Table 1. Characteristics of randomised patients.

	Intervention (*n*=17)	Control (*n*=10)
Mean age (SD)	59 (12.03)	63 (14.06)
Male/Female	8/9	8/2
Median time since stroke* (25th, 75th Percentiles)	22 Weeks (16.00, 59.50)	12 Weeks (7.75, 20.25)
Dominant side affected	13	7
Median wolf motor function test (seconds) at baseline (pre randomisation) (25th, 75th Percentiles)	2.60 (1.65, 6.00)	3.34 (1.90, 4.92)

*Mann Whitney indicated a difference significant at $P<0.05$.

those who only completed baseline and midpoint outcome measures. Scores from the outcome measures were not always normally distributed, so the intervention group was compared with the control group on change from baseline to midpoint and final using the Mann Whitney test. Effect sizes have been estimated using r for nonparametric small samples. The only measures to show a significant difference were Wolf Grip strength at midpoint, Motor Activity Log Amount of Use at final and Motor Activity Log number of activities attempted at final with a greater improvement from baseline in the intervention group.

Taking the Wolf Motor Function Test as the primary outcome measure, it is possible to calculate sample size for a comparison between the intervention and control groups on final outcome measures. To detect a difference of 1 second (the published Minimal Detectable Change based on a 95% confidence interval being 0.7 seconds)[16] with a probability of 0.05 and 80% power (effect size 0.314) using a two tailed Mann Whitney test, 38 patients per group would be required. Taking into account the time it took to recruit 27 and a 67% retention rate at the collection of final outcome measures, 114 would need to be randomised. If it took 15 months to recruit 27, this would take approximately 63 months if recruited at the same rate.

Those in the intervention group received a total of 78 (median per patient = 4.0; minimum = 3.0, maximum = 14) visits from the research team in addition to those that were solely to collect outcome measures. Two patients (04, 13) received more than 10 visits in addition to those solely to collect outcome measures, but this could be explained by the need to resolve technical problems. A total of 92 hours 45 minutes (median per participant = 6 hours 10 minutes; minimum = 1 hour 20 minutes; maximum = 18 hours 10 minutes) contact time from the researchers was spent on delivering the intervention to patients. Table 3 breaks this down into different categories of researcher activity. Training in the correct rehabilitative use of the equipment and resolving technical issues accounted for a considerable proportion of the time spent in homes by the researchers.

Discussion

In terms of the first and third aims of the study, recruitment rates were so low that an impractically long recruitment period would be required to achieve the sample size indicated by the outcome measures. This was in spite of broad inclusion criteria and working closely with staff at the stroke unit and from three community teams. Approaching patients before discharge from hospital does give access to a larger group before they disperse to a wide range of services. However, at this early stage of their recovery it was difficult to determine which patients would recover enough movement to play the easiest level of the games and for staff to know which patients would meet inclusion criteria in terms of having no further intensive rehabilitation. Another challenge is that, on stroke units, rehabilitation studies compete with acute medical studies for recruitment.

An advantage of recruiting from the stroke unit is that there were dedicated staff to promote recruitment to studies. This was not the case for the community teams so more time was required from the research team for recruitment especially to make

Table 2. Outcome measures (median, minimum, maximum) for intervention and control at each time point. *Mann Whitney indicated significantly larger improvement in the intervention group than the control at $P<0.05$, ** significant at $P<0.01$. For full explanation see text.

