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Wristband Accelerometers to motiVate arm Exercises after Stroke (WAVES): a pilot randomised controlled trial

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Abstract

Objective: To evaluate the feasibility of a multi-centre, observer blind, pilot randomised controlled trial (RCT) of a wristband accelerometer with activity-dependent vibration-alerts to prompt impaired arm use after stroke.

Design: Parallel-group pilot RCT

Setting: Four English stroke services

Participants: 0 - 3 months post-stroke with a new arm deficit.

Intervention: Participants were randomised to wear a prompting or 'sham' wristband during a four week self-directed therapy programme with twice weekly therapy review.

Main Outcomes: Recruitment, retention and adherence rates, safety and completion of assessments were reported. Arm recovery was measured by Action Research Arm Test (ARAT) and Motor Activity Log (MAL) without statistical comparison.

Results: 33 patients were recruited (0.6 per month/site; median time post-stroke 26 days (IQR:15.5-45)). Baseline, 4 week and 8 week median [IQR] ARAT for control group (n=19) were 15[2-35], 35[15-26] and 31[21-55], and for intervention (n=14) were 37[16-45], 57[29-57] and 57[37-57]; for MAL Amount of Use, the control group was 0.2[0.0-1.2], 1.1[0.3-2.9] and 1.2[0.7-2.9], and intervention was 1.4[0.5-2.6], 3.8[1.9-4.5], and 3.7[2.1-4.3]. Four participants withdrew. Wristbands were worn for 79% of the recommended time. Intervention and control participants received a median of 6.0 [IQR: 4.3-8.0] and 7.5 [IQR: 6.8-8.0] therapy reviews. A median of 8 [IQR: 6-10] prompts were delivered per intervention participant/day. Research assessments were completed for 28/29 and 25/28 patients at four and eight weeks. Eight serious adverse events were reported, all unrelated to the intervention.

Conclusion: A multi-centre RCT of wristband accelerometers to prompt arm activity early after stroke is feasible. A total sample of 108 participants would be required.

Title: Wristband Accelerometers to motiVate arm Exercises after Stroke (WAVES): a pilot randomised controlled trial

Running Title: Wristband accelerometers after stroke

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Introduction

Loss of function in the arm affected by stroke is a common problem resulting in long term disability[1]. Although some patients will regain full function, up to 60% will make no recovery and as many as 74% will become dependent on another person for assistance[2]. Further research to enhance arm recovery has been identified as one of the top priorities by stroke survivors, carers and health care professionals[3].

Current evidence suggests that optimal rehabilitation of the arm after stroke requires doses of therapy above a certain threshold, with more than 20 hours being recommended[4]. To overcome the resource demands of these more intensive therapy programmes, self-directed interventions have been developed[5]. Despite improvements in arm impairment however, therapy driven practice does not necessarily lead to improved use of the arm outside of therapy sessions[6]. This may be due to a lack of integration between formal practice sessions and applying the movements to more context-specific tasks[6, 7]. Rehabilitation is likely to be more effective if the patient is encouraged to support their recovery by actively engaging the impaired arm within routine daily activities.

Accelerometers have become an increasingly popular means of monitoring and providing summary feedback on arm activity in stroke survivors outside of a clinical setting[8]. Data collected in this way have been reported to offer a better measure of how much stroke survivors are using their impaired arm than self-report or diaries[8-13]. Although the clinical application of this type of technology to support rehabilitation is still very much in its infancy, emerging literature is beginning to describe devices which not only measure activity

but also support motor recovery by providing feedback to the wearer [14, 15]. One such study provided visual feedback of arm activity following twice weekly uploads of accelerometer data[15]. Although participants reported that they thought they had used their impaired arm more, the accelerometer data did not show an actual increase in the amount of arm use[15]. In another study arm activity was measured by an actometer worn on the wrist which prompted arm movement with a vibration cue every five minute over a 3 hour period[16]. This study found that the sensory cueing led to more arm movements for the intervention group but there was no impact upon functional performance.

Both the aforementioned studies employed very different approaches to the type and frequency of the feedback being delivered, which may explain the disparity in outcomes. Despite strong evidence to support the use of extrinsic feedback in motor recovery, the effectiveness of different aspects of feedback, such as frequency of delivery, in stroke patients remains inconclusive[17-19]. There could be a number of reasons for this but it is likely that the varying degree of arm impairment between participants may require the delivery of feedback to be based on individual need[19] and that an increase in activity should reflect how the individual would have used the arm prior to the stroke.

In this study, a prototype wrist-worn tri-axial accelerometer device (the CueS wristband) was used with a vibration prompt to remind patients to use the impaired arm if activity levels fell below a pre-determined level[20]. A novel feature of the device is that the threshold and frequency of delivery of the prompt is tailored to the level of activity of the wearer at different times across the day and is reset every three days to reflect any changes in recovery. The technical feasibility of the CueS wristband has been reported elsewhere[20]. Following on

from this earlier proof of concept work, we aimed to assess the feasibility of a multi-centre, observer blind, randomised controlled trial (RCT) of the wristband to prompt independent practice of functional activity of the impaired arm during rehabilitation after stroke. Feasibility was operationalised as (1) the ability to recruit one patient per month from each study site up to a total of 60; (2) participant adherence to the programme (defined as wearing the wristband for >80% of recommended hours); (3) attrition of participants from each group; (4) the frequency of usual rehabilitation care received for the impaired arm during the study intervention period; (5) the success of outcome assessor blinding (measured by assessor self-report after the week 4 visit); (6) any serious adverse events (SAE); (7) completeness of clinical outcome data collection with summary statistics at baseline, four weeks and eight weeks and (8) the objective measurement of impaired arm activity at four and eight week outcomes.

