



GaitSmart rehabilitation exercise programme for gait and mobility issues

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

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This guidance replaces MIB283.

1 Recommendations

Adults at risk of falls

1.1 For adults at risk of falls, GaitSmart rehabilitation exercise programme can be used to treat gait and mobility issues in the NHS while more evidence is generated.

Adults having hip or knee replacements

- For adults having hip or knee replacements, more research is needed on GaitSmart rehabilitation exercise programme to treat gait and mobility issues before or after surgery.
- 1.3 Access to the technology for adults having hip or knee replacements should be through company, research or non-core NHS funding, and clinical or financial risks should be appropriately managed.

Evidence generation and research

- 1.4 Further evidence is needed on the clinical effectiveness of GaitSmart, including:
 - studies with larger populations
 - comparative studies
 - adherence to the rehabilitation exercise programme
 - · adverse effects.

What this means in practice

NICE has made this recommendation because there is evidence suggesting benefits of using GaitSmart in people at risk of falls. But more evidence is needed comparing GaitSmart with standard care in this group of people. GaitSmart would be another treatment option that could fill a treatment gap for some people who may otherwise not be able to access gait rehabilitation services.

GaitSmart is intended to be delivered by a trained healthcare assistant, with referral to a physiotherapist if needed. The cost analysis shows that it is potentially cost saving compared with standard care because it needs less healthcare professional time and resources than in-person rehabilitation exercise programmes.

Evidence generation alongside using GaitSmart in the NHS for adults at risk of falls should enable clinical-effectiveness evidence to be collected to support the benefits shown in evidence already.

These recommendations will be reviewed within 3 years, or sooner if new evidence becomes available. Take this into account when negotiating the length of contracts.

This guidance is not accompanied by an evidence generation plan. Details of the types of evidence that should be generated are included in section 4.12.

Why the committee made these recommendations

The clinical evidence on GaitSmart in people at risk of falls, and people having hip or knee replacements is limited but shows benefits.

Adults at risk of falls

Of the 4 relevant studies in people at risk of falls, 3 measured the clinical effects of GaitSmart. None compared it with standard care, but the results suggest that GaitSmart improves gait and quality of life, and people report less fear of falling.

The cost analysis shows that GaitSmart is potentially cost saving compared with standard care to treat gait and mobility issues in people at risk of falls. Comparator costs for

standard care are variable. But GaitSmart is likely to be cost saving if its cost is similar that of standard care. There are also several ongoing or planned real-world evaluations of using GaitSmart in the NHS in this group of people. These may address the uncertainties in whether the clinical and system benefits are realisable in clinical settings in the NHS. So, GaitSmart is recommended for use in this group of people while evidence is generated. NHS organisations that are collecting real-world evidence on GaitSmart are encouraged to share these findings as they become available.

Adults having hip or knee replacements

Of the 3 relevant studies in people having hip or knee replacements, 1 measured the clinical effects of the GaitSmart rehabilitation exercise programme. The results of this small clinical trial suggest potentially greater improvements for people using GaitSmart after surgery compared with standard care. But there is no formal analysis of the differences between the groups, and no evidence on using GaitSmart before surgery.

The cost analysis shows that GaitSmart is cost saving compared with standard care in people having hip or knee replacements. But, in this group of people, there is limited clinical-effectiveness evidence, and no ongoing real-world evaluations. So, more research is needed.

2 The technology

Technology

2.1 GaitSmart rehabilitation exercise programme (Dynamic Metrics) is intended for people who are ambulatory or partially ambulatory and have gait and mobility issues. It comprises digital gait assessment and personalised rehabilitation exercises. GaitSmart is a CE marked class 1 medical device that uses sensorbased digital technology to monitor limb movement. Seven sensors are placed 1 on either side of the pelvis, 1 on each thigh and calf, and 1 at the base of the spine. Objective measurements are taken while the person is 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 any gait issues and the severity. The test takes 10 minutes to complete and can be done by a healthcare assistant in a variety of settings. The gait assessment produced by GaitSmart is used with an integrated app for healthcare professionals, vGym. This produces a personalised rehabilitation programme consisting of 6 exercises to help improve mobility. The report includes photos and descriptions of each exercise, and advice. It can be printed off and used without patients needing access to a digital device. They can also view the report on a web browser if preferred. Once allocated to the GaitSmart programme, each person should have a total of 4 gait assessments, done by a healthcare assistant, every 3 to 6 weeks. Each gait assessment identifies any changes in gait and mobility and alters the exercises accordingly.

