NICE advice

QTUG for assessing falls risk and frailty

Medtech innovation briefing
Published: 26 July 2016

www.nice.org.uk/guidance/mib73

Summary

- The **technology** described in this briefing is the Quantitative Timed Up and Go (QTUG). It uses body-worn sensors and a mobile software app to assess mobility, falls risk and frailty. It is used during the standard Timed Up and Go (TUG) test.
- The **innovative aspects** are that QTUG uses proprietary algorithms to give an objective assessment of falls and frailty risk using average values for age and gender and statistical models. QTUG can be used by non-specialists and is wireless and portable.
- The intended **place in therapy** for QTUG would be as an alternative to the standard TUG test. QTUG is intended to be used to assess mobility, falls risk or frailty in people needing a mobility assessment, including older people, those with disabilities affecting gait and mobility, and those with chronic neurological conditions.

- The **key points from the evidence** summarised in this briefing are from 2 observational studies on QTUG. These studies involved a total of 841 community-dwelling adults 60 years and over who could walk unaided. The studies both suggest that the accuracy of falls risk assessment is greatest when QTUG is combined with clinical risk factor assessment, when compared to either QTUG alone or clinical risk factor assessment alone. The evidence also suggests that the assessment of frailty is most accurate using a TUG test with inertial sensors, such as QTUG. Both studies had methodological limitations.
- **Key uncertainties** exist around the ability of QTUG to assess frailty as there is a lack of evidence to support this function of the device.
- The indicative **costs** for the QTUG hardware (including a hand held tablet computer and 2 inertial sensors) is £675 excluding VAT and for the annual software licence fee is £1,500 excluding VAT.

The technology

Quantitative Timed Up Go (QTUG) measures gait and mobility using body-worn sensors during a standard Timed Up and Go (TUG) test. It produces an objective assessment of mobility, falls risk and frailty based on average values for age and gender.

The QTUG system includes inertial sensors which are placed on a person's shins. The sensors record movement and transfer these data wirelessly to a handheld tablet computer (also included with the system), where it is analysed by QTUG application software using proprietary algorithms. The inertial sensors include a tri-axial accelerometer and a tri-axial gyroscope. QTUG application software displays results for:

- Time taken to complete the TUG test in seconds.
- Statistical risk of falls, presented as a percentage and level of risk.
- Statistical estimate of frailty level, presented as a percentage and level of frailty (as defined by Fried's frailty phenotype).
- Comprehensive quantitative assessment of mobility including temporal gait, spatial gait and turn parameters, as recorded by the sensors.

These values (and time taken to complete the TUG test) are compared with average values for gender and age range.

The handheld tablet is used to analyse the data from the sensors using the QTUG software and the person's results are displayed on the screen. An option is available for indicating if a mobility aid was used during the TUG test. QTUG includes an optional falls questionnaire which is based on American Geriatric Society/British Geriatrics Society clinical practice guidelines. This is used to improve the statistical falls risk estimate. QTUG records and stores the person's clinical falls risk and falls history for future reference.

The innovation

QTUG provides an objective assessment of mobility, falls risk and frailty. It uses proprietary algorithms to identify specific mobility impairments by comparing a person's results against reference values.

QTUG can be administered by non-specialists and it is wireless and portable.

Current NHS options

The NICE guideline on falls in older people recommends that older people with a history of falls, or who are considered to be at risk of falling, should be observed for balance and gait deficits. The TUG test is a frequently used test of balance and gait. This test is referred to in the NICE guideline on falls in older people and in the joint American Geriatric Society/ British Geriatrics Society guidelines (2010). In the TUG test, a person is observed and timed as they rise from a chair, walk 3 metres, turn, walk back to the chair and sit down. It can be used in any setting and needs no specialist equipment. The time taken to complete the test, measured using a stopwatch, is compared with standard values. Longer times are associated with a greater risk of falls. Clinical judgement of stability, gait, stride and sway can also be used as a component of the assessment. Other clinical tests used in current practice to assess balance and mobility include the Turn 180 degree test, the Tinetti scale, the Functional reach test and the Berg balance test. None of these assess frailty, which is generally determined using a range of indices within a clinical assessment.

NICE is aware of the following CE-marked devices with gait assessment functions:

- GaitRite sensorised walkway (CIR Systems Inc)
- GaitUP wearable sensors (Physilog) (GaitUp SA)
- RehaWatch wearable sensors (Hasomed GmbH)

- Dynaport MoveTest (McRoberts)

Population, setting and likely place in therapy

QTUG would be used in the same settings as the TUG test. This would be in primary, secondary or social care as a component of a multifactorial falls assessment of someone at risk of falling or who has had one or more falls. This could include older adults, people with disabilities affecting mobility and gait, and people with long-term neurological conditions such as Parkinson's disease or multiple sclerosis. In addition, QTUG could potentially be used to monitor response to interventions such as rehabilitation or medication.

