

Mollii suit for spasticity

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is the Mollii suit. It is used for reducing spasticity and improving motor impairment which happens because of upper motor neuron damage.
- The **innovative aspects** are that Mollii suit delivers electrical stimulation through a full-body garment that aims to produce a whole-body response to reduce spasticity through a mechanism called reciprocal inhibition.
- The **intended place in therapy** would be for treating people with muscle spasticity, although at which point in the care pathway is not yet clear. It would mainly be used in the home setting as either an alternative to, or as well as, current treatment options. These include physical therapies and medication.
- The **main points from the evidence** summarised in this briefing are from 2 unpublished, non-comparative before and after studies available on the manufacturer (Inventions) website. These studies include a total of 151 people (adults, young people and children) in Sweden. They suggest that the Mollii suit could be an effective option for people with conditions that cause spasticity.
- **Key uncertainties** around the technology are that the evidence base is still developing with, as yet, no randomised controlled trials or independent comparative observational studies. Therefore, it is not clear whether the Mollii suit is effective when compared with other treatments. Because the available evidence was generated in Sweden and baseline care was not reported, it is unclear how generalisable findings are to the UK.

- The cost of the Mollii suit is £4,100 per unit (excluding VAT). The resource impact for the NHS is highly uncertain because of a lack of evidence.

The technology

The Mollii suit (Inventions), previously known as the Elektrodress, is a jacket and trousers that are designed to give therapeutic electrical stimulation to people with muscle spasticity.

The Mollii suit is a full-body garment which uses a type of transcutaneous electrical nerve stimulation (TENS). It delivers electrical stimulation to the wearer's skin through electrodes in the suit. The Mollii suit includes 58 electrodes, a subset of which are activated for each person, depending on the muscle pairs being targeted. The electrical stimulation is intended to stimulate the sensory nerves through the muscle spindles, while avoiding contraction of the muscle spindles themselves, so-called 'sub-threshold sensory stimulation'. The suit has a programmable control unit. Negative side effects have been reported to be minimal and short lived (for example, tingling but no pain).

The device is designed for home use after an initial assessment, in which a trained therapist sets the device settings to the individual's needs. The settings are saved to allow for home use with minimal training. The Mollii suit is worn for 60 to 90 minutes every other day, with the aim of reducing muscle spasticity and improving movement for up to 48 hours after each session. The company states that with regular use the effects may extend beyond 48 hours, and that the system is suitable for long-term use.

The device can be worn by both adults and children with muscle spasticity caused by brain injury (for example, because of stroke or cerebral palsy). It aims to reduce muscle stiffness and undesired reflexes. This enables improved muscle and joint movements, including greater balance and muscle control. The Mollii suit is available in 26 different sizes and is suitable for children aged 2.5 years and over (about 95 cm) up to adults with a maximum weight of 19 stones (120 kg).

Innovations

The potentially innovative aspect of the Mollii suit is the sub-threshold sensory electrical stimulation to cause reciprocal inhibition of the muscles.

The design of the full-body suit is intended to target a range of different muscles simultaneously, rather than focusing on an isolated muscle contraction. This is claimed to improve muscle tone, range, control and movement.

The Mollii suit is designed to address several muscle and motor function problems. The manufacturer proposes that it therefore differs from most TENS and functional electrical stimulation devices, which are more commonly used for a specific indication, for example, to reduce pain in a localised area or to help walking.

Current NHS pathway

Currently, a person with a motor function or muscle tone disorder will typically be referred to secondary care. Many different management techniques are used depending on the severity of spasticity. Management may be directed by different professionals (a paediatrician or paediatric neurologist, physiotherapist, occupational therapist, orthotist, surgeon, parent or carer).

Management approaches will be determined by each person's specific health condition. They can include: physical and occupational therapy, orthoses, and pain and spasticity medication (for example, baclofen, diazepam or local injection of botulinum toxin type A). In certain people, surgery (for example, orthopaedic surgery or selective dorsal rhizotomy) may be also considered. NICE guidance on [managing spasticity in under 19s](#) gives options specifically for children.

