National Institute for Health and Care Excellence

Medical technologies evaluation programme

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

Consultation comments table

Final guidance MTAC date: 17 November 2023

There were 28 consultation comments from 9 consultees:

- 6 comments from 1 company
- 20 comments from 6 healthcare professionals
- 1 comment from 1 patient organisation
- 1 comment from the Medicines and Healthcare products Regulatory Agency (MHRA)

One comment was removed because it was a duplicate from the same consultee. All other comments are reproduced in full. Some comments have been split because they represented multiple themes. The following themes have been identified:

- Recommendations (comments 1 to 5)
- The technology (comments 6 to 9)
- Care pathway (comments 10 to 20)
- Alignment with scope and EAG report (comments 21 to 23)
- Patient benefits (comments 24 to 26)
- Clinical evidence (comments 27 to 30)
- Cost modelling (comments 31 to 36)
- Further research (comments 37 to 42)
- Equality considerations (comments 43 to 45)

#	Consultee ID	Role	Section	Comments	Notes for chair/committee leads
Recommendations (n=5)					
1	2	Healthcare professional	Are the recommendations sound and a suitable basis for guidance to the NHS?	In the context that Gaitsmart submitted the scope application as an early intervention gait assessment ,as an alternative to standard care in a real world evidence environment , the recommendations are a sound and a suitable basis for guidance to the NHS. However, the guidance seems to have diverged from the EAG report and focused on long term outcomes and use as an adjunct to standard care- neither were the focus for this specific application.	Thank you for your comment. Sections 2.5 and 4.4 of the guidance have been amended to state that GaitSmart is intended to be used as an alternative to standard care gait assessment and rehabilitation exercise programmes.
2	2	Healthcare professional	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	The EAG report, focuses on the positive clinical and economic outcomes using GaitSmart as an alternative care intervention for joint arthroplasty and falls risk assessment in comparison to the same outcome measures in standard care. Based on the evidence in the EAG report and supporting research evidence,it is not felt that it is justified that it is put as a research tool only. This will prevent its use as an intervention to the NHS and it will reduce its availability to develop it as a further intervention towards the NHS goal of Net Zero, both in the community and hospital setting, as the NHS will be unable to use it outside of the research protocol. Therefore the committee should reconsider this decision and move to the 'NICE Real-World Evidence Framework' in line with the EAG's recommendations.	Thank you for your comment. The committee carefully considered the consultation comments along with the clinical and economic evidence, external assessment group (EAG) report and input from clinical experts and patients. Following this, section 1 of the guidance has been updated to a partial recommendation to use GaitSmart to treat gait and mobility issues in people at risk of falls while more evidence is generated. The committee considered that there was enough evidence of benefits in this population for GaitSmart to be used while more evidence is generated through several ongoing and planned evaluations in the NHS. The committee considered that more research is needed on

					GaitSmart to treat gait and mobility issues in people having hip or knee replacements, including larger comparative studies. Recommendations for use in research 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. Access to the technology for this population should be through company, research or non-core NHS funding. This is outlined in Section 1.3 of the final guidance.
3	3	Company	Are the recommendations sound and a suitable basis for guidance to the NHS?	The draft guidance has drifted quite significantly from the EAG's report with limited reasons as to why. My primary concerns relate to the apparent weight place upon; 1. Need for additional evidence to drive understanding of potential longer term value when the long term value is not considered in the scope of this application and is only likely to provide additional value on top of the already positive clinical and economical outcome. 2. Lack of recognition to the natural heterogeneity in the care pathway environment and Dynamic Metrics ability to control this and the presentation that this is an easily solved weakness in the studies provided. 3. No consideration of the EAGs recommendations to support the use of GaitSmart in a real world evidence environment which would could help address the above. 4. Drop-out rates which were identified as missing by the draft guidance although were published in the supporting literature The studies provided to support this application and the EAG report, focus on the positive clinical and economic outcomes available when using GaitSmart to facilitate an alternative care pathway for 'risk of falls' and 'joint reconstruction' when compared to the same outcome measure used to assess standard care at the end of treatment. The EAG also recognises that the challenges with the heterogeneity in the study protocols are a	Thank you for your comment. The medical technologies advisory committee (MTAC) makes recommendations on medical technologies after careful consideration of the EAG report, the clinical and economic evidence and other sources of information such as clinical and patient advice. While the committee considered that longer-term outcomes would be useful, these were not included in the key outcomes in Section 1.2 of the draft guidance. Section 4.14 (previously 4.11) of the guidance has been amended to read: "The committee agreed that long*er*-term outcomes *of around 3 to 6 months* should also be reported". Section 3.4 of the draft guidance described the heterogeneity in the care pathway. The strapline for this

