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"Remind-to-Move" for promoting upper extremity recovery using wearable devices in subacute stroke: a multi-center randomized controlled study

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***Abstract*—This study examined the effects of "Remind-to-Move" (RTM) via vibration cueing using wearable devices to increase the use of the affected upper limb and integrate upper limb activities undertaken at home in patients with subacute stroke after inpatient discharge. In a multi-centered randomized controlled trial, 84 eligible patients from four general hospitals who had had a first stroke in the last six months were randomly allocated to either an experimental, sham, or control group, stratified by arm function levels. Patients in the experimental group were treated by RTM, using wearable devices for three consecutive hours daily, over four weeks. The sham group used sham devices and the control group received usual care alone. A masked assessor evaluated the patients at 0, 4th, 8th and 12th weeks using outcome measures included arm function tests, motor activity log, and movement recorded by the devices. Results showed that there was a significant group by time interaction, and the average movement amount and Action Research Arm Test score in the experimental group was significantly higher than in the sham group. This study demonstrates that RTM via wearable devices used for the hemiplegic upper extremities could promote more arm recovery than the sham or control, and hence, produce an optimal functional improvement for subacute stroke patients.**

***Index Terms*—Stroke, upper extremity, wearable device, Remind-to-Move**

I. Introduction

Upper extremity paresis after stroke is one of the biggest concerns following hospital discharge, only 5-20% of acute stroke patients will regain full function but 33-60% will continue to have no function at 6 months [1]. Patients have to go home once they become more independent in basic self-care, and they frequently receive much less intensive training on the upper extremity [2-3]. Most of the patients with stroke developed learned non-use of their paretic arms in their daily lives, that could further inhibit the neurological recovery of the upper extremity [4].

Recovery of upper extremity is more likely following intensive and frequent practice of task-specific training in activities of daily living [5], and post-discharge rehabilitation is also common at outpatient departments, however, the intensity of such services is usually inadequate. Most of the rehabilitation training is not home-based, there are also few post-discharge interventions focusing on the upper extremity in the home environment, through professional-supervised rehabilitation on home visits or as self-administered (including caregivers' supervision) training programs [3], however, it is not conclusive that usual care or supervised therapy carried out is better than home-based training. In terms of such training there is a lack of sham and intervention groups to test efficacy or cost-efficiency [3].

Constraint-Induced Movement Therapy (CIMT) was considered to be an effective approach in the literature for upper extremity training [6, 7], although some limitations have been reported - only patients with mild arm impairment can benefit from CIMT [2, 8]. The involvement of bilateral upper extremities is required most of the time in activities of daily living, and the long period of restraint on the less-affected side in CIMT would trade-off any self-care independence of using both arms [9]. In addition, there is also an increased risk of falling when using CIMT [10].

We have therefore developed a new approach - the "Remind-to-Move" (RTM), delivered via a wearable device, to be used in the home environment for stroke patients after discharge from hospital. RTM is an innovative treatment that involves promoting the awareness of and overcoming learned nonuse of the paretic upper extremity in stroke patients by activating the affected limb through a vibration cue emitted by a portable wristwatch device strapped to the forearm [11]. The device is to remind the wearer to incorporate the upper extremity motor skills, taught by therapists, into their normal daily routines, and the ultimate goal of RTM, is to encourage the patient to increase the amount of affected upper extremity activity throughout the wearing period. In our previous proof-of-concept studies, RTM has already been proved to be useful for adults, who have had a

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stroke [11] or for children with cerebral palsy [12, 13], to promote upper extremity and unilateral neglect recovery [14, 15]. Instead of restraints in CIMT, we have now adopted a more user-friendly approach by reminding the individual through a strong and repetitive cue which do not require their arms to be restrained. It was also recently recommended as an alternative or supplement to CIMT for arm training in adults with chronic stroke [11], and demonstrated similar therapeutic effects with CIMT in manual dexterity and functional hand use in children with unilateral cerebral palsy [16]. The purpose of this study was to ascertain whether RTM by means of vibration cueing emitted through a wearable wristwatch device was applicable for stroke patients to use at home as a means of increasing intensity of post-discharge training to maximize hemiplegic upper extremity recovery following subacute hospital discharge. We hypothesized that RTM used for the upper extremities could promote more arm recovery than the sham or control, and hence, produce an optimal functional improvement.