Care pathway

People at risk of falls

- 2.2 <u>NICE's guideline on falls in older people</u> states that a multifactorial falls risk assessment should be offered to people:
 - presenting for medical attention after a fall

- · reporting recurrent falls in the past year
- with gait or balance abnormalities.

This should be done by a healthcare professional with appropriate skills and experience, usually in a specialist falls service. People reporting recurrent falls or assessed to be at risk of falls should be considered for individualised, multifactorial interventions. These should include a gait assessment, and strength and balance training. For people at risk of falls, GaitSmart provides 2 functions, an objective assessment of gait and a personalised exercise programme.

People having a joint replacement

NICE's guideline on joint replacement (hip, knee and shoulder) outlines the treatment options that are available for people who are offered primary elective hip, knee or shoulder replacement. Referral for surgery should be considered for people who have knee or hip joint symptoms (pain, stiffness and reduced function) that substantially affect their quality of life. They should have been offered non-surgical treatment options or have symptoms that have not resolved with the core non-surgical treatment options. A GaitSmart assessment would be offered as part of pre- and postoperative management. The focus of the GaitSmart programme is to strengthen muscles in preparation for surgery, and to support recovery after surgery.

Innovative aspects

The innovative aspects of the technology are that it uses a fully automated process to identify each gait cycle from the sensor data and extracts key gait kinematic features. Muscle weakness can also be calculated using this data. Key features from the gait data are presented in a report that uses traffic light coding and scoring to aid understanding for healthcare professionals and patients. The personalised rehabilitation programme is also produced automatically and generates 6 exercises based on the muscles that need strengthening. The company claims that GaitSmart would improve gait assessment and choice of

intervention, and increase access to objective gait analysis, which may result in benefits from improved patient outcomes.

Intended use

2.5 The GaitSmart programme is intended for people who are ambulatory or partially ambulatory and have gait and mobility issues. This evaluation focuses on people at risk of falls, and people having hip or knee replacements. GaitSmart is intended to be used as an alternative to standard-care gait assessment and exercise programmes for gait or mobility issues. The GaitSmart assessment is intended to be done by a healthcare assistant. Additional training on using the technology and reading the report is needed for healthcare professionals and people having treatment.

Costs

The cost of GaitSmart was calculated by the external assessment group (EAG) to be £82.00 per user. This included the costs of 4 sessions of GaitSmart assessment, the vGym rehabilitation exercise programme and employing a healthcare assistant to do the tests. The cost of each GaitSmart session was £10.00 (£40.00 for 4 sessions). The cost of employing a band 4 healthcare assistant for 4x15 minute sessions was estimated to be £34.00. The EAG also included 5 minutes of physiotherapist oversight time, estimated to be £4.58. Administration costs for 10 minutes per user was estimated to be £3.42. There is an additional one-off cost of £1,000 for loan of the GaitSmart system to the NHS and for training. This cost was not included in the economic modelling because it may be negotiable depending on contract and setting. For more details, see the website for GaitSmart.

3 Evidence

NICE commissioned an external assessment group (EAG) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the <u>project documents on the NICE website</u>.

Clinical evidence

The clinical evidence comprises 11 studies, 1 of which is a randomised controlled trial

3.1 The EAG's review included 11 studies: 1 randomised controlled trial, 4 diagnostic studies, 1 cross-sectional design study, 1 case report, and 4 publications that included a mix of before-and-after and case-series study design. Six of the studies included a total of 656 people with hip or knee osteoarthritis. Four of the studies included a total of 242 people at risk of falls. One study was done in a healthy population of 136 people with no existing gait problems. For full details of the clinical evidence, see section 3 of the assessment report in the supporting documentation.

