



Using rhythm for rehabilitation: evaluation of a novel haptic device

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Executive Summary

This project explored how new and novel approaches to stroke rehabilitation could improve physical function and the confidence of stroke survivors to remain active and engaged in the community. The innovation trialed was a 'Haptic bracelet/cueing device', developed at The Open University. An overview of the Haptic device, its development and role in stroke rehabilitation can be viewed at: <https://www.youtube.com/watch?v=S4ZxN6H6XGk>

The Haptic bracelets provide a physical (embodied) beat that someone can walk to as an alternative to existing audio cueing ways of working. The haptic device provides a non-invasive, relatively cheap way of facilitating people after stroke to continue to maintain or even improve their mobility after intensive rehabilitation has finished. This research explored the impact of the haptic device to gains in mobility.

The project had two key aims:

1. To develop a usable and practical prototype of a haptic device to restore gait symmetry after stroke.
2. To investigate the feasibility and acceptability of the prototype in stroke patients.

Summary of findings and recommendations

When introduced to the Haptic Bracelets participants hoped the product would provide them with:

- More confidence and make them feel safer when walking.
- Greater ability to take bigger strides rather than little steps.
- A way to combat the silly mistakes participants reported making due to tiredness.
- Reduced pain (knees, hips)

The physiotherapists saw potential for the Haptic devices as part of post stroke rehabilitation, but expressed concern about their lack of access to mobile technologies when out in community practice settings. There were also concerns about use with some stroke survivors because of issues of cognition; and the sensation from the Haptic beat.

In the Haptic gait testing

- All the participants demonstrated good mobility performance prior to the study (high score on the Rivermead mobility scale)
- 4/7* (57.1%) participants who were the *most asymmetrical at baseline* improved their gait symmetry whilst wearing the haptic device
- 3/7* (42%) participant's gait symmetry continued to improve in the post off condition.

- All the participants walked quicker in post-op condition. However, gait speed varied between participants when they were wearing the haptic bracelets.
- Participants were had had their strokes between 3-10 years ago, but there was still an indication that the Haptic bracelets were having some impact on mobility.
- Syncing of the Haptic device and more mobile Inertial Measurement Unit (IMU) to the fixed gait laboratory (gold standard) system has improved the potential for more community based rehabilitation and commercialisation of the Haptic bracelets.
- Post Haptic interviews identified that there were mixed participant feelings about the bracelets. However, some did express positive experiences from testing the Haptic bracelets, including a carry over effect after the devices were removed.

Recommendations

As this was a pilot study more work is now required to explore the:

- use of the Haptic bracelets in community rehabilitation settings
- feasibility of the using Haptic bracelets in community settings, particularly looking at staff access to new technologies
- potential for the Haptic bracelets to be used in the home as part of ongoing rehabilitation
- benefits of Haptic bracelets in the context of longer term stroke rehabilitation
- future design needs to improve the look, size and ease of application
- cost benefits of using Haptic bracelets as part of an overall program of stroke rehabilitation.

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Background and context

In the UK, 100,000 people will have a stroke this year (Stroke Association, 2017). While advances in medical treatment mean that many people are more likely to survive stroke and have improved outcomes, walking and specifically walking in the community, continues to be a significant problem for over half of all stroke survivors.

Restoration of walking ability is a key and common goal to both stroke survivors and their therapists. However, the intensity and duration of rehabilitation available to people after stroke is often limited by service constraints. Despite having further potential for improvement, once intensive rehabilitation has ended, many stroke survivors struggle to improve or maintain benefits in their walking in the community. This results in persistent restrictions in mobility for many stroke survivors, which contributes to a significant reduction in their quality of life and participation (Bohannon et al., 1991; Ferreira et al., 2015).

Common mobility restrictions typically include reduced symmetry of walking with greater weight being taken on the side unaffected by the stroke, impaired balance and reduced walking speed (Bohannon et al., 1991). These impairments are associated with an increased risk of falls, fear of falling, difficulties returning to work and/or hobbies and precipitate and/or accelerate degeneration of the hip and knee joints on the side unaffected by stroke, producing pain and dysfunction and compounding mobility problems (Ferreira et al., 2015). The effects of reduced mobility after stroke are significant. Restricted mobility in the community has been shown to contribute to social isolation, which is reported by over a third of people after stroke, in addition to poorer mental and physical health (Ferreira et al., 2015). Increased isolation is likely to lead to a loss of sense of self, greater carer burden and can produce other significant health conditions, with associated healthcare costs, secondary to a sedentary lifestyle. An adjunct to therapy, which improves outcomes, without necessarily increasing service costs would then be desirable.

2) Underlying costs and trends

The annual health and social care costs of stroke are around £1.7 billion a year in England (Stroke Association 2017). Informal health care is estimated to cost over £2.42 billion whilst lost productivity as a direct result of the disabilities brought about by stroke costs £1.33 billion. Furthermore, there are the additional costs, which are difficult to estimate, of potentially preventable complications such as falls (which costs £2.5 billion a year) and reduced quality of life. A mechanism to improve mobility, particularly in the community, such as the proposed haptic device could reduce the financial and social impact of stroke for a significant proportion of stroke survivors and their families and so present a better return for the expenditure on stroke by health and social care agencies.

Advancing age is the single most important risk factor for stroke; by the age of 75 at least one in six people will have had a stroke (Stroke Association, 2015). As the population ages, the numbers of people having a stroke are likely to rise. The advent of new medical therapies mean that more people than ever before are surviving, and living for many years after stroke (Stroke Association, 2015). This highlights the demand for efficacious treatments, which do not require intensive therapist-led, and therefore costly, interventions, but that can improve key functions for people after stroke. Recognising this challenge, the project and associated findings, described in this report, brought together physiotherapists, computer scientists and nurses with the aim of trialing a new innovation for stroke rehabilitation, the Haptic Bracelet.

