considering the population of people at risk of falls, one before and after study (Rodgers 2020) is most applicable to the scope but only people who suffered an injurious fall were included. The quality of the study is impacted by the fact that reporting of some methods is unclear and the personalised exercise programme provided is not generated by the vGym app which may result in inconsistency in exercise programmes between participants.

The remaining studies had more limited applicability to the scope either because they were about validation of GaitSmart measures or because the diagnostic potential of GaitSmart was being assessed. In addition, the studies did not include the exercise part of the intervention.

5.3 *Results from the evidence base*

The EAG considered that the included studies fell into one of 3 categories

- validation studies including participants not relevant to scope (e.g. healthy participants
- studies including people with hip or knee osteoarthritis
- studies including people at risk of falls and

Reported results can be grouped into two broad outcomes – gait parameters and patient reported outcome measures (PROMs) although within these two groups, there is wide variation in the outcomes and comparisons reported. In addition, one study reported outcomes related to patient experience using the GaitSmart technology.

Validation Studies / Diagnostic Studies

Four studies were either validation studies or studies investigating the diagnostic / prognostic potential of GaitSmart (IMI - APPROACH, McCarthy 2013, Monda 2015, Zugner 2019). None of the studies included a comparison with a visual assessment however, which is the approach to gait analysis recommended in current NICE guidance. Detailed results are reported in Appendix C.

Validation of GaitSmart against optical tracking systems (Zügner 2019, Monda 2015) suggest that GaitSmart measurements are correlated with more comprehensive gait analysis systems. In a study including 49 people who underwent hip replacements, Zügner (2019) reported no significant difference with high interclass correlation coefficients (ICC) between the two gait analysis systems for mean pelvic tilt range (ICC 0.08) and mean knee flexion range (ICC 0.83 for right knee and 0.86 for left knee) but did record significantly less hip flexion compared with optical tracking. ICC was still good (0.75 for right hip and 0.73 for left hip). Monda (2015) included 136 healthy participants and compared gait parameters in different age groups. Stride duration and knee, thigh and shank ROM differed significantly when comparing people aged over 80 years with all other age groups (p values not reported). Relationship between angles and age was non-linear with little change in most of the angle parameters until after age of 70 years with a rapid decrease after age 80 years. A comparison with an optical tracking system indicated no significant difference between GaitSmart and the optical tracking system however it should be noted that only 9 participants were included and it is not clear whether they were also included in the main study cohort.

In the IMI-APPROACH study, principal component analysis (PCA), a method for reducing the dimensionality of a dataset and increasing interpretability of

data, identified five underlying GaitSmart domains (**Error! Reference source not found.**) which were used in regression analysis (van Helvoort 2021a). In addition, one function domain (total function) and two additional domains (objective function and subjective function) were identified from six measures of function including two performance-based tests, two KOOS subscales and two SF-36 subscales (van Helvoort 2022).

Table 4: GaitSmart Domains from PCA

GaitSmart Domain	Parameter
GS Knee	• ROM index knee in swing • ROM contralateral knee in swing • ROM index calf • ROM contralateral calf • ROM index knee in stance • ROM contralateral knee in stance
GS Hip	• ROM index hip • ROM contralateral hip • Speed (m/s) • Average duration per stride (s) • Stride length (m)
GS Difference Knee	• Difference ROM knees in swing • Difference ROM calves
GS Difference Stance	• Difference ROM knees in stance
GS Difference Hip	• Difference ROM hip

In assessing the relationship between the presence of radiographic knee osteoarthritis (ROA), addition of GaitSmart data to the regression model with demographics and PROMs improved the association (R^2 increased from 0.075 to 0.150, 71% sensitivity and 52% specificity). KOOS pain, knee/calf ROM and difference in ROM (swing phase) were all statistically significant contributors. For the domains GS knee and GS difference knee, association with ROA was dependent on pain levels – with the effect of GaitSmart

domains on the likeliness of having ROA decreasing with less pain. The study concluded that combining GaitSmart parameters into five domains may have value as additional outcome measures to assess OA (van Helvoort 2021a).

In a follow-up publication (van Helvoort 2022), a full regression model including all GaitSmart parameters was used to construct GaitSmart based function scores relating to total, objective and subjective function. The model explored the relationship between GaitSmart and derived function domains. In a model for subjective function, ROM and stance flexion in the index knee and ROM in the index hip were statistically significant. In the model for objective function only ROM in the contralateral knee, difference between both sides and speed were significant. In the model for total function, parameters for index side (stance flexion index knee and ROM index hip), contralateral side (ROM contralateral knee) and general parameters (average duration and stride length) were significant.

Considering whether GaitSmart parameters could distinguish between groups with poor or good general health, GaitSmart based function scores (GS objective function, GS subjective function and GS total function) could discriminate between health status.

GaitSmart based function scores correlated best with performance-based tests. A change in sit to stand activity (decrease or improvement) was most prominently detected by GaitSmart function scores whereas GaitSmart function scores were minimally responsive to detect an actual change in self-reported function. The study concluded that GaitSmart is related to commonly used function measures and is responsive to changes in aspects of objective function but that while GaitSmart may be of value in the evaluation of function in knee OA, further research is needed to validate whether GaitSmart could be used as a clinical outcome measure.

People referred for hip or knee arthroplasty

Three studies reported on use of GaitSmart for people referred for hip or knee arthroplasty (Hanley 2016, NNUH unpublished, Rahman 2015). Results are reported in Table 5**Error! Reference source not found.**.

The study most clinically relevant to this population is the unpublished randomised trial (McNamara unpublished) which compares GaitSmart with standard of care for rehabilitation following hip or knee surgery. The economic model for this population is also based on this trial. The trial included a total of 44 participants (22 in each arm) who had undergone hip or knee surgery and received routine inpatient physiotherapy followed by outpatient follow-up until discharge. GaitSmart was used to conduct a gait analysis in both groups however only participants in the GaitSmart group were provided their personalised exercise plan. The results of the trial indicated [redacted].

Findings from Rahman (2015) indicate that there are significant differences in gait variables when comparing people who have undergone or are waiting to undergo knee replacement when compared with healthy controls. The EAG consider the results of this study to have limited applicability as a comparison with healthy controls is not within the scope and the study did not investigate the impact of the exercise aspect of GaitSmart. Similarly, Hanley (2016) reported gait differences in a group of patients with hip arthrosis and included comparisons with a group of healthy controls. It is important to note that again, the exercise component and impact of GaitSmart programme as an intervention was not assessed in this study therefore the EAG considers this

to have limited applicability. In addition, information was reported only in an abstract and study details are therefore extremely limited.

Table 5: Results from studies including people referred for hip / knee arthroplasty

Study	Gait Parameters	PROMs
Hanley (2016) Abstract only, limited information to report	**Hip measures** Pre-operative mean range in sagittal plane was • 20.4° in the ipsilateral hip • 35.3° in the contralateral hip • Reduced compared to the healthy group (40.5°; p<0.001) Post-operative ipsilateral hip movement improved significantly but did not reach normal values • Mean range 28.9°, SD 6.6°; p<0.001 Movement in the contralateral hip reduced • Mean difference -5.25° (95% CI -8.06 to -2.43) **Knee Measures** Preoperative movement of both knees was reduced compared with healthy comparators (p<0.001) Knee movement on both sides increased but not to normal values (p<0.001)	
Norfolk and Norwich University Hospital Results from McNamara (Unpublished)	[redacted]	[redacted]

Study	Gait Parameters	PROMs
Rahman (2015)	Significant differences in gait variables between patient groups and healthy controls (p<0.001) Knee swing increased by almost 10° on the operated side at 52 weeks (p=0.02) Knee stance was lower on the operated side at all 3 time points Stride duration decreased by 52 weeks (p=0.053) No significant changes in any parameters for the non-operated leg	**Oxford Knee Scores** Mean pre-operative knees scores were not significantly different between the groups: • 20.3 (7.7) for pre-op • 21.5 (8.6) for 8 weeks • 20.1 (7.7) for 52 weeks Considering patients with both a pre-op and 52-week post-op questionnaire: Mean pre-op OKS was 21.2 (7.6) compared with 38.1 (7.9) at 52 weeks post-op (p value not reported)

Abbreviations: EFS, Edmonton Frail Scale; FES-I, Falls Efficacy Scale International; KO, knee osteoarthritis; OKS, Oxford knee score; PROMs, patient reported outcome measures; TKA, total knee arthroplasty

People at risk of falling

Four studies reported on outcomes in people considered to be at risk of falling (Care City Pilot unpublished, Hodgins 2015, NHS Glasgow unpublished, Rodgers 2020) including gait parameters and PROMS (Table 6). All four studies were conducted in the UK, with two conducted in conducted in NHS community settings (Rodgers 2020, NHS Glasgow Falls report, unpublished) and one in a primary care setting (Care City Pilot, unpublished). Overall, the results from the studies in this population indicate that Gait parameters and PROMs may be improved through exercise however it is less clear the extent to which one is correlated with the other as only one study included a correlation analysis.

The most relevant study to this population and the study on which the economic analysis has been based (Rodgers 2020) included 121 participants who had suffered an injurious fall. Results reported a change in mean GaitSmart score from 26.1 to 46.3 (p<0.001) with 76% of participants

improving. Mean gait speed increased from 0.46 to 0.62 m/s ($p<0.001$) with 80.5% of participants improving. Gait score and speed were moderately correlated with measures of frailty and fear of falling, with correlations increased from beginning to end of the study. The EAG note that although exercise was prescribed as part of this study, it was not generated using the integrated vGym app. A database was developed based on the Otago exercise program or NHS published exercises and excluding exercises from sitting / lying. An algorithm was developed to allow GaitSmart values to generate a set of recommended exercises. In addition, the study lacked a long-term follow-up and did not include people who did not have an injurious fall but who may be at risk of falling.

Two unpublished before and after studies (Care City Pilot and NHS Glasgow Falls Clinic report) reported on changes in gait parameters including speed, gait scores, knee angle and on changes in PROMs including Falls Efficacy Scale scores, Edmonton frailty scores and EQ5D scores in people at risk of falls. Both studies reported improvements in outcomes over the assessment period with the NHS Glasgow study ([redacted]) reporting an [redacted] while the results of the Care City Pilot ([redacted]) reported [redacted] from the start to end of the studies. Both studies report [redacted] from start to end of study period and the NHS Glasgow study reported [redacted] from start to end of study. [redacted].

Hodgins 2015 reported on how gait parameters in a healthy older population (n=11) differed from those of an older population with gait and balance issues (n=18) with results indicating that people with balance and gait problems average knee ROM was lower and stride duration was slower compared with healthy participants of a similar age. The participants with balance and gait issues were provided with a personalised exercise plan to follow over a period

of 130 weeks gait data changed with time and came closer to the normal range. The EAG note that again, the exercise programme was not generated by the vGym app as it was not part of the GaitSmart system at the time the study was conducted. The EAG note that applicability of this study is limited as it compares with a group of participants who do not have gait and balance issues.

Table 6:Results from studies including people at risk of falling.

Study	Gait Parameters	PROMs
[redacted]	[redacted]	[redacted]
Hodgins (2015)	Reference group measure is average of single measure for each participant (average of 18 measures) Balance class measure is overall average for 11 participants where for each subject it is average over time (average of averages) For the whole cohort average knee ROM was 61° with a spread of 22°. **Knee ROM (mean)** • Balance class: 52.6±12.7° • Reference group: 61.3±6.0° • 3/11 participants were consistently below -2 SD level for knee flexion (foot at risk of catching things on the ground)	

Study	Gait Parameters	PROMs
	• 4/11 were consistently above -1 SD and 4/11 ranged between normal and -2 SD **% Knee asymmetry (mean)** • Balance Class: -3.3±4.4 • Reference Group: 0.9±8.2 • Majority of participants were close to the -1 SD value **Stride Duration (mean)** Balance Class: 1.24±0.17 Reference Group: 1.05±0.11	
[redacted]	[redacted]	[redacted]
Rodgers (2020)	**Gait Score (%)** • Mean score changed from 26.1 (±21.7) to 46.3 (±27.3); p<0.001 • 76% of participants improved, 16% remained the same and 8% worsened **Speed (m/s)** • Mean score changed from 0.46 (±0.17) to 0.62 (±0.23); p<0.001 • 80.5% of participants improved and 19.5% worsened	

Study	Gait Parameters	PROMs
	Correlations between gait score / speed measure and EFS / FES-I measures were increased at end of the study: • Gait score vs FES-I: 0.33 to 0.5 • Gait score vs EFS: 0.32 to 0.58 • Speed vs FES-I: 0.22 to 0.48 Speed vs EFS: 0.24 to 0.56	

Abbreviations: EFS, Edmonton Frail Scale; FES-I, Falls Efficacy Scale International; KO, knee osteoarthritis; OKS, Oxford knee score; PROMs, patient reported outcome measures; TKA, total knee arthroplasty

Patient Feedback

Ward (unpublished)

[redacted] Detailed results are reported in Appendix C.

Although there were only [redacted], discussion with clinical experts supports the idea that patients like the GaitSmart approach and find the reports useful and motivating.

5.4 *Ongoing Studies*

The EAG did not identify any ongoing studies relevant to the scope of this assessment.

6 Adverse events

The company submission reported no adverse events associated with the use of GaitSmart. The EAG conducted searches of MAUDE and MHRA databases and found no adverse event reports. Clinical experts noted that it is important

to assess individuals' ability to perform the prescribed exercises as some exercises may need to be adapted to accommodate any issues such as balance problems to prevent injury. The EAG consider this to be something not unique to GaitSmart however, as patients would be assessed by a clinician to make sure they have the ability to perform prescribed exercises safely regardless of method of prescription.

7 Evidence synthesis and meta-analysis

The company submission did not include a meta-analysis. The EAG agrees that this is appropriate and has not conducted a meta-analysis either. This is because there is little consistency in measures used, analysis approaches and outcomes reported in the published literature giving rise to a high degree of heterogeneity.

8 EAG interpretation of the clinical evidence

Although the majority of the studies used GaitSmart I, the EAG consider the gait assessment evidence to generalisable between version I and II for gait parameters. The one key limitation however is that Version I had no integrated exercise component. The EAG notes that the clinical evidence has primarily been generated in relevant settings and is therefore likely generalisable to the NHS. There is however a high degree of heterogeneity in terms of comparisons made and outcomes reported which results in limited evidence for relevant clinical outcomes. There are limited studies where GaitSmart is compared with standard of care however the EAG notes that the standard of care pathway is extremely variable which makes it difficult to identify appropriate comparators for GaitSmart.

The company identified two clear populations and there is limited clinical evidence that the use of GaitSmart may improve clinical outcomes for patients in each of these populations although the most relevant evidence has yet to be published in the public domain. In randomised trial comparing outcomes in people who underwent surgery,

[redacted]

[redacted]The EAG consider this

study to be the most relevant and informative but note that the comparisons are not being made directly between GaitSmart and standard of care. The results do suggest potentially more improvement with GaitSmart but [redacted] which may strengthen the clinical case. Considering people at risk of falls, 2 unpublished studies reported improvements in outcomes including gait parameters and PROMs in people at risk of falls but neither study included a standard care comparator.

From a limited evidence base, the direction of effect appears to be that use of GaitSmart technology improves outcomes for people referred for hip or knee surgery and for people at risk of falls but there is a lack of directly comparative evidence. There are strengths in the available studies in that they use validated tools to measure PROMs and function and consideration is given to whether changes are clinically significant.

Based on the clinical evidence the EAG consider that the case for adoption is potentially supported but that further evidence generation would be beneficial. GaitSmart provides accurate gait assessments, clinical experts like the integrated exercise component and patients like the report and the information it provides. Patient choice will be important to consider when determining whether GaitSmart approach is appropriate as some people may not want to do multiple assessments or exercise at home in isolation. GaitSmart may afford an opportunity to bring some consistency to clinical pathways however there are a lot of different patient groups that would need to be considered and it is important the patient preference is considered. GaitSmart technology could possibly be useful where there is variation in practice due to lack of resource or joined up service delivery.

9 Economic evidence

9.1 *Published economic evidence*

Search strategy and selection

The company submission included 5 studies but did not provide detail of searches or the selection process for economic evidence. The EAG excluded 3 of the studies as they were not relevant to the scope and the studies' data or findings were not used in the company's models. The EAG conducted a combined search for clinical and economic evidence, which identified a total of 596 database records none of which were economic studies.

Published economic evidence review

No relevant published economic evidence.

Results from the economic evidence

The economic models submitted by the company were the same as reported in 2 unpublished economic evaluations by Zanghelini. The economic analyses undertaken were the same as in the company's submission, in terms of model structure, model inputs and economic results. This will be discussed in detail in the report.

9.2 *Company de novo cost analysis*

Economic model structure

The company submitted 2 models for (i) patients referred for knee or hip surgery (pre-operative and post-operative management) and (ii) people above 65 years that are at risk of falling. Although the models share some similarities in terms of structure and the approach used to estimate falls risks, different sets of clinical inputs and cost inputs are used.

The EAG will describe each model and its inputs, and report the results separately. The scopes of the 2 models are summarised in Table 7.

Table 7 Model Scope

Model	PICO and key clinical sources of information
Rehabilitation model Decision tree, 17-week time horizon	P: Patients referred for hip or knee arthroplasty I: GaitSmart sessions over 12 weeks, 1 session every 3 weeks C: Standard care – self-managed home exercise or group/individual physiotherapy O: Falls with injury Clinical inputs are taken from McNamara unpublished (RCT): [redacted]
Falls model Decision tree, 1-year time horizon	P: Patients over 65 years at risk of falling – 2 subpopulations: (i) patients who had a fall and (ii) patients with moderate to high fear of falling I: GaitSmart sessions over 12 weeks, 1 session every 3 weeks C: Standard care – individual physiotherapy O: Falls with injury Clinical inputs are taken from Rodgers 2020 (single arm study): 121 people who suffered an injurious fall and were under the care of a community hospital; GaitSmart; follow-up to 12 weeks.

Rehabilitation model: People referred for hip or knee arthroplasty

The company's rehabilitation model employed a simple decision tree structure comparing GaitSmart and standard care (

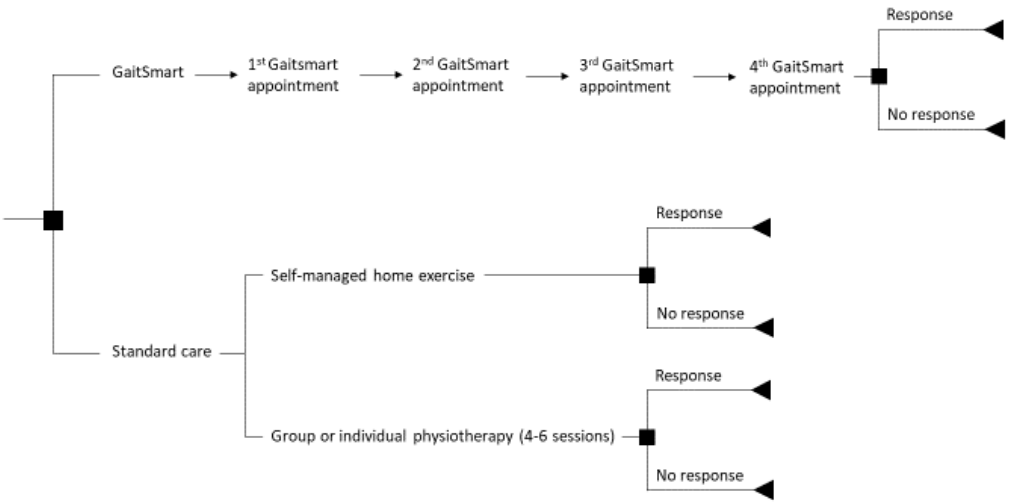


Figure 3). At the end of the decision tree, patients were either responding or not responding to the intervention. The company defined a response as any

improvement in gait speed. Following a response to the intervention, the model considered the change in falls risk for each intervention using the association between gait speed and falls risk. This was followed by falls outcomes where falls would be treated at an A&E with or without hospitalisation. An NHS perspective over a 17-week time horizon was used. No discounting was applied.

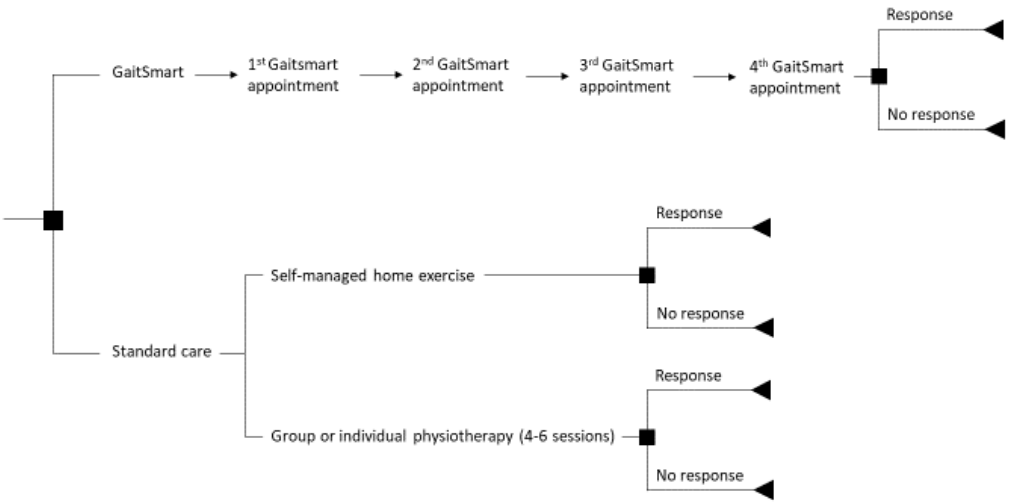


Figure 3 Replicating company's rehabilitation model

The standard care arm assumed that [redacted]. This was based on expert opinion derived from an unpublished study by McNamara (unpublished). Key assumptions are summarised in Table 8 and Table 9.

The model comparator and structure were appropriate to the scope, and the time horizons chosen were based on the duration of available evidence.

Table 8 Assumptions in economic model (Rehabilitation)

Assumption	Justification (summary, see company submission for full text)	EAG Comment
[redacted]	To represent the actual practice. The EAG noted that the assumption was made based on expert opinion derived from an unpublished study by McNamara (Zanghelini Unpublished).	The EAG accept this and variations are explored in the sensitivity analysis.

Assumption	Justification (summary, see company submission for full text)	EAG Comment
THA in conjunction with hip OA as base case population	The company did not provide any relevant justifications.	The EAG accept this and other patient populations are explored in the sensitivity analysis.
Similar response probability for self-managed home exercise and group/individual physiotherapy	Due to lack of evidence.	The EAG accept this and discuss further in section 9.2.2.

Table 9 Additional assumptions identified by the EAG

Additional assumptions identified	EAG Comment
100% individual physiotherapy for group/individual physiotherapy arm in standard care	The EAG think this is not reflective of the actual representation of group and individual physiotherapy. Some patients would have been offered group physiotherapy when limited individual physiotherapy is available or patient preference for group physiotherapy. This is amended in the EAG model.
Similar falls risk reduction for self-managed home exercise and group/individual physiotherapy	The EAG noted that the data on the type of rehabilitation in standard care group in McNamara (Unpublished) are lacking, therefore it is unclear how representative the average falls risk reduction derived from the study comparator group as a whole, to the proportion of self-managed home exercise and group/individual physiotherapy used in the model. As exercise adherence can affect treatment outcome, different treatment modalities would result in different falls risk reduction. A different proportion of treatments would yield different average falls risk reduction for standard care arm in the model. The EAG recognise the lack of relevant evidence, and accept this.

Economic model parameters (Rehabilitation model)

The following sections outline the key clinical parameters and resources used in the company rehabilitation model.

Costs come from standard sources and are reported in detail in later sections.

Clinical parameters and variables (Rehabilitation model)

The main clinical parameters include the response to the intervention, falls risk at baseline, falls risk of intervention through gait speed and falls outcomes.

Response to intervention

The model incorporates the probability of response to intervention derived using individual-level data on pre- and post-intervention gait speed from McNamara (Unpublished). There is additional discussion on the study design in Table 3, and the findings reported by McNamara (Unpublished) in **Error! Reference source not found.**. The company defined response as any improvement in gait speed, and based on this, it is found a [redacted] (see further discussion in change in falls risk with intervention).

The EAG noted that McNamara (Unpublished) compared [redacted] and variation using these established values to define a response is explored.

Baseline falls risk

The probability of falls is derived using the proportion of patients who had fall after arthroplasty and the odds of falls resulting from symptomatic OA (Smith 2016, Doré 2015). Using these values, the probability of falls was estimated to be 0.4 and being incorporated in the model for THA with hip OA as the base case population.

Smith (2016) analysed data from the US Osteoarthritis Initiative programme between 2004 and 2006 for people who had undergone a THA (n=104) and TKA (n=165). They considered the data for the first 12 months post-operatively, and compared these 12 months of data for people who were unmatched, but had not received joint replacements (4692 people who did not have a THA and 4631 people who did not have TKA). The mean age of included participants ranged from 66.8 to 71.1 years, where the cohort of people who received THA was 4 years older than cohort who received TKA (THA 71.1 vs TKA 67.6). Longitudinal follow ups were up to 84 months, and 25% and 26.1% had a fall in the past 12 months after THA and TKA, respectively.

Doré (2015) completed a longitudinal analysis of 2 time points (between 1999-2003 and between 2006-2010) using a community-based prospective cohort study in the US. With a mean of 5.96 years follow up period, 1619 participants were included in the analysis, where 20.2% had symptomatic knee OA and 12.9% had symptomatic hip OA. The mean age was 62 years and mean BMI was 31 kg/m² at baseline. Logistic regression (controlled for baseline risk factors) found that the OR was 1.39 and 1.60 of falling in patients who had symptomatic knee and hip OA, respectively. The EAG is concerned about the generalisability the US findings to the NHS setting, but have not found alternative sources of evidence.

Change in falls risk with intervention

The company model considers the change in falls risk of each intervention through the observed change in gait speed using individual-level data from McNamara (Unpublished) and the risk ratio (RR) between gait speed and falls risk (RR of 1.069 per 10cm/s decrease) (Verghese 2009). Verghese (2009) included 647 eligible participants between November 2004 to February 2008 in the US. A total of 597 participants with mean age 80.5 years, 62% female were analysed. With mean follow up of 20 months, 226 people experienced falls where 115 people fell only once and 111 people had recurrent falls. The mean gait speed was 92.8±24.1cm/s. Compared with participants with gait speed of 100 cm/s and above, a fully-adjusted generalised estimation model found a 1.069 (95% CI 1.001-1.142) RR of falling per 10 cm/s decrease in gait speed.

The company submitted model calculates the initial/final falls RR by multiplying the difference between individual's initial/final gait speed and an average initial gait speed in each intervention group with the RR per 10cm/s. Subsequently, the initial and final falls risk is calculated by deducting the baseline falls risk with initial/final falls RR. An average initial and final falls risk difference is derived and subtracted from the baseline falls risk to give the number of falls. The EAG did not agree with the company calculation and have altered it to yield the falls RR for each intervention using the formula: (1.069) ^ (change in speed in units of 10 cm/s). The RR is then applied to the

baseline falls probability to yield falls probability of each intervention. The EAG applied the calculation only to those participants whose initial gait speed was less than 1.0 m/s from McNamara gait speed data, as Verghese (2009) specified that the increased falls risk was for patients with gait speed less than 1.0m/s. In addition, The EAG also suggests to separate the falls risk ratio to responders and non-responders in the rehabilitation model for better accuracy and fitting to the model structure.

[redacted]in McNamara (Unpublished) were included in the EAG calculation, after excluding participant whose initial gait speed was 1.0 m/s and above.

[redacted]

Falls outcomes

The rehabilitation model considers only falls that require medical treatment, by applying the probability of falls requiring A&E attendance and hospitalisation to the number of falls generated in the model (Watson 2011). Watson (2011) studied the economic burden of injurious falls between 2006 to 2007 in Australia. Out of 507,207 falls, 18,466 falls were attended in A&E and 25,561 required hospitalisations. The EAG is concerned about the generalisability of the study findings to the NHS setting. While a UK-based paper (Craig 2013) may be more relevant (see further discussion in the falls model), the EAG believes any changes made are unlikely to have a significant impact on the overall findings due to marginal number of falls yielded from the model.

All clinical parameters in the rehabilitation model are presented in Table 10.

Table 10 Clinical parameters used in the company's rehabilitation model and any changes made by the EAG

Variable	Company value	Source	EAG value	EAG comment
Relative risk of gait speed and risk of falls	1.07	Verghese 2009	No change	Verghese (2009) reports a 1.069 RR of falls associated with every decrease of 10 cm/s in gait speed.
Probability of response: *Self-managed home exercise* *Group/ individual physiotherapy* *GaitSmart*	[redacted] [redacted] [redacted]	McNamara (Unpublished)	[redacted] [redacted] [redacted]	Recalculated using company definition using data whose initial gait speed less than 1.0m/s. The EAG accepted this, and variation using [redacted] (McNamara Unpublished).
Falls risk reduction: *Standard care* *GaitSmart*	[redacted] [redacted]	Company estimate of falls risk reduction (McNamara Unpublished)	[redacted] [redacted]	Using McNamara data whose initial gait speed less than 1.0m/s, the EAG recalculated falls risk ratio based on responders and non-responders
Probability of falls in knee OA	1.39	Doré 2015	No change	Doré (2015) reports a 1.39 OR of falls associated with patients with knee osteoarthritis
Probability of falls in hip OA	1.60	Doré 2015	No change	Doré (2015) reports a 1.60 OR of falls associated with patients with hip osteoarthritis.
Probability of falls following THA	0.25	Smith 2016	No change	Smith (2016) reports a 0.25 of falls following THA in the past 12 months.
Probability of falls following TKA	0.26	Smith 2016	No change	Smith (2016) reports a 0.26 of falls following TKA in the past 12 months.
Calculated probability of fall following THA for people with hip OA	0.4			Calculated as 0.25 x 1.6
Calculated probability of fall following TKA for people with knee OA	0.36			Calculated as 0.26 x 1.39

Variable	Company value	Source	EAG value	EAG comment
Probability of fall resulting in emergency attendance	0.07	Calculated using estimates from Watson 2011 (18,466 falls with A&E attendance / 251,433 number of fallers)	0.03	The EAG value was recalculated (18,466 falls required A&E attendance / 507,207 falls). The EAG accepted this and noted that this may not be generalisable to NHS A&Es.
Probability of fall resulting in hospitalisation	0.61	Watson 2011	0.05	The EAG have not been able to reproduce the company value. EAG value was recalculated (25,561 falls with hospital admission / 507,207 falls).

Resource identification, measurement and valuation (Rehabilitation model)

Technology costs and training

The GaitSmart system comprises a tablet, 7 sensor modules and elastic straps. The company states that following an order of the GaitSmart system, the system will be provided and 2 training sessions will be arranged and delivered to any healthcare staff, who do not require any previous experience or qualifications. The cost of the initial device set up and training is £1000. Subsequently there is a charge of £10 for every GaitSmart session used. There is no charge for any replacement items or for additional staff training, and no time limit for this arrangement, this is dependent on the use of at least [redacted] sessions per month.

Training is provided by the company. The first session is in person and consists of 2 hours theory and practical training on the system, data storage and access to GaitSmart Cloud server and the usefulness of GaitSmart data. The second training can be conducted online to help users to understand the GaitSmart data. Following the completion of a successful test after each training, a certificate is provided.

Staff time costs in GaitSmart sessions

The company model has included only healthcare assistant costs for each GaitSmart session. The EAG amended by including healthcare assistant costs, administrative costs (10 mins per patient) and physiotherapist oversight (5 mins per patient). GaitSmart sessions are delivered by healthcare assistants with each session lasting for 15 minutes. The company costs were based on PSSRU 2020 by applying the annual mean pay of a healthcare assistant and other costs (overheads and capital overheads) were assumed to be that of a band 4 community-based scientific and professional staff. The EAG accepts this assumption, and substituted using the values from PSSRU 2022. While the EAG agree on the feasibility of GaitSmart delivery by healthcare assistants, the clinical experts advised that oversight by a physiotherapist might be required, and the EAG added this to the model.

For the administrative costs, the EAG substituted the mean annual pay of an administration and estates staff from PSSRU 2022.

Standard care costs

The company model assumes that standard care consists of 20% self-managed home exercise and 80% group/individual physiotherapy, although 100% individual sessions are assumed, with no group physiotherapy. Self-managed home exercise consisted of one 20-minute session of a band 4 community physiotherapist and 10 mins for administration, while group/individual physiotherapy consists of 6 x 1-hour sessions with band 6 physiotherapist and 6 x 30-minute consultant sessions and 15 administrative mins per session. The EAG feels this is an overestimation, particularly implausible with the high consultant sessions and unlikely to reflect the actual situation in NHS. However, the EAG noted that there is high variability in the standard care, limiting the generalisability of any standard care considered in the model. The EAG accepted the majority of the company assumptions but excluded the consultant sessions and applied an assumption that 50% patients would attend group sessions in the model. Variations in the delivery were explored in the scenario analysis.

The costs of ambulance call out

The costs of an ambulance call out in the submission were based on PSSRU 2019 for ambulance service, see and treat and convey. To avoid any impact from Covid, the EAG have substituted the costs from NHS reference costs 2019/20, and inflated the costs to 2021/22.

The costs of A&E visit without admission

The costs of an average A&E visit were based on NHS reference costs 2018/19. The EAG have substituted the weighted average of non-admitted A&E visits from NHS reference costs 2019/20 and inflated to 2021/22.

The costs of A&E visit with admission

The costs were based on PSSRU 2018, with the reference provided the company upon the EAG request, however the EAG was unable to identify the costs in PSSRU 2018 and the accuracy cannot be verified. The EAG

substituted weighted average of admitted A&E visits from NHS reference costs 2019/20 and inflated to 2021/22.

All cost inputs in the rehabilitation model are presented in Table 11.

Table 11 Cost parameters used in the company's rehabilitation model and changes made by the EAG

Parameter	Company value	Source	EAG value	Comment
GaitSmart Intervention				
Equipment set up				
Device set up and training	Not included	£1000 from company estimate	No change	
Equipment use				
Per use charge	£10	Company estimate	No change	
Number of sessions per person	4	Company estimate	No change	This is the number advised by the company, however experts stated that in some cases it was not achieved and GaitSmart may be implemented with an expectation of only 3 sessions per person.
Staff requirement				
Health care assistant for 15 mins per session	£6.75	PSSRU 2020 Company estimate based on healthcare assistant, mean annual basic pay per FTE, plus overheads, capital overheads of community-based scientific and professional staff, band 4, £27 per hour	£8.50	EAG recalculated the hourly rate based on PSSRU 2022 (mean annual pay of 20148 and 28% oncosts, and other overheads of a community-based band 4) and the total working hours (1618), resulted in £34.06 per hour. EAG calculation: £34.06 per hour x 15 mins = £8.50.
Administration time for 10 mins per patient	£1.55	PSSRU 2019 (administration and estates staff, mean	£3.42	EAG recalculated the hourly cost using the mean annual basic pay of £32,340

Parameter	Company value	Source	EAG value	Comment
		annual basic pay per FTE)		(PSSRU 2022) and the total paid working hours (210 days x 7.5 hours), resulted in £20.53 per hour. Paid working days = 365 days – 104 weekends – 51 paid off days (33 annual leave, 8 bank holidays and 10 training days) EAG cost calculation - £20.53 per hour x 10 min = £3.42
Physiotherapist oversight time for 5 mins per patient	£0		£4.58	EAG cost calculation, band 6 = £55 per hour x 5 mins = £4.58 (PSSRU 2022)
Total cost for all GaitSmart sessions per patient	£67	Company submission	£82.02	EAG figure includes additional staff costs.
Standard care:				
Self-managed home exercise				
Physiotherapist time for 20 mins per session	£10.33	PSSRU 2020 (community therapy assistant, band 4)	£12.33	EAG cost calculation = £37 per hour x 20 mins = £12.33. (PSSRU 2022)
Administration time for 10 mins per session	£1.55	PSSRU 2019 (administration and estates staff, mean annual basic pay per FTE)	£3.42	EAG cost calculation = £20.53 x 10 mins = £3.42 (PSSRU 2022)
Number of sessions	1	Company assumption	No change	EAG: A reasonable assumption
Total cost for all self-management sessions per patient	£11.89		£15.76	
Group / individual physiotherapy				

Parameter	Company value	Source	EAG value	Comment
Physiotherapist time for 60 mins per session	£48	PSSRU 2020 (Community physiotherapist, band 6)	£55	EAG cost calculation = £55 per hour x 60 mins = £55 (PSSRU 2022)
Consultant time for 30 mins per session	£57	PSSRU 2020 (Consultant, surgical, £114 per hour)	£0	EAG think this is unlikely to be plausible, and excluded this.
Administration time for 15 mins per session	£2.33	PSSRU 2019 (administration and estates staff, mean annual basic pay per FTE)	£5.13	EAG cost calculation = £20.53 per hour x 15 min = £5.13 (PSSRU 2022) .
Number of sessions	6	Company assumption	No change	
Number of patients per group session	n/a		10	EAG assumption
Proportion of group sessions	0		50%	EAG assumption and variation is explored in the sensitivity analyses
Total cost for all individual sessions per patient	£643.98	Calculated from above	£360.80	EAG: Recalculated using EAG value.
Total cost for all group sessions per patient			£36.08	EAG: Calculated using the total cost of individual sessions per patient and the number of patients per group session
Total cost for all group / individual physiotherapy per patient	£643.98	Company estimate	£198.44	EAG: Applied the proportion of group physiotherapy
Total standard care costs				
Total cost	£517.56	Company assumption – 20% self-managed home exercise and 80% group/individual physiotherapy	£307.83	EAG: Calculated using company assumption

Parameter	Company value	Source	EAG value	Comment
Costs for events following a fall				
Ambulance call out	£257	PSSRU 2019 (Ambulance service, see and treat and convey, 2017/18 value)	£307.45	EAG: £292 (NHS reference costs 2019/20), inflated to 2021/22
A & E visit, no admission	£166	NHS reference costs, 2018/19 (average accident & emergency)	£163.48	EAG: £155.31, weighted average of non-admitted, inflated to 2021/22 (NHS reference costs)
A & E visit, admission	£377	PSSRU 2018	£327.15	EAG: £310.81, weighted average of admitted, inflated to 2021/22 (NHS reference costs 2019/20)

Falls model: People at risk of falling

The company submission described the submitted falls model as a decision tree comparing GaitSmart and standard care, similar to the company rehabilitation model. The standard care arm was stated in the company submission to be self-managed home exercise or group/individual physiotherapy. Two subpopulations in a community care unit were considered in the model – (i) patients who had a fall and (ii) patients who had a moderate to severe fear of falling. An NHS perspective over 12-month time horizon was used. No discounting was applied.

The model considered the change in falls risk through different approaches specific to the subpopulation – the change in gait speed was used for patients who had a fall, while the change in fear of falling scores using FES-I was used for people who have moderate to severe fear of falling.

The EAG noted a mismatch between the company submission and the company model, in terms of model structure and model inputs. The main discrepancies include:

- each intervention is applied only patients after a fall with injury, which was calculated based on the risk ratio of each intervention,
- the response rate of each intervention was not considered in the model,
- standard care was assumed to be individual physiotherapy in the company model,
- GaitSmart was delivered as an adjunct to standard care

The company confirmed that response rates were not considered in the model.

The EAG's interpretation of the company falls model (Figure 4):

A decision tree model was constructed to compare GaitSmart and standard care. Patients entered the falls model and then had either falls or no falls. Falls were divided to falls with injury or falls with no injury. For those who experienced an injurious fall, they received medical attention through ambulance call-out, GP visit or A&E attendance. The company model also assumed that the intervention (GaitSmart or standard care) was only given to those patients had an injurious fall. Key assumptions are summarised in Table 12 and Table 13.

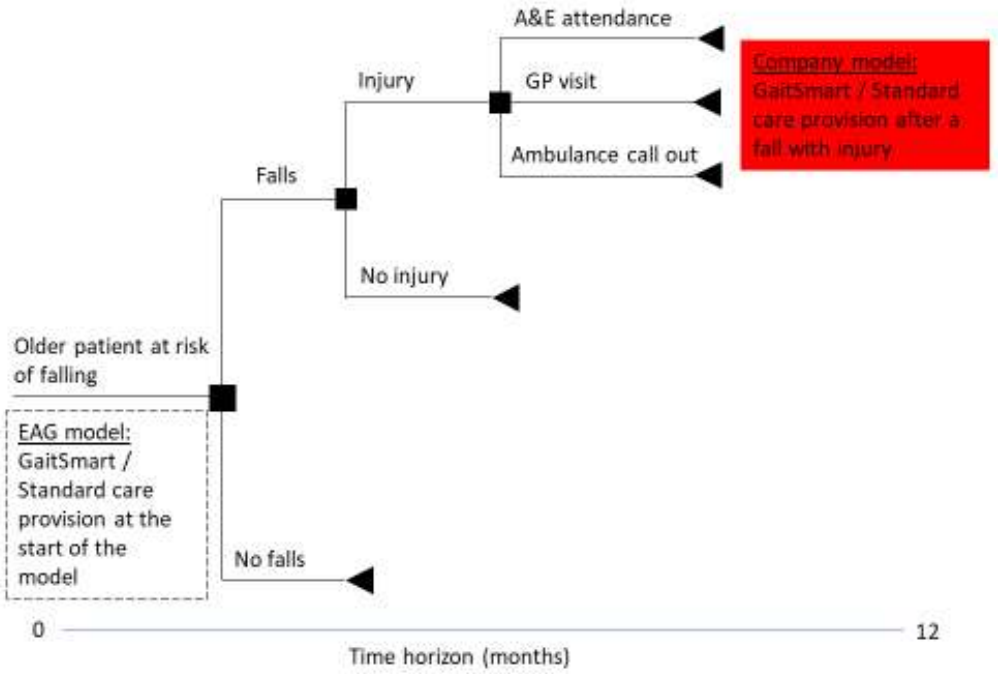


Figure 4 EAG interpretation of the company falls model

The EAG think the company falls model is flawed due to the time point when the intervention is to be provided. The company model did not model further outcomes at all after an intervention was given for those with injurious fall. Additional discussions related to this are in Table 13.

The EAG made a number of amendments. The EAG falls model starts with patient receiving either GaitSmart or standard care. At the end of each branch, patients had either falls or no falls. The fall outcomes were modelled following a fall.

Table 12 Assumptions in falls model

Assumption	Justification (summary, see company submission for full text)	EAG Comment
Time horizon of 12 months	As the benefit of treatment is generally seen in the short term.	The EAG believe this is a reasonable assumption.
The risk of falling based on different levels of fear of falling based on published data	As there was no randomised clinical trial setting with a comparator, and the study population was only monitored for a limited follow-up period in Rodgers 2020.	The EAG accept this and discuss further in section 9.2.2.

Assumption	Justification (summary, see company submission for full text)	EAG Comment
Similar response probability for self-managed home exercise and group/individual physiotherapy	Due to lack of evidence.	This is not relevant given the discrepancies noted by the EAG.

Table 13 Additional assumptions identified by the EAG

Additional assumptions identified	EAG Comment
Physiotherapy and GaitSmart were provided to patients after a fall with injury as base case scenario based on how intervention costs were applied in the model	The EAG think this is inappropriate as if interventions are given after a fall with injury, the model should also capture any further outcomes. But the company model ends with provision of the intervention, and does not include any outcomes at all. Furthermore, the company model estimates the number of falls with injury using the risk reduction associated with the intervention before an intervention is given. This is amended by EAG so that the patients receive the intervention at the start of the model.
A proportion of patients have 2 recurrent falls in a given year	This is a conservative approach. Patients could have more than 2 recurrent falls. The EAG accept this and variations are explored in the sensitivity analysis.

Economic model parameters (Falls model)

The following sections outline the key clinical parameters and resources used in the company falls model, where these are different from those previously discussed in the rehabilitation model. The company also submitted a variation of the model based on a population who had moderate to high fear of falling. The results for the population who had fallen and those with a fear of falling are very similar in all versions of the model. This is due to the dominance of the intervention costs in the modelling results, meaning that the method of calculating falls is relatively unimportant. The EAG preferred to focus on the model that is based on a population who had fallen, but have included information on the alternative version in Appendix E: Falls model: people with moderate to high fear of falling.

Costs come from standard sources and are reported in detail in later sections.

Clinical parameters and variables (Falls model)

The main clinical parameters include falls risk at baseline, falls risk of intervention through gait speed and falls outcomes (

Table 14).

Baseline falls risk

The company model estimates the number of falls at baseline, including recurrent falls in the same year.

The model uses the probability of falls amongst community dwelling adults over 65 and the average probability of recurrent falls by fear of falling levels are used (Berry 2008, Tinetti 1998, Arfken 1994). The model assumes that for those who had fallen, 14% will have a further 2 falls in the same year.

Berry (2008) cited a study by Tinetti (1998), a 1-year US-based prospective study with 336 community-dwelling participants of a mean age 78.3 taken from the Yale Health and Aging Project in 1985. They found 32% reported falling at least once. The EAG noted a similar statistic stated in NICE guideline CG 161, and in PHE 2018. The EAG used the source paper for these reports (Craig 2013), which reports falls for people aged 65 and older in Scotland.

Arfken (1994), a 1-year follow up of a random sample of 1358 people aged over 65 years, and living in the community, from the St Louis Older Adult Service and Information System in the US. Age and sex-stratified prevalence of fear of falling levels were reported in 4 age groups: 66-70, 71-75, 76-80 and >80 years. The proportion of participants who had falls (at least 1 fall and 2 or more recurrent falls) by fear of falling levels was reported. The EAG noted that these may not be representative of the UK in 2023, given that older patients might differ considerably in terms of mobility and frailty with better health care as opposed to 30 years ago. But, the EAG have not found alternative sources of evidence.

Change in falls risk with intervention

The submitted falls model applied the same approach as in the rehabilitation model to calculate the falls risk reduction associated with GaitSmart, and then

deducted this from the baseline population risk in the model. The EAG did not agree with the calculation and applied the same method used by the EAG for the rehabilitation model. The company calculated a falls risk reduction with GaitSmart of -1.77%. The EAG recalculated and yielded a RR of 0.88, which was then multiplied by the baseline falls risk.

As Rodgers 2020 is a single arm study, there was no comparator data to derive the falls risk reduction with standard care. The model assumes standard care does not result in any additional benefits, therefore the risk of falling after the intervention equates to baseline risk. This is unlikely to reflect the actual differential effectiveness between GaitSmart and standard care, however there are wide variations in the possible standard care programmes. Therefore the EAG have not changed the value of the base case, but completed extensive two-way sensitivity analyses and scenario analysis. Although additional evidence on falls prevention programs is identified, it is unclear how representative the program in the studies due to the high variation, hence the effectiveness. The EAG explored the impact of this uncertainty using a scenario analysis.

Falls outcomes

The EAG identified alternative sources to populate the falls outcome. The probability of falls with injury and medical treatment following a fall are taken from Craig (2013) which has been used to populate the return on investment (ROI) tool developed by Public Health England (PHE) for falls prevention programmes for elderly people in the community. Craig (2013) analysed data from Information Services Division (ISD) and the Scottish Ambulance Service in Scotland, and obtained the number of falls that visited a general practitioners' (GP) practices, requiring ambulance service, A&E, hospitalisation and subsequent care home residence. Out of 294,195 fallers over 65 years living in the community, 20% suffered serious injury following a fall and sought for medical attention. As some people may be treated at more than one medical setting, 51% attended a GP practice, 61% called for an ambulance and 80% visited an A&E. In those with serious injury, 28% would be hospitalised (Craig 2013).

Table 14 Clinical parameters used in the company's falls model and any changes made by the EAG

Variable	Company value	Source	EAG value	EAG comment
Probability of a fall in community dwelling adults over 65 years in a year	33.33%	Berry 2008, Tinetti 1998	34%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years, however in the base case this is not used, as the population is those identified as requiring access to falls intervention
Relative risk of gait speed and risk of falls	1.07	Verghese 2009	No change	Verghese (2009) reports a 1.069 RR of falls associated with every decrease of 10 cm/s in gait speed.
Probability of recurrent falls	14%	Arfken 1994	No change	
Probability of falls that result in an injury requiring medical attention	20%	Berry 2008, Tinetti 1995	20%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years, classed as serious falls.
Probability of falls that result in A&E attendance	34%	Berry 2008, Tinetti 1995	80%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years,
Probability of falls that result in GP visit	51%	Berry 2008, Tinetti 1995	51%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years,
Probability of falls that result in ambulance call out	15%	Berry 2008, Tinetti 1995	61%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years,
Probability of falls requiring admission	33%	33% of those needing attention	28%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years, proportion of serious injuries resulting in admission
Risk reduction for intervention	1.77%	Company estimate falls	0.89	The EAG recalculated to give a RR of 0.89.

Variable	Company value	Source	EAG value	EAG comment
		risk reduction using NELFT study, patient data in model		
Risk reduction for comparator	0%	Assumption	No change	The EAG have not changed this assumption in the base case, but have explored this at length in sensitivity and scenario analysis.

Resource identification, measurement and valuation (Falls model)

This section outlines additional or different cost parameters to those already discussed in the rehabilitation model. The EAG has adjusted the company GaitSmart costs in the falls model by including the same staff time costs as in the rehabilitation model. Details on costs related to the technology and staff time requirement are Table 11.

Standard care costs

Given the high variation in falls prevention programmes currently offered in the NHS, the EAG made a number of assumptions based on the information gathered from 12 falls prevention programs across different Trusts. The standard care is assumed to consist of an initial one-to-one assessment with a band 5 community physiotherapist (45 mins), followed by 8 group sessions of 10 participants (60 mins per session) with 2 band 5 physiotherapists. Administration costs of 10 mins per session are assumed, similar to the GaitSmart arm.

All cost inputs in the models are presented in Table 15.