There are 4 relevant studies in people at risk of falls

- 3.2 The relevant evidence for people at risk of falls included:
 - a before-and-after study of 121 people who had an injurious fall and were in community care (Rodgers et al. 2020)
 - a before-and-after study of 46 people at risk of falls from 2 GP surgeries (Hodgins and Newby 2023a)
 - a before-and-after study of 46 people at risk of falls in community care (Hodgins and Newby 2023b)
 - a case series that reported on how gait parameters in a healthy older population differed from 18 older people with gait and balance issues

(Hodgins and McCarthy 2015). The EAG considered that this study had limited applicability because it used a healthy control group and did not use the vGym app to generate the personalised exercise plan.

There are 3 relevant studies in people having a hip or knee replacement, including a randomised controlled trial

- The study most clinically relevant to people having hip or knee replacements was the parallel group randomised controlled trial (McNamara et al. 2023). This compared GaitSmart with standard-care rehabilitation after surgery in 44 people who had total knee or hip arthroplasty, but whose rehabilitation goals had not been met. Other relevant studies included:
 - a cross-sectional study in 74 people who had or were having a knee replacement, in which outcomes were compared between 4 groups who were each at different timepoints relating to surgery (Rahman et al. 2015)
 - a case series that reported gait differences in a group of 55 people with hip arthrosis and included comparisons with a control group of people with no health issues (Hanly et al. 2016).

The EAG considered that these 2 studies had limited applicability because they both used a healthy control group and did not evaluate the GaitSmart exercise programme. There were also 3 diagnostic studies in relevant populations, which compared GaitSmart with optical tracking systems (IMI-APPROACH, McCarthy et al. 2013, Zügner et al. 2019). Outcomes from these studies suggested that GaitSmart measurements correlate with other comprehensive gait analysis systems.

There is a high degree of heterogeneity in the evidence, which reflects the variation in the care pathway

There was a high degree of heterogeneity in terms of the comparisons made and outcomes reported in the studies. So, a meta-analysis was not done. The clinical experts noted that the care pathways are extremely variable for people at risk of

falls, and for people who have had a hip or knee replacement. This may make it difficult to identify appropriate comparators. The EAG also noted that there was poor reporting of study designs and recruitment methods in the included studies. There was also a lack of long-term follow up for clinical outcomes and data on adherence to the intervention protocol.

Results from the studies indicate that GaitSmart has the potential to improve gait parameters and patient-reported outcomes

The relevant evidence for changes in gait parameters and patient-reported outcomes was based on comparative studies that included control groups and single-arm studies. The clinical evidence was primarily generated in settings that are generalisable to the NHS. There were strengths in the available studies in that they used validated tools to measure patient-reported outcomes and function. Also, consideration was given to whether observed changes were clinically significant. Based on the limited clinical evidence, the EAG considered that the case for adoption of GaitSmart was potentially supported, but that further evidence generation would be beneficial.

No adverse events are reported in the literature

No adverse events were reported in any of the studies relating to GaitSmart or vGym. For full details of adverse events, see <a href="mailto:seeting-s

Cost evidence

The company's cost model for people at risk of falls finds GaitSmart to be cost saving compared with standard care

The company developed a decision-tree model from an NHS perspective with a time horizon of 1 year, which compared GaitSmart with individual physiotherapy. Clinical inputs were taken from the single-arm Rodgers et al. (2020) study. In the

company's model, each intervention was applied only after a fall that had resulted in an injury. People who had an injurious fall had medical attention through ambulance call-out, a GP visit or attendance at an emergency department. The model used the probability of falls among community-dwelling adults aged over 65. It used the average probability of recurrent falls by fear of falling from Berry and Miller (2008), Tinetti and Williams (1998) and Arfken et al. (1994). The falls risk reduction was assumed to be 0% with standard care and 1.77% with GaitSmart. The response rate of each intervention was not considered in the company's model. The company's base case showed a cost saving of £2.90 per person using GaitSmart. For full details of the cost evidence, see section 4 of the assessment report in the supporting documentation.