Methods

The study was funded by a Stroke Association grant (TS 2014/01) with additional support from local National Health Service (NHS) Trusts including Northumbria Healthcare NHS Foundation Trust as sponsor. It ran for 17 months between May 2016 and September 2017. Ethical approval was granted by the National Health Service (NHS) Newcastle Central Research Ethics Committee (reference number 16/NEC/0063) and the trial was registered (Ref: ISRCTN82306027). The protocol with full details of the study design has been published elsewhere but is summarised briefly below [21].

This was a pragmatic, parallel group pilot randomised controlled trial with blinded outcome assessment. Patients between 24 hours and three months post stroke were identified by

occupational therapists, physiotherapists and local research support staff from four stroke services in North East England (Northumbria Healthcare NHS Foundation Trust, Gateshead Health NHS Foundation Trust, Newcastle upon Tyne NHS Foundation Trust and North Tees and Hartlepool NHS Foundation Trust). All study sites provided both in-patient and community therapy services and therefore the intervention was designed to be delivered whilst still an inpatient on the stroke unit, in the community or both, depending on when participants were recruited.

Inclusion criteria were: aged ≥18 years; any new arm impairment limiting functional use of the affected arm as a result of stroke but with the ability to lift the affected hand off their lap; judged to be able to follow the study intervention and to provide informed consent; living within the community team catchment area and expected to continue to receive at least twice weekly NHS therapy sessions for the duration of the intervention period. Patients were excluded if in the opinion of treating clinical therapists, cognitive or communication difficulties were likely to inhibit them from following the intervention or providing informed consent, or if they had any significant arm difficulties such as severe pain or fixed contractures that would restrict participation in the programme.

Potentially suitable participants were approached by local research support staff and provided with study information prior to written consent being obtained. To estimate identification rates, an estimate of the number of potential participants admitted to the four sites was calculated as a percentage of the total number of stroke patients admitted, based on clinical registry data from one site (A) of patients admitted with an upper limb impairment who did not have significant dysphasia.

Clinical data collected at baseline included: demographics; stroke details (time since onset; first ever or a recurrence; ischaemic or haemorrhagic aetiology) and hand dominance. The following outcome measurements were taken at baseline, immediately after the intervention at four weeks and again at eight weeks by trained research support staff blinded to randomisation group allocation: arm function (measured using the Action Research Arm Test (ARAT))[22], arm strength (measured using the arm section of the Motricity Index)[23], patient reported outcome of amount and quality of use of the arm in daily activities (measured using the Motor Activity Log)[24], National Institutes of Health Stroke Scale (NIHSS)[25], pre and post-stroke Barthel Activities of Daily Living Index[26], modified Rankin Scale [27], arm pain and overall fatigue (each measured using a numerical visual analogue scale, 0-10), and unilateral spatial neglect (measured by the Star Cancellation Test)[28].

Randomisation was conducted after completion of the baseline assessment. To ensure staff collecting study data remained blinded to group allocation, a member of the NHS therapy team contacted the co-ordinating centre at Newcastle University Stroke Research group to request randomisation. Participants were stratified according to study centre and randomised by an independent online database in a 1:1 ratio. Participants randomised to the intervention group received a CueS wristband with the prompting and visual feedback and those in the control group were provided with a 'sham' CueS wristband which still recorded activity but provided no feedback. It was expected that receiving regular activity prompts and visual feedback would lead to an increase in impaired arm activity for the intervention group.

To reduce control group expectations that prompts may occur, participants were provided with a general participant information sheet which did not describe the difference between to intervention and control group wristbands. After randomisation participants were informed that they had been allocated to either 'Group 1' or 'Group 2' and a group-specific 'Therapy Handbook' provided with details about what to expect from their wristband. Only the NHS occupational or physio therapists providing twice weekly reviews, and the co-ordinating centre staff were aware to which group participants had been allocated.

To prevent participants from inadvertently disclosing their group allocation to outcome assessors, they were requested not to discuss their experiences of wearing the wristband during these assessments. Following the four-week outcome assessment, assessors were asked to record whether they had unintentionally become aware of treatment allocation and, if so, to indicate which group they thought the participant had been allocated to. This information was recorded on the outcome assessment form.

Study Intervention

The study intervention consisted of wearing a wristband during a four-week therapy programme which was in addition to usual NHS therapy. Standard care varies according to individual patient need and local resources, but clinical guidelines recommend inpatients should receive a daily 45 minute therapy review which may reduce on discharge from hospital depending on local criteria[29]. To capture information about this variability, participants recorded the frequency of sessions spent treating their arm on a daily log sheet in their Therapy Handbook (see Appendix 1).