Table 15 Cost parameters used in the company's falls model and changes made by the EAG

Parameter	Company value	Source	EAG value	Comment
GaitSmart Intervention				
Total cost for all GaitSmart sessions per patient	£40	Company submission, included only 4 GaitSmart sessions costs	£82.02	EAG figure includes additional staff costs.
Standard care:				
Physiotherapist, band 5 per hour,	£34	PSSRU 2020 physiotherapist band 5, per hour	£42	PSSRU 2022, physiotherapist band 5, per hour
Initial assessment cost	-	Not included	£31.50	EAG assumption: 45 minutes, 1:1 with band 5 physiotherapist

Parameter	Company value	Source	EAG value	Comment
Cost of subsequent sessions, per patient	£25.50	Company assumption: 45 minutes, 1:1 with band 5 physiotherapist	£8.40	EAG: 60 minutes, group of 10, 2 x band 5 physiotherapist
Number of sessions	30	Company assumption	8	EAG: expert opinion
Administration	-	Not included	£0.33	EAG assume 10 minutes per group session
Total cost for all self-management sessions per patient	£765.00	For 30 x 1:1 sessions with band 5 physiotherapist	£102.71	For 1 x 1:1 assessment plus 8 x group sessions with 2 band 5 physiotherapists.
Costs for events following a fall				
Ambulance call out	£257	PSSRU 2019 (Ambulance service, see and treat and convey, 2017/18 value)	£282	EAG: £258 (source value), inflated to 2021/22
A & E visit	£166	NHS reference costs, 2018/19 (average accident & emergency)	£118	EAG: £118 weighted average assuming 33% are admitted, and the remainder are not. Costs inflated to 2022
GP visit	£36	NHS reference costs 2016	£42	EAG: GP appointment of 9.22 mins, including direct care staff costs and qualifications (PSSRU 2022)
Inpatient stay	£1,609	PSSRU 2018 (average of long and short stay of non-elective inpatient stays)	£1,950	Total HRG for non-elective inpatient costs (long and short stay, weighted average 2019/20 inflated to 2022

Sensitivity analysis

The company carried out probabilistic sensitivity analysis to test parameter uncertainty using a Monte Carlo simulation of 1000 replicates in both models. This was repeated by varying the model inputs sampled randomly from the pre-defined distributions. Both cost-effectiveness scatter plot and cost-effectiveness acceptability curves were presented.

Rehabilitation model

The EAG performed a series of one-way sensitivity analyses for a number of key parameters, all of which were varied using plausible ranges. Since the baseline falls probability of TKA with knee OA patients (0.36) is within the range for baseline falls probability (0.2-0.6) in the one-sensitivity analyses, an additional subgroup analysis using TKA with knee OA was not carried out. The EAG results were presented in a table and a tornado diagram. In addition, the EAG also conducted two additional scenarios: (1) substitute a physiotherapist band 6 for a therapist assistant band 4 in physiotherapy sessions in standard care arm, and (2) increase the group session proportion in physiotherapy from 50% to 75%.

Falls model

The EAG carried out a 2-way sensitivity analysis between the standard care costs and its effectiveness. The EAG also completed a scenario analysis, which took the costs and effectiveness of Otago strength and balance exercise from the PHE ROI tool (2008).

9.3 *Results from the economic modelling*

Base case results

Rehabilitation model: People referred for hip or knee arthroplasty

Results from both the company's submitted rehabilitation model and the EAG base case indicate that GaitSmart is cost-saving (Table 16). Costs associated with falls are not included in the company base case result, as reported in the company submission. The EAG considers that the fall outcomes as a result of the intervention use should be captured and included in the total costs. The

overall cost saving is dominated by the cost difference between interventions, while a marginal number of falls are prevented by GaitSmart. The results should be interpreted with caution as the existing evidence on the change in gait speed is generated from a small RCT, and the standard care program in the model may not reflect the range of common practice. While falls are associated with significant impact to patients and the NHS, the impact of falls in the model is limited by the short duration. The EAG have addressed some issues with standard care as an additional scenario due to the limited evidence available.

Table 16 Summary of base case results: rehabilitation model

	Company's results			EAG results		
	Technology	Comparator	Cost saving per patient	Technology	Comparator	Cost saving per patient
Intervention	[redacted]	[redacted]	[redacted]	£82.02	£161.90	£79.89
Falls	Not included in the submission	Not included in the submission	-	£6.52	£7.02	£0.50
Total	[redacted]	[redacted]	[redacted]	**£88.54**	**£168.92**	**£80.39**
Number of falls per person	**0.343**	**0.347**	**0.004**	**0.356**	**0.384**	**0.027**

Falls model: People at risk of falling

The company base case is for a cohort of 1000, but assumes that only those people who experience a fall with injury receive the intervention, and that those that receive GaitSmart also receive the comparator intervention. The number falling prior to the intervention is not the same for both arms.

The EAG assumed that all those in the cohort received the intervention, and that subsequently a number of falls would be experienced with a range of consequences. Therefore, the company and EAG do not represent the same points in the pathway.

The EAG base case, shows a cost saving of £29 per patient using GaitSmart, although there are a number of limitations to this result (Table 17). It is important to note that 70% of the EAG base case cost difference is due to the relative costs of the interventions. Therefore, by far the most important economic input to the model is the cost of the comparator. This will be very variable across different regions and populations, and a variety of options are considered in two-way sensitivity analysis. For the introduction of GaitSmart to be cost neutral or cost saving, then the cost of the comparator must be very close to the cost of delivering GaitSmart.

Although there is a considerable personal and economic cost associated with falls, GaitSmart results in a relatively small reduction in the number of falls (11%) in the model, and therefore the modelled impact of falls on cost saving is small. The cost calculations for falls are likely to underestimate the full cost of falls, as they do not include longer term consequences such as the need for additional care after discharge from hospital.

Table 17 Summary of base case results: falls model

	Company's results			EAG results		
	Technology	Comparator	Cost saving per patient	Technology	Comparator	Cost saving per patient
Intervention	[redacted]	[redacted]	[redacted]	£82.02	£102.12	£20.10
Falls	[redacted]	[redacted]	[redacted]	£72.65	£81.24	£8.59
Total	[redacted]	[redacted]	[redacted]	£154.66	£183.36	£28.70
Number of falls/1000 patients	[redacted]	[redacted]	[redacted]	390	436	46

The reduction in falls for GaitSmart is based on increased speed observed in a single arm study, and applying a RR to this. Given the variation in comparators that are found across the UK, it is very hard to be sure of GaitSmart's relative efficacy. The company assumed that the comparator made no improvement at all. The EAG retained this assumption in the EAG

base case, but carried out two-way sensitivity analysis, and also considered a scenario analysis based on data from alternative interventions.

Sensitivity analysis results

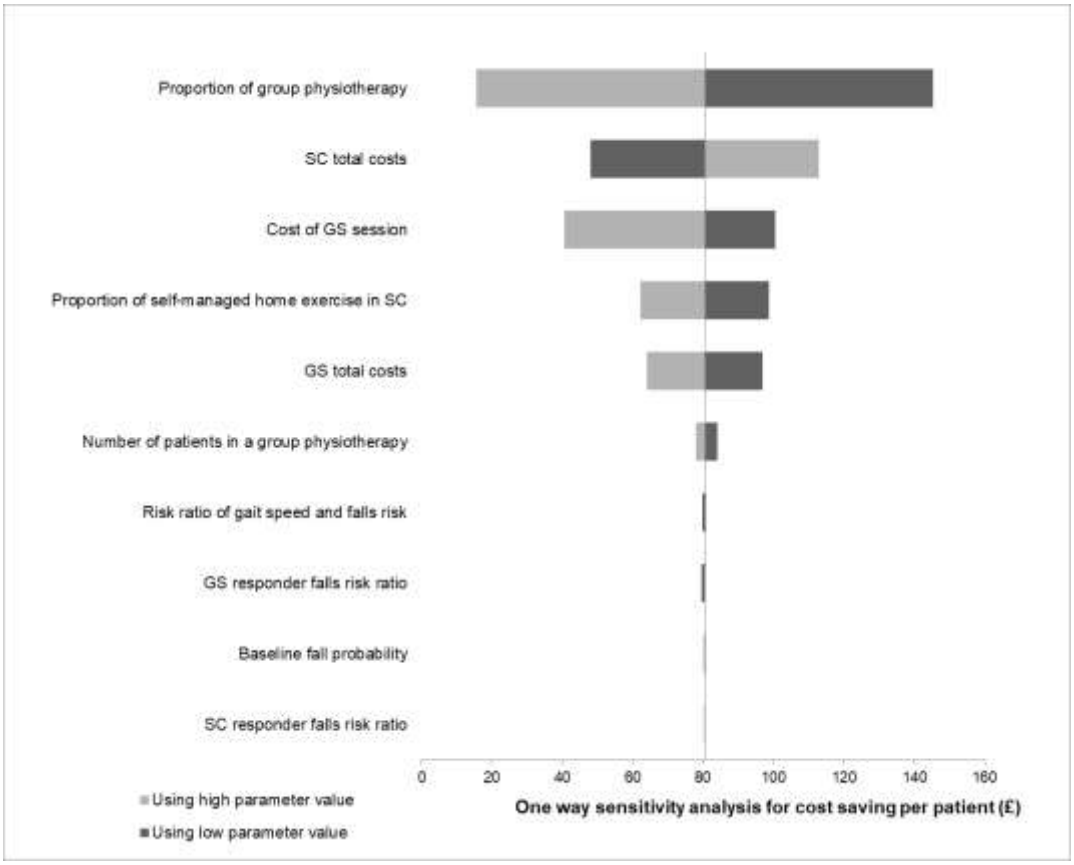
Rehabilitation model: People referred for hip or knee arthroplasty

The company carried out a probabilistic analysis and found GaitSmart was cost saving in all iterations. This remains unchanged in the EAG base case.

The tornado diagram for the EAG base case is shown in **Error! Reference source not found.**, with the full list of parameter values used in Appendix D: Ranges used in one-way sensitivity analysis (Rehabilitation model: People referred for hip or knee arthroplasty).

The cost saving findings are sensitive to variations in intervention costs. By varying the proportion of group physiotherapy by +/- 50% from the base case input, this yields a small cost saving of £15.44 with 75% group sessions. In addition, standard care total costs and GaitSmart session costs are noted to have considerable impact. As demonstrated by the tornado diagram, variations in standard care cost contribute the most uncertainties to the cost saving results. None of the parameter changes resulted in GaitSmart becoming cost incurring.

Figure 5 Tornado diagram for EAG base case rehabilitation model



Falls model: People at risk of falling

The EAG selected a variety of assumed comparator options, all of which included an initial 45-minute assessment by a band 5 physiotherapist, followed by a variety of group or 1:1 interventions. The costs ranged from £57 to £1,292 per patient. The base case retained the company's assumption that the comparator did not change the number of falls experienced. The sensitivity analysis in Table 18 uses RR ranging from 0.5 (50% reduction in falls) to 1 (no reduction in falls) to 1.5 (an increase in falls). Table 18 shows this analysis, with Table 19 showing a choice of comparator costs that are much closer to cost neutrality. It can be seen that cost neutrality is likely to lie between £70 and £110 per patient, where GaitSmart costs £82.02 per patient to deliver. This reflects the dominance of the model calculations by the costs of the interventions.

Table 18 Two-way sensitivity analysis of comparator cost and effectiveness, EAG base case.		**Risk ratio for standard care**			
Comparator cost: Initial assessment plus:		**0.5**	**0.75**	**1**	**1.5**
1 x band 5, 6 x 1 hour, group of 10	**£57**	£57	£37	£17	-£24
2 x band 5, 6 x 1 hour, group of 10	**£82**	£32	£12	-£8	-£49
2 x band 5, 12 x 1 hour, group of 10	**£132**	-£18	-£39	-£59	-£99
2 x band 5, 20 x 1 hour, group of 10	**£200**	-£85	-£106	-£126	-£167
1 x band 5, 6 x 45 min, 1:1	**£221**	-£106	-£127	-£147	-£188
1 x band 5, 20 x 45 min, 1:1	**£662**	-£547	-£568	-£588	-£629
1 x band 5, 30 x 45 min, 1:1	**£977**	-£862	-£883	-£903	-£944
1 x band 5, 30 x 1 hour, 1:1	**£1,292**	-£1,177	-£1,198	-£1,218	-£1,259

Table 19 Additional two-way sensitivity analysis showing the points of cost neutrality

Comparator cost	**Risk ratio for standard care**						
	0.5	**0.65**	**0.75**	**0.8**	**0.9**	**1**	**1.5**
£60	£54	£42	£34	£30	£22	£13	-£27
£70	£44	£32	£24	£20	£12	£3	-£37
£80	£34	£22	£14	£10	£2	-£7	-£47
£90	£24	£12	£4	£0	-£8	-£17	-£57
£100	£14	£2	-£6	-£10	-£18	-£27	-£67
£110	£4	-£8	-£16	-£20	-£28	-£37	-£77
£120	-£6	-£18	-£26	-£30	-£38	-£47	-£87

Additional results

The company did not carry out any additional analyses for subgroups or different scenarios in both models. The EAG has conducted a number of scenario analyses to address the uncertainty associated with standard care.

Rehabilitation model: People referred for hip or knee arthroplasty

The EAG scenario that substitutes a band 6 physiotherapist to a band 4 therapy assistant for physiotherapy session in the standard care, yielded a change in the cost saving from £80.39 to £24.45. Subsequently, combining scenario 1 and 2 (scenario 2: increasing the proportion of group physiotherapy session from 50% to 75%), this resulted a cost incurring of £17.32 (Table 20).

Table 20 Results of EAG scenario analyses

	Base case value	Alternative value	EAG alternative cost scenario
EAG base case	-	-	£80.39
Scenario 1: Substituting a band 6 physiotherapist to a band 4 therapy assistant	£55	£34	£24.45
Combining scenario 1 and 2 Scenario 2: Increasing the group physiotherapy session	50%	75%	-£17.32

Falls model: People who are at risk of falling

The Public Health England 2018 publication: A Return on Investment Tool for the Assessment of Falls Prevention Programmes for Older People Living in the Community describes the effectiveness and costs of 2 different falls intervention programmes. The Otago falls intervention programme had a cost of £441 (2015/16 prices) and an incident rate ratio of 0.65, indicating that for this group of patients the number of falls in the Otago group was 35% less than in the control group, which was no intervention. The annual rate of falls in the control group was 1.06 per year. Data comes from a meta-analysis of 4 studies that include different populations:

- Women aged 80 or over
- Adults aged 65 or over and currently taking psychotropic medications
- Adults aged 75 or over
- Adults aged 80 or over

In all cases, participants were identified as potentially benefiting from the intervention by their doctor and were invited to participate in the trial. The intervention was a set of exercises and walking plan carried out in the participants home, and involving 4-5 home visits from a physiotherapist and follow up phone calls.

The EAG inflated the costs of the intervention (PHE 2018), after removing the cost of evaluation as this is not included in other parts of the model. Table 21 shows that although the model shows GaitSmart to result in 372 more falls per 1000 patients, there is an increased cost saving with GaitSmart due to the relative costs of the interventions. The report by PHE (2018) noted that

although the Otago programme is reported to be in use in 54% of falls services, fidelity to the original intervention is often poor. This may mean that the reported reduction in falls is not experienced in practice. Following advice from experts, the EAG considered it was likely that many people would receive less intensive interventions, and therefore this result has been presented as a scenario analysis.

Table 21 EAG scenario analysis using Otago exercise as comparator

	EAG results for scenario using Otago intervention as comparator		
	Technology	**Comparator**	**Cost saving per patient**
Intervention	£82.02	£474.70	£392.68
Falls	£198.14	£128.79	-£69.35
Total	**£280.15**	**£603.49**	**£323.33**
Number of falls/1000 patients	1063	691	-372

10 EAG interpretation of the economic evidence

Key changes made by the EAG include:

- Change of falls risk calculation
- Adjustment of the assumptions made in standard care costs
- Change of staff time costs to the latest PSSRU
- Rehabilitation model: Change of falls risk to responders and non-responders
- Falls model: Change of the time point of intervention provision from after an injurious fall event to the start of the model, excluding standard care costs from the GaitSmart arm

The most important change was the adjustment of the assumptions in standard care costs. The company estimated the standard care costs based on their assumptions, however the EAG noted that a number of company

assumptions were implausible. Standard care costs became lower in both models after the EAG adjustment.

The EAG consider, in the **rehabilitation model**, the population is clearly identified and appropriate. The company model structure is likely to be suitable for patients referred for knee or hip surgery (pre- and post-operative management). Given the short time horizon, subsequent non-fall related outcomes such as further OA treatments are not captured in the model. As the full consequences of falls are not considered, the costs of falls are very likely to be underestimated. The model may be improved by extending the time horizon. However, no data on longer term falls outcomes associated with GaitSmart are available for inclusion.

In the model, the number of falls is estimated based on the change in gait speed, instead of the actual falls observed. The EAG consider data from McNamara (Unpublished) to be the most appropriate source for gait speed input due to the patient population. To predict the falls using gait speed, the EAG consider the association between gait speed and falls risk reported by Verghese (2009) as appropriate due to the large number of patients and sufficiently long follow up.

Given the short time horizon, the economic results are driven by the cost differences between interventions. This is very dependent on the standard care pathway, which varies considerably across localities. Consistent with the sensitivity analyses, the key drivers of the model are the proportion of group physiotherapy and the total standard care costs. Given the high variability in standard care and the lack of data, the EAG modelled additional scenarios to reflect different variations in the standard care, this leads to a change from cost saving to cost incurring.

The EAG consider, in the **fall model**, the population is clearly identified and appropriate. The company model structure did not consider any outcomes after the provision of the intervention (after a fall with injury). Following the EAG amendments, the model is likely to be suitable for this population and includes falls outcomes for 1 year after the interventions. Similar to the

rehabilitation model, non-fall related outcomes and full falls consequences are not captured due to the short time horizon. Given the high degree of variability with standard care in terms of the staff mix and how they manage the program, the validity of the cost estimate may fall short in representing actual practice.

The same approach as the rehabilitation model is used to estimate falls based on the change in gait speed. Data from from a single arm study, Rodgers (2020) is used as the source for gait speed due to the limited available evidence. In addition, the clinical evidence on standard care is lacking. The company model assumes the standard care has no additional efficacy, which the EAG believes is not the case. The EAG has carried out a number of sensitivity analyses and scenario analysis to explore the impact of relative efficacy and comparator costs. Given the uncertainties in this model and the dominance of overall economic findings by the intervention costs, GaitSmart can vary from cost saving to cost neutrality, depending on the comparator costs.

11 Integration into the NHS

GaitSmart is a compact and mobile system which is easy to transport and needs little in the way of space which may make it particularly suitable for community settings where healthcare professionals are moving around from location to location. It should be noted however that use of the system does require a 10 metre stretch for walking and a wifi connection sufficiently strong to allow data to be uploaded and a report viewed on a web browser or app or to be downloaded and printed for people who prefer a physical copy. The technology includes an exercise app, the vGym app, which is integrated into the system and incurs no additional costs. Information from the gait assessment is used to generate a personalised report highlighting gait problems and prescribing specific exercises to target those problems. Although the technology requires training to use, one potential benefit of the system is that once training has been completed, GaitSmart assessment can be done by a trained healthcare assistant meaning there is some potential to save on staff costs in certain situations. Clinical experts reported that the

system is easy to use and were particularly supportive of the integrated exercise element. The experts reported that patients liked having the objective data provided in their GaitSmart report as it gave them targets for change. The clinical evidence is limited and does not directly address the question of whether GaitSmart improves outcomes, rather it focuses on the accuracy of GaitSmart in measuring gait parameters. It should be noted that much of the evidence available for GaitSmart has been generated in a UK setting, primarily in NHS settings which means that it can be considered broadly generalisable to the NHS. Broadly, GaitSmart if used purely as a gait assessment tool would be an addition to the clinical pathway as formal gait assessment is not currently part of standard care. Where GaitSmart is used as a tool to guide exercise delivery and feedback it may replace other forms of standard care, for example in post surgery rehabilitation or falls clinics. Integration of GaitSmart technology would therefore have initial cost implications to set up and train healthcare providers to use the system. Whether use of GaitSmart leads to cost savings in any single situation will depend on a number of factors, but primarily on the comparator that is appropriate for that site.

For people referred for hip or knee surgery, although still needing a more standardised approach, the clinical pathway appears reasonably clearly defined and it is easier to see where GaitSmart may lead to improved outcomes for patients. One clinical expert reported that GaitSmart may be beneficial if introduced at the point a patient presents with hip or knee problems as a means to delaying or preventing surgery. Once referred for surgery the clinical expert reported that patients wait up to 6 months before seeing a consultant and that GaitSmart could be introduced at this point with the aim of preventing condition deteriorating while on a waiting list. In the post-operative setting, the introduction of GaitSmart may support patients through rehabilitation through provision of a report which can help them to see objective improvement in their gait. The use of GaitSmart in this population may lead to cost savings.

For people at risk of falls, a key issue identified by both the clinical experts and the EAG is that there is a large amount of variability in the current standard of care. Currently standard of care interventions range from dedicated community-based falls clinics where participants join group sessions to a single assessment where advice is provided with no follow-up. The GaitSmart approach is based on a baseline assessment and prescribed exercise programme followed by 3 follow-up assessments every 3-4 weeks although the company does state that there can be flexibility in the frequency and number of assessments. This means that, depending on current practice in a given location, GaitSmart may lead to cost savings.

The EAG considers that introduction of GaitSmart programme of assessment and exercise into the NHS may result in better outcomes for patients. GaitSmart purely as an assessment tool will result in additional costs incurred however the additional integrated exercise element of the programme and the fact that a range of healthcare providers can be trained to deliver the programme gives GaitSmart the potential to be cost saving in some scenarios.

Patient choice is an important factor, GaitSmart means 1-2-1 assessments and doing the exercises at home and some people may prefer a group setting such as a falls clinic. Clinical experts noted that patients find the report and the information in it to be useful and motivating. This is supported by limited evidence from 3 participants in a clinical trial. In circumstances where falls clinics are not available or where people get limited advice and support, GaitSmart may offer a good alternative.

Overall, the EAG consider that GaitSmart could provide an additional option for both population groups with a number of places in the clinical pathway where it could be of benefit.

12 Conclusions

12.1 *Conclusions from the clinical evidence*

The EAG considers that based on the evidence available, GaitSmart technology is correlated with optical tracking systems and so is an appropriate system for gait analysis. No comparison has been made with a visual assessment but the EAG considers that gait analysis with GaitSmart is likely to more specifically identify gait deficiencies than a visual assessment as it provides more objective gait data. There is no evidence however around whether this results in more accurately targeted exercises as a result (i.e. exercises specifically targeting hips if gait problems are identified in the hip) and subsequently whether more specifically targeted exercises improve outcomes for patients.

The company identified two populations where it considered GaitSmart could have most benefit: people at risk of falls and people referred for hip or knee surgery. For people at risk of falls, one study (Rodgers 2020) GaitSmart score improved in 76% of participants and gait speed increased in 80.5% of participants over the course of the study period. Both of these measures were moderately correlated with measures of frailty and fear of falling suggesting that as gait parameters improved, risk of falling and fear of falling decreased. This is supported by results from two unpublished studies reporting improvements in gait parameters and PROMs outcomes over the course of the study period. For people referred for hip or knee surgery, the results from one study (McNamara unpublished)

[redacted]

One of the key limitations of the clinical evidence is that while studies show improvements in gait parameters and in PROMs measures, there is limited evidence on how well correlated these outcomes are. Clinical experts did note that improving gait is the key purpose of surgery and exercise as improving gait ultimately improves outcomes for patients. A second key limitation is a lack of evidence comparing with current standard of care in the NHS. The

EAG therefore considers that the evidence for GaitSmart in these populations is limited but indicative of a possible benefit.

12.2 *Conclusions from the economic evidence*

The submitted rehabilitation model reflects the decision problem defined in the final scope, but the submitted falls model is flawed. Following the EAG amendments, the falls model fits the final scope. Standard care is not well-defined in both models due to the high variability in the actual practice in terms of the staffing and the programs offered in the clinic. Although the EAG has modelled standard care in both models, it is difficult to tell how representative the modelled standard care to the actual programs. The cost saving is largely dependent on the relative costs between interventions, and it is sensitive to the variations of standard care.

One of the key limitations is that the models rely on gait speed change as a surrogate endpoint to inform clinical outcomes (falls), and the gait speed evidence is derived from studies which are not of high quality. In people referred for hip or knee arthroplasty, the change in gait speed results in a [redacted] reduction in falls with GaitSmart [redacted], which is an additional 6[redacted] falls prevented compared with standard care [redacted]. Another key limitation is the lack of comparative evidence for standard care in people at risk of falling. A meaningful comparison is limited where only a single-arm clinical study is identified (Rodgers 2020). It is therefore unclear if GaitSmart is more effective in preventing falls than standard care. This is consistent with the findings on falls clinics reported by Lamb (2008) where the assessment of falls clinics' clinical effectiveness is limited by the variability in the organisation and the lack of outcome data.

Despite high healthcare costs of falls and fracture, major fall-related injuries such as fractures and head injuries are not considered in both models. The longer-term cost impact such as home care or rehabilitation is not included within the models' short time horizon.

The modelling supports the company claims that the delivery of GaitSmart by trained healthcare assistants, would reduce staff time costs. In both models

the EAG base cases are cost saving, however there is more uncertainty in the falls model. The EAG considers GaitSmart may offer patients additional choices of treatment.

13 Summary of the combined clinical and economic sections

Clinical evidence suggests that GaitSmart provides objective gait data which could help to provide patients with a more personalised and targeted rehabilitation programme. Comparison of outcomes with standard of care are lacking however the EAG acknowledges that there is a high degree of variability in standard care practices which make this difficult.

Economic modellings indicate that GaitSmart is potentially cost saving based on the reduced resources associated with a shorter staff time and the delivery of GaitSmart by a trained healthcare assistant (band 2). In both models, the EAG base case is cost saving, and the rehabilitation model is reasonably robust to sensitivity analyses. The falls mode is much more uncertain, and both models are largely driven by the type of standard care Given the uncertainties surrounding standard care, GaitSmart can vary from cost saving to cost incurring, depending on the comparator. The evidence base for falls prevention is limited, and the full consequences of GaitSmart have not been captured in the model.

14 Implications for research

Based on the current evidence base, GaitSmart shows promise in both populations in this assessment and acceptability from clinical experts and patients seems good. The EAG identified a number of gaps in the current evidence base, some of which are beyond the control of the company to address. For example, there is a high degree of variability within standard care practices particularly when considering people at risk of falls. The lack of clear pathways for standard of care means it is very difficult to identify an appropriate comparator for GaitSmart. The EAG acknowledges that these

uncertainties with standard care make it difficult to design a high-quality study that addresses the current evidence gaps.

Generating good quality evidence for GaitSmart therefore depends on defining an appropriate standard of care comparator. The EAG has outlined some possible considerations for future evidence generation in the two identified populations

People at risk of falls

The EAG suggest that if Gait Smart is introduced in this population then the standard care comparator should be clearly described so as to enable understanding of how data may generalise to other settings where there may be variations in standard of care. It should be reported whether GaitSmart is in addition to existing standard of care or a replacement. A plan to collect evidence and report findings within a defined follow-up period should be in place to ensure that data on relevant comparisons, outcomes and costs are captured. Where feasible, long term follow to collect data on falls should be considered.

Possible areas for evidence generation identified by the EAG include

- GaitSmart approach compared with a Community Falls Clinic approach considering factors such as number of assessments, staff time, home versus community and group versus 1-2-1 settings, patient preference
- GaitSmart in a care home setting

People referred for hip or knee surgery

If introduced in this population, the EAG suggest that evidence generation could focus on identifying whether there is a particular point in the pathway where GaitSmart would provide most benefit.

Possible areas for evidence generation identified by the EAG include assessment of GaitSmart compared with standard care in the preoperative and postoperative setting considering separately the following subgroups:

- people who are prescribed GaitSmart with the aim of avoiding or delaying surgery
- people who have been referred for surgery and are prescribed GaitSmart with the aim of preventing decline while on waiting list
- people who have had surgery and are prescribed GaitSmart for rehabilitation

In addition, the EAG note that there is evidence to suggest that GaitSmart may have diagnostic / prognostic potential and this is an area that could be explored further through research. The current evidence is generated in either healthy people, people who already have balance problems or have suffered a fall or people who have had surgery. Clinical experts noted that balance begins to deteriorate around age 50 years with risks of fall increasing over aged 65 years. Clinical experts also noted that community falls clinics are attended by a range of people including people who have had a fall, post-menopausal women who are worried about osteoporosis and people with osteoarthritis. The ability of GaitSmart to identify gait problems early in people at risk or concerned about their risk of falling or to identify specific gait problems in people with a diagnosis of osteoarthritis but who are still in a position to manage their condition non-surgically and to prescribe exercise to help correct these is potentially worth exploring.

Given the difficulty with identification of suitable comparators, the EAG considers a real-world evidence generation approach as outlined in the NICE Real-World Evidence Framework would be appropriate for this technology.

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16 Appendices

Use the appendices to describe additional data and information as needed – we've given some examples as a guide.

List the titles of the appendices here.

Appendix A: Clinical and economic evidence identification

Company search strategy, screening criteria and process for clinical evidence

A literature search, which encompassed the key components of the decision problem was performed in one database (PubMed). Four searches, using a combination of key terms were conducted as follows:

1. People referred for knee or hip surgery (pre-operative and post-operative management):

   Key Words: Gait speed Biomechanics Joint replacement

2. Rehabilitation for people referred for knee or hip surgery(pre-operative and post-operative management):

   Key Words: Gait Speed Rehabilitation Biomechanics Replacement

3. People aged 65 or older that are at risk of falling:

   Key Words: Gait Biomechanics Falls Risk Older

4. Rehabilitation for people aged 65 or older that are at risk of falling:

   Key Words: Gait Speed Rehabilitation Biomechanics Falls

Company study selection for clinical evidence

The company did not detail a selection process for the clinical evidence.

Company search strategy, screening criteria and process for economic evidence

The company did not detail a process for searching for or screening the economic evidence.

Company search strategy for adverse events

The company did not detail any search strategy for adverse events.

EAG search strategy and study selection for clinical and economic evidence

The EAG conducted a single search for both clinical and economic evidence as directed by the scope. Ten bibliographic databases were searched to include the period from 1st January 2014 to 24th April 2023, using a range of free text terms and, where appropriate, indexed terms. The searches were not restricted by language of publication. Two clinical trial registries were also searched for ongoing and unpublished trials; the company's website was also searched for additional literature. The MHRA's medical device alerts and field safety notices and the FDA MAUDE database were searched for adverse events.

Date	Database Name	Total Number of records retrieved	Total number of records from database after de-duplication
19/04/23	Medline ALL (includes Medline In Process & Medline Epub Ahead of Print)	187	
19/04/23	EMBASE	339	
24/04/23	Cochrane Library CDSR CENTRAL	 0 24	
24/04/23	CRD (DARE, NHS EED)	0	
24/04/23	INAHTA	0	
18/04/23	PubMed	3	
24/04/23	Web of Science	225	
24/04/23	Scopus	216	
18/04/23	Company website	16	
18/04/23	MHRA	0	
18/04/23	FDA MAUDE	0	
19/04/23	Clinical Trials.gov	2	
19/04/23	ICTRP	1	596 records after manual deduplication

EAG Search Strategies

Ovid MEDLINE(R) ALL <1946 to April 18, 2023>

1	gaitsmart.tw.	2
2	vgym.tw.	0
3	"virtual gym".tw.	3
4	dynamic metrics.in.	2
5	gaitWALK.tw.	1
6	(digital adj3 gait).tw.	53
7	Gait Analysis/mt [Methods]	410
8	("inertial measurement unit*" and gait).tw.	703
9	or/1-8	1148
10	Accidental Falls/	27928
11	exp Aged/ and fall*.tw.	45857
12	(fall* adj3 (prevent* or risk)).tw.	19924
13	(fall* adj3 (old* or elderly or geriatric* or aged)).tw.	8018
14	Osteoarthritis, Knee/	26690
15	Osteoarthritis, Hip/	9696
16	((knee or hip) adj3 osteoarthritis).tw.	26516
17	Arthroplasty, Replacement, Knee/	31078
18	Arthroplasty, Replacement, Hip/	33915
19	((knee or hip) adj3 (replace* or arthroplasty)).tw.	75932

20	((knee or hip) adj3 surgery).tw.	15774
21	or/10-20	188270
22	9 and 21	188
23	exp animals/ not humans.sh.	5115078
24	22 not 23	187
25	limit 24 to yr="2008-Current"	187

Embase <1974 to 2023 April 18>

1	gaitsmart.tw.	7
2	vgym.tw.	0
3	"virtual gym".tw.	4
4	dynamic metrics.in.	4
5	gaitWALK.tw.	2
6	(digital adj3 gait).tw.	103
7	gait analysis system/	911
8	("inertial measurement unit*" and gait).tw.	877
9	or/1-8	1875
10	falling/	48976
11	exp Aged/ and fall*.tw.	55324
12	(fall* adj3 (prevent* or risk)).tw.	29043
13	(fall* adj3 (old* or elderly or geriatric* or aged)).tw.	10907

14	knee osteoarthritis/	43694
15	hip osteoarthritis/	14094
16	((knee or hip) adj3 osteoarthritis).tw.	39622
17	exp knee replacement/	24553
18	exp hip replacement/	16545
19	((knee or hip) adj3 (replace* or arthroplasty)).tw.	93524
20	((knee or hip) adj3 surgery).tw.	21690
21	or/10-20	252892
22	9 and 21	339
23	limit 22 to yr="2008-Current"	339

Cochrane Library

#1	(gaitsmart):ti,ab,kw	2
#2	(vgym):ti,ab,kw	0
#3	("virtual gym"):ti,ab,kw	0
#4	("dynamic metrics")	0
#5	(gaitwalk):ti,ab,kw	1
#6	(digital NEAR/3 gait):ti,ab,kw	8
#7	MeSH descriptor: [Gait Analysis] this term only	62
#8	("inertial measurement unit*" AND gait):ti,ab,kw	12
#9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	83

#10 MeSH descriptor: [Accidental Falls] this term only 1921

#11 MeSH descriptor: [Aged] explode all trees 254822

#12 (fall*):ti,ab,kw 27263

#13 #11 AND #12 5473

#14 (fall* NEAR/3 (prevent* or risk)):ti,ab,kw 5436

#15 (fall* NEAR/3 (old* or elderly or geriatric* or aged)):ti,ab,kw 1972

#16 MeSH descriptor: [Osteoarthritis, Knee] this term only 5940

#17 MeSH descriptor: [Osteoarthritis, Hip] this term only 1216

#18 ((knee OR hip) NEAR/3 osteoarthritis):ti,ab,kw 15288

#19 MeSH descriptor: [Arthroplasty, Replacement, Knee] this term only 3372

#20 MeSH descriptor: [Arthroplasty, Replacement, Hip] this term only 2369

#21 ((knee OR hip) NEAR/3 (replace* OR arthroplasty)):ti,ab,kw 15444

#22 ((knee OR hip) NEAR/3 surgery):ti,ab,kw 9154

#23 #10 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 39475

#24 #9 AND #23 with Publication Year from 2008 to present, in Trials 24

#25 #9 AND #23 in Cochrane Reviews 0

CRD

1 (gaitsmart) 0

2 (vgym) 0

3 ("virtual gym") 0

4 ("dynamic metrics") 0

5 (gaitWALK) 0

6 (digital adj3 gait) 0

7 MeSH DESCRIPTOR Gait Analysis 0

8 ("inertial measurement unit*" and gait) 0

9 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8) IN DARE, NHSEED, HTA 0

NB No technology terms retrieved any references, so did not search for population terms.

INAHTA

24 #23 AND #9 0

23 #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #10 455

22 (knee OR hip) AND surgery 140

21 (knee OR hip) AND (replace* or arthroplasty) 194

20 "Arthroplasty, Replacement, Hip"[mh] 101

19 "Arthroplasty, Replacement, Knee"[mh] 64

18 (knee OR hip) AND osteoarthritis 97

17 "Osteoarthritis, Hip"[mh] 30

16 "Osteoarthritis, Knee"[mh] 71

15 fall* AND (old* or elderly or geriatric* or aged) 61

14 fall* AND (prevent* or risk) 101

13 #12 AND #11 32

12 fall* 205

11 "Aged"[mhe] 375

10 "Accidental Falls"[mh] 38

9 #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1 1

8 "inertial measurement units" AND gait 0

7 "Gait Analysis"[mh] 1

6 digital AND gait 0

5 gaitWALK 0

4 "dynamic metrics" 0

3 "virtual gym" 0

2 vgym 0

1 gaitsmart 0

Web of Science

1: TS=(gaitsmart)		3
2: TS=(vgym)		0
3: TS=("virtual gym")		7
4: OO=("dynamic metrics")		0
5: TS=("gaitWALK")		1
6: TS=("digital NEAR/3 gait")		0
7: TS=("inertial measurement unit*" AND gait)		1649
8: #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1		1660
9: TS=("accidental falls")		2643
10: TS=(fall* NEAR/3 (prevent* OR risk))		26539
11: TS=(fall* NEAR/3 (old* OR elderly OR geriatric* OR aged))		15533
12: TS=((knee OR hip) NEAR/3 osteoarthritis)		41791
13: TS=((knee OR hip) NEAR/3 (replace* OR arthroplasty))		88854
14: TS=((knee OR hip) NEAR/3 surgery)		18635
15: #14 OR #13 OR #12 OR #11 OR #10 OR #9		167459
16: #15 AND #8	Timespan: 2008-01-01 to 2023-12-31	225

Scopus

((TITLE-ABS-KEY ((knee OR hip) W/3 surgery)) OR (TITLE-ABS-KEY ((knee OR hip) W/3 (replace* OR arthroplasty))) OR (TITLE-ABS-KEY ((knee OR hip) W/3 osteoarthritis)) OR (TITLE-ABS-KEY (fall* W/3 (old* OR elderly OR geriatric* OR aged))) OR (TITLE-ABS-KEY (fall* W/3 (prevent* OR risk))) OR (TITLE-ABS-KEY ("accidental falls"))) AND ((TITLE-ABS-KEY (gaitsmart)) OR (TITLE-ABS-KEY (vgym)) OR (AFFILORG ({dynamic metrics})) OR (TITLE-ABS-KEY ({virtual gym})) OR (TITLE-ABS-KEY (gaitwalk)) OR (TITLE-ABS-KEY (digital W/3 gait)) OR (TITLE-ABS-KEY ("inertial measurement unit*" AND gait)))

Pubmed

Gaitsmart	3
“Dynamic metrics” and gait	0

MHRA

Gaitsmart	0
“Dynamic metrics”	0

FDA MAUDE

Gaitsmart	0
“Dynamic metrics”	3 – 0 relevant to GaitSmart

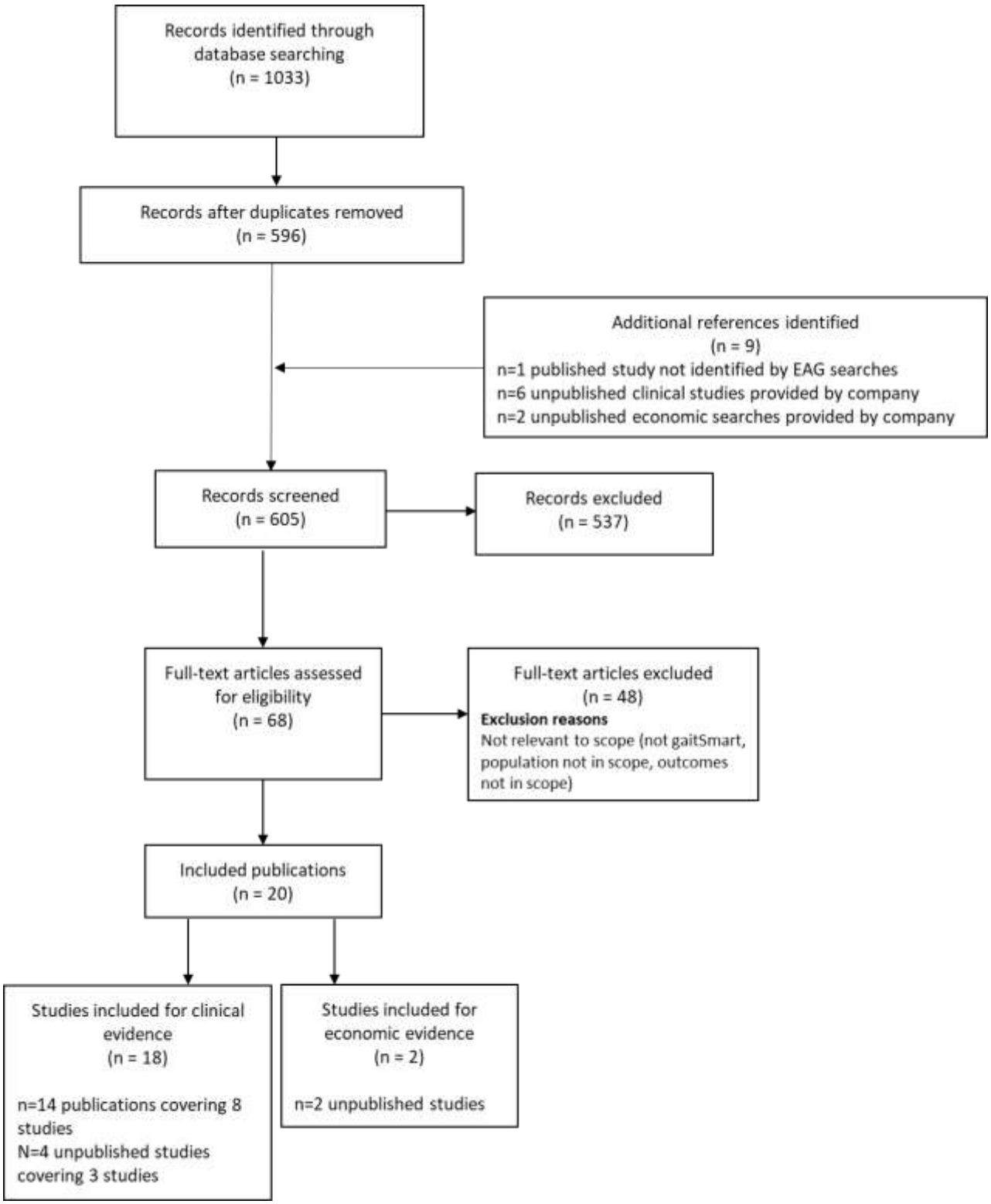
ClinicalTrials.gov

GiatSmart	1 study
“Dynamic metrics”	0 additional
IMI-APPROACH	0 studies
NCT03883568	1 study

ICTRP

Gaitsmart	1 study
“Dynamic metrics”	0

EAG Study Flow Chart



Appendix B: Critical Appraisal Approach

EAG assessment of study design and rationale for choice of appraisal checklist

Study	Checklist used and rationale
Care City Pilot (Unpublished)	**Design as stated in study:** [redacted]**EAG assignment**: Before and After Study **Critical Appraisal Checklist used**: JBI case series **Rationale:** Gait is assessed and a programme of exercise is prescribed with follow-up assessments over a defined time period in a single patient group. Pre and post data are compared. Would not designate as quasi-experimental as there is no control group.
Hanley (2016)	**Design as stated in study:** Case series **Critical Appraisal Checklist used**: None **Rationale:** Abstract only, information provided is not enough to facilitate a formal critical appraisal.
Hodgins (2015)	**Design as stated in study:** Not defined **EAG assignment**: Case series study **Critical Appraisal Checklist used**: JBI Checklist for Case series study **Rationale**: A comparator group comprising people with no walking / balance problems was included. While the comparator group appeared to have measurements taken only at a single time point, the results of the study are comparing outcomes between the intervention and comparator reference group.
IMI-APPROACH Study Jansen 2023 (poster) Van Helvoort 2022 (full publication)	**Design as stated in study:** Prospective Cohort Study **EAG assignment:** Diagnostic Study

Study	Checklist used and rationale
Van Helvoort 2021a (full publication) Van Helvoort 2021b (abstract) Hodgins 2019 (abstract)	**Critical Appraisal Checklist used**: JBI checklist for Diagnostic Accuracy Studies **Rationale:** The wider IMI-APPROACH study is described as a cohort study with participants drawn from a range of existing cohorts to create a single cohort of people with osteoarthritis. The data from this cohort is then used to conduct 'sub-studies'. In terms of the GaitSmart studies relevant to this assessment, both studies are aiming to assess whether domains measured by GaitSmart parameters are predictive of osteoarthritis and whether these are as informative as established assessments such as radiographic assessments and PROMs. Regression models are used to investigate the relationship between parameters and outcomes reported include diagnostic outcomes (sensitivity / specificity / AUC)
McCarthy (2013)	**Design as stated in study:** Case Control Study **EAG assignment:** Diagnostic Accuracy Study **Critical Appraisal Checklist used**: JBI Checklist for diagnostic accuracy studies **Rationale:** Study includes two groups (patients with knee OA and healthy controls for comparison). Some outcomes are diagnostic therefore chose to use the diagnostic studies checklist
Monda (2015)	**Design as stated in study:** Not defined **EAG assignment:** Case series study **Critical Appraisal Checklist used**: JBI Checklist for case series studies **Rationale:** No comparator group, results / outcomes are reported by age group and not over time.
NHS Glasgow Falls Clinic Final Report (unpublished)	**Design as stated in study:** Not defined **EAG Assignment:** Before and After Study

Study	Checklist used and rationale
	Critical Appraisal Checklist used: JBI checklist for case series studies **Rationale:** Gait is assessed and a programme of exercise is prescribed with follow-up assessments over a defined time period. Pre and post data are compared. Would not designate as quasi-experimental as there is no control group.
Norfolk and Norwich University Hospital McNamara (Unpublished) Ward (Unpublished)	**Design as stated in study:** [redacted]**EAG Assignment:** Randomised controlled trial (with Ward designated a case report study) **Critical Appraisal Checklist used**: JBI checklist for RCT's / Cochrane Risk of Bias Tool and JBI checklist for case reports **Rationale:** The study has two groups, randomly assigned using appropriate methods.
Rahman (2015)	**Design as stated in study:** Cross sectional study with an additional 29 age matched controls included. **EAG Assignment:** Cross Sectional Study **Critical Appraisal Checklist used**: JBI Checklist for Cross Sectional studies **Rationale:** Study includes two groups (patients with knee OA and healthy controls for comparison). Measures are taken at different time points but results are reported as comparisons between patient groups and healthy controls. Measures are taken pre and post intervention, the EAG noted however that the patients are not the same patients in the pre / post intervention measurement groups (i.e. the measures are not true before and after measures)
Rodgers (2020)	**Design as stated in study:** Quality Improvement Project **EAG Assignment:** Before and After Study

Study	Checklist used and rationale
	Critical Appraisal Checklist used: JBI checklist for case series studies **Rationale**: Gait is assessed and a programme of exercise is prescribed with follow-up assessments over a defined time period. Pre and post data are compared.
Zügner 2019 Mohaddes 2016 (abstract) Blixt 2016 (thesis)	**Design as stated in study:** Not defined **EAG Assignment:** Diagnostic Accuracy Study **Critical Appraisal Checklist used**: JBI checklist for diagnostic accuracy studies **Rationale:** This study is primarily a validation study which reports on the correlation between measures recorded by the intervention (GaitSmart) and by a 'gold standard' optical tracking system.

Appendix C: Detailed Study Results

Validation and Diagnostic Results

Study	Gait Parameters	
[redacted]	[redacted]	[redacted]

Study	Gait Parameters	
[redacted]	[redacted]	

Study	Gait Parameters	
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Study	Gait Parameters	
[redacted]	[redacted]	[redacted]

Study	Gait Parameters	
[redacted]	[redacted]	
[redacted]	[redacted]	

Study	Gait Parameters	
[redacted]	[redacted]	

Study	Gait Parameters	
[redacted]	[redacted]	

Study	Gait Parameters	
[redacted]	[redacted]	
[redacted]	[redacted]	

Study	Gait Parameters	
	[redacted]	

Abbreviations: KO, knee osteoarthritis; PROMs, patient reported outcome measures; TKA, total knee arthroplasty; EFS, Edmonton Frail Scale; FES-I, Falls Efficacy Scale International; KO, knee osteoarthritis; OKS, Oxford knee score; PROMs, patient reported outcome measures; TKA, total knee arthroplasty

Patient Feedback results (Ward unpublished)

Study	Patient Reported Outcome Measures
Norfolk and Norwich University Hospital Results from Ward (Unpublished)	[redacted]

Appendix D: Ranges used in one-way sensitivity analysis (Rehabilitation model: People referred for hip or knee arthroplasty)

Variable	Input values			Results		
	Low	Model	High	Low	Model	High
GS arm: response rate, equal to 1 for high, equal to MID-defined improvement for low	0.733	0.933	1.000	£80.14	£80.39	£80.47
SC arm: response rate, equal to 1 for high, equal to MID-defined improvement for low	0.294	0.824	1.000	£80.46	£80.39	£80.36
GS arm: falls risk ratio, falls RR, equal to RR derived from MID-defined improvement for high, equal to 1 for low	1.000	0.879	0.856	£79.56	£80.39	£80.54
SC arm: falls risk ratio, equal to risk derived from MID-defined improvement for high, equal to 1 for low	1.000	0.959	0.906	£80.75	£80.39	£80.21
Fall probability, +/- 50%	0.200	0.400	0.600	£80.14	£80.39	£80.64
Risk ratio of gait speed and falls risk, 95%CI	1.001	1.069	1.142	£79.89	£80.39	£80.79
SC arm: home exercise proportion, +/- 50%	0.100	0.200	0.300	£98.66	£80.39	£62.12
Cost of GaitSmart session, -20% for low, equal to cost per session based on 50% of the minumum uses per month for high	5	10	20	£100.39	£80.39	£40.39
SC arm: group session proportion, +/- 50%	0.25	0.50	0.75	£145.33	£80.39	£15.44
Number of patients in a group session, -/+20%	8	10	12	£83.99	£80.39	£77.98
Total costs of GaitSmart, -/+ 20%	65.61	82.02	98.42	£96.79	£80.39	£63.98
Total costs of standard care, -/+ 20%	129.52	161.90	194.28	£48.01	£80.39	£112.77

Appendix E: Falls model: people with moderate to high fear of falling

Clinical parameters and variables

Variable	Company value	Source	EAG value	EAG comment
Probability of fear of falling with GaitSmart: *Low* *Moderate* *High*	 69.43% 25.13% 5.44%	Company calculation using transition of fear of falling levels after intervention and baseline probability of fear of falling for >80 years	 69.16% 25.36% 5.48%	EAG recalculated using the EAG probability of fear of falling for >80 years.
Transition of fear of falling after intervention: *Low to Moderate* *High to Low* *High to Moderate* *Low to High* *Moderate to Low* *Moderate to High*	 [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]	NELFT study results	No change	The EAG was unable to verify the accuracy of company values due to insufficient information in Rodgers 2020 and no additional information has been provided by the company upon EAG's request.
Probability of low fear of falling: *65-70y* *70-74y* *75-79y* *80y+*	 83% 74% 73% 63%	Calculated mean (non-weighted) of age-specific estimates from Arfken 1994	 82.42% 73.55% 72.02% 66.75%	Recalculated weighted mean using the sex ratio of each age group. Arfken (1994) reports a 79% low fear of falling in men 80y+. This value replaced the company in EAG calculation. The EAG accept the slight difference in the age groups between Arfken 1994 and the company model.
Probability of moderate fear of falling: *65-70y* *70-74y* *75-79y* *80y+*	 13% 21% 20% 25%	Calculated mean (non-weighted) of age-specific estimates from Arfken 1994	 12.56% 20.72% 20.60% 25.19%	As above
Probability of high fear of falling: *65-70y*	 5%	Calculated	 4.53%	As above

Variable	Company value	Source	EAG value	EAG comment
70-74y *75-79y* *80y+*	6% 7% 8%	mean (non-weighted) of age-specific estimates from Arfken 1994	5.72% 7.38% 8.06%	
Probability of at least 1 fall in different fear of falling levels: *Low* *Moderate* *High*	 26% 36% 48%	Arfken 1994	No change	Arfken (1994) reports 26%, 36% and 48% of participants with low, moderate and high fear of falling level, respectively who had at least 1 fall in the past 12 months.
Probability of recurrent fall in different fear of falling levels: *Low* *Moderate* *High*	 8% 13% 22%	Arfken 1994	No change	Arfken (1994) reports 8%, 13% and 22% of participants with low, moderate and high FoF level, respectively who had recurrent falls in the past 12 months.

