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Title: Feedback device for improvement of coordination of reach-to-grasp following stroke

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Keywords: Stroke, Physical Therapy, Feedback, Equipment and Supplies

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Abstract:
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8th July, 2011

Dear Dr Rogers,

This is a resubmission of a manuscript with the title '**Feedback device for improvement of coordination of reach-to-grasp following stroke',** manuscript number ARCHIVES-PMR-D-11-00621.

Thank you for your email requesting minor revision of this Brief Report. The required changes have now been made to the manuscript, and a separate document itemising the response to each reviewer comment has been attached.

Changes to the manuscript have been highlighted in yellow.

Many thanks for your further consideration of this manuscript.

Yours sincerely

Paulette van Vliet

*Detailed Response to Reviewers

Ms. Ref. No.: ARCHIVES-PMR-D-11-00621

Title: Feedback device for improvement of coordination of reach-to-grasp following stroke

Archives of Physical Medicine and Rehabilitation

<u>Itemised Responses to reviewer comments</u>

Reviewer Comment	**Response**
ABSTRACT Better wording: "A multiple baseline design across six subjects was used, with each subject performing forty repetitions of reaching to grasp a jar." Two subjects each performed 10, 15, or 20 randomly assigned baseline repetitions."	Design section of abstract has been changed to : "A multiple baseline design across six subjects was used, with each subject performing forty repetitions of reaching to grasp a jar. Two subjects each performed 10, 15, or 20 randomly assigned baseline repetitions."
INTRODUCTION Line 25..preliminary multiple baseline design across six subjects to assess.. Line 66..the following multiple baseline design.	Line 25 is now line 86 and has been changed to: " ..to report the results of a preliminary multiple baseline design across six subjects to assess the utility of the device.." Line 66 is now line 127 and has been changed to: "..the following multiple baseline design."
METHODS 69 DELETE	Line 69 is now line 130 and heading 'SINGLE CASE STUDIES' deleted.
94 A multiple baseline design across six subjects was conducted with each subject completing 40 trials.	Line 94 is now line 155 and is changed to: "A multiple baseline design across six subjects was conducted with each subject completing 40 trials."
96-97 A multiple baseline approach was used to decrease.	Line 96-97, now line 157-158 is changed to: "A multiple baseline approach was used to decrease.."
RESULTS Please add "levels" to Figure 1.	A line for each "level" (mean) in each phase has been added to Figure 1.

DISCUSSION DISCUSSION is true to the RESULTS Because the changes are in milliseconds, the authors need to address the "so what" question. Are the changes "functional" and "meaningful" ?	The following has been inserted into the discussion, lines 246-249. “The improved temporal coordination in participants 2, 5 and 6 indicates that this aspect of the motor control of reach to grasp was executed in a more normal way. This is a meaningful change, as improvements in motor control are likely to lead to improved arm function.”
DISCUSSION Study limitations: Following resubmission of the manuscript, the editorial office suggested adding a ‘study limitations’ subheading, and some wording about limitations.	Lines 250-254 of the discussion have been changed to: “These preliminary findings provide valuable data on the utility of our prototype. **Study limitations** Due to the small sample size, the results cannot be generalised to a wider population. The next step will be a controlled clinical trial with a larger group, to test whether GRASP as an adjunct to reach-to-grasp training yields better outcomes than reach-to-grasp training alone.”

***Title page with author details**

Running Head: Feedback device for arm movements in stroke

Title Page

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Figures: 2

Tables: 1

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We certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization with which we are associated AND, if applicable, we certify that all financial and material support for this research (eg, NIH or NHS grants) and work are clearly identified in the title page of the manuscript.

The device(s) that is/are the subject of this manuscript is/are not FDA-approved and is/are not commercially available in the United States.

The work described in this manuscript was supported by a Spinner Pathfinder grant.