NHS occupational therapists and physiotherapists who were working with participants at the time guided them on the selection of appropriate ADL-orientated tasks or part tasks that they were able to safely do using the impaired arm and advised on how to build in repetitive practice where possible[30] (see Appendix 2). Participants recorded these study tasks on a 'Daily Activities List' in their Therapy Handbook and kept a record of which ones they had practised on the daily log sheet. Therapy Handbooks were returned to local research support staff at the end of the intervention period and the data entered onto an online database.

Participants were asked to wear the wristbands for 12 hours every day between 8am and 8pm. The wristbands (see Figure 1) contained an Axivity WAX9 tri-axial accelerometer (Axivity, Newcastle UK), sampling data at 100Hz per second with a dynamic range of ±8g (for technical data see www.axivity.com). At twice weekly therapy sessions NHS therapists connected the wristband to a tablet computer to download data and recharge the battery.

Once downloaded, participants in the intervention group viewed a visual display of their activity data with their NHS therapist and discussed their progress (see Figure 2). If activity levels were particularly low at set times of the day, therapists would suggest ways to incorporate additional arm activity e.g. using the impaired arm to turn pages of a magazine, use television controls, eat finger foods. Conversely, if excessive activity in the morning was resulting in fatigue, advice could be offered around pacing activities across the whole day.

A target amount of how much to increase their future arm activity by was then agreed using the previous three days' data as a baseline. This could be 5%, 10% or 20% above the median baseline or 0%, depending upon how much the participant chose to be challenged. Once

programmed, the wristband monitored activity on a minute by minute basis and alerted participants by a gentle vibration if activity levels fell below the agreed target over the previous 60 minutes.

Participants could monitor their progress throughout the day by tapping the watch to trigger LED lights indicating how close they were to meeting their activity target for that hour (Figure one). If prompted by the wristband, the wearer could choose to increase activity by selecting an activity from their daily activities list or alternatively just trying to engage their arm more in routine activities at the time.

The control group received the same arm therapy programme as the intervention group with two differences: 1) when the accelerometer data were downloaded they were hidden from view of both the NHS therapist and the participant; 2) their wristbands were not set to prompt the wearer and the LED lights only provided information of battery life status. Thus the control group had no additional feedback to support them in remembering to use their arm throughout the day.

A standard accelerometer was given to each participant and used to capture arm activity across three days at the week 4 and week 8 outcome measures. These were returned by the participant in a pre-paid envelope. The feasibility of this approach was reflected by the number of days of data collected at each time-point. The activity data stored will be reported elsewhere.

Statistical analysis

As this was a pilot study, it was not powered to detect clinically important changes between the groups and therefore comparative statistics are not reported.

Descriptive statistics were analysed using SPSS software (IBM Corp., Released 2013, IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY). Nominal and ordinal data are reported as a number and percentage. Continuous variables are reported as mean and standard deviation (SD) except where the distribution was skewed, in which case they are reported as median and interquartile range [IQR].

Results

A total of 1270 stroke patients were admitted across the four sites during the recruitment period. Based on clinical registry data from site A, approximately 46.2% percent were admitted with an upper limb impairment which was reduced to 36.8% when those with significant dysphasia were removed. Although only 33 of the anticipated 60 participants were recruited, two sites achieved the target of recruiting one participant per site per month and there were times during the study when the other two sites also managed this. There was an average recruitment rate of 0.6 per month per site. Difficulties with the availability of local research support staff to recruit and NHS therapists to review participants every three-four days, impeded recruitment. The contribution of participants towards the study is shown in Figure 3.

The baseline characteristics of participants in each randomisation group is shown in Table 1. Baseline characteristics indicated that stroke severity was similar across randomisation groups but that there was some disparity between the groups for arm function.

Participants' adherence to wearing the wristbands is shown in Table 3. The median number of days that the wristband was worn by the control group was 18.5[IQR: 8.0 - 23.5] and 25.0[IQR: 21.8 - 28.0] for the intervention group A number of technical issues with the devices meant that for 134 days across the study a working wristband was not available. Only seven days of data was lost due to participants not wearing the wristband. On the days when wristband wear was possible, they were worn for 79% of the recommended time per day between the hours of 8am and 8pm. The accelerometer data showed that some participants did not don the wristband until later in the morning which impacted on their overall wear time. This may have been out of their control if they required assistance.

During therapy reviews, NHS therapists viewed the activity data with the intervention participants and asked how they had responded to receiving a prompt. Participants reported practising the activities from their Daily Activities List (43% of responses), practising their own self-chosen activity at the time (38% of responses) or ignoring the prompt (17% of responses).

When adjusting the frequency of the prompt delivery, participants showed a preference for hourly prompt settings on nearly all occasions. Greater variability was seen when adjusting the threshold setting for the activity target. The preferred option, selected 35 / 67 times (52%), was for 10% above the median baseline activity level. The lowest setting (5% above baseline) was selected 18 times (27%) and the neutral and high settings seven times each (10%). The total number of prompts received across the study was 2273 with a median of 8 [IQR: 6-10] prompts being delivered to each participant per day.

Participants kept a daily log of which study programme activities they had carried out from the Daily Activities List generated during therapy review sessions. For the intervention group a median of 8 [IQR: 6, 11] different activities were practised each day with a maximum of 20 and minimum of 1 practised on some days. For the control group a median of 10 [IQR: 6-14] activities were practised with a maximum of 24 and minimum of 1.

