

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

GaitSmart rehabilitation exercise programme for gait and mobility issues

1 Technology

1.1 *Description of the technology*

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

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

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

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

1.2 Relevant diseases and conditions

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

People at risk of falling

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

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

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

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1.3 Current management

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

People at risk of falling

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

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

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

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

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

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

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

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

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

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

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

1.4 Regulatory status

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

1.5 Claimed benefits

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

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

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

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

2 Decision problem

| | |
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| Population | <p>People with gait and mobility issues, specifically:</p> <ul style="list-style-type: none"> • people that are at risk of falling, • people referred for knee or hip surgery (pre-operative and post-operative management). |
| Intervention | GaitSmart programme including 4 GaitSmart assessments and personalised rehabilitation via the vGym app |
| Comparator(s) | <ul style="list-style-type: none"> • Visual assessment of gait by physiotherapist or occupational therapist including scales such as Tinetti Performance Orientated Mobility Assessment and the Timed Get up and Go Test score <p>and</p> <ul style="list-style-type: none"> • Exercise and rehabilitation (including supervised and independent exercise or rehabilitation and NHS group-based exercise), or • Devices for support (such as supports, other gait training tools, splints or braces), or • Pharmacological treatment such as intra-articular corticosteroids (osteoarthritis) |
| Outcomes | <p>The outcome measures to consider include:</p> <p>Outcome measures for effectiveness relevant to all populations:</p> <ul style="list-style-type: none"> • Changes to gait, balance, mobility, and muscle weakness measures • Incidence of falls and associated injuries and hospitalisations • Patient reported outcome measures of pain • Patient reported outcome measures of functional ability • Health related quality of life (measures such as, EQ-5D and SF-36) <p>Outcomes measures for effectiveness in people who have suffered a fall or recurrent falls:</p> <ul style="list-style-type: none"> • Change in number of falls • Patient fear of falling using the Falls Efficacy Scale – International (FES-I) • Patient frailty (using NHS validated tool such as, gait speed test, PRISMA-7 and up and go test) • STEADI assessment for screening patients for fall risk |

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| | <p>Outcomes measures for effectiveness in people that have been referred for hip or knee replacement:</p> <ul style="list-style-type: none"> • Delay of hip or knee surgery • Oxford hip score or Oxford knee score • Western Ontario and McMaster Universities Arthritis Index • Repeat surgery • Patient reported satisfaction with outcome of surgery <p>Outcomes measures for resource use:</p> <ul style="list-style-type: none"> • Further treatments (such as pain medication, corticosteroid use, surgery, days in hospital, and further rehabilitation) • Training time and costs for staff and non-registered support workers • Time needed to calibrate technology to ensure accurate measurements • Healthcare professional time (and banding) associated with patient follow up and care • Admission or readmission to secondary or tertiary care <p>Device-related outcomes measures</p> <ul style="list-style-type: none"> • Rates of adherence to programme • Device related adverse events |
| <p>Cost analysis</p> | <p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.</p> |
| <p>Subgroups to be considered</p> | <p>N/A</p> |
| <p>Special considerations, including those related to equality</p> | <p>People who have difficulty accessing or using a device for the GaitSmart report and vGym exercise programme may be excluded from being able to use this technology.</p> <p>Patient-facing digital health technologies such as vGym exercise programme are delivered through a mobile phone or tablet. People will need regular access to a device with internet access to use the application. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies, do not have access to smart devices and may be unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities.</p> <p>The technology may be unsuitable for some people who have had a lower limb amputation.</p> <p>People at risk of falls and people who have been referred for knee or hip surgery are likely to be aged 65 years and older.</p> |

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

3 Related NICE guidance

Published

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

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

In development

NICE is developing the following guidance:

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

4 External organisations

4.1 Professional

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

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

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

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

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