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Following stroke, only 20% to 56% [1] of people regain useful upper limb function after three months. New technologies to assist more people to regain useful arm movement would therefore have major benefits. An important motor impairment resulting from stroke is a lack of coordination between arm and hand [2,3]. This brief report evaluates a feedback device that can be used to improve the coordination of arm and hand at the beginning of a reach-to-grasp movement.

In the reach-to-grasp of healthy subjects, an invariant temporal relationship exists between transport and grasp components [4]. The start time of the hand opening is correlated with the start of hand movement towards the object, and the time of maximum hand opening is correlated with the time of peak deceleration of the hand [4]. Stroke [3,5], especially involving the middle cerebral artery (MCA) [2] can cause difficulties with this temporal coordination.

Feedback about the time between the start of hand opening and the start of transport could be used to direct the participant's efforts to timing these events to start together, thereby inducing a more normal temporal coordination of reach-to-grasp. Currently no feedback devices perform this function for reach-to-grasp, though feedback devices can improve performance of other body movements [6].

This report aims to (a) describe a device called 'GRASP' – 'grasp rehabilitation accessory for stroke participants'- that gives feedback to both participant and therapist about the time lag between the start of hand opening and the start of the transport and (b) to report the results of a preliminary multiple baseline design across six subjects to assess the utility of the device for improving the coordination of arm and hand at the beginning of a reach-to-grasp movement, in people with lesions of MCA.

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The device (Figure 1) comprises (1) sensors to detect the start of both hand opening and hand transport; (2) a timer measuring the time elapsed between these events; and (3) a user interface communicating the lapsed time.

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The two electrodes and wristband are connected by leads to the control unit. The thumb electrode is a copper ring with an insulated plastic inner surface. Several sizes are available to comfortably fit over an adult thumb. The wrist electrode comprises a circular stainless steel base plate of a size to accommodate an adult user's wrist and hand when in a loose fist. The wristband is an elasticised bracelet of the type used widely in the electronics industry as a static grounding system. The materials are stainless steel and plastic and can be cleaned with alcohol or soapy water. Any danger of electric shock is removed by using a low and isolated internal source voltage (12 V) complying with SELV as defined by IEE Regulations – 16 Edition. Such voltages are considered universally hazard free. A patent application, containing further details, has been published [7].

Communication of the lapsed time enables instant feedback on the correlation of the two events and therefore on their coordination at the start of the movement. It also allows successive movements to be compared and the temporal order of the movements to be seen, i.e. whether the hand opened or moved forward first.

Preliminary data of the utility of the device was collected within the following multiple baseline design.

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Stroke participants were recruited consecutively from physiotherapy outpatient departments. Testing took place at the participants' location - inpatient or outpatient physiotherapy department, or at home. The local Research Ethics Committee and Medicines and Healthcare products Regulatory Agency approved all procedures. Inclusion criteria were: MCA or parietal stroke, a score of 5 or more on the arm section of the Rivermead Motor Assessment (Reach forward, pick up large ball with both hands and place down again) and ‘time between start of hand opening and start of hand transport > 60 ms’ (exceeds normal limits). Exclusion criteria were: cognitive dysfunction which prevented understanding of the task, severe concurrent medical problems that prevent repetitive reaching (including shoulder pain), lack of informed consent. Six stroke participants took part consisting of 2 women and 4 men, with a mean age of 48.2 years (SD 14.6) and time since event causing brain damage was 22.1 months (SD 19.2). None had receptive but two had expressive communication difficulties. Participant characteristics are shown in Table 1. In summary, none had receptive or expressive communication difficulties, the group had a moderate degree of arm impairment, minor increases in muscle tone apart from participant 6, minor proprioception loss except for participant 3, minimal presence of neglect, optic ataxia, and impairments of spatial perception.

Design

A multiple baseline design across six subjects was conducted with each subject completing 40 trials. An AB design was used because the participants’ performance was not expected to revert to baseline after withdrawal of the intervention. A multiple baseline approach was used to decrease the likelihood of extraneous variables causing a change from baseline to intervention phase – an effect would be demonstrated if the measure changed only when the intervention is introduced. The baseline phase consisted of a randomly assigned length of 10, 15 or 20 repetitions, two participants performing each length. This was followed by a series of intervention trials, numbering 30, 25 or 20 trials, depending on the number of repetitions in the baseline phase.