The number of therapy review sessions participants received was a median of 7.5 [IQR: 6.8-8.0] for the intervention group and 6.0 [IQR: 4.3-8.0] for control group. Reasons for receiving less than the anticipated seven reviews were largely related to staffing issues such as part-time NHS therapists being unable to commit to two sessions per week.

Twenty-two participants recorded their usual care sessions on the daily log sheets with a total of 257 recorded sessions giving a median of 10 [IQR: 6, 18] sessions per participant. Four participants had not recorded usual care sessions in their log sheets, and five participants did not return their handbooks.

Outcome assessors remained blinded to group allocation for 27 / 28 participants up to the four week outcome assessments (96%).

Eight SAEs were reported although none were related to the study. There were no concerns that the intervention had caused an increase in pain or fatigue.

Clinical outcome measures with completeness of clinical outcome data are shown in Table 2. Excluding patients who had withdrawn or died, outcome assessments were completed for 28/29 participants at four weeks and 25/ 28 participants at eight weeks. Two participants (one from each group) were unable to complete the baseline Star Cancellation Test due to inability to understand the instructions. The four week NIHSS score was missing for one participant due to assessor error. One participant was bedbound and too unwell to sit up to complete the four week ARAT. One participant declined the Motor Activity Log at four weeks and the ARAT at both four weeks and eight weeks.

The median ARAT scores for both groups showed an improvement during the four-week study intervention phase with the intervention group continuing to improve up to the eight week follow-up outcome. The amount of use of the impaired arm as measured by the Motor Activity Log and the accelerometers also indicated an increase for both groups, which continued up to the week eight outcome for the intervention group but not for the control group.

The number of days of accelerometer data collected at the four and eight week outcomes are shown in Table 3. All returned wristbands had been worn for the required 3 days at each outcome. At the four week outcome, one participant declined to wear a device and one device was lost as the participant had died. Two other device were not returned (intervention group n= 1). At eight week, the same participant as in week four declined to wear a device and two were not returned.

Discussion

The results from this feasibility study suggest that a multi-centre, observer blind, randomised controlled trial of a wristband accelerometer to prompt independent practice of functional activity of the impaired arm after stroke is possible, although difficulty recruiting the pre-specified number of participants would need to be addressed prior to a larger clinical trial of efficacy.

The overall recruitment was 3% of the estimated number of potential participants which is in line with similar studies[30, 31] and the agreed target rate of one participant per month was achieved by all sites at different time-points. Recruitment fluctuated due to the availability of local research support staff for identification and NHS therapists for providing twice weekly reviews. Funding limitations prevented a screening log from being recorded and so the number of potential participants was estimated instead. This was a weakness of the study as there was no record of specific reasons why participants were not recruited into the study..

As a feasibility study, we purposely kept the inclusion criteria broad to ensure that a wide range of patients would be eligible and relied upon local staff to identify potential participants. Whilst clinicians may be best qualified to select appropriate participants for research, their professional relationship with the patient and personal views about the intervention can influence their decision on whether or not an individual might "benefit".[32] This may have resulted in potential participants not being invited.

The time commitment from therapists for performing study reviews and data download may also have contributed to the low recruitment rates. This was estimated at 15 minutes twice a week to be done within usual care sessions. However, difficulties were reported in providing

twice weekly sessions within usual care particularly once patients had been discharged from hospital when travel time to participants' homes became an additional time factor. Regular upper limb therapy at some sites would normally be delivered by support staff/assistants. The requirement therefore to deliver the study intervention by a qualified therapist will have impacted on the workload for that therapist. In designing a future clinical efficacy study, consideration should be given to how the intervention can be delivered without increasing the amount of therapist involvement. One study, for example, is exploring the use of a similar device with chronic stroke patients using a mobile phone to Bluetooth the movement data straight to a phone app where the patient interprets the data independently of a therapist.[14]

A strength of this study was the high retention of participants particularly in the intervention group. Only one participant who was receiving the prompting feedback withdrew which was for reasons unrelated to the intervention itself. It is important to note that three participants withdrew from the control group early after recruitment. This level of loss of primary outcome data would need to be factored into a later clinical trial.

The novel features of the CueS wristband enabled therapists to personalise the prompting mechanism for each patient in order to better support the wide variability of stroke patients' abilities. As in our previous study, participants showed a preference for choosing a regular hourly prompting schedule[20]. However, when setting the threshold they opted for a slightly higher target of activity than previously, choosing the medium level of 10% above their new baseline activity level for each hour. This may explain the higher number of prompts being delivered to patients than our previous study with some being prompted every hour[20]. Whether this is an indication that the prompt threshold was set too high or whether it is an

indication that patients preferred and benefitted from receiving more frequent reminders to use their arm is yet unclear. A frequent prompt reminder did not appear to deter continuing wear, and there was often documentation of an activity response. Further evaluation of the benefits of receiving frequent feedback is required whilst also considering the possibility of participants habituating to prompts. This would be an area for further consideration in a future study.