				reflection of the high degree of variability in the care pathway and are not an easy solve. Their recommendation was therefore to support use of GaitSmart whilst collecting real-world evidence across a much larger cohort to help counteract some of the heterogeneity through volume and explore the potential for further longer term benefits. Based on the evidence and the comments in the text it is not felt that it is justified that it is put as a research tool only. By placing it in this category it will be detrimental to the NHS and it will reduce GaitSmart's ability to collect further evidence in the community as the NHS will be unable to use it outside research. I feel the recommendation should be for GaitSmart to be under the 'NICE Real-World Evidence Framework', in line with the EAG's recommendations.	section has been amended to make this clearer and now reads: "There is a high degree of heterogeneity in the evidence, *which reflects the variation in the care pathway*". This section has also been amended to remove drop-out rates. Please also see response to comment 2.
4	6	Healthcare professional	Are the recommendations sound and a suitable basis for guidance to the NHS?	In our opinion, the technology is ready for real-world testing and data gathering. More research evidence is required in the areas indicated however, this seems best achieved within a clinical setting.	Thank you for your comment. Please see response to comment 2.
5	4	Healthcare professional	1.1	Disappointing that the case for routine adoption is not supported. GaitSmart is currently in use and planned to be piloted in number of NHS organisations, including Bedford, Luton and Milton Keynes ICS and Norfolk and Waveney ICS in the East of England. NHSE, East of England have created a GaitSmart group to share experience of implementing GaitSmart to support the adoption and spread	Thank you for your comment. Please see response to comment 2.
The technology (n=4)					
6	1	MHRA	Has all of the relevant evidence been taken into account?	We note that the product is registered with us as a Class 1 medical device, however we are reviewing the classification of this device and app.	Thank you for your comment.
7	3	Company	2.1	[redacted] **Response to specific questions within the draft Guidance** My specific response to comments within the document is provided below: 2.1: Technology description is correct.	Thank you for your comment.
8	3	Company	2.4	2.4: The innovative aspects are clearly articulated.	Thank you for your comment.

9	4	Healthcare professional	2.4	Physiotherapists usually assess Gait by analysing walking visually. GaitSmart provides an objective measure and reports can be shared with patients and other professionals. An orthopedic consultant has commented that the objective assessment produced by a GaitSmart assessment would be very useful when triaging referrals as currently does not receive objective gait analysis on referral.	Thank you for your comment. The committee values the input of healthcare professionals in guidance development. Please see response to comment 2.
Care pathway (n=11)					
10	3	Company		The company studies compare short term outcomes with standard care, which is standard practice in the care-pathways we have identified. GaitSmart uses a lower skilled resource that is readily available, in a standardized protocol, relieving pressure on current physiotherapy resources by reducing the time they need to spend with an individual patient. It also provides objective data that can be used to track a patients' progress more effectively through their care pathways with an easy feedback mechanism. The clinical and economic evidence provided in response to this application supports it as an alternative to standard care, not an adjunct. Whilst GaitSmart could be used in addition to standard care this would be considered 'an unnecessary repeat of effort' preventing the freeing up resources, which is an integral part of the GaitSmart implementation proposal as part of this guidance. The evidence provided to support this application is limited to the early intervention period where care is being delivered and uses the same outcome measures as those used to assess the incumbent care pathway. By using these measures it is assumed that GaitSmart will be able to deliver longer term outcomes and cost savings that are at least as good as the incumbent care pathway / 'standard care'. Whilst both the EAG and Dynamic Metrics believe that the GaitSmart technology has the potential to deliver further improved longer term outcomes and cost savings, there are not robust studies available to support these claims and as the evidence for use in the early intervention space is positive with no adverse consequences identified, there appears to be no reason to explore this longer term space in this guidance. The draft guidance has identified this as a weakness, however, we feel	Thank you for your comment. The guidance has also been amended to include committee discussions on the intended delivery of GaitSmart in the NHS. This is described in Section 4.6 of the final guidance under the strapline '*GaitSmart is intended to be delivered by a trained healthcare assistant, with referral to a physiotherapist if needed*'. Please also see responses to comments 2 and 3.

				this aligned with the company's integrity to only make claims on things when there is supporting evidence. To date the use of GaitSmart has been limited to single hospital studies which has reduced the number of participants and driven a high level of heterogeneity in the study protocols including assessment criteria resulting from the high variability in the care pathways across these different sites. Whilst larger more controlled studies are always desirable, this would require significant cross site collaboration and modification of care pathways to align on 'standard care' and measurement criteria. The EAG have recognised these challenges and reflected this in their report noting that this is beyond the control of Dynamic Metrics leading to their recommendation for use within a real-world evidence environment. Whilst the weaknesses in these studies have been recognised in the draft guidance, it has omitted to also identify the challenges in identifying and deploying 'standard care' upon which a larger study would require, instead implying that this relates to poor study design. Dynamic Metrics remain very keen to continue research around the value of GaitSmart and are happy to look at any potential study opportunities, particularly around the longer term value and the benefits of use in different scenarios, however, given the challenges (including cost) of orchestrating this on a clinical study type basis would be prohibitive. The EAG's recommendations of conducting this research in parallel to use (i.e. real world) so that larger cohorts can be explored to navigate the heterogeneity in the care pathways and PROMS measurement is the most cost effective way of proceeding. I have outlined our specific responses to key points within the draft guidance below, which I believe supports GaitSmart being used in these specific populations whilst research and data collection continues.	
11	7	Healthcare professional		The draft Guidance provides an excellent assessment of the clinical and economic benefit of GaitSmart in Falls Prevention and Joint replacement rehabilitation. We are currently implementing a pilot for falls prevention in our GP practice. We are following the NICE Guidelines - Falls in older	Thank you for your comment. The committee values the input of healthcare professionals in guidance development. Please see response to comment 2.