Approximately 30% of all people 65 years and over fall each year and this rises to approximately 50% in those 80 years and over (Age UK 2015). Their risk of falling can be increased further by conditions such as dementia or delirium (Royal College of Physicians 2015).

Chronic difficulties with gait and balance can also increase the risk of falls. For example, people with cerebral palsy may fall frequently, and report greater fear of falling (Morgan 2013).

Neurological conditions such as Parkinson's disease, multiple sclerosis or stroke are estimated to affect over 10 million people in the UK (Neurological Alliance 2003). People with these conditions have an increased risk of falling, with reported fall rates varying from 43-70% in stroke survivors and 35-90% in Parkinson's disease (Multiple Sclerosis Trust; Weerdesteyn 2008; Allen 2013). Falling is a common issue among young people who have neurological disorders, although the prevalence of falling is difficult to quantify.

Falls risk assessments are generally done by physiotherapists, geriatricians, occupational therapists or nurses. The manufacturer states that QTUG can be administered by non-specialists with some additional training. The manufacturer provides instructional videos and training over the telephone or in a face-to-face training session. QTUG would be used as part of a standard falls risk assessment and is therefore unlikely to need any changes to the relevant care pathways (these include falls in older people, multiple sclerosis and stroke rehabilitation).

Costs

Device costs

Table 1 shows indicative pricing for QTUG. The manufacturer states that pricing has not been fixed in the UK and is likely to be adjusted.

Table 1: Prices of QTUG (excluding VAT)

Component	List price	Other information
Hardware cost (includes hand held tablet computer, 2 inertial sensors, 1 package of disposable bandages)	£675	Anticipated lifespan 3 years.
Annual software licence fee	£1,500	Discounts are available on the licence fee for organisations purchasing multiple units.
Disposable tubular bandages	£2.47 for 20 metres	To be purchased separately (see above). Used to secure sensors to the outside of patient's clothing. Each test uses 60cm.
Alcohol wipes	£0.02	To be purchased separately
Onsite training	£500 (plus travel expenses)	Can be provided if needed in addition to free telephone and video training.

Costs of standard care

The standard TUG incurs the cost of clinical time only.

Resource consequences

The manufacturer states that QTUG is currently in use in 3 NHS trusts. The QTUG

manufacturer, Kinesis Health Technologies Ltd, has been selected to participate in the NHS England Test Beds initiative.

If adopted, QTUG would be used in place of the standard TUG test and is not considered to need any significant changes to current infrastructure.

Potential benefits of QTUG include use by lower grades of staff such as health care support staff, with further clinical assessment by appropriately qualified professionals. Improved prediction of falls risk and frailty could contribute to falls prevention measures and could help to assess whether therapies to improve gait were effective. It is unclear whether fewer resources would be needed to administer and interpret QTUG compared with TUG.

Regulatory information

QTUG was CE-marked as a class I device in July 2014 to Kinesis Health Technologies Ltd.

A search of the Medicines and Healthcare Products Regulatory Agency website revealed that no manufacturer Field Safety Notices or Medical Device Alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The risk of falling increases with age, and can be more common in those who have disabilities causing issues with gait and mobility, or in those who have a neurological condition. Age and disability are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published process and methods statement. This briefing includes the most relevant/best publicly-available evidence relating to the clinical and cost effectiveness of the technology. The literature search strategy, evidence selection methods and detailed data extraction tables are available on request by contacting medtech@nice.org.uk.

Published evidence

Two studies were selected for inclusion in this briefing, on the basis of the most relevant clinical outcomes. The first was a re-analysis of data from 2 datasets, taken from participants in an ageing research project, and included 442 people (Greene et al. 2016). The study outcome was the prediction of falls risk. The study reported that fall-risk assessment accuracy was greatest when QTUG was used alongside clinical risk factor assessment. Accuracy was greater when using QTUG alone compared with clinical risk assessment alone.