Base case results

	Company's results			EAG results		
	Technology	Comparator	Cost saving per patient	Technology	Comparator	Cost saving per patient
Intervention	[redacted]	[redacted]	[redacted]	£82.02	£102.12	£20.10
Falls	[redacted]	[redacted]	[redacted]	£7.06	£10.38	£3.32
Total	[redacted]	[redacted]	[redacted]	£89.08	£112.51	£23.43
Number of falls	[redacted]	[redacted]	[redacted]	38	56	18

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health technology evaluation

Assessment report overview

GaitSmart rehabilitation exercise programme for gait and mobility issues

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the external assessment group (EAG) report. It includes **brief** descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the committee may wish to discuss. It should be read along with the company submission of evidence and with the external assessment report. The overview forms part of the information received by the medical technologies advisory committee when it develops its recommendations on the technology.

Key issues for consideration by the committee are described in section 6, following the brief summaries of the clinical and cost evidence.

This report contains information that has been supplied in confidence and will be redacted before publication. This information is underlined and highlighted in either [redacted] (for academic in confidence information) or in [redacted] (for commercial in confidence information). Any depersonalised data in the submission document is underlined and highlighted in [redacted].

This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional organisations
- Appendix C: Comments from patient and carer organisations

1 The technology

The GaitSmart programme (Dynamic Metrics) comprises digital gait assessment and personalised rehabilitation exercises. GaitSmart is a CE marked class Im medical device that uses sensor-based digital technology to monitor limb movement. The technology requires 7 sensors to be placed on the pelvis, thigh and calf on either side of the body, as well as the base of the spine. Objective measurements are taken while walking to identify any problems with gait. Information from the sensors is automatically processed to produce a colour coded report that helps the person and healthcare professional to understand the gait issue and its severity. The test takes 10 minutes to complete and can be done by a healthcare assistant in a variety of settings.

The GaitSmart gait assessment is used with an integrated app vGym which provides a personalised rehabilitation programme, consisting of 6 exercises, to help improve mobility. The app provides photos and descriptions of each exercise. The reports and advice provided by the technology can also be printed off and used without needing access to a personal device. Once allocated to the programme, each person should have a total of 4 GaitSmart gait assessments under the supervision of a healthcare assistant, with each assessment taking place every 4-6 weeks. The gait assessment identifies any changes in gait and mobility and then alters exercises accordingly.

2 Proposed use of the technology

2.1 Disease or condition

GaitSmart is intended for people who are ambulatory or partially ambulatory with gait and mobility issues. This assessment focuses on the use of GaitSmart in two specific subgroups:

- People at risk of falling
- People referred for knee or hip replacements

2.2 Patient group

People at risk of falling

People aged 65 and over have the highest risk of falling. 30% of people older than 65, and 50% of people older than 80, fall at least once a week (NICE CG161 Falls in older people: assessing risk and prevention). Falling can be distressing and cause pain, injury, and loss of mobility. People can lose confidence and, in some cases, lose their independence because of a fall.

People referred for surgery (pre-operative and post-operative management)

Knee or hip replacement refers to a surgical procedure where a person has their knee joint, or hip joint, replaced (wholly or partially) with an artificial one (known as an implant). The NHS website states that a knee or hip replacement is needed when the joint is worn or damaged so that a person's mobility is reduced and they are in pain even when resting. Between 1 January 2018 to 30 December 2020, The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, notes that osteoarthritis was given as a documented indication for surgery in 97.4% of knee replacement cases and 93.1% of hip replacement surgery cases. It states there were 226,350 primary total knee replacements and 250,278 primary hip procedures. The majority of procedures were carried out in women for both knee (women 56.3%; men 43.7%) and hip (women 59.9%: men 40.1%) procedures, and the median age was 70 years in people that had knee replacement surgery and 69 in those that had hip replacement procedures.

2.3 Current management

People at risk of falling

NICE's clinical guideline on falls in older people states that people presenting for medical attention resulting from a fall, people reporting recurrent falls in the past year or people who demonstrate abnormalities of gait and/or balance should be offered a multifactorial falls risk assessment conducted by a healthcare profession with appropriate skills and experience. Assessment

should normally be conducted in a specialist falls service. People reporting recurrent falls or assessed to be at risk of falls should be considered for individualised, multifactorial interventions. Part of the multifactorial risk assessment includes a gait assessment and strength and balance training are recommended as part of the interventions.

People referred for knee or hip replacements

NICE's guideline on joint replacement (hip, knee and shoulder) outlines the recommendations and treatment options that are available for people who are offered primary elective hip, knee or shoulder replacement. Clinical experts indicated that there is a lot of variability in the current care pathway which makes it difficult to clearly define a standard care comparator for GaitSmart. Referral for surgery should be considered for people who experience knee or hip joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life, and have been offered non-surgical treatment options, or have symptoms that are not resolved by the core non-surgical treatment options.

2.4 Proposed management with new technology

People at risk of falling

The company submission states that for people at risk of falling, GaitSmart provides two functions in one assessment – an objective assessment of gait and an exercise programme as part of an individualised intervention – both of which are recommended in current NICE guidelines. The proposed pathways were based on GaitSmart taking at least 12 weeks to complete (baseline assessment and 3 follow-up assessments around 3 weeks apart). Clinical experts noted that it might be difficult for some practitioners to implement a 12-week programme of GaitSmart with some services only commissioned to provide 6-week interventions. The company has stated that there is flexibility in the number and frequency of assessments.

People referred for knee or hip replacements

The company submission states that a GaitSmart assessment as part of pre-operative management will provide an exercise programme to enable individuals to strengthen muscles in preparation for surgery.

3 Company claimed benefits and the decision problem

Table 1 describes the decision problem in the scope. No variation to the decision problem was proposed by either the company or EAG.

Table 1: The Decision Problem

Population	People with gait and mobility issues, specifically: • people that are at risk of falling, • people referred for knee or hip surgery (pre-operative and post-operative management).
Intervention	GaitSmart programme including 4 GaitSmart assessments and personalised rehabilitation via the vGym app
Comparator(s)	• Visual assessment of gait by physiotherapist or occupational therapist including scales such as Tinetti Performance Orientated Mobility Assessment and the Timed Get up and Go Test score and

	• Exercise and rehabilitation (including supervised and independent exercise or rehabilitation and NHS group-based exercise), or • Devices for support (such as supports, other gait training tools, splints or braces), or • Pharmacological treatment such as intra-articular corticosteroids (osteoarthritis)
Outcomes	The outcome measures to consider include: Outcome measures for effectiveness relevant to all populations: • Changes to gait, balance, mobility, and muscle weakness measures • Incidence of falls and associated injuries and hospitalisations • Patient reported outcome measures of pain • Patient reported outcome measures of functional ability • Health related quality of life (measures such as, EQ-5D and SF-36) Outcomes measures for effectiveness in people who have suffered a fall or recurrent falls: • Change in number of falls • Patient fear of falling using the Falls Efficacy Scale – International (FES-I) • Patient frailty (using NHS validated tool such as, gait speed test, PRISMA-7 and up and go test) • STEADI assessment for screening patients for fall risk Outcomes measures for effectiveness in people that have been referred for hip or knee replacement: • Delay of hip or knee surgery • Oxford hip score or Oxford knee score • Western Ontario and McMaster Universities Arthritis Index • Repeat surgery • Patient reported satisfaction with outcome of surgery Outcomes measures for resource use: • Further treatments (such as pain medication, corticosteroid use, surgery, days in hospital, and further rehabilitation) • Training time and costs for staff and non-registered support workers • Time needed to calibrate technology to ensure accurate measurements • Healthcare professional time (and banding) associated with patient follow up and care • Admission or readmission to secondary or tertiary care

	Device-related outcomes measures • Rates of adherence to programme • Device related adverse events	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Special considerations, including those related to equality	People who have difficulty accessing or using a device for the GaitSmart report and vGym exercise programme may be excluded from being able to use this technology. Patient-facing digital health technologies such as vGym exercise programme are delivered through a mobile phone or tablet. People will need regular access to a device with internet access to use the application. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies, do not have access to smart devices and may be unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities. The technology may be unsuitable for some people who have had a lower limb amputation. People at risk of falls and people who have been referred for knee or hip surgery are likely to be aged 65 years and older. Age and disability are protected characteristics under the Equality Act.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	For some people, a self-help type solution may be an advantage for convenience, however others will place a high value on group activity and individualised support.	

4 The evidence

Full details of the evidence can be found in the EAG's Assessment Report.

4.1 Summary of evidence of clinical benefit

In total, the EAG included 11 studies (reported in 18 publications or reports) for the clinical evidence. These comprised 14 published studies and 4 unpublished studies. There was 1 randomised trial (McNamara, unpublished), 4 publications with a diagnostic study design (McCarthy 2013, van Helvoort 2021a, van Helvoort 2022, Zügner 2019), 1 publication with a cross sectional study design (Rahman 2015), 1 case report (Ward, unpublished) and 4 publications that comprised a mix of before and after study design and case series study design (Care City Pilot, unpublished, Hodgins 2015, Monda 2015, NHS Glasgow Falls Clinic Report unpublished and Rodgers 2020). In total, 6 studies included people with hip or knee osteoarthritis (IMI-APPROACH, McCarthy 2013, Glasgow Falls Clinic Report, NNUH RCT, Rahman 2015, Zugner 2019) and 4 studies included people at risk of falls (Care City Pilot report, Hanley 2016, Hodgins 2015, Rodgers 2020) though it should be noted that in one study, the population was defined as people with balance and mobility problems (Hodgins 2015). In one study, only a healthy population was included (Monda 2015). The company submission also included a PhD thesis (Walters, 2018) and an additional validation study (Heaps 2019), both of which were excluded by the EAG.

Patient reported outcomes measures (PROMs) were collected in a number of studies using a range of tools including Oxford hip and knee scores, KOOS scores, EQ-5D-5L and EQ-5D VAS scores, Edmonton Frail Scale (EFS) scores and Falls Efficacy Scale International (FES-I) scores.

The selected studies and rationale are in Section 4.2 of the EAG's Assessment Report.

Table 2: Included studies and details

Study	Participants and setting	Outcomes	EAG Comments
Studies included by both EAG and company			
[redacted] Before and after study	[redacted]	[redacted]	Study design not defined, so allocated by EAG Short report of a pilot study Limited details on methodology
Hanley 2016 (abstract only) Location not reported Case series	55 people with hip arthrosis in outpatient setting 92 healthy people assessed for comparison	Measurements taken pre-operatively and one-year post-operatively - Movement in sagittal plane of hips - Knee movement	Study described as case series Abstract only, not related to any full text publications GaitSmart not stated, but abstract provided by company
Hodgins 2015 Location: UK Case series study	11 older people with walking and balance problems in community setting (mean age 78 years old) 18 older people with no walking and balance problems (mean age 70 years old	Gait pattern, which was used to calculate: - Knee range of motion - Symmetry between left and right knees	Study design not defined, so allocated by EAG Advice on exercise provided based on evidence from GaitSmart assessment Unclear, but assumed that the reference group were measured once, only for reference purposes
IMI-APPROACH Jansen 2023 (poster)	297 people with knee osteoarthritis	- Range of motion for both knees in swing and stance - Range of motion for both hips and both	Listed as prospective cohort study but EAG allocated as diagnostic study due to purpose

Van Helvoort 2022 (full text) Van Helvoort 2021a (full text) Van Helvoort 2021b (abstract) Hodgins 2019 (abstract) Location: European, multi-centre Diagnostic study		calves - Differences between both legs - Average stride duration, speed and length - Radiographic knee osteoarthritis - Pain and function	and outcomes Principal component analysis of GaitSmart parameters identified 5 underlying domains related to: - Range of motion in hips Range of motion in knees and calves - Difference in either range of motion of knees and calves in swing phase - Differences in range of motion in hips - Differences in range of motion in knees during stance

McCarthy 2013 Location: UK/Israel Diagnostic accuracy study	23 people with medial compartment knee osteoarthritis in community setting 21 people in control group	- Range of motion of knee flexion angle in swing and stance over a stride	- Listed as case series study but allocated diagnostic study by EAG - 4 sensors were used for analysis - For patients with unilateral osteoarthritis, data for unaffected limb analysed separately
Monda 2015 Location: UK Case series study	9 adults in study comparison between GaitSmart (n=4) and optoelectronic gait system (n=5) 136 people with no existing gair problems	- Stride duration - Knee range of motion - Knee stance - Thigh range of motion - Shank range of motion	Study design not defined, so allocated by EAG - Does not meet scope, but informative comparison with electronic gait system - No exercise component
[redacted] Before and after study	[redacted]	[redacted]	Study design not defined, so allocated by EAG [redacted]
Norfolk and Norwich University Hospital McNamara (unpublished)	[redacted]	[redacted]	Study design stated as RCT which the EAG agree with. Ward study is a case report Within group

Ward (unpublished) [redacted]	[redacted]		comparisons were made before and after surgery but there were no between group comparisons

Rahman 2015 Location: UK Cross sectional study	74 people aged between 40 and 80 years old who had a knee replacement in the previous year or were waiting for one. Study was done in an outpatient clinic	- Knee range of motion during swing and stance phases - Overall thigh sagittal range of motion - Overall shank sagittal range of motion - Difference in timing between the two peaks of thigh sagittal angle - Stride duration - Passive range of motion - Oxford Knee scores	Caution in interpreting the results from this study as the measurements are not matched (i.e. different patients in the before and after groups) therefore results do not represent a change in outcomes, rather a difference in outcomes People did not have gait measurements taken before and after surgery, so not clear that this study can indicate whether people have not improved their gait post-surgery
Rodgers 2020 Location: UK Before and after study	121 people who suffered an injurious fall and were under the care of a community hospital	- Change in frailty score - Change in fear of falling score - Gait score - Gait speed - Correlation between gait score and speed	Described as quality improvement study, but designed as before and after study by EAG Frailty determined using EFS, FES-I Study shows improvements in measured outcomes following GaitSmart programme
Zugner 2019 Mohaddes 2016 (abstract)	25 people who had total hip arthroplasty and reported	- Pelvic tilt - Range of knee flexion	Study design not defined, so allocated by EAG

Blixt 2016 (thesis) Location: Sweden Diagnostic accuracy study	mobility problems within one year and 25 people with no reported mobility problems	and extension - Range of hip flexion and extension	Limited applicability to the scope but shows reliability of GaitSmart measures compared with a 'gold standard' gait analysis method

The EAG noted that the clinical evidence has primarily been generated in settings that are generalisable to the NHS. There is a high degree of heterogeneity in terms of comparisons made and outcomes reported which results in limited evidence for relevant clinical outcomes. There are limited studies where GaitSmart is compared with standard of care, however, the EAG noted that the standard of care pathway is extremely variable which makes it difficult to identify appropriate comparators for GaitSmart. A number of studies included a comparative element but there was little consistency, with comparators. The published literature includes validation studies in which GaitSmart technology is compared against alternative gait assessment methods. Although validation studies may not be directly relevant to the decision problem, they provide an indication of the accuracy of the GaitSmart technology in measuring gait parameters thus may support its use as an alternative to visual gait assessment. Unpublished studies provided by the company provided evidence that may be more directly relevant to the decision problem in that they used GaitSmart in line with the scope, reporting on gait outcomes and PROMs.

People referred for hip or knee arthroplasty

Three studies reported on use of GaitSmart for people referred for hip or knee arthroplasty (Hanley 2016, NNUH unpublished, Rahman 2015). Findings from Rahman (2015) and Hanley (2016) were deemed to have limited applicability as they made comparisons with healthy controls, which is not within the scope and the studies did not investigate the impact of the exercise aspect of GaitSmart. The study most clinically relevant to this population is the unpublished randomised trial (McNamara unpublished) which compares GaitSmart with standard of care for rehabilitation following hip or knee

surgery. The economic model for this population is also based on this trial. The study was considered to be medium risk of bias based on the information reported. The EAG noted that there was no treatment blinding although participants in the standard care arm were blinded to their GaitSmart assessment results.

The results of the McNamara trial indicated [redacted].

People at risk of falls

Four studies reported on outcomes in people considered to be at risk of falling (Care City Pilot unpublished, Hodgins 2015, NHS Glasgow unpublished, Rodgers 2020). All four studies were conducted in the UK, with two conducted in conducted in NHS community settings (Rodgers 2020, NHS Glasgow Falls report, unpublished) and one in a primary care setting (Care City Pilot, unpublished).

The most relevant study to this population and the study on which the economic analysis has been based (Rodgers 2020) included 121 participants who had suffered an injurious fall. Results reported a change in mean GaitSmart score from 26.1 to 46.3 ($p<0.001$) with 76% of participants improving. Mean gait speed increased from 0.46 to 0.62 m/s ($p<0.001$) with 80.5% of participants improving. Gait score and speed were moderately correlated with measures of frailty and fear of falling, with correlations increased from beginning to end of the study. The EAG note that although exercise was prescribed as part of this study, it was not generated using the integrated vGym app.

Two unpublished before and after studies (Care City Pilot and NHS Glasgow Falls Clinic report) reported on changes in gait parameters including speed, gait scores, knee angle and on changes in PROMs in people at risk of falls. Both studies reported improvements in outcomes over the assessment period with the NHS Glasgow study reporting an [redacted] while the results of the Care City Pilot reported [redacted]. Both studies report [redacted] and the NHS Glasgow study reported [redacted]. [redacted]. Hodgins (2015) reported on how gait parameters in a healthy older population differed from those of an older population with gait and balance issues but the applicability of this study is limited as it compares with a group of participants who do not have gait and balance issues.

EAG interpretation of the clinical evidence

The company identified two clear populations and there is limited clinical evidence that the use of GaitSmart may improve clinical outcomes for patients in each of these populations, although the most relevant evidence has yet to be published in the public domain. In a randomised trial comparing outcomes

in people who underwent surgery, [redacted]. The EAG consider this study to be the most relevant and informative but note that the comparisons are not being made directly between GaitSmart and standard of care. The results do suggest potentially more improvement with GaitSmart but [redacted] which may strengthen the clinical case. Considering people at risk of falls, 2 unpublished studies reported improvements in outcomes including gait parameters and PROMs in people at risk of falls but neither study included a standard care comparator.

From a limited evidence base, the direction of effect appears to be that use of GaitSmart technology improves outcomes for people referred for hip or knee surgery and for people at risk of falls but there is a lack of directly comparative evidence. There are strengths in the available studies in that they use validated tools to measure PROMs and function and consideration is given to whether changes are clinically significant. Based on the available clinical evidence, the EAG consider that the case for adoption is potentially supported but that further evidence generation would be beneficial.

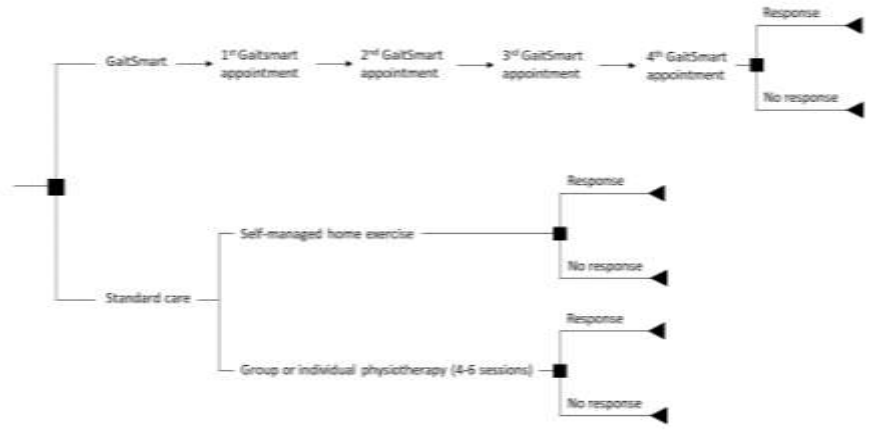
4.2 Summary of economic evidence

The company submission included 5 studies. The EAG excluded 3 of the studies as they were not considered relevant to the scope or the studies' data and findings were not used in the company's models. The economic models submitted by the company were the same as reported in 2 unpublished economic evaluations by Zanghelini. The economic analyses undertaken were the same in terms of model structure, model inputs and economic results.

Company models

The company submitted 2 models for (i) patients referred for knee or hip surgery (pre-operative and post-operative management) and (ii) people above 65 years that are at risk of falling. Although the models share some similarities in terms of structure and the approach used to estimate falls risks, different sets of clinical inputs and cost inputs are used. Therefore, each of the models and their associated parameters and results will be presented separately.

Figure 1: Rehabilitation model structure



The company's rehabilitation model employed a simple decision tree structure comparing GaitSmart and standard care. At the end of the decision tree, patients were either responding or not responding to the intervention. The company defined a response as any improvement in gait speed. Following a

response to the intervention, the model considered the change in falls risk for each intervention using the association between gait speed and falls risk. This was followed by falls outcomes where falls would be treated at an A&E with or without hospitalisation. An NHS perspective over a 17-week time horizon was used. No discounting was applied. The standard care arm assumed that [redacted]. This was based on expert opinion derived from an unpublished study by McNamara (unpublished).

Table 3: Rehabilitation model key parameters

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Variable	Company value (Source)	EAG value	EAG comment
Relative risk of gait speed and risk of falls	1.07 (Verghese 2009)	No change	Verghese (2009) reports a 1.069 risk ratio of falls associated with every decrease of 10 cm/s in gait speed.
Probability of response: *Self-managed home exercise* *Group/ individual physiotherapy* *GaitSmart*	[redacted]	[redacted]	Recalculated using company definition using data whose initial gait speed less than 1.0m/s. The EAG accepted this, and variation using [redacted](McNamara Unpublished).
Falls risk reduction: *Standard care* *GaitSmart*	[redacted] [redacted] (Company estimate of falls risk reduction from McNamara, unpublished)	[redacted] [redacted]	Using McNamara data whose initial gait speed less than 1.0m/s, the EAG recalculated falls risk ratio based on responders and non-responders
Probability of falls in knee OA	1.39 (Doré 2015)	No change	Doré (2015) reports a 1.39 OR of falls associated with patients with knee osteoarthritis
Probability of falls in hip OA	1.60 (Doré 2015)	No change	Doré (2015) reports a 1.60 OR of falls associated with patients with hip osteoarthritis.
Probability of falls following THA	0.25 (Smith 2016)	No change	Smith (2016) reports a 0.25 of falls following THA in the past 12 months.
Probability of falls following TKA	0.26 (Smith 2016)	No change	Smith (2016) reports a 0.26 of falls following TKA in the past 12 months.

Variable	Company value (Source)	EAG value	EAG comment
Calculated probability of fall following THA for people with hip OA	0.4		Calculated as 0.25 x 1.6
Calculated probability of fall following TKA for people with knee OA	0.36		Calculated as 0.26 x 1.39
Probability of fall resulting in emergency attendance	0.07 (Calculated using estimates from Watson 2011 (18,466 falls with A&E attendance / 251,433 number of fallers)	0.03	The EAG value was recalculated (18,466 falls required A&E attendance / 507,207 falls). The EAG accepted this and noted that this may not be generalisable to NHS A&Es.
Probability of fall resulting in hospitalisation	0.61 (Watson 2011)	0.05	The EAG have not been able to reproduce the company value. EAG value was recalculated (25,561 falls with hospital admission / 507,207 falls).
Abbreviations EAG – External Assessment Group, OR – odds ratio, TKA – total knee arthroplasty, THA – total hip arthroplasty, OA – osteoarthritis			

Table 4: Rehabilitation model costs/resource use for GaitSmart and comparators

Parameter	Company value	Source	EAG value	Comment
GaitSmart				
Equipment set up				
Device set up and training	Not included	£1000 from company estimate	No change	
Equipment use				
Per use charge	£10	Company estimate	No change	
Number of sessions per person	4	Company estimate	No change	Experts stated that in some cases GaitSmart may be implemented with an expectation of only 3 sessions per person.
Staff requirement				
Health care assistant for 15 mins per session	£6.75	PSSRU 2020 Company estimate based on healthcare	£8.50	EAG recalculated the hourly rate based on PSSRU 2022 (mean annual

Parameter	Company value	Source	EAG value	Comment
		assistant, mean annual basic pay per FTE, plus overheads, capital overheads of community-based scientific and professional staff, band 4, £27 per hour		pay of 20148 and 28% oncosts, and other overheads of a community-based band 4) and the total working hours (1618), resulted in £34.06 per hour. EAG calculation: £34.06 per hour x 15 mins = £8.50.
Administration time for 10 mins per patient	£1.55	PSSRU 2019 (administration and estates staff, mean annual basic pay per FTE)	£3.42	EAG recalculated the hourly cost using the mean annual basic pay of £32,340 (PSSRU 2022) and the total paid working hours (210 days x 7.5 hours), resulted in £20.53 per hour. Paid working days = 365 days – 104 weekends – 51 paid off days (33 annual leave, 8 bank holidays and 10 training days) EAG cost calculation - £20.53 per hour x 10 min = £3.42
Physiotherapist oversight time for 5 mins per patient	£0		£4.58	EAG cost calculation, band 6 = £55 per hour x 5 mins = £4.58 (PSSRU 2022)
Total cost for all GaitSmart sessions per patient	£67	Company submission	£82.02	EAG figure includes additional staff costs.
Standard care:				
Self-managed home exercise				
Physiotherapist time for 20 mins per session	£10.33	PSSRU 2020 (community therapy assistant, band 4)	£12.33	EAG cost calculation = £37 per hour x 20 mins = £12.33. (PSSRU 2022)
Administration time for 10 mins per session	£1.55	PSSRU 2019 (administration and estates staff, mean annual basic pay per FTE)	£3.42	EAG cost calculation = £20.53 x 10 mins = £3.42 (PSSRU 2022)
Number of sessions	1	Company assumption	No change	Reasonable assumption

Parameter	Company value	Source	EAG value	Comment
Total cost for all self-management sessions per patient	£11.89		£15.76	
Group / individual physiotherapy				
Physiotherapist time for 60 mins per session	£48	PSSRU 2020 (Community physiotherapist, band 6)	£55	EAG cost calculation = £55 per hour x 60 mins = £55 (PSSRU 2022)
Consultant time for 30 mins per session	£57	PSSRU 2020 (Consultant, surgical, £114 per hour)	£0	EAG think this is unlikely to be plausible and excluded this.
Administration time for 15 mins per session	£2.33	PSSRU 2019 (administration and estates staff, mean annual basic pay per FTE)	£5.13	EAG cost calculation = £20.53 per hour x 15 min = £5.13 (PSSRU 2022)
Number of sessions	6	Company assumption	No change	
Number of patients per group session	n/a		10	EAG assumption
Proportion of group sessions	0		50%	EAG assumption and variation is explored in the sensitivity analyses
Total cost for all individual sessions per patient	£643.98	Calculated from above	£360.80	Recalculated using EAG value.
Total cost for all group sessions per patient			£36.08	EAG: Calculated using the total cost of individual sessions per patient and the number of patients per group session
Total cost for all group / individual physiotherapy per patient	£643.98	Company estimate	£198.44	EAG: Applied the proportion of group physiotherapy
Total standard care costs				
Total cost	£517.56	Company assumption – 20% self-managed home exercise and 80% group/individual	£307.83	EAG: Calculated using company assumption

Parameter	Company value	Source	EAG value	Comment
		physiotherapy		
Costs for events following a fall				
Ambulance call out	£257	PSSRU 2019 (Ambulance service, see and treat and convey, 2017/18 value)	£307.45	EAG: £292 (NHS reference costs 2019/20), inflated to 2021/22
A & E visit, no admission	£166	NHS reference costs, 2018/19 (average accident & emergency)	£163.48	EAG: £155.31, weighted average of non-admitted, inflated to 2021/22 (NHS reference costs)
A & E visit, admission	£377	PSSRU 2018	£327.15	EAG: £310.81, weighted average of admitted, inflated to 2021/22 (NHS reference costs 2019/20)
Abbreviations EAG – External Assessment Group, PSSRU – personal social services research unit, FTE – full-time equivalent				

Rehabilitation model results

Results from both the company's submitted rehabilitation model and the EAG base case indicate that GaitSmart is cost-saving. Costs associated with falls are not included in the company base case result. The EAG considers that the fall outcomes as a result of the intervention use should be captured and included in the total costs. The overall cost saving is dominated by the cost difference between interventions, while a marginal number of falls are prevented by GaitSmart. The results should be interpreted with caution as the existing evidence on the change in gait speed is generated from a small RCT, and the standard care program in the model may not reflect common practice. While falls are associated with significant impact to patients and the NHS, the impact of falls in the model is limited by the short duration.

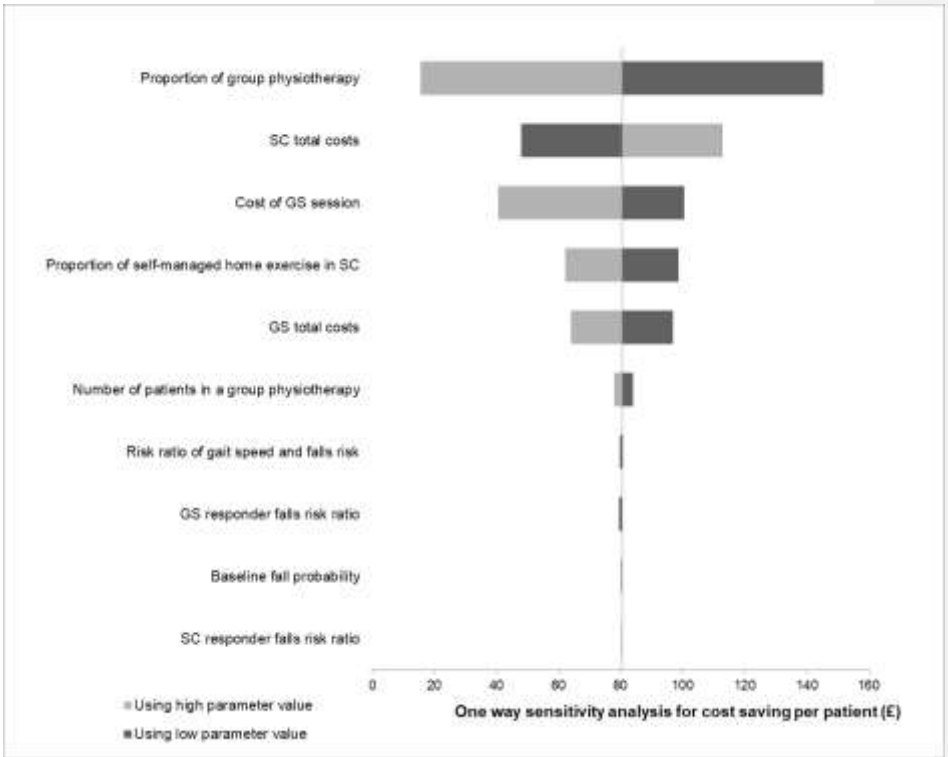
Table 5: Company and EAG results for rehabilitation model

	Company results			EAG results		
	Technology	Comparator	Cost saving per patient	Technology	Comparator	Cost saving per patient
Intervention	[redacted]	[redacted]	[redacted]	£82.02	£161.90	£79.89
Falls	Not included in submission	Not included in submission	-	£6.52	£7.12	£0.60
Total	[redacted]	[redacted]	[redacted]	**£88.54**	**£169.03**	**£80.49**
Number of falls per person	**0.343**	**0.347**	**0.004**	**0.356**	**0.389**	**0.033**

[redacted]Rehabilitation model sensitivity analyses

The EAG performed a series of one-way sensitivity analyses for several key parameters, all of which were varied using plausible ranges. The EAG results were presented in a tornado diagram.

Figure 2: Tornado diagram (one way sensitivity analysis)



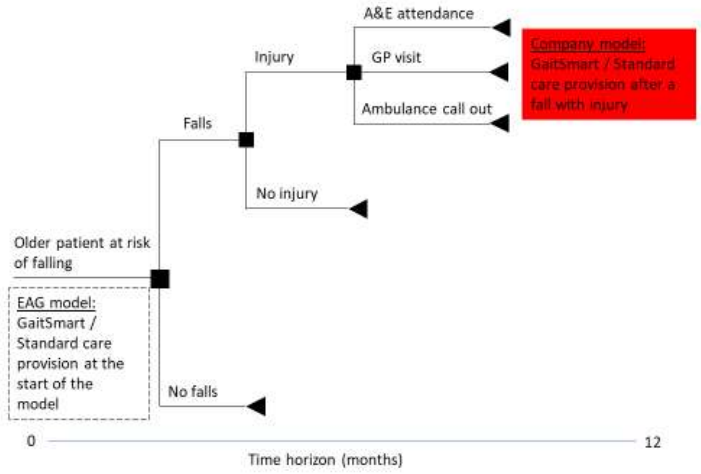
The EAG scenario that substitutes a band 6 physiotherapist to a band 4 therapy assistant for physiotherapy session in the standard care, yielded a change in the cost saving from £81.12 to £25.05. Subsequently, combining scenario 1 and 2 (scenario 2: increasing the proportion of group physiotherapy session from 50% to 75%), resulted in a cost incurring of £17.22.

Table 6: EAG alternative cost scenarios

	Base case value	Alternative value	EAG alternative cost scenario
EAG base case	-	-	**£80.49**
Scenario 1: Substituting a band 6 physiotherapist to a band 4 therapy assistant	£55	£34	**£25.05**

	Base case value	Alternative value	EAG alternative cost scenario
Combining scenario 1 and 2 Scenario 2: Increasing the group physiotherapy session	50%	75%	**-£17.22**

Figure 3: Falls model structure



A decision tree model was constructed to compare GaitSmart and standard care. Patients entered the falls model and then had either falls or no falls. Falls were divided to falls with injury or falls with no injury. For those who experienced an injurious fall, they received medical attention through ambulance call-out, GP visit or A&E attendance. The company model also assumed that the intervention (GaitSmart or standard care) was only given to those patients had an injurious fall. The EAG felt that the company falls model was flawed due to the time point when the intervention was provided. The company model did not model further outcomes after an intervention was given for those with injurious fall. The EAG made amendments such that the falls model starts with patient receiving either GaitSmart or standard care. At the end of each branch, patients had either falls or no falls. The fall outcomes were modelled following a fall.

Table 7: Falls model key parameters

Variable	Company value (Source)	EAG value	EAG comment
Probability of a fall in community dwelling adults over 65 years in a year	33.33% (Berry 2008, Tinetti 1995)	34%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years, however in the base case this is not used, as the population is those identified as requiring access to falls intervention
Relative risk of gait speed and risk of falls	1.07 (Verghese 2009)	No change	Verghese (2009) reports a 1.069 RR of falls associated with every decrease of 10 cm/s in gait speed.
Probability of recurrent falls	14% (Arfken 1994)	No change	
Probability of falls that result in an injury requiring medical attention	20% (Berry 2008, Tinetti 1995)	20%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years, classed as serious falls.
Probability of falls that result in A&E attendance	34% (Berry 2008, Tinetti 1995)	80%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years,
Probability of falls that result in GP visit	51% (Berry 2008, Tinetti 1995)	51%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years,
Probability of falls that result in ambulance call out	15% (Berry 2008, Tinetti 1995)	61%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years,
Probability of falls requiring admission	33%	28%	EAG: Changed source to Craig 2013, based on Scottish population over 65 years, proportion of serious injuries resulting in admission
Risk reduction for intervention	1.77% (Company estimate falls risk reduction using NELFT study, patient data in model)	0.89	The EAG recalculated to give a RR of 0.89.
Risk reduction for comparator	0% (Assumption)	No change	The EAG have not changed this assumption in the base case, but have explored this at length in sensitivity and scenario analysis.

Table 8: Falls model costs/resource use for GaitSmart and comparators

Parameter	Company value	Source	EAG value	Comment
GaitSmart Intervention				
Total cost for all GaitSmart sessions per patient	£40	Company submission, included only 4 GaitSmart sessions costs	£82.02	EAG figure includes additional staff costs.
Standard care:				
Physiotherapist, band 5 per hour,	£34	PSSRU 2020 physiotherapist band 5, per hour	£42	PSSRU 2022, physiotherapist band 5, per hour
Initial assessment cost	-	Not included	£31.50	EAG assumption: 45 minutes, 1:1 with band 5 physiotherapist
Cost of subsequent sessions, per patient	£25.50	Company assumption: 45 minutes, 1:1 with band 5 physiotherapist	£8.40	EAG: 60 minutes, group of 10, 2 x band 5 physiotherapist
Number of sessions	30	Company assumption	8	EAG: expert opinion
Administration	-	Not included	£0.33	EAG assume 10 minutes per group session
Total cost for all self-management sessions per patient	£765.00	For 30 x 1:1 sessions with band 5 physiotherapist	£102.71	For 1 x 1:1 assessment plus 8 x group sessions with 2 band 5 physiotherapists.
Costs for events following a fall				
Ambulance call out	£257	PSSRU 2019 (Ambulance service, see and treat and convey, 2017/18 value)	£282	EAG: £258 (source value), inflated to 2021/22
A & E visit	£166	NHS reference costs, 2018/19 (average accident & emergency)	£118	EAG: £118 weighted average assuming 33% are admitted, and the remainder are not. Costs inflated to 2022
GP visit	£36	NHS reference costs 2016	£42	EAG: GP appointment of 9.22 mins, including direct care staff costs and qualifications (PSSRU 2022)

Parameter	Company value	Source	EAG value	Comment
Inpatient stay	£1,609	PSSRU 2018 (average of long and short stay of non-elective inpatient stays)	£1,950	Total HRG for non-elective inpatient costs (long and short stay, weighted average 2019/20 inflated to 2022

Falls model results

The company base case is for a cohort of 1000, but assumes that only those people who experience a fall with injury receive the intervention, and that those that receive GaitSmart also receive the comparator intervention. The EAG assumed that all those in the cohort received the intervention, and that subsequently a number of falls would be experienced with a range of consequences. The EAG base case, shows a cost saving of £29 per patient using GaitSmart. It is important to note that 70% of the EAG base case cost difference is due to the relative costs of the interventions, therefore, the most important economic input to the model is the cost of the comparator. GaitSmart results in a relatively small reduction in the number of falls (11%) in the model, and therefore the modelled impact of falls on cost saving is small.

Table 9: Falls model results

	Company results			EAG results		
	Technology	Comparator	Cost saving per patient	Technology	Comparator	Cost saving per patient
Intervention	[redacted]	[redacted]	[redacted]	£82.02	£102.12	£20.10
Falls	[redacted]	[redacted]	[redacted]	£72.65	£81.24	£8.59
Total	[redacted]	[redacted]	[redacted]	£154.66	£183.36	**£28.70**
Number of falls/1000 patients	[redacted]	[redacted]	[redacted]	436	390	46

Falls model sensitivity analyses

The EAG selected a variety of assumed comparator options, all of which included an initial 45-minute assessment by a band 5 physiotherapist, followed by a variety of group or 1:1 interventions. The costs ranged from £57 to £1,292 per patient. The base case retained the company's assumption that the comparator did not change the number of falls experienced. The sensitivity analysis uses risk ratio ranging from 0.5 (50% reduction in falls) to 1 (no reduction in falls) to 1.5 (an increase in falls). An additional two-way sensitivity analysis was done to identify the point of cost neutrality when factoring in the risk ratio for standard care. Cost neutrality is likely to lie between £70 and £110 per patient, where GaitSmart costs £82.02 per patient to deliver. This reflects the dominance of intervention cost in the model.

Table 10: Two-way sensitivity analysis of comparator cost and effectiveness, EAG base case

Comparator cost: Initial assessment plus:		**Risk ratio for standard care**			
		0.5	**0.75**	**1**	**1.5**
1 x band 5, 6 x 1 hour, group of 10	**£57**	£57	£37	£17	-£24
2 x band 5, 6 x 1 hour, group of 10	**£82**	£32	£12	-£8	-£49
2 x band 5, 12 x 1 hour, group of 10	**£132**	-£18	-£39	-£59	-£99
2 x band 5, 20 x 1 hour, group of 10	**£200**	-£85	-£106	-£126	-£167
1 x band 5, 6 x 45 min, 1:1	**£221**	-£106	-£127	-£147	-£188
1 x band 5, 20 x 45 min, 1:1	**£662**	-£547	-£568	-£588	-£629
1 x band 5, 30 x 45 min, 1:1	**£977**	-£862	-£883	-£903	-£944
1 x band 5, 30 x 1 hour, 1:1	**£1,292**	-£1,177	-£1,198	-£1,218	-£1,259

Table 11: Additional two-way sensitivity analysis showing the points of cost neutrality

Comparator cost	**Risk ratio for standard care**						
	0.5	**0.65**	**0.75**	**0.8**	**0.9**	**1**	**1.5**
£60	£54	£42	£34	£30	£22	£13	-£27
£70	£44	£32	£24	£20	£12	£3	-£37
£80	£34	£22	£14	£10	£2	-£7	-£47
£90	£24	£12	£4	£0	-£8	-£17	-£57
£100	£14	£2	-£6	-£10	-£18	-£27	-£67
£110	£4	-£8	-£16	-£20	-£28	-£37	-£77
£120	-£6	-£18	-£26	-£30	-£38	-£47	-£87

EAG interpretation of the economic evidence

Key changes made by the EAG include:

- Change of falls risk calculation
- Adjustment of the assumptions made in standard care costs (Standard care costs became lower in both models after adjustment)
- Change of staff time costs to the latest PSSRU
- Rehabilitation model: Change of falls risk to responders and non-responders
- Falls model: Change of the time point of intervention provision from after an injurious fall event to the start of the model and excluding standard care costs from the GaitSmart arm

In the rehabilitation model, the EAG consider the population to be clearly identified and appropriate. The company model structure is likely to be suitable for patients referred for knee or hip surgery (pre- and post-operative management). As the full consequences of falls are not considered, the costs of falls are very likely to be underestimated. However, no data on longer term falls outcomes associated with GaitSmart are available for inclusion.

In the model, the number of falls is estimated based on the change in gait speed, instead of the actual falls observed. The EAG consider data from McNamara (Unpublished) to be the most appropriate source for gait speed input due to the patient population. To predict the falls using gait speed, the EAG consider the association between gait speed and falls risk reported by Verghese (2009) as appropriate due to the large number of patients and sufficiently long follow up. Given the short time horizon, the economic results are driven by the cost differences between interventions. This is very dependent on the standard care pathway, which varies considerably across localities. Given the high variability in standard care and the lack of data, the EAG modelled additional scenarios to reflect different variations in the standard care, this led to a change from cost saving to cost incurring.

In the falls model, the EAG consider the population to be clearly identified and appropriate. The company model structure did not consider any outcomes after the provision of the intervention (after a fall with injury). Following the EAG amendments, the model is likely to be suitable for this population and includes falls outcomes for 1 year after the interventions. Similar to the rehabilitation model, non-fall related outcomes and full falls consequences are not captured due to the short time horizon. The same approach as the rehabilitation model is used to estimate falls based on the change in gait speed. Data from a single arm study, Rodgers (2020) is used as the source for gait speed due to the limited available evidence. This study is from an indexed journal and can only be accessed via the journal's own website. No description is included of interests, funding ethics or adverse events. In addition, the clinical evidence on standard care is lacking. The company model assumes the standard care has no additional efficacy, which the EAG believes is not the case. The EAG carried out a number of sensitivity analyses and scenario analysis to explore the impact of relative efficacy and comparator costs. Given the uncertainties in the model and dominance of the intervention costs, GaitSmart can vary from cost saving to cost neutrality.

5 Ongoing research

The company and the EAG are not aware of any ongoing research on GaitSmart.

6 Issues for consideration by the committee

Issues identified by during the evaluation process that the committee may consider discussing during guidance development:

Clinical evidence

- It appears that the use of GaitSmart improves outcomes for people referred for hip or knee surgery and for people at risk of falls, though the evidence is limited and there is a lack of directly comparable evidence. The committee may wish to consider whether the evidence is

sufficient to support the adoption of GaitSmart and whether further evidence generation is needed.

- For people referred for hip or knee arthroplasty, the most relevant study found increases in GaitSmart score in both the standard care and intervention arm, but these increases were not statistically significant. Results indicated potentially greater improvements in the GaitSmart group, but between group differences were not formally analysed. Therefore, it is unclear how GaitSmart measures compare against visual assessment.

- For people at risk of falling, the most relevant studies used gait score and speed to assess changes in frailty and fear of falling. The EAG considers these outcome measures to be moderately correlated. The committee may wish to consider whether this is an appropriate method of measuring improvements in relation to frailty and fear of falling.

- There are no safety concerns relating to the use of GaitSmart.

Cost evidence

- In the rehabilitation model, non-fall related outcomes such as additional osteoarthritis treatment are not captured due to the short time horizon. There is also no available data on long-term falls outcomes associated with GaitSmart for inclusion in the model. Therefore, the number of falls are predicted using gait speed. This is done using the association between gait speed and falls risk reported by Verghese (2009). The committee may wish to consider whether these aspects affect the plausibility of the economic model for people referred for hip or knee arthroplasty.

- In the falls model, the same approach is used to estimate falls based on the change in gait speed. Data from a single arm study, Rodgers (2020), is used as the source of this data. In addition, clinical evidence on standard care is lacking. The EAG carried out sensitivity analyses and scenario analysis to explore the impact of relative efficacy and

comparator costs. Given the uncertainties in the model and the dominance of intervention costs, GaitSmart can vary from cost saving to cost neutrality, depending on the comparator costs. The committee may wish to consider the most plausible scenario to determine whether GaitSmart is cost saving compared to standard care.

7 Authors

Farhaan Jamadar, Technical Lead

Kimberley Carter, Technical Advisor

NICE Medical Technologies Evaluation Programme

July 2023

Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

- O'Connell S, Chong HY, Willis S et al., GaitSmart rehabilitation exercise programme for gait and mobility issues, June 2023.

B Submissions from the following company:

- Dynamic Metrics

C Related NICE guidance

- Osteoarthritis in over 16s: diagnosis and management. NICE guideline 226 (2022). Available from https://www.nice.org.uk/guidance/ng226
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Appendix B: Comments from clinical experts and healthcare professional organisations

Expert advice was sought from clinical experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Professor Alison McGregor

Professor of Musculoskeletal Biodynamics, Imperial College London

Ms Andrea Sargeant

Senior Pathway Redesign Manager, NHS Norfolk and Waveney Integrated Care Board

Mr Julian Owen

Consultant Trauma and Orthopaedic Surgeon, Addenbrookes Hospital Cambridge

Ms Emma Brown

Physiotherapist and Innovation Lead, Eastern and Oxford AHSN

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

GaitSmart rehabilitation exercise programme for gait and mobility issues

1 Technology

1.1 Description of the technology

The GaitSmart programme (Dynamic Metrics) comprises digital gait assessment with GaitSmart followed by personalised rehabilitation exercises.

GaitSmart is a sensor-based digital technology that monitors limb movement. The technology requires 7 sensors to be placed on the pelvis, thigh and calf on either side of the body, as well as the base of the spine. Objective measurements are taken while walking to identify any problems with gait. The test takes 10 minutes to complete and can be done by a healthcare assistant in a variety of settings.

Information from the sensors is automatically processed to produce a colour-coded report that helps the person and healthcare professional to understand the gait issue and its severity. The GaitSmart gait assessment is used with an integrated app vGym which provides a personalised rehabilitation programme, consisting of 6 exercises, to help improve mobility. The app provides photos and descriptions of each exercise. The reports and advice provided by the technology can also be printed off and used without needing access to a personal device. Once allocated to the programme, each person is expected to do a total of 4 GaitSmart gait assessments, with each assessment taking

place every 4-6 weeks. The gait assessment identifies any improvements in gait and mobility and then alters exercises accordingly.

1.2 Relevant diseases and conditions

GaitSmart is intended for people who are ambulatory or partially ambulatory with gait and mobility issues. This evaluation will focus on its use in older people at risk of falling and people referred for knee or hip replacements (as part of pre-operative and post-operative rehabilitation).

People at risk of falling

People aged 65 and over have the highest risk of falling. 30% of people older than 65, and 50% of people older than 80, fall at least once a week (NICE CG161 Falls in older people: assessing risk and prevention). Falling can be distressing and cause pain, injury, and loss of mobility. People can lose confidence and, in some cases, lose their independence because of a fall.