				people assessing risk and prevention Clinical guideline Published: 12 June 2013. GaitSmart offers the assessment of gait, balance and mobility and muscle weakness and provides the strength and balance training through their personalised exercise plan. GaitSmart enables our GP practice to offer the entire service using our healthcare assistants, providing a full, objective assessment of the patient's obs and gait analysis which can be reviewed by the clinical team. I am keen to be able to use GaitSmart in our GP practice routinely for falls prevention. Guidance which supports this would therefore be invaluable to me	
12	9	Healthcare professional		**GaitSmart Rehabilitation Programme - Draft Feedback** **Introduction** [redacted] is a social enterprise, I, [redacted], has been employed by [redacted] since 2008 and [redacted] are commissioned by ICB to provide different services. I qualified as a physiotherapist in [redacted] in Denmark and worked until [redacted] in acute hospital in varies wards for last 3 years in geriatric ward in Denmark. [redacted] and obtained my HCPC registrations without any adaptations, as stated was employed by [redacted] in [redacted], since 2012, I have led the falls prevention service, it has been an on-going issues within the service as well as within the community having staff enough to accommodate NICE guidelines. Furthermore an on-going challenge is to reduce wait time so patients doesn't end up falling and often end up in hospital ,at times with a fracture, while on waiting list for the falls service. This is not what any service aspire to occur. I first happened to come upon GaitSmart at a conference in 2020 as Covid and many other challenges took priority, the business proposal which I put forward during this time, was not initially accepted. In July 2023 the business case was accepted and [redacted] is in the very exciting process of implementing it into the falls service in Kingston.	Thank you for your comments. The committee values the input of healthcare professionals in guidance development. Please see response to comment 2 on changes to the recommendations following consultation. Please also see response to comment 1 on amendments to the guidance to clarify that GaitSmart is intended to be used as an alternative to standard care.

				GaitSmart has been very accommodating towards providing training and on-going support. The plan is to roll it out alongside standard care, with the aim that referrals will be triaged by physiotherapist to be added to list for GaitSmart assessment done by in [redacted] band 4 clinical exercise specialist with the possibility for staff to liaise with Physiotherapist as needed. This will lead to reduced wait time for falls multifactorial risk assessment (MFRA) as per NICE guidelines and physiotherapist to be able to see the most complex patients. [redacted] Muscular skeletal outpatient (MSKOP) has requested to know more as they might consider implementing GaitSmart as part of their offer. Generally, there is unlimited options of how GaitSmart can be used, falls patients for many none complex/fear of falling the main aim to reduce falls risk is to get patient to exercise, which GaitSmart offer, for osteoarthritis patient it could be an offer to patient, who doesn't want/are not suitable to have an operation to engage with GaitSmart which will strengthening their muscle and by the reduce their falls risk and many patients with osteoarthritis falls. **Response/comments** Only recommended to use in research, might be linked with the fact that there was limited input from experts including experts that were running a standard service as well as having some experience with GaitSmart. Standard care varies extremely and depend on where you live, so as much as there is NICE guidelines towards Falls and osteoarthritis, there is a huge variation of what is being provided in standard care very much depending on postcode. Standard care as stated has a great variety in wait time, what is offered and data towards adherence, drop out and long term follow up is generally not something that is part of standard, so the request to GaitSmart to provide data that most standard care might not be able to provide is unfair. Standard care and wait time have a great variation.	

				From a physiotherapist prospective it is essential that GaitSmart become part of NICE with the aim of implementing it in normal practice whilst continuing on with research. Patients would always want more, but that is not possible for either GaitSmart or standard care. In Standard care it is generally recommended to follow one intervention as it can be contradictive to be seen by more than one service/intervention. GaitSmart plus the vGym exercises will be a benefit to patients as we can already see with our patients. GaitSmart has massive potential towards an assessment and intervention for falls risk and osteoarthritis patient and for the future it could be a tool towards prevention as most standard services are reactive and not preventative.	
13	4	Healthcare professional	Section 1 'Why the committee made these recommendations'	What is meant by 'standard care'? I do not understand why GaitSmart would be combined with 'standard care'. GaitSmart can provide a treatment option/pathway for people that require gait analysis and tailored exercises to help improve gait and mobility.	Thank you for your comment. This has been amended in the final guidance. Please see response to comment 1.
14	3	Company	2.2 and 2.3	2.2: In NICE Falls in older people assessing risk and prevention Clinical guideline Published: 12 June 2013: This guideline recommends: • multifactorial risk assessment of older people who present for medical attention because of a fall, or report recurrent falls in the past year • multifactorial interventions to prevent falls in older people who live in the community Multifactorial falls risk assessment includes a gait assessment and multifactorial intervention includes a personalised exercise rehabilitation programme. GaitSmart performed this role in both the NELFT and care city pilots. This data was also provided as the evidence in the clinical and economic arguments. Implementation in new NHS sites offers GaitSmart falls clinics. 2.3: In accordance with Joint Replacement NICE 1.10.5: NICE 1.10.5 Offer supervised group or individual outpatient rehabilitation to people who: • have difficulties managing activities of daily living or	Thank you for your comment. This has been clarified in the final guidance. Please see response to comment 1.