The company's cost model for hip and knee rehabilitation finds GaitSmart to be cost saving compared with standard care

3.8 The company developed a decision-tree model from an NHS perspective with a time horizon of 17 weeks. It compared GaitSmart with self-managed home exercise, or group or individual physiotherapy. It was assumed that 20% of people carry out self-managed rehabilitation, and 80% have group or individual physiotherapy. Clinical inputs were taken from the McNamara et al. (2023) randomised controlled trial. This included estimates of the response rate of each intervention and the reduction in falls risk. The company's model considered the change in falls risk of each intervention through the observed change in gait speed. It did this using individual-level data from McNamara et al. (2023), and a risk ratio between gait speed and falls risk of 1.069/10 cm/s decrease from Verghese et al. (2009). A response rate of 0.79 was assumed for the standardcare arm and of 0.93 for the GaitSmart arm. This rate was defined as any improvement in gait speed. The probability of falls was estimated as 0.4. This was calculated using the proportion of people who had falls after arthroplasty from Smith et al. (2016) or because of symptomatic osteoarthritis from Doré et al. (2015). The company's base case showed a cost saving of £450.56 per person using GaitSmart. For full details of the cost evidence, see section 4 of the assessment report in the supporting documentation.

The company's cost model for people at risk of falls is

appropriate, but there are EAG changes to the model structure and parameters

- 3.9 The EAG stated that the company's falls model was flawed because of the time point when the intervention was provided. It meant that each intervention was applied only after an injurious fall. The company's model did not model further outcomes after an intervention was given for people who had an injurious fall. The EAG's falls model started with people having either GaitSmart or standard care. At the end of each branch, people had either falls or no falls. The falls outcomes were modelled following a fall. The EAG was concerned that the probability of falls needing medical treatment in the company's model was taken from an Australian study, Watson et al. (2011). This may not be generalisable to the NHS setting. In the EAG's model, the probability of injurious falls and medical treatment after a fall were taken from Craig et al. (2013). This was used to populate the return on investment tool developed by Public Health England for falls prevention programmes for older people in the community. The EAG increased the total cost for all GaitSmart sessions per patient from £40.00 to £82.00. This included the total staff costs for the intervention. The total cost for standard care was calculated by the EAG to be £102.71 rather than £765.00. This large decrease was primarily because the number of physiotherapy sessions was reduced from 30 to 8. Also, sessions after the initial appointment were assumed to be group rather than individual physiotherapy. The EAG made small changes to the cost of events after a fall, which were:
 - GP visit: from £36 to £42
 - ambulance call-out: from £257 to £282
 - emergency department visit with no admission: from £166 to £118
 - inpatient stay: from £1,609 to £1,950.

The company's cost model for people having hip or knee replacements is appropriate, but there are some EAG changes to model parameters

3.10 The EAG did not agree with the company's calculation of the response rate for

each intervention in the rehabilitation model. In the EAG's model, the falls risk ratio for each intervention was calculated using the approach detailed in Verghese et al. (2009). This study specified that there was a change in the risk of falls of 1.069 per 10 cm/s decrease in gait speed. The risk ratio was then applied to the probability of baseline falls to yield the falls probability of each intervention. The EAG also separated the falls risk ratio for people who did or did not have a response to the intervention in the rehabilitation model. The EAG used updated Personal Social Services Research Unit cost data and inflated it for 2021/2022. This increased the total cost for all GaitSmart sessions per patient from £67.00 to £82.00. The total cost for all group or individual physiotherapy sessions per patient was calculated by the EAG to be £198.44 rather than £643.98. This decrease was primarily because consultant time was excluded.

GaitSmart is cost saving compared with standard care in the EAG's base-case models

3.11 In the EAG's base-case model for people at risk of falls, GaitSmart remained cost saving by £28.70 compared with individual physiotherapy. In the sensitivity analysis, the EAG selected a variety of comparator options. All included an initial 45-minute assessment by a band 5 physiotherapist, followed by a variety of group or 1:1 interventions. The sensitivity analysis also used a risk ratio ranging from 0.5 (50% reduction in falls) to 1 (no reduction in falls) to 1.5 (50% increase in falls). A two-way analysis was done to identify the point of cost neutrality when factoring in the risk ratio for standard care. Cost neutrality was likely to lie between £70.00 and £110.00 per person for standard care, with GaitSmart costing £82.00 per person to deliver. When using the EAG's base-case model for rehabilitation, GaitSmart remained cost saving by £80.39 per person compared with standard care. The EAG did a series of one-way sensitivity analyses for several key parameters. GaitSmart was found to be cost saving across the range of results for each parameter. One EAG scenario varied standard care by substituting a band 6 physiotherapist for a band 4 therapy assistant for physiotherapy sessions. This yielded a change in the cost saving from £80.39 to £24.45. Combining this scenario with an increase in the proportion of people having group physiotherapy sessions (from 50% to 75%) resulted in incurred costs of £17.32.