People referred for surgery (pre-operative and post-operative management)

Knee or hip replacement refers to a surgical procedure where a person has their knee joint, or hip joint, replaced (wholly or partially) with an artificial one (known as an implant). The NHS website states that a knee or hip replacement is needed when the joint is worn or damaged so that a person's mobility is reduced and they are in pain even when resting. Between 1 January 2018 to 30 December 2020, The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, notes that osteoarthritis was given as a documented indication for surgery in 97.4% of knee replacement cases and 93.1% of hip replacement surgery cases. It states there were 226,350 primary total knee replacements and 250,278 primary hip procedures. The majority of procedures were carried out in women for both knee (females 56.3%; males 43.7%) and hip (females 59.9%: males 40.1%) procedures, and the median age was 70 (IQR 63 to 76) years in people that had knee replacement surgery and 69 (IQR 61 to 76) in those that had hip replacement procedures.

1.3 Current management

Current management options for people with gait and mobility issues varies depending on the underlying cause and severity of the symptoms.

People at risk of falling

When seeing a health care professional, people over the age of 65 are asked about any falls within the last year, as recommended in the NICE guideline for falls in older people. The guideline states that older people who present for medical attention because of a fall, or report recurrent falls in the past year, or demonstrate abnormalities of gait and/or balance are offered a multifactorial falls risk assessment. This assessment should be performed by a healthcare professional with appropriate skills and experience, normally in the setting of a specialist falls service. The multifactorial falls risk assessment may include:

- Identification of falls history
- assessment of gait, balance and mobility, and muscle weakness
- assessment of osteoporosis risk
- assessment of the older person's perceived functional ability and fear relating to falling
- assessment of visual impairment
- assessment of cognitive impairment and neurological examination
- assessment of urinary incontinence
- assessment of home hazards
- cardiovascular examination and medication review

Following the assessment, an intervention made up of multiple components to address the risk factors identified through the risk assessment should be developed. This is called a multifactorial intervention, the components offered within this intervention are tailored to each person depending on their assessment. Common components of a multifactorial intervention are:

- Strength and balance training individually prescribed and monitored by an appropriately trained professional.

- Home hazard assessment and intervention is offered as part of the discharge process for people that have received hospital treatment following a fall. This includes an assessment and safety modifications to the home. A home hazard assessment is carried out by an appropriately trained professional, within an appropriate timeframe.
- Vision assessment and intervention
- Medication review, particularly for patients that take psychotropic medication.

Patients can also be encouraged to participate in a falls prevention programme, such as the 7 week programme, STEEP (Staying Steady Exercise and Education Programme), as referenced in the NICE shared learning database. The STEEP programme includes 7 1-hour long sessions which are made up of a 30-minute educational talk and a 30-minute exercise circuit. People that are at risk of falling and their carers are also given advice about what measures to take to prevent further falls, how to stay motivated, the benefits of modifying falls risk and how they can seek further advice and assistance.

People referred for surgery (pre-operative and post-operative management)

Referral for surgery should be considered for people who experience knee or hip joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life, and have been offered, or have symptoms that are not resolved by the core (non-surgical) treatment options. NICE's guideline on joint replacement (primary): hip, knee and shoulder recommends offering a choice of partial or total knee or hip replacement to people with isolated medial compartmental osteoarthritis. It also recommends a posterior or anterolateral approach for primary elective hip replacement. Surgery may not be suitable for some people who are unable, or do not want to undergo surgery.

People that are referred for hip or knee surgery, because of osteoarthritis, a fall or for another reason, are offered advice on preoperative and postoperative rehabilitation.

Preoperative advice for people having a hip or knee replacement outlines exercises for the patient to do before and after the surgery to aid recovery. People should also be offered advice on relevant lifestyle modifications, such as weight management and smoking cessation, as well as advice on how to maximise functional independence and quality of life, before and after surgery.

After surgery, and before discharge, advice is given by a physiotherapist or an occupational therapist about self-directed rehabilitation as well as a point of contact for advice and support. Supervised group or individual outpatient rehabilitation is given to people that have difficulties with managing daily activities, ongoing functional impairment leading to specific rehabilitative needs or where self-direct rehabilitation is not meeting their rehabilitative needs.

1.4 Regulatory status

GaitSmart received a CE mark in November 2019 as a class Im medical device for measuring gait in people with gait and mobility issues.

1.5 Claimed benefits

Compared with patients that receive gait assessment followed by advice about exercises as either post-surgery rehabilitation, osteoarthritis care or management, or through a multifactorial assessment for assessing risk of falls the benefits to patients using GaitSmart, claimed by the company are:

- Reduces need for further treatment
- Improves mobility
- Increases self-management
- Increases quality of life

The benefits to the healthcare system claimed by the company are:

- Increases compliance
- Lower grade of staff can deliver care compared to current practice
- Is cost saving compared to current practice.

2 Decision problem

Population	People with gait and mobility issues, specifically: • people that are at risk of falling, • people referred for knee or hip surgery (pre-operative and post-operative management).
Intervention	GaitSmart programme including 4 GaitSmart assessments and personalised rehabilitation via the vGym app
Comparator(s)	• Visual assessment of gait by physiotherapist or occupational therapist including scales such as Tinetti Performance Orientated Mobility Assessment and the Timed Get up and Go Test score and • Exercise and rehabilitation (including supervised and independent exercise or rehabilitation and NHS group-based exercise), or • Devices for support (such as supports, other gait training tools, splints or braces), or • Pharmacological treatment such as intra-articular corticosteroids (osteoarthritis)
Outcomes	The outcome measures to consider include: Outcome measures for effectiveness relevant to all populations: • Changes to gait, balance, mobility, and muscle weakness measures • Incidence of falls and associated injuries and hospitalisations • Patient reported outcome measures of pain • Patient reported outcome measures of functional ability • Health related quality of life (measures such as, EQ-5D andSF-36) Outcomes measures for effectiveness in people who have suffered a fall or recurrent falls: • Change in number of falls • Patient fear of falling using the Falls Efficacy Scale – International (FES-I) • Patient frailty (using NHS validated tool such as, gait speed test, PRISMA-7 and up and go test) • STEADI assessment for screening patients for fall risk

	Outcomes measures for effectiveness in people that have been referred for hip or knee replacement: • Delay of hip or knee surgery • Oxford hip score or Oxford knee score • Western Ontario and McMaster Universities Arthritis Index • Repeat surgery • Patient reported satisfaction with outcome of surgery Outcomes measures for resource use: • Further treatments (such as pain medication, corticosteroid use, surgery, days in hospital, and further rehabilitation) • Training time and costs for staff and non-registered support workers • Time needed to calibrate technology to ensure accurate measurements • Healthcare professional time (and banding) associated with patient follow up and care • Admission or readmission to secondary or tertiary care Device-related outcomes measures • Rates of adherence to programme • Device related adverse events
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	N/A
Special considerations, including those related to equality	People who have difficulty accessing or using a device for the GaitSmart report and vGym exercise programme may be excluded from being able to use this technology. Patient-facing digital health technologies such as vGym exercise programme are delivered through a mobile phone or tablet. People will need regular access to a device with internet access to use the application. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies, do not have access to smart devices and may be unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities. The technology may be unsuitable for some people who have had a lower limb amputation. People at risk of falls and people who have been referred for knee or hip surgery are likely to be aged 65 years and older.

	Age and disability are protected characteristics under the Equality Act.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	For some people, a self-help type solution may be an advantage for convenience, however others will place a high value on group activity and individualised support.	

3 Related NICE guidance

Published

- Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis (2022) NICE Interventional procedures guidance IPG726
- Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain (2021) NICE guideline NG193
- Magnetic resonance therapy for knee osteoarthritis (2021) NICE interventional procedure guidance IPG702
- Joint replacement (primary): hip, knee and shoulder (2020) NICE guideline NG157
- Platelet-rich plasma injections for knee osteoarthritis (2019) NICE interventional procedure guidance IPG637.
- Osteoarthritis: care and management (2014) Clinical guideline NICE guideline CG177
- Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (2014) NICE technology appraisal guidance TA304

- Falls in older people: assessing risk and prevention (2013) NICE guideline CG161.

In development

NICE is developing the following guidance:

- AposHealth for osteoarthritis (OA) of the knee NICE medical technology guidance. Publication expected March 2023

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- British Association of Surgery for the Knee
- British Hip Association
- British Orthopaedic Association
- British Society for Rheumatology
- Chartered Society of Physiotherapy
- NHS transformation directorate
- Primary Care Rheumatology Society
- Royal Collage of Nurses
- Society of Rehabilitative Medicine

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Africa Advocacy Foundation
- African Health Policy Network
- Age UK
- Arthritis Action
- Arthritis and Musculoskeletal Alliance (ARMA)
- Beth Johnson Foundation
- Black Health Agency (BHA) for Equality

- Bringing Us Together
- Carers Federation Limited
- Carers Trust
- CAUSE (NI)
- Chinese National Healthy Living Centre (CNHLC)
- Chinese Welfare Association (NI)
- Crossroads Caring for Carers - NI
- Dystonia Society
- Independent Age
- Life Story Network
- Lindsay Leg Club Foundation
- Mobility and Sickness Information Service
- Multiple Sclerosis Society (MS Society)
- Multiple Sclerosis Trust
- Multiple Sclerosis-UK
- National Voices
- The Patients Association (PA)
- The Relatives and Residents Association
- Tide
- Versus Arthritis
- Voice4Change England (V4CE)
- Walk Unlimited

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technologies guidance

GID-MT575 GaitSmart rehabilitation exercise programme

Company evidence submission

Company name: Dynamic Metrics Ltd

Submission date: 4th May 2023

Regulatory documents attached: List regulatory documents submitted, for example, UKCA or CE certificate/declaration of conformity, instructions for use; separate documentation (e.g. DTAC) may be available for digital technologies. We expect all regulatory documentation on submission.

Contains confidential information: Yes

Instructions for companies

This is the template for submission of evidence to NICE as part of the medical technologies evaluations process. Note that the information requirements for evidence submissions are summarised in this template; **full details of the requirements are in the user guide for company evidence submissions**

Please keep evidence submissions (including any supporting evidence) as succinct as possible by avoiding unnecessary repetition and keeping text relevant and focussed. If it is too long it will not be accepted.

Companies making evidence submissions to NICE should also refer to NICE health technology evaluations: the manual.

Contents

1 Decision problem, the technology and clinical context

1.1 Decision problem

Part of decision problem	Scope issued by NICE	Variation from scope (if applicable)	Rationale for variation
Population	People with gait and mobility issues, specifically: ● People aged 65 or older that are at risk of falling ● People referred for knee or hip surgery(pre-operative and post-operative management)	-	-
Intervention	GaitSmart programme including 4 GaitSmart assessments and personalised rehabilitation via the vGym app	The vGym exercises are integrated in to a protocol chosen by the user.	This is a clarification of the wording. The user chooses the protocol with exercises at the start of the process in the Smart App, there is no separate vGym App. The User proceeds through the test in exactly the same way whether exercises are chosen on not. The only difference is in the post processing which is done automatically.
Comparator(s)	• Visual assessment of gait by physiotherapist or occupational therapist including scales such as Tinetti Performance Orientated Mobility	-	-

	Assessment and the Timed Get up and Go Test score and • Exercise and rehabilitation (including supervised and independent exercise or rehabilitation and NHS group-based exercise), or • Devices for support (such as supports, other gait training tools, splints or braces), or • Pharmacological treatment such as intra-articular corticosteroids (osteoarthritis)		
Outcomes	The outcome measures to consider include: Outcome measures for effectiveness relevant to all populations: • Changes to gait, balance, mobility, and muscle weakness measures • Incidence of falls and associated injuries and hospitalisations • Patient reported outcome measures of pain • Patient reported outcome measures of functional ability • Health related quality of life (measures such as, EQ-5D and SF-36)	For the entire population our primary outcome is a change in gait. These includes gait speed, changes in gait kinematics (combined hip and knee range) and GaitSmart Score. Collectively they provide an accurate assessment of gait. Incidence of falls has been recorded, but because of the short timescales of the studies (9 weeks) no falls have been recorded.	Gait kinematic and temporal data is an objective assessment of a person's ability to walk. This data can be used directly to assess the probability of a fall, without the need to predict future events. It also makes the economic modelling more robust. Visual assessment has known limitations and lack of specificity [Toro 2003] and also requires a skilled physiotherapist. We have

	Outcomes measures for effectiveness in people who have suffered a fall or recurrent falls: • Change in number of falls • Patient fear of falling using the Falls Efficacy Scale – International (FES-I) • Patient frailty (using NHS validated tool such as, gait speed test, PRISMA-7 and up and go test) • STEADI assessment for screening patients for fall risk	Gait speed is a universally accepted metric that predicts functional ability and the level of risk for future adverse effects such as falls, reduced ADLs, institutionalisation and future hospital admissions [Abellan Van Kan 2009]. An increase in gait speed predicts a substantial reduction in mortality [Hardy 2007]. Our goal is that an improvement in gait will have a corresponding improvement in patient reported outcomes and reduce the number of falls. For people who have suffered a fall we also quote change in walking aid. We have determined the risk of	only used our objective gait assessment. We calculate muscle weakness and use this to determine the exercises. But we do not quote muscle activation. EQ-5D and SF-36 have been used in some of our studies. Incidence of falls has been recorded, but because of the short timescales of the studies (9 weeks) no falls have been recorded. Gait speed is a universally accepted metric that predicts functional ability and the level of risk for future adverse effects such as falls, reduced ADLs, institutionalisation and future hospital admissions [Abellan Van Kan 2009]. An increase in gait speed predicts a substantial reduction in mortality [Hardy 2007].

	Outcomes measures for effectiveness in people that have been referred for hip or knee replacement: • Delay of hip or knee surgery • Oxford hip score or Oxford knee score • Western Ontario and McMaster Universities Arthritis Index • Repeat surgery • Patient reported satisfaction with outcome of surgery Outcomes measures for resource use: • Further treatments (such as pain medication, corticosteroid use, surgery, days in hospital, and further rehabilitation) • Training time and costs for staff and non-registered support workers • Time needed to calibrate technology to ensure accurate measurements • Healthcare professional time (and banding) associated with patient follow up and care	falls, but not stated the number of falls prevented. For joint replacement, gait kinematics and gait speed provide a more objective assessment of outcomes. The combined hip and knee range provides objective data that can be referenced back to healthy subjects Further treatments were not captured in the 9 weeks programme. However, some are estimated in the economic model.	Hip and knee range correlates directly with an increased risk of falls. This is applicable to both patient groups, but more relevant to hip or knee replacement [Kerrigan 2001]. 36% and 39% of patients with hip and knee replacement respectively, suffered a fall within 12 months of operation [Chen 2019]. Training time for Users is 2 hrs. There is no calibration time to ensure accurate measurements. Healthcare professional time is included in the economic model

	• Admission or readmission to secondary or tertiary care Device-related outcomes measures • Rates of adherence to programme • Device related adverse events	Training in included in the one off setup and training cost. These are captured in the trials	
Economic analysis	Two models have been developed by the University of East Anglia, one for older people at risk of falls and one for post-op joint replacement	-	-
Other considerations, including issues related to equality	People who have difficulty accessing or using a device for the GaitSmart report and vGym exercise programme may be excluded from being able to use this technology. Patient-facing digital health technologies such as vGym exercise programme are delivered through a mobile phone or tablet. People will need regular access to a device with internet access to use the application. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies, do not have access to smart devices and may be	-	GaitSmart has been used over the years on people of all ages and levels of disabilities that affect mobility. The patient does not have any interaction with the technology so manual dexterity is not applicable. The concern regarding the patient accessing the technology has been considered. In all

	unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities. The technology may be unsuitable for some people who have had a lower limb amputation. People at risk of falls and people who have been referred for knee or hip surgery are likely to be aged 65 years and older.		applications over the last 10 years the people who undergo a GaitSmart test have their report provided before they leave the appointment. This negates the need for patients to access digital technologies. Only recently has direct access been offered for patients to view their report through a web browser. This facility is only enabled if the patient requests it and provides their email address. The report for GSI had a scientific appearance which was relatively difficult for a patient to understand. The Lead Nurse from North East London Foundation Trust (NELFT) worked with DML to develop a more patient-friendly report. This new format is used in GSII with very positive patient feedback.

	For some people, a self-help type solution may be an advantage for convenience, however others will place a high value on group activity and individualised support.		The technology will work with lower-limb amputees, although very few have been included in our studies. One longitudinal study over 2 years with an amputee attending a balance class showed the effectiveness of GaitSmart and exercises [Hodgins 2015] Many of the GaitSmart studies have been on patients over 65. The two large intervention studies on older people at risk of falls had an average age of 80. The majority also used a walker or frame and were considered frail or vulnerable. The joint replacement patients had an average age of 70.

1.2 The technology

Give the brand name, approved name and details of any different versions of the same device (including future versions in development and due to launch). Provide links to (or send copies of) the instructions for use for each version of the device.

Brand name: GaitSmart

Approved name: GaitSmart II

Any alternative names for technology (e.g. in the literature): None

UKCA/CE-mark class and date of authorisation: GaitSmart I Class 1. First registered November 2010. GaitSmart II Class 1m. First registered October 2020, CE 709431

Indications and any restriction(s) as described in the labelling or instructions for use (IFU): The GaitSmart®II device intended purpose is to measure the movement of the lower limbs of a human. You must observe the following safety instructions before use of this system. Intended user's only requirement is that they can walk 10-15 meters, this can include with a walking aid and/or prosthetic. To use the system training is required by Dynamic Metrics Limited. There is no requirement, previous experience or qualifications to receive this training. There are no specific indications or contra-indications beyond the patient selection criteria. Lower limbs must be covered, GSII straps must not be placed onto bare skin. The system must not be used if the client has any object impeding lower limb movement, such as a catheter bag.

Different versions of the same device

Version(s)	Date launched	Features
GaitSmart 1	Nov 2010	Stand alone system. Added exercise in 2016. Self certified. No longer available
GaitSmart II	Oct 2020	Cloud based system with fully automated personalised exercise plan if required

What are the key claimed benefits of using the technology for patients and the NHS?

Type of benefit	Description of benefit	Supporting evidence	Rationale
Patient	Reduces need for further treatment	Rodgers et al. 2020 (NELFT study) McNamara et al. submitted 2023 (NNUH study)	See text below
Patient	Improves mobility	Rodgers et al. 2020 (NELFT study) McNamara et al. submitted 2023 (NNUH study) Hodgins unpublished data 2023a (NHS Glasgow) Hodgins unpublished data 2023b (Care City) Walters 2018	See text below
Patient	Increases self management	Rodgers et al. 2020 (NELFT study) McNamara et al. submitted 2023 (NNUH study) Hodgings unpublished data 2023a (NHS Glasgow) Hodgings unpublished data 2023b (Care City) Walters 2018	See text below
Patient	Increases quality of life	McNamara et al. submitted 2023 (NNUH study) Hodgins unpublished data 2023a (NHS Glasgow)	See text below

System	Increases compliance	Rodgers et al. 2020 (NELFT study) McNamara et al. submitted 2023 (NNUH study) Hodgins unpublished data 2023a (NHS Glasgow) Hodgins unpublished data 2023b (Care City) Walters 2018	See text below
System	Lower grade of staff can deliver compared to current practice	Rodgers et al. 2020 (NELFT study) McNamara et al. submitted 2023 (NNUH study)	See text below
Sustainability	See text below	See text below	See text below

The GaitSmart intervention programme was developed to use GaitSmart kinematic data. With GaitSmart I, personalised exercises were calculated automatically using joint kinematic data. For GaitSmart II, the GaitSmart data provided the input to a musculoskeletal model, from which muscle weakness is identified and the most appropriate strength and balance exercises calculated. This is a more robust scientific solution.

Patient – Improves Mobility

Identifying gait deficiencies is an important first step in order to be able to improve mobility. The GaitSmart intervention programme works on the basis of (i) identifying deficiencies in gait kinematics, by comparing to a healthy reference, and (ii) determining the most effective strength and balance exercises that will strengthen the muscles known to be deficient and providing this list of exercises, with the gait report to the healthcare professional and client. The extensive systematic review of the literature that we have carried out provides further supporting evidence for this approach.

The first set of papers focus on measuring gait kinematics in the two populations being considered.

Identifying gait deficiencies

The publications quoted in the clinical evidence section support the claim that improved gait kinematics equates to improved mobility and this brings a number of benefits that can be quantified. Our publications provide the evidence that GaitSmart can quantify gait kinematics and show how these vary for an individual with reference to a healthy person. This data provides the baseline for our rehabilitation programme.

The first study defines how gait varies with age and gender in a healthy population. The Royal National Orthopaedic Hospital (RNOH) London used GaitSmart to identify gait kinematic parameters in healthy subjects over the age range 18-97 (Monda et al. 2015). This data provides the basis of a healthy reference for both patient cohorts.

Published evidence of how the GaitSmart measurement has been used to identify gait deficiencies in both patient cohorts is summarised. This evidence supports the rationale around accurately measuring gait kinematics to identify and quantify the severity of the gait deficiency.

Publications where GaitSmart has been used to quantify gait kinematic deficiencies pre and post hip and knee replacement quantify how the specific joint is affected and how this can also affect other joints (Blixt et al. 2017, Hanly et al. 2016, Rahman et al. 2015, Zugner et al. 2019). GaitSmart has also been used in a large European multisite 2-year longitudinal study on 300 patients with knee OA, alongside imaging, functional tests and PROMS. The published papers conclude that GaitSmart kinematic data is a more sensitive measure than functional tests (Chair Stands and 6 minute walk test) and changes over time correlate to a worsening of the condition (Jansen et al. 2023, van Helvoort et al. 2021, van Helvoort et al. 2022).

Individuals classified as frail or suffering from sarcopenia were included in intervention studies but not measured alone. A special article jointly authored by the CEO at DML, who is also a visiting professor at the University of Hertfordshire (UH) and a gait lab specialist at University College London (UCL) considered the evidence

for gait rehabilitation (Hodgins and McCarthy. 2015). The conclusion was gait kinematic data would help guide gait rehabilitation in both patient groups.

Interventions to improve mobility using GaitSmart data

There are four published studies [Balance Class, IMechE, Rodgers et al. 2020, Walters 2018] and one in review (Mcnamara et al. submitted 2023), which use GaitSmart data to guide rehabilitation for falls and joint replacement. These are supported by unpublished studies [NHS Glasgow, Care city] and more recent case studies [CUH and care home pilots].

For people at risk of falls, a 2-year longitudinal study was undertaken with eleven older adults, with a mean age of 78, participating in a balance class. This group had a range of conditions, including one with a below knee amputee who wore a prosthesis and one who had suffered a stroke. In this study the gait kinematic data was used by the balance class teacher to provide individuals with exercises to address their gait deficiencies. The reports provided the individuals with an understanding and to motivate them to do the exercises. This did result in improved gait kinematics after 2 years [Hodgins 2015], or improved mobility. No PROMS were collected in this study.

A more in-depth study included 121 older people, average age 79, under the care of a community hospital who followed the GaitSmart 1 intervention programme (Rodgers et al. 2020). GaitSmart Score, which is a summary of the gait kinematics, gait speed and the type of walking aid were all recorded. In addition, Fear of falling (FES-I) and Frailty (EFS) were collected. The change over the intervention period was statistically significant for each parameter, confirming it improved the mobility of these patients, reduced their reliance on walking aids, reduced their fear of falling and reduced their frailty level.

In 2015 GaitSmart was integrated with the Docobo Care Portal in a SBRI pilot. The goal was to have GaitSmart used by a volunteer at home and be guided through their rehabilitation by a remote clinician. A presentation at IMechE summarises the findings (Hodgins 2015). Whilst only a very small sample size it did show a system could be used at home and it could help in both diagnosis and rehabilitation.

GaitSmart was used in a PhD study 'Task-orientated rehabilitation can improve knee function and satisfaction in patients 12 months after knee replacement surgery for osteoarthritis'. Seventy-six patients one year post knee replacement surgery were tested (Walters 2018). Twenty-four had an OKS below 30 and 21 showed abnormal knee flexion in stance, with a good correlation between OKS and gait. Twenty-one with poor stance flexion underwent a task orientated rehabilitation programme to improve knee flexion in stance. All gait parameters and the OKS showed a statistically significant improvement between the start and the end of the programme. This further supports the argument that gait kinematics can effectively drive a rehabilitation programme and is affective one year post surgery.

The limitations of these studies was the lack of a control group.

The final case control study intervention study is currently under review (YMATH-D-23-00200). This study included 44 patients at Norfolk and Norwich University Hospital rehabilitating following total hip and knee replacement. There was a greater improvement in gait kinematics and gait speed for the intervention group compared to Standard of Care (SoC). Furthermore, hip and knee patients showed the same increase. When asked about their confidence in walking, a greater percentage of the intervention group were significantly more confident at the end of the programme than the SoC group (54% to 16%). The EQ5D (index and VAS) showed improvements for the intervention and SoC groups. For the OHS the SoC group showed greater improvement than the intervention group, whereas for the OKS the intervention group were greater. These results demonstrate that objective gait data improved for both hip and knee patients. However, the EQ5D and OHS/OKS score, which are patient reported outcomes, were more varied. The limitation of this study was the small cohort size.

Unpublished work

[redacted]

[redacted]

All of the above intervention studies demonstrate how the GaitSmart intervention programme [redacted].

Patients – Reduces need for further treatment

The GaitSmart intervention programme improves gait kinematics, which results in a more uniform gait which is closer to a healthy reference and a subsequent increase in gait speed. The GaitSmart programme has also demonstrated a self reported reduction in the fear of falling and frailty.

No long-term studies have been undertaken with GaitSmart so the statement that it reduces need for further treatment is supported by published evidence which correlate GaitSmart outcomes to adverse effects.

There is significant evidence that confirm [redacted], which increased in all of our studies [Rodgers et al. 2020, [redacted] is an excellent predictor of the overall state of healthy of an individual and adverse effects, which would require treatment. One review summarises this very well (Albellan et al. 2009).

In addition, one published and two unpublished GaitSmart studies collected [redacted] (Rodgers et al. 2020, [redacted]). These all demonstrated

[redacted]. This would reduce adverse outcomes and hence the need for further treatment (Clegg et al. 2013).

One published and two unpublished GaitSmart studies collected [redacted] [Rodgers et al. 2020, [redacted]]. These all demonstrated [redacted]. There are many published studies that look at the adverse effect for [redacted]. Two reviews (Denkinger et al 2014, MacKay et al. 2021) summarised the risk factors associated with [redacted] and found the related to impaired physical function and difficulties with activities of daily living. There is also a Cochran report (Kendrick et al. 2014) which looked at the effect of exercise and concludes that exercise may reduce [redacted] in the short term but long-term outcomes were less predictable. This may be because it is patient reported outcome, which may not relate directly to an objective metric such as gait speed. In our studies, it has been demonstrated [redacted].

Patients – Increases self-management

The GaitSmart four session programme requires the individual to attend four 20-30 minute sessions and then perform their personalised exercise plan at home. They are not required to complete a diary, visit a class or have any other enforced activity outside of these sessions.

The results from our intervention studies [Rodgers et al. 2020, [redacted]] [redacted]. [redacted].
The results show [redacted].

An earlier study on older people at risk of falling and attending a balance class were motivated to do their exercises by the GaitSmart report (Hodgins and McCarthy 2015) .

Another earlier study on 47 patients attending the Outpatient clinic of Professor Hart at RNOH London, showed patients found the report of value and would like the test to guide their rehabilitation (Hodgins and Hart 2016)

In addition, three gait days (appendix I) were arranged in 2015-2016 and whilst this data has not been published it does demonstrate the positive feedback from potential users. This feedback shows that the GaitSmart report provided attendees with an understanding of their gait issues and therefore the potential to address those issues and make clinical improvements.

Patients – Increases

[redacted]

System - Increases compliance

In each of our intervention programmes the number of people recruited and the number of people that complete the programme has been documented. In the [redacted].

In the Rodgers et al. (2020) study 169 participants were recruited and twenty-eight were unable to complete the programme for medical reasons. Of the remaining 141, twenty did not continue, resulting 86% compliance of those able to continue.

[redacted]

[redacted]

[redacted].

The PhD study (Walters 2018), which had its own Task Orientated Rehabilitation programme assessed 21 people over 4 weeks. No-one withdrew from the study.

The results for each of these trials have shown compliance is generally higher that for physiotherapy led programmes (McLean et al. 2010), where one study quoted 47% of patients attended all prescribed sessions (Lenguerrand et al. 2020).

System – Lower grade of staff can deliver compared to current practice

Gait assessment and personalised gait rehabilitation are currently provided by a physiotherapist.

[redacted]. Furthermore, the early study on people attending a Balance Class used a lower skilled provider to deliver their exercise programme based on the GaitSmart data (Hodgins and McCarthy 2015). It is therefore considered a fair statement that lower grade staff can deliver gait assessment and gait rehabilitation compared to current practice, potentially representing a cost saving and freeing up resources.

System – Is cost saving compared to current practice

The data provided in the economic model for the [redacted]

As described in the clinical review, there is a considerable body of evidence that shows that an improvement in gait kinematics and a corresponding increase in gait speed has a number of benefits. These include a reduced risk of falling, an improvement in Quality of Life (QoL), a reduction in the need for hospitalisation, an improvement in normal Activities of Daily Living (ADL).

For clinical review section

Knee OA is a significant risk factor for falls (Doré et al. 2015) due to muscle weakness, balance, gait deficiency and poor mobility (Rubenstein et al. 2006) and a further study concluded that gait deficiencies post knee replacement are the major risk of falls (Matsumoto et al. 2012). Need ref for Hip OA and THR. This supports our clinical and economic arguments that gait data is a good predictor for risk of falls.

Briefly describe the technology (no more than 1,000 words). Include details on how the technology works, any innovative features, and if the technology must be used alongside another treatment or technology.

The GaitSmart programme (Dynamic Metrics) comprises digital gait assessment with GaitSmart followed by personalised rehabilitation exercises.

GaitSmart is a sensor-based digital technology that monitors limb movement. The technology requires seven sensors to be placed on the pelvis, thigh and calf on either side of the body, as well as the base of the spine. Objective measurements are taken while walking. This data is used to calculate the gait kinematics, and by comparing this data to healthy reference values, it is possible to identify any problems with gait. The test takes 10 minutes to complete and can be done by a healthcare assistant in a variety of settings.

Information from the sensors is automatically processed to produce a colour-coded report that helps the healthcare professional and client to understand the gait issue and its severity. The GaitSmart gait assessment is used with an integrated app vGym which provides a personalised rehabilitation programme, consisting of 6 exercises, to help improve mobility, specifically gait. The report also includes photos and descriptions of each exercise. Once allocated to the programme, each person is expected to do four GaitSmart gait assessments, each at least 3 weeks apart. Each gait assessment identifies any improvements in gait and mobility and the exercises are automatically altered accordingly. All the exercises are load bearing and are generally available from the NHS as strength and balance exercises.

There are a number of innovative features with the GaitSmart system.

- Fully automated process to identify a gait cycle from the sensor data and extract key gait kinematic features
- Presentation of the gait data using traffic light coding and scoring to aid understanding for clinicians and clients
- Calculation of muscle weakness from gait kinematic data
- Automated process to produce personalised exercise programme

Collectively this provides a data driven gait assessment and gait rehabilitation programme that provides accurate and repeatable results. This means that subtle changes in gait will be identified in follow up tests that aren't visible to the human eye. For example, if the knee range of motion in the swing phase increases from 50° to 52° between two sessions, the client sees that the exercises are helping. This encourages the client to continue their exercises and over four sessions significant improvements may be realised. It removes the subjectivity associated with gait assessment by a physiotherapy and the corresponding strength and balance exercises they may provide.

The system does not need to be used alongside any other technology.

Provide an assessment of whether the use of this technology is likely to raise any equality issues.

The system is portable and can therefore be used at any healthcare clinic or at a community setting. The person can be of any age, ethnicity or gender and can use any walking aid. The client can receive a hard copy of the report and does not need to use the technology. The healthcare assistant places the straps over clothing and then provides instructions on when to walk.

The exercises include a photo of how to perform the exercise plus a simple description. The exercises are load bearing and simulate part of the gait cycle, so if the client is able to walk they should be able to perform the exercises. The healthcare assistant much run through the exercises before the client leaves the appointment.

Those with cognitive impairment may need prompts to do their exercises. There is no strict protocol for when clients should perform their exercises so can adapt around when support is available.

Those with visual impairment may find the 10m walk test and undertaking exercises difficult.

Briefly describe the environmental impact of the technology and any sustainability considerations (no more than 1,000 words).

GaitSmart's data supports diagnosis and the personalised exercise plan encourages self-management.

For the two different patient groups under consideration this supports net zero personalised care. Firstly there are anticipated benefits of providing an assessment and personalised exercise plan in one visit.

For people at risk of falling it provides two functions in one assessment. The GaitSmart data provides an objective assessment of gait, and the exercise programme provides part of the individualised intervention. Both are recommended in the NICE Guidelines and would involve the individual travelling to a specialist assessment centre where a skilled physiotherapist would perform the assessment. It

may also require an additional appointment for follow up. For the GaitSmart assessment this could be performed locally, thus reducing travel and hence the environmental impact.

For people referred for surgery, a GaitSmart assessment as part of pre-operative management will provide an exercise programme to enable the individual to strengthen muscles in preparation for surgery. This could reduce the hospital stay time and the corresponding environmental impact. For post-operative management, rehabilitation programme could be provided locally, and the number of visits tailored to the individual's objective gait data. Research shows that people waiting for hip or knee replacement become less active due to pain when walking, with increased risk of falling due to their poor gait. Reduced activity often leads to muscle wastage, weight increase, more frequent visits to the GP, higher consumption of pain killers and general deconditioning. The result is an increased risk of complications following the procedure and longer recovery time in hospital, leading to a greater number of bed-days. Additionally, post-operative rehabilitation may require specialist physiotherapy and, in extreme cases, the patient may lose their mobility. Collectively this would provide a corresponding reduction in the environmental impact for managing gait retraining.

For both cohorts, the overall aim of the GaitSmart intervention programme is to reduce adverse effects such as falls and to improve normal activities of daily living and an individual's Quality of Life. Our clinical and economic evidence suggests that with both cohorts there is an improvement in gait and this corresponds to a reduction in the risk of falls.

Whilst an environmental impact model has not been produced, it would be feasible to assume that the reduction in risk of falls alone would have a positive impact on the environment.

With respect to the GaitSmart system, all components are reusable and it is manufactured in the UK.

1.3 Clinical context

Describe the current use of the technology in the NHS (e.g. number of hospitals using technology)

[redacted]

[redacted]

Describe the clinical care pathway(s) that includes the proposed use of the technology, ideally using a diagram or flowchart. Provide source(s) for any relevant pathways.

[redacted]

Describe any training (for healthcare professionals and patients) and system changes that would be needed if the NHS were to adopt the technology.

When NHS Users contact us requesting more information regarding GaitSmart, we offer a conference call to discuss the system and their interest. On this call we run through our presentation. The current version is Generic MSK Presentation V4 and is provided in the submission documents. We would then send a copy of the presentation plus an example report for their internal distribution, also provided in the submission documents.

Once an order is received a training day is agreed. DML do not limit the number of people who can be trained.

The company has developed two training modules and delivered these to our users within the NHS.

The first module is how to use the system and includes information on how the system works, where data is stored and accessed and why this information is useful to both the healthcare provider and the client. This typically takes 2 hours. Users are then asked to perform a test on their own. A training certificate is provided once a successful test has been completed.

The second training module is to help users understand the GaitSmart data so that they can explain it to their clients. This can be done remotely and a training certificate issued when they have answered questions successfully on gait profiles provided.

2 Clinical effectiveness evidence

2.1 Identification and selection of studies

Complete the following information about the number of studies identified.

Report in full transparent and reproducible detail the search methods as used for all search resources, and provide a detailed list of any excluded studies, in appendix A. Number of studies reported below should be after any duplicates have been removed.

The clinical evidence identification contains two subsections, research projects evaluating the GaitSmart programme and a systematic search. The systematic search is further divided into four, identifying studies for falls risk and rehabilitation in both of the specified populations detailed in the scope (People aged 65+ and people referred for knee or hip surgery). The studies evaluating the GaitSmart programme are shown in Tables 1 to 3, these are additionally present in Appendix H: References and Tables, where each paper included and excluded has a hyper link provided. Where unpublished data has been used the paper or proceedings has been submitted as additional material.

Research projects evaluating the GaitSmart programme

Number of studies identified as being relevant (i.e. directly relevant to the decision problem by ensuring it fits the eligibility criteria outlined in the scope)	16
Of the relevant studies identified, the number of published, peer-reviewed full-text studies	11
Of the relevant studies identified, the number of conference abstracts.	2
Of the relevant studies identified, the number of unpublished (without peer-review) studies	3

Systematic search

Number of studies identified in a systematic search: *People referred for knee or hip surgery (appendix H tab: Joint Replacement)*	184
Number of studies identified as being relevant (i.e. directly relevant to the decision problem by ensuring it fits the eligibility criteria outlined in the scope)	19, of which two where systematic review
Of the relevant studies identified, the number of published, peer-reviewed full-text studies	19
Of the relevant studies identified, the number of conference abstracts.	none
Of the relevant studies identified, the number of unpublished (without peer-review) studies	none

Number of studies identified in a systematic search. *Rehabilitation for people referred for knee or hip surgery (appendix H tab: Joint Replacement Rehab)*	86
Number of studies identified as being relevant (i.e. directly relevant to the decision problem by ensuring it fits the eligibility criteria outlined in the scope)	24
Of the relevant studies identified, the number of published, peer-reviewed full-text studies	24
Of the relevant studies identified, the number of conference abstracts.	none
Of the relevant studies identified, the number of unpublished (without peer-review) studies	none

Number of studies identified in a systematic search. *People aged 65 or older that are at risk of falling (appendix H tab: Falls Risk)*	253
Number of studies identified as being relevant (i.e. directly relevant to the decision problem by ensuring it fits the eligibility criteria outlined in the scope)	33
Of the relevant studies identified, the number of published, peer-reviewed full-text studies	33
Of the relevant studies identified, the number of conference abstracts.	none
Of the relevant studies identified, the number of unpublished (without peer-review) studies	none

Number of studies identified in a systematic search. *Rehabilitation for people aged 65 or older that are at risk of falling (appendix H tab: Falls Rehab)*	125
Number of studies identified as being relevant (i.e. directly relevant to the decision problem by ensuring it fits the eligibility criteria outlined in the scope)	15
Of the relevant studies identified, the number of published, peer-reviewed full-text studies	15
Of the relevant studies identified, the number of conference abstracts.	none
Of the relevant studies identified, the number of unpublished (without peer-review) studies	none

2.2 List of relevant clinical effectiveness studies

In table 1 give brief details of all studies identified as relevant (consider the decision problem, particularly the eligibility criteria of studies).

For any unpublished studies, please provide a structured abstract in appendix A. If a structured abstract is not available, you must provide a statement from the authors to verify the data.

Any data that is submitted in confidence must be correctly highlighted. See section 1 of the user guide for how to highlight confidential information. Include any confidential information in appendix F. Please provide details as to how the systematic reviews have been carried out, including the number of reviewers.

Table 1 Summary of all clinical effectiveness studies (published full text, abstracts and unpublished) identified as being relevant (i.e. directly relevant to the decision problem by ensuring it fits the eligibility criteria outlined in the scope)

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
NELFT - Rodgers, G., Mottley, A., & Hodgins, D. . (2020). Novel Digital Gait Kinematic Solution to Improve Frailty . British Journal of Healthcare and Medical Research, 7(5), 01–10. https://doi.org/10.14738 /jbemi.75.8894	Introduction: Frailty effects a person's health and correlates with mobility and falls. Intervention studies that focus on exercise have demonstrated improved mobility and functional ability in some frailty groups. This study tested a personalised intervention programme generated from digital gait data on frail older people under the care of the North East London Foundation Trust, Community Hospital setting.	Methods: One hundred and twenty one people, average age 79, who suffered an injurious fall and were under the care of the Community Hospital, completed the personalised intervention programme. Objective gait kinematic data, obtained using GaitSmart generated a personalised exercise programme. Each participant received four tests, approximately 3 weeks apart and was provided with a copy of their report plus personalised exercises. Frailty was measured using the Edmonton Frailty Scale (EFS), fear of falling was measured using the Falls Efficacy Scale-International (FES-I) and speed was determined from the gait data (GS).	Results: Five parameters were analysed for all 121 participants at the start and end of the intervention: EFS; FES-I; GaitSmart Score; speed; walking aid. There was a statistically significance between the start and end ($p<0.001$) for all the parameters.	The results demonstrate that addressing frailty using a digital gait solution that sets exercises based on the gait kinematic data, did reverse frailty. This four session programme has shown to improve frailty levels and fear of falling. It also reduced the reliance on walking aids and increased average walking speed from 0.46 to 0.62 m/s.

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
	[redacted]			
PhD - Walters, Yelena. (2018). Task-orientated rehabilitation (TOR) can improve knee function and satisfaction in patients 12 months after knee replacement surgery for osteoarthritis.	This study tested the hypothesis that TOR can improve gait and patient reported functional outcome following TKA. Patient reported functional outcome was assessed using the Oxford Knee Score (OKS) and gait characteristics were measured using inertial measurement units (IMUs). A subset of 21 patients, exhibiting abnormal gait, entered a 4-week TOR programme, based on daily walking and stair climbing. Patients were re-assessed with OKS and IMUs, and gait quantity compared pre- and post-intervention using pedometers. A subset of 4 patients' baseline gaits was compared to 5 controls, and to their own gait following the TOR, while subjected to differing treadmill conditions	Seventy six patients were studied 12 months after TKA during follow up at the Royal National Orthopaedic Hospital, Stanmore	Multiple regression analysis showed that stride duration significantly predicted OKS ($p<0.0001$, $n=76$). Higher OKS was observed in patients who have shorter stride duration, which was in turn a result of greater RoM of the leg joints and segments in the sagittal plane. Following TOR, 21 patients exhibited a significantly higher OKS ($p=0.001$, $n=21$). Stride duration, thigh, knee and calf sagittal range of motion and knee flexion in stance also significantly increased in both limbs following TOR.	The results indicate that there is scope to improve rehabilitation of patients after TKA, even after one year. This intervention programme is not the same as the GaitSmart programme as it focusses on one aspect of gait, knee flexion on load. However, what it does demonstrate is that with knowledge of a gait deficiency a focussed intervention programme to address the deficiency does improve gait and patient reported outcome measures for TKA patients accordingly,

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
Blixt S. Patient-reported Mobility Problems after Total Hip Arthroplasty. https://gupea.ub.gu.se/handle/2077/45217	Since 1979 the Swedish Hip Arthroplasty Register (SHAR) has been gathering data on patients being operated with a total hip prosthesis in Sweden. In 2002 SHAR introduced measurement of patient-reported outcomes (PROM) [1]. Six years later all Swedish hospitals were participating in this program. PROM-data are collected preoperatively and one, six and 10 years postoperative. One-year postoperative 14% of patients report having mobility problems associated with the operated hip. The purpose of this study was to determine whether the patient reported problems with mobility can be identified using gait analysis.	Patients operated at Sahlgrenska University Hospital during years 2011-2013, reporting problems with the mobility 1 year postoperatively were identified (n=54). 25 patients (Group I) accepted participation. A matched cohort (Group II, n=25), reporting no problems with mobility was included as controls. A portable gait analysis instrument was used to analyse the gait pattern.	Patients reporting problems with mobility had a lower range of motion in the operated hip (p=0.04).	Our study shows a correlation between patient-reported mobility problems one-year post surgery and decreased hip range of motion measured with GaitSmart. This supports our argument that gait deficiencies are associated with patient reported outcomes (PROMS). It is therefore a fair assumption that improving gait kinematics will have a corresponding improvement in PROMS.

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
E.M. van Helvoort et al. Motion analysis using the GaitSmart system in the IMI-APPROACH cohort. Osteoarthritis and Cartilage Abstract only Volume 29 Supplement 1 S22-S24 April 1st 2021	To assess underlying domains measured by GaitSmart parameters and whether these are additional to established OA markers including patient reported outcome measures (PROMs) and radiographic parameters, and to evaluate if GaitSmart analysis is related to the presence and severity of radiographic knee OA.	GaitSmart analysis was performed during baseline visits of participants of the APPROACH cohort (n = 297). Principal component analyses (PCA) were performed to explore structure in relationships between GaitSmart parameters alone and in addition to radiographic parameters and PROMs. Logistic and linear regression analyses were performed to analyse the relationship of GaitSmart with the presence and severity of radiographic OA (Kellgren and Lawrence grade ≥2 in at least one knee).	Two hundred and eighty-four successful GaitSmart analyses were performed. The PCA identified five underlying GaitSmart domains. Radiographic parameters and PROMs formed additional domains indicating that GaitSmart largely measures separate concepts. Several GaitSmart domains were related to the presence of ROA as well as the severity of joint damage in addition to demographics and PROMs with an area under the receiver operating characteristic curve of 0.724 and explained variances (adjusted R2) of 0.107, 0.132 and 0.147 for minimum joint space width, osteophyte area and mean subchondral bone density, respectively.	GaitSmart analysis provides additional information over established OA outcomes. GaitSmart parameters are also associated with the presence of ROA and extent of radiographic severity over demographics and PROMS. These results indicate that Gaitsmart may be an additional outcome measure for the evaluation of OA.

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
Hanly, R., Doyle, F., Whitehouse, S. and Timperley, A. (2016) "OUTPATIENT 3-D GAIT ANALYSIS ONE YEAR AFTER THA USING A PORTABLE IMU SYSTEM." Orthopaedic Proceedings, 98-B(SUPP_11), pp. 1-1. Available at: https://doi.org/10.1302/1358-992X.98BSUPP_11.BHS2016-001	Post-operative gait abnormalities are recognized following total hip arthroplasty (THA). Despite global improvement in functional outcome, gait abnormality persists for a decade or more. In this study 3-dimensional gait analysis (3DGA) was performed using a portable system with Inertial Measurement Units (IMUs) to quantify this abnormality.	The gait of 55 patients with monarthrodial hip arthrosis was measured pre-operatively and at one year post-surgery. Patients with medical co-morbidity or other conditions affecting their gait were excluded. Six IMUs were aligned at the level of the anterior superior iliac spines, mid-thigh and mid-leg. Data was analysed using proprietary software. Each patient underwent a conventional THA using a posterolateral approach. 92 healthy individuals were assessed for comparison.	Pre-operative movement in the sagittal plane of the ipsilateral hip (mean range 20.4) and the contra-lateral non-diseased hip (35.3 degrees) was reduced compared to the control group (40.5 degrees), (P<0.001). The pre-operative movement of both knees was reduced compared with normal (P<0.001). Pelvic movement on the ipsilateral side was increased. After one year ipsilateral hip movement significantly improved (Mean range 28.9 deg SD 6.6) but did not reach normal values (P<0.001). Movement measured in the contralateral hip was further reduced with a mean difference of −5.25 degrees (95% CI −8.06 to −2.43). Knee movement on both sides increased but not to normal values (p<0.001). There was increased coronal movement bilaterally at the thigh and calf one year after surgery.	Gait after routine THA may not return to normal. Unilateral hip pathology causes bilateral gait abnormality affecting the entire kinematic chain. GaitSmart is a portable technology which allows practical assessment of gait in the outpatient setting and will enable identification of key aspects of gait abnormality to target during rehabilitation following THA.

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
Hodgins D, Hart A. Gait monitoring using inertial measurement units in an orthopaedic outpatient clinic: IET conference Human motion analysis for healthcare applications 2016.	a) to ascertain whether a portable Gait Monitoring system could be used in an Orthopaedic Out Patient Clinic without disrupting the flow or delaying the consultant. b) to capture the user experience.	47 patients attending the Out Patient Clinic of one consultant were invited to take a gait test over a 2 month period. • Each measurement took around 10 minutes. • Patients were shown their report. • A further 5 minutes was normally given to explain the results.	The 15 minute slot was taken from their waiting time and on no occasion was the patient late for their appointment. All found the information useful and would like to be monitored throughout their recovery. All of the gait data was shared with the consultant. In most cases it provided a reference to support their treatment. In two cases additional action was required to assist in the future care of the patient.	DML demonstrated that our portable gait monitoring equipment can be used in an Out Patient Clinic without affecting the flow. Patients responded favourably to the test and found the information understandable and helpful and wanted to continue to be monitored. The data enabled the patients to understand their specific limitations regarding mobility, thus enabling them to take responsibility of their own outcomes. As with all medical sectors, measurements are becoming more routine and patients both like and expect it. Now that the technology is available for routine use in a clinic it is anticipated that gait monitoring will be an integral part of orthopaedic rehabilitation
Hodgins, Diana & Mccarthy, Ian. (2015). How measuring an older person's walking pattern can help keep them mobile 'Personalised healthcare for mobility'.	One of the common causes of falls is gait deficiency and the first aim of the study was to understand how specific gait parameters of elderly people with gait and balance issues compare to those of the healthy elderly population	Eleven 'at risk' elderly people were compared with eighteen healthy people. The aim was to explore the potential of using objective data to support personalised exercise over a two year period to help prevent falls. The 'at risk' group attended a weekly balance class and were monitored regularly.	The results indicate that gait can be adapted by instruction and exercises. Regular monitoring provided the participants with the incentive to continue with the exercises. No participant fell during the monitoring period and all remained active.	These results indicate that it is possible to personalise exercises and provide motivation using gait data and this could potentially reduce falls in the elderly.

