NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Draft guidance

GaitSmart rehabilitation exercise programme for gait and mobility issues

How we develop NICE medical technologies guidance

If a technology is recommended for use, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Recommendations

1.1 GaitSmart rehabilitation exercise programme shows promise for gait and mobility issues in people at risk of falls, and people having hip or knee replacements. But there is not enough evidence to support the case for routine adoption. So, it is only recommended for use in research.

1.2 Further research is needed on the clinical effectiveness of GaitSmart, including:

- studies with larger populations
- comparative studies
- studies that investigate using GaitSmart alongside standard care
- drop-out rates and adherence.

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. 11 studies were identified as relevant to GaitSmart, but only 3 measured the effect of GaitSmart in people at risk of falls, and only 1

measured the effect in people having hip or knee replacements. Just 1 of the studies in people at risk of falls has been peer reviewed, and none compared GaitSmart to standard care. The one study in people having hip or knee replacements was small and has not been peer reviewed. The cost analysis shows that GaitSmart is cost saving compared with standard care. But the clinical benefits and costs of GaitSmart combined with standard care compared with standard care alone are unknown. 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 sensor-based 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, vGym. This produces 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 can also be printed off and used without needing access to a personal device. 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 NICE's clinical guideline on falls in older people states that people presenting for medical attention after a fall, people reporting recurrent falls in the past year, and people who show gait or balance abnormalities should be offered a multifactorial falls risk assessment. 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 joint replacement

2.3 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

2.4 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 clinicians 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 with gait and mobility issues. This evaluation focuses on people at risk of falls, and people having hip or knee replacements. 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

2.6 The cost of GaitSmart was calculated by the external assessment group (EAG) to be £82.00 per user. This includes 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 is £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. 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 project documents on the NICE website.

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.

Three studies are relevant to the decision problem for people having hip or knee replacement, including the randomised controlled trial

3.2 The study most clinically relevant to people having hip or knee replacements was the unpublished randomised controlled trial (McNamara, unpublished). This compared GaitSmart with standard care for rehabilitation in 44 people who had either had total knee or hip arthroplasty, and who had had a course of physiotherapy but whose rehabilitation goals had not been met. There was also:

- a cross-sectional study in 74 people who had 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, 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 (Hanley, 2016)
- 3 diagnostic studies in relevant populations, which compared using GaitSmart with optical tracking systems (IMI-APPROACH, McCarthy, 2013; Zugner, 2019).

Outcomes from these studies suggested that GaitSmart measurements correlate with other comprehensive gait analysis systems.

Four studies are relevant to the decision problem for people at risk of falls

3.3 The evidence base for people at risk of falls included:

- a study of 121 people who had had an injurious fall and were in community care (Rodgers, 2020)
- a study of 46 people at risk of falls from 2 GP surgeries (Care City Pilot, unpublished)
- a study of 14 people at risk of falls in community care (Glasgow Falls Clinic Report, unpublished)
- 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, 2015).

All the studies were relevant to the decision problem.

There is a high degree of heterogeneity in the evidence, and the lack of long-term studies makes any long-term outcomes uncertain

3.4 There is 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, with incomplete reporting of factors such as participant demographics. There was also a lack of:

- long-term follow-up in relation to clinical outcomes
- data on adherence to the intervention protocol
- data on drop-out rates.

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

3.5 The published evidence for changes in gait parameters and patient-reported outcomes for GaitSmart 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. It was also noted that the most relevant evidence had not been peer reviewed or published in the public domain.

No adverse events are reported in the literature

3.6 No adverse events were reported in any of the studies relating to GaitSmart or vGym. For full details of the adverse events, see section 3 of the assessment report in the supporting documentation.

Cost evidence

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

3.7 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 do self-managed rehabilitation, and 80% have group or individual physiotherapy. Clinical inputs were taken from the unpublished McNamara 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 (unpublished), and a risk ratio between gait speed and falls risk of 1.069/10 cm/s decrease from Verghese (2009). A response rate of 0.79 was assumed for the standard-care 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, using the proportion of people who had falls after arthroplasty from Smith (2016) or because of symptomatic osteoarthritis from Doré (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 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 1 year, which compared GaitSmart with individual physiotherapy. Clinical inputs were taken from the single-arm Rodgers (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 over 65 and the average probability of recurrent falls by fear of falling from Berry (2008), Tinetti (1998) and Arfken (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 people having hip or knee replacements is appropriate, but there are some EAG changes to model parameters

3.9 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 (2009). This study specified that there was a change in the falls risk of 1.069/10 cm/s decrease in gait speed. The risk ratio was then applied to the baseline falls probability 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.

The company's cost model for people at risk of falls is appropriate, but there are EAG changes to the model structure and parameters

3.10 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 starts 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 (2011), which 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 (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.