Population, setting and intended user

The Mollii suit can be used for adults and children with muscle spasticity or other motor function disorders. Examples of relevant populations include, but are not limited to, people with neurological disease such as cerebral palsy or multiple sclerosis, stroke, acquired brain injury and spinal cord injury. The Mollii suit could be considered as well as, or instead of, standard treatment options, including functional electrical stimulation, in several different post-acute care pathways. However, it is expected that all people using the Mollii suit would continue with physical therapy and exercise treatments. Because the suit is not yet used within the NHS, it is not clear how the Mollii suit would be integrated into existing pathways. Current NHS practice is unlikely to change substantially if the Mollii suit is used as part of the current treatment options.

Before starting treatment with the Mollii suit, the person is assessed to identify their individual response and whether the device is effective. The treatment is deemed to be suitable for the person if they show a noticeable neurological response, such as reduced spasticity or reduced pain. The manufacturer states that people with spasticity, high muscle tone, over activity or balance issues tend to show the most noticeable responses during the initial assessment.

After the initial assessment in an outpatient or inpatient secondary care setting, the Mollii suit is mainly intended to be used at home (with additional help from a carer if needed). It may also be used in an inpatient or outpatient setting in hospitals and rehabilitation centres.

If the Mollii suit were to be adopted by the NHS, appropriately trained physiotherapists or other clinicians would offer it to people for whom it would be suitable. Training takes 2 days and covers the theoretical and practical aspects of the technology. Therapists must have enough knowledge and experience in neurophysiology to be suitable for training. No formal training is needed for the person having the Mollii suit, or their carer.

Costs

Technology costs

The 2017 list price of the Mollii suit and its consumables is £4,100 (excluding VAT). This includes the initial assessment and programming of the device, as well as a follow-up assessment with a Mollii suit-trained clinician or therapist. Growing children and some adults may need reassessment to adjust the suit settings. These sessions are provided by the company and currently cost £100 to £150. The cost of an NHS physiotherapist's time to do an assessment is expected to be similar (grade and setting dependent; [PSSRU 2016](#)). Alterations for size and fit of the suit cost between £190 and £260 (excluding VAT).

The manufacturer's warranty for the device is 2 years, but it is expected that an adult can use the device for 3 to 4 years. The lifespan of the device is expected to be shorter with children because they are growing, but if a suit is returned within 1 year, another new or reconditioned garment may be bought at half the cost. The Mollii suit is sold with 4 AAA rechargeable batteries and a wall charger. Depending on the person's patterns of use, batteries should allow 4 to 6 sessions of use before they need recharging. It is expected that the batteries will need replacing after 1 to 2 years of use. The cost of replacement batteries, as well as home washing of the garment, is expected to be incurred by the person using the device.

Costs of standard care

Several options are available in current standard NHS care. The least costly therapeutic option is oral baclofen, costing £40.30 per year for a 60 mg/day dose ([Drug Tariff January 2017](#)), in addition to the costs of monitoring and consultations. Local injection with botulinum toxin twice yearly has an estimated annual cost of £870 and £1,263 for adults and children respectively, including follow-up but not the first initial consultation for treatment ([NHS reference costs 2015/16](#)). Intrathecal baclofen therapy, taking into account the implantable pump lifetime (7 years), has an average

annual cost of £2,093 and £3,318 for adults and children respectively ([NHS reference costs 2015/16](#); [Drug Tariff January 2017](#)). The annual cost of staff time for physiotherapy once per week is about £6,686 ([PSSRU 2016](#)). The cost of selective dorsal rhizotomy surgery is estimated at £25,362 (NICE guideline on [spasticity](#)).

Resource consequences

The Mollii suit is currently provided by private or third-sector health organisations. Some NHS trusts have been involved with initial assessments of the technology but it is not currently in routine NHS use.