				• have ongoing functional impairment leading to specific rehabilitation needs or • find that self-directed rehabilitation is not meeting their rehabilitation goals. In the McNamara study this guidance has been referenced, patients join the study if they met these criteria. The economic and clinical evidence reviewed by NICE is based on this guidance.	
15	3	Company	2.5	2.5: The intended use is very clear and states that it should be used by a healthcare assistant as a stand-alone system and not alongside standard care.	Thank you for your comment. This has been amended in the final guidance. Please see response to comment 1.
16	8	Healthcare professional	2.5	Feedback on panel outcome 2.5 The intended use for GaitSmart is for a healthcare assistant to use it as a stand-alone system. This technology could replace standard care, as a more effective and individualised solution. Standard care is currently not individualised nor allowing complete patient participation in their exercise programmes and health choices. Standard care varies across patients and across pathways, and with the re-active state and recovery of the NHS as a whole this cannot be overlooked as a stand-alone system as it will be more supportive to the NHS in its post pandemic recovery measures.	Thank you for your comment. This has been amended in the final guidance. Please see response to comment 1.
17	3	Company	4.4	4.4: This statement we completely disagree with as it is an alternative to standard of care and follows a very specific place in the care pathway of falls and joint replacement. We agree with the sentiment that patients should have choice but we do not agree that the intervention sits alongside standard care. People are recruited to this service as they are at risk of falls or they have not met their needs following joint replacement in accordance with the guidance. The GaitSmart programme length is comparable to standard care at many NHS trusts. It may offer additional benefits in terms of the objective nature of the GaitSmart data, but this is not within the current scope.	Thank you for your comment. This has been amended in the final guidance. Please see response to comment 1.
18	4	Healthcare professional	4.4 “With this in mind, it concluded that the most appropriate place	Disagree with this conclusion. Why does it need to be an adjunct?	Thank you for your comment. This has been amended in the final guidance. Please see response to comment 1.

			for GaitSmart in the clinical pathway would be as an adjunct to standard care."	GaitSmart provides is an assessment and treatment option for those with gait and mobility issues. Why would it need to be an adjunct. As explained previously BLMK ICS are piloting GaitSmart in 3 different areas 1. Discharge to assess in a care home- residents do not currently access physiotherapy. GaitSmart will enable to the assessment of Gait and provision of exercises to reduce de-conditioning, improve mobility and monitor changes to mobility. 2. Falls pathway- GaitSmart clinic is a treatment option following triage. Clinic will be run by a therapy assistant. 3. GaitSmart assessment offered at NHS Health checks at a GP surgery and 3 follow GaitSmart assessments provided.	
19	4	Healthcare professional	4.10 "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."	Disagree- does not have to be used in addition to physiotherapy- can have it's own pathway. If people access GaitSmart who are not accessing physiotherapy this is positive and likely to be cost saving as increasing activity levels and strength- a preventative approach	Thank you for your comment. This has been amended in the final guidance. Please see response to comment 1.
20	4	Healthcare professional	4.11 "It also said that inclusion criteria and place in the treatment pathway should be clearly outlined"	There are many points in the treatment pathway that GaitSmart could be used e.g. pre-operative, post operative, preventative at health checks, in care homes to help reduce de-conditioning and falls pathways. Pathways are very variable across the NHS and it's use should be decided locally.	Thank you for your comment. The committee values the input of healthcare professionals in guidance development. Section 4.11 of the draft guidance (now 4.14 in the final guidance) described the information that should be collected during further evidence generation. The committee acknowledged the

					variation in the care pathway and therefore highlighted the need for future research to clearly describe where and how GaitSmart was used. The guidance has been amended to make this clearer: "*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*."
Alignment with scope and EAG report (n=3)					
21	2	Healthcare professional	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	The application was submitted with Gaitsmart being used as an alternative to standard care in early intervention period ,with its summary of clinical and cost effectiveness based on this ,not the misinterpretation as an adjunct to standard care that the consultation appears to have made.	Thank you for your comment. This has been amended in the final guidance. Please see response to comment 1.
22	3	Company	Has all of the relevant evidence been taken into account?	No. After appraisal of the draft guidance, I feel that it does not appear to appropriately consider the conclusions from the EAG report and indeed in some places appears to misrepresent the information therein. In my opinion this has resulted in a decision which appears misaligned to the planned scope of this guidance and the recommendations of the EAG report.	Thank you for your comment. MTAC makes recommendations on medical technologies after careful consideration of the EAG report, the clinical and economic evidence and other sources of information such as clinical and patient advice. After consultation, section 1 has been updated to a partial recommendation to use GaitSmart to treat gait and mobility issues in people at risk of falls while more evidence is generated. Details of this are provided in the response to comment 2. Additional

					amendments have also been made to the guidance to more clearly describe the intended use of GaitSmart as an alternative to standard care. Please see response to comment 1.
23	3	Company	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	For the use cases reviewed, the EAG report concludes both positive clinical and economic outcomes (i.e. cost saving) for the two specified patient cohorts, at risk of falls and joint rehabilitation, when used as an alternative to standard care and assessed based on the same outcome measures. Whilst the EAG report recognises the value of further research to both address the heterogeneity in the study protocols and understand any additional value that using GaitSmart might deliver with respect to long term outcomes, it has highlighted that this is beyond the control of Dynamic Metrics and the use case covered by this guidance. As such the EAG report recommends the use of GaitSmart within a real-world evidence environment. However, these recommendations by the EAG do not appear to be reasonably reflected in the draft guidance. In summary there are 3 headline themes where the EAG report and the draft guidance appear to diverge: 1. The focus of this application is comparing GaitSmart to standard care using the same outcome measures used to assess a patient immediately after standard care intervention. The studies provided, along with the cost comparison (adjusted and supported by the EAG) have shown GaitSmart to deliver improved outcomes and be cost beneficial as an alternative to the standard care for this period of intervention. In comparison, the draft guidance appears to have placed significant weight to the need for additional evidence to explore the use of GaitSmart in addition to the standard of care and the potential for further longer-term improvements in outcomes and cost benefits, despite these being outside of the focus of this guidance. 2. Whilst both the EAG and the draft guidance highlight the heterogeneity in the study protocols, the EAG report recognises that this is due to a large variability in the care pathway making it very difficult to define ‘standard care’ and beyond the control of Dynamic Metrics. Conversely the draft guidance appears to imply	Thank you for your comment. MTAC makes recommendations on medical technologies after careful consideration of the EAG report, the clinical and economic evidence and other sources of information such as clinical and patient advice. Please see response to comment 1 on the intended use of GaitSmart as an alternative to standard care. Please also see responses to comments 2 and 3.