Frequent use of the impaired arm in normal daily routines naturally opens up opportunities to increase the type of practice that involves variability of the task, random task practice and distributed practice – all of which are well documented for improving motor learning[33, 34]. Following the four week therapy programme, both groups showed longitudinal improvements in arm function and amount of use in daily activities. It was noted that participants in the intervention group continued to improve past the point where the therapy programme stopped and the wristband was removed. Due to the small sample size, one cannot conclude that this was an effect of the intervention. Additionally, a confounding factor was the difference in ARAT scores at baseline, with the intervention group having a higher median score than the control group, reflecting better arm function. Furthermore difficulties in interpreting the ARAT outcomes occurred from some participants already meeting the maximum score of 57 at baseline therefore being unable to show further improvements on this scale. We specifically avoided using a cut-off score on the ARAT as we were keen to include those participants with a high score but with reduced arm function because of other impairments.

Whilst wrist-worn accelerometers have been validated as a reliable tool to measure arm activity, it is important to recognise that the data collected may not simply reflect purposeful

arm movement but also arm swing through walking. Based upon previous studies, we assumed that due to the sedentary nature of stroke patients, diurnal walking activity would only change gradually[35] and that gains in mobility are likely to reflect increasing opportunities for arm use[36]. Future research should include additional activity recordings, such as accelerometer data from the unimpaired arm and/or leg, to confirm the relationship between prompts, functional arm use and walking.

The size of a future clinical efficacy study can be estimated from our results. As the intervention purpose is to increase arm use rather than recover fine motor skills, we have chosen the Motor Activity Log (Amount of Use Scale) as the primary outcome measure. Based on a previously reported minimal detectable change of 1 point[37] and data from this study (a standard deviation between baseline and eight weeks of 1.2 points), 108 participants would be required to detect a clinically important effect with a power of 90% in a two-arm trial with attrition of 12%.

Future research should also consider optimal timing of the intervention, and the requirement for therapist supervision. Previous trials of self-directed interventions have shown that there are benefits beyond the early rehabilitation stage[38] and it is possible that stroke survivors may benefit more from using wearable monitors to encourage self-directed activity at a later stage. There is often a reduction in usual care as the rate of arm motor function improvement slows down and this may be the point when patients have more time, energy and ability to take on more responsibility for their recovery. This approach is also likely to improve study recruitment as guaranteed continuity of clinical care would not be needed. A longer period of

use with a matching follow up interval would also be required to consider habituation and sustainability[17].

In conclusion, a multi-centre, observer blind, randomised controlled trial of the CueS wristband to prompt independent practice of functional activity of the impaired arm during rehabilitation early after stroke is feasible. There was a high level of adherence and no evidence of safety concerns. A future clinical efficacy study would have an achievable sample size but sufficient research and clinical support would be needed according to the degree of patient self-direction. Recruitment rates may be improved by further development of the technology to include interfaces which are easy to use and interpret without additional therapist involvement.

Clinical Messages

- Daily feedback from a wristband accelerometer to prompt greater use and independent practice of the impaired arm after stroke is feasible when integrated into a four week therapy programme.
- A multi-centre, observer blind RCT of the intervention is feasible and would require a total sample size of 108 participants.

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Competing interests

None declared

Contributors

R Da Silva was responsible for writing the paper and making amendments to draft articles following review, developing the therapy intervention, writing the study protocol, co-ordinating the day-today running of the study and analysis and interpretation of the data.

C Price was involved in initiating and designing the study, overseeing the running of the study, analysis and interpretation of the data, and reviewing the draft article.

H Rodgers, L Shaw and F van Wijck were involved in initiating and designing the study, monitoring progress and reviewing the draft article.

S Moore was involved in the study set-up and writing the study protocol and reviewing draft article

L Sutcliffe was involved in data monitoring and reviewing the draft article.

Table 1 – Baseline Characteristics

	Intervention group N=14	Control Group N=19
Gender Male n (%)	6 (43%)	7 (37%)
Age Median [IQR] years	73 [65-80]	69 [61-80]
Pre-stroke Barthel Range 0-20	20 [20-20]	20 [20-20]
Stroke type Infarct / Haemorrhage	13 / 1	18 / 1
Stroke sub-type n (%) TACS PACS LACS POCS Uncertain	 4 (28.6%) 4 (28.6% 5 (35.7%) 1 (7.1%) 0 (0%)	 5 (26.3%) 5 (26.3%) 7 (36.8%) 1 (5.2%) 1 (5.2%)
First ever stroke	12	15
Time from stroke to consent Median [IQR] days	27 [13-48]	26 [18-33]
NIHSS score (Range 0-42, no symptoms – severe impairment) Median [IQR]	4 [3-5]	5 [3-7]

Abbreviations: IQR, Interquartile range; TACS, Total anterior circulation stroke; PACS, partial anterior circulation stroke; LACS, lacunar stroke; POCS, posterior circulation stroke; NIHSS, National institutes of health stroke scale