If the Mollii suit were shown to improve clinical outcomes compared with current interventions, it has the potential to be cost neutral or cost saving, for example, through reduced length of stay if used concurrently in hospital rehabilitation, or reduced need for health and social support because of improved rehabilitation outcomes. Cost savings could also result if the technology was shown to reduce the need for concurrent medication or the need for surgery. However, if the Mollii suit was adopted as an adjunct to existing therapies, more costs might be incurred, especially if there was no long-term reduction in medication use or surgical procedures.

Because of variation in practice and the different needs and severity of spasticity in people affected by the various conditions mentioned, the resource impact of adopting this technology is highly uncertain. However, it is not anticipated that the adoption of this technology would present practical difficulties or need changes in facilities and infrastructure.

Regulatory information

The Mollii suit (previously known as Elektrodress) was CE marked as a class IIa medical device in December 2012.

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).

People with spasticity may be regarded as having a disability under the Equality Act 2010 if their condition adversely affects their ability to carry out daily activities for more than 12 months. The Mollii suit is contraindicated for people with implanted electronic medical devices and may not be suitable for pregnant women. Disability and pregnancy are protected characteristics under the Equality Act.

Clinical and technical evidence

A literature search was done for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Two pilot studies are summarised in this briefing, both done in Sweden and reported on the manufacturer's website. These are an effectiveness study ([Westerlund et al. 2012](#); n=117), and a cost-effectiveness study ([Shi et al. 2012](#); n=35).

Overall assessment of the evidence

The current evidence base for this technology is low in quality and quantity. There are no published randomised controlled studies or high quality comparative observational studies available to assess the effectiveness of the Mollii suit. The pilot studies summarised in [table 1](#), alongside several patient case studies and expert testimony, suggest that the Mollii suit could be clinically and cost effective. However, poor reporting of the pilot studies makes quality assessment and interpretation of findings difficult. It is not clear how well the findings apply to the NHS because baseline care is not clearly described in the studies and the study setting is Sweden.

The available studies have not been published in a peer-reviewed journal. This means that the design, methods and conclusions of these studies have not been critiqued by experts in the field. The studies have academic authorship but some of the authors are directly employed by the manufacturer and this raises the potential for conflicts of interest. It is understood that a multi-

centred randomised crossover study is ongoing and this may improve the quality of the evidence base and reduce uncertainty.

Based on the current evidence there is uncertainty about the population group which would benefit most from using the Mollii suit, and whether it is best used as a first-line therapy option or in addition to ongoing care. These 2 treatment strategies could be assessed as 2 distinct interventions in future studies. Clear description and selection of study participants is needed, including information on concurrent therapies. Subgroup analysis of people with different conditions should be considered.

Apart from improvement in specific clinical outcomes, the pilot studies suggest there may be an improvement in quality of life, as well as a reduction in resource use (because study participants cancelled planned healthcare contacts). The size of effect is currently unclear and although short-term side effects are reported to be minimal, the long-term effect of regular use is uncertain. Future studies should consider measuring quality of life and resource use to allow for cost-utility analysis.

Table 1 summarises the clinical and economic evidence as well as its strengths and limitations.

Table 1 Summary of the best available evidence for the Mollii suit

<u>Westerlund et al. (2012)</u>	
Study size, design and location	A before and after observational pilot case series of 117 people with cerebral palsy (79%), acquired brain injury or stroke (8%) and other neurological diagnoses (13%) who had used the device for at least 6 months (average 12 to 15 months), in Sweden.
Intervention and comparator(s)	Intervention: the Mollii suit Comparator: none.
Key outcomes	Movement improved in 61% of patients; ability to straighten the hand or fingers improved in 46% and 34% respectively, and general spasticity was reduced in 60%. At baseline, 32% of the patients had planned spasticity treatments (for example, botulinum toxin injection) and 90% of these patients were able to cancel these treatments because of improvement. Use of 1 or more assistive devices, such as wheelchair and walker, was stopped by 24% of the patients. Negative effects on digestion, mobility, spasticity or pain were reported by 4% of patients.