3) Methods of rehabilitation - audio cueing

One successful approach to gait rehabilitation uses audio based rhythmic cueing. This provides an audible sound which the user follows when walking (e.g. similar to marching to a musical beat). Despite improving gait symmetry and cadence in people after stroke (Nascimento et al., 2015; States et al., 2009, Thaut et al., 2007) its effectiveness outside of a clinical setting is limited by the environmental noise of daily life (Wittwer et al., 2013).

Cueing using metronomic rhythmic sensory stimulation has been shown to improve gait for stroke survivors, but most versions of this approach have used auditory and visual cues. In contrast, The Open University have developed a prototype wearable system for rhythmic cueing based on haptics, which has been shown to be effective in pilot studies (Holland et al. 2014, 2015). Cues provided by touch (haptic cues) may also be more practical for walking in the community as they can provide a consistent cueing stimulus without being affected by background noise or other competing stimuli. It is likely that haptic cues utilise the same processes within the central nervous system as audio cues (entrainment) and so will have similar efficacy. Entrainment is the mechanism by which an individual can follow and reproduce rhythmical stimuli, for example, tapping along to a beat.

4) The Haptic device

Called “*The Haptic Bracelets*”, these wearable devices were originally designed and developed at the Open University. The Haptic Bracelets are designed to work in pairs with one device worn on the shank of each leg at ankle level. Each device contains a microcontroller, wifi capabilities and precise vibrotactiles capable of delivering the rhythmic haptic cueing on alternate legs. Each device also contains an *inertia monitoring unit (IMU)* which can monitor and record data relevant to the wearer’s gait characteristics. These data are logged for offline analysis, aiming to help physiotherapists and health practitioners understand how the patient is performing during rehabilitation sessions using the devices – although data can also be transmitted in real time with potential for adaptive real-time use.

The Haptic Bracelets are shown below

Image 1 – The Haptic Bracelets



5) The project

This project had two key aims:

1. To develop a usable and practical prototype of a haptic device to improve gait symmetry after stroke.
2. To investigate the feasibility and acceptability of the prototype in stroke patients.

The stated deliverables for this project were a prototype and supporting data, which can be presented to interested parties for future funding applications. The project team included NHS stroke services leads, health devices manufacturers and the patient and carer community. The planned timescale was 8 months. The two aims of the project were underpinned by three work packages.

Work package 1: The project team developed an iterative protocol to develop a usable prototype and establish the Intellectual Property (IP) status of the device, its components and concept. The objectives of this work package included exploration of the key features of the haptic device and feedback usability of the device. Patient partner involvement (PPI) was embedded

throughout this process of product development.

Features that were explored with patient partners during this stage included:

- Wearability – the device must be easy to don and doff so that users with impairments in dexterity and sensation in one hand (which is relatively common after stroke) can wear the device with minimal assistance.
- Aesthetics – it was important to consider how the device could be developed so that it is comfortable, appropriately sized and practical to wear for long periods, and had an acceptable visual appearance to potential users.
- Mode of use - including the nature and location of the haptic stimulus, the ability to easily deactivate the device when appropriate (e.g. if walking on uneven ground) and the duration of the stimulus to ensure that it provides a cue to elicit restoration of more symmetrical walking but does not become annoying or distracting.
- Functionality – how much control over parameter settings is possible and wanted by users and therapists.

Workpackage 2: Two focus groups with physiotherapists, who were recruited from local clinical networks. The key objectives of these sessions was to:

- Showcase the existing prototype to get feedback from a therapist perspective based on their experience of working with people after stroke.
- Identify issues and requirements for a user interface so that therapists can easily input the range of desirable walking parameters and extract walking data.

Work package 3: A mixed methods prospective evaluation of the latest iteration of the haptic device was undertaken. The key objectives of this work were to determine the:

- Acceptability of wearing the haptic device to stroke survivors
- Feasibility of using the device to restore gait symmetry after stroke,

6) Research design

The work outlined in the work packages was undertaken using a mixed methods feasibility approach, which aimed to develop and undertake:

- A qualitative approach to explore the concept and ideas.
- Convenience sample gait trialling of the haptic devices and evaluation and impact on (biometric) physical health.

- Post-trial service user evaluation of engagement with the haptic device.
- Recommendations for future haptics development.

7) Data collection, analysis and findings.

7.1 Development of protocol and Focus Groups (Work packages 1 and 2)

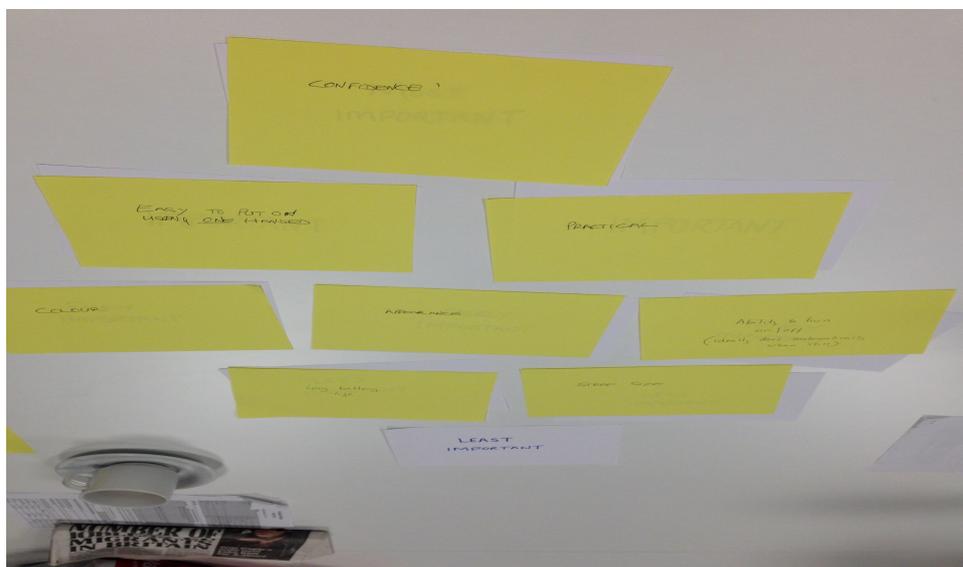
Prior to undertaking the focus groups a protocol for the iterative development of the haptic bracelets was developed, see Appendix 1. The iterative work to inform that development of the bracelets was then undertaken.