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Two research physiotherapists not involved with the design of GRASP conducted these studies. Participants reached to grasp a glass jar (height 92mm, diameter 70 mm, weight 230g) , placed 30 cm anterior to the starting position of the hand, and moved it onto a round mat (14 cm diameter) on the table, placed closer to the body (5 cm in front of start position). The hand started directly in front of the elbow, with the jar directly ahead of the hand so that no change in shoulder rotation was required to grasp the jar. At the start, the finger was touching the thumb sensor, the forearm was in mid-pronation, the elbow was at 100 degrees flexion, and the wrist rested on the metal plate, positioned along the edge of the table. The other arm rested in the participant's lap. Instructions were "reach forward, pick up the jar, and place it on the mat".

During baseline, the device was attached and performance was recorded but no feedback was given. During the intervention phase, feedback was given. The following instructions ensued at the beginning of the intervention phase:

"When reaching to grasp an object, the start of your hand opening and the start of your arm movement forwards , usually occur at the same time, i.e. they are synchronised.

Some people with stroke have difficulty with this synchronisation. This machine is designed to give you feedback to make these two events more synchronised. The display will tell you the time, in number of milliseconds, between the two events. Your aim is to try to make this number as small as possible, by thinking about making the start of the hand opening and the start of arm movement forward, happen at the same time".

Then the required number of trials was performed for the intervention phase. After each trial, the participant observed the result shown on the display, which indicated the time between the start of hand transport and start of grasp, in milliseconds, and which of these components started first.

Data analysis

The outcome measure was the time between start of hand transport and start of grasp (time lag), measured in milliseconds by GRASP. This was recorded for each of the 40 trials of each of the participants and depicted graphically for visual inspection (Figure 2). Mean time lag in each of the baseline and intervention phases were calculated. To determine whether there was a significant difference between time lag results during baseline and intervention phases, the two-standard deviation band method, described by Nourbaksh and Ottenbacher (1994) [8] was used. Following the method as described by Nourbaksh and Ottenbacher, the standard deviation is computed for the baseline data, then bands are drawn on the graph that contain scores within ± 2 standard deviations from the mean. A significant difference is considered to have occurred if 'at least two successive data points in the intervention phase fall outside the two-standard deviation band'[8]. This procedure has the advantage of 'being sensitive to changes in the variability across phases of a single-subject design' [8].

RESULTS

Visual inspection of results

Results are shown graphically in Figure 2. On visual inspection, participant 3 showed an increasing time lag during Phase A, the baseline, followed by a decreasing time lag during Phase B, the intervention. The remaining five participants demonstrated a decreasing time lag already during Phase A, the baseline phase. The time lag of participants 2 and 5 continued to decrease in the intervention phase. For participants 1 and 4 however, there was a trend towards increasing the time lag in the intervention phase. Participant 5 demonstrated an uncharacteristically large time lag on the second trial of the baseline phase (5559 ms). This value was atypical as all other values for other subjects were below 1410ms. "

Statistical analysis

All participants decreased the mean time lag during intervention compared to baseline (Figure 2). Mean decreases in time lag between phases within each participant were, for participants 1 through to 6 respectively: 35, 296, 34, 34, 1212 and 114 milliseconds. Participants 2 and 6 showed a significant decrease of time lag in the intervention compared to the baseline phase, using the two-standard deviation band method. Participant 5 did not show a significant decrease of time lag in the intervention compared to the baseline phase, when the atypical value was included. However, we hypothesised that the reason for this atypical value which occurred on only the second trial, was that this participant's performance was initially affected by a lack of familiarity with the task and the device and for this reason the analysis was repeated with this value was removed from the analysis, leaving 9 baseline trials instead of 10. In this case, there was a significant decrease of time lag in the intervention compared to the baseline phase. Participants 1, 3 and 6 did not show a significant difference between the phases.