Table 2 Clinical outcomes

	Intervention			Control		
	Baseline N=14	4 weeks N=12	8 weeks N=11	Baseline N=19	4 weeks N=15	8 weeks N=14
ARAT[22] (Range 0-57: no function – normal function)						
Median [IQR]	37 [16-46]	57 [29-57]	57 [37-57]	15 [2-35]	35[15-56]	31 [21-55]
Missing data					2	1
Motor Activity Log[24] (Range 0-5: not used - normal use)						
Amount of Use Median [IQR]	1.4 [0.5-2.6]	3.8 [1.9-4.5]	3.7 [2.1-4.3]	0.2 [0.0-1.2]	1.1 [0.3-2.9]	1.2 [0.7-2.9]
How well Median [IQR]	1.5 [0.7-2.4]	3.4 [1.6-3.9]	3.6 [2.2-3.9]	0.3 [0.1-1.0]	1.3 [0.3-2.2]	1.3 [0.5-2.8]
Missing data					1	
Motricity Index[23] (Range 0-100: no movement – normal power)						
Median [IQR]	77 [54-84]	92 [77-100]	93 [77-100]	51 [38-70]	79 [54-88]	75 [50-93]
Pain numeric rating scale (Range 0-10: no pain – worst pain ever)						
Median [IQR]	0 [0-3]	0 [0-4]	0 [0-5]	0 [0-4]	1 [0-8]	5 [0-8]
Fatigue numeric rating scale (Range 0-10: not tired at all – extremely tired)						
Median [IQR]	6 [5-7]	5 [2-5]	5 [2-5]	7 [5-9]	5 [5-8]	7 [5-8]
Star cancellation[28] (Range 0-54: ≤44 indicates spatial neglect)						
Median [IQR]	53 [51-54]	54 [53-54]	54 [51-54]	52 [48-54]	53 [51-54]	54 [51-54]
Missing data	1			1		
NIHSS[25] score (Range 0-42, no symptoms – severe impairment)						
Median [IQR]	4 [3-5]	2 [1-4]	1 [1-3]	5[3-7]	4 [1-5]	3 [1-4]
Missing data					1	
Modified Rankin Scale[27] (Range: 0-2 = Good outcome; 3-5 = poor outcome)						
0-2 (n=)	3	7	7	6	6	4
3-5 (n=)	11	5	4	13	10	10
Barthel Index[26] (Range: 0-20, unable to do – independent)						
Median [IQR]	15 [10-18]	19 [16-19]	19 [17-20]	12 [10-16]	17 [12-19]	15 [15-18]

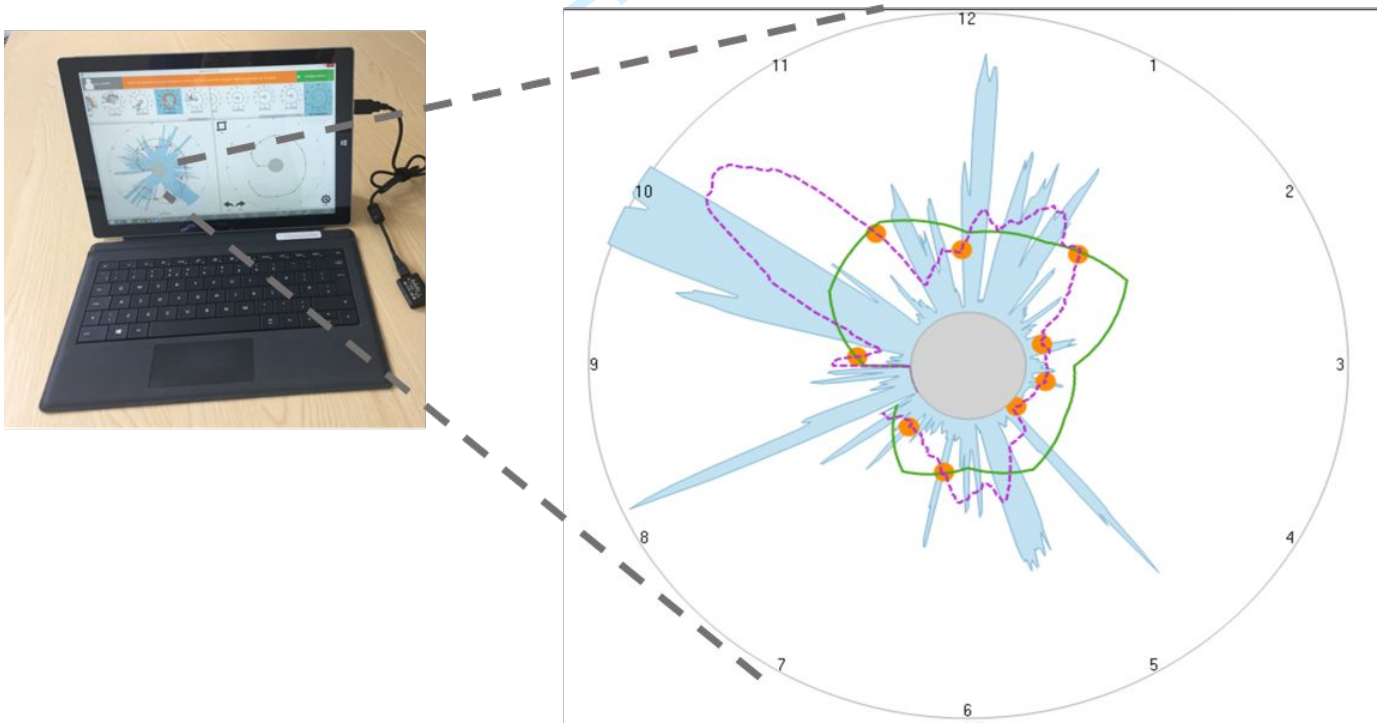
Abbreviations: ARAT, Action Research Arm Test; IQR, Interquartile range; NIHSS, National institutes of health stroke scale