Costs of GaitSmart and standard care are the key cost drivers in the economic models

For the falls model, 70% of the base-case cost difference was because of the relative costs of the interventions. So, by far the most important economic input to the model was the cost of the comparator. For GaitSmart to be cost neutral or cost saving, the cost of comparator needed to be very close to the cost of GaitSmart or higher. Falls can have a significant impact on people who have them and on the NHS. But GaitSmart resulted in a relatively small reduction in the number of falls (11%) in the model, so the modelled impact of falls on cost saving was small. In the rehabilitation model, overall cost saving was also dominated by the cost difference between interventions, while a marginal number of falls were prevented by GaitSmart. The impact of falls in the model was limited by the short duration.

4 Committee discussion

Clinical-effectiveness overview

GaitSmart shows benefits in improving gait and patient-reported outcomes in people at risk of falls, but more evidence is needed

The relevant clinical evidence suggested that GaitSmart improved gait and patient-reported outcomes in people at risk of falls. This included improvement in fear of falling, frailty and fitness, and health-related quality of life. The clinical experts and patient survey also reported benefits with GaitSmart in helping people to improve their gait and mobility issues. Reported benefits included better understanding of gait and mobility issues, more independence and confidence, and improvement in daily activities such as walking. The committee considered the evidence to be generalisable to the NHS, but there was no clinical evidence comparing GaitSmart with standard care in people at risk of falls. The committee concluded that GaitSmart showed enough benefits to be used to treat gait and mobility issues in people at risk of falls while more evidence is generated to address these gaps.

More comparative studies are needed on GaitSmart for people having hip and knee replacements

The committee considered that there was limited clinical-effectiveness evidence on GaitSmart in people having hip and knee replacements. The randomised controlled trial (McNamara et al. 2023) showed potentially greater improvements in people with hip or knee replacements who used GaitSmart after surgery. But differences in effectiveness between GaitSmart and standard care were not formally analysed. This study included a relatively small sample size and there was no evidence on using GaitSmart preoperatively. The committee concluded that the limited clinical evidence showed that GaitSmart may have the potential to improve gait outcomes in people having hip or knee replacements. But it thought more comparative studies are needed with larger sample sizes.

More evidence is needed on adherence to GaitSmart

The committee considered that the included clinical studies did not report on outcomes for adherence to the GaitSmart rehabilitation exercise programme. The clinical evidence reported adherence as the proportion of people who completed the required assessment sessions, which ranged from 3 to 4 sessions (Hodgins and Newby 2023a, 2023b). The clinical experts explained that people with gait and mobility issues need about 12 weeks of rehabilitation to have improvement in gait outcomes. They also said that the wider evidence base on people with gait and mobility issues showed that adherence to exercise programmes is essential for improvements in patient-reported outcomes. The committee concluded that additional evidence is needed about adherence to the GaitSmart exercise programme and how patient motivation is related to clinical outcomes.

Care pathway and patient selection

GaitSmart is intended as an alternative to standard-care gait assessment and rehabilitation exercise programmes for gait and mobility issues

GaitSmart would provide another treatment option for gait and mobility issues in 4.4 people at risk of falls, or people having hip or knee replacements. The clinical experts advised that GaitSmart may fill a treatment gap for some people who may otherwise not be able to access gait rehabilitation services. The EAG explained that the included studies had a high degree of heterogeneity in terms of the comparators that were included for control groups. The clinical experts advised that the standard-care pathway is highly variable, and that people may be offered different treatments in line with their individual needs and preferences. The committee considered that some people may have complex problems and comorbidities that need more than 1 intervention. The clinical experts explained that, in clinical practice, people at risk of falls would usually have one-to-one physiotherapy after a falls incident. They also explained that people having rehabilitation after a hip or knee replacement would be offered group physiotherapy sessions. In addition, people having hip or knee replacements have visual gait assessments. The committee concluded that GaitSmart would be an

alternative to standard-care gait assessment and exercise rehabilitation programmes. But some people may have a combination of treatments in line with their individual treatment plan and needs.

People at risk of falls should be assessed for eligibility for treatment with GaitSmart, and patient choice should be considered

4.5 The committee discussed selecting people for treatment with GaitSmart in clinical practice. It also considered that some people may have gait and mobility issues that are not related to muscle weakness. The clinical experts advised that, according to published evidence, 80% to 90% of falls are in people with muscle weakness. In clinical practice, people may not be offered GaitSmart if they have a vestibular problem or complex medical history that needs physiotherapy, or are unable to walk 10 strides. GaitSmart may also not be suitable for people with moderate to severe cognitive impairment that affects their ability to follow the programme. The clinical experts also said that some people may prefer group physiotherapy sessions rather than a personalised rehabilitation exercise programme that is intended to be completed at home. The committee concluded that all people considered for treatment with GaitSmart would need to be screened for other underlying causes such as neurological impairment. It added that patient choice should be a significant consideration for using GaitSmart as an intervention if it is adopted into clinical practice. Treatment options should be discussed with patients, and should consider their individual needs and preferences. Healthcare professionals should present information clearly using language that is easy to understand. People should be offered standard care if GaitSmart is not suitable, or if face-to-face or group interventions are preferred.

GaitSmart is intended to be delivered by a trained healthcare assistant, with referral to a physiotherapist if needed

4.6 The committee considered that GaitSmart is intended to be delivered by healthcare assistants, who would do the gait assessment and demonstrate the rehabilitation exercise programme. The clinical experts advised that most

services would have a triage process with a physiotherapist, who would determine if a person should be offered GaitSmart or another treatment option. Once someone is referred for GaitSmart, a trained healthcare assistant would carry out the gait assessment and explain the exercise programme. GaitSmart is also being piloted as part of GP health checks, in which a healthcare assistant does the assessment without physiotherapist triage. The clinical experts noted that the healthcare assistants would be appropriately trained and supervised to use GaitSmart. The integrated vGym programme automatically selects the exercises in the personalised rehabilitation programme, so there is no need for exercise prescribing by a physiotherapist. Services should have a clear pathway to escalate any issues to a qualified physiotherapist if needed. The committee considered that people should also have the option to be referred to physiotherapy if preferred.

The impact of GaitSmart on physiotherapy waiting lists and any subsequent effect on patient wellbeing should be considered

4.7 The committee discussed the potential impact of GaitSmart on physiotherapy waiting lists in the NHS for relevant populations. People may experience deterioration in outcomes related to wellbeing and ability to complete daily activities while waiting for treatment. The clinical experts explained that GaitSmart may offer an alternative treatment option for people who are on physiotherapy waiting lists. This has the potential to improve patient outcomes. But it may lead to an increase in healthcare costs for people who would otherwise not have any intervention. The EAG advised that there was no evidence on the impact of GaitSmart on waiting lists, and that this was not included in the economic modelling. The committee concluded that further information is needed on how GaitSmart may affect physiotherapy waiting lists, and how this affects clinical and resource outcomes by enabling earlier access to treatment.

Other patient benefits or issues

The patient expert comments are positive on the ability of GaitSmart to help monitor progress with the support of a

healthcare professional

The patient expert said that the most beneficial aspect of a GaitSmart assessment was being able to track progress using objective measures. They also found the personalised exercise programme to be useful, and stated that the exercises were similar to those done in physiotherapy. The patient expert found some aspects of the GaitSmart report difficult to interpret. But they acknowledged that they had support from the healthcare professional at each session to help them understand the report. It was noted that video representations of each exercise, in addition to the exercise descriptions and photos already included, would improve the intervention. The patient expert added that they had no issues with access to GaitSmart or the convenience of the assessments, which took place in a designated centre at the local hospital.

Cost modelling overview

The EAG's updated models are plausible and appropriate for decision making, and GaitSmart is cost saving compared with standard care

- The committee considered that the EAG's base-case models were appropriate for decision making. It also agreed with the parameters included in the models. The clinical experts explained that the risk of falls calculated by the EAG was more realistic than that included in the company's models. It was noted that the reduction in falls because of GaitSmart had a relatively small impact in the economic models. The EAG's base-case models showed that GaitSmart was cost saving by:
 - £80.39 for people having hip or knee replacements
 - £28.70 for people at risk of falls.

Main cost drivers

The cost of GaitSmart and standard care are the key cost drivers in both economic models

The committee considered that the overall estimated cost saving with GaitSmart compared with standard care alone was dominated by the cost difference between the interventions. Injurious falls are associated with a significant impact for patients and the NHS. But a marginal number of falls were prevented by GaitSmart, so the impact of falls in both models was limited. The committee concluded that the most important economic input in the models was the cost of the comparator. For GaitSmart to be cost neutral or cost saving, the cost of the comparator would need to be very close to or higher than the cost of GaitSmart.

Scenario analyses

GaitSmart remains cost saving in the one-way sensitivity analyses but could be cost incurring if its and standard-care costs change

4.11 For people at risk of falls, the EAG's sensitivity analyses varied the type of comparator used (either group or individual physiotherapy) and the associated staff time. The committee considered that GaitSmart was cost saving in most scenarios, but not when standard care was a small number of group physiotherapy sessions. The clinical experts explained that people who have a fall are expected to have one-to-one physiotherapy in clinical practice. So, the costs of standard care are substantially higher than the cost of GaitSmart, which means the intervention is likely to be cost saving for people at risk of falls. The committee also agreed with the EAG's estimate that the point of cost neutrality for standard care is expected to be similar to the cost of the GaitSmart intervention. For people having hip or knee replacements, the committee considered that all the EAG's one-way sensitivity analyses showed GaitSmart to be cost saving compared with standard care alone. This applied to the entire plausible range of values for each parameter that was explored. But the

committee also commented that GaitSmart has the potential to increase costs for the NHS if used when physiotherapy is not currently offered to everyone eligible for it. The committee also noted that cost savings with GaitSmart would be highly dependent on the grade of the staff delivering it, and how long the GaitSmart assessment takes. So, it concluded that cost savings may not be realised in clinical practice if use varied from that in the economic models.

Further evidence and research

Further evidence is needed to support the benefits of using GaitSmart to treat gait and mobility issues in people at risk of falls

The committee said that more evidence is needed on GaitSmart to support the benefits shown in the current clinical evidence. The clinical experts said that there are several ongoing or planned pilots evaluating the use of GaitSmart in the NHS in people at risk of falls. These include use in a range of settings, including a GP surgery, frailty clinic, care home and falls team. The committee considered that these real-world evaluations could address some of the uncertainties in the evidence outlined in the assessment for using GaitSmart in people at risk of falls. It concluded that there was enough evidence of benefits in this population for GaitSmart to be used in the NHS while this evidence is generated.

More research is needed to determine the clinical effectiveness of GaitSmart in people having hip or knee replacements

The committee said that larger comparative studies are needed to determine the clinical effectiveness of GaitSmart compared with standard care alone in people having hip or knee replacements. It noted that, at the time of the committee meeting, there were no ongoing real-world evaluations in this population. The most relevant clinical studies should be peer reviewed and published in the public domain.

Several outcomes should be included in the research

- 4.14 For both populations, further evidence and research should clearly outline:
 - the inclusion criteria
 - place in the treatment pathway
 - any other interventions that people had before or during the GaitSmart programme.

The committee agreed that longer-term outcomes of around 3 to 6 months should also be reported, including gait outcomes, patient-reported outcome measures, adverse events and adherence rates. Evidence of the impact of GaitSmart on waiting lists would also be useful to show any additional clinical and system benefits not captured in the existing evidence base. The committee encouraged that any future evidence and research should be disseminated when available.

5 Committee members and NICE project team

Committee members

This topic was considered by <u>NICE's medical technologies advisory committee</u>, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The <u>minutes of the medical technologies advisory committee</u>, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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Accreditation