INSERT FIGURE 2 ABOUT HERE

DISCUSSION

Several participants were able to use the feedback to continue to significantly reduce the time lag between the start of transport and the start of grasp and there was a reduction in mean time lag in the intervention phase compared to the baseline phase for all participants. Thus GRASP could act as a useful adjunct to current physiotherapy intervention for coordination. Participants 2, 5 and 6 benefited most and two of these (2 and 6) were earlier after stroke and with less motor impairment than other participants, so GRASP may be of greater benefit to people in this group. However, three of these participants did not show that GRASP demonstrated an additional effect to that of practising the task.

The improved temporal coordination in participants 2, 5 and 6 indicates that this aspect of the motor control of reach to grasp was executed in a more normal way. This is a meaningful change, as improvements in motor control are likely to lead to improved arm function. These preliminary findings provide valuable data on the utility of our prototype.

Study limitations

Due to the small sample size, the results cannot be generalised to a wider population. The next step will be a controlled clinical trial with a larger group, to test whether GRASP as an adjunct to reach-to-grasp training yields better outcomes than reach-to-grasp training alone.

CONCLUSION

This preliminary investigation of GRASP indicates that it is potentially beneficial as an adjunct to physiotherapy training of reach-to-grasp function after stroke.

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Figure 1 GRASP ready to record a reaching movement

Figure 2. Results for baseline (Phase A) and intervention phase (Phase B) for participants 1 to 6. The vertical line denotes the start of phase B. Trial number is shown on the horizontal axis and time between start of hand transport and start of grasp (ms) is shown on the vertical axis. Mean time lag values are shown for each phase. The 2 standard deviation bands above and below the mean are also indicated. Negative standard deviation bands are not shown as there were no negative values. Mean levels are also shown by horizontal lines in each phase.

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Results are shown graphically in Figure 2. On visual inspection, participant 3 showed an increasing time lag during Phase A, the baseline, followed by a decreasing time lag during Phase B, the intervention. The remaining five participants demonstrated a decreasing time lag already during Phase A, the baseline phase. The time lag of participants 2 and 5 continued to decrease in the intervention phase. For participants 1 and 4 however, there was a trend towards increasing the time lag in the intervention phase. Participant 5 demonstrated an uncharacteristically large time lag on the second trial of the baseline phase (5559 ms). This value was atypical as all other values for other subjects were below 1410ms. "

Statistical analysis

All participants decreased the mean time lag during intervention compared to baseline (Figure 2). Mean decreases in time lag between phases within each participant were, for participants 1 through to 6 respectively: 35, 296, 34, 34, 1212 and 114 milliseconds. Participants 2 and 6 showed a significant decrease of time lag in the intervention compared to the baseline phase, using the two-standard deviation band method. Participant 5 did not show a significant decrease of time lag in the intervention compared to the baseline phase, when the atypical value was included. However, we hypothesised that the reason for this atypical value which occurred on only the second trial, was that this participant's performance was initially affected by a lack of familiarity with the task and the device and for this reason the analysis was repeated with this value was removed from the analysis, leaving 9 baseline trials instead of 10. In this case, there was a significant decrease of time lag in the intervention compared to the baseline phase. Participants 1, 3 and 6 did not show a significant difference between the phases.

INSERT FIGURE 2 ABOUT HERE

DISCUSSION

Several participants were able to use the feedback to continue to significantly reduce the time lag between the start of transport and the start of grasp and there was a reduction in mean time lag in the intervention phase compared to the baseline phase for all participants. Thus GRASP could act as a useful adjunct to current physiotherapy intervention for coordination. Participants 2, 5 and 6 benefited most and two of these (2 and 6) were earlier after stroke and with less motor impairment than other participants, so GRASP may be of greater benefit to people in this group. However, three of these participants did not show that GRASP demonstrated an additional effect to that of practising the task.