The second study was a cohort study assessing frailty in 399 people (Greene 2014). The evidence suggests that the assessment of frailty was most accurate when a TUG test with inertial sensors (such as those used in QTUG) was used.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

Table 2: Summary of selected studies

Study	Details of intervention and comparator	Outcomes	Strengths and limitations

Greene et al. 2016 Study title: 'Fall risk assessment through automatic combination of clinical fall risk factors and body-worn sensor data'. 442 (of 748 participants recruited). Retrospective analysis of 2 data sets. Single centre (Ireland).	QTUG sensor based risk factor assessment. Clinical risk factor assessment (questionnaire). QTUG and clinical risk factor assessment (combined). Independent validation sample, QTUG sensor based risk factor assessment (n=22).	The study favoured combined QTUG and clinical risk factor assessment compared with either QTUG alone or clinical risk assessment alone in terms of the percentage of participants correctly classified as being a 'faller' or 'non-faller'.	Limited details of participants provided. A large proportion of the people in the study did not have data recorded. It was unclear what questions were used in the clinical risk factor assessment questionnaire or whether this was validated. QTUG was validated by classifying participants into 'faller' or 'non-faller' based on retrospective falls reports, not on prospective falls outcomes. The paper reported on 2 data sets but data is presented for data sets 1 and 1+2 combined (not data set 2 separately). Results differed between dataset 1 and dataset 1+2 combined, suggesting differences between datasets. Few measures of variance around estimates are presented in the paper. The study also reported clinical risk factor assessments for all 748 participants, with more

			favourable results than the subgroup. The study used self-reported history of falls, which can be unreliable, to classify participants. The independent validation sample was small.

Greene et al. 2014 Study title: 'Frailty status can be accurately assessed using. inertial sensors and the TUG test'. 399 (of 479 participants recruited). Cross-sectional study. Single centre (Ireland).	TUG sensor based assessment. Manual TUG based assessment. Maximum grip strength (lbs) from left and right hand (using a handheld dynamometer). All were compared with frailty category (as defined using modified Fried criteria).	The study favoured TUG with inertial sensors compared with manual TUG in terms of the proportion of participants identified by the system as 'frail' or 'non-frail'. The study favoured maximum grip strength compared with manual TUG or TUG with sensors when models are stratified by gender (not in the single regression model).	Owing to missing data, approximately 17% of participants were not analysed. Significant differences between frailty subgroups at baseline were identified. 'Pre-frail' and 'frail' categories were combined because of the small number of participants in the 'frail' category. Results from a single regression model of all participants and from the mean of models stratified by gender were reported. Results cited as headline were from the means of models stratified by gender. Few measures of variance around estimates were included.

Strengths and limitations of the evidence

The 2 studies identified were both observational studies and no randomised studies were identified. Limited details of the studies were reported and as such there is a risk of bias that may influence the results. Data were missing for a large proportion of people in both studies. Neither of the studies describe any blinding of outcome assessors, therefore it is uncertain whether test results were interpreted without knowledge of the results of the other tests that were used. These studies were both carried out as part of a larger cohort

study and it is possible that some of the same people were included in both studies. Neither of these studies included adults with physical disability or neurological diseases and the effectiveness of QTUG to predict frailty and falls in these populations is unclear. The lead author of both studies is a Director of Kinesis Health Technologies Ltd, which manufactures QTUG.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

Three specialist commentators agreed that QTUG is expensive compared to standard testing. They reflected that the total cost of hardware, software licence fees may be prohibitively high and may not offer value for money over and above existing assessments. They noted that many centres would need more than one QTUG and this would increase the cost.

One specialist commentator stated that lower grade staff could be used to do the QTUG test, but that a full clinical assessment with qualified professionals would still be needed and therefore the potential savings may not be realised. Another specialist commentator stated that lower grade staff are already undertaking falls assessments, while another commented that the standard TUG could be administered by lower grade staff with minimal training. One specialist commentator noted that there should be an estimate of the time required for a healthcare professional to administer and interpret QTUG compared with TUG.

One specialist commentator did not feel that QTUG would provide a robust method of assessing frailty compared with currently used markers and systems. They felt that QTUG could measure some aspects of frailty associated with slow gait speed and low physical activity, but that these were only a small component of frailty.

One specialist commentator stated that the research studies used to establish the validity of QTUG were of a low standard (noting that no randomised controlled trial evidence was available). Another commentator stated that QTUG requires further research to validate its use in adults with a physical disability or neurological disease.

Specialist commentators

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

The following clinicians contributed to this briefing:

- Vicky Johnston, Specialist Physiotherapist, Cumbria Partnership NHS Foundation Trust. No conflicts of interest declared.
- Dr Victoria Goodwin, Senior Research Fellow, University of Exeter/Honorary physiotherapist, Torbay and South Devon NHS Foundation Trust. No conflicts of interest declared.
- Dr Jonthan Treml, Consultant Geriatrician and Medical Examiner, Elderly Care, University Hospitals Birmingham NHS Foundation Trust. No conflicts of interest declared.

Development of this briefing

This briefing was developed for NICE by Birmingham and Brunel Consortium. The interim process & methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-1972-7