Three focus groups were held during June and July 2016 to get patient/stroke survivors (2 groups) and physiotherapists (1 group) opinions on the development of the haptic device. In total, eight stroke survivors took part and three physiotherapists. All participants were shown a film of the haptic devices in use from a previous pilot study, see

<https://www.youtube.com/watch?v=S4ZxN6H6XGk>

The patient/stroke survivor focus group was undertaken using an approach called Diamond Nine. Diamond Nine (Clark, 2012) allows participants to engage in-group discussions, to generate ideas. Participants were asked to identify nine factors that they considered important in the development of the haptic device. They were then asked, as a group, to rank the priorities from most important to least important. They placed the cards on the table identifying the highest priority, two high priorities, three middle priorities, two lower priorities and the lowest priority so that the cards became a diamond shape. The discussion that takes place during this activity highlights justifications for choices and discussion of any disagreements. A photograph was taken of the cards once they had been prioritised and the discussion and final ranking of cards was absorbed into the thematic analysis of the focus group data, see image below.

Image 2 Diamond Nine



The findings from the focus groups have been split into i) stroke survivor views and ii) physiotherapist views.

Stroke Survivors focus group

Interest in Technology

In order to ascertain how receptive to new technology participants were likely to be, the groups were asked about what kinds of home-based devices they use on a regular basis and about their views on health technology. Across the two focus groups, six participants used mobile phones, two didn't. All used a computer/laptop at home but mostly in a limited way. There were a number of comments about not being 'well up' on technology. The majority of participants were retired and some said they had lost touch a bit. The general sense was that participants were happy to try new things that might be helpful.

When asked about wearable technology the participants did not have much to say – there was mention of Fitbits and of stop watch monitor watches for people doing marathons. One participant has tried another 'piece of kit' that stimulated muscles on leg. Some concerns were mentioned in both groups about whether wearable technology would interfere with other health conditions – one mentioned pacemaker and another mentioned concern that devices could spark off a seizure for people with epilepsy.

Problems with Walking

Participants were asked to explain their problems with walking. Common problems mentioned were: balance, leg swinging, leg stiffening in winter (emphasised that this was about cold and not about confidence), loss of feeling in foot (making it difficult to place properly on the floor), negotiating stairs, turning around, and negotiating uneven ground.

"I particularly wobble and I am a bit unsure about losing my balance if I have to climb stairs, just the fact that you are taking one foot off the floor makes me feel totally unstable unless I'm holding onto something".

"Balance again is the thing and it takes a lot of your confidence away of course when you are not sure of turning round quickly or crossing the road"

"I'd like to be able to just walk in a straight line rather than be dragged about as somebody who appears to have had a drink or something because then when you try to correct yourself sometimes that's when you feel like you are going to stumble and get tied in a knot."

Impact on Daily Activities

The participants explained that they have to adapt their behaviour to deal with the problems; they have to think about every trip they make and modify the activities they take part in or make complex plans to make sure they feel confident. Examples of how the behaviour is adapted include: wearing flat shoes, holding on to walls, knowing where handrails are, using a stick, avoiding slopes, avoiding crowds (to prevent being pushed or jostled),

avoiding unfamiliar places unless you have a friend with you, carrying bags if difficult – both in terms of balance and also because it means there isn't a hand free to grab onto something if balance is lost.

“I mean it's just like if you are going to cross a busy road and because of your balance you don't know if you are going to fall so you've got to really think about it all, just step back till the road's clearer and anything that will help you like with your balance”.

“My workplace is only a bus stop from my house but if my husband couldn't come and pick me up I have to use the bus but I couldn't get off at my bus stop because it's a really busy road to cross the road so I have to think about another bus stop, get off and just try to cross the road. I was easier to cross the road at the next stop. It takes me one-and-a-half hours to go home but if you drive only fifteen minutes from work to home so I have to make sure I get a seat you know, another bus, two buses I have to take to home”.

“You are slightly like - at home you get used to where things are so if you know you are going to just lose your balance or fall you can just grab onto something you know that's there to get hold of. But if you are out somewhere strange or different – what am I going to get hold of? If I just go what can I get hold of, and there might be nothing there”.

“I think there are certain situations, I go to football matches and like you say unless you've got somebody with you I won't go into the stands because they don't have handrails when you come down the steps, and there is no way I can free walk down steps, I'm just so unstable. So I would only go if I had help”.

Enthusiasm for product

All participants were interested in trying the product. One of the eight was slightly more reticent (having tried an earlier prototype from The Open University). Although participants want the device for use out of the home, they said they would like to try it in the home initially to build confidence.