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
M.P Jansen et al. Can gait patterns in knee osteoarthritis patients be explained or predicted by joint structure. Poster at OARSI 2023	Gait changes in knee osteoarthritis is most often considered associated with knee pain. However structure might have an effect, indirectly through pain or directly e.g. osteophytes APPROACH cohort Objective to evaluate whether: Structural joint characteristics and gait parameters are associated (cross-sectionally)	In the observational IMI-APPROACH study, 297 participants with clinical knee OA were included in five centres throughout Europe and followed for two years.	Of the 297 participants in IMI-APPROACH, 271 had baseline gait measurements and imaging and thus could be included in the analyses. Of those, 122 (45%) participants did not have ROA. Baseline characteristics and joint structure parameters of both groups was compared to gait kinematic data. The conclusion was joint structure could partially explain gait deficiencies and even predict gait changes in people with knee OA..	This large database with GaitSmart data has enabled other researchers to explore how gait changes and what causes these changes over time. Structure has been shown to have an effect.
Monda M, Goldberg A, Smitham P, Thornton M, McCarthy I. Use of inertial measurement units to assess age-related changes in gait kinematics in an active population. J Aging Phys Act. 2015 Jan;23(1):18-23. doi: 10.1123/japa.2012-0328. Epub 2013 Dec 4. PMID: 24306618.	To study mobility in older populations it can be advantageous to use portable gait analysis systems, such as inertial measurement units (IMUs), which can be used in the community	To define a normal range, 136 active subjects were recruited with an age range of 18 to 97. Four IMUs were attached to the subjects, one on each thigh and shank. Subjects were asked to walk 10 m at their own self-selected speed. The ranges of motion of thigh, shank, and knee in both swing and stance phase were calculated, in addition to stride duration.	Thigh, shank, and knee range of movement in swing and stance were constant for each healthy people from 18-80. There was a slight change for people in the > 80 age group. Stride duration showed a weak linear relationship with age, increasing by approximately 0.1% per year.	This data provides the healthy reference data and is the basis for estimating gait changes due to medical conditions.

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
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 Musculoskelet Disord. 2015 Mar 22;16:66. doi: 10.1186/s12891-015-0525-2. PMID: 25886558; PMCID: PMC4374376.	Background: The aim of the study was to assess gait in total knee arthroplasty (TKA) patients, using a technique that can to be used on a routine basis in a busy orthopaedic clinic.	Methods: A total of 103 subjects were recruited: 29 pre-op TKA patients; 17 TKA patients at 8 weeks post-op; 28 TKA patients at 52 weeks post-op; and 29 age-matched controls. Inertial measurement units (IMUs) were used to assess gait. Limb segment angles, knee angle and temporal parameters of gait were calculated. Specific gait parameters were quantified, and data analysed using MANOVA and discriminant analysis.	Results: The gait of TKA patients as a group was only slightly improved at 12 months when compared with the pre-operative group, and both groups were significantly different to controls in several variables. Knee flexion range in stance was the most important variable in discriminating between patients and controls; knee flexion range in swing was the only variable that showed a significant difference between pre- and post-operative patients. When considered individually, only 1/29 patient was within the normal range for this variable pre-operatively, but 9/28 patients were within the normal range 12 months post-operatively.	This study provides the evidence that even after 12 months after surgery, many TKA patients have not improved their gait relative to pre-operative patients or reached the values of a healthy reference. Routine gait assessment may be used to guide post-operative rehabilitation, and to develop strategies to improve mobility of these patients.

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
Redesigning rehabilitation services for total hip and knee arthroplasty using telehealth. Hodgins D.Conference Proceedings IMechE. Hip Surgery: A joint engineering and surgical challenge (Nov 2015)	Pilot study to indicate whether gait data: -in the home plus targeted physio can improve outcomes for joint replacement -can help provide personal diagnosis for individuals with poor mobility	Male, post unilateral hip replacement – Monitored twice weekly over 7 month period Female, living at home, poor mobility – Monitored over a 2 week period Male, previous hip and knee replacement – Monitored twice	THR patient a) At one week it was possible to provide a 'Start Point' for the patient. b) After 3 months range had improved significantly on the operated side, but still outside normal limits. c) Signed off by physio and subsequent plateau from 3-6 months. d) Focused rehab at 6 months to initiate further improvement. e) After 7 months the range of motion on both hips is within normal range, but asymmetry needs to be improved. f) Monitoring and focused input enabled this person to resume an almost normal gait after 7 months and there continues to be improvement <u>Older person</u> a) When examined it was found that the right hip had severe OA and a replacement hip was necessary. Without surgery her risk of falling or becoming immobile was very high	- Patient with THR benefited from gait data plus targeted input - Frail person was easily diagnosed and now awaiting surgery - Person with no targeted physio after knee and hip replacement has very poor gait and is now suffering pain and mobility issues

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
van Helvoort EM, Hodgins D, Mastbergen SC, Marijnissen ACA, Kloppenburg M, Blanco FJ, Haugen IK, Berenbaum F, Lafeber FPJG, Welsing PMJ. GaitSmart motion analysis compared to commonly used function outcome measures in the IMI-APPROACH knee osteoarthritis cohort. PLoS One. 2022 Mar 23;17(3):e0265883. doi: 10.1371/journal.pone.0265883 . PMID: 35320321; PMCID: PMC8942249.	There are multiple measures for assessment of physical function in knee osteoarthritis (OA), but each has its strengths and limitations. The GaitSmart system, which uses inertial measurement units (IMUs), might be a user-friendly and objective method to assess function. This study evaluates the validity and responsiveness of GaitSmart motion analysis as a function measurement in knee OA and compares this to Knee Injury and Osteoarthritis Outcome Score (KOOS), Short Form 36 Health Survey (SF-36), 30s chair stand test, and 40m self-paced walk test.	The 2-year Innovative Medicines Initiative—Applied Public-Private Research enabling OsteoArthritis Clinical Headway (IMI-APPROACH) knee OA cohort was conducted between January 2018 and April 2021. For this study, available baseline and 6 months follow-up data (n = 262) was used. Principal component analysis was used to investigate whether above mentioned function instruments could represent one or more function domains. Subsequently, linear regression was used to explore the association between GaitSmart parameters and those function domains. In addition, standardized response means, effect sizes and t-tests were calculated to evaluate the ability of GaitSmart to differentiate between good and poor general health (based on SF-36). Lastly, the responsiveness of GaitSmart to detect changes in function was determined.	KOOS, SF-36, 30s chair test and 40m self-paced walk test were combined into two function domains :performance based (objective function) or self-reported (subjective function) function. It was found that GaitSmart parameters were able to distinguish a difference in general health status, and was responsive to changes in the different aspects of objective function	GaitSmart analysis can reflect performance based and self-reported function and may be of value in the evaluation of function in knee OA.
Heaps J. Inertial Measurement Unit Characterisation for Gait Analysis. 3DMC 2019 Here East, London 5 –7 November 2019	Evidence of the accuracy of the IMU in normal cyclic motion,	Photogrammetry system developed by the National Physical Laboratory (NPL) compared to the IMU from GaitSmart 1 and GaitSmart II	The accuracy for both IMUs was within 0.1° compared to SI units	This is the evidence that the dynamic accuracy of both of our systems quoted is well within 1°.

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
Zügner R, Tranberg R, Timperley J, Hodgins D, Mohaddes M, Kärrholm J. Validation of inertial measurement units with optical tracking system in patients operated with Total hip arthroplasty. BMC Musculoskelet Disord. 2019 Feb 6;20(1):52. doi: 10.1186/s12891-019-2416-4. PMID: 30727979; PMCID: PMC6364439.	Background: Patient reported outcome measurement (PROMs) will not capture in detail the functional joint motion before and after total hip arthroplasty (THA). Therefore, methods more specifically aimed to analyse joint movements may be of interest. An analysis method that addresses these issues should be readily accessible and easy to use especially if applied to large groups of patients, who you want to study both before and after a surgical intervention such as THA. Our aim was to evaluate the accuracy of inertial measurement units (IMU) by comparison with an optical tracking system (OTS) to record pelvic tilt, hip and knee flexion in patients who had undergone THA.	Methods: 49 subjects, 25 males 24 females, mean age of 73 years (range 51-80) with THA participated. All patients were measured with a portable IMU system, with sensors attached lateral to the pelvis, the thigh and the lower leg. For validation, a 12-camera motion capture system was used to determine the positions of 15 skin markers (Oqus 4, Qualisys AB, Sweden). Comparison of sagittal pelvic rotations, and hip and knee flexion-extension motions measured with the two systems was performed. The mean values of the IMU's on the left and right sides were compared with OTS data.	Results: The comparison between the two gait analysis methods showed no significant difference for mean pelvic tilt range (4.9-5.4 degrees) or mean knee flexion range (54.4-55.1 degrees) on either side ($p > 0.7$). The IMU system did however record slightly less hip flexion on both sides (36.7-37.7 degrees for the OTS compared to 34.0-34.4 degrees for the IMU, $p < 0.001$).	Conclusions: We found that inertial measurement units can produce valid kinematic data of knee and hip flexion-extension range. The small difference in hip range between the two systems is considered to be due to the difference in the modelling of the pelvis.
Systematic Search: People aged 65 or older that are at risk of falling	Appendix: H	Appendix: H	Appendix: H	Appendix: H
Systematic Search: Rehabilitation for people aged 65 or older that are at risk of falling	Appendix: H	Appendix: H	Appendix: H	Appendix: H
Systematic Search: People referred for knee or hip surgery(pre-operative and post-operative management)	Appendix: H	Appendix: H	Appendix: H	Appendix: H

Study name, location, status and funding	Design and intervention(s)	Participants and setting	Main outcomes	Company comments
Systematic Search: Rehabilitation for people referred for knee or hip surgery(pre-operative and post-operative management)	Appendix: H	Appendix: H	Appendix: H	Appendix: H

Key: ☑ aspect of study in scope; ☒ aspect of study in scope ☑☒ aspect of study partially in scope, or elements of this are not in scope.

Systematic search summary:

People aged 65 or older that are at risk of falling

These papers demonstrate age-related changes in gait demonstrating the clinical need to provide personalised intervention to the population of people aged 65 or older that are at risk of falling (Alcock et al. 2013, Boelens, et al. 2013, Menz et al. 2003, Santos Bueno et al. 2019). While the studies evidence the association between poor gait and increased risk of falls, there is also evidence of the underlying factors contributing to poor gait development such as physical inactivity and reduced muscle strength (Cabell et al. 2013, Lim et al. 2022). This provides support for the implementation of the personalised exercise programme vGym, targeting an individual's muscle weakness to improve gait, which in turn, would reduce the risk of falls and reduce the potential need for treatment from future incidences.

These papers provide evidence for measuring gait kinematic data and the association with the risk of falls, where people at higher risk can be identified through kinematic data analysis (Marques et al. 2017, Marques et al. 2018, Marques et al. 2021, Martinez et al. 2019, Porta et al. 2020, Smith et al. 2022). Others investigate the relationship between the risk of falls and speed (Callisaya et al. 2012, Oliveira et al. 2017, Schulz. 2017, Mademli et al 2014). Collectively they support the GaitSmart and vGym programme that intervenes to improve mobility through the kinematic quality of gait, which subsequently reduces their risk of falls. This can be said to increase the quality of life for the patient.

These studies provide evidence for individual elements of the GaitSmart and vGym protocol inducing evidence that a sensor-based assessment can be conducted on the older population (Howcroft et al. 2017). A link between measurements on a flat surface and risk of tripping (Benson et al 2018), evidences that IMUs can detect disturbances in gait (Nouredanesh et al. 2020). Evidence to support the measurement of dynamic gait instead of standing posture (Lee at al. 2005) and support for providing a system that can provide an accurate automated assessment of falls risk in comparison to the timed up and go test (Greene et al. 2010) allowing timely intervention and ease the burden on overstretched healthcare system.

Rehabilitation for people aged 65 or older that are at risk of falling

These studies demonstrate that exercise or increased physical activity can be an effective intervention for improving mobility in older adults (Granacher et al. 2021, Morat et al. 2020, Sadeghi et al 2021, Saleh et al. 2019). In addition, these studies support the implementation and

suitability of an individualised exercise programme (Okubo et al. 2019) that can be completed in the patient's home (van Diest et al. 2016).

These studies provide evidence that exercise can improve gait kinematic parameters that are related to falls (Byl et al. 2015, DiBenedetto et al. 2005 Fujita et al. 2020, Schafer et al. 2018, Skiadopoulos et al 2021) in frail and older populations (Fiatarone et al. 1990, Fujita et al. 2021, Persch et al. 2009). A further study provides evidence that the reduced risk of falls is due to improvements in gait following an exercise programme (Apóstolo et al 2019).

People referred for knee or hip surgery (pre-operative and post-operative management)

These papers describes the use of the Rehagait IMU system to measure gait kinematics and spacial/ temporal data pre and post hip replacement and pre knee replacement. Whilst conclusions don't fully align with GaitSmart findings, they do all suggest similar gait deficiencies to GaitSmart for each patient cohort. The papers support the use of IMUs for gait kinematic assessment in these cohorts (Son and Lee. 2023, Kaufmann et al. 2023 Ismailidis et al. 2021, Ismailidis et al, 2020).

These papers use a gait lab to analyse gait kinematics. They do conclude that knowledge of the gait kinematics pre and post op are beneficial and identify where issues remain post op. This data could help guide gait rehabilitation or explain low patient reported outcomes post op (Kurihara et al. 2022, Booij et al. 2021, Kurihara et al. 2021, KolÁŘovÁ et al. 2020, Ro et al 2018, Hajduk et al 2016). One paper (Burnett et al. 2015) shows how gait kinematics differ between knee OA patients with and without lower back pain.

This systematic review and meta-analysis discusses the benefits of using gait kinematics to differentiate between two types of surgery. Whilst gait speed was one outcome, a second key outcome was hip flexion. This conclusion shows the value of capturing gait kinematics to support surgical techniques (Yoo et al. 2019)

Further reading on topic:

Gait abnormalities can increase the risk of developing OA in other joints (Shakoor et al. 2002, van Drongelen et al. 2020). These studies use an optical gait lab and musculoskeletal modelling to look at the joint contact forces post-surgery. Whilst the conclusions between studies varied, this is likely due to the way different patients rehabilitate post-surgery by strengthening weakened muscles. This is relevant to the GaitSmart procedure because it too measures gait kinematics and

uses this data to identify muscle weakness. If the muscle weakness is corrected then normal joint contact forces will be realised and OA in other joints can potentially be avoided.

Because patients are generally unaware of how their walking pattern has adapted, many continue with their abnormal pattern of joint loading and muscle usage. In the longer term, the lack of correction of gait abnormalities can lead to falls, reduced activity, and pain in muscles or other joints (Chen KH 2015).

This is one of the drivers for correcting gait post-surgery and could help reduce the number of people with multiple joint replacements. Whilst this hasn't been factored in to the economic model, an improvement in gait would save NHS costs. A review from THR provides the status from 133, 654 patients in Sweden, and this provides some indication as to potential cost savings within the NHS (Cnudde et al. 2018).

A study that compares patient reported outcome measures (WOMAC) and gait changes for THR patients showed weak to moderate correlation between the two methods, with gait changes more sensitive to changes over 12 months post op compared to WOMAC (Bolink et al. 2015).

Rehabilitation

These studies provide supporting evidence for implementation of an individualised exercise rehabilitation programme to improve gait in total patients undergoing knee and hip arthroplasty (An et al. 2023, Blue et al 2018, Martinez et al. 2022, Röhner et al. 2021).

These studies provide support for gait assessment in the target population. There is also evidence of a link between gait deficiency and muscle weakness, suggesting that there is a need for personalised rehabilitation programmes that improve gait through muscle specific exercises (Behery and Foucher 2014, Böhm et al. 2016, Foucher 2016, Kline et al. 2019, Lee 2016, Naili et al. 2017, Perron et al. 2000, Pua et al. 2018, Queen et al. 2016, Zhang et al. 2016).

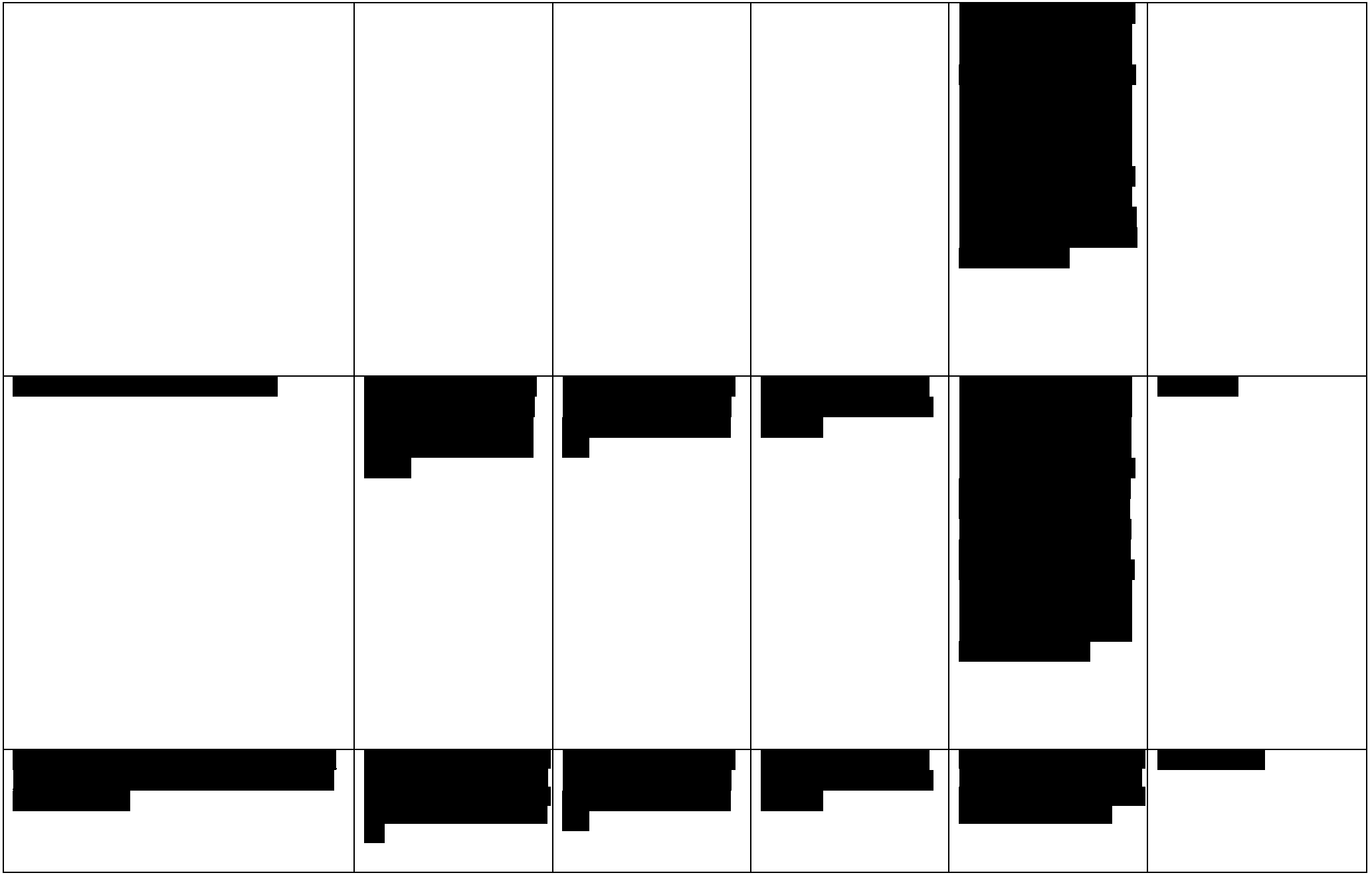
2.3 Critical appraisal of the clinical effectiveness studies

In appendix B, provide the complete quality assessment for each included study using an appropriate and validated tool specific to the study design. See the user guide for further details of the information required. ROBIS-A or another relevant tool is recommended for quality assurance of systematic reviews and meta-analyses, which will be needed if the company has presented such a review or analysis instead of presenting its own de novo review or analysis.

Summarise the relevance of each of the included studies to the decision problem in table 2.

Table 2 Critical appraisal summary for the clinical effectiveness studies

Study	How are the findings relevant to the decision problem?	Does this evidence support any of the claimed benefits for the technology? If so, which?	Will any information from this study be used in the economic model?	What are the limitations of this evidence?	How was the study funded?
NELFT - Rodgers, G., Mottley, A., & Hodgins, D. . (2020). Novel Digital Gait Kinematic Solution to Improve Frailty . British Journal of Healthcare and Medical Research, 7(5), 01–10. https://doi.org/10.14738 /jbemi.75.8894	The study was conducted in one of the target populations: People aged 65 or older that are at risk of falling.	Supports patient benefits.	Yes	Limitations of this study are the lack of a control cohort and no long term follow up as it was a quality improvement programme to help NELFT improve outcomes for their frail older population under the care of the Community Hospital.	NELFT and DML funded their own work
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]



	[redacted]			[redacted]	
PhD - Walters, Yelena. (2018). Task-orientated rehabilitation can improve knee function and satisfaction in patients 12 months after knee replacement surgery for osteoarthritis.	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management)	Supports patient benefits.	No	Please see section 8.3 Limitations within the thesis via the link provided.	DML Sponsored PhD by providing technology.
Blixt S. Patient-reported Mobility Problems after Total Hip Arthroplasty. https://gupea.ub.gu.se/handle/2077/45217	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management)	Supports patient benefits.	No	Please see paragraph 6 to 9 in discussion section.	-
E.M. van Helvoort et al. Motion analysis using the GaitSmart system in the IMI-APPROACH cohort. Osteoarthritis and Cartilage Abstract only Volume 29 Supplement 1 S22-S24 April 1st 2021	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management)	Supports patient benefits.	No	The main limitation of this study is the translation to the general OA population. APPROACH participants were selected based on a high probability of structural and/or pain progression. This may restrict the	Funding: This work was supported by the Innovative Medicines Initiative Joint Undertaking under Grant Agreement no. 115770, resources of which are composed of financial contributions from the European Union's Seventh Framework Programme (FP7/2007–

				generalizability of the results. However, the domains identified were stable over subgroups of severity, and selection bias regarding the associations found, taking into account other demographic and PROM outcomes, is likely limited. However, the specific size of the association may be different in e.g. very early disease. Another limitation is the lack of follow-up data. Any prognostic value of the GaitSmart parameters or any time relationship (e.g. does progression lead to a difference in GaitSmart or the other way around?), which is highly relevant, could not be evaluated. Furthermore, the development of gait characteristics over time might be of additional value above a single gait analysis.	2013) and EFPIA companies. See www.imi.europa.eu and www.approachproject.eu. This communication reflects the views of the authors and neither IMI nor the European Union and EFPIA are liable for any use that may be made of the information contained herein. See www.approachproject.eu
Hanly, R., Doyle, F., Whitehouse, S. and Timperley, A. (2016) "OUTPATIENT 3-D GAIT ANALYSIS ONE YEAR AFTER THA USING A PORTABLE IMU SYSTEM." Orthopaedic Proceedings, 98-B(SUPP_11), pp. 1-1. Available at:	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative	Supports patient benefits.	No	-	-

https://doi.org/10.1302/1358-992X.98BSUPP_11.BHS2016-001	and post-operative management)				
Hodgins D, Hart A. Gait monitoring using inertial measurement units in an orthopaedic outpatient clinic: IET conference Human motion analysis for healthcare applications 2016.	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management)	Supports patient benefits.	No	-	-
Hodgins, Diana & Mccarthy, Ian. (2015). How measuring an older person's walking pattern can help keep them mobile 'Personalised healthcare for mobility'.	The study was conducted in one of the target populations: People aged 65 or older that are at risk of falling.	Supports patient benefits.	No	-	-
M.P Jansen et al. Can gait patterns in knee osteoarthritis patients be explained or predicted by joint structure. Poster at OARSI 2023	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management)	Support patient benefits	No	Limitation: Gait might be influenced by other factors, such as hip or ankle OA.	-
Monda M, Goldberg A, Smitham P, Thornton M, McCarthy I. Use of inertial measurement units to assess age-related changes in gait kinematics in an active population. J Aging Phys Act. 2015 Jan;23(1):18-23. doi: 10.1123/japa.2012-0328. Epub 2013 Dec 4. PMID: 24306618.	The study was conducted in one of the target populations: People aged 65 or older that are at risk of falling.	Supports patient benefits.	No	-	-
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 Musculoskelet Disord. 2015 Mar 22;16:66. doi: 10.1186/s12891-015-0525-2. PMID: 25886558; PMCID: PMC4374376.	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management)	Supports patient benefits.	No	-	-

Redesigning rehabilitation services for total hip and knee arthroplasty using telehealth. Hodgins D.Conference Proceedings IMechE. Hip Surgery: A joint engineering and surgical challenge (Nov 2015)	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management) and People aged 65 or older that are at risk of falling.	Supports patient benefits	No	-	-
van Helvoort EM, Hodgins D, Mastbergen SC, Marijnissen ACA, Kloppenburg M, Blanco FJ, Haugen IK, Berenbaum F, Lafeber FPJG, Welsing PMJ. GaitSmart motion analysis compared to commonly used function outcome measures in the IMI-APPROACH knee osteoarthritis cohort. PLoS One. 2022 Mar 23;17(3):e0265883. doi: 10.1371/journal.pone.0265883. PMID: 35320321; PMCID: PMC8942249.	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management)	Supports patient benefits.	No	The main limitation of the study is that no difference is made between patients with unilateral or bilateral OA. Although gait is a characteristic of an individual rather than of a specific joint, in future studies GaitSmart should be evaluated in specific subgroups of OA (e.g. different Kellgren and Lawrence grades, unilateral vs bilateral, with vs without concomitant OA in other joints). Nevertheless, the results of this subanalysis of the IMI-APPROACH cohort study provide a first indication of the additional value of GaitSmart motion analysis in the assessment of physical function in OA patients.	The research leading to these results have received support from the Innovative Medicines Initiative Joint Undertaking under Grant Agreement n° 115770, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution. See www.imi.europa.eu and www.approachproject.eu. SM and FL are supported by the Dutch Arthritis Society This communication reflects the views of the authors and neither IMI nor the European Union and EFPIA are liable for any use that may be made of the information contained herein. See www.approachproject.eu.

Zügner R, Tranberg R, Timperley J, Hodgins D, Mohaddes M, Kärrholm J. Validation of inertial measurement units with optical tracking system in patients operated with Total hip arthroplasty. BMC Musculoskelet Disord. 2019 Feb 6;20(1):52. doi: 10.1186/s12891-019-2416-4. PMID: 30727979; PMCID: PMC6364439.	The study was conducted in one of the target populations: People referred for knee or hip surgery(pre-operative and post-operative management)	Supports patient benefits.	No	-	No funding was obtained for this study.
Search: People aged 65 or older that are at risk of falling	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H
Systematic Search: Rehabilitation for people aged 65 or older that are at risk of falling	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H
Search: People referred for knee or hip surgery(pre-operative and post-operative management)	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H
Search: Rehabilitation for people referred for knee or hip surgery(pre-operative and post-operative management)	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H

2.4 Results from the clinical evidence base

For each study identified in section 2.2 as relevant to your submission, provide results for all outcomes specified in the NICE scope and those used to inform the decision model.

Summarise the results in an appropriate format, such as by study design, quality, other study characteristic or by outcome. Use a table, if most of the studies can be captured succinctly in a single table, for ease of comparison. Alternatively, present results with separate sections and subsections, for example for each key outcome across all relevant studies, using descriptive text, tables, or both.

Comment below table 3 if any of the key outcomes are a surrogate endpoint; see the NICE health technology evaluations: the manual (see sections 4.6.6 to 4.6.10) – discuss what level of evidence (1-3) supports the surrogate relationship for decision making, and comment whether the surrogate endpoint is considered validated.

Table 3 Key results from the clinical evidence base

Study	Outcome 1	Outcome 2	Outcome 3	Outcome 4	Outcome 5	Other outcomes
NELFT - Rodgers, G., Mottley, A., & Hodgins, D. . (2020). Novel Digital Gait Kinematic Solution to Improve Frailty . British Journal of Healthcare and Medical Research, 7(5), 01–10. https://doi.org/10.14738 /jbemi.75.8894	Gait Speed	Gait Kinematic Data (GaitSmart)	Walking Aid	FES-I	EFS	-
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
PhD - Walters, Yelena. (2018). Task-orientated rehabilitation can improve knee function and satisfaction in patients 12 months after knee replacement surgery for osteoarthritis.	Gait Kinematic Data (GaitSmart)	Oxford Knee Score		-	-	-
Blixt S. Patient-reported Mobility Problems after Total Hip Arthroplasty. https://gupea.ub.gu.se/handle/2077/45217	Gait Kinematics (GaitSmart)	EQ-5D	-	-	-	-
E.M. van Helvoort et al. Motion analysis using the GaitSmart system in the IMI-APPROACH cohort. Osteoarthritis and Cartilage Abstract only Volume 29 Supplement 1 S22-S24 April 1st 2021	Gait Kinematic Data (GaitSmart) and OA markers	Radiographic parameters	PROMS	Severity of radiographic OA	Presence of radiographic OA	-
Hanly, R., Doyle, F., Whitehouse, S. and Timperley, A. (2016) “OUTPATIENT 3-D GAIT ANALYSIS ONE YEAR AFTER THA USING A PORTABLE IMU SYSTEM.” Orthopaedic Proceedings, 98-B(SUPP_11), pp. 1-1.	Gait Kinematic Data					

Available at: https://doi.org/10.1302/1358-992X.98BSUPP_11.BHS2016-001						
Hodgins D, Hart A. Gait monitoring using inertial measurement units in an orthopaedic outpatient clinic: IET conference Human motion analysis for healthcare applications 2016.	Gait Kinematic Data (GaitSmart)	Patient Experience - All yes or very to usefulness of information - Varied responses in relation to individual report. - All responded yes to monitoring throughout recovery	-	-	-	-
Hodgins, Diana & Mccarthy, Ian. (2015). How measuring an older person's walking pattern can help keep them mobile 'Personalised healthcare for mobility'.	Gait Kinematic Data (GaitSmart)	Falls	Physical activity	-	-	-
M.P Jansen et al. Can gait patterns in knee osteoarthritis patients be explained or predicted by joint structure. Poster at OARSI 2023	Gait Kinematic Data (GaitSmart)	Joint structure by MRI	-	-	-	-
Monda M, Goldberg A, Smitham P, Thornton M, McCarthy I. Use of inertial measurement units to assess age-related changes in gait kinematics in an active population. J Aging Phys Act. 2015 Jan;23(1):18-23. doi: 10.1123/japa.2012-0328. Epub 2013 Dec 4. PMID: 24306618.	Gait Kinematic Data (GaitSmart)	Age	-	-	-	-
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 Musculoskelet Disord. 2015 Mar 22;16:66. doi: 10.1186/s12891-015-0525-2. PMID: 25886558; PMCID: PMC4374376.	Gait Kinematic Data (GaitSmart)	Oxford Knee Score (Pre- and post-op)	-	-	-	-
Hodgins D. Redesigning rehabilitation services for total hip and knee arthroplasty using telehealth. .Conference Proceedings	Gait Kinematic Data (GaitSmart)	THR Patient - Hip and Knee angle recorded daily	Older person risk of falls –	THR & TKR Pervious – measured twice.	-	-

IMechE. Hip Surgery: A joint engineering and surgical challenge (Nov 2015)	(appendix: IMECH presentation)	post op to 7 months	monitored over 2 weeks.			
van Helvoort EM, Hodgins D, Mastbergen SC, Marijnissen ACA, Kloppenburg M, Blanco FJ, Haugen IK, Berenbaum F, Lafeber FPJG, Welsing PMJ. GaitSmart motion analysis compared to commonly used function outcome measures in the IMI-APPROACH knee osteoarthritis cohort. PLoS One. 2022 Mar 23;17(3):e0265883. doi: 10.1371/journal.pone.0265883. PMID: 35320321; PMCID: PMC8942249.	Gait Kinematic Data (GaitSmart)	Knee injury and Osteoarthritis Outcome Score (KOOS)	Short Form 36 Health Survey (SF-36)	30s chair stand	40m self-paced walk	Total function
Zügner R, Tranberg R, Timperley J, Hodgins D, Mohaddes M, Kärrholm J. Validation of inertial measurement units with optical tracking system in patients operated with Total hip arthroplasty. BMC Musculoskelet Disord. 2019 Feb 6;20(1):52. doi: 10.1186/s12891-019-2416-4. PMID: 30727979; PMCID: PMC6364439.	Gait Kinematic Data – inertial measurement units (IMU-GaitSmart) by comparison with an optical tracking system (OTS)	Pelvic tilt - mean pelvic tilt range (4.9-5.4 degrees) no significant difference.	Knee flexion - mean knee flexion range (54.4-55.1 degrees).	Hip flexion -(36.7-37.7) degrees (OTS) compared to 34.0-34.4 (IMU) $p < 0.001$).	-	-
Search: People aged 65 or older that are at risk of falling	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H
Search: Rehabilitation for people aged 65 or older that are at risk of falling	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H
Search: People referred for knee or hip surgery(pre-operative and post-operative management)	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H
Search: Rehabilitation for people referred for knee or hip surgery(pre-operative and post-operative management)	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H	Appendix: H

2.5 Adverse events

Describe any adverse events and outcomes associated with the technology recorded in national regulatory databases such as those maintained by the Medicines and Healthcare products Regulatory Agency (MHRA) and the US Food and Drug Administration (FDA; the MAUDE, manufacturer and user facility device database). Provide links and references. If appropriate, do a systematic review and provide details in appendix C.

There are no reported adverse events for GaitSmart.

As stated DML runs a quality management system that complies with ISO 13485 and ISO 9001, with BSi as our Notified Body. GaitSmart is also registered on the MHRA database.

As part of ISO13485 the company has to comply with post market surveillance for all GaitSmart Users and any adverse events must be logged immediately with MHRA and BSi notified.

Describe any adverse events and outcomes associated with the technology in the clinical evidence.

None

2.6 Evidence synthesis and meta-analysis

Although evidence synthesis and meta-analyses are not mandatory for a submission to be accepted, they are strongly encouraged if data is available to support such an approach. If an evidence synthesis is not considered appropriate, instead complete the section on qualitative review. If a quantitative evidence synthesis is appropriate, describe the methods used along with a rationale for the studies selected. The description of methods and any assumptions or calculations used should be clear and detailed such that the EAG can reproduce the analysis, see the example text in the table below and user guide fomore information on what to include.

N/A

Table 4 Evidence synthesis description of outcomes, sources and other relevant details

Study	Outcome	Intervention	Comparator	Comments
N/A	N/A	N/A	N/A	N/A

Report all relevant results, including diagrams if appropriate. Provide the results in an appropriate format (i.e. so it is accessible and can clearly be followed by an EAG so they can quality assure the analyses). See the user guide for more information on what to present here.

N/A

Enter text.Explain the main findings and conclusions drawn from the evidence synthesis.

N/A

Qualitative review

Only complete this section if a quantitative evidence synthesis is not appropriate.

Explain why a quantitative review is not appropriate:

N/A

Instead provide a qualitative review by summarising the overall results of the individual studies with reference to their critical appraisal.

N/A

2.7 Summary and interpretation of clinical evidence

Summarise the main clinical evidence, highlighting the clinical benefit and any risks relating to adverse events from the technology.

The whole premise for the GaitSmart programme is that gait deficiencies can be rectified by strengthening the appropriate muscles. This basic philosophy is the basis for strength and balance classes provided for those at risk of falls (Quality Statement 8 Falls in older people Quality standard [QS86] Published: 25 March 2015 Last updated: 31 January 2017) and exercise intervention for osteoarthritis (1.3 Non-pharmacological management Osteoarthritis in over 16s: diagnosis and management NICE guideline [NG226]Published: 19 October 2022) and management for joint replacement patients (Joint replacement (primary): hip, knee and shoulder NICE guideline [NG157]Published: 04 June 2020). The difference with the GaitSmart programme and general exercise classes is muscle weakness is determined from a musculoskeletal model generated from our GaitSmart data and exercises are personalised to the individual. The choice of six exercises from the long list of Strength and Balance exercises that may be prescribed across the NHS helps the individual focus on the muscles most in need of strengthening. Repeat tests provides the individual with the evidence that the exercises are working, only possible because GaitSmart has an accuracy to within a degree on their measurements. This evidence motivates the individual to continue and over time the improvements are visible and have a positive impact on their mobility.

Because the GaitSmart programme utilises the GaitSmart gait kinematic data all of our published evidence relating to falls and osteoarthritis provide the foundation for our intervention programme.

The evidence presented demonstrates that GaitSmart is able to detect gait deficiencies that are relevant to the different conditions included in the scope. Specifically, GaitSmart has been able to identify healthy gait kinematics and determine gait biomarkers for hip and knee osteoarthritis, which is the leading cause of joint replacement, (Monda et al. 2015, van Helvoort et al. 2021, Blixt et al. 2017, Hanly et al. 2016, Rahman et al. 2015, Zugner et al. 2019). This evidence is supported by many other gait kinematics studies on late stage hip and knee osteoarthritis (Son and Lee. 2023, Kaufmann et al. 2023 Ismailidis et al. 2021, Ismailidis et al, 2020). GaitSmart has also been used to identify gait deficiencies in the older population at risk of falls. This study also demonstrated how gait kinematic data can help guide rehabilitation (Hodgins and McCarthy 2015). The conclusions are supported by many other gait kinematics studies on this cohort (Alcock et al. 2013, Boelens, et al. 2013, Menz et al. 2003, Santos Bueno et al. 2019, Cabell et al. 2013, Lim et al. 2022).

Informal unpublished gait days confirmed that our GaitSmart technology was acceptable to people with different gait issues of all ages [Appendix I].

[redacted]

Our overall sample size for gait assessment is considerable, whilst for our gait rehabilitation studies it is accepted that it is smaller. However, the conclusions were the same for all intervention studies, and the approach is aligned to NICE Guidelines, where gait assessment and personalised gait rehabilitation are proposed. Furthermore, the evidence investigating the GaitSmart programme is supported by a wealth of evidence in the literature gait kinematic data changes for the target populations and rehabilitation of gait through exercise intervention.

Briefly discuss the relevance of the evidence base to the scope. This should focus on the key claimed benefits described in the scope and the quality and quantity of the included studies.

See text below benefits section.

Identify any factors which might be different between the patients in the submitted studies and patients having routine care in the NHS. Provide appropriate references, including clinical experts who you consulted, to identify these differences.

There are many places where older people at risk of falls may be in contact with NHS services. These include primary, secondary and community care. In our referenced GaitSmart studies patients were identified by NHS personnel as at risk of falling, with the exception of our early study with a balance class, where the individuals identified themselves as at risk. Two studies were in primary care and one in secondary care. The results show that it doesn't matter what level of disability the individual has or where they are identified in their care pathway. The small pilots at a

care hotel and care home shows that even those with very limited mobility and not living independently could still benefit from a GaitSmart assessment.

In our discussions with N&W ICB and falls clinics, it is clear that there are a few options for helping people who would benefit from the GaitSmart programme to reduce falls. Three falls groups would run a GaitSmart falls class and N&W ICB is planning on utilising community workers to run GaitSmart clinics.

For people under secondary care management for hip or knee replacement patients can be identified either in primary or secondary care.

[redacted]

Describe any criteria that would be used in clinical practice to select patients for whom the technology would be most appropriate. Provide appropriate references, including clinical experts who you consulted, to identify these criteria.

As stated, our studies have included a range of patients in both cohorts.

The NHS groups who now use, or plan to use GaitSmart imminently do not plan to segregate out patients for GaitSmart.

Briefly summarise the strengths and limitations of the clinical evidence for the technology.

Please see strength and limitations discussed through the tables 1 to 3 and in the benefits text section.

2.8 Ongoing studies

Provide details of all relevant ongoing or planned studies using the technology. See the user guide for full details of the information required and suggested table format.

Principal investigator and location	**Year (expected completion date)**	**Patient population, setting, and withdrawals/ lost to follow up.**	**Intervention and version(s)**	**Comparators**	**Outcomes**
Professor Iain Mcnamara Norfolk and Norwich University Hospital England	2023/2024	Current Status – Ethical approval pending. Eligible patients on the waiting list for hip or knee arthroplasty will be identified based on inclusion/exclusion criteria. Participants will then be randomised to a control or intervention group	All participants will receive standard of care plus gait kinematic and patient outcome assessment at -12, -6 and 0 weeks pre-op then at 6 and 12 weeks post-op. Intervention group will receive the gait assessment results and personalised exercise intervention.	Standard of care.	Gait Kinematic Data Patient reported outcomes; pain, function, and quality of life. Qualitative patient feedback.

3 Published economic evidence

3.1 Identification and selection of studies

Economic evidence in this section refers to economic evidence specifically on the use of the intervention technology. Unpublished economic evidence is not normally accepted unless there is justification provided why it has not been published and the study considered particularly important and relevant. Complete the following information about the number of studies identified.

Report in full transparent and reproducible detail the search methods as used for all search resources, and provide a detailed list of any excluded studies, in appendix D. Number of studies reported below should be after any duplicates have been removed.

Number of studies identified in a systematic search.	Text
Number of studies identified as being relevant (i.e. directly relevant to the decision problem by ensuring it fits the eligibility criteria outlined in the scope))	5 studies submitted for publication
Of the relevant studies identified, the number of published, peer reviewed studies.	3 studies submitted for publication to peer reviewed journals
Of the relevant studies identified, the number of conference abstracts.	0

3.2 List of relevant economic studies

In table 5, provide brief details of any published economic studies or abstracts identified as being relevant (i.e. directly relevant to the decision problem by ensuring it fits the eligibility criteria outlined in the scope)).

Table 5 Summary of relevant economic studies

Author, year, location, status and funding	Summary of decision model	Patient population and setting	Intervention and comparator	Unit costs and resource use	Decision model outputs	Description of Sensitivity or scenario analyses
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

				[redacted]		
Theodoros Mantopoulos, Paul M. Mitchell, Nicky J. Welton, Richard McManus, Lazaros Andronis. 2016. Choice of statistical model for cost-effectiveness analysis and covariate adjustment: empirical application of prominent models and assessment of their results. The European Journal of Health Economics volume 17, pages927–938, no mention about any funding directly applicable to research, but the paper mentions that the authors were supported by different MRC and NIHR grants.	Data from the the tele-monitoring and self-management in the control of hypertension (TASMINH2) trial was analysed using different statistical models such as seemingly unrelated regressions, linear regression of net monetary benefits, and Bayesian generalized linear models that made five distributional assumptions. These models were adjusted for covariates that were prognostic of costs and outcomes. The study was conducted in 24 general practices in the UK. Patients were randomly assigned to tele-monitoring and self-management or usual care. The main outcome measure was the change in mean systolic blood pressure after 6 and 12 months.	The study was conducted in 24 general practices located in the West Midlands, UK. The participants were individuals between the ages of 35 and 85 who had high blood pressure of over 140/90 mmHg, even though they were undergoing antihypertensive treatment. Patient randomization into either the telemonitoring and self-management group or the usual care group was stratified by GP and included minimizing factors such as sex, baseline systolic blood pressure, and the presence or absence of diabetes or chronic kidney disease.		Intervention group (n=263) received telemonitoring service in addition to the usual care to self-manage and control their hypertension, however the people in the control/usual care group (n=264) did not receive any such intervention.	The cost data were informed by the trial, the cost was presented as per patient NHS cost over a 12-month period was estimated as the sum of the cost for medications, training and equipment, inpatient and outpatient care and GP visits. In addition to measuring the patient's mean systolic blood pressure, which was the primary clinical outcome in the RCT, the study also assessed the patient's responses to EQ-5D-3L, a generic tool used to measure preference-based health-related quality of life. The EQ-5D scores were then utilized to compute QALYs from baseline to 12 months using the "area under the curve" (AUC) approach with the UK tariff being used to calculate the EQ-5D scores.	The primary objective of this study was not to conduct an economic evaluation but rather to undertake a methodological investigation that utilised the cost-effectiveness of the TASMINH2 trial as a case study. The study evaluated the cost-effectiveness using three different methods: seemingly unrelated regressions (SUR), linear regression of net monetary benefits, and Bayesian generalized linear models with five different distributional assumptions. The researchers employed all three methods to calculate the incremental cost, incremental QALYs, and incremental net benefit. The mean incremental net benefit was reported to be within the range of GBP -378 (214.1) to GBP 94.8 (199.0).
E.L. Heath, I. N. Ackerman, K. Cashman, M. Lorimer, S. E. Graves, and I. A. Harris. 2021. Patient- reported outcomes after hip and knee arthroplasty. Bone Jt Open 2021;2-6:422–432. Funded by Commonwealth of Australia's Department of Health	This is not a decision model, this data from this study was used in economic evaluation of the GaitSmart Study 2 above, because it reports outcomes for the patients before and after conventional hip arthroplasty (THA) and total	For analysis purposes, 5,228 preoperative procedures for THA and 8,299 for TKA, along with 3,215 postoperative procedures for THA and 4,982 for TKA, were included. The majority of patients were female, with mean ages of 66.8 years for THA and 67.5 years for	This study employed a retrospective pre-post-surgery approach to compare outcomes before and after THA and TKA procedures. As the study design was based on a before-and-after comparison, no comparator groups were included.		The study utilised validated Patient-Reported Outcome Measures (PROMs), including the EuroQol five-dimension five-level questionnaire (EQ-5D-5L), Oxford Hip/Knee Scores (OHS/OKS), and the 12-item Hip/Knee disability and Osteoarthritis Outcome Score (HOOS-12/KOOS-	The study analysed patient characteristics and outcomes for total hip arthroplasty (THA) and total knee arthroplasty (TKA) separately. The proportion of patients who reported their joint as 'much better' was higher for THA (92.6%) compared to TKA (81.6%), and the majority of patients

	knee arthroplasty (TKA) in Australia	TKA. Mean BMI was 29.9 kg/m2 for THA and 32.5 kg/m2 for TKA.			12), to measure health status, hip/knee function, and osteoarthritis outcomes. Additionally, preoperative expectations, patient-perceived improvement, and postoperative satisfaction were also assessed. The data was analysed using descriptive statistics.	in both groups were satisfied with their procedure. However, a small percentage of patients reported dissatisfaction with their surgery, with 9.7% of THA patients and 10.5% of TKA patients reporting 'dissatisfied' or 'very dissatisfied'.
Abraham, L., Halsby, K., Stein, N. et al. (2022) An Observational Retrospective Matched Cohort Study of Healthcare Resource Utilisation and Costs in UK Patients with Moderate to Severe Osteoarthritis Pain. Rheumatol Ther 9, 851–874, funded by the Pfizer and Eli Lilly and Company. Pfizer and Eli Lilly and Company	This is not a decision model, this data from this study was used in economic evaluation of GaitSmart Study 2 mentioned above. The study aimed to compare healthcare resource utilisation (HCRU) and costs between patients with moderate to severe or severe osteoarthritis (OA) pain and those without OA using data from patients in Salford, UK. Patients with M-S OA pain were identified from the Salford Integrated Record between 2010 and 2017, and patients with severe pain were classified as an OA sub cohort. Each OA cohort was matched with a control group without OA.	The study indexed patients ≥ 18 years old with at least one moderate to severe or severe pain event within an episode of chronic pain between 2010 and 2017. Patients must have had at least one prior diagnosis of OA in their recorded medical history, and the chronic pain episode was initiated when a patient attended a GP consultation relating to OA pain. Patients were indexed in the moderate to severe or severe OA pain cohort based on certain criteria, and some patients were indexed in both cohorts.		The study matched each patient with OA by age, sex, and Charlson Comorbidity Index (CCI) to a control patient without a diagnosis of OA in their medical history. The controls were matched using logistic-regression-based propensity scoring, and matching was done independently for moderate to severe and severe OA pain cohorts. Controls were assigned a pseudo-index date equal to the patient they were matching, and all patients had to be continuously registered with a GP in Salford for 12 months prior and 12 months following the index. The OA patients and controls formed the intervention and comparator group, respectively.	The study calculated healthcare resource utilisation (HCRU), prescribed analgesic drugs, and total direct costs per UK standardised tariffs for one year post-index, and used multivariable models to identify healthcare cost drivers.	Patients with moderate to severe (M-S) or severe osteoarthritis (OA) pain had significantly higher mean numbers of general practitioner encounters, inpatient, outpatient, and accident and emergency visits, and were prescribed a broader range of analgesic drugs in the year post-index than respective controls. Mean healthcare costs of all types were significantly higher in the M-S and severe OA pain cohorts vs controls (total: M-S £2519 vs £1379; severe £3389 vs £1397). Paracetamol (M-S: 40% of patients had at least one prescription; severe: 50%) and strong opioids (34% and 59%) were the analgesics most prescribed to patients with OA pain. Multivariable models showed that a higher age at index, the presence of gout, osteoporosis, type 2 diabetes, or coronary artery disease significantly contributed towards higher healthcare costs in all cohorts.

3.3 Critical appraisal of relevant economic studies

In appendix E, provide the complete quality assessment for each included study using an appropriate and validated tool: a table is provided in appendix E based on the NICE economic evaluations appraisal checklist (2019). See the user guide for the information required.

Summarise the relevance of each of the included studies to the decision problem in table 5.

Table 6 critical appraisal summary for economic evidence

Study	What are the main differences in resource use and clinical outcomes between the technologies?	How are the findings relevant to the decision problem?	Does this evidence support any of the claimed benefits for the technology? If so, which?	Will any information from this study be used in the decision model?	Which cost analysis was done in the study? Explain the results.	What are the limitations of this evidence?	How was the study funded?
Enter text. Theodoros Mantopoulos, Paul M. Mitchell, Nicky J. Welton, Richard McManus, Lazaros Andronis. 2016. Choice of statistical model for cost-effectiveness analysis and covariate adjustment: empirical application of prominent models and assessment of their results. The European Journal of Health Economics volume 17, pages927–938, no mention about any funding directly applicable to research, but the paper mentions that the authors were supported by different MRC and NIHR grants.	Enter text.	Enter text.	Enter text.	The analysis of the probabilistic distributions that best fit costs and health outcomes	Enter text.	Enter text.	Enter text.