				that this heterogeneity relates to poor study design which can easily be fixed with further research. 3. No adverse consequences were identified within either the EAG report or the draft guidance, however despite this the draft guidance concluded the need for additional research before recommending the use of GaitSmart despite the positive clinical and economic outcomes. This is contrary to the EAG findings who concluded that "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" and that it should be "recommended for use in a real-world evidence environment"	
Patient benefits (n=3)					
24	3	Company	3.6	3.6: It is positive that the GaitSmart technology is not causing any adverse effects and as this clinical population is an extremely vulnerable and only currently treated by physiotherapy led care. This is currently limiting the number of people receiving care, a further positive reason for GaitSmart adoption.	Thank you for your comment.
25	4	Healthcare professional	4.6	De-conditioning is a huge problem, leading to reduced mobility and falls. GaitSmart provides tailored exercises, encouraging people to increase their activity and mobility. It is important to also consider the preventative approach of GaitSmart. In BLMK ICS were are offering GaitSmart at an NHS Health Check at a GP Surgery. We value the importance of identifying gait problems as early as possible and providing treatment. This will have long term benefit and cost savings. People who are awaiting physiotherapy are not necessarily the people that need to access GaitSmart. It can be an alternative. For example, another GaitSmart pilot in BLMK ICS will be in a falls team. People will be triaged and one of the treatment pathways will be access to a GaitSmart clinic which will be run by a therapy assistant. These patients do not need to be seen by a physiotherapist (but can be referred by the therapy assistant to be reviewed by a physiotherapist if required).	Thank you for your comment. The committee values the input of healthcare professionals in guidance development. The guidance has been amended to more clearly describe the intended use of GaitSmart as an alternative to standard care. Please see response to comment 1.
26	5	Patient organisation	4.7	4.7 Patients choice. Most patients that have come into the Gaitsmart clinic have already had some intervention either with a physiotherapist or attending a escape pain exercises classes. It has been recommended that they should attend a gaitsmart clinic.	Thank you for your comments. Section 4.1 of the guidance has been amended to include additional patient benefits that

				Information was given in a form of a leaflet and the patients have made their own choice whether or not they should attend. The patients I have seen have been intrigued to see if the report reflex as to where they have their pain & issues. The traffic light coding makes it easy to quickly see where they have problems without having to look to deeply into figures and %. The exercise have been very easy to follow and easy to adapt if the patient has problems doing them. They can be done within their daily routine. i.e when standing at the sink. Having a report that is repeated over 12 weeks has given patients a visual that actually exercise aren't a waist of time and do work when done as a regular routine. It has also made the patients aware of just how they are walking and have made a conscious effect to improve this.	were shared during consultation and the patient survey.
Clinical evidence (n=4)					
27	2	Healthcare professional	Has all of the relevant evidence been taken into account?	All of the relevant evidence does not appear to have been taken into account , as it does not focus on the conclusion of the EAG Report which is based on evidence supporting positive clinical and economical outcomes within a real world environment; More emphasis appears to have been placed on further long term research. Whilst the EAG report acknowledges the benefit of further research to explore the delivery & efficacy of Gaitsmart within long term outcomes, the focus of this guidance was the comparison between Gaitsmart as a stand-alone intervention used for patient gait assessment and standard care intervention using the same outcome measures as the comparator.	Thank you for your comment. MTAC makes recommendations on medical technologies after careful consideration of the EAG report, the clinical and economic evidence and other sources of information such as clinical and patient advice. The EAG advised that the EAG report included all relevant GaitSmart evidence (whether it was compared with standard care or not) and reported the findings as related to the final scope. The assessment acknowledged the positive clinical findings from the evidence as well as the potential positive economic outcomes. The EAG report also acknowledged the difficulty with variability in standard care and the impact of this on the evidence. The lack of long-term outcomes was noted by the EAG

					as a potential gap as this was highlighted by the clinical experts as relevant. But the EAG accepts the potential difficulties of collecting such long-term data. Please also see response to comment 3.
28	3	Company	3.2 and 3.4	3.2: i) In clarification this statement is incorrect 'who had a course of physiotherapy'. Patients had received Postoperative rehabilitation as described in NICE Guideline [NG157] - 1.10 1.10.1 - A physiotherapist or occupational therapist should offer rehabilitation, on the day of surgery if possible and no more than 24 hours after surgery, to people who have had a primary elective hip, knee or shoulder replacement. Rehabilitation should include: • advice on managing activities of daily living and • home exercise programmes and • mobilisation for people who have had knee or hip replacement or • ambulation for people who have had shoulder replacement. The GaitSmart rehabilitation program comes in as outpatient rehabilitation at the point of 1.10.2 in the NICE Guideline [NG157] 1.10.2. ii) It is advised here that 'Outcomes from these studies suggested that GaitSmart measurements correlate with other comprehensive gait analysis systems.' This is extremely relevant when gait analysis is required in a falls clinic, this provides superior data to current practice. 3.4: Gait speed is a common objective measure that is used in all of the GaitSmart studies and widely adopted across literature. I would argue that all of the demographics are clearly identified in the publications. i) The company has have never claimed long term benefits. Studies compare short term outcomes of the GaitSmart Rehabilitation Programme with standard care. The standard care	Thank you for your comment. The description of the McNamara RCT has been amended in section 3.3 (previously 3.2) to read: "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." On demographics in the evidence, the EAG responded that table 3 of the EAG report outlined what demographic information was reported in each study. It acknowledged that all studies reported demographic details to some extent. At the time of the assessment, the EAG noted incomplete reporting of demographics as there were some inconsistencies and gaps across the body of evidence which contributed to difficulties in determining generalisability. For example, not all studies reported

for falls prevention and joint replacement rehab does not does not consider long term outcome measures in accordance with the NICE guidelines.