Potential Benefits of the product

Participants hoped the product would provide them with:

- More confidence and make them feel safer when walking.
- Greater ability to take bigger strides rather than little steps.
- A way to combat the silly mistakes participants reported making due to tiredness.
- Reduced pain (knees, hips)

Patient public requirements

The patients/stroke survivors identified key requirements for the product which are detailed below. Drawing on the 'Diamond 9' approach in the groups the

patient/stroke survivors prioritised their ideas. The suggestions below have been ranked according to the group's discussions:

- It has to work well so that users feel confident in its ability
- Must be able to put on and take off with one hand. Velcro was suggested a number of times. One handed pulling over to adjust tightness
- Needs to be lightweight –small enough to wear under trousers and made of a fabric that is comfortable to wear, even in hot weather
- The device should be made in skin colours (or ability to choose strap colour and change the strap)
- Ability to turn it off so it wasn't 'beating' while someone was sitting (e.g. in a restaurant). Ideally it would notice when you have stopped and work automatically according to the speed you are walking
- An information sheet (with pictures and simple language) and telephone helpline number to ensure patients are confident with its use
- Long battery life
- Silent
- Wearing it just above the knee was the preference because that is where it would be the easiest for patients to put on and take off without help from others. Both groups also raised the issue of the device looking like a 'tag' if it was worn around the ankle
- Speed variation (so when 'good leg' walks faster or slower the vibration keeps real time pace with that)
- Make it look more like a Fitbit – stylish rather than a medical device
- Ability for patients to make any adjustments

In both groups there was a minority voice that said that it didn't really matter what it looked like as long as it helped with walking, then participants would wear it.

Concerns:

When participants walk they gradually tire – so would the vibrating take that into account? (e.g. a walk home from the shops may need to be at a slower pace than a walk to the shops)

Wouldn't want to wear a device on leg with a skirt.

A lot of the participants said that they needed to have a try of the next prototype (especially outside of the lab) and would then feel in a better position to provide input into development.

Physiotherapists Focus Group

One focus group was held with three physiotherapists, all female, who were recruited through stroke rehabilitation units the Greater Manchester.

Priorities for treatment

The physiotherapists said that when treating stroke survivors they concentrate on improving speed of walking, endurance and time (pace - metres per

second) on a treadmill. There was, however, concern about the use of treadmills because of the need to be able to multi-task on a treadmill:

so you cannot speak to them while they are on it. You have to say step, step, step, as so many of them don't step and the treadmill's carrying on and there's a lot of 'heart in your mouth' moments.

The also concentrate on limb loading - how effective their gait is within the developing walk. Apart from treadmills and normal walking the physiotherapists also sometimes use a Nintendo Wii - for balance and reaction (used for people with higher level gait).

Potential Interest from Stroke Survivors?

The physiotherapists were interested in the haptics device. They felt it had potential to improve gait and distance. They also mentioned reducing the risk of falls. They were asked if they thought patients they worked with would find the device of interest.

The physiotherapists mentioned factors that would need to be incorporated into the device for it to appeal to patients such as ease of putting on, size (see below for more detail)

"I think it's a good point, I think a lot of – some of our patients are a little bit kind of, they don't want to think of themselves as having a disability and therefore when they have to wear a kind of a splint, a foot or something like that, they're very much aware of that and kind of want that to be where people can't see it really".

"I mean I would agree. It depends on the patients because some will try anything and everything that's out there. They'll just give you newspaper clippings – I've seen this, can I try this. Other people you mention a splint to [them] and they look in horror and say – there's no chance I'm wearing that – particularly with ladies who wear skirts".

The physiotherapists thought that there was a relatively small group of patients that it would appeal to – those who are walking but have safety concerns, people wanting to get back to work, 'young neuro survivor'.

"I've got a patient who that would go down really well with right now, a chap who is really normally very high level, he's in his sixties and he's a fell runner and the stroke was whilst fell running. He's got loads of activity but no sensation so actually his feedback is really poor. He's got a level of dyspraxia as well so he needs verbal cuing, visual cueing and repeated instruction. But actually when you give him a repeated instruction he responds very well but the minute you take it away the gait deteriorates so much."

Concerns

The physiotherapists also raised a few concerns with the device:

- They felt there might be quite a narrow market for the device because a lot of patients they work with have reduced cognition which may make using the device complex.
- Sensation can also be affected by stroke so should be considered when developing the strength of the vibration.
- They also commented that it could become irritating to wear the device all of the time.
- They also expressed concern for how well the device would work in a home environment. It was anticipated that patients may want to trial the device initially at home, but there was concern that the patient would not develop enough of a stride/ walking pattern within a small home for it to be effective.
- If the device is to be developed to link in with NHS services, there needs to be a financial benefit.
- Upkeep. Who will look after it if it goes wrong, who will help patients struggling with it?
- Cost / life expectancy
- The device would probably be better suited to be used by the community teams rather than on wards. Patients are in high acute ward for 2-3 days and then in rehab ward for approximately 17 days. So patients move through very quickly, so the physiotherapists that took part in the focus groups may not be the ones to engage with the product.
- Concern about demonstrating need for it for inpatients because it would not impact on length of stay – quality of walking is not a consideration for that.

Preferred interface to work with the device

The physiotherapists were asked how they would want to interact with the device. They explained that they had very limited access to any technology; clinicians use paper documentation and do not have ipads, mobile phones or tablets as standard equipment.

There was a suggestion that it work in a similar way to a Garmin watch – stores the data and then links to app or to computer and produces graphs of speed and distance. Ideally it would be able to demonstrate improvements over times – number of steps, step length. Reference point for patient and families. Maybe be able to see the data on an app – own personal device so patients can see own improvements. On mobile / tablet.

Most Important Features

The physiotherapists identified key requirements for the product which are detailed below (physiotherapists did not take part in the same 'Diamond 9' task, so these are not prioritised):

- Ease of use (do not over-complicate, some patients may have cognitive deficits).