The improved temporal coordination in participants 2, 5 and 6 indicates that this aspect of the motor control of reach to grasp was executed in a more normal way. This is a meaningful change, as improvements in motor control are likely to lead to improved arm function. These preliminary findings provide valuable data on the utility of our prototype.

Study limitations

Due to the small sample size, the results cannot be generalised to a wider population. The next step will be a controlled clinical trial with a larger group, to test whether GRASP as an adjunct to reach-to-grasp training yields better outcomes than reach-to-grasp training alone.

CONCLUSION

This preliminary investigation of GRASP indicates that it is potentially beneficial as an adjunct to physiotherapy training of reach-to-grasp function after stroke.

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Figure 1 GRASP ready to record a reaching movement

Figure 2. Results for baseline (Phase A) and intervention phase (Phase B) for participants 1 to 6. The vertical line denotes the start of phase B. Trial number is shown on the horizontal axis and time between start of hand transport and start of grasp (ms) is shown on the vertical axis. Mean time lag values are shown for each phase. The 2 standard deviation bands above and below the mean are also indicated. Negative standard deviation bands are not shown as there were no negative values. Mean levels are also shown by horizontal lines in each phase.

Table 1. Characteristics of participants

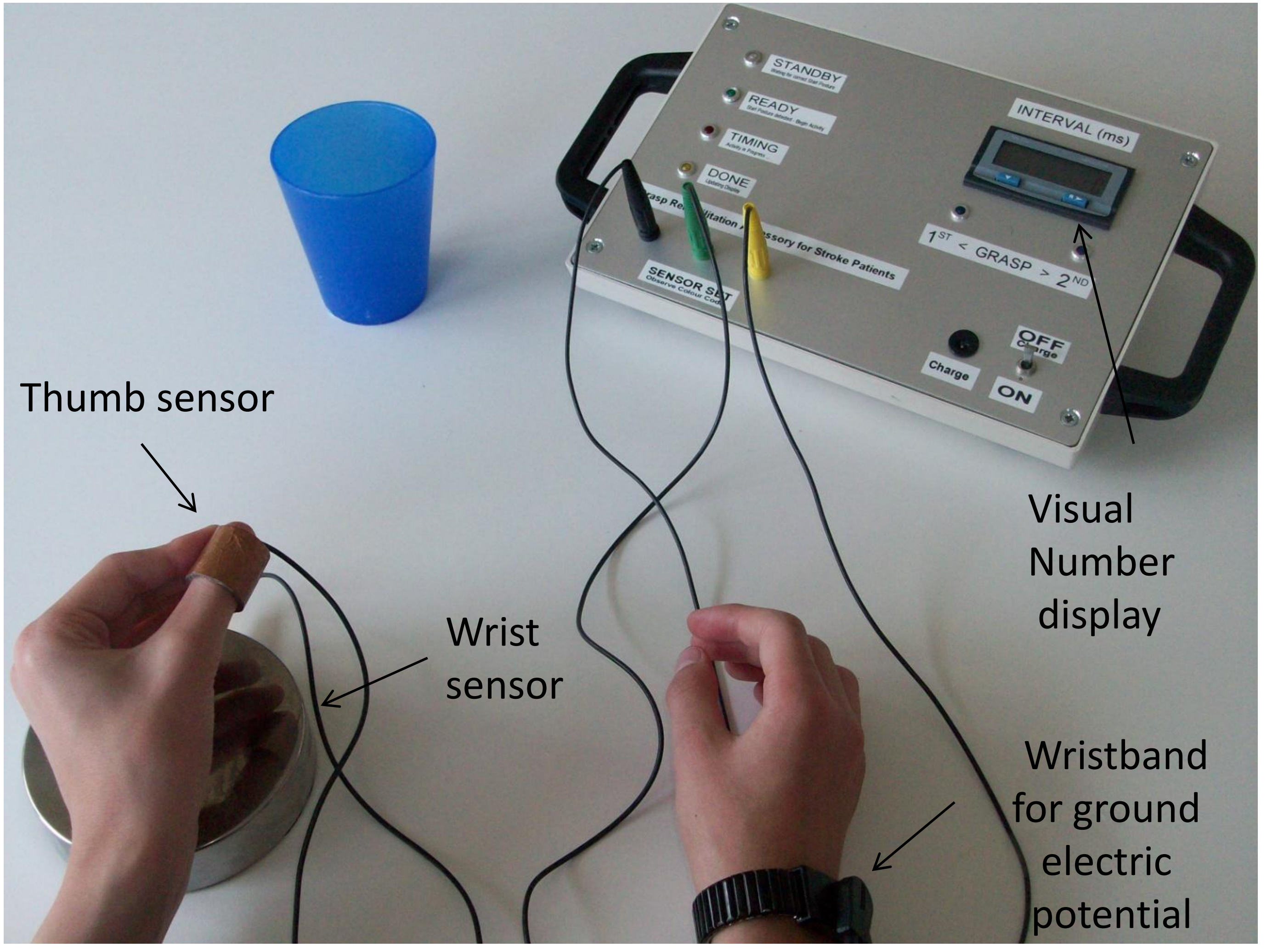
Participant no.	CT scan result	Time since stroke (months)	Arm function *	Muscle tone (wrist, finger, elbow) †	Neglect §	Spatial perception	Optic ataxia ∏	Proprioception (wrist, finger, elbow) #
1	Right middle cerebral artery infarct	14	10	1,0,1	55	36	35	3,2,2
2	Right middle cerebral artery infarct, particulary parieto-temporal	8	11	1,1,0	54	27.5	35	2,0,2

	junction and internal capsule							
3	Left fronto-parietal infract	21	5	0,0,0	54	24	39	2,3,3
4	Left Parietal intracranial haemorrhage	17	12	0,0,1	55	30	36	3,3,3
5	Left middle cerebral infarct	9	11	0,0,1	55	31	39	3,2,3
6	Left middle cerebral artery infarct	64	5	1,3,3	55	34	35	3,3,3

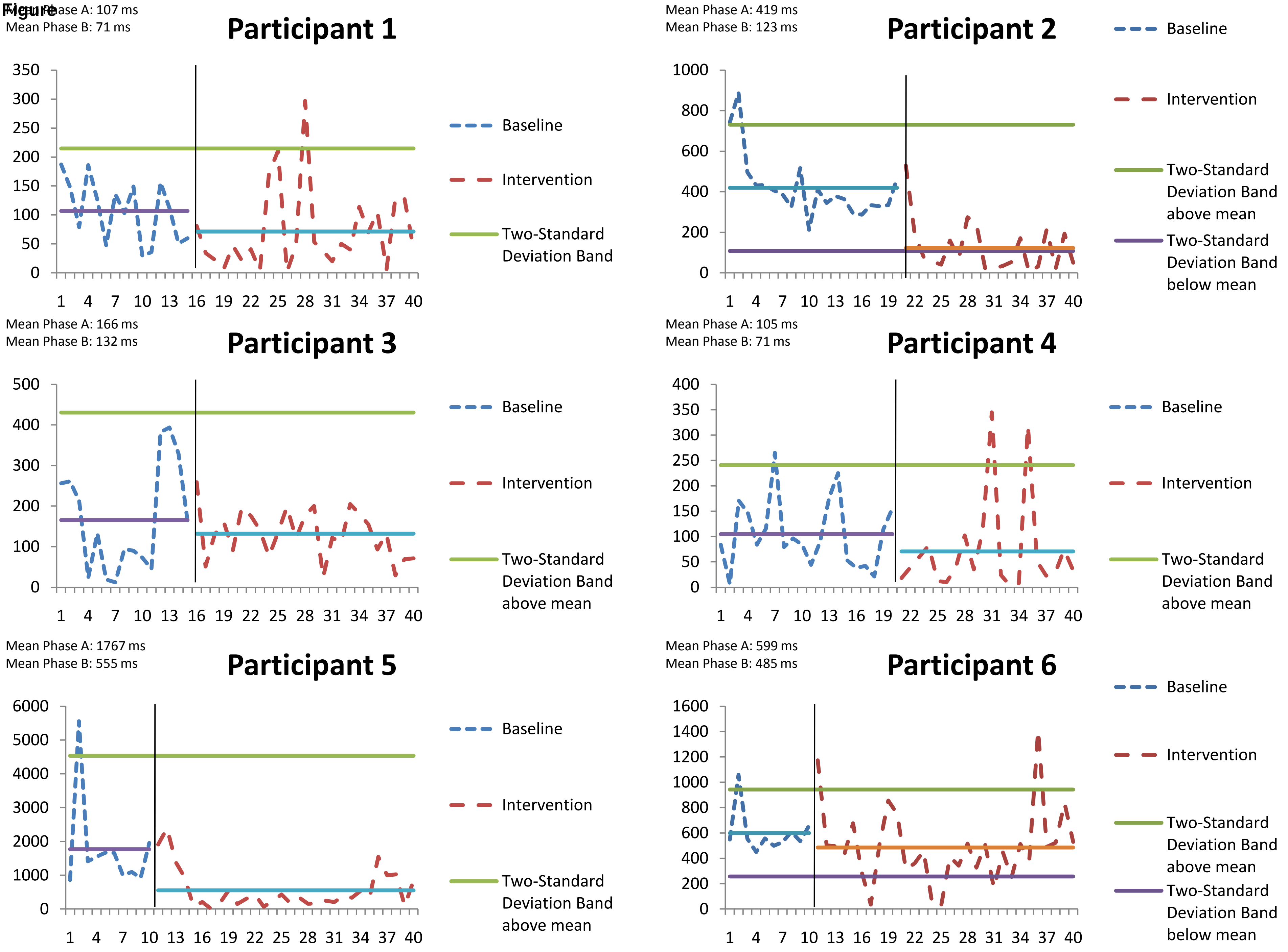
- * Arm function (Rivermead Motor Assessment) maximum score, 15.

- † Muscle tone (Modified Ashworth Scale) score range: 0, no increase in muscle tone; 4, affected part rigid in flexion or extension.
- § Neglect (star cancellation) normal scoring range, 51-54; spatial perception (Rey figure copy) normal scoring range, 31-36.
- ∏ optic ataxia (adapted from the 'reaching for an object' test described by Perenin [8]: maximum score, 40).
- # Proprioception (Nottingham Sensory Assessment) score range: 0, no appreciation of movement; 1, appreciates movement takes place but direction incorrect; 2, mirror the direction of the test movement, but it inaccurate in its new position; 3, Accurately mirrors the test movement to within 10° of the new test position

Figure


STANDBY
READY
TIMING
DONE
INTERVAL (ms)
Grasp Rehabilitation Accessory for Stroke Patients
1ST < GRASP > 2ND
SENSOR SET
Observe Colour Code
Charge
OFF
Charge
ON
Thumb sensor
Wrist sensor
Visual Number display
Wristband for ground electric potential

Figure


Mean Phase A: 107 ms
Mean Phase B: 71 ms
Participant 1
Baseline
Intervention
Two-Standard Deviation Band
Mean Phase A: 419 ms
Mean Phase B: 123 ms
Participant 2
Baseline
Intervention
Two-Standard Deviation Band above mean
Two-Standard Deviation Band below mean
Mean Phase A: 166 ms
Mean Phase B: 132 ms
Participant 3
Baseline
Intervention
Two-Standard Deviation Band above mean
Mean Phase A: 105 ms
Mean Phase B: 71 ms
Participant 4
Baseline
Intervention
Two-Standard Deviation Band above mean
Mean Phase A: 1767 ms
Mean Phase B: 555 ms
Participant 5
Baseline
Intervention
Two-Standard Deviation Band above mean
Mean Phase A: 599 ms
Mean Phase B: 485 ms
Participant 6
Baseline
Intervention
Two-Standard Deviation Band above mean
Two-Standard Deviation Band below mean

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