The company does intend to evaluate long-term outcomes, this would need further research for GaitSmart and standard care. This would take at least a decade to complete and include numerous additional epidemiological factors and measures. Standard care would also need to be clearly described.
ii) Data on adherence and drop-out is included in the studies, however, the terminologies may appear differently. Please see table below, where the information is summarised.

Table & Definitions of Adherence and Attrition.

Paper	Attrition (%)	Adherence (%)	% of recruited who fully complete the programme
I McNamara et al. 2023 total *Due to medical condition*	**4** *4*	**100**	**96**
Craig et al. 2023(unpublished) *Due to medical condition* *Due to dropout*	**23** *10* *13*	**100**	**77**
Glasgow et al 2023 (unpublished) *Due to medical condition* *Due to dropout*	**13.4** *7.8* *4.6*	**100**	**86.6**
Rodgers et al 2020 *Due to medical condition* *Due to dropout*	**27** *16* *11*	**100**	**73**
Osho et al 2018	**19**	**66**	**53.5**

age, one study defined population as 'older people' without defining 'older', and some studies did not report clear exclusion or inclusion criteria. Some of the included studies have been published since the EAG report. This is reflected in the final guidance.

On drop-outs, the EAG advised that drop-out rates were reported in the studies and are included in table 3 of the EAG report. Section 3.4 of the guidance has therefore been amended to remove drop-out rates.

On adherence, the EAG advised that the EAG report mentioned adherence in the context of the adherence to an exercise programme and its impact on average falls risk reduction. The committee noted the definition of adherence used in the studies but considered that data was needed on adherence to the full exercise programme. Section 4.3 (previously 4.2) has been amended to read:
"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*

				(A Systematic Review and Meta-Analysis)				*(Hodgins and Newby 2023a, 2023b).”*
				Table 1: Attrition and Adherence rates in GaitSmart and literature. **Attrition**: Attrition was measured as the proportion of participants who dropped out of the study after being randomized to the intervention or control groups (Kelly & Kelly, 2013). This is related to intervention participation. If participants dropped out of the study after being randomized into their groups and did not complete the required sessions for intervention specified for the studies and did not provide data after dropping out; this was regarded as attrition (Osho et al 2017). The GaitSmart protocol does not allow for missed sessions therefore any non-attendance of appointments is classed as drop-out attrition and non-continuation of the programme. **Adherence**: Adherence was measured as the proportion of the required sessions that the participants completed in the intervention group (McPhate et al., 2013, Osho et al 2017). **Total percentage who fully complete the programme:** This is a combination of the attrition and adherence rate. Note in Standard care just 53.5% of patients fully comply with the programme. For the GaitSmart intervention this is between 73 and 96%.				
29	8	Healthcare professional	3.4	Feedback from panel outcome 3.4 Degree of heterogeneity. This is not the issue of GaitSmart technology, across the NHS variability of care pathways for people at risk of falls will always be evident. As will the reason for the patient falling. Meta-analysis is a quantitative, formal, epidemiological study design used to systematically assess the results of previous research to derive conclusions about that body of research. This usually is based on quantitative, randomised control trials but should cover both quantitative and qualitative data. The GaitSmart technology being relatively new would only, at this point in time, allow for systematic review. The committee seem to not have the	Thank you for your comment. The EAG agreed that heterogeneity is a wider care pathway problem. This was acknowledged in the EAG report when discussing the standard care comparators and the variability within them. Section 3.4 of the draft guidance described the heterogeneity in the care pathway. The strapline for this section has been amended to make this clearer and now reads:

				same desire to explore the qualitative patient stories or feedback in this report.	"There is a high degree of heterogeneity in the evidence, *which reflects the variation in the care pathway*". On meta-analysis, the EAG responded that section 3.4 of the draft guidance described why data from the GaitSmart studies could not be used to conduct a meta-analysis. No change to this has been made in the guidance. On patient stories and feedback, the committee carefully considered all the clinical evidence and input from clinical experts and patients. This included consultation comments from a patient organisation and a patient survey. Patient input and considerations were integral in the committee discussion and are reflected throughout the guidance.
30	3	Company	4.2 and 4.3	4.2: As mentioned above, adherence and drop-out rates are quoted in the table above. Motivation is supported by the outcome measures. Overall, GaitSmart shows better overall patient engagement compared to standard care. 4.3: The patient population and care pathway for both patient cohort Joint Rehabilitation and Falls has been covered previously.	Thank you for your comment. Please see response to comment 28.
Costs and economic modelling (n=6)					
31	6	Healthcare professional	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	Time taken to demonstrate the exercises does not appear to be included and, in our experience, so far in our falls population, this has taken around 10-15 minutes or even 20 minutes in one case.	Thank you for your comment. The EAG agreed that some people may need more time for exercise demonstration. An additional 20 mins per patient would increase the total staff time from 60 mins to