- Simple and streamlined - “I think when carers see wires and bits and pieces they just run away from it apart from the ones that are really, really motivated. You take something and it’s ending up in a cupboard. All this time and effort that goes into something and how many times do we see things, and the fight for funding or something, and then it ends up in a drawer because actually it’s not fit for purpose”.
- Lightweight
- Robust
- Made of material that will not get “hot and sweaty”
Feedback if patient does a “really nice” step - it could pick up the quality of the step.
- Feedback for relatives to be able to see (maybe a light that shows that steps have been good).
- Ability to turn off any noises or feedback
- Provide data of step length
- Skin coloured
- Simple to don and doff for people who live alone or with only one functioning limb
- Contain enough charge to last a day
- There was agreement that it should be worn around the ankle as it could be uncomfortable higher up the leg (NB this is in contrast to patient views).

Developing the Haptic

Based on the focus group feedback Lucid Innovation innovative product designers who are also ISO 13485 accredited medical device development business developed an idea for a neoprene sheath to hold the haptic device, see Appendix 1.

7.2 Gait trialing of the Haptic device (work package 3)

For this study, we followed a repeated measures design, with a “before”, “with” and “after” condition. The participant was asked to walk the length of a ten metre runway as follows:

- **before:** six times (three each way) normally, with no cueing,
- **with:** six times with rhythmic cueing from the haptic bracelets ,
- **after:** a final six times, again with no cueing.

The before condition acted as a baseline where each participant’s natural walking tempo was calculated and used for setting the haptic metronome for the “with” condition.

Data collected during the “with” and “after” conditions were also compared against this baseline when looking for any effects the haptic rhythm had on the participant’s gait. Comparing the data against the baseline also allows

each participant to act as their own control, making any walking effects because of the cue more prominent.

Recording took place in the Movement Analysis laboratory, MMU. Each participant was fitted with the motion analysis markers and with the haptic device and the location and intensity of the stimulus was optimized for them. From a standing start, they then walked in a straight line turn around and walked back to the start. This was repeated, as described, for each of three treatments: pre-(stim off), on and then post-(stim off). This set of three treatments was repeated once. Gait asymmetry and gait speed were recorded with the Qualysis motion capture system.

Testing took place in the movement laboratory at Manchester Metropolitan University during a 7-week period (February - March 2017). Participants were recruited from the Manchester Stroke Association and from a focus group conducted previously at Manchester Metropolitan University in Cheshire. Of the nine participants recruited, seven of these met the final study inclusion criteria. However, there was also had the opportunity to recruit someone with Parkinson's Disease who had a specific interest in the project. This provided information and experience of how the device might be deployed for another neurological condition that can lead to gait asymmetry. All participants were assessed using the Rivermead mobility index, a generic tool that gives an indication of the participants mobility status.

An overview of the final participants whose data was included in the analysis is given in Table 1. A key of abbreviations is given below the table.

Table 1 participant's demographics

Participant	Name/ hemiparetic side	Age	Rivermead mobility index	Time of stroke
002	(DP) Right	53	14/15	10 yrs.
005	(LH) Right	57	14/15	3 yrs.
007	(AS) Left Wears AFO	74	14/15	3 yrs.
008	(KR) Right Foot drop wears AFO	63	14/15	7 yrs.
009	(JR) Right hemiplegia Wears AFO	62	14/15	5 yrs.
010	(CH) Right hemiparesis	55	14/15	5 yrs.
011	(DK) RT	47	14/15	CP since birth

Mean age of the participants 58.71 (± 8.65)

Mean time since stroke 11.42 (± 15.87)

Key

AFO = Ankle Foot Orthosis

CP = Cerebral Palsy

Results

Gait asymmetry and measures for the seven participants are shown in Table 2. The data is a ratio of stance to swing time

Table 2 Temporal symmetry and gait speed under three test conditions pre off, on, and post off

Participants	Paretic limb Gait symmetry pre off	Gait symmetry on	Gait symmetry post off	Gait speed pre off	Gait speed on	Gait speed post off
002	1.44*	1.36	1.53	0.96	0.93	1.00
005	0.99	1.05	0.99	0.67	0.81	0.94
007	1.49*	1.37	1.25*	0.44	0.41	0.51
008	1.39*	1.33	1.32*	0.95	0.97	1.04
009	2.70*	2.27	2.33*	0.68	0.55	0.57
010	1.00	1.03	1.00	1.08	0.88	0.99
011	1.23	1.32	1.09	0.75	0.69	0.82

All speeds were meters per second

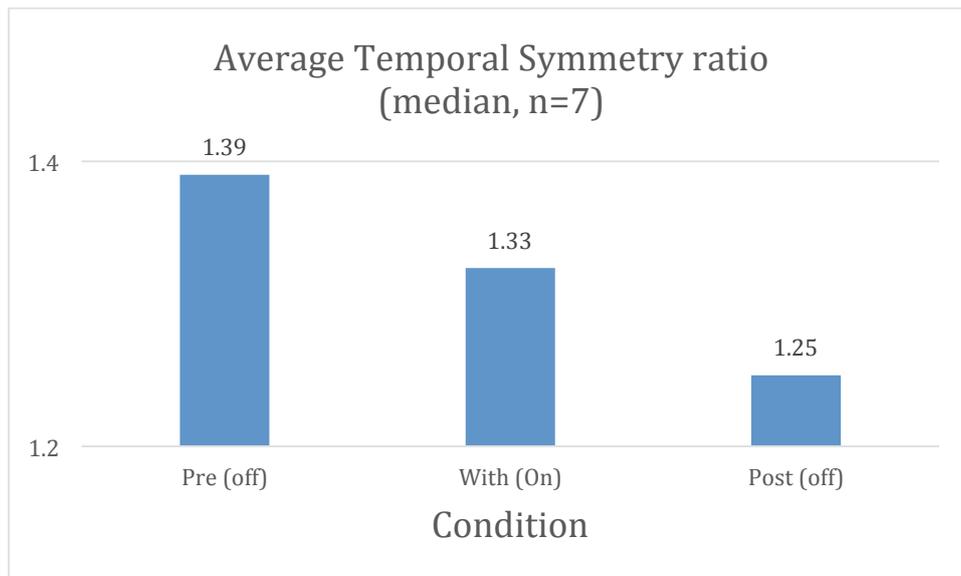
A normative range for temporal symmetry = 0.9-1.1