Study	What are the main differences in resource use and clinical outcomes between the technologies?	How are the findings relevant to the decision problem?	Does this evidence support any of the claimed benefits for the technology? If so, which?	Will any information from this study be used in the decision model?	Which cost analysis was done in the study? Explain the results.	What are the limitations of this evidence?	How was the study funded?
E.L. Heath, I. N. Ackerman, K. Cashman, M. Lorimer, S. E. Graves, and I. A. Harris. 2021. Patient-reported outcomes after hip and knee arthroplasty. Bone Jt Open 2021;2-6:422–432. Funded by Commonwealth of Australia's Department of Health	Enter text.	This is not a decision model, this data from this study was used in economic evaluation of the GaitSmart Study 2 above, because it reports outcomes for the patients before and after conventional hip arthroplasty (THA) and total knee arthroplasty (TKA) in Australia The study analysed patient characteristics and outcomes for total hip arthroplasty (THA) and total knee arthroplasty (TKA) separately. The proportion of patients who reported their joint as 'much better' was higher for THA (92.6%) compared to TKA (81.6%), and the majority of patients in both groups were satisfied with their procedure.	Enter text.	This is not a decision model, this data from this study was used in economic evaluation of the GaitSmart Study 2 above, because it reports outcomes for the patients before and after conventional hip arthroplasty (THA) and total knee arthroplasty (TKA) in Australia	Enter text.	Firstly, selection bias may have been introduced with the hospitals participating in the pilot study. Hospitals were selected based on volunteering and by invitation to those hospitals/orthopaedic surgeons who were previously involved with the AOANJRR via existing collaborations. Additionally, HOOS-12 and KOOS-12 instruments were available for optional completion to decrease patient burden; positively, most patients completed the optional questions (59.40% preoperatively and 66.10% postoperatively),	No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. The AOANJRR is funded by the Commonwealth of Australia's Department of Health.

Study	What are the main differences in resource use and clinical outcomes between the technologies?	How are the findings relevant to the decision problem?	Does this evidence support any of the claimed benefits for the technology? If so, which?	Will any information from this study be used in the decision model?	Which cost analysis was done in the study? Explain the results.	What are the limitations of this evidence?	How was the study funded?
						increasing the volume of data collected.	
Abraham, L., Halsby, K., Stein, N. et al. (2022) An Observational Retrospective Matched Cohort Study of Healthcare Resource Utilisation and Costs in UK Patients with Moderate to Severe Osteoarthritis Pain. Rheumatol Ther 9, 851–874, funded by the Pfizer and Eli Lilly and Company. Pfizer and Eli Lilly and Company	Enter text.	This is not a decision model, this data from this study was used in economic evaluation of GaitSmart Study 2 mentioned above. The study aimed to compare healthcare resource utilisation (HCRU) and costs between patients with moderate to severe or severe osteoarthritis (OA) pain and those without OA using data from patients in Salford, UK. Patients with M-S OA pain were identified from the Salford Integrated Record between 2010 and 2017, and patients with severe pain were classified as an OA	Enter text.	This is not a decision model, this data from this study was used in economic evaluation of GaitSmart Study 2 mentioned above. The study aimed to compare healthcare resource utilisation (HCRU) and costs between patients with moderate to severe or severe osteoarthritis (OA) pain and those without OA using data from patients in Salford, UK. Patients with M-S OA pain were identified from the Salford Integrated Record between 2010 and 2017, and patients with severe pain were classified as an OA	Multivariable models were used to identify drivers of healthcare cost.	Limitations of this analysis include those common to the use of retrospective data. The SIR is limited to patients treated in Salford, UK, but it provides a rich source of healthcare data for this population. Although the representativeness of SIR data with respect to other regions of the UK is unproven, it is likely to be at least broadly representative of other urban populations in the North West. Limitations for the SIR include that it is missing sexual and mental health data and out-of-area hospital data	This study was sponsored by Pfizer and Eli Lilly and Company. Pfizer and Eli Lilly and Company contributed to the study design; Pfizer contributed to the management and collection of data. In their role as authors, employees of Pfizer were involved in the interpretation of data, the preparation, review, and approval of the manuscript, and the decision to submit for publication, along with their co-authors. The study sponsors approved the manuscript

Study	What are the main differences in resource use and clinical outcomes between the technologies?	How are the findings relevant to the decision problem?	Does this evidence support any of the claimed benefits for the technology? If so, which?	Will any information from this study be used in the decision model?	Which cost analysis was done in the study? Explain the results.	What are the limitations of this evidence?	How was the study funded?
		sub cohort. Each OA cohort was matched with a control group without OA.		sub cohort. Each OA cohort was matched with a control group without OA.		(mainly cardiac surgery). Specific to our analysis, the lack of OA pain scoring made defining cohorts of patients with chronic OA pain more complex. The definitions used were clinically realistic but complex, and HCRU cannot be definitively linked to chronic pain caused by OA. Surgeries are an important cost for patients with OA, and our 2-year follow-up limited the ability to evaluate the impact of OA-related surgical procedures.	from an intellectual property perspective but had no right to veto the publication. Pfizer and Eli Lilly and Company funded the Rapid Service Fee associated with this publication.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.

Enter text.

3.4 Results from the economic evidence base

Describe the results from each of the relevant economic studies. Use a table if appropriate.

4 Company decision model

Two economic models were developed for the technology – 1) Early Evidence Economic Model (Model1), and 2) Main Economic Model (Model 2), The first part of this section deals with the early evidence and the subsequent section provides information on main model.

4.1 Early Evidence Economic Model (Model 1)

Decision model description

Patients

Describe which patient groups are included in the decision model.

The target population consisted of older persons who had suffered a fall or had a moderate to

severe FoF (fear of falling) and were in a community care unit.

Technology and comparator(s)

State the technology and comparators used in the decision model. Provide a justification if the comparator(s) used in the decision model is different to that in the scope.

The GS is a sensor-based digital medical device (CE Marked Class 1M Medical Device), which has been used in clinical settings for the health rehabilitation of older persons who have suffered falls or are at risk of falling, due to different levels of frailty. Using an algorithm, the GS provides a detailed and objective measure of a patient's walking ability, in which the collected data are used to automatically define a personalized exercise program. All exercises were recommended either in the Otago Exercise Program (OEP) or in the NHS older people guidance, as per current appropriate practice. The OEP is considered for implementation in patients because it is one of the most beneficial programs for preventing falls (17). The difference between the exercises recommended by the OEP, NHS and GS is that the GS system only recommends exercises that focus on the specific weaknesses identified by itself. Furthermore, patients and health professionals have objective and clear data that quantify gait issues and allow them to define their own goals. Patients assigned to the intervention group (GS) were monitored four times during the implementation of the intervention, three weeks apart. To deliver the intervention, a 20-meter quiet

(unobtrusive) 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. All interventions were delivered by the research team. Training of the research team was carried out by Dynamic Metrics (DML).

Patients in the SoC group were given advice on self-directed rehabilitation.

Decision model structure

Provide a diagram of the decision model structure you have chosen in appendix F.

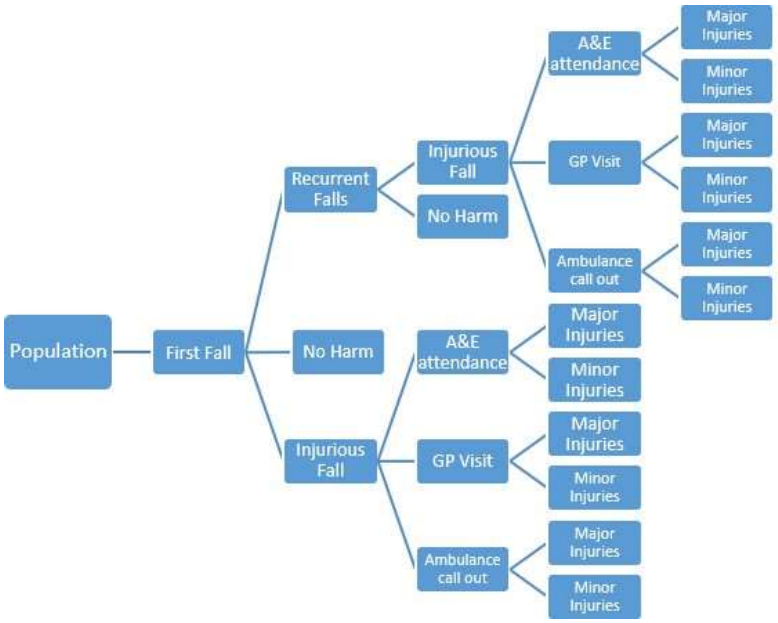
Justify the chosen structure of the decision model by referring to the clinical care pathway outlined in section 1.3. Decision model structures should normally incorporate clinical parameters based on appropriate estimates of clinical effectiveness. This allows for sensitivity analyses to be done on the impact of varying the clinical parameters to explore any uncertainty in the estimates. For this reason, decision model structures should not just be based on simple cost calculations.

An analytic decision tree model was developed in Microsoft Excel 2013 to compare the costs and benefits (effectiveness) of the current Standard of Care (SoC) pathway versus a new pathway with the introduction of a GaitSmart (GS) intervention. Figure 1 illustrates how a cohort of patients who had suffered a fall or had moderate to severe fear of falling (FoF) could progress through the hypothetical decision tree over a twelve-month time horizon.

Subjects assigned to the GS group were monitored four times during intervention implementation, with three-week intervals between each monitoring session. They were compared to the SoC group, which followed the National Institute for Health and Care Excellence (NICE) guidelines (18) and did not receive GS monitoring. SoC patients could be allocated to either self-managed home exercise or group/individual physiotherapy (4-6 sessions). At the end of each path in the decision tree, the model provides the outcomes (response or no response).

Furthermore, the model takes into consideration the risk rates of falling incidents within the time frame of the model, based on literature, and associates the various levels of patients' speed before and after a cycle of four GS sessions with changes in this risk rate, as determined by previous studies. This allows for a personalized calculation of total reduction in rate of falls (RoF) associated with the cohorts under examination by policy makers. The model also calculates fall incidents based on improvement in FoF, using data collected from the Falls Efficacy Scale International (FES-I) tool administered before and after the four GS test sessions. Falls incidents were categorized into injurious falls and falls with no harm based on parameters extracted from

literature, as there were no fall incidents during the short-term follow-up of the subjects. Evidence on FoF and its correlation with falling incidents was gathered from the literature, as FoF can significantly impact independence and increase the risk of further falls.



Injurious Falls That will result in A&E attendance	34.00%
Injurious Falls That will result in GP visit	51.00%
Injurious Falls That will result in ambulance call out	15.00%
% Community Dwelling Adults over 65 that will experience a Fall each year	33.33%
% Institutionalised Adults over 80 that will experience a Fall each year	50.00%
% of Falls that result in an injury that requires medical attention	20 %
% that result in fractures	15%
% that result in head Minor Injuries	34%
No Harm	33%

Table 7 Assumptions in the decision model

In this table, list the main assumptions in the decision model and justify why each has been used.

<table>
<tr><th>Assumption</th><th>Justification</th><th>Source</th></tr>
<tr><td>Time horizon of 12 months</td><td>As the benefit of treatment is generally seen in the short term, we developed a cost ffectiveness analysis (CEA) with a time horizon of twelve months to estimate the incrementa costs and benefits of using the GS</td><td>Expert opinion</td></tr>
<tr><td>As there was no randomized clinical trial setting with a comparator, and the study population was only monitored for a limited follow-up period, we had to rely on published data that examined the risk of falling based on different levels of fear of falling.</td><td>We used Fear of Falling Level and probabilities of experience a fall or recurrent falls per fear of falling level based on the published article. The transition probabilities used for both deterministic and probalistic model is shown in the Table below:
<table>
<tr><th>Input Parameters</th><th>Deterministic</th><th>Probabilistic</th></tr>
<tr><th>Transition probabilities</th><th colspan="2">Values (RR)</th></tr>
<tr><td>Low Fear of Falling</td><td>0.6685</td><td>0.7833</td></tr>
<tr><td>Moderate Fear of Falling</td><td>0.2852</td><td>0.1862</td></tr>
<tr><td>High Fear of Falling</td><td>0.0463</td><td>0.0356</td></tr>
<tr><td>At least 1 fall (Low Fear of Falling)</td><td>0.260</td><td>0.201</td></tr>
<tr><td>At least 1 fall (Moderate Fear of Falling)</td><td>0.360</td><td>0.357</td></tr>
<tr><td>At least 1 fall (High Fear of Falling)</td><td>0.480</td><td>0.443</td></tr>
<tr><td>Recurrent fall (Low Fear of Falling)</td><td>0.080</td><td>0.717</td></tr>
<tr><td>Recurrent fall (Moderate Fear of Falling)</td><td>0.130</td><td>0.100</td></tr>
<tr><td>Recurrent fall (High Fear of Falling)</td><td>0.220</td><td>0.183</td></tr>
</table></td><td>Arfken CL, Lach HW, Birge SJ, Miller JP. The prevalence and correlates of fear of falling in elderly persons living in the community. American journal of public health. 1994 Apr;84(4):565-70.</td></tr>
<tr><td>We assumed a similar response probability for self-managed and group/individual rehabilitation</td><td>We assumed a similar response probability for self-managed and group/individual rehabilitation due to lack of evidence</td><td></td></tr>
</table>

Clinical parameters and variables

Table 8 Clinical parameters, patient and carer outcomes and system outcomes used in the decision model

In this table, describe the clinical parameters, patient and carer outcomes and system outcomes used in the decision model. Please include sufficient detail to allow the reader to clearly identify the input from the source data

Input Parameters Group	Input Parameters	Deterministic	Probabilistic	Distribution	Resources	How these parameters were used
General Parameters	**Transition probabilities**	**Values (RR)**				
	% Community Dwelling Adults over 65 that will experience a Fall each yr	0.333	0.35	Beta	Berry et al.,2008; Tinetti et al.,1995	Used in the model
	% Institutionalised Adults over 80 that will experience a Fall each yr	0.50	0.47	Beta		
	% of Falls that result in an injury that requires medical attention	0.20	0.22	Beta		
	% of persons over 70 years old that will go to A&E after a Fall	0.080	0.11	Beta		
	% that result in fractures	0.150	0.14	Beta		
	% that result in head trauma/serious injury	0.340	0.34	Beta		
	% that result in injury requiring medical attention	0.20	0.22	Beta		
	% that result in minor injuries	0.333	0.31	Beta		
	Falls That will result in A&E attendance	0.340	0.29	Beta		
	Falls That will result in GP visit	0.510	0.51	Beta		
	Falls That will result in ambulance call out	0.150	0.17	Beta		
Fear of Falling Level and probabilities of experience a fall or recurrent falls per fear of falling level	Low Fear of Falling	0.6685	0.7833	Calculated	FES-I questionnaire	Used in the model
	Moderate Fear of Falling	0.2852	0.1862	Beta		
	High Fear of Falling	0.0463	0.0356	Beta		
	At least 1 fall (Low Fear of Falling)	0.260	0.201	Beta	Arfken et al.,1994	
	At least 1 fall (Moderate Fear of Falling)	0.360	0.357	Beta		
	At least 1 fall (High Fear of Falling)	0.480	0.443	Beta		
	Recurrent fall (Low Fear of Falling)	0.080	0.717	Beta		

	Recurrent fall (Moderate Fear of Falling)	0.130	0.100	Beta		
	Recurrent fall (High Fear of Falling)	0.220	0.183	Beta		

If expert elicitation methods were used to identify any model parameters and/or a plausible distribution, fully justify this and the methods outlined.

N/A

If any outcomes listed in table 10 are extrapolated beyond the study follow-up periods, explain the assumptions that underpin this extrapolation.

N/A

Table 9 Other parameters in the decision model

Describe any other parameters in the decision model. Examples are provided in the table. You can adapt the parameters as needed. Please include sufficient detail to allow the reader to clearly identify the input from the source data.

Parameter	Description	Justification	Source
Time horizon	1 year	GS benefit is assumed to be accumulated for short term.	Expert opinion
Discount rate	0	The time horizon of the model spans over a year, hence the discounting is not applicable.	HM Treasury Green Book Available at: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020
Perspective (NHS/personal social services)	NHS perspective	From the NHS perspective, the economic model estimated the relative cost-effectiveness of the	Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, et al. Consolidated Health Economic

Parameter	Description	Justification	Source
		GS compared with SoC for improving the gait and mobility issues in people undergoing THA or TKA, adhering to good practice guidelines and the NICE reference case. Therefore, only healthcare costs (direct medical costs) related to the disease were included.	Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. Value Health [Internet]. 2022 Jan 1 [cited 2023 Feb 20];25(1):3–9. Available from: https://pubmed.ncbi.nlm.nih.gov/35031096/ National Institute for Health and Care Excellence (NICE). NICE health technology evaluations: the manual | Guidance [Internet]. [cited 2023 Feb 21]. Available from: https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation
Cycle length	1	The structure of the model is a decision tree model	Enter text.
Health states	GS system -> Yes/No response SoC -> Self managed home exercise (Yes/No reponse)/ Group or individual therapy (Yes/No reponse)	Based on NELFT data and model structure	Enter text.
Sources of unit costs	Department of Health. NHS Reference Costs 2018-19 GaitSmart stakeholders	GaitSmart internal costs were used for the cost of the intervention	Curtis, Lesley A., Burns A. Unit Costs of Health and Social Care 2020 | PSSRU. 2020 355 [cited 2023 Feb 22]; Available from: https://www.pssru.ac.uk/project-

Parameter	Description	Justification	Source
	Costs of Health and Social Care 2020		pages/unit- 356 costs/unit-costs-2020/ Department of Health. NHS Reference Costs 2018-19

Explain the transition matrix used in the decision model and the transformation of clinical outcomes, health states or other details.

The transition probabilities used in the decision model is presented in the table below

Input Parameters Group	Input Parameters	Deterministic	Probabilistic	Distribution	Resources
Self-Managed Rehabilitation	**Transition probabilities**	**Values (RR)**			
	Self-Managed Rehabilitation (SMR - SoC)	0.200	0.208	Beta	Experts' Opinion
	Self-Managed Rehabilitation (SMR- Int)	0.000	0.000	Beta	
	SMR Response Probability	[redacted]	[redacted]	[redacted]	[redacted]
	SMR No Response Probability	[redacted]	[redacted]	[redacted]	[redacted]
	Group / Individual Rehabilitation (GIR- Soc)	0.800	0.792	Calculated	Experts' Opinion
	Group / Individual Rehabilitation (GIR - Int)	0.000	0.000	Calculated	
	GIR Response	[redacted]	[redacted]	[redacted]	[redacted]
	GIR No Response	[redacted]	[redacted]	[redacted]	[redacted]
GaitSmart Intervention	**Transition probabilities**	**Values (RR)**			
	GaitSmart Rehabilitation (GSR)	1.000	1.000	Beta	Assumption
	GSR Response	[redacted]	[redacted]	[redacted]	[redacted]
	GSR No Response	[redacted]	[redacted]	[redacted]	[redacted]
	Primary Care	0.000	0.000	Gamma	Curtis & Burns, 2020

Resource identification, measurement and valuation

NB: the sections below should be completed with a view to ensuring the EAG can understand clearly and quickly where all figures have been obtained e.g. all source detail should be sufficiently detailed. It is also important to describe how any figures have been calculated (including all assumptions, sources, calculations etc.)

Intervention and comparator technology costs

Provide the price for the intervention technology, which should reflect as closely as possible the price(s) paid in the NHS (excluding VAT). Describe any uncertainty over the appropriate price to use in the submission.

Costs	Values (£)			
GaitSmart Intervention Cost Per Patient per Session	[redacted]	[redacted]		[redacted]
Secondary Care Costs Per Patient per Session	6.75	6.73	Gamma	Curtis & Burns, 2020
Follow-Up Cost	0.000	0.000	Gamma	Curtis & Burns, 2020
Number of Sessions	[redacted]	[redacted]		[redacted]

Provide the price for the comparator technology, which should reflect as closely as possible the price(s) paid in the NHS (excluding VAT). Describe any uncertainty over the appropriate price to use in the submission.

Costs	Values (£)			
Physiotherapy Cost	10.333	11.126	Gamma	Curtis & Burns, 2020
Follow-Up Cost	0.000	0.000	Gamma	Curtis & Burns, 2020
Administration Cost	1.553	1.009	Gamma	Curtis & Burns, 2020
Utilities	Values			
QoL SMR Responder	[redacted]	[redacted]	[redacted]	[redacted]
QoL SMR No Responder	[redacted]	[redacted]	[redacted]	[redacted]

NHS and unit costs

Describe how the clinical management of the condition is currently costed in the NHS, for example using the latest Health Resource Group (HRG) codes via the National Cost Collection (NCC; previously called ‘reference costs’), the unit costs (from the Personal Social Services Research Unit. Provide relevant codes and values (for example, OPCS codes and ICD codes) for the operations, procedures and interventions included in the decision model. Present the value using inflation indices appropriate to the cost perspective (see User Guide for suggested sources), and ensure all costs are presented in GBP.

Resource use

Describe any relevant resource data for the NHS from published and unpublished studies. Provide sources and rationale if relevant. If a literature search was done to identify evidence for resource

use, provide details in appendix D.

The cost of resource were taken from various resources mentioned in the last column

Resources	Deterministic	Probabilistic	Distribution	Resources
GP cost per average appointment (10 min)	£ 36.00	£ 38.21	Gamma	Public Health England, 2018
A&E attendance – no admission	£ 100.53	£ 101.29	Gamma	Public Health England, 2018
Non Elective Inpatients	£ 1,609.00	£ 1,557.02	Gamma	Curtis, L. & Burns, A., 2016
Ambulance call-out	£ 236.00	£ 250.55	Gamma	Public Health England, 2018
Excess length of Stay cost per day	£ 306.00	£ 298.26	Gamma	Curtis, L. & Burns, A. 2016

Describe the resources needed to implement the technology in the NHS. Provide sources and rationale.

Resources	Values (£)			
	Deterministic	Probabilistic	Distribution	Resources
Physiotherapy Cost	10.333	11.126	Gamma	Curtis & Burns, 2020
Follow-Up Cost	0.000	0.000	Gamma	Curtis & Burns, 2020
Administration Cost	1.553	1.009	Gamma	Curtis & Burns, 2020

Describe the resources needed to manage the change in patient outcomes after implementing the technology. Provide sources and rationale.

N/A

Describe the resources needed to manage the change in system outcomes after implementing the technology. Provide sources and rationale.

N/A

Table 10 Resource use costs

In this table, summarise how the decision model calculates the results of these changes in resource use. Adapt the table as necessary.

Cost	Technology costs (GS)	Comparator 1 costs (self-managed rehabilitation)	Comparator 2 costs (group/ individual rehabilitation)	Difference in resource use costs (technology versus comparator 1)	Difference in resource use costs (technology versus comparator 2)
Cost of resource use to implement technology	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Cost of resource use associated with patient outcomes	N/A	N/A	N/A	N/A	Enter text.
Cost of resource use associated with system outcomes	N/A	N/A	N/A	N/A	Enter text.
Total costs	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Adverse event costs

If costs of adverse events were included in the analysis, explain how and why the risk of each adverse event was calculated.

Separate adverse event costs were not included in the model.

Table 11 Adverse events and costs in the decision model

In this table, summarise the costs associated with each adverse event included in the decision model. Include all adverse events and complication costs, both during and after long-term use of the technology. Explain whether costs are provided per patient or per event.

Adverse event	Items	Cost	Source
Estimated falls incidents costs based risk of falling for GS per patient (Emergency admission, hospital admission. Ambulance call out based on the incident probability in the decision tree)	Technology	Enter text.	Enter text.
	Staff	Enter text.	Enter text.
	Hospital costs	Enter text.	Enter text.
	[Other items]	Enter text.	Enter text.
	Total	Enter text.	Enter text.
Estimated falls incidents based risk of falling for SoC per patient (Emergency admission, hospital admission. Ambulance call out based on the incident probability in the decision tree)	Technology	Enter text.	Enter text.
	Staff	Enter text.	Enter text.
	Hospital costs	Enter text.	Enter text.
	[Other items]	Enter text.	Enter text.
	Total	Enter text.	Enter text.
[Add more rows as needed]			

Miscellaneous costs

Describe any additional costs or resource considerations that have not been included elsewhere (for example, Personal Social Services costs, and patient and carer costs). If none, state.

N/A

Are there any other opportunities for resource savings or redirection of resources that have not been possible to quantify?

N/A

Total costs

In the following tables, summarise the total costs:

- Summarise total costs for the technology in table 12.
- Summarise total costs for the comparator in table 13. This can only be completed if the comparator is another technology.

Table 12 Total costs for the technology in the decision model

Description	Cost	Source
Cost per treatment/patient over lifetime of device	[redacted]	[redacted]
Consumables per year (if applicable) and over lifetime of device	[redacted]	[redacted]
Maintenance cost per year and over lifetime of device	[redacted]	[redacted]
Training cost over lifetime of device	[redacted]	[redacted]
Other costs per year and over lifetime of device	[redacted]	[redacted]
Total cost per treatment/patient over lifetime of device	[redacted]	[redacted]

Table 13 Total costs for the comparator in the decision model.

Description	Cost	Source
Cost per treatment/patient over lifetime of device	£517.56	PSSRU,2020
Consumables per year (if applicable) and over lifetime of device	£0	PSSRU,2020
Maintenance cost per year and over lifetime of device	£0	PSSRU,2020
Training cost over lifetime of device	£0	PSSRU,2020
Other costs per year and over lifetime of device	£0	PSSRU,2020
Total cost per treatment/patient over lifetime of device	£517.56	PSSRU,2020

Table 14 Summary of all resource use and unit costs used in decision model. Please ensure you identify all component costs and include sufficient detail to allow the reader to clearly identify the input from the source data

Description	Unit costs	Resource use	Included cost	Source
Group / individual Physiotherapy Physiotherapist Band 6	£48 per hour	60 minutes	£48	Band 6 hospital based physiotherapist (PSSRU 2020)
Group / individual Physiotherapy - Consultant (Surgical)	£114 per hour	30 min	£57	PSSRU 2020
Group / individual Physiotherapy - Administration	£9.32 per hour	15 min	£2.33	PSSRU 2020
Self-managed rehabilitation – physiotherapist band 4	£31 per hour	20 min	£10.33	PSSRU 2020
Self – managed rehabilitation – Administration	£9.32 per hour	10 min	£1.55	PSSRU 2020
GaitSmart- device cost per session	£10 per session			GaitSmart
GaitSmart- healthcare Assistant	£28 per hour	20 min	£9.33	PSSRU 2020
GaitSmart – Administration	£9.32 per hour	10 min	£1.55	PSSRU 2020

Base-case results

Table 15 Base-case results

In this table, report the results of the base-case analysis. Specify whether costs are provided per treatment or per year. Adapt the table as necessary to suit the decision model. If appropriate, describe costs by health state. In line with section 4.7.12 of the manual, results should be presented as probabilistic cost savings where possible unless a deterministic approach can be justified.

Scenario analysis

If relevant, explain how scenario analyses were identified and done. Cross-refer your response to the decision problem in section 1.1. Justify if scenario analyses are not probabilistic. See the user guide for full details of the information required.

Some scenario analyses based on the percentage of reduction in physiotherapy costs were performed in order to see how ROI varies according to such cost changes.

Describe the differences between the base case and each scenario analysis.

The reduction of 1%, 3% and 5% in the physiotherapy cost compared to base case (0%) were used in the scenario analysis.

Describe how the scenario analyses were included in the cost comparison analysis.

Based on the above mentioned three different scenarios, separate ROIs were calculated for each reduction scenarios.

Describe the evidence that justifies including any scenario analyses.

N/A

Table 16 Scenario analyses results

In this table, describe the results of any scenario analyses that were done. Adapt the table as necessary.

Sensitivity analysis

Probabilistic sensitivity analysis

Describe the methods of the probabilistic sensitivity analysis. See the user guide for full details of the information required. If no probabilistic sensitivity analyses have been done, explain why.

Uncertainty around the parameter estimates used in our model was fully characterized and propagated through to the model results by conducting probabilistic sensitivity analyses (PSA). This was done by defining parameter values using distributions rather than point estimates. The model was then run 1000 times with a value randomly drawn from the assigned probability distribution. This produced a distribution of model outputs which was represented visually on the cost-effectiveness plane. Cost-effectiveness acceptability curves (CEACs) were used to represent the probability that an intervention would be cost-effective compared to the control group at a range of willingness-to-pay thresholds

Present the results of the probabilistic sensitivity analysis.

Figure: Scatter plot of ICER of GS vs SoC

Figure: Cost-effectiveness acceptability curves of GS system vs SoC

Deterministic sensitivity analyses

Describe the methods of the deterministic sensitivity analyses. See the user guide for full details of the information required.

N/A

Present the results of the deterministic sensitivity analyses, focusing on the key drivers of the decision model. Consider the use of tornado diagrams.

N/A

Threshold analysis

Identify and present relevant parameter boundaries via threshold analyses. Explain whether these boundaries will fall within the expected uncertainty boundaries.

N/A

Summary of sensitivity analysis results

Summarise the main findings of the sensitivity analyses. What are the main sources of uncertainty about the decision model's conclusions?

Considering the uncertainties of the values inserted in the model, a PSA was carried out. The figure above represents the incremental cost-effectiveness plane and demonstrates the robustness of the results. All simulations are distributed in the southeast quadrant, confirming that GS is more effective and less costly when compared to the SoC. Further details on the PSA results are described in the result table which is presented along with the deterministic results and confirms that GS is a dominant strategy to improve the movements of older persons who have suffered a fall or are afraid of falling. The CEAC plot above for the scenario studied indicates the probability of the intervention being cost-effective when compared to the alternatives, according to the different thresholds. In all cases, the curves support the results suggested by the scatter plot. When comparing GS with SoC all scenarios show that GS is a cost-effective option regardless willingness-to-pay threshold

Miscellaneous results

Include any other relevant results here.

N/A

Validation

Describe the methods used to validate, cross-validate (for example, with external evidence sources) and quality assure the decision model, and complete the checklist in Appendix E. Provide sources, and cross-refer to evidence when appropriate.

NA

Give details of any clinical experts who were involved in validating the decision model, including names and contact details. Highlight any personal information as confidential.

N/A

5 Summary and interpretation of economic evidence (Early evidence economic model – Model 1)

Describe the main findings from the economic evidence and decision model. Explain any potential cost savings and the reasons for them.

A decision tree analysis with a time horizon of twelve months was developed to estimate the potential results. Based on our predefined parameters, this study showed [redacted]. The EEE used the most relevant parameters, [redacted]. This is the first UK-specific study and the first internationally to develop a novel health economics model to assess the cost-effectiveness of the GS system in [redacted] using the NHS perspective [redacted].

Briefly discuss the relevance of the evidence base to the scope.

Aiming to translate the clinical improvements observed in the data into tangible economic benefits for healthcare payers, we built an exploratory economic model sophisticated enough to carry out an economic assessment in an area where both physical and psychological parameters influence the ability to walk confidently. One of the main aims of the study was to examine the [redacted]

Briefly discuss if the results are consistent with the published literature. If they are not, explain why and justify why the results in the submission be favoured over those in the published literature.

[redacted]. Previous studies have evaluated the walking speed of individuals of different ages, and their results show that when this speed deviates from the normal pattern, this represents a potential problem related to walking. All studies nominally agreed that a change of 0.05 meters/second (m/s) has a significant impact on the risk of falls and well-being in older adults, also stating that for those with gait issues, improved speed should be greater than 0.1 m/s (25–28). Hospital costs are not the only components of care that arose since a substantial

proportion of people who fall lose their independence and an FoF can lead to a greater risk of future falls which require further resources from many different stakeholders, including families and caregivers, the NHS, and local authorities. Several interventions have been shown to be effective in preventing falls, in particular, interventions that contain challenging balance and functional elements result in the most beneficial outcomes (29,30).

Describe if the cost comparison analysis is relevant to all patient groups and NHS settings in England that could potentially use the technology as identified in the scope.

The study population comprised participants who were approached by a member of the research team. The target population consisted of [redacted]

Briefly summarise the strengths and limitations of the cost analysis, and how these might affect the results.

Strength

The model supporting this analysis is interactive and as such can be updated to reflect ongoing changes in fall prevention practice. Using the NELFT data provided by DML, the model shows that the [redacted]. Finally, the model can provide useful information [redacted], making it a powerful tool to help policymakers. The current study demonstrated that it is feasible to use widely available published evidence t estimate the personal [redacted]. The current model has incorporated objective and subjective data into the [redacted]t, providing a robust assessment of the cost and impact associated with the GS system. This translates the observed clinical improvements in the data into tangible economic benefits for healthcare payers.

Limitation

A limitation of simulation models in complex areas such as health and health care are that they rely on many assumptions about important, but unknown parameters. Whilst the main data sources for the analysis are robust, there is relatively limited follow-up data on the effectiveness of each intervention. Consequently, the timeframe of the analysis has been limited to one year with the assumption made that all benefits from the intervention will cease by the end of this one-year. Clearly, this is not always the case. Furthermore, the data should be considered in terms of generalizability. The distinction between the characteristics of the study participants also limits the generalizability of the results of this analysis. Therefore, they only remain

valid if the intervention is targeted at populations that are like the study cohort. The results are valid for the intervention targeted for populations similar to the study cohorts. However, it is expected that there will be a degree of variation in local practice, and this will impact the results of the analysis. In particular, the location is expected to impact the cost of implementing the intervention (e.g., exercise classes may be more expensive to implement in rural locations due to a need for staff to travel greater distances) and the costs related to falls may differ across Integrated Care Boards (ICBs). Furthermore, long-term fall incidents' costs and consequences were not included as this would require further assumptions to be made in the lack of long-term participant monitoring by the study. If these costs were included, the cost-effectiveness of screening with the intervention would potentially improve. As the model does not consider social care costs when a broader societal perspective is adopted and the impact of any intervention on a participant's quality of life is formally quantified, then returns with each intervention increase. However, if the GS system were introduced into the lower-risk population, the expected return on investment would be different.

Detail any further analyses that could be done to improve the reliability of the results.

A long term follow up RCT

5.1 Main Economic Model (Model 2)

This section refers to the decision model that you have submitted.

Decision model description

Patients

Describe which patient groups are included in the decision model.

The study population comprised participants who were approached [redacted]. The target population was adults who met the following criteria: [redacted]

The study managed to recruit [redacted]

Technology and comparator(s)

State the technology and comparators used in the decision model. Provide a justification if the comparator(s) used in the decision model is different to that in the scope.

The GaitSmart (GS) is a sensor-based digital medical device (CE Marked Class 1M Medical Device). Using an algorithm, the GS provides a detailed and objective measure of a patient's walking ability, in which the collected data are used to automatically define a personalized exercise program. Patients assigned to the intervention group (GS) were monitored [redacted]. All exercises were recommended either in the Otago Exercise Program (OEP) or in the NHS older people guidance, as per current appropriate practice. All interventions were delivered by the research team. Training of the research team was undertaken by Dynamic Metrics. To deliver the intervention, a 20-metre
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. Patients in the SoC group received postoperative rehabilitation according to the NICE Quality Standard (QS 206) (16). All patients were advised on self-directed rehabilitation. Those who had difficulties managing activities of daily living with an ongoing functional impairment or felt that they were not achieving their goals through self-directed rehabilitation were offered group or individual outpatient rehabilitation

Decision model structure

Provide a diagram of the decision model structure you have chosen in appendix F.

Justify the chosen structure of the decision model by referring to the clinical care pathway outlined in section 1.3. Decision model structures should normally incorporate clinical parameters based on appropriate estimates of clinical effectiveness. This allows for sensitivity analyses to be done on the impact of varying the clinical parameters to explore any uncertainty in the estimates. For this reason, decision model structures should not just be based on simple cost calculations.

We need the NELFT decision model in as well for falls

The economic model was based on a previous early economic model and is in line with the current clinical pathway described for patients undergoing THA or TKA who are eligible for SoC, according to the guidance set out by NICE (Figure 1). The seventeen weeks (GS RCT period) are represented by a decision tree model, developed in Microsoft Excel 2013. In summary, patients assigned to the GS group were [redacted], while

patients assigned to the SoC group were not monitored with GS and could be allocated to

receive either self-managed home exercise or group or individual physiotherapy (4-6 sessions). At the end of the path, each branch of the decision tree provides the outcomes of the model (response or no response).

Table 7 Assumptions in the decision model

In this table, list the main assumptions in the decision model and justify why each has been used.

<table>
<tr><th>Assumption</th><th>Justification</th><th>Source</th></tr>
<tr><td>In the standard of care (SoC) cohort we assumed that 20% of the participants will follow a self-managed rehabilitation while 80% will follow a group / individual rehabilitation</td><td>This was in order to represent more accurately what is happening in practice. The percentages can be changed in the model to create and check a range of scenarios</td><td></td></tr>
<tr><td>In regards to the falls incidents calculation we assumed a THA in conjunction with Hip osteoarthritis</td><td>We investigated the literature for the falls odds ratio under various conditions and we calculated a joint risk with THA and TKA. Users can choose any factor of the list to create and check a range of scenarios
Fall Incident Probabilities
<table><tr><th>Factors</th><th>OR</th><th>Reference</th></tr><tr><td>Female</td><td>1.61</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>Overweight (BMI≥25kg/m2)</td><td>1.18</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>Falls history</td><td>3.56</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>Use of walking aid</td><td>1.71</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>Diabetes</td><td>1.39</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>Cardiac disease</td><td>1.25</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>Hypertension</td><td>1.10</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>Depressive symptoms</td><td>1.27</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>COPD</td><td>1.11</td><td>Liu et al., 2020. doi: 10.1097/MD.0000000000023664</td></tr><tr><td>Knee osteoarthritis</td><td>1.39</td><td>Doré et al., 2015. doi: 10.1002/acr.22499</td></tr><tr><td>Hip osteoarthritis</td><td>1.60</td><td>Doré et al., 2015. doi: 10.1002/acr.22499</td></tr></table><table><tr><th>THA</th><th>Arthroplasty group</th><th>Non-arthroplasty group</th><th>Odd ratio</th><th>(95 % CI)</th></tr><tr><td>Fall in past 12 months (%)</td><td>0.25</td><td>0.27</td><td>0.9</td><td>0.58 - 1.14</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td>TKA</td><td></td><td></td><td></td><td></td></tr><tr><td>Fall in past 12 months (%)</td><td>0.261</td><td>0.271</td><td>0.95</td><td>0.67-1.35</td></tr></table>Reference: Smith et al., (2016). DOI 10.1007/s00402-016-2445-5</td><td>Liu, Y., Yang, Y., Liu, H., Wu, W., Wu, X., & Wang, T. (2020, December 11). A systematic review and meta-analysis of fall incidence and risk factors in elderly patients after total joint arthroplasty. Medicine (United States). Lippincott Williams and Wilkins. https://doi.org/10.1097/MD.0000000000023664
Doré, A.L., Golightly, Y.M., ... Nelson, A.E., 2015. Lower-extremity osteoarthritis and the risk of falls in a community-based longitudinal study of adults with and without osteoarthritis. Arthritis Care and Research 67, 633–639. doi:10.1002/acr.22499
Smith, T.O., Pearson, M., Latham, S.K., 2016. Are people following hip and knee arthroplasty at greater risk of experiencing a fall and fracture? Data from the Osteoarthritis Initiative. Archives of Orthopaedic and Trauma Surgery 136, 865–872. doi:10.1007/s00402-016-2445-5</td></tr>
<tr><td>We assumed a similar response probability for self-managed and group/individual rehabilitation</td><td>We assumed a similar response probability for self-managed and group/individual rehabilitation due to lack of evidence</td><td></td></tr>
</table>

Clinical parameters and variables

Table 8 Clinical parameters, patient and carer outcomes and system outcomes used in the decision model

In this table, describe the clinical parameters, patient and carer outcomes and system outcomes used in the decision model. Please include sufficient detail to allow the reader to clearly identify the input from the source data

Parameter/outcomes	Source	Relevant results	Range or distribution	How are these values used in the decision model?
Response / No response to rehabilitation	[redacted]	[redacted]	[redacted]	These values used in the main modelling as the transition probabilities of response and n response to rehabilitation stages
Walking Speed / increase or decrease and how affects the risk of falling	[redacted] and Verghese, J., Holtzer, R., ... Wang, C., 2009. Quantitative gait	[redacted]	[redacted]	Used in secondary calculation of falls incidents

Parameter/outcomes	Source	Relevant results	Range or distribution	How are these values used in the decision model?
	markers and incident fall risk in older adults. Journals of Gerontology - Series A Biological Sciences and Medical Sciences 64, 896–901. doi:10.1093/gerona/glp033	[redacted]		
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.

If expert elicitation methods were used to identify any model parameters and/or a plausible distribution, fully justify this and the methods outlined.

N/A

If any outcomes listed in table 10 are extrapolated beyond the study follow-up periods, explain the assumptions that underpin this extrapolation.

N/A

Table 9 Other parameters in the decision model

Describe any other parameters in the decision model. Examples are provided in the table. You can adapt the parameters as needed. Please include sufficient detail to allow the reader to clearly identify the input from the source data.

Parameter	Description	Justification	Source
Time horizon	17 weeks	In accordance to the SoC horizon which is 6-17 weeks For patients to respond to rehabilitation program and implement all GaitSmart tests.	Sokou, S.T., Roos, E.M., 2019. Physical therapy for patients with knee and hip osteoarthritis: supervised, active treatment is current best practice. Clinical and experimental rheumatology.

Parameter	Description	Justification	Source
		According to NICE guideline NG157 more than 8 weeks required to extract data on knee and hip function	NICE guideline NG157 NHS UK https://www.nhs.uk/conditions/hip-replacement/recovery/
Discount rate	0.035 0r 3.5% for costs and 0.015 or 1.5% for benefits	In accordance to the HM Treasury Green Book	HM Treasury Green Book Available at: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020
Perspective (NHS/personal social services)	NHS perspective	From the NHS perspective, the economic model estimated the relative cost-effectiveness of the GS compared with SoC for improving the gait and mobility issues in people undergoing THA or TKA, adhering to good practice guidelines and the NICE reference case. Therefore, only healthcare costs (direct medical costs) related to the disease were included.	Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. Value Health [Internet]. 2022 Jan 1 [cited 2023 Feb 20];25(1):3–9. Available from: https://pubmed.ncbi.nlm.nih.gov/35031096/ National Institute for Health and Care Excellence (NICE). NICE health technology evaluations: the manual | Guidance [Internet]. [cited 2023 Feb 21]. Available from: https://www.nice.org.uk/process/pmg36/chapter/introduction-to-

Parameter	Description	Justification	Source
			health-technology-evaluation
Cycle length	1	The structure of the model is a decision tree model	Enter text.
Transition probabilities	[redacted]	[redacted]	Enter text.
Health states	Rehabilitation – Response / No response	Based on GaitSmart RCT and model structure	Enter text.
Sources of unit costs	Department of Health. NHS Reference Costs 2018-19 GaitSmart stakeholders Costs of Health and Social Care 2020	GaitSmart internal costs were used for the cost of the intervention	Curtis, Lesley A., Burns A. Unit Costs of Health and Social Care 2020 | PSSRU. 2020 355 [cited 2023 Feb 22]; Available from: https://www.pssru.ac.uk/project-pages/unit- 356 costs/unit-costs-2020/ Department of Health. NHS Reference Costs 2018-19

Explain the transition matrix used in the decision model and the transformation of clinical outcomes, health states or other details.

The transition probabilities of patients assigned to the SoC group receiving self-managed home exercise or group/individual physiotherapy sessions were based on expert opinions that were derived from the GS RCT study and converted into appropriate parameters for our model ([redacted]

All medical resources costs were gathered from the Unit Costs of Health & Social Care 2020 report and Department of Health. NHS Reference Costs 2018-19 and expressed in British pounds.

QALYs were defined as the primary health outcome of the cost-effectiveness analysis. Healthutility estimates were measured using the EuroQol 5 Dimension (EQ-5D 5L) questionnaire and obtained from GS RCT study

Resource identification, measurement and valuation

NB: the sections below should be completed with a view to ensuring the EAG can understand clearly and quickly where all figures have been obtained e.g. all source detail should be sufficiently detailed. It is also important to describe how any figures have been calculated (including all assumptions, sources, calculations etc.)

Intervention and comparator technology costs

Provide the price for the intervention technology, which should reflect as closely as possible the price(s) paid in the NHS (excluding VAT). Describe any uncertainty over the appropriate price to use in the submission.

	Cost	Lower Confidence Interval (LCI) 95%	Upper Confidence Interval (UCI) 95%	Distribution for sensitivity analysis
GaitSmart Intervention Cost Per Patient per Session	£10	–	–	Calculated from GS RCT
Secondary Care Costs Per Patient per Session	£6.75	£2.66	£12.71	GAMMA

Follow-Up Cost	£0	£0	£0	GAMMA
Total Number of Sessions	[redacted]	_	_	Calculated from GS RCT

Provide the price for the comparator technology, which should reflect as closely as possible the price(s) paid in the NHS (excluding VAT). Describe any uncertainty over the appropriate price to use in the submission.

Self-managed Rehabilitation	Cost	Lower Confidence Interval (LCI) 95%	Upper Confidence Interval (UCI) 95%	Distribution for sensitivity analysis
Physiotherapy Cost per session	£10.33	£5.02	£17.52	Calculated from GS RCT
Secondary Care Costs Per patient	£0	£0	£0	GAMMA
Follow-Up Cost	£0	£0	£0	GAMMA
Administration costs per session	£1.55	£0.12	£4.77	Calculated from GS RCT
Total Number of Sessions	6	_	_	Calculated from GS RCT

Group/Individual rehabilitation	Cost	Lower Confidence Interval (LCI) 95%	Upper Confidence Interval (UCI) 95%	Distribution for sensitivity analysis
Physiotherapy Cost per session	£48	£35.39	£62.50	Calculated from GS RCT
Secondary Care Costs Per patient	£57	£43.17	£72.72	GAMMA
Follow-Up Cost	£0	£0	£0	GAMMA
Administration costs per session	£2.33	£0.35	£6.13	Calculated from GS RCT
Total Number of Sessions	6	_	_	Calculated from GS RCT

NHS and unit costs

Describe how the clinical management of the condition is currently costed in the NHS, for example using the latest Health Resource Group (HRG) codes via the National Cost Collection (NCC;

previously called ‘reference costs’), the unit costs (from the Personal Social Services Research Unit. Provide relevant codes and values (for example, OPCS codes and ICD codes) for the operations, procedures and interventions included in the decision model. Present the value using inflation indices appropriate to the cost perspective (see User Guide for suggested sources), and ensure all costs are presented in GBP.

Self-managed Rehabilitation	Cost	Lower Confidence Interval (LCI) 95%	Upper Confidence Interval (UCI) 95%	Distribution for sensitivity analysis
Health assistant per session	£10.33	£5.02	£17.52	Calculated from GS RCT
Secondary Care Costs Per patient	£0	£0|	£0	GAMMA
Follow-Up Cost	£0	£0	£0	GAMMA
Administration costs per session	£1.55	£0.12	£4.77	Calculated from GS RCT
Total Number of Sessions	6	_	_	Calculated from GS RCT

Curtis & Burns, 2020

Group/Individual rehabilitation	Cost	Lower Confidence Interval (LCI) 95%	Upper Confidence Interval (UCI) 95%	Distribution for sensitivity analysis
Physiotherapy Cost per session	£48	£35.39	£62.50	Calculated from GS RCT
Secondary Care Costs Per patient	£57	£43.17	£72.72	GAMMA
Follow-Up Cost	£0	£0	£0	GAMMA
Administration costs per session	£2.33	£0.35	£6.13	Calculated from GS RCT
Total Number of Sessions	6	_	_	Calculated from GS RCT

Curtis & Burns, 2020

Resource use

Describe any relevant resource data for the NHS from published and unpublished studies. Provide sources and rationale if relevant. If a literature search was done to identify evidence for resource use, provide details in appendix D.

Group/Individual rehabilitation	Staff
Physiotherapy Cost per session	1 Band 6
Secondary Care Costs Per patient	Consultant surgical
Administration costs per session	1 Admin staff
Total Number of Sessions	6

Self-managed Rehabilitation	Staff
Physiotherapy Cost per session	1 Band 4 for 1 session
Administration costs per session	1 Admin staff for one session

GaitSmart	Staff
Health assistant	[redacted]
Administration costs per session	[redacted]
Total Number of Sessions	[redacted]

Costs of resources taken from:

Curtis, Lesley A., Burns A. Unit Costs of Health and Social Care 2020 | PSSRU. 2020
355 [cited 2023 Feb 22]; Available from: https://www.pssru.ac.uk/project-pages/unit- 356 costs/unit-costs-2020/

Department of Health. NHS Reference Costs

Describe the resources needed to implement the technology in the NHS. Provide sources and rationale.

GaitSmart	Staff

Health assistant	[redacted]
Administration costs per session	[redacted]
Total Number of Sessions	[redacted]

Describe the resources needed to manage the change in patient outcomes after implementing the technology. Provide sources and rationale.

N/A

Describe the resources needed to manage the change in system outcomes after implementing the technology. Provide sources and rationale.

N/A

Table 10 Resource use costs

In this table, summarise how the decision model calculates the results of these changes in resource use. Adapt the table as necessary.

Cost	Technology costs	Comparator 1 costs	Comparator 2 costs	Difference in resource use costs (technology versus comparator 1)	Difference in resource use costs (technology versus comparator 2)
Cost of resource use to implement technology	[redacted]	[redacted]	N/A	[redacted]	Enter text.
Cost of resource use associated with patient outcomes	N/A	N/A	N/A	N/A	Enter text.
Cost of resource use associated with system outcomes	N/A	N/A	N/A	N/A	Enter text.
Total costs	[redacted]	[redacted]	N/A	[redacted]	Enter text.

Adverse event costs

If costs of adverse events were included in the analysis, explain how and why the risk of each adverse event was calculated.