Strengths and limitations	<p>The population and intervention were not fully described. The population group appears to be heterogeneous in terms of health condition and concurrent therapy options such as physiotherapy regimes. No subgroup analysis was given, making interpretation of results difficult. The intervention was not compared directly to a specific form of standard care, or other alternative treatments.</p> <p>Outcomes were not validated (only 'positive' or 'negative' changes from baseline, represented graphically as the proportion of people experiencing change rather than an indication of magnitude) and there was a variable length of follow-up.</p> <p>It is unclear if the findings have potential to be clinically or statistically significant.</p>
<u>Shi et al. (2012)</u>	
Study size, design and location	An economic pilot study, in 34 children with cerebral palsy, based on clinical measurements, interviews and a survey before and after use of the Mollii suit in Sweden.
Intervention and comparator(s)	The Mollii suit was compared with oral baclofen, botulinum toxin injection or surgery. A precise definition of the intervention and comparators was not given.
Key outcomes	Spasticity in the hip, knee and foot improved in 100% of the sample. Absolute values (derived using a visual analogue scale) were given graphically for life quality, pain, spasm, daily activity, functional mobility, ability to sit and stand, body structure and function, and gross motor function. Costs were reported in Swedish Krona. Reduced healthcare resource use was reported with use of the intervention, except for an increase in the use of assistive devices. The authors state that the Mollii suit was more effective than all alternative treatments in this study, and less costly than baclofen and surgery (with similar costs to botulinum toxin).

Strengths and limitations	<p>The selection of the sample was reported to be randomised, but no further detail of the baseline patient characteristics was given.</p> <p>Costs were sourced from Swedish providers and from the literature. Non-health care costs, such as work and study costs, were included and this suggests a societal rather than a health and social care perspective. It appears that discounting was not appropriately applied. Sensitivity analysis was only done on costs, but the most and least costly scenarios were not further described.</p> <p>Authors reported graphically that the intervention was as or more effective, and as or less costly, than its comparators thus indicating cost effectiveness. The final outcome of the study is unclear because the composite measure of effectiveness was not clearly defined. Also, it is not clear how effectiveness estimates for the comparator interventions were derived.</p>
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Recent and ongoing studies

No ongoing or in-development trials were identified from a search of publically available clinical trial databases. However, the manufacturer identified the following studies that are currently in development:

- An international 3-centre randomised crossover study of patients with cerebral palsy and stroke, with an observational study in patients with spinal cord injury in close collaboration with the Karolinska Institute, Hvidovre Hospitale in Copenhagen and the Medical University of Vienna. Status: preliminary work started in October 2016, with a study end date in 2018. Indication: stroke, cerebral palsy and spinal cord injury. Comparators: the Mollii suit.
- A clinical trial to compare the effect of the Mollii suit with that previously achieved with botulinum toxin, in children with cerebral palsy (County Hospital in Falun, Sweden). Status: preliminary work has started, and the trial duration will be 6 months. Publication is expected in 2017. Comparators: the Mollii suit, botulinum toxin.

Specialist commentator comments

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.

One of the commentators has used the device with 9 patients (each using the suit for 1 hour) as part of a trial with the manufacturer. Two other commentators were familiar with the technology, but 1 stated that this was only through reading of the literature and neither had used the technology with their own patients. None of the commentators were involved in the development of the technology.

Level of innovation

One commentator stated that the use of electrical stimulation for the treatment of medical disorders has been limited because of lack of efficacy and tolerance by patients, especially children with learning disabilities. However, they added that the Mollii suit is a promising concept because current treatments, such as medication and surgical options, are associated with side effects, need monitoring or are expensive to administer. A second commentator stated that the Mollii suit is completely new compared with existing technologies and there is no other whole-body sub-threshold electrical stimulation suit currently available. This commentator was not aware of any other technology that would already supersede or replace this technology. A third commentator felt that more evidence would be needed to determine the benefits of the technology.