Mild asymmetry 1.1 -1.5

Severe asymmetry >1.5

Summary table for haptics

Median	Pre haptic	Haptic on	Post haptic
Speed	0.75	0.81	0.95
Temporal Symmetry	1.39	1.33	1.25



Symmetry values closer to 1 indicate better temporal gait symmetry. The table and chart indicate that, on average, compared with baseline measurements, temporal symmetry improved with haptic cueing, and then improved again immediately after haptic cueing

Summary of the results

- All the participants demonstrated good mobility performance prior to the study (high score on the Rivermead mobility scale)
- 4/7 * (57.1%) participants who were the *most asymmetrical at baseline* improved their gait symmetry whilst wearing the haptic device
- 3/7 * (42%) participant's gait symmetry continued to improve in the post off condition.
- All the participants walked quicker in post-op condition. Gait speed varied between participants in the haptic on condition.

Gait laboratory versus community walking with a Haptic bracelet

The project team aimed to undertake work on the suitability and practicality of the haptic bracelets in external environments. An important part of this this was to investigate the kinematic accuracy of the bracelets for measuring gait data outside the lab. Measurements of the *timing* accuracy of gait data from the bracelets proved to be excellent, and comparable to the gold standard (and very expensive) motion capture system (Visi, et al., 2017). However, during the initial stages of the trial it became clear that the Inertial Measurement Unit (IMU), used to measure *spatial* data such as stride length outside of the gait laboratory was less accurate. Work was therefore undertaken to quantify this discrepancy. We were able to establish that (Visi, et al.,-2017) for the purposes of taking baseline measurements from new users, mean relative measurement discrepancies relative to the gold standard motion capture system varied between 0.4 % and 5.7 %. While not ideal, this is entirely workable for estimating baseline mean spatial gait performance, and tracking trends in these parameters over time. This gives valuable

evidence of the potential commerciality of the wearable haptic system outside the lab. More work is now required to test the haptic bracelets in community settings.

Having measured the quantitative outcome from the haptic trial we also wanted to understand the qualitative experiences of the participants, which are presented next.

7.3 Post movement lab analysis

Participants:

Short semi-structured interviews with all 10 participants, including those whose data was not included in the final analysis. The interviews generally lasted around 10-15 minutes. They were kept quite short because most of the participants had taken part in more walking than they had done for a considerable time and were fatigued.

Results:

The main concern of both the research team and the participants was whether the device had been effective. At the time of interview, participants were not aware of their results so the following comments on the effectiveness of the device were their perceptions on how well it had worked and if they thought their walking had improved.

Participants Perceptions of Effectiveness:

a) Positive

I'm used to using a walking stick and I didn't use the walking stick inside when I was walking and I felt a lot stronger...walking in there without the stick.....it made a difference in that I had a bit more confidence. I felt confident without the stick (participant 5).

I did fine. As I say I wasn't aware you know, from the beeping noise when we went through the procedure to start with and then when I started walking I wasn't actually aware of anything. Yet I felt it was quite rhythmic that I was going so I thought it was an excellent step forward if you like (participant 8).

Well I think it would be [helpful] for me (participant 10).

I found it very good actually, it's interesting. I was walking a little bit better than I thought I was but I'm still unsteady (participant 3).

b) Negative

A couple of the participants (9 and 7) felt that it had not been beneficial. Participant 9 thought the device possibly made him more unstable:

In terms of the purpose of the trial to use the Haptics for rhythm I'm not sure I did use it.... just kind of made me more aware of my steps and if

anything it was set too fast at first so instead of walking normally but faster I cut my pace size and step link (participant 9).

Participant Experience of Haptic Beat

Participants talked about their experience of 'walking to the beat':

*That was alright yes, yes, it took a bit of getting used to. (participant 3)
I think it's a background thing that like all background noise, in a sense, in your life you become accustomed to so it wouldn't be something that you would be conscious of being aware of after a while really. (participant 1).*

Yes that was absolutely fine. (participant 2) Yes it was fine, actually I could feel it more on my stroke leg which is strange but I was more aware of it on my stroke leg than the other leg, which I wouldn't have expected (participant 2).

It was an experience, quite challenging as well but it felt alright (participant 5).

Yes because I think you are visualising when the beat is coming in. (participant 2).

Yes because it's made me think about slowing down, it's made me realise that slowing down is definitely what I've got to do, because by slowing down as well it made me think about the way I walk and it's obviously safer as well isn't it. But yes and trying to think about the beat obviously makes sense to do that and yes without this I wouldn't have done that (participant 2).

Some of the participants also experienced a noticeable lasting effect of the beat after they had finished in the movement lab:

Yes you got some carry-over (participant 9).

Yes because I pictured the beat, a natural beat for me. But probably I would forget it in an hour's time (participant 10).

....but I had this beating still going in my head so still doing that trying to get the beat (participant 5).

In some cases the participants felt that it did not seem to be working but their comments suggest that it might have been effective without them realising:

you are not necessarily conscious, in my case not necessarily conscious of where you are fitting in with the rhythm of the beat but you probably are actually. Because they told us it had been worked out to go at the pace that I walk at normally you see, so they are trying to accommodate me in that way I think (participant 1).