The main event is the non-response to the technology that does not lead to different costs than the non-response to the standard of care

As a secondary calculation we estimated the risk and probability of falling based on walking Speed / increase or decrease and how affects the risk of falling (GS RCT and Verghese, J., Holtzer, R., ... Wang, C., 2009. Quantitative gait markers and incident fall risk in older adults. Journals of Gerontology - Series A Biological Sciences and Medical Sciences 64, 896–901. doi:10.1093/gerona/glp033)

as well as based on the falls odds ratio under various conditions and we calculated a joint risk with THA and TKA. Users can choose any factor of the list to create and check a range of scenarios

Fall Incident Probabilities

Factors	OR	Reference
Female	1.61	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
Overweight (BMI≥25kg/m2)	1.18	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
Falls history	3.56	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
Use of walking aid	1.71	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
Diabetes	1.39	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
Cardiac disease	1.25	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
Hypertension	1.10	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
Depressive symptoms	1.27	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
COPD	1.11	Liu et al., 2020. doi: 10.1097/MD.0000000000023664
Knee osteoarthritis	1.39	Doré et al., 2015. doi: 10.1002/acr.22499
Hip osteoarthritis	1.60	Doré et al., 2015. doi: 10.1002/acr.22499

THA	Arthroplasty group	Non-arthroplasty group	Odd ratio	(95 % CI)
Fall in past 12 months (%)	0.25	0.27	0.9	0.58 - 1.14
TKA				
Fall in past 12 months (%)	0.261	0.271	0.95	0.67-1.35

Reference: Smith et al., (2016). DOI 10.1007/s00402-016-2445-5

(Liu, Y., Yang, Y., Liu, H., Wu, W., Wu, X., & Wang, T. (2020, December 11). A systematic review and meta-analysis of fall incidence and risk factors in elderly patients after total joint arthroplasty. Medicine (United States). Lippincott Williams and Wilkins. https://doi.org/10.1097/MD.0000000000023664

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Smith, T.O., Pearson, M., Latham, S.K., 2016. Are people following hip and knee arthroplasty at greater risk of experiencing a fall and fracture? Data from the Osteoarthritis Initiative. Archives of Orthopaedic and Trauma Surgery 136, 865–872. doi:10.1007/s00402-016-2445-5)

Table 11 Adverse events and costs in the decision model

In this table, summarise the costs associated with each adverse event included in the decision model. Include all adverse events and complication costs, both during and after long-term use of the technology. Explain whether costs are provided per patient or per event.

Adverse event	Items	Cost	Source

Estimated falls incidents costs based risk of falling for GS per patient (Emergency admission, hospital admission. Ambulance call out based on the incident probability in the decision tree)	Technology	Enter text.	Enter text.
	Staff	Enter text.	Enter text.
	Hospital costs	Enter text.	Enter text.
	[Other items]	Enter text.	Enter text.
	Total	£58	Department of Health. NHS Reference Costs 2018-19
Estimated falls incidents based risk of falling for SoC per patient (Emergency admission, hospital admission. Ambulance call out based on the incident probability in the decision tree)	Technology	Enter text.	Enter text.
	Staff	Enter text.	Enter text.
	Hospital costs	Enter text.	Enter text.
	[Other items]	Enter text.	Enter text.
	Total	£532	Department of Health. NHS Reference Costs 2018-19
[Add more rows as needed]			

Miscellaneous costs

Describe any additional costs or resource considerations that have not been included elsewhere (for example, Personal Social Services costs, and patient and carer costs). If none, state.

N/A

Are there any other opportunities for resource savings or redirection of resources that have not been possible to quantify?

N/A

Total costs

In the following tables, summarise the total costs:

- Summarise total costs for the technology in table 12.
- Summarise total costs for the comparator in table 13. This can only be completed if the comparator is another technology.

Table 12 Total costs for the technology in the decision model

Description	Cost	Source
Cost per treatment/patient over lifetime of device	[redacted]	GaitSmart
Consumables per year (if applicable) and over lifetime of device	[redacted]	GaitSmart
Maintenance cost per year and over lifetime of device	[redacted]	GaitSmart
Training cost over lifetime of device	[redacted]	GaitSmart
Other costs per year and over lifetime of device	[redacted]	GaitSmart
Total cost per treatment/patient over lifetime of device	[redacted]	GaitSmart

Table 13 Total costs for the comparator in the decision model.

Description	Cost	Source
Cost per treatment/patient over lifetime of device	£517.56	PSSRU,2020
Consumables per year (if applicable) and over lifetime of device	£0	PSSRU,2020
Maintenance cost per year and over lifetime of device	£0	PSSRU,2020
Training cost over lifetime of device	£0	PSSRU,2020
Other costs per year and over lifetime of device	£0	PSSRU,2020
Total cost per treatment/patient over lifetime of device	£517.56	PSSRU,2020

Table 14 Summary of all resource use and unit costs used in decision model. Please ensure you identify all component costs and include sufficient detail to allow the reader to clearly identify the input from the source data

Description	Unit costs	Resource use	Included cost	Source
Group / individual Physiotherapy Physiotherapist Band 6	£48 per hour	60 minutes	£48	Band 6 hospital based physiotherapist (PSSRU 2020)
Group / individual Physiotherapy - Consultant (Surgical)	£114 per hour	30 min	£57	PSSRU 2020
Group / individual Physiotherapy - Administration	£9.32 per hour	15 min	£2.33	PSSRU 2020
Self-managed rehabilitation – physiotherapist band 4	£31 per hour	20 min	£10.33	PSSRU 2020
Self – managed rehabilitation – Administration	£9.32 per hour	10 min	£1.55	PSSRU 2020
GaitSmart- device cost per session	£10 per session			GaitSmart
GaitSmart- healthcare Assistant	£28 per hour	20 min	£9.33	PSSRU 2020
GaitSmart – Administration	£9.32 per hour	10 min	£1.55	PSSRU 2020

Base-case results

Table 15 Base-case results

In this table, report the results of the base-case analysis. Specify whether costs are provided per treatment or per year. Adapt the table as necessary to suit the decision model. If appropriate, describe costs by health state. In line with section 4.7.12 of the manual, results should be presented as probabilistic cost savings where possible unless a deterministic approach can be justified.

–	Mean discounted cost per patient using the technology (£)	Mean discounted cost per patient using the comparator 1 (£)	Mean discounted cost per patient using the comparator 2 (£)	Difference in mean discounted cost per patient (£): technology versus comparator 1 (negative values indicate a cost saving)	Difference in mean discounted cost per patient (£): technology versus comparator 2 (negative values indicate a cost saving)
Device cost	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Training cost	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Administration cost	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Monitoring costs	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Consumables	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Adverse events	Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Total	[redacted]	[redacted]	N/A	[redacted]	Enter text. N/A

Scenario analysis

If relevant, explain how scenario analyses were identified and done. Cross-refer your response to the decision problem in section 1.1. Justify if scenario analyses are not probabilistic. See the user guide for full details of the information required.

N/A

Describe the differences between the base case and each scenario analysis.

N/A

Describe how the scenario analyses were included in the cost comparison analysis.

N/A

Describe the evidence that justifies including any scenario analyses.

N/A

Table 16 Scenario analyses results

In this table, describe the results of any scenario analyses that were done. Adapt the table as necessary.

–	Mean discounted cost per patient using the technology (£)	Mean discounted cost per patient using the comparator (£)	Difference in cost per patient (£; negative values indicate a cost saving)
Scenario 1 (total costs)	Enter text.	Enter text.	Enter text.
Scenario 2 (total costs)	Enter text.	Enter text.	Enter text.

Sensitivity analysis

Probabilistic sensitivity analysis

Describe the methods of the probabilistic sensitivity analysis. See the user guide for full details of the information required. If no probabilistic sensitivity analyses have been done, explain why.

Uncertainty around the parameter estimates used in our model was fully characterized and propagated through to the model results by conducting probabilistic sensitivity analyses (PSA). This was done by defining parameter values using distributions rather than point estimates. The model was then run 1000 times with a value randomly drawn from the assigned probability distribution. This produced a distribution of model outputs which was represented visually on the cost-effectiveness plane. Cost-effectiveness acceptability curves (CEACs) were used to represent the probability that an intervention would be cost-effective compared to the control group at a range of willingness-to-pay thresholds

Present the results of the probabilistic sensitivity analysis.

Deterministic sensitivity analyses

Describe the methods of the deterministic sensitivity analyses. See the user guide for full details of the information required.

N/A

Present the results of the deterministic sensitivity analyses, focusing on the key drivers of the decision model. Consider the use of tornado diagrams.

N/A

Threshold analysis

Identify and present relevant parameter boundaries via threshold analyses. Explain whether these boundaries will fall within the expected uncertainty boundaries.

N/A

Summary of sensitivity analysis results

Summarise the main findings of the sensitivity analyses. What are the main sources of uncertainty about the decision model's conclusions?

The cost-effectiveness plane shows the results of running the model 1000 times and recording the difference in cost and effectiveness between the GS and SoC. Using 1,000 Monte-Carlo simulations, PSA has shown that at a willingness to pay (WTP) £20,000, the GS system is dominant over SoC to improve gait and mobility issues in people undergoing THA and TKA. Although most data points are observed in the southeast quadrant of the plane (representing the scenario of 'less costly and more effective', that is, a dominant strategy), there is considerable uncertainty surrounding the extent and existence of the additional expected costs and the existence and extent of the additional expected QALYs

The CEAC shows the probability of GS being cost-effective for different levels of willingness-to-pay thresholds, compared with SoC (Figure 3). The CEAC shows that, at a willingness-to-pay threshold of £20,000 per QALY gained, GS has a [redacted] probability of being cost-effective, compared with SoC.

Overall, regardless of these limitations, the current study adds to this body of evidence that the use of GS in clinical practice for the rehabilitation of patients undergoing THA or TKA seems to be cost-effective. Sensitivity analysis performed to evaluate our assumptions regarding the input parameters indicated that even when we range the input values around the mean, the GS system remains a more cost-effective option.

Miscellaneous results

Include any other relevant results here.

N/A

Validation

Describe the methods used to validate, cross-validate (for example, with external evidence sources) and quality assure the decision model, and complete the checklist in Appendix E. Provide sources, and cross-refer to evidence when appropriate.

We have performed an external quality assurance investigation of the model through an independent academic health economist from University of Manchester with extensive experience with NICE submissions and Innovate UK projects ([redacted])

Give details of any clinical experts who were involved in validating the decision model, including names and contact details. Highlight any personal information as confidential.

N/A

6 Summary and interpretation of economic evidence (Main economic model – Model 2)

Describe the main findings from the economic evidence and decision model. Explain any potential cost savings and the reasons for them.

We need to include the falls cohort and the NELFT study results

Our results indicate that the GS, compared with the SoC,

[redacted].

There are a limited number of studies focusing on the cost-effectiveness analysis of rehabilitation forms following THA or TKA. To the best of our knowledge, this is the first study assessing the cost-effectiveness of the GS system for THA or TKA patients. Therefore, the comparison of our results with those from the literature is problematic. However, our study results were consistent

with other economic evaluations that evaluated different rehabilitation components for patients with THA or TKA, suggesting that these

[redacted]

Overall, regardless of these limitations, the current study adds to this body of evidence that the use of GS in clinical practice for the rehabilitation of patients undergoing THA or TKA

[redacted]e. Sensitivity analysis performed to evaluate our assumptions regarding the

input parameters indicated that even when we range the input values around the mean, the

[redacted].

Briefly discuss the relevance of the evidence base to the scope.

Briefly discuss if the results are consistent with the published literature. If they are not, explain why and justify why the results in the submission be favoured over those in the published literature.

Our study results were consistent with other economic evaluations that evaluated different rehabilitation components for patients with THA or TKA, suggesting that [redacted]

Describe if the cost comparison analysis is relevant to all patient groups and NHS settings in England that could potentially use the technology as identified in the scope.

The study population comprised participants who were approached at their [redacted]. The target population was adults who met the following criteria: [redacted].

Briefly summarise the strengths and limitations of the cost analysis, and how these might affect the results.

The main strength of the study is that all input parameters used in the model, such as resource use, probabilities, and costs, are real-life parameters retrieved at the individual level from the GS RCT funded by Innovate UK, which supports the reliability and validity of these parameters. The main limitation of the study is that the GS RCT had [redacted]

These limitations should be addressed in future RCTs.

In the current study, healthcare costs per QALY were assessed over a 17-week horizon (GS RCT period). OA is a long-term chronic condition (24), so analysing cost-effectiveness over a seventeen-week horizon is a relatively short time horizon, warranting further long-term cost-effectiveness analyses. However, a model-based cost-effectiveness analysis suggested that a physical activity program for patients with knee OA [redacted].

Detail any further analyses that could be done to improve the reliability of the results.

A long term follow up RCT

7 Resource impact analysis

The resource impact team at NICE estimates the costs or savings (budget impact) associated with technologies so the NHS can plan for and implement guidance. In order to produce a resource impact report and template the team requests the following information:

7.1 Population and uptake estimates

In table 17, provide estimates of the number of people who would be eligible to use your technology in years 1 to 5 and the expected uptake in each of the 5 years.

Table 17 Population and uptake estimates

Early evidence economic model – Model 1

Year	1	2	3	4	5
Number of people eligible to use technology	**3.3 million**	**3.3 million**	**3.4 million**	**3.4 million**	**3.5 million**
Uptake of technology	**2.5%**	**5%**	**7.5 %**	**12.5%**	**17.5%**

Ref: Office for National statistics 2021 Census. 10.9 million people 65 or over in England and Wales and 30% of these will suffer a fall. This number will increase each year.

Main Model (Model 2)

Year	1	2	3	4	5
Number of people eligible to use technology	**145,000**	**145,000**	**145,000**	**145,000**	**145,000**
Uptake of technology	**5%**	**7.5%**	**10 %**	**12.5%**	**15%**

This is for joint replacement.

Eligible population based on

Nagra, N.S., Hamilton, T.W., ... Wilson, W., 2017. Enhanced recovery programmes for lower limb arthroplasty in the UK. Annals of the Royal College of Surgeons of England 99, 631–636. doi:10.1308/rcsann.2017.0124

7.2 Sales

In table 18, provide estimates of the number of items of this technology you expect to sell in years 1 to 5 in the UK.

Table 18 Sales estimates

Early evidence economic model – Model 1 Falls prevention

Year	1	2	3	4	5
Sales of technology	330,000	660,000	1 million	1.6 million	2.3 million

Number of tests, assuming 4 tests per person. Year 1 commences 6 months after Guidance is published

Main Model (Model 2) Joint replacement

Year	1	2	3	4	5
Sales of technology	29,000	43,500	58,000	72,500	87,000

Assumes [redacted] tests per eligible person

7.3 Acquisition costs

The price of the technology should reflect as closely as possible the price(s) paid in the NHS, and analyses should be based on price reductions, if the price reduction is available across the NHS. In table 19, provide an estimate of the aggregate purchase costs of the technology and associated set-up and implementation costs across the NHS in each of the 5 years, excluding VAT.

Table 19 Aggregate total costs

Early evidence economic model – Model 1

Year	1	2	3	4	5
Purchase cost of technology excluding VAT	£3.3 million	£6.6 million	£10 million	£16 million	£23 million
Other set-up and implementation costs	£100,000+ £2.2 million	£100,000+ £4.4 million	£100,000+ £6.75 million	£200,000+ £10.8 million	£300,00
Total costs excluding VAT	£5.6 million	£11.1 million	£16.85 million	£27 million	£23.8 million

Assumes £10 per test. Each site could do 4,000 tests per year.

Set up costs are £1,000 per site. Once sites are set up there is no ongoing cost, so only additional costs are included. Number of sites increases in line with the number of tests.

Implementation is assumed to be £6.75 per test with a Healthcare Assistant performing the test.

Year	1	2	3	4	5
Sales of technology	29,000	43,500	58,000	72,500	87,000

Main Model (Model 2)

Year	1	2	3	4	5
Purchase cost of technology excluding VAT	£290,000.00	£465,982.88	£643,056.37	£831,954.18	£1,033,287.09
Other set-up and implementation costs	£78,880.00	£126,747.34	£174,911.33	£226,291.54	£281,054.09
Total costs excluding VAT	£368,880.00	£592,730.22	£817,967.70	£1,058,245.71	£1,314,341.17

Assumes £10 per test. Each site could do 4,000 tests per year.

Set up costs are [redacted] per site. Number of sites increases in line with the number of tests.

Costs inflate by 3.5% per year an estimated for the total of sales per year as they are presented in Table 18

If the purchase cost reported in table 19 does not represent the technology price and other charges used in the base case of the decision model, record which unit prices are used and explain the differences.

Enter text.

8 References

Include all references below using NICE's standard referencing style.

Enter text.

Clinical Effectiveness

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Systematic Search: Gait Speed Rehabilitation Biomechanics Falls

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9 Appendices

Appendix A: Identification and selection of relevant studies

Search methods for clinical evidence

Describe the process and methods used to identify and select the studies relevant to the technology; a pragmatic literature search is acceptable if justified. Include searches for published studies, abstracts and ongoing studies in separate tables as appropriate. See section 1.2 of the user guide for full details of how to complete this section.

<table>
<tr><th>Topic</th><th>Method details</th></tr>
<tr><td>Eligibility criteria</td><td>Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.

Clinical evidence has been divided into 2 sections;
-Research projects evaluating the GaitSmart programme,
-a systematic search.

The systematic search was further divided into 4 individual searches based on the scope population. These 4 searches are;
- Systematic Search People referred for knee or hip surgery(pre-operative and post-operative management),
- Systematic Search rehabilitation for people referred for knee or hip surgery(pre-operative and post-operative management),
- Systematic Search People aged 65 or older that are at risk of falling,
- Systematic Search Rehabilitation for people aged 65 or older that are at risk of falling.</td></tr>
<tr><td>Information sources</td><td>Use the table below to specify all databases (e.g. MEDLINE), registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted and the number of results.

Enter text.

<table>
<tr><th>Database/other source</th><th>Database provider</th><th>Database segment/version</th><th>Date search conducted</th><th>No of results</th></tr>
<tr><td>https://pubmed.ncbi.nlm.nih.gov/</td><td>National Library of Medicine</td><td>National Centre for Biotechnology Information</td><td>March 16th 2023</td><td>4</td></tr>
</table>
</td></tr>
</table>

Topic	Method details
	Provide details of the reference management system used (for example, EndNote, Zotero, RefWorks etc): Excel
Search strategy	Present the full search strategies for all databases, registers and websites i.e. all the search terms: textwords (free text), subject index headings (for example, MeSH; medical subject headings) and the relationship between the search terms (for example, Boolean). PubMed Each search was performed on PubMed with the subsequent key words: People referred for knee or hip surgery(pre-operative and post-operative management): Key Words: Gait speed Biomechanics Joint replacement Rehabilitation for people referred for knee or hip surgery(pre-operative and post-operative management): Key Words: Gait Speed Rehabilitation Biomechanics Replacement People aged 65 or older that are at risk of falling: Key Words: Gait Biomechanics Falls Risk Older Rehabilitation for people aged 65 or older that are at risk of falling: Key Words: Gait Speed Rehabilitation Biomechanics Falls Record brief details of any additional searches, such as searches of company or professional organisation databases (include a description of each database): Enter text. Provide details of any limits applied to the search strategy (e.g. English language, date limits): Enter text. Provide details of any search filters applied to the search strategy (provide citations where relevant): Enter text.
Selection process	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process. Studies were included if the population included participants from either; ● People aged 65 or older that are at risk of falling ● People referred for knee or hip surgery(pre-operative and post-operative management)

Topic	Method details
	Studies were also included if gait kinematic data was measured or exercise rehabilitation was used.
Data collection process	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process. Data was obtained from abstract or manuscript of available studies.
Any other notes helpful for reviewer	Enter text.

Excluded clinical effectiveness studies

List any excluded studies below. These are studies that were initially considered for inclusion at the level of full text review, but were later excluded for specific reasons; hyperlink text to the available abstract online e.g. PubMed. Highlight any studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.

Excluded study	Design and intervention(s)	Rationale for exclusion	Company comments
Please see appendix H for a full list of studies from the PubMed Search	-	-	-

Record the numbers of published studies included and excluded at each stage in an appropriate format (for example, the PRISMA flow diagram).

Enter text.

Structured abstracts for unpublished studies

Study title and authors
Introduction
Objectives
Methods
Results
Conclusion
Article status and expected publication: Provide details of journal and anticipated publication date

Appendix B: Critical appraisal of relevant clinical effectiveness studies

Table [X] Quality assessment results for parallel group RCTs

Trial number (acronym)	Trial 1	Trial 2	[Add more columns as needed]
Was randomisation carried out appropriately?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Was the concealment of treatment allocation adequate?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Were the groups similar at the outset of the study in terms of prognostic factors?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Were the care providers, participants and outcome assessors blind to treatment allocation?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Were there any unexpected imbalances in drop-outs between groups?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	

Adapted from Systematic reviews: CRD's guidance for undertaking reviews in health care (University of York Centre for Reviews and Dissemination).

Table [X] Quality assessment results for non-randomised and non-controlled studies

Study name	Study 2	[Add more columns as needed]	Study name
Was the cohort recruited in an acceptable way?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Was the exposure accurately measured to minimise bias?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Was the outcome accurately measured to minimise bias?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Have the authors identified all important confounding factors?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
Have the authors taken account of the confounding	Yes / no / not clear / N/A	Yes / no / not clear / N/A	

factors in the design and/or analysis?			
Was the follow up of patients complete?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	
How precise (for example, in terms of confidence interval and p values) are the results?	Yes / no / not clear / N/A	Yes / no / not clear / N/A	

Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study

Appendix C: Identification and selection of adverse events

Table [X] Reporting search for adverse events

<table>
<tr><th>Topic</th><th>Method details</th></tr>
<tr><td>Eligibility criteria</td><td>Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.

Enter text.</td></tr>
<tr><td>Information sources</td><td>Use the table below to specify all databases (e.g. MEDLINE), registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted and the number of results.

Enter text.

<table>
<tr><th>Database/other source</th><th>Database provider</th><th>Database segment/version</th><th>Date search conducted</th><th>No of results</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
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</table>

Provide details of the reference management system used (for example, EndNote, Zotero, RefWorks etc):

Enter text.</td></tr>
<tr><td>Search strategy</td><td>Present the full search strategies for all databases, registers and websites i.e. all the search terms: textwords (free text), subject index headings (for example, MeSH; medical subject headings) and the relationship between the search terms (for example, Boolean).

Database name 1 search strategy:

Database name 2search strategy:

Database name 3 search strategy:

Record brief details of any additional searches, such as searches of company or professional organisation databases (include a description of each database):</td></tr>
</table>

Topic	Method details
	Enter text. Provide details of any limits applied to the search strategy (e.g. English language, date limits): Enter text. Provide details of any search filters applied to the search strategy (provide citations where relevant): Enter text.
Selection process	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process. Enter text.
Data collection process	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process. Enter text.
Any other notes helpful for reviewer	Enter text.

Adverse events evidence

List any relevant studies below. If appropriate, further details on relevant evidence can be added to the adverse events section.

Study	Design and intervention(s)	Details of adverse events	Company comments
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.

Record the numbers of published studies included and excluded at each stage in an appropriate format (for example, the PRISMA flow diagram).

Enter text.

Appendix D: Identification and selection of relevant economic evidence

Describe the process and methods used to identify and select the studies relevant to the technology being evaluated. See section 2 of the user guide for full details of how to complete this section.

<table>
<tr><th>Topic</th><th>Method details</th></tr>
<tr><td>Eligibility criteria</td><td>Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.

Enter text.</td></tr>
<tr><td>Information sources</td><td>Use the table below to specify all databases (e.g. MEDLINE), registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted and the number of results.

Enter text.

<table>
<tr><th>Database/other source</th><th>Database provider</th><th>Database segment/version</th><th>Date search conducted</th><th>No of results</th></tr>
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</table>

Provide details of the reference management system used (for example, EndNote, Zotero, RefWorks etc):

Enter text.</td></tr>
<tr><td>Search strategy</td><td>Present the full search strategies for all databases, registers and websites i.e. all the search terms: textwords (free text), subject index headings (for example, MeSH; medical subject headings) and the relationship between the search terms (for example, Boolean).

Database name 1 search strategy:

Database name 2search strategy:

Database name 3 search strategy:</td></tr>
</table>

Topic	Method details
	Record brief details of any additional searches, such as searches of company or professional organisation databases (include a description of each database): Enter text. Provide details of any limits applied to the search strategy (e.g. English language, date limits): Enter text. Provide details of any search filters applied to the search strategy (provide citations where relevant): Enter text.
Selection process	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process. Enter text.
Data collection process	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process. Enter text.
Any other notes helpful for reviewer	Enter text.

Excluded economic studies

List any excluded studies below. These are studies that were initially considered for inclusion at the level of full text review, but were later excluded for specific reasons. Provide hyperlinks to the paper or abstract where possible. If not possible please explain why.

Excluded study	Design and intervention(s)	Rationale for exclusion	Company comments
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.

Record the numbers of published studies included and excluded at each stage in an appropriate format (for example, the PRISMA flow diagram).

Enter text.

Appendix E: Critical appraisal of relevant economic evidence

Table [X] Quality assessment results for economic studies

Study	Response	Comments
Section 1: Applicability (relevance to specific review questions and the NICE reference case)	–	–
1.1 Is the study population appropriate for the review question?	Yes / partly / no / not clear / N/A	Enter text.
1.2 Are the interventions appropriate for the review question?	Yes / partly / no / not clear / N/A	Enter text.
1.3 Is the system in which the study was done sufficiently similar to the current UK context?	Yes / partly / no / not clear / N/A	Enter text.
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes / partly / no / not clear / N/A	Enter text.
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes / partly / no / not clear / N/A	Enter text.
1.6 Are all future costs and outcomes discounted appropriately?	Yes / partly / no / not clear / N/A	Enter text.
1.7 Is quality-adjusted life year (QALY) used as an outcome, and was it derived using NICE's preferred methods? If not, describe the rationale and outcomes used in line with the analytical perspectives taken (row 1.4, above).	Yes / partly / no / not clear / N/A	Enter text.
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	Yes / partly / no / not clear / N/A	Enter text.
1.9 Overall judgement: directly applicable	Yes / partly / no / not clear / N/A	Enter text.
Section 2: Study limitations (the level of methodological quality)	–	–
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes / partly / no / not clear / N/A	Enter text.
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes / partly / no / not clear / N/A	Enter text.
2.3 Are all important and relevant outcomes included?	Yes / partly / no / not clear / N/A	Enter text.
2.4 Are the estimates of baseline outcomes from the best available source?	Yes / partly / no / not clear / N/A	Enter text.

2.5 Are the estimates of relative intervention effects from the best available source?	Yes / partly / no / not clear / N/A	Enter text.
2.6 Are all important and relevant costs included?	Yes / partly / no / not clear / N/A	Enter text.
2.7 Are the estimates of resource use from the best available source?	Yes / partly / no / not clear / N/A	Enter text.
2.8 Are the unit costs of resources from the best available source?	Yes / partly / no / not clear / N/A	Enter text.
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes / partly / no / not clear / N/A	Enter text.
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes / partly / no / not clear / N/A	Enter text.
2.11 Is there any potential conflict of interest?	Yes / partly / no / not clear / N/A	Enter text.
2.12 Overall assessment:	Minor limitations/Potentially serious limitations/Very serious limitations	Enter text.

See Appendix H of the Developing NICE guidelines: the manual (updated 2022), pages 10 and 11 have additional questions if the study is a cost benefit or cost consequences analysis, respectively. Pages 12 to 23 contain notes for how to carry out the critical assessment for each question.

Appendix F: Model structure

Provide a diagram of the structure of your decision model.

Appendix G: Checklist of confidential information

See section 1 of the user guide for instructions on how to complete this section.

Does your submission of evidence contain any confidential information? Check the appropriate box:

No ☐

If no, proceed to declaration (below).

Yes x

If yes, complete the table below, and insert or delete rows as necessary. Ensure that all relevant sections of your submission of evidence are clearly highlighted and underlined in your submission document (see User Guide for more details on how to do this) and match the information in the table. Add the referenced confidential content (text, graphs, figures, illustrations and so on) to which this applies.

Page number	Nature of confidential information	Rationale for confidential status	Timeframe of confidentiality restriction
35 36 53 54 73 74	☐ Commercial in confidence x Academic in confidence ☐ Depersonalised data	Academic-in-confidence (AIC) information refers to data where public disclosure would seriously jeopardise the ability of the data owner to publish the information in a scientific paper.	Enter text.

Details	The content from the tables is considered AIC.	–	–
27 28	x Commercial in confidence ☐ Academic in confidence ☐ Depersonalised data	Commercial in confidence (CIC) information that includes sensitive individual and location data.	Enter text.
Details	Enter text.	–	–
Supporting documentation	x Commercial in confidence x Academic in confidence x Depersonalised data	Documents include submitted or unpublished studies (AIC) and documents from NHS organisations (CIC).	Indefinitely.
Details	All documents uploaded as supporting evidence have been labelled with, ACIC, AIC, CIC, noACIC and DPD accordingly.	–	–

Confidential information declaration

I confirm that:

- All relevant data pertinent to the development of medical technology guidance (MTG) has been disclosed to NICE.
- All confidential sections in the submission have been marked correctly.
- If I have attached any publication or other information in support of this notification, I have obtained the appropriate permission or paid the appropriate copyright fee to enable my organisation to share this publication or information with NICE.

Note that NICE does not accept any responsibility for the disclosure of confidential information through publication of documentation on our website that has not been correctly marked. If a completed checklist is not included, then NICE will consider all information contained in your submission of evidence as not confidential.

Signed*:
** Must be medical director or equivalent*

Date: 4th May 2023

Enter text.

Print: [redacted]

Role / organisation: [redacted] **Dynamic Metrics Ltd**

Enter text.

Contact email: [redacted]

National Institute for Health and Care Excellence

Collated comments from expert questionnaire

MTG Medtech Guidance: GID-MT575 GaitSmart rehabilitation exercise programme for gait and mobility issues

			Response
1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	Expert #1 I have researched and performed complex optical motion and other objective assessment of gait and function over many years. I am also a past clinician being a physiotherapist prior to my research career. I have not used this system but others, the approach is not novel but its is well packaged and perhaps a starting point but I would require more information on the product and concept to assess this further The concept is sound but how translatable and how usable in a clinical environment is less clear. What is interesting and clever is that the technology will grow and be strengthened by use as it is trained on more data. But I suspect users may find the system clunky and I am not convinced how it will improved patient adherence and compliance.	
		Expert #2 Having been made aware of the technology from the Eastern AHSN (Academic Health Science Network) in October 2021 in my role as Orthopaedics Lead NHSEI East of England (EoE), I have taken time to familiarise myself with both	

		the technology and the supporting literature. The technology has been successfully trailed several times in the region, but as is the case across the NHS it has not been adopted in routine practice The technology has potential roles throughout Musculoskeletal Services, from diagnostics, though early rehab therapy to waiting list stratification and post surgical rehabilitation for total joint replacement Additionally, the technology has a potential role in falls prevention / frailty management within Elderly Care Services The team at NHSEI EoE has made a thorough technology appraisal detailing this	
		Expert #3 − I was introduced to GaitSmart in my previous role as Regional Clinical Leadership Fellow- NHS England 21/22 − I implemented it's use in a Care Hotel (pilot for 2 months) in Norfolk alongside a small physiotherapy team, co-ordinated the training, funding for the pilot, outcome measures used and it's use in the therapy pathway − Since it's use at the Care Hotel, it has now been funded by a community service for 12 months in the Norfolk and Waveney system − This technology is not currently widely used across the NHS- there have been pilots and trials carried out in the NHS- some pilots are currently taking place − In my opinion, until services in the NHS are brave enough to implement the technology the current update will be poor. As soon as it is being used in NHS clinical pathways and the outcomes are shared, in	

		my opinion, GaitSmart is likely to spread very quickly across Msk pathways and frailty.	
		Expert #4 I have used Gait analysis (many different types) in my research over the years. I am not familiar with GaitSmart though. I am aware that many NHS falls services now do a basic gait assessment but mostly using Timed Up and Go or a 10m gait speed assessment.	
		Expert #5 I am not familiar with the proposed technology and I have not used it before. I have used instrumented physical function assessments before such as an instrumented Timed Up and Go on a smartphone as a digital outcome in a trial (I also collected feedback from patients and health professionals about its use within community falls services). I have also tested several apps to (and developed one) to support home exercise for falls rehabilitation. I cannot speak specifically for pre-surgery or post-surgery rehabilitation but for falls rehabilitation in community settings my experience is that physiotherapists just observe when doing tests for balance, strength and function and currently don't routinely assess gait on its own (but as part of the TUG).	
2		Expert #1	

	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. Other (please comment) I have research gait analysis and the use of wearable sensors to assess gait just not this system.	
		Expert #2 I have done bibliographic research on this procedure.	
		Expert #3 - I have experience of implementing in a clinical setting (Care Hotel) with the collation of outcome measures.	
		Expert #4 I have had no involvement in research on this procedure. (GaitSmart) – I have however published many studies with Timed Up and Go or Gait Speed and have used the GaitRite, motion capture using multiple different camera systems.	
		Expert #5 I have done bibliographic research on this procedure. - **Not specifically on this but I did look at remote physiotherapy during the COVID pandemic for older adults and I have revisited the studies having been asked to do this.**	

		I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. **I have had no involvement in research on this procedure.** Other (please comment). **See above on TUG**	

Current management

3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Expert #1 The device is not innovative but the pipeline and linking the measures to treatment solutions is but as above patient engagement with this acceptability feasibility of use etc is less clear. Also clinicains ie therapist normally responsible for this service need to comment on its use etc What is novel is linking gait with exercise prescription and the route they are proposing to do this I don't think there is anything currently at this stage on the market but many tools in this area are being developed.	
		Expert #2 Very innovative; the simplicity of use and report production belies the highly sophisticated technology behind it The first in a new class of procedure	
		Expert #3 - In my opinion, this approach is novel in terms of the simplicity of the technology to both the user and the patient. It is easy to administer. With training it does not have to be set up by a clinician e.g. it could be a rehabilitation assistant. The Gaitsmart report that is produced is easy to understand and the creation of 6 tailored exercises based on the gait analysis is an essential part of a rehabilitation package. It is very useful to have a GaitSmart score, it is unique to have a objective measure which could also help towards triage within	

		services, an outcome measure and a motivator for patients. The list below is difficult to fit this technology- ? 'the first in a new class of procedure' *"Established practice and no longer new.* *A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.* *Definitely novel and of uncertain safety and efficacy.* *The first in a new class of procedure."*	
		Expert #4 Novel as it will give much more information about gait variability, cadence, gait width, as well as speed. As an exercise physiologist who specialises in the exercise prescription for falls prevention and the importance of using an evidence-based programme (as over half of the studies in the Cochrane reviews designed by experienced physiotherapists have NOT shown a reduction in falls rate!) I am more concerned with the exercise prescription that will be offered by the system. At the moment most rehab for fallers is indeed delivered by healthcare assistants (not physios) I am interested to see the quality of the training and the anticipated dose (as falls prevention requires 50+ hours of exercise!) and also whether it is expected to be supervised or done unsupervised (in which case what behaviour change techniques support people exercising at home when frail/in pain etc).	

		Definitely novel and of uncertain safety and efficacy.	
		Expert #5 Quite a novel concept for current care for falls, more technology is used as part of the MSK pathway. During our survey on remote physiotherapy during COVID19 pandemic people used some apps but for heart disease and COPD not really in other areas. There are technologies such as SWORD for remote rehabilitation using sensors and instrumented assessments but not any that I am currently aware of that combine the two. Definitely novel and of uncertain safety and efficacy.- This is because we do not yet really know what the exercises are- it says 6 exercises (which for falls is not sufficient) but based on Otago- but I would want to see it to be sure what it involves. There are gait assessments on the markets but for sway, TUG, not for gait assessment for clinical use (just research I think).	
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Expert #1 Unclear until issues of feasibility, patient adherence and engagement are addressed. It may be that this is suitable for specific age groups but perhaps not all. Some group require in person reassurance and guidance	

		Expert #2 This technology has the potential to redefine current standard care	
		Expert #3 -This technology is a very useful tool that can be added to current clinical pathways. No one technology can meet the needs and wishes of all patients. It does help to provide choice and provide additional rehabilitation and encourage self- management for musculoskeletal problems and frailty through exercise.	
		Expert #4 I expect it to be an addition	
		Expert #5 I am not sure how routinely clinicians do a full gait assessment- in my experience they don't do this in community falls service- they do Tinetti or BERG balance scale, 30 second sit to stand and then TUG-(this is also supported by research I have done) when I have asked them what assessment tools they use. This only covers one aspect of what they do and so could not replace current care- this also has to be considered in the health economic modelling.	

Potential patient benefits

5	Please describe the current standard of care that is used in the NHS.	Expert #1 Unable to as not practising	

		Expert #2 Management of Hip Osteoarthritis as an example: Diagnosis: Clinical examination and plain X-Ray Initial and post-surgical management: Rehab physiotherapy Waiting list management / prioritisation: Initial consultation prioritisation P1-5 followed by reprioritisation via patient / GP updates as appropriate	
		Expert #3 - Gait maybe analysed by a clinician e.g., physiotherapist or doctor and exercises can be prescribed following further assessment. - A 'gaitsmart' score can not be provided - Due to the current workforce and service pressure, some patients may not be referred or have to wait for a long time to see a clinician e.g. physiotherapist. For patients such as those awaiting elective orthopaedic surgery, they may not receive prehabilitation.	

		Expert #4 Sadly inadequate dose to effect changes in most patients. Manpower, too few appointments, too spaced apart and not enough time in an appointment to elicit the vital information on barriers and facilitators to help with behaviour change conversations. Never mind the lack of an adequate challenge (intensity or resistance) to have training effects that are beyond short term practice.	
		Expert #5 It depends on where it is aimed for falls, they may attend an MDT clinic and get a multifactorial assessment in acute care followed by 6-12 weeks of either one to one or group rehabilitation and 'should' get a personalised and tailored home exercise programme. This should then lead onto community provision so it is ongoing as a dose of 50 hours is needed before you will see a reduction in falls (as per Sherrington et al, 2019). In the community they tend to get between 12 weeks and 6 months of rehabilitation following the Otago home exercise programme (with some FaME additions). My experience is if they need a community rehabilitation team it is dependent on the patient and the goals they set.	
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Expert #1 There are lots of novel technologies being developed and lots of technology to support gait assessment and exercise prescription what this does is both things together which is less common.	
		Expert #2 No	
		Expert #3 Not aware	

		Expert #4 Instrumented Timed Up and Go As far as I am aware Instrumented TUG tells the practitioner if the persons main problems are getting out of a chair, turning or speed of walking, rather than the wider potential of gait analysis.	
		Expert #5 There are two instrumented timed up and go tests that I am aware of. One of which is used in practice in some areas and includes a falls risk assessment, one of them is Italian and I have used it within research. There is the Biosway which assesses balance and sway and can both assess and be used to train. There is the SWORD home exercise system aimed at pre and post op for knees but is designed for patients to use at home. I am aware of this as our rehab teams in Manchester asked me about it but it was never adopted or tested as there was a worry that patients would not manage the sensors.	
7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Expert #1 It could facilitate greater access of patients to care, but cost implications need exploration in that some groups don't routinely get offered this care (even though perhaps they should) so it has cost implications that are not usually faced.	
		Expert #2 Management of Hip Osteoarthritis as an example: Early cost-effective diagnosis with contemporaneous provision of appropriate exercise	

		Appropriate waiting list management according to need Early discharge following joint replacement with active rehabilitation monitoring, linking with Virtual Ward initiatives, permitting refined physiotherapy resource allocation and early identification of problems	
		Expert #3 - The most important benefit is improved quality of life by providing tailored exercises to improve lower limb function and gait - Patients receive a gaitsmart assessment- RAG rated, easy to understand with a score. Helps to motivate and assist with self-management to carry out the exercises.	
		Expert #4 More nuanced exercise prescription (potential but sadly unlikely in the current workforce/brief intervention/long wait for appt and few appt/delivered by healthcare assistants rather than physios or specialist L4 exercise instructors/exercise physiologists that can tailor an exercise intervention to specific gait problems)	
		Expert #5 It may lead to better assessment and could lead to a more specific home exercise programme but I don't know if that is the case without access to the technology. My experience is that even when clinicians (and rehab assistants) use a more advanced assessment, they tend to just use only the basic functions and for example with the TUG just note the time rather than really explore the different parameters (power to stand, walking speed, turning speed and time etc).	

Potential system impact

8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Expert #1 Not really potentially vulnerable subject who don't want to attend in person care	
		Expert #2 Patients with Hip & Knee Osteoarthritis Patients at risk of falls and those who have fallen and required surgery and subsequent rehabilitation	
		Expert #3 - People who are at risk of falls or frequent fallers - Frailty pathways - Prehabilitation- as part of 'waiting well pathways' for elective surgery- particularly orthopaedics - Post operative rehabilitation. Particularly orthopaedic patients	
		Expert #4 Already identified, patients with hip and knee pain, frailer less mobile patients.	
		Expert #5	
		I am not sure, I would want to see some real evidence of the additional benefits above and beyond standard service and how it would fit in with their other assessments and delivery. For falls it is multifactorial and multi-dimensional exercises so what is being delivered by the app? It may be different for pre-and post-knee surgery which may have a narrower scope.	

9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Expert #1 Unclear	
		Expert #2 Yes; improved outcomes, fewer hospital visits and less invasive treatment (Some knee replacements become stiff and need manipulation; monitoring rehabilitation and prioritising at risk patients, could reduce this risk)	
		Expert #3 - It could reduce the need for elective orthopaedic surgery e.g. hip and knee replacements if exercises were prescribed early and self management was encouraged - If patient had prehabiliton prior to elective orthopaedic surgery, post operative recovery could be better which could help to reduce hospital length of stay. - By improving mobility/gait in frail population, it could help to reduce risk of falls and therefore hospital admissions and care needs	

		Expert #4 Only if the patients do the exercise programme (if it is a well evidenced programme!) and this sadly is a large problem, most patients do not complete home exercise programmes to a level that effects change which is why supervised group sessions nearly always have better long term outcomes.	
		Expert #5 I think that technology always has the ability to enhance what clinicians deliver as long as it is used with the right patient, at the right time and is the right programme. I am yet to be convinced it goes above and beyond the very well-evidence based programmes for falls. As already articulated the major issue is with compliance but I cannot see a lot from the existing evidence about how it promotes compliance and dose, how it has been developed with older adults to make it acceptable to them. I also don't know how it facilitates a tailored and individual programme- if it does this then fantastic! There is no discussion around any motivation aspects.	
10	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Expert #1 I think this will help a small proportion of the population. Its hard to engage people in exercise and its not clear how this device will engage those that are traditionally the hardest to engage in exercise who need it the most.	
		Expert #2 Less	

		Expert #3 - In my experience the technology cost for our pilot £1000 for the 'kit' and then £1000 per month on-going costs for the technical support and monitoring from the company. -This is not a large financial cost if patients are engaging in exercise which has huge physical and psychological benefits as well as the longer-term possible cost savings as outlined in the question above.	
		Expert #4 More – considerably. And at the moment most physiotherapists cannot get funding for basic exercise equipment (such as ankle weights, therabands, balance balls) to meet the needs of their department so I worry that this might just be another great assessment tool but at a cost to the important part – effective progression of exercise intensity/resistance over time	
		Expert #5 I am not sure it can be cost saving for falls as it is not long enough in duration, it may be for knee and hip rehabilitation.	
11	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Expert #1 Device cost, set up time, training patient to use it. Poor compliers	
		Expert #2 Less	
		Expert #3	

		- Should produce cost saving as it does not need to be administer by a clinician e.g., could be a rehabilitation assistant under the guidance of a therapist. - Will promote self-management and motivation to carry of exercises independently	
		Expert #4 Likely to take considerably more time than a 10m gait speed test and/or TUG – so more staff time. Assuming the assessment gives some indication on tailoring the exercise programme to suit an individuals needs following gait assessment, as if not (and this is likely with a healthcare assistant who is not trained in exercise delivery or progression), everyone will get the same exercise prescription and the assessment will have been a waste of time.	
		Expert #5 Training of staff and additional support to enable older adults to use it. Investment in their support as otherwise there will be digital exclusion of a large number of participants. During my study recruited via falls services only 40% owned a smartphone and only 30% actually used it. This should be less of an issue overtime.	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Expert #1 Unclear form text	
		Expert #2 None	

		Expert #3 -GaitSmart is a portable device and can be used in a clinical setting, ward or in the community. It is small and easy to transport. It does not need to be left with the patient, only used during the duration of the assessment.	
		Expert #4 I am not aware of the distance needed for GaitSmart, but assuming it can be used in a corridor the same as the other tests already used. Considerable cost to hire the system and parts of it may need to be stored securely and therefore potentially not be used if not easily available?	
		Expert #5 Very little change as they are doing similar assessments and interventions just digitally rather than manually.	

General advice

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Expert #1 Yes I suspect so otherwise the device may be used incorrectly and the subsequent exercise prescription	
		Expert #2	

		Yes, though this is simple and straightforward	
		Expert #3 -Training provided by the company- does not have to be professional that is trained e.g., could be a health care assistant or a therapy assistant. -Would require professional oversight and support e.g., a physiotherapist to provide advice and joint sessions for more complex patients with the therapy assistant.	
		Expert #4 I doubt it. Gait assessment commonly done	
		Expert #5 Just to ensure adequate safety procedures and support if following the exercises at home on the app.	

Other considerations

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Expert #1 I don't think there are any potential harms. There is potential that patients do too much too soon but I am sure they have safety checks.	
		Expert #2 n/a	
		Expert #3 -Exercises provided should be checked and demonstrated when prescribed (as done in	

		usual exercise prescription). Adapted as need to patient specific needs. -I am not aware of any adverse events	
		Expert #4 Always a risk of falling but gait assessments done often in clinial practice and rarely are there adverse events as we are not asking people to walk as fast as possible for eg.	
		Expert #5 Unlikely to be many additional adverse effects. From implementing digital rehabilitation tools before the most important thing is that they can set up the smartphone/tablet in a safe manner when exercising at home.	
15	Please list the key efficacy outcomes for this procedure/technology?	Expert #1 Impact recovery rates and post op functional levels	
		Expert #2 Improved Hip & Knee OA outcomes Reduced falls and associated fractures	
		Expert #3 -Quality of Life -Fear of falling -Speed of walking -Improved functional ability	

		-? Reduced pain	
		Expert #4 I would want to see a benefit to functional tests which are useful in the patient populations involved – for eg. 30s chair rise, gait speed, TUG, and I would want these to be BETTER improvements than the current programmes get (without the bonus of a more detailed gait assessment). I would want to see that the exercise programme had the prescription that we know works for fallers for eg.	
		Expert #5 TUG Balance- BERG or Tinetti FES-I 30 second sit to stand Falls Adherence to exercises in the long term. EQ5D (QOL) and also ICECAP-O	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Expert #1 Use in falls population is less clear how they intend to implement this	
		Expert #2 n/a	
		Expert #3 -Staff would require training to use the GaitSmart technology and would already have a role within health care so it can be a tool used alongside other assessment and treatment pathways.	

		Expert #4 Concerns on efficacy without seeing the suggested exercise regimens offered after assessment	
		Expert #5 I do not think the current evidence shows efficacy, specially for falls. I would be concerned about this replacing the current evidence based programmes with the current level of data and without further understanding recruitment and adherence. This is not well covered in the publications. There is little data on it having been designed with older adults.	
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Expert #1 My key issue is how does this improve engagement in exercise in these groups where its hard to get them to engage. Yes it provides an objective assessment but is that going to be enough without a proper complex intervention package and translation. Care requirement may need to be beyond exercise	
		Expert #2 Not that I'm aware of	
		Expert #3 None known	
		Expert #4 No	

		Expert #5 I don't understand how many exercises the app provides and how they are chosen. I would like to understand more about how health professionals might use the assessment as I currently feel it may be under utilised at least by falls services because of the additional components of fitness that may need to be assessed and prescribed. I can understand how it may be more easily focused on specific muscle groups related to hip and knee surgery.	
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Expert #1 Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. **Cannot predict at present.**	
		Expert #2 Most or all district general hospitals	
		Expert #3 Most or all district general hospitals.	
		Expert #4 Most or all district general hospitals.	
		Expert #5 Cannot predict at present.	

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Expert #1 None that I have seem	
		Expert #2 n/a	
		Expert #3 Blank	
		Expert #4 None	
		Expert #5 None that I am aware of.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Expert #1 Not aware of any	
		Expert #2 Only small studies	
		Expert #3 -Not known	
		Expert #4 Not aware of	
		Expert #5 Blank	

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Expert #1 Several joint replacement are done but post op and pre op rehab is not currently routine but this could be of value	
		Expert #2 Management of Hip Osteoarthritis as an example: 200,00 Total Hip & Knee Replacements / year nationally	
		Expert #3 -All patients within a frailty pathway or musculoskeletal pathway could be eligible for this this technology- need to be able to walk approx. 10 meters, turn and walk back 10 meters with or without a walking aid.	
		Expert #4 One third of older people fall every year, but most falls services see between 5-20 people a month	
		Expert #5 In my experience around 40 new patients a month go through community falls services but a large number of these are just not eligible for rehabilitation and physiotherapy for a broad range of reasons.	

22		Expert#1	

	Are there any issues with the usability or practical aspects of the procedure/technology?	Patient usability and reach not clear from what is presented	
		Expert#2 No	
		Expert#3 -If using the technology in a patient's home, would need space to be able to walk 10 meters and turn and walk back 10 meters e.g. a hallway. -Ensure wearing suitable clothing to place the electrodes and straps over the top of clothing	
		Expert #4 Potential storage and space	
		Expert #5 Yes, we do not have evidence for falls on it having been developed with older adults which in my experience is the best way to foster usability and acceptability, especially with the patient facing app interface.	
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Expert#1 Who is responsible for this care pathway? GP, physio or surgeon?	
		Expert#2 Some reluctance to change	
		Expert#3 -No	

		Expert #4 Cost and resource	
		Expert #5 I think understanding how it would fit within the falls pathway more clearly. Health professionals need to see the additional benefit for their patients above and beyond to commit to using it at appoint where de-conditioning has led to resources being very stretched.	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Expert#1 Patient acceptability and usability needs to be clearer	
		Expert#2 Wider use should be monitored to clarify its absolute beneficial value	
		Expert#3 Potential for further research with other clinical groups e.g. stroke rehabilitation	
		Expert #4 Yes, head to head of functional outcomes of exercise programme guided by gaitsmart and the 'normal' ones offered after a brief gait and balance assessment without such equipment.	