Outcome measures		Baseline		Midpoint		Effect size (r) of baseline/ midpoint comparison	Final		Effect size (r) of baseline/ final comparison
		Intervention	Control	Intervention	Control		Intervention	Control	
Wolf MFT (secs)	Patients completing final outcome measures	2.00 (1.49, 16.15) N = 9	2.72 (1.19, 8.84) N = 9	2.22 (1.00, 8.03) N = 9	2.28 (1.18, 6.22) N = 9		2.47 (1.06, 6.58) N = 9	2.19 (1.43, 5.62) N = 9	0.40 N = 18
	Patients who did not complete final outcome measures	2.21 (1.49, 16.15) N = 12	2.60 (1.19, 8.84) N = 10	2.44 (1.00, 10.25) N = 12	2.17 (1.18, 6.22) N = 10	0.17 N = 22			
Wolf Grip	Patients completing final outcome measures	14.55 (6.33, 35.10) N = 8	12.77 (2.20, 47.27) N = 9	20.17 (5.83, 37.5) N = 9	12.23 (3.97, 34.70) N = 9		12.80 (2.30, 37.47) N = 9	12.53 (5.03, 29.40) N = 9	1.37 N = 18
	Patients who did not complete final outcome measures	12.93 (1.93, 35.10) N = 11	14.25 (2.20, 47.27) N = 10	15.50 (2.23, 37.50) N = 12	13.50 (3.97, 34.70) N = 10	0.51* N = 21			
NHPT (secs) Affected arm	Patients completing final outcome measures	45.17 (40.16, 292.52) N = 8	45.66 (31.50, 136.41) N = 7	55.45 (31.28, 270.18) N = 8)	43.81 (31.27, 109.60) N = 9		53.34 (36.93, 311.92) N = 8	37.39 (27.79, 120.85) N = 7	1.34 N = 15
	Patients who did not complete final outcome measures	53.06 (26.68, 292.52) N = 11	46.44 (31.50, 136.41) N = 8	53.65 (25.45, 270.18) N = 11	43.12 (31.27, 109.60) N = 8	0.04 N = 19			
MAL amount of use	Patients completing final outcome measures	66.00 (21.00, 113.00) N = 9	69.00 (24.00, 150.00) N = 9	74.00 (34.00, 130.00) N = 9	83.00 (38.00, 145.00)) N = 9		76.00 (22.00, 135.00) N = 9	56.00 (18.00, 125.00) N = 9	2.26* N = 18
	Patients who did not complete final outcome measures	69.00 (21.00, 140.00) N = 12	69.50 (24.00, 150.00) N = 10	81.50 (34.00, 149.00) N = 12	81.00 (38.00, 145.00) N = 10	–0.01 N = 22			

(Continued)

Table 2. (Continued)

Outcome measures		Baseline		Midpoint		Effect size (r) of baseline/ midpoint comparison	Final		Effect size (r) of baseline/ final comparison
		Intervention	Control	Intervention	Control		Intervention	Control	
MAL quality of movement	Patients completing final outcome measures	54.00 (10.00, 86.00) N = 9	53.00 (16.00, 133.00) N = 9	61.00 (32.00, 117.00) N = 9	67.00 (27.00, 132.00) N = 9		74.00 (25.00, 125.00) N = 9	51.00 (9.00, 122.00) N = 9	1.68 N = 18
	Patients who did not complete final outcome measures	60.00 (10.00, 130.00) N = 12	56.00 (16.00, 133.00) N = 10	69.00 (32.00, 145.00) N = 12	65.00 (27.00, 132.00) N = 10	0.20 N = 22			
MAL activities attempted	Patients completing final outcome measures	17.00 (8.00, 23.00) N = 9	16.00 (7.00, 30.00) N = 9	18.00 (13, 26) N = 9	19.00 (10.00, 29.00) N =9		20.00 (9.00, 27.00) N = 9	17.00 (6.00, 29.00) N = 9	2.50** N = 18
	Patients who did not complete final outcome measures	18.00 (8.00, 28.00) N = 12	16.00 (7.00, 30.00) N = 10	20.00 (13.00, 30.00) N = 12	19.00 (10.00, 29.00) N = 10	–0.04 N = 22			
NEADL	Patients completing final outcome measures	38.00 (22.00, 59.00) N = 9	39.00 (15.00, 63.00) N = 9	41.00 (20.00, 57.00) N = 9	50 (13.00, 62.00) N = 9		39.00 (28.00, 57.00) N = 9	46.00 (11.00, 63.00) N = 9	1.06 N = 18
	Patients who did not complete final outcome measures	39.00 (12.00, 63.00) N = 12	41.00 (15.00, 63.00) N = 10	42.00 (13.00, 63.00) N = 12	48.50 (13.00, 62.00) N = 10	0.09 N = 22			

Wolf MFT: Wolf Motor Function Test, NHPT: Nine Hole Peg Test, MAL: Motor Activity Log, NEADL: Nottingham Extended Activities of Daily Living.