I found it very interesting but when it came down to the vibration bit it was a bit disappointing as I couldn't feel anything through my left leg so

I felt that my walking was more working on the memory than it was on the device. I was concentrating on responding to the right leg but I felt after a while that what was happening is I was anticipating the rhythm of doing it to my rhythm rather than to the device's rhythm. But overall, that's your question, the bottom line is overall interesting and I think it's helped me (participant 6).

Yes but if I'm truthful if we'd had just done a kind of, just a walking exercise of doing the same amount of walking without any devices I suspect it would have been similar in outcome. Because I've always felt that when I've been walking if I was given a straight runway I could get the rhythm right and I'd be alright but I've always got shouted at for going too fast. So I think the exercise has been very helpful to me, it's proved to me that I can do that much. I think there was a rhythm developing and kind of building and internalising if that's the right way of putting it (participant 6).

Concentration

A number of participants talked about concentration. For the device to be beneficial to people, it would need to be something stroke survivors could wear and still be able to carry on with other activities such as talking to companions, looking out for traffic and obstacles. Many of the participants talked about the concentration required in the sessions in the movement laboratory (this could, of course, be partly because of the experience of trying something new, in a new environment, with people they do not know). Participant three was asked if they could concentrate on feeling it and walking at the same time and confirmed that she/he could. But was then asked if they could also concentrate if someone spoke to them.....

Then I'd be! (He breaks into laughter) I couldn't do both together, I don't think anyway, no. It would be something that I would have to work out but I don't think the two would work together because if I'm concentrating on something, as I said before, if I'm on the computer and I'm concentrating on that I can't, you know, if someone's talking to me I've got to cut that off and listen with this one ear. I've got to switch the telly off to concentrate (Participant 3).

Q -when you walked then did you walk on your own or were you walking with Glenis? Well Glenis was behind me. I don't know. I was thinking of the beat (Participant 10).

I was really concentrating on it yes.(participant 2) I think it was a case of trying to get my brain to appreciate what we were trying to do with it really. To me that was multi-tasking which is something that my brain can't do anymore (participant 2).

I think it needs – it's difficult, I don't know whether Parkinson's is different from other conditions as you have kind of a limited amount of cognitive space if you like, so it's something that's taken up with the rhythm. You perhaps have to concentrate on it or it demands more

attention than it might otherwise so it becomes quite upfront in your mind so multi-tasking would be more difficult I think (participant 9).

Where on your body?

Participants talked about where on the body they thought they would like to wear the haptic device. Some thought they would like to wear it on both legs:

Yes because that makes it sort of synchronised doesn't it (participant 2).

Some thought one leg would be better:

Well when you are learning yes but maybe if you were to wear it all the time you perhaps didn't need it then, perhaps you only need it for your stroke leg when it was a permanent thing to make sure that you were picking that up, the right times. But I think now in this sort of situation to act with both legs I think if it was a permanent thing that you had to wear all the time maybe you would only need it on your affected side (participant 2).

Most wanted it on their leg despite being told it could be anywhere – or that they could just 'listen' to the beat while sitting and not even wear it. Maybe people don't want to take the leap without trying.

I think both legs would be, I'm just thinking around it, but I think with both legs yes, because you are conditioning both legs to the rhythm then, you are not just sort of trying to do it with one leg and the other one might be marching off and the other one staying behind (participant 8).

Participant seven said he'd wear it on his lower calf because it would be easier to ask his wife to put it on there and also easier for him to do it himself.

Participants view of controlling the device

Participants discussed whether they thought the device should be given to them pre-programmed by a physiotherapist without having the ability to adjust its settings, or whether they would prefer to be able to make adjustments themselves.

One participant felt that if it was always switched on, yet 'smart' enough to know when the patient was sitting or walking that would be beneficial:

...if I was sat here and then suddenly got up that would remind me to walk steady (Participant 3).

No, as a health professional I think somebody that knows what they are doing should be doing that only for health and safety issues in that respect because it would be easy for someone to think they can do more than they can do and they could come unstuck from that perspective. As in people being able to do what they want to do then maybe people should have the right to be able to do things, that might be a different story, but with health issues I wonder whether people

think they can do it more than they can really do, you know (participant 2).

However most participants wanted to be able to have the control of the device themselves:

Well I think I'd like control really because I can look and see where I want to go and whether it's how far I'm going and then I can set it slow or fast, not fast but you understand what I mean, sort of normal or a bit slower if I'm thinking a bit off (participant 3).

I think if the person sets it [rather than physio] because it depends on how they feel day by day, they might feel tired one day so they don't want to walk fast or anything but on another day they are fine and they want to walk a little bit faster or further (participant 4).

I think to alter the rhythm would be a good thing. Remember when I was talking about stepping out and if you are walking further distances and things like that, for somebody who likes walking I think it would be a great advantage (participant 8).

You want to be able to change that, there are a few settings that you would want to be able to change – the intensity of the buzz; the rate of step; and on and off. I think those are the three things you do or at least want control of.....But the physiotherapist would make the initial assessment and do the starting settings but I would still want some control over it (Participant 9).

Where would you use it?

I could use it without any problem you know, if I'd got a good length of walking to do more or less in a straight line. I'm not sure how it would be if you weren't walking in a straight line in a controlled environment. If I was walking down a footpath, say at the side of the road where you tend to wander a little bit I'm not sure how much the rhythm would have been there then, if that's kind of answer you are looking for (participant 6)

Not in the house no.....Because I don't think in the house there's rarely a time when I am walking any length, any distance, mostly I'm walking in a constrained environment where a lot of the concentration is not on the rhythm of walking, it's avoiding furniture and obstacles so I don't catch my feet in things when I'm walking. So that's why I wouldn't wear it in the house because the majority of movement around the house is just for short distances (participant 6)

I think both because like if I use it outside I would need to like a more sturdy footing that would support my foot wherever I go (participant 4).