Table 3: Adherence to wearing CueS wristband and outcome accelerometers

	Number of days CueS wristband worn				Number of days of outcome data collected	
	Days data collection possible	Days working wristband worn	Days working Wristband not worn	Days without working wristband	Week 4	Week 8
Intervention N=14	389	367	1	21	33 / 36	33 / 33
Control N=19	462	343	6	113	39 / 48	33 / 42
Total number of days across study	851	710	7	134	72 / 84	66 / 72

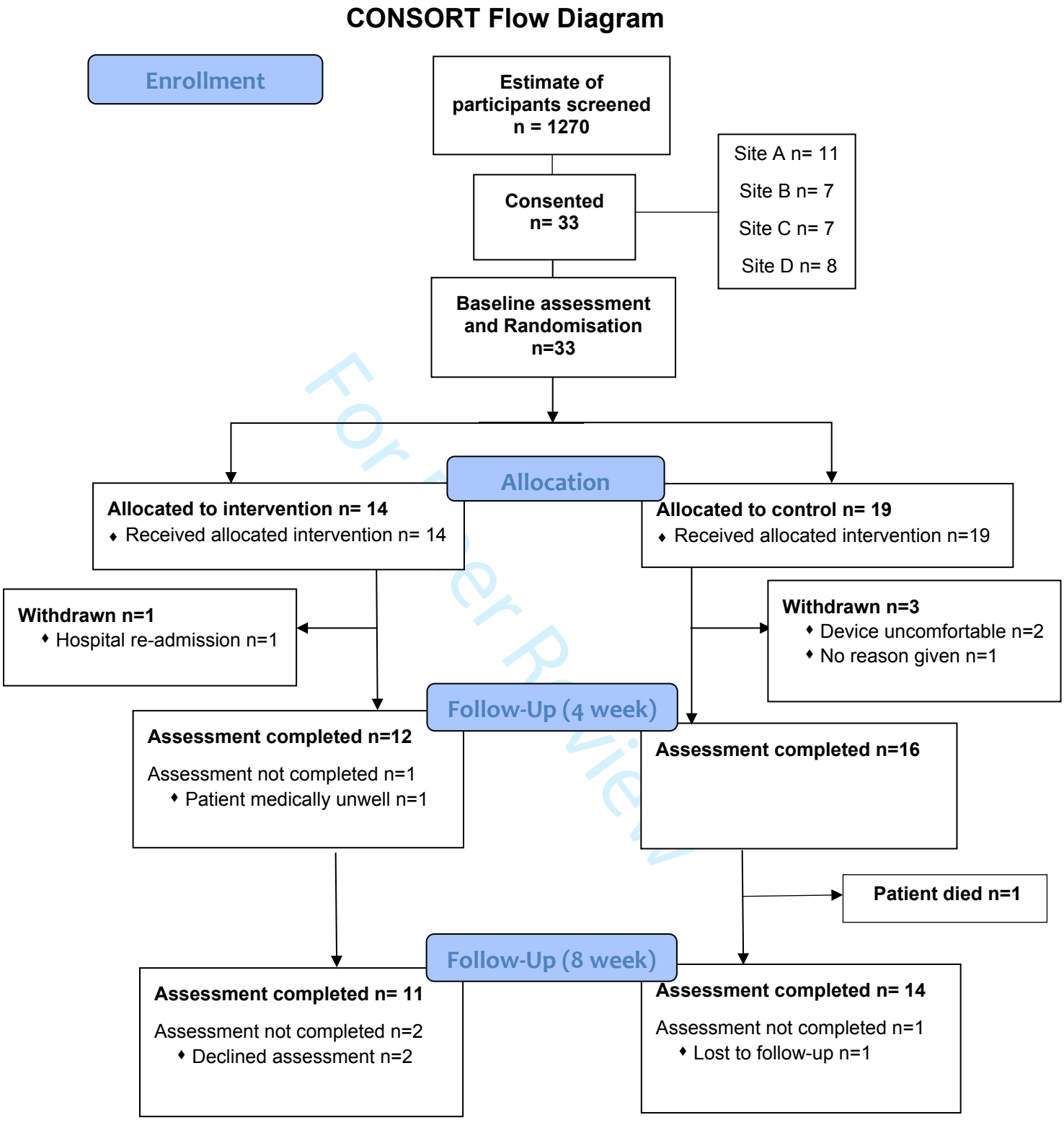
Figure 1: CueS wristband

Figure 2: Display of data



Key: Shaded area represents arm activity between 8am and 8pm; solid green line represents the target threshold and is variable across the day according to participant's routines; orange dots indicate when a vibration prompt was delivered; dashed magenta line is the movement average taken in a window size of 120 minutes.