					80 mins per patient. This would increase total GaitSmart costs from £82 to £93 (extra staff time costs of £11). This higher value has been considered in the plausible range used in the EAG one-way sensitivity analyses (±20% GaitSmart total costs, £66 to £99), with GaitSmart still cost saving.
32	3	Company	2.6	2.6: The costs are realistic and acceptable.	Thank you for your comment.
33	8	Healthcare professional	3.10	Feedback on panel outcome 3.10 '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.' Did the committee understand that a patient in the NHS in the UK has to now be deemed suitable for reablement (usually Pathway 1 or Pathway 2 classified patients) to receive referral and physio/OT input. The offer of reablement is much reduced due to many factors of resources and reablement bed availability, this is not likely to resolve in the short term. The costs for the GaitSmart intervention on all patients following a fall may be much more beneficial to reduce overall NHS and social care costs of patients that would continue to fall or require higher levels of intervention and social care as a result. Also if these patients have co-morbidities the chance of discharge from ED is low, and often when presenting with a fall these patients are deemed frail and other health morbidities may result in a considerable hospital stay for further investigations (again due to lack of social care beds and onward places of care for these patients, length of stay can be high) due to variances in pathways	Thank you for your comment. The EAG acknowledged the high costs of falls to NHS and social care but responded that the falls data available was not sufficiently long enough to extrapolate long-term cost impacts in the economic model. In people at risk of falls, inpatient stay was considered in the EAG model. The company submission was not specific to people with frailty or comorbidities, so the EAG did not consider other patient populations. The EAG agreed that additional analyses could be done if direct fall evidence becomes available. Despite this, both the company and EAG models suggest that GaitSmart would be cost saving compared with standard care for people at risk of falls and people having hip or knee replacements. No change has been made to the guidance on this.

				across all acute providers in the care of frail patients, this does need to be considered as would potential add to the cost effectiveness of the GaitSmart technology.	
34	3	Company	3.11 and 3.12	3.11: The EAGs base-case models show that GaitSmart is cost saving compared to standard care. I agree with the clear statement that using a higher graded staff member is cost incurring and this is why the intended use section only specifies the Healthcare Assistant conducting the assessment. 3.12: In accordance with the statement, "For GaitSmart to be cost neutral or cost saving, the cost of comparator must be very close to the cost of GaitSmart." – This therefore means that the clinical outcomes are comparable to standard care. It is therefore irrelevant what the reduction (11%) of falls is as it is the same as standard care. The impact of falls in the model was limited by the short duration, because it is comparing to standard care. This is for the duration of the intervention, therefore this would also true for the standard care comparator.	Thank you for your comment. The EAG conducted scenario analyses varying how standard care was delivered. The EAG only considered using healthcare assistants to deliver GaitSmart as intended by the company and described in the guidance. Section 3.11 has been amended to make this clearer: "One EAG scenario *varied standard care* by substituting a band 6 physiotherapist for a band 4 therapy assistant for physiotherapy sessions." On the impact of falls, section 3.12 in the draft guidance outlined the key drivers in the economic models which were found to be the costs of GaitSmart and standard care. The statement on the relatively small reduction in the number of falls was included to show that falls had a small impact on the cost model. The EAG advised that because falls is associated with high healthcare costs and long-term cost impact, this is important to be considered in future economic models to determine the full consequences of GaitSmart. No change to the guidance has therefore been made on this.
35	3	Company	4.6	4.6: It is stated that it could clear waiting lists, as GaitSmart would only be offered in the care pathways identified in NICE guidance. The guidance is written to offer treatment to reduce the overall	Thank you for your comment.

				cost to the NHS. As GaitSmart replaces standard care it cannot increase costs and is economically and clinically viable it cannot lead to an increase to an increase in healthcare costs as stated 'it may lead to an increase in healthcare costs for people who would otherwise not have any intervention'. If resources were available standard care would be delivered.	The clinical experts advised that GaitSmart could provide another treatment option and may fill a treatment gap for some people who may otherwise not be able to access gait rehabilitation services (section 4.4 of final guidance). The EAG noted that considering intervention costs only, delivering GaitSmart costs less than standard care but cost more when compared with not delivering any interventions. The EAG did not conduct any additional modelling to compare GaitSmart and waiting list. In addition, there was no evidence on outcomes with waiting list, which is important to be considered in an economic model. No change to the guidance has been made on this.
36	3	Company	4.8 to 4.10	4.8: The cost model overview shows that it is cost saving. 4.9: This section is a repeat from earlier, the outcomes are the same therefore the cost should be the same. 4.10: It is agreed that GaitSmart may increase cost as an adjunct to standard care, but this is not in the scope of this Guidance. If GaitSmart is offered to people that are unable to access physio, e.g due to capacity, this would provide the cost savings, equal to the NICE guidance of providing care. It is agreed that the grade of staff needs to adhere to the intended use (Healthcare Assistant). We do not agree with the statement that the cost savings would not be realised in clinical practice. Healthcare assistants can provide the programme in the time allocation, therefore cost savings are realised.	Thank you for your comment. Section 4.8 of the draft guidance stated that the EAG models showed that GaitSmart is cost saving compared with standard care. For clarity, section 4.11 (previously 4.10) has been amended to read: "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*."