I think it would be useful when I go out to go to do something, like in my garden, I've got rails around my garden but I would probably walk more steadily than holding onto the rails...But I should imagine that when I

go out to do the bins and things like that if I had something to just – because when I get up quick I wander off and that's when things go wrong (participant 3).

Most of the participant felt it was not something they would use in the house:

Well I get round the house. How do I put it, I've got different things I get hold of. I've got railings in the house as well you know in the toilet and bathroom, and I've got a walking chair and all that to steady myself so I'm alright there (participant 3).

Not so much inside the house but certainly outside the house because in houses you can't step out in the house too much you know, that's the hall and that's about it (participant 8).

Aesthetics

Participants were asked for their views on how they would like the device to look and for their suggestions on how it could be developed to attach to the body. At the time of undertaking this trial participants thought the current device was too heavy, it needed to be much smaller. However, many participants pointed out that in terms of aesthetics, looks were not important as long as the device worked and benefitted patients.

It wouldn't matter to me whatsoever if it helped me to make things easier and more how it was before or to stop pain, anything that helped I wouldn't care what it looked like (participant 2).

In terms of how it would attach to the body a few suggestions included magnetic attachments, and Velcro – but this was also rejected by one participant because Velcro can get stuck on clothes and cause some difficulties to people with limited mobility.

I can do this one, that sort of a clasp I can do that but I can't do an ordinary one. So I can do that sort of one but I couldn't do an ordinary one or a buckle so yes, something like that is probably better for someone like a stroke survivor yes (participant 2).

It's not only that but if you've only got the use of one hand to try and hold it on and Velcro it - you've got the use of your hand to a fashion so you can hold it with your stroke hand and fasten it with the one. Not everybody's got the use of two or got someone to help them so the magnets would be really good (participant 2 supporter).

No I'm just thinking, if it does the job for the patient it doesn't matter what it looks like or what it sounds like (participant 4).

No but I've got to admit if you are going to do long walking that's when you might start feeling it (participant 4 referring to the weight of a large device)

Q - Ok and can you think of anything that could prevent you from using it? A - Yes it was big and chunky so that people could actually see it and then when you are walking they've got their eyes on you, you know what I mean. If it's nice and compact I think it would be great (participant 5).

No suggestions on looks because it isn't a beauty parade, it's about the functionality of it (participant 6)

But I think it would have to be smaller and less – well I suppose some people would be, you know, when they first look at it if it's, you know, as much involved as that, if you get it on smaller areas I think that would certainly ease their minds (participant 8).

I don't like walking with it especially everyone looking because some people do look, and I'm used to that, but it's a gadget on your leg and then they are looking at that then looking at you and looking at my arm it's ...(participant 10).

Not aesthetics but about the development of the device:

It's just whether they would have to, from a stroke perspective, whether they would have to link it up and if they would have to do anything with it if it was on a phone because a lot of people can't use phones. And technology is just like – especially a lot of the people that we go out and see are of the older generation. I know stroke attacks more young people nowadays but a lot of people still are quite older and have involvement with the Stroke Association and are willing to try other things and they are not going to be technology [competent] so if it was to link up then it would be good but like somebody ... (Participant intercepts) (supporter of participant 2)

With a stroke survivor the less technology involved that they've got to deal with the better (participant 2).

Based on these findings Lucid Innovation also developed an idea for a body shape for the haptic device, to work in conjunction with the neoprene holder, see Appendix 2.

8) Medical impact

The haptic device we describe here could provide a non-invasive, relatively cheap way of facilitating people after stroke to maintain or improve their mobility after intensive rehabilitation has finished. In our case studies we have seen, on average, improved gait symmetry during or immediately following use. In terms of kinematic accuracy of the bracelets for potential self-monitoring use outside the lab, we have demonstrated that the bracelets can provide *temporal* symmetry data comparable with gold standard systems, and can provide *spatial* (stride length) data accurate enough to provide baseline measurement and trend data needed to support worthwhile gait

rehabilitation applications. If effective in wider use, the device could produce gains in mobility, with less intensive clinical intervention, and could mitigate the impact of a growing, ageing population on health and social care services by enabling people after stroke to continue to function in the community for longer. Further benefits from improving mobility include delaying the onset of frailty, and resultant isolation, in addition to reducing health care costs of preventable problems such as falls, which are reported in over half of stroke survivors. It is clear that in moving this work out of the lab, more work will be needed on power supplies and recharging methods, data transfer methods, privacy, device co-ordination with smart-phones and other controllers, fastenings, software individualisation, analytical methods and algorithms.

9) Conclusion and recommendations

In relation to the first project aim: to develop a usable and practical haptic device to restore gait symmetry.

Participants had had strokes quite some ago but there was still change and improvement, demonstrating the benefits of longer term stroke rehabilitation.

The results of this small-scale study adds to the body of evidence supporting the use of the haptic device as an adjunct to physiotherapy in the post rehabilitation phase of stroke survivors. The research design meant that the participants acted as their own controls. The positive change in the participant's temporal symmetry between the pre-haptic and haptic on conditions demonstrates coupling between the steady rhythm provided by the Haptic Bracelet and the motor response. Importantly this positive change is maintained in the post haptic condition. This suggests a carryover effect which could contribute to the overall role of the haptic bracelets contributing to positive outcomes in stroke rehabilitation, even if not worn all the time.

As this was a pilot study more work is now required to explore the:

- use of the Haptic bracelets in community rehabilitation settings
- feasibility of the using Haptic bracelets in community settings, particularly looking at staff access to new technologies
- potential for the Haptic bracelets to be used in the home as part of ongoing rehabilitation
- benefits of Haptic bracelets in the context of longer term stroke rehabilitation
- future design needs to improve the look, size and ease of application
- cost benefits of using Haptic bracelets as part of an overall program of stroke rehabilitation.

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