Figure 3



Appendix 1: Daily log sheet

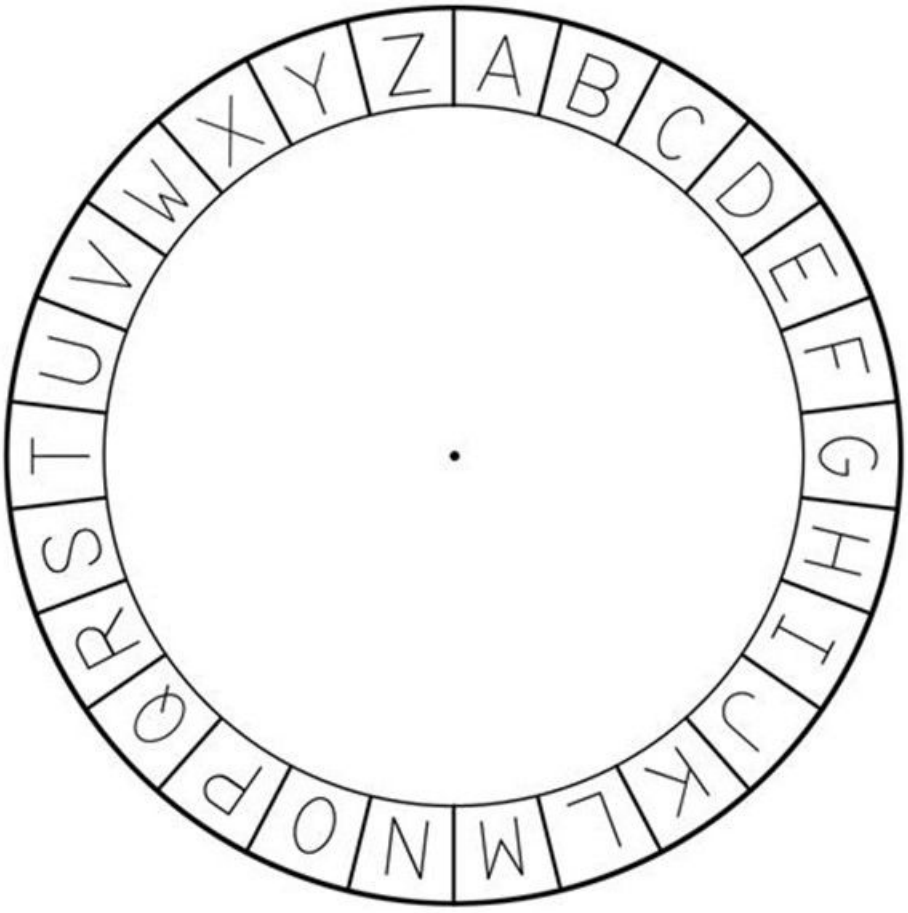
WAVES Study	Participant Number ☐ ☐ ☐	_____Day: ____/____/201_____

Daily Log Sheet

Remember: the aim of the programme is to use your stroke hand as much as possible. Use the activity list for ideas of what you could do using your stroke hand. The Cues wristband will help to ensure that you are doing enough.

At the end of each day, cross out the letters which corresponds with the activities you have practised.

Today I practised the following activities:



Total number of activities practised today: ☐

Did you receive any therapy on your arm today? Yes ☐ No ☐

Appendix 2 – Sample of Daily Activities List

WAVES Study	Participant Number XXXXXX	Start Date: XXXXX

DAILY ACTIVITIES LIST

The aim of the WAVES study is to increase the amount you use your stroke arm in your normal daily routines because this will help the arm to recover more quickly.

Use this form to make a list of some of the activities you think you would be able to carry out using your stroke hand. Start with around 5 activities and add to the list as you feel able to do more activities.

To make your list it may help to think through your normal daily routine, hour by hour or to go around each room in your house to generate ideas of things you could practise in each room.

The Cues wristband will let you know how much activity your arm has been involved in as the day goes on and will vibrate to remind you to use your arm if activity levels drop.

At the end of each day record on the Daily log sheet which activities you did for that day.

Examples of activities:

- turning the pages of the newspaper over
- drying up the plates
- feeding myself toast
- holding an apple while I eat it
- stroking the dog

With my stroke arm I would like to practise:	
A	Positioning hand where able to see it
B	Holding objects while left hand does activity.
C	Reach for bottle with stretch at elbow bring closer.
D	Wipe down benches
E	Wash up left arm to shoulder.
F	have lunch
G	take tissue out of box
H	zip slipper up

20 reps +2 daily

Daily Activity List (WAVES) Version 1.0 26 January 2016

WAVES Study	Participant Number XXXXX	Start Date: _____

When prompted to use my arm I would like to practise:	
I	hold Book
J	Squeeze toothpaste.
K	Apply deodorant.
L	Pull clothes up
M	tip medication out of blister pack, into plastic dish
N	make pastry : mince pies.
O	wash under arms.
P	use door handle
Q	pick phone up & hold phone while putting charger in with other hand.
R	turn TV on / skip channels with right hand (remote control)
S	peg squeezing
T	picking items off floor (in sitting)
U	Hand upto hair.
V	Put slide in - try.
W	Scones
X	Grate cheese
Y	
Z	

At the end of each day, mark off the corresponding letter to each activity you have completed on your daily log sheet. You can add activities to the list whenever you like and discuss them with your therapists.

Daily Activity List (WAVES) Version 1.0 26 January 2016

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