Potential patient impact

One commentator remarked that for people with neurological impairment, the device could have a large effect, including reducing spasticity, increasing muscle strength and control and decreasing stiffness and pain associated with tone and lack of movement. This could reduce the need for drug therapy and increase quality of life, as well as improve recovery after injury. They reflected that in their limited experience of using the Mollii suit, each of the people who had used the suit experienced benefits.

A second commentator noted that several benefits have been proposed in the literature, such as improved muscle mass, increased range of movement, improved walking speeds and improved posture. They added that this could be helpful to prevent secondary musculoskeletal complications, especially in children with cerebral palsy, stroke and other acquired brain injuries. This commentator also stated that children with unilateral spastic disorders (of static causes) might benefit more than children with severe spastic quadriplegic cerebral palsy, although more long-term studies are needed to confirm this.

A third commentator stated that the current evidence is insufficient to draw any conclusions about potential patient benefit. They note that obnoxious stimuli can trigger spasticity and further research is needed to establish if the Mollii suit could cause harm to patients.

Potential system impact

One commentator reported that the person providing the assessment for use of the technology would need training and also noted that additional storage and washing facilities would be needed. This commentator believed the person using the suit would need minimal training. A second commentator felt that use of the technology would not need, or lead to, any significant changes in facilities or infrastructure.

One commentator felt the technology could reduce costs by increasing the speed of recovery and reducing the need for drug therapy. Another commented that in theory the technology could lead to fewer hospital visits but several factors may influence this outcome (for example, the severity of spasticity, level of cognitive impairment, and other co-morbidities could mean the technology may not be suitable for all patients). Two commentators noted that there is a lack of evidence on the cost impact of the device.

Patient organisation comments

The patient organisation Cerebra was asked to comment on this briefing. Cerebra asked the Peninsula Cerebra Research Unit (PenCRU) to provide comments, which are given here. These comments are those of PenCRU and do not represent the views of Cerebra.

PenCRU works with families of children with cerebral palsy but has not evaluated the Mollii suit before.

The Mollii suit is a novel approach to treating spasticity, far extending transcutaneous electrical nerve stimulation (TENS) applications.

However, there is a need for robust evidence to understand the effectiveness of TENS alone in reducing spasticity and improving function, in order to understand the comparative effectiveness of the Mollii suit.

Other whole-body garments made of Lycra, which have been used as orthoses, have been reported as hot, difficult to tolerate and can make going to the toilet difficult. It was also noted that it is likely that help would be needed with dressing.

The commentator remarked that a meaningful difference between standard care and the Mollii suit is yet to be determined. They believed a large effect on patient experience would need to be shown

to alter therapy programmes. The patient experience would depend on whether any improved outcomes offset the burden of wearing the suit.

People using the Mollii suit would be likely to need special training, ongoing physiotherapy and monitoring by a paediatrician or clinician. Even if the effectiveness of Mollii suit was proven in research studies, there is large uncertainty that a reduction of cost would be realised.

Specialist commentators

The following clinicians contributed to this briefing:

- Ms Kirsten Hart, clinical specialist physiotherapist, National Spinal Injury Centre, Buckinghamshire Healthcare NHS Trust. No conflicts of interest declared.
- Dr Santosh Mordekar, consultant paediatric neurologist, Sheffield Children's Hospital NHS Foundation Trust. No conflicts of interest declared.
- Dr Bhaskar Basu, consultant in rehabilitation medicine, University Hospital of South Manchester NHS Foundation Trust. Member of guideline development group for the NICE guideline on [major trauma: service delivery](#), published February 2016.

Representatives from the following organisation responded to a request for patient and carer organisation commentary on this briefing:

- Peninsula Cerebra Research Unit (PenCRU) University of Exeter Medical School.

Development of this briefing

This briefing was developed for NICE by Newcastle and York assessment Centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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