		Expert #5 Proper cost effectiveness and full trial, from what I can see the unpublished study is not a fully powered trial. For falls it would have to be a full trial powered to detect a difference in falls unless I can be convinced it fully adopts the evidence based programme and then adherence measures and other measures might suffice. I would also like to see more usability and acceptability data for the different pathways proposed.	
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured	Expert#1 Beneficial outcome measures: Tool to guide rehab Rapid access of patient to exercises to guide recovery BUT exercise might not be only intervention required Adverse outcome measures: There may need to be safety checks in use of device and exercise prescription this is hard to assess on information provided.	
		Expert#2 Beneficial outcome measures: Falls and fracture rates Joint replacement PROMS	

		Adverse outcome measures: n/a	
		Expert#3 Beneficial outcome measures: • Quality of Life e.g. EQ-5D-5L • Functional outcome measures such as Barthel • Frailty scale e.g. Rockwood • Personal goal setting Adverse outcome measures: Blank	
		Expert #4 Beneficial outcome measures: TUG Gait speed 30s chair rise Fear of falling (FES-I) Confidence in balance (ConfBal) Adverse outcome measures: Falls during assessment	
		Expert #5	

		Beneficial outcome measures for at least 6 months: TUG BERG Balance Falls (including injurious and non-injurious) FES-I EQ5D ICECAP-O Adherence- is it recorded in the app? (dose, intensity) Usability- perhaps system usability scale (SUS) Adverse outcome measures: Blank	
26	Please add any further comments on your particular experiences or knowledge of the procedure/technology	Expert#1 Blank	
		Expert# 2 Blank	
		Expert#3 Blank	
		Expert #4 Blank	
		Expert #5 Many years ago when I worked in Public Health and commissioned falls services, I took over as the colleague previously doing the job had ordered a Biosway to be used to assess balance in clinical practice. No discussion had been carried out with the clinicians.	

		They were going to order a lot of them and I agreed we would order one and test it. One of the issues was that it was bulky to transport and storage. It also had to have a maintenance contract so this needs to be checked for this product (or upgrades). It was never really used or adopted as it did not really fit within existing pathways. Even with the instrumented TUG I have found that there was the same argument- rehab assistants could do the TUG and record all the different parameters when they would normally just record time. Again, this was not really utilised as an assessment measure- simply as an outcome measure (time) as part of KPI's.	

NICE National Institute for Health and Care Excellence

External Assessment Centre correspondence log

MTG575 GaitSmart

The purpose of this log is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the company's original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the company;
b) needs to check "real world" assumptions with NICE's expert advisers, or;
c) needs to ask the company for additional information or data not included in the original submission, or;
d) needs to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is captured. The table is shared with the NICE medical technologies advisory committee (MTAC) as part of the committee documentation, and is published on the NICE website at public consultation.

#	Date	Who / Purpose	Question/request	Response received
X.	*XX/XX/XXXX*	*Who was contacted? (if an expert, include clinical area of expertise)* *Why were they contacted? (keep this brief)*	*Insert question here. If multiple questions, please break these down and enter them as new rows*	*Only include significant correspondence and attach additional documents/graphics/tables in Appendix 1, citing question number*
1.	12/05/2023	Meeting with Dynamic Metrics Ltd	The EAG sent a list of queries related to the company submission in advance of the meeting. These were then discussed at the meeting.	Responses are noted in Appendix 1: Meeting with Dynamic Metrics Ltd

2.	19/05/2023	E-mail to Dynamic Metrics Ltd	Follow up question to query current progress on UKCA	DML has now instructed BSi, our notified body to commence the certification process, but they haven't provided us with the timescales yet.
3.	25/05/2023	Meeting with UAE	The EAG sent a list of questions to the team who developed the economic models in advance of the meeting. These were then discussed at the meeting. Additional information on the references for cost and clinical inputs were requested.	Written responses by the company are noted in Appendix 2.
4.	06/06/2023	E-mail to UAE to clarify economics	The EAG sent a list of additional questions to the team who developed the economic model.	Responses are noted in Appendix 3
5.	23/05/2023 06/06/2023	Meeting with clinical experts	Two meetings were held with a range of clinical experts. A list of questions was sent in advance of the meeting.	Responses are noted in (please note these have not been verified by all experts)
6.	09/06/2023	E-mail to Dynamic Metrics Ltd	Follow up queries on the GaitSmart technology	Responses noted in Appendix
7.	14/06/2023	E-mail to clinical experts	The EAG had a number of follow up queries for the clinical experts to help clarify inputs into the economic model 1. Falls prevention program Having looked at some prevention programs in NHS England, the general consensus seems to be a 12-week program with an initial risk assessment by	One expert commented that they did not work in a clinical environment and could not provide any answers.

			a physiotherapist, then a weekly session of 30 mins exercise and 30 mins educational talk by any 2 staff in the team. Most of them are offering as group sessions. The team running the program consists of 4 staff - a community physiotherapist (band 5), an occupational therapist (band 5) and 2 assistant practitioners (band 4). How reasonable does this look to you, despite the high variation on the program structure? Can you also comment on the staff and their band? 2. Are you aware of any sources/literature that report the ratio/number of group and individual physiotherapy? This can be for other settings or conditions etc. We just want to get a general sense of the practice. 3. 3. From your experience with GaitSmart, what is the minimum sessions/uses per month? We are looking for a ballpark figure or a range is good as well.	
8.	22/06/2023	E-mail to Dynamic Metrics Ltd	Follow-up Queries to clarify GaitSmart costs	Responses noted in Appendix
9.	29/06/2023	E-mail to Dynamic Metrics Ltd	E-mail to clarify number of sensors in the kit and to ask about ethics statements for one of the published studies	Additional sensor provided a spare Regarding Ethics we worked with the NELFT Quality Improvement Programme and this is their statement. This is in alignment with our paper and the economic study which is currently under

				review. As stated, there was no randomisation so patients were compared to those who would have gone through SoC in accordance with NICE Guidelines

During correspondence with the company and experts, additional information is sometimes included as file attachments, graphics and tables. Any questions that included additional information of this kind is added below in relation to the relevant question/answer:

Appendix 1: Meeting with Dynamic Metrics Ltd

Questions to the company following submission
Meeting Date: 12/05/2023
Company: Diana Hodgins (Dynamic Metrics Ltd)

No.	EAG Question	Company response
The technology		
1.	Can you describe any earlier / alternative versions of the technology (e.g. GaitWalk) and whether evidence related to these should be included?	This is an older version of the technology. It is functionally the same, just a different name and any evidence / studies referencing this can be considered relevant to GaitSmart.
2.	Are the sensors and vGym app included in the intervention costs, or are there any additional charges?	Yes – all included
3.	Do GaitSmart sensors require connection to a special device? If yes, would the device be provided by the company or to be sourced by the user?	No special connections are required, it comes provided with a tablet which has the app installed and communicates via Bluetooth
4.	What is the lifespan of GaitSmart sensors?	No defined lifespan. No charge for any replacements and no time limit for replacements.
5.	What are the costs for training sessions provided to the healthcare staff, and will there be any follow up training after the initial trainings to ensure the programme is run properly?	One off cost to set up and train (£1,000) with as many people as necessary trained. No further costs for training and will train new staff as required within the original costs.
Use of the technology		

No.	EAG Question	Company response
6.	In which care settings will the technology be used?	Primary care (falls clinics), community setting such as MSK clinics (Escape pain programme) and Orthopaedic consultancy (pre / post op). Currently working with NHS trusts to work out a care pathway which can be discussed. EAG noted that a clear patient pathway will be required for the committee to discuss and EAG will work with company to clarify this through development.
7.	Is GaitSmart an additional technology or replacement technology?	It started as additional, but is now used as a replacement. For example, there are areas where Falls Clinics are being replaced by GaitSmart clinics and instead of ~12 weekly group sessions with face to face time, people have only four face to face GaitSmart sessions, but then take their recommended exercises with them and do these at home. The 4 GaitSmart sessions run over a similar period to the 12 weeks. Currently in secondary care it's an alternative. In addition to providing a rehabilitation programme, GaitSmart provides additional information. Although gait analyses is quoted in NICE guidance it's normally quick visual assessment. This means that surgeons will get people added to list, don't know about them, don't know if they should be prioritised. No knowledge of their ability to function. Feedback from surgeons suggest that they think it would be really helpful to know more about patients. It could therefore be used to provide more detailed information when assessing patients and adding to surgical waiting lists.
8.	Is there any group element, and do people miss out on some benefits of being in a group?	There is no group exercise component to GaitSmart, people do their exercises at home. They have the report and this motivates them. To do the classes alongside this could be confusing, and they wouldn't know what to focus on. Staff providing GaitSmart can have good empathy and provide a good patient rapport.

No.	EAG Question	Company response
9.	For clarity, are there any differences in terms of healthcare resources (staff time) between risk of falling and pre- and post-operative management with GaitSmart? Total costs for the technology reported on p.94 and p.121 are different.	No differences. Ideally, healthcare assistant time in each session should be included in the intervention costs for fall and post-op model.
10.	Despite four GaitSmart assessments are recommended, is there any expectation that patients would receive additional follow up after the recommended sessions?	No evidence to suggest this would be the case, NHS may not do 4 (evidence suggests 3-4)
11.	Can you describe how GaitSmart programme is set up – will any special facilities be required and does NHS have the capacity to meet this need?	No special requirements, can be used in corridors etc just need wifi / 4G and a 10m corridor. It would normally be set up in a room, and then patient and staff move to the corridor to carry out the test.
12.	The pre- and post-operative management with GaitSmart seems to be unclear. Can you provide more clarity?	No pre-op intervention study yet.
Evidence and benefits		
13.	Can you clarify the comparator used and costs in model 1 for fall prevention? Discrepancy is noted between the submission document (p.95) and the model ('Care_InterventionCosts').	Cedar to send query to UEA economics team, with any other questions on modelling that arise.
14.	Please justify the assumption made on the population in model 2 for undergoing THA or TKA as THA in conjunction with hip osteoarthritis.	Seldom find individuals with unilateral osteoarthritis. The population assumed was based on the study cohort unpublished evidence.
15.	Are there any validation studies available?	Yes, GaitSmart validation studies are available. EAG will follow this up with company during evidence assessment.

Appendix 2: Follow up economic questions

EAG question	Company response
Model 1 – fall prevention	
1. Model structure The report describes the decision tree as providing the outcomes of the model (response or no response) at the end of each branch (p.84 paragraph 5). I'd imagine that response rate of each intervention would be applied to inform the corresponding change in gait speed, change in fear of falling and risk of falling. However, no response rate was used in the model. We interpret the model as ending each branch with a fall outcome, as shown in the diagram on page 83.	Response rates were not used as this was a preliminary analysis without a proper comparator. Incident probabilities were used and outcomes were measured based on these probabilities. A risk profile was created based on the speed change before and after the intervention and the relative risk to have a fall incident (Verghese, J., Holtzer, R., Lipton, R.B., Wang, C., 2009. Quantitative gait markers and incident fall risk in older adults. Journals of Gerontology - Series A Biological Sciences and Medical Sciences 64, 896–901. doi:10.1093/gerona/glp033)
2. Assumptions On a similar note to Q1, an assumption of a similar response probability for self-managed and group/individual rehabilitation is made in the submission. Can you clarify how the response rate is applied in the model for FOF and ROF?	The first model was a preliminary calculation without a proper comparator and thus no self-managed and group/individual rehabilitation were used. Prevalence FOF data and their potential im pact on falls incidents were gathered from Arfken et al.. 1994. The falls incidents were calculated based on the difference of FOF in the beginning and after the intervention. (Arfken, C.L., Lach, H.W., Birge, S.J., Miller, J.P., 1994. The prevalence and correlates of fear of falling in elderly persons living in the community. American Journal of Public Health 84, 565–570. doi:10.2105/AJPH.84.4.565)
3. Comparators Self-managed home exercise or group/individual physiotherapy is used as comparators in the model, and costed £765 per patients (Care_InterventionCosts, cell F40). This appears to be based on 30 x 45 minute sessions at a therapist cost of £34 per hour. Could you explain where the number and duration of sessions is derived from, and if some of these sessions should be costed as group interventions?	This was an assumption provided by the clinical team.
4. Intervention costs It is costed as £40 per patient. It appears only GaitSmart session costs are included.	According tpo the clinical team, the GaitSmart sessions does not need additional healthcare assistant cost as it

Should healthcare assistant costs be included?	would be carried out as a part of normal appointment.
5. Risk reduction We have noted some incomplete data from NELFT134-147. Are there any specific reasons for incomplete data? Are the data included in the calculation for risk reduction?	Gaitsmart peers and clinical team reassured us that this was just a change in sudo anonymised tracking.
6. Fall_Calc sheet Can you explain briefly on how 'transition of fear of falling' and 'fear of falling level after intervention' are derived and if they are used in the model? We've noted that cells V21-V23 are hidden, just wanted to check if these are used in the model? They seem to be PSA values for cells P21-P23?	• Patients assigned to the intervention group (GS) were monitored four times during the implementation of the intervention, three weeks apart. To deliver the intervention, a 20-meter quiet (unobtrusive) 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. All interventions were delivered by the research team. Training of the research team was carried out by Dynamic Metrics (DML). • Briefly, the relative effects of the GS system were focused on gait improvement in terms of changing speed and reducing FoF. Both measures were used to calculate the change in fall risk and assess their impact on fall incidents. • Comparison between both interventions (GS vs. SoC) was performed in terms of clinical outcomes, health effects and costs, with the clinical outcomes rated as mild or severe injuries due to a fall or multiple falls incident in the timeframe of the model.
7. Model inputs Can you clarify the RR for different fear of falling – how are these RRs derived and how are these used in the model?	Standard method Literature Arfken, C.L., Lach, H.W., Birge, S.J., Miller, J.P., 1994. The prevalence and correlates of fear of falling in elderly persons living in the community. American Journal of Public Health 84, 565–570. doi:10.2105/AJPH.84.4.565)

Additional questions	
8. What is the patient population in the base case analysis?	The target population consisted of older persons (85+ years old) who had suffered a fall or had a moderate to severe FoF and were in a community care unit.
9. Was the age group 85+ and high risk?	Yes.
10. Were the patients all 85+ in the primary data, and if the 65+ category is chosen, does this mean that the primary data for speed increase remains the same, but a different risk reduction is applied?	Yes. If the 65 + option is chosen then the model calculates falls incuidents based on the probabilities of that cohort. The relative risk in both cases was based on Verghese, J., Holtzer, R., Lipton, R.B., Wang, C., 2009. Quantitative gait markers and incident fall risk in older adults. Journals of Gerontology - Series A Biological Sciences and Medical Sciences 64, 896–901. doi:10.1093/gerona/glp033.
11. Can you provide justifications on the scenario 2 (applying physiotherapies to fall resulting in an injury) as the base case?	This was suggested by the clinical team as usually at this cohort are in community care units people that had already suffered an injurious fall and usually an injurious fall is the starting point for pearticipants to engage with physiotherapists to improve their balance and gait.
12. Can you clarify on how the probabilities of FoF with GaitSmart are derived ('Model_Inputs, cells D6:D8)? These are not readily available from Rodgers 2020.	These were provided by the study results of the FoF questionnaires and Arfken et al.. 1994.
13. Can you confirm that 'Model_Inputs, cell D35 and D39' are duplicates? If not, please explain the differences.	Yes this is a duplication.
Model 2 – post-operative rehabilitation	
14. Response rate Can you describe the definition of response, and how response rate is calculated from the GaitSmart study for SoC and intervention? Additional question: Was there any threshold for a response?	As Response we defined any improvement in gait speed. A risk profile was created based on the speed change before and after the intervention and the relative risk to have a fall incident (Verghese, J., Holtzer, R., Lipton, R.B., Wang, C., 2009. Quantitative gait markers and incident fall risk in older adults. Journals of Gerontology - Series A Biological Sciences and Medical Sciences 64, 896–901. doi:10.1093/gerona/glp033)
15. Self-managed home exercise An assessment after 1 week is included in the model diagram, but this is not explicitly costed.	This is a common step for all and hence cancel each other out.

We noted that there is 20 minutes of physiotherapist time included – is this for the 1week assessment? Can you tell us a bit more about the assessment?	
16. Cost-effectiveness results Can you comment if there are any particular reasons that only intervention costs are included in the mean total costs, without costs of falls?	We adopted a conservative approach based on primary collected objective data. The falls profile is estimated as in model 1 through the risk of falling and not the follow up of the RCT participants. Including the falls in CE analysis would only improve the outcomes but we decided to use only the objective data we had.
17. Should the administration cost be included in the GaitSmart costs?	GaitSmart intervention would be performed as a part of routine check-up.
18. As healthcare assistant can be under the supervision of a physiotherapist, can you comment if any supervision time should be added in?	GaitSmart intervention would be performed as a part of routine check-up, we don't expect this will increase clinicians' (physiotherapists'). The device is made as if it can be done by healthcare assistant and assume does not incur additional supervisory time. The supervision the physiotherapist needs to provide is very minimal if applied in routine practice.
19. Group / individual costs – would it be normal for patients to see a consultant as part of this pathway, but not in other pathways?	EAG: Company did not respond.
20. This is costed at 60 min of physiotherapist time plus 30 min of a consultant time, each for 6 sessions, per patient. What are the assumption about how many patients are seen in a group, the group size and the number of sessions for individual or groups?	Thank you for highlighting this one. Yes, we need to factor this into the model. This can easily be amended in the provided model.
21. Why are the administration cost higher for the group/individual costs than for the other options?	This is because of the frequency of visits.
22. Is there any inflation of costs to account for them having been taken from unit cost sources from different dates? If so, what inflation method was used?	EAG: Company provided a separate document.
Additional questions	

23. Where does the £9.32 per hour for administration cost come from?	Unit Costs of Health and Social Care 2019 pg 156 £29,344 yearly earnings /52 weeks/48 hrs per week it should be 11.75 But as it was used across it should have a minimal impact
24. Can you tell us on the proportion of individual and group physiotherapy that were see in the study, and if any of the assumptions were based on the study data, or entirely on clinical advice? Do the cost assumptions reflect the clinical distribution, as clinical outcomes may be impacted by the mode of delivery.	Clinical assumption. The effectiveness of group physio was used for both cases and only the cost was the factor of change.
25. Can you send additional referencing for costs, as it is difficult to verify them where the full reference is not included, and there may be inflation meaning that the number in the model is not the same as in the source data.	Yes in the separate documentation provided.

Additional referencing for cost and clinical inputs

Models inputs	Full references (please provide details, e.g., HRG code, band etc)	Inflated (Y/N)? Please provide the cost year if inflated.
Model 1 – fall prevention		
1. Costs – ambulance call out	PSSRU 2018 pg 89 See and treat and convey (including carbon 59 kgCO2e	N
2. Costs – A&E attendance, no admission	PHE, 2018. A Return on Investment Tool for the Assessment of Falls Prevention Programmes for Older People Living in the Community	N
3. Costs – A&E attendance, admission	PHE, 2018. A Return on Investment Tool for the Assessment of Falls Prevention Programmes for Older People Living in the Community	N
4. Costs – GP visit	PHE, 2018. A Return on Investment Tool for the Assessment of Falls Prevention Programmes for Older People Living in the Community	Y to 2018 using Hospital & community health services (HCHS)Pay & prices index
5. Costs – NHS reference cost	PSSRU 2018 pg 89 Weighted average of all outpatient attendances (inc. carbon 32 kgCO2e)	N
6. Costs – Non-Elective Inpatients	It should be £1841 based on pssru 2018 non Non-elective inpatient stays (average of long and short stay)	N
7. Costs – Non-Elective Inpatient Excess Bed Days	NHS Reference Costs 2016/2017 – Index - Non-elective inpatient excess bed day cost. Weighted average of all admission types.	N
8. Various fall inputs - Berry 2008	Berry, S.D., Miller, R.R., 2008. Falls: Epidemiology, pathophysiology, and relationship to fracture. Current Osteoporosis Reports. doi:10.1007/s11914-008-0026-4	
9. Various fall inputs - Tinetti 1995	Tinetti, M.E., Doucette, J., ... Marottoli, R., 1995. Risk Factors for Serious Injury During Falls by Older Persons in the Community. Journal of the American Geriatrics Society 43, 1214–1221. doi:10.1111/j.1532-5415.1995.tb07396.x	
Model 2 – post-operative rehabilitation		
10. Costs – ambulance call out	Unit Costs of Health and Social Care 2019 pg 82	N

11. Costs – A&E attendance, no admission	National Cost Collection: National Schedule of NHS costs - Year 2018-19 - NHS trust and NHS foundation trusts Accident & Emergency 2018-19 National cost collection index (NCCI) by department and service code (Activity/ Actual costs adjusted)	N
12. Costs – A&E attendance, admission	Unit Costs of Health and Social Care 2018 lower CI	N
13. Various fall inputs – Watson 2011	Watson, W., Clapperton, A., Mitchell, R., 2011. The burden of fall-related injury among older persons in New South Wales. Australian and New Zealand Journal of Public Health 35, 170–175. doi:10.1111/j.1753-6405.2010.00656.x	
14. Group/Individual Physiotherapy - Physiotherapist - Consultant (surgical) - Administrator	PSSRU 2020 pg119 Pssru2020 pg 159 Admin Unit Costs of Health and Social Care 2019 pg 156 £29,344 yearly earnings /52 weeks/48 hrs per week it should be 11.75	N
15. Self-managed home exercise - Physiotherapist - Administrator	PSSRU 2020 pg119 Unit Costs of Health and Social Care 2019 pg 156 £29,344 yearly earnings /52 weeks/48 hrs per week it should be 11.75	N
16. Intervention/GaitSmart - Healthcare assistant - Administrator	PSSRU 2020 pg119 PSSRU 2020 pg166 Unit Costs of Health and Social Care 2019 pg 156 £29,344 yearly earnings /52 weeks/48 hrs per week it should be 11.75	N

Appendix 3: Additional follow up economic questions

EAG question	Company response
Model 1 – fall prevention	
1. Can you clarify for the base case scenario [2] "applying physiotherapies and intervention to falls with injury" - does this mean that patients would receive physiotherapies and the GS intervention after a fall with injury? It appears that, in the model, GS efficacy is used in calculating the number of falls with injury when patients have not had any interventions at that point?	In this tool the effectiveness is relying on the number of falls and the probability to cause a major injury.
2. Are we correct that after the physiotherapy and/or GS intervention there are no further outcomes included in the model?	Yes in this tool there was neither a proper comparator nor a follow up for further outcomes. the effectiveness is relying on the number of falls and the probability to cause a major injury.
3. We would have expected, based on the model diagram, that all 1,000 patients receive the intervention at the start of the model, followed by subsequent falls outcomes based on the risk reduction of each intervention. Can you comment?	Yes in this tool there was neither a proper comparator nor a follow up for further outcomes. We had not advised the data collection and the study was formed with the data available. It was not constructed as a study to be in accordance to NICE standards for a submission.
4. It appears that physiotherapy costs are included in GS strategy (referring to 'PSA', cell L5, P5). Can you clarify if GS is to be provided alongside physiotherapy?	At this stage yes it was not clear if GS would be an alternative or a companion to the current physio scheme. The second model examine the option of GS being an alternative to the current SoC.
5. For risk calculation ('Study Risk Reduction'), the use of average initial speed in column L is unclear. Are we correct that the average initial speed is assumed as the population speed, and used as a benchmark to calculate the risk of falling based on individual's speed. Can you clarify?	The individuals initial and final speed are both calculated from the person's GaitSmart data. Population speed is not used anywhere.

Appendix 4: Meeting with Clinical Experts

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
Medical Technologies Evaluation Programme

Clinical Expert Engagement Meeting
MTG575 GaitSmart for fall prevention and pre / post-operative rehabilitation

This document summarises the discussions that took place at the GaitSmart Expert Engagement meetings for MTG575, which took place on Tuesday 23rd May 2023,10:00 to 11:30am and on Tuesday 06th June 2023, 10:00am to 12:00pm.

A list of questions was shared with the clinical experts in advance of the meeting to allow them to prepare some responses where appropriate.

Attendees:
NICE:

- Kimberley Carter
- Haider Shamsi

EAG

- Ayesha Rahim (23/05/2023)
- Huey Yi Chong (23/05/2023 & 06/06/2023)
- Megan Dale (23/05/2023 & 06/06/2023)
- Meg Kiseleva (23/05/2023 & 06/06/2023)
- Susan O'Connell (06/06/2023)
- Simone Willis (06/06/2023)

Clinical Experts

- Alison McGregor (23/05/2023)
- Andrea Sargeant (23/05/2023)
- Julien Owen (06/06/2023)
- Emma Brown (06/06/2023)

Welcome and introductions

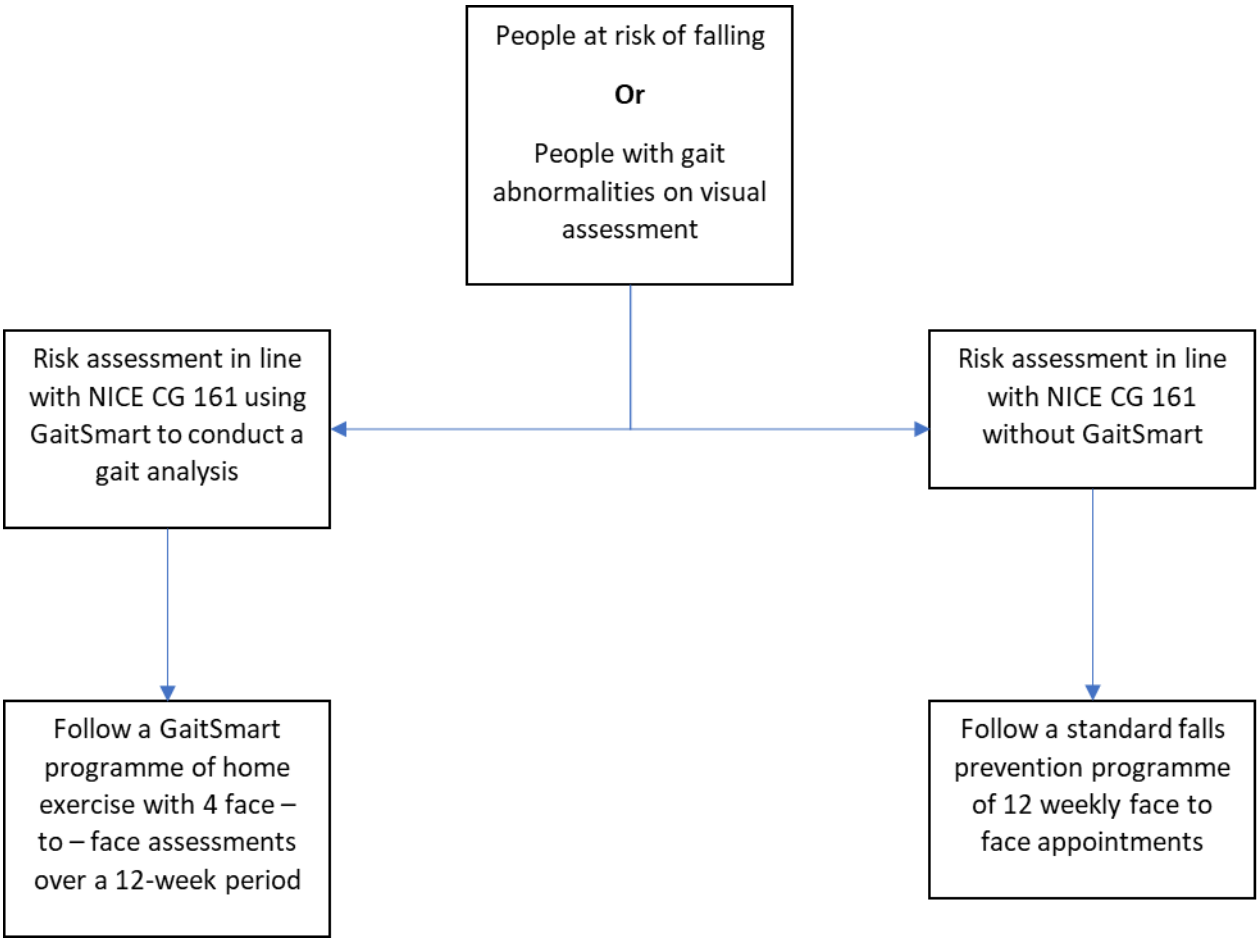
NICE briefly introduced everyone on the call and outlined the format for the meeting. Discussion centred around some key topic areas including:

- The Clinical Pathway
- The technology
- Use of the technology
- Evidence and Benefits

The Clinical Pathway

- **Fall prevention: would assessment be done by a GP or are there other people who may do a falls risk assessment (home care worker / community nurse)? pathway?**

  EAG proposed that in the community/primary care setting, GaitSmart is positioned alongside a risk assessment in line with NICE GC161, followed by a GaitSmart programme of home exercise with 4 face-to-face assessments over 12-week period, whilst standard care starts with risk assessment in line with NICE GC161, followed by a standard fall prevention programme of 12 weekly face to face appointments.



One expert stated that it is difficult to get elderly people to come forward. It may be better to target certain age groups, rather than relying on patients to identify risks of falling themselves. The expert added that a lot of communities have fall clinics. Patients going to the clinics are people who have had a fall, post-menopausal women worried about osteoporosis, and people with osteoarthritis (OA). GP practices could identify at-risk patients by asking a standard question about balance to people aged >50s as balance starts to deteriorate at 50 and the risks become greater over 65. One expert noted that there are a lot of falls that we don't hear about as people don't always seek help following a fall.

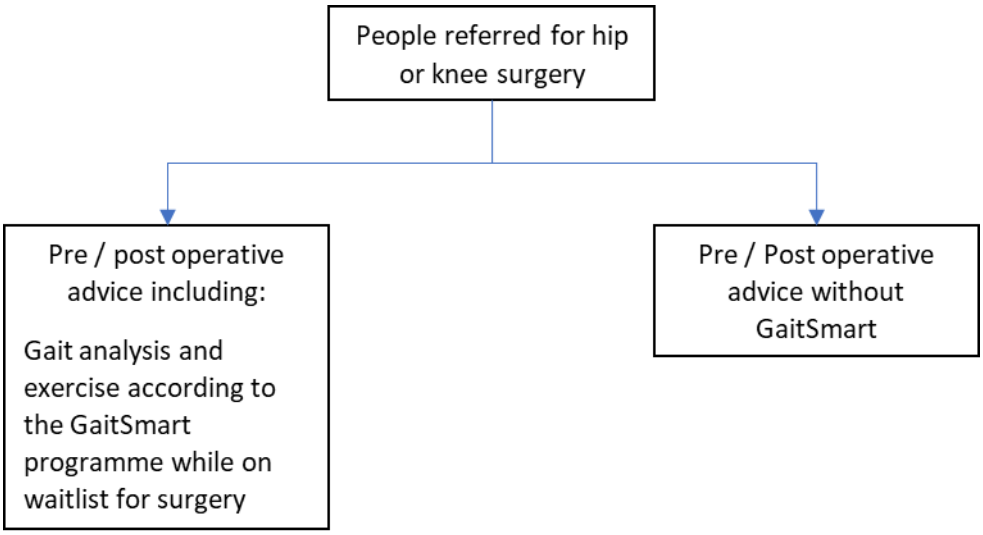
One expert noted that it might be tricky for some practitioners to implement a 12-week programme and queried whether there would be any flexibility in the number of GaitSmart assessments needed? In addition, the clinical expert noted that a 12-week intervention might be ambitious for standard care. Some services are only commissioned to provide 6 weeks interventions.
All clinical experts reported that there is a lot of variability in the pathway at the moment so it is difficult to clearly define a standard care comparator for GaitSmart.
The EAG asked about the staff who would do the risk assessment.
The GP can identify if there is a problem. If GaitSmart is effective, it can be administered by any trained personnel. Gait analysis may not be the only way to measure treatment outcome. The expert commented that GaitSmart would be useful to enhance patients' engagement with the exercise programme and to be more motivated because of the monitoring. It could be seen more of a complimentary approach rather than an alternative. For patients with ongoing problems, a stepped approach should follow, including seeing a physiotherapist and doing more investigations, or different interventions. The expert queried if GaitSmart could give feedbacks on patients' progress.
Another expert stated that in their organisation, four face-to-face GaitSmart appointments are currently offered and a few areas are trialling this approach. Due to staffing level, all four sessions might not be provided. Patients would present at physiotherapy or to health connector or social prescriber and be advised to self-refer for GaitSmart assessment by a Healthcare Assistant, band 4. The risk assessment is done during the first GaitSmart appointment, the expert will provide confirmation on this.
The EAG requested GaitSmart patient flow and patient leaflet from the expert. The expert agreed.
One expert reported that assessments could be done by a range of trained staff such as physiotherapists / occupational therapists or healthcare / rehab assistants.

- **Fall prevention: Understanding that there is variability in the standard care practices, is there a sensible approximation of what a Falls Prevention Programme might look like?**

  One expert stated that, based on the experience in back pain clinic, if 12 weeks were offered, patients would be likely to attend 8 sessions, not all of them. Another expert stated that the 12-week fall programme is not available in their organisation.

- **Pre / post-operative rehabilitation: Who refers people for surgery and should that be the starting point for the pathway?**

  The EAG proposed, that in orthopaedics, GaitSmart is positioned alongside pre/post-operative rehabilitation advice include GaitSmart programme, whilst for standard care, pre/post-operative advice is given.



One expert commented that people with arthritis tend to self-manage at first and go to the GP when pain develops, and then get referred to surgery. The decision for surgery is made based on symptoms and investigations. Patients may not see a physiotherapist throughout the process because they tend to self-manage. One expert commented that although Enabling Self-management and Coping with Arthritic Pain using Exercise (ESCAPE) pain clinics are recommended by NICE, patients often do not attend the clinics as they believe surgery is the solution. For pre-operative rehabilitation, patients will get a pre-operative work up, but don't tend to see a physiotherapist. For post-operative rehabilitation, patients are seen by physiotherapists in the ward (usually 3 days stay in hospital) with exercises demonstrated. A simple exercise sheet is provided at discharge. Thereafter, there is follow up with a GP or in the hospital at 6 weeks or 2 months. Patients with ongoing problems are referred to physiotherapy. The expert also commented that the post-operative rehabilitation is not well-established as routine practice. Patients often feel abandoned after surgery dealing with their knee problem as care provision is slow. GaitSmart could be useful to support patients through outcome measures, but they expressed concern on how well it helps in engaging patients in the exercise programme.

Another expert sought feedback from Musculoskeletal Physiotherapy (MSK) colleagues and shared at the meeting. This will be provided in writing to the EAG. One expert noted that the Knee / Hip OA pathway is a seamless process and GaitSmart could come in at any point. The expert noted there are triage hubs which are physiotherapist run and when people meet surgical criteria, they are referred to secondary care. The expert noted that is could be used pre-operatively to prevent / delay referrals. Currently working on a single point of access where physiotherapists would be responsible for assessing and referring to secondary care (surgery) so physiotherapists could deliver GaitSmart interventions.

One expert noted that the MSK Best Practice pathway might provide a sensible approach as currently there are difficulties in getting services to 'talk to each other' which results in wide variations in practice. Efforts are being made to standardise approach according to this pathway. A second expert agreed that there is a need for standardised approaches but noted that this would be difficult as it was dependent on factors such as funding and commissioning priorities.

- **If done by the consultant, how long do people usually wait before seeing a consultant for an initial appointment to discuss their referral?**

  One expert stated that a lot of hospitals run knee clinics. The waiting time is very variable across hospitals depending on how they operate. The wait for a decision on surgery may not be long, but the wait from decision to surgery can be very long. One expert reported that patients could wait up to 72 weeks although this is coming down. Some patients wait up to 6 months from referral so introducing GaitSmart early could be of benefit. Once patients have been referred, they are usually discharged from physiotherapy and may / may not keep up with any exercise / symptom management they were provided however if they do, this will be self-directed.

- **Should pre and post-operative rehabilitation be considered separately? If someone used a GaitSmart approach for pre-op it would appear it would largely be a similar process. Would current standard care be the same for both pre and post op or are there differences?**

  Two experts stated that management is similar between pre and post-operative rehabilitation.
  One expert considered GaitSmart to be a diagnostic tool in that it provides information on gait problems. Having this information earlier in the pathway would be useful as it gives patients and clinicians something to work on. The expert noted the existence of 'Waiting Well' pathways where the intention is to prevent conditions deteriorating while on a waiting list and considered GaitSmart could be introduced at this point. They also noted that these were n development and may not be standardly available to all patients
  The EAG asked if it was feasible for healthcare assistants to deliver post-operative GaitSmart programme.
  One expert stated that in their organisation, physiotherapist oversight is set up to review patient notes and provide advice and support.

- **If done by the physio, could / should this pathway start at a point where people are diagnosed with osteoarthritis rather than waiting until at the point of referral for surgery?**

  One expert commented that the same staff should be delivering ideally, but raised concerns on the affordability. Different ways to deliver should be looked into. In terms of pre-operative appointments, some patients will receive a sheet of exercises, whereas others will have exercise classes. Not all patients will have the time to attend, and some do not like group sessions. Delivering the digital intervention allows patients to do the exercises in their own time.
  One expert raised concerns around a post Covid trend towards virtual clinics, with patients having video calls / assessments with physiotherapists which can make it difficult to identify when someone is deteriorating. The expert considered that GaitSmart may help with this by providing objective measures which allow patient and clinician identify potential problems. The clinical expert discussed the possibility of GaitSmart clinics where clinicians can book an appointment / assessment for a patient.

- **Are there potentially two populations here – people diagnosed with osteoarthritis who are not at the point of needing surgery with the intention of delaying surgery and people who are already referred and waiting for surgery who may have better surgical outcomes as a result of following a GaitSmart programme while on the waiting list?**

  One expert stated that those waiting for surgery may potentially benefit from GaitSmart programme due to less heterogeneity. Identifying early markers and targeting patients early may delay disease progression, hence this should be the target group, however they noted that at present it was hard to identify these patients. The expert commented that there is a need for behavioural and belief change through educational sessions, to show patients that OA can be managed by exercise. GaitSmart may be useful by showing the improvements gained through exercise, thus avoiding disease progression. Research on mass screening with simple gait analysis and machine learning was discussed.
  Another expert stated that these two populations are expected. ESCAPE pain clinics have just started in their organisation. They clarified that GaitSmart is used to measure and record patient's progress for ESCAPE, however patients still attend ESCAPE group exercise and educational sessions and complete the exercises recommended by the ESCAPE programme.
  A third clinical expert noted that GaitSmart could be introduced early in the pathway, perhaps at the point where and individual seeks out treatment for knee problems. This could help prevent / delay the need for surgery.

- **How is a gait assessment currently done? Is there likely to be variation depending on the setting?**

  Two experts stated that visual assessment is currently done, to look at how patients walk. One expert commented that the effectiveness of visual assessment depends on the experience, space and attention of the evaluator, as well as the pain level patients are experiencing when walking. Formal gait analysis in a lab is not routinely used, where up to 30 markers, force plates and a treadmill may be available to examine kinematics, symmetry etc. Paediatrics in the NHS are using this service, but many clinicians may not know how to interpret gait results. The use of artificial intelligence (AI) in interpreting the results was discussed. Another expert commented that there was no variation depending on the setting.

- **Could you comment on the relative importance of the gait assessment and balance training / exercise element of the multifactorial approach?**

  One expert stated that it has always been individualised for arthritis given the disease complexity. Getting the right balance of balance training / exercise is the key. They explained that exercise can be boring and repetitive, while patients are unsure when to progress and are nervous that they will make it worse. They advised that having a range of exercises, with grades of difficulty would be important. GaitSmart might help with engagement and adherence. Another expert stated that, with risks of falls, it is likely to be more related to balance, higher fear of falling for osteoporosis group and for arthritis, the emphasis is more about strengthening issue.

The Technology

- **Are there any alternative gait analysis apps / devices currently being used in your practice?**

  One expert stated that a number of apps are being developed – including monitoring balance and recommending exercise, guiding exercise but not analysing gait. Shoe insoles are also being developed to measure pressure and give feedback. Development of smaller devices and AI was discussed, leading to simple and cheaper technologies.
  Another expert stated that in their organisation, self-help programmes are available before patients come in.
  Two experts noted that there was nothing equivalent to GaitSmart available. One expert reported that a competitor analysis conducted didn't identify any alternatives. Both experts reported that the unique aspect of GaitSmart is that it combines the measurement and exercise element into an assessment, that the exercises are tailored based on the results of the gait assessment and that a Red/Amber/Green rating gives feedback on progress.
  The EAG asked whether the experts could comment on patient experience using GaitSmart? Both experts responded that patients like it as they like having the targets to improve their outcomes. They find it easy to use and follow the programme.

- **If yes, how does the comparative efficacy look like and how accurate it helps in guiding the physiotherapy treatment plan?**

  One expert stated that wearable sensors may have more functions than GaitSmart, but they are more expensive. Sensors adapted to clothing could enable continuous monitoring, thus less conspicuous and eliminating the issue of 'being watched' for assessment. Gait changes throughout the day should be monitored continuously, rather than at a single timepoint – gait maybe good in the morning, but limp or poor balance by end of the day. A number of developments are underway.

Use of the Technology

- **If you have experience using GaitSmart, can you describe on the follow up requirement for both populations?**

  One expert commented that changes with GaitSmart can be quite subtle, where 6-8 weeks would be minimum to see an effect. More follow up time may be needed to review the effects. It might be quicker to capture changes in balance depending on how compromised. Another expert stated that in their organisation, review dates are planned within the 12-week programme.

- **How compliant are GaitSmart patients to vGym personalised rehabilitation programme? How does it differ to standard care?**

  One expert commented that increased compliance would be what they have been hoping for. Clinicians inputs will be obtained and shared with EAG.
  Two experts commented that in their experience, patients were fairly compliant with the exercises.

- **For vGym: How is compliance measured and how the programme of exercise personalised to the patient needs?**

  One expert stated that it is important to personalise to enhance patients' engagement and making sure the right level for them. Another expert stated, based on the feedback from physio and health connectors, the change in exercise and reasons for change are recorded, thus the exercise is personalised and provide feedback to GaitSmart.
  The EAG requested for the full quote of physio and health connectors' feedback by email.
  NICE asked if vGym is able to pick appropriate exercises.
  One expert stated that, given only certain muscles can be strengthened, patients prefer variations in the exercise such as some weight bearing, a range of progression and different ways of doing it.
  NICE sought clarification if it is about the variety, then escalating as it goes.
  The expert clarified that the exercise needs to be a variety with a range of difficulties (very easy to very difficult) for each muscle. This is to keep patient motivated.

- **Other than the technology and healthcare assistant time, are there any other additional resources required when using GaitSmart?**

  One expert stated that in their organisation, administrative staff are utilised to do bookings and transferring GaitSmart data to patient records. This is a Band 2 administrator, with 5-10 minutes per patient, in addition to standard care. They explained that they were currently trialling the use of GaitSmart at patient's homes, however to facilitate the 10m walk they needed to use outdoor space, and this was weather dependent. Realistically, clinic space or other facilities is needed. An internet connection is needed, and phone sim cards have been used to overcome internet black areas in the clinics to connect GaitSmart.
  One expert noted that patients prefer to have their report printed out for them. The expert also noted that a good wifi / internet connection is required as the system first uploads the data from assessment to the cloud then downloads results and reports.

  In terms of staffing, one expert noted that a healthcare assistant / rehab assistant in the community will visit patients by themselves but may be overseen by a physiotherapist / occupational therapist. The EAG asked whether the healthcare / rehab assistant could deliver the GaitSmart programme from start to finish and to what extent a physiotherapist / occupational therapist would be needed? The clinical expert considered that healthcare / rehab assistants could be trained in the GaitSmart system and signed off to deliver the intervention with physiotherapist / occupational therapist available to provide supervision where necessary and be available to discuss any issues.

Evidence and Benefits

- **How accurate is gait speed in predicting falls? Are there any stronger fall predictors?**

One expert stated gait speed is not that accurate to predict falls, and that it is more about swaying and balance, tandem stand etc. The expert was not aware of any key papers on this topic.

- **Is there any specific evidence for the use of gait training as a surrogate for the clinical outcomes in the scope?**
  This doesn't have to be specifically related to GaitSmart, we just want to get a sense of whether there is a clinical consensus that improving gait can improve clinical outcomes or whether there has been any validation of gait improvement / changes as a surrogate outcome?
  One expert stated that gait is used to identify the problem and target muscles that need strengthening, so gait is a surrogate outcome. As the exercise aims to change muscle function, gait symmetry is a good indicator of outcomes. The expert queried if GaitSmart examines this aspect. The expert added that balance is more complicated as other factors are involved.
  One expert reported that improving gait is the main purpose of doing surgery because this helps improve pain and function for patients.
  One expert noted that improving gait in people at risks of falls can help improve quality of life as improving gait improves mobility and can enable people to be more independent.

Appendix 5: Follow up questions to the company

To your knowledge is GaitSmart I still in use anywhere?

GaitSmart 1 is not longer in use anywhere

When did it stop being used - essentially would any study post 2016 be using GaitSmart II? GaitSmart 1 was used until 2020 in the IMI APPROACH project. Publications from this project are still being published, because, as you know, the research continues regarding analysing data. We have very recently had two poster presentations at OARSI 2023 and EULAR 2023 on the association between the structure of the knee and GaitSmart data. GaitSmart II has been in use since 2020 but all the papers are currently in the review process. So all publications are still for GaitSmart 1.

A lot of the studies talk about 4 or 6 sensors being used but the instructions for GaitSmart say 7 sensors - could you just give a quick insight as to when / why that changed

We started with 4 sensors and could monitor the knee joint and thigh and calf range of motion. In 2014 we were asked by Royal Devon and Exeter Hospital to extend the system to 6 sensors so that we could monitor the hip and knee joint, as well as pelvis, thigh and calf range. [redacted]

GaitSmart I and GaitSmart II perform the same calculations to obtain the gait kinematic data. And the accuracy for both is almost identical, as proven by NPL and detailed in their 3D Metrology presentation. The main difference is GaitSmart II has been automated to make it more suitable as a clinical tool. I'm happy to provide more information if this would help.

Is there any flexibility around the frequency of GaitSmart assessments? The submission says at least 3 weeks apart, would there be a maximum gap between assessments?

Yes their is flexibility in the frequency of the GaitSmart assessments and we have demonstrated that it can be up to 12 weeks and still be effective. The NNUH study on joint replacement patients ran through COVID and some patients were part way through the process when there was a lockdown around January 2023. The patients with this extended gap did get very similar results to those with a shorter gap

Appendix 6: Additional questions on costs

There is an upfront cost for the GaitSmart kit, but this is just to get set-up with the kit in a clinic/trust including training.

The upfront cost includes set up of the system for a Trust and training of all staff.

On an ongoing basis there is cost per session (so if a patient has 4 sessions, the cost per patient is 4xthe session cost? Have I understood that correctly?)

The cost is £10 per test, so if a patient has 4 tests, then their cost is £40.

In the MIB it states that a minimum number of GaitSmart sessions needed per month is 100 (equating to 25 patients assuming each of them has a full 4 sessions) – if a clinic doesn't reach the minimum number of sessions, would they pay for 100 sessions regardless? Essentially, is there a minimum monthly cost for GaitSmart, so if one session if £10 does a user pay £1,000 per month in addition to the set-up costs even if they only do 50 sessions?
In the MIB we have stated a minimum number of tests/ month of 100. [redacted]

Do the costs change if numbers increase? Is there any discounting on session costs if users have say 500 sessions a month?
[redacted]

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence

Centre for Health Technology Evaluation

Pro-forma Response

External Assessment Report factual check

MTG575 GaitSmart rehabilitation exercise programme for gait and mobility issues

Please find enclosed the external assessment report prepared for this assessment by the External Assessment Group (EAG).

You are asked to check the external assessment report from CEDAR to ensure there are no factual inaccuracies contained within it. If you do identify any factual inaccuracies you must inform NICE by 12pm, **Tuesday 11th July** using the below proforma comments table. All your comments on factual inaccuracies will receive a response from the EAG and when appropriate, will be amended in the external assessment report. This table, including EAG responses will be presented to the Medical Technologies Advisory Committee and will subsequently be published on the NICE website with the external assessment report.

EAG Assessment Report submitted to company Thursday 6th July 2023

NICE National Institute for Health and Care Excellence

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
P8 For people referred for surgery, GaitSmart score improved in 76% of participants and gait speed increased in 80.5% of participants over the course of the study period (Rodgers 2020) Also on P94	This study is for frail older people under the care of the community hospital after an injurious fall. Could alter to For frail older people who have had an injurious fall	Correcting the cohort type	Thank you for your comment. The EAG has made this correction to the text in both places. We have rephrased to say 'For people at risk of falls,…' to be in line with the scope populations.

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
P11 Additional sensors are provided as spares	Additional sensor is provided as a spare	The protocols offered now only allow for hip and knee measurement so required 7 sensors	Thank you for the clarification, we have made the correction.

Issue 3

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
P14 The EAG proposed pathways were based on GaitSmart intervention taking	Four sessions, 3 weeks apart can be completed in 9 weeks	Elapsed time is 9 weeks min	Thank you for the clarification. The EAG has not made any changes to sentence in question as this was a conservative

at least 12 weeks to complete (baseline assessment and 3 follow-up assessments around 3 weeks apart)			approach to allow flexibility in timing of follow-up assessments. The EAG has added addition wording to the last sentence however which now reads: 'The EAG notes that the company has stated that there is flexibility in the number and frequency of assessments and if assessments are carried out at 3-week intervals, a full GaitSmart programme would be completed in 9 weeks.'

Issue 4

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
P67 physiotherapist oversight (5 mins per patient).	Based on experience this is considerably lower	Will affect the cost model	Thank you for your comment. The EAG has not make any changes to the economic models. The EAG understands the variable oversight time across settings, however any changes to the already small costs are likely to have a minimal impact on the overall cost of providing GaitSmart.

Issue 5

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
P91 wifi connection sufficiently strong to allow data to be uploaded and a report downloaded	Clinicians and patients view the report on a web browser through the App. The report is not downloaded Could state: and a report to be viewed on a web browser	To align with client usage	Thank you for your comment. The clinical experts noted that there are some people who prefer to have a printed copy of the report hence the use of 'downloaded'. The EAG had added clarity to the sentence which now reads '…uploaded and a report viewed on a web browser or app or to be downloaded and printed for people who prefer a physical copy.'

Issue 6

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
P91 exercise app, the vGym app Also in the on line questionnaire	It would be more accurate to state exercises are included in one of the protocols, Gait with vGym, available to the User	To align with client usage	Thank you for your comment. The EAG cannot identify which part of the report this comment relates to and have therefore not made any changes.