					Please also see response to comment 34 and 35.
Further research (n=6)					
37	6	Healthcare professional	Has all of the relevant evidence been taken into account?	All of the relevant published evidence has been considered. Following the NICE innovation award for GaitSmart, clinical interest has been generated in this technology and real-world evidence is needed to inform future use of the technology. We are running an NHSE funded pilot project within a community-based falls service. This was to enable us to meet NICE clinical guidance on falls in older people by providing a gait specific assessment and rehabilitation programme as part of an MFRAT. Previously, subjective gait outcome measures such as the Dynamic Gait Index or other measures may have been used. Gait exercise prescription following this would have been by a clinician. GaitSmart provides an objective assessment with AI technology prescribing appropriate exercises. It is too early to evaluate this current pilot, but real-world evidence is being generated that could inform clinical practice in the near future. In our experience so far, this could enhance a falls service by helping to meet NICE guidelines and provide a high-quality gait re-education programme. This appears to be suitable for community falls prevention.	Thank you for your comment. The committee values the input of healthcare professionals in guidance development. It carefully considered the ongoing real-world evaluations on using GaitSmart in the NHS to treat gait and mobility issues in people at risk of falls. The committee considered that these real-world evaluations could address some of the uncertainties in the evidence outlined in the assessment for this population. It concluded that there was enough evidence of benefits in people at risk of falls for GaitSmart to be used in the NHS while this evidence is generated. This is reflected in the updated recommendations and section 4.12 of the guidance. Please also see response to comment 2.
38	3	Company	3.5	3.5: I fully agree with the EAG conclusion that adoption is potentially supported but further evidence generation would be beneficial. I fully support their suggestion that 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. The company is already collecting this evidence from the NHS sites currently using GaitSmart and any future implantations. The relevant clinical evidence has now been peer reviewed and published.	Thank you for your comment. Please see responses to comments 2 and 37.
39	3	Company	4.1	4.1: The most relevant study has now been published of McNamara and others are in review. Needing large studies has	Thank you for your comment.

				been discussed previously and the company does intend to continue to gather evidence throughout NHS sites.	The committee considered that 3 of the unpublished studies in the EAG assessment and report have now been published: • Hodgins & Newby (2023a) • Hodgins & Newby (2023b) • McNamara et al. (2023) This has been amended in the final guidance.
40	8	Healthcare professional	4.2 4.11	Feedback from panel outcome 4.2 From use in clinical areas patient experience and feedback can be ascertained easily using standard patient evaluation scores (EQ5D5L) as well as qualitative patient stories, this qualitative field of data will increase over time the GaitSmart units are being used to prove patient compliance and adherence. Feedback on panel outcome 4.11 'The committee agreed that long term outcomes should also be reported, including gait outcomes, patient reported outcome measures and adherence rates.' What do the Committee class as long-term outcome data? GaitSmart is used for 4 assessments its use as clearly stated within the report in section 2.4. Patients understanding is enhanced by the data presented in the GaitSmart report and the exercise programmes are individualised to improve each individual patient's issues resulting in improved mobility and thus quality of life. To get long term outcome data this would require the GaitSmart assessment to be continually used on the same patient, for how long? And how can this be compared to physiotherapy which doesn't have long-term outcome measures? If the patient's Gait issues are due to joint degeneration but not severe enough to warrant being referred for surgery/or referred for surgery but refused on other health related grounds or left on a waiting list for years, the actual possibility of these patients getting lower scores due to ongoing age/health related conditions and joint issues would surely result in inconclusive long term data….?? For	Thank you for your comment. The committee considered that more evidence on longer-term outcomes of around 3 to 6 months is needed to show the clinical and economic consequences of using GaitSmart as an alternative to standard care. Please also see responses to comments 3 and 27.

				example, an obese 75 year old, who has 4 GaitSmart assessments and then re assessed in 10 years' time that was compliant with GaitSmart exercises but continues to increase in weight would potentially show what in terms of outcome at age 85? I suspect long term outcome measures are not used for many physio interventions particularly the physio patient leaflets of generic exercises given to most patients when presented with symptoms? many exercise classes conducted for many patients are not followed up either as to long term outcomes.	
41	8	Healthcare professional	4.2	Feedback panel outcome 4.2 From use in clinical areas patient experience and feedback can be ascertained easily using standard patient evaluation scores (EQ5D5L) as well as qualitative patient stories, this qualitative field of data will increase over time the GaitSmart units are being used to prove patient compliance and adherence.	Thank you for your comment.
42	3	Company	4.11	4.11: Larger cohort studies would be beneficial. The scope of this Guidance is for the GaitSmart programme to be offered instead of standard care. It is not clear what evidence the committee has made this assumption on.	Thank you for your comment. The committee considered 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. Section 4.13 (previously 4.11) has been amended to better reflect the intended use of GaitSmart as an alternative to standard care.
Equality considerations (n=3)					
43	3	Company	Are there any equality issues that need special consideration and are not covered in the medical technology	No	Thank you for your comment.

			consultation document?		
44	6	Healthcare professional	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	There could be clothing considerations for those from different cultures / ethnicity where trousers are not worn. Reports from the gait assessment are colour coded but some of the wording could be less technical to make sense to the lay person. Font size on the exercises descriptors would be better in Arial size 12 as recommended to meet with national best practice for communication standards.	Thank you for your comment. The committee carefully considered potential equality issues around using GaitSmart. These are described in more detail in the equality impact assessment on the topic website.
45	3	Company	4.7	4.7: The video would reduce accessibility due to not all patients being able to access a device able to shown the video or have internet access. This is however technically feasible. Additionally, the outcomes presented are based on a patient receiving a paper copy and the Healthcare Assistant going through exercises with the patient, which provides total equality for all and no segregation of patients due to digital ability.	Thank you for your comment. The committee carefully considered potential equality issues around using GaitSmart. These are described in more detail in the equality impact assessment on the topic website.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."