II. METHODS

A. Study Design

This was a multi-center, parallel-group, assessor-blinded, randomized controlled trial with sham and control groups. All the subacute stroke patients were recruited consecutively as they were discharged from rehabilitation wards at four trial centers: two hospitals in Hong Kong — Kowloon Hospital, located in Central Kowloon, and Tuen Mun Hospital, in the Northwest New Territories; and two hospitals in Guangzhou, mainland China — Guangzhou First People's Hospital, located in Central Guangzhou and Panyu Central Hospital, located in South Guangzhou, during the period from November 2013 to May 2016. The Human Subjects Research Ethics Committee of The Hong Kong Polytechnic University (Ref. no. HSEARS20110401010) and research ethics committees of Kowloon Central/ Kowloon East Cluster (Ref. no. KC/KE-11-0099/ER-1) and New Territories West Cluster (Ref. no. NTWC/CREC/1048/12) approved the study before enrolment of patients started. The clinical trial registration number is: NCT02952677 (URL: http://www.clinicaltrials.gov).

B. Participants

Participants who met certain criteria were referred by the treating physicians who were responsible for inpatient stroke rehabilitation. The inclusion criteria included: 1) first-time ischemic or hemorrhagic stroke confirmed by magnetic resonance imaging or X-ray computed tomography; 2) unilateral hemispherical involvement; 3) aged 18 or above; 4) time since onset, less than 6 months; 5) Functional Test for Hemiplegic Upper Extremity (FTHUE) ≥ 3 (maximum 7) [17]; 6) able to understand verbal instruction and follow one-step commands; 7) Modified Ashworth Scale (MAS) ≤ 2 [18]; 8) Mini-mental State Examination (MMSE) ≥ 19 [19]; and 9) no complaint of excessive pain or swelling over hemiplegic arm. Patients were excluded if they were: 1) participating in any experimental or drug study; 2) unable to give consent to participate; 3) of inadequate balance as indicated by the inability to stand for at least two minutes with or without arm support; and 4) having a history of botulinum toxin injection in the previous three months. Informed written consent was obtained from all patients prior to data collection.

C. Sample Size

Since there have been no similar controlled trials using sensory cueing or RTM on the hemiplegic upper extremity, except for our previous single group preliminary study [11], the sample size calculation was determined by using the pooled effect size. The size was estimated from a meta-analysis of constraint-induced movement therapy (CIMT) studies on hemiplegic upper extremity of stroke patients [20]. The studies in this review used either, Action Research Arm Test (ARAT)-arm motor function, or Fugl-Meyer Assessment (FMA)-arm motor impairment, as primary outcomes that were then taken as effect size F for a repeated measures analysis of variance (ANOVA) with three groups for the sample size estimation. According to the arm motor function (the majority of the tests were ARAT) of the pooled effect size of nine studies on CIMT vs. usual care [20] with Cohen's d =0.36, taking into account that there would be 4 repeated measurements, and an estimated 20% attrition rate, a sample of 83 patients was needed to achieve 99% in power and Type I error set at the 0.05 significance level. Therefore, we estimated that a total of 84 participants was needed, with 28 in each group, for a 3-group design (G*Power Version 3.0.10).

D. Randomization and masking

Before the patient was discharged from the hospital, treating physicians informed the occupational therapists of the referral. The occupational therapists, who were informed about the recruitment criteria for the study and assessed patients for eligibility, notified the blind assessor, who was one of the investigators, to obtain informed written consent and then assessed the patient in the three days before discharge. Following the baseline assessment, the blind assessor informed a research assistant responsible for the intervention to allocate the patient randomly to either the experimental, sham, or control group using block randomization (block size of three). The randomization was stratified by center and baseline arm functioning (FTHUE level 3-4 versus levels 5-7). The patient and the research assistant in charge of the allocation and intervention could not be masked; however, they were advised not to talk with the assessor about their intervention or group allocation during the post assessment and follow-up periods.

E. Vibration cueing device

The wristwatch device for delivering RTM was the same as in our previous study [10]. It is light (70g), looks like a small pager (6.5X6.0X2.5cm), and is easy to secure comfortably to the wrist using non-allergenic neoprene straps with a Velcro™ closure (Fig. 1) [21]. The device emitted a vibration cue in the form of a rhythmic vibration (196Hz, similar to the vibration

mode of a mobile phone) every 10 minutes. The signal would not stop until the acknowledgment button on the device was pressed (Fig. 1). The purpose would be to encourage the wearer to increase the amount of impaired upper limb activity in response to a cue throughout the wearing period. This means that a wearer who wants to stop the cues must press the button as soon as possible. The SCW-V2 has a built-in logger to detect the amount of upper extremity movement in the X, Y, and Z directions and the speed at which the signal is switched off, which indicates