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

3.11 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 substituted a band 6 physiotherapist for a band 4 therapy assistant for physiotherapy sessions in standard care. 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. 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 is likely to lie between £70.00 and £110.00 per person for standard care, in which GaitSmart costs £82.00 per person to deliver.

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

3.12 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 is the cost of the comparator. For GaitSmart to be cost neutral or cost saving, the cost of comparator must be very close to the cost of GaitSmart. Falls can have a significant impact on people who have them and on the NHS. But GaitSmart results in a relatively small reduction in the number of falls (11%) in the model, so the modelled impact of falls on cost saving is 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

The limited clinical evidence suggests that GaitSmart may have the potential to improve gait outcomes, but further evidence is needed

4.1 The committee considered that the clinical evidence available is generalisable to the NHS setting. But the available studies included relatively small populations. The committee also noted that the most relevant studies are not published in the public domain, although the randomised controlled trial by McNamara has been submitted for publication. The clinical experts explained that the outcomes used to

measure the effectiveness of GaitSmart are validated tools for measuring patient-reported outcomes and function. So, consideration was given to the clinical significance of results. No adverse events were recorded in any of the studies. The committee concluded that the limited clinical evidence showed that GaitSmart may have the potential to improve gait outcomes in people at risk of falls and people having hip or knee replacements. But it thought that larger comparative studies are needed.

More evidence is needed on adherence to the GaitSmart intervention and drop-out rates

4.2 The committee considered that the included clinical studies had relatively short follow-up times. It also noted that they did not report on outcomes for adherence to the GaitSmart programme. 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 published evidence 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 programme and how patient motivation is related to clinical outcomes.

A clear description of patient populations is lacking in the available clinical evidence

4.3 The external assessment group (EAG) explained that the included clinical studies did not clearly outline the inclusion criteria for participants or the interventions that they had had before having a GaitSmart assessment. The committee noted that it was important for the clinical evidence to reflect the expected treatment pathway for people in clinical practice. The committee concluded that additional evidence should include clear details on who was recruited, and on the other interventions that they had had before or during the GaitSmart programme.

Care pathway and patient selection

GaitSmart is expected to be used in addition to standard care for people with gait and mobility issues

4.4 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 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 regular visual gait assessments. The committee also had input from a patient expert. This suggested that some people would prefer a combination of GaitSmart and group physiotherapy. The committee noted that the GaitSmart programme consists of 4 sessions lasting between 9 and 24 weeks in total. With this in mind, it concluded that the most appropriate place for GaitSmart in the clinical pathway would be as an adjunct to standard care.

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

4.5 The committee discussed selecting people for treatment with GaitSmart in clinical practice. It also took into account 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. They 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.

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

4.6 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 to have 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 committee concluded that further information is needed on how GaitSmart may affect physiotherapy waiting lists and how this affects patient wellbeing by enabling access to treatment.

Other patient benefits or issues

Patients commented on the ability of GaitSmart to help monitor progress with the support of a healthcare professional

4.7 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. They 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 model is plausible and appropriate for decision making, and GaitSmart is cost saving compared with standard care

4.8 The committee considered that the EAG's base-case model was appropriate for decision making, and agreed with the parameters included in the model. The clinical experts explained that the risk of falls calculated by the EAG was more realistic than that included in the company's model. It was noted that the reduction in falls because of GaitSmart had a relatively small impact in the economic model. The EAG's base-case model 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 the GaitSmart intervention and standard care are the key cost drivers in both economic models

4.9 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. Falls are associated with a significant impact for patients and the NHS. Also, 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 model 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 significantly higher than the cost of GaitSmart.

Scenario analyses

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

4.10 For people having hip or knee replacements, the committee considered that the 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:

- in addition to standard care such as group physiotherapy or
- when physiotherapy is not currently offered to everyone eligible for it.

The committee also noted that cost savings with GaitSmart are highly dependent on the grade of the staff doing it, and how long the GaitSmart assessment takes. So, it concluded that cost savings may not be realised in clinical practice. 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 standard care costs 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.

Further research

Further research would help to determine the clinical effectiveness of GaitSmart and should include long-term outcomes data

4.11 The committee said that larger comparative studies are needed to determine the clinical efficacy of GaitSmart compared with standard care alone. It added that these studies should use GaitSmart as an adjunct to standard care because this is how it is expected to be used in clinical practice. It also said that inclusion criteria and place in the treatment pathway should be clearly outlined, and that the most relevant clinical studies should be peer reviewed and published in the public domain. The committee agreed that long-term outcomes should also be reported, including gait outcomes, patient-reported outcome measures and adherence rates.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, 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 minutes of the medical technologies advisory committee, 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.

Farhaan Jamadar and Evan Campbell

Health technology assessment analysts

Kimberley Carter

Health technology assessment adviser

Catherine Pank

Project manager

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