Table 3. Median (minimum and maximum) time in minutes per patient spent in different activities during home visits to the intervention group only. Other research (eg checking data log), other communications (eg giving advice on general rehabilitation).

	Activities			
	Rehabilitation and training	Technical issues	Other research	Other communication
Median	230	45	30	65
Minimum	50	0	0	0
Maximum	540	430	50	135

sure that referrals to the team did not exclude potential participants. Once data collection had started, time for liaising with the community teams was restricted.

There was a higher level of drop outs from the intervention group than in the control group where only one of those randomised was lost after completing midpoint outcome measures. Reasons given concerned factors that would have affected the use of the intervention but were not necessarily specific to this particular form of intervention. For example, physical ill health prevented its use or the patient was absent from home. Interviews with the intervention group after final outcome measures were collected[27] also highlighted the role of ill health as well as competing commitments in using the intervention to the recommended level. However, both of these factors would affect any unsupervised, home based intervention for arm rehabilitation. Analysis of the interviews also suggested the possibility that the patients recruited were those who were more likely to be trying to return to their prestroke life, and attempts to return to work or other activities away from the home precluded the recommended level of use of the intervention. Obviously the reasons given to the research team may not have been the true reasons for dropping out and it is possible that the intervention itself may have been the reason for the high loss to the intervention group.

With such a small sample and considerable variation in outcome measures, it was only possible to detect differences on three outcome measures but these results give no reason to drop any of the outcome measures if planning a definitive trial. The variation is unsurprising given the deliberately wide inclusion criteria as during the development of the equipment[13] it was only possible to gain a limited indication of which patients would benefit from the intervention. Although a small number of patients were unable to complete the Wolf Grip strength test and Nine Hole Peg Test at baseline this inability did not stop those in the intervention group from continuing with the intervention for the full eight weeks and one was able to complete the Wolf Grip strength test at midpoint data collection. However, the between group differences in change from baseline at final data collection detected by the Motor Activity Log suggest this is a useful addition to the battery of outcome measures and may indicate improvement before any improvements on tests of functional ability. Future research may indicate whether the Motor Activity Log might be mediating any improvement in functional ability in a home based self-directed intervention.

The intervention did require a considerable level of support from the research team. However, this is predictable given the complexities of delivering a novel intervention in a community setting and the fact that some of the patients had complex stroke pathology (cognitive issues, sensory disturbance) and thus demanded more support. The intervention was at prototype stage and the support required to deal with technical issues will diminish as the technology evolves. The team included three experienced members of staff supporting patients but in future, costs could be reduced if the initial assessment is carried out by experienced staff with trained support staff providing ongoing support.

The study suffered from limitations in terms of sample size, the difficulty ensuring that midpoint measures were carried out blind and in the low use of the intervention by some patients.[27] However, the evaluation of home-based technology for rehabilitation post stroke poses challenges not seen in other evaluations. These need to be considered in the design of future studies.

In conclusion, this feasibility study found that recruitment rates were so low that an impractically long recruitment period would be required to achieve the sample size indicated by the outcome measures. In spite of considerable variation in outcome measures, a significantly greater change from baseline in the intervention group was found on the Wolf Grip strength at midpoint and two subscales of the final Motor Activity Log. The median number of visits from the research team to those in the intervention group was four with training in the correct rehabilitative use of the equipment and resolving technical issues accounting for the majority of the time spent in homes by the researchers. To achieve the required sample size indicated a definitive home-based trial would require additional strategies to boost recruitment rates and would have to include adequate resources for patient support.

Clinical messages

- To ensure satisfactory recruitment to community based trials, criteria given to those who are referring patients need to be very broad with the research team carrying out the final selection at the appropriate time .
- Therapist support should be factored in to any home based, self-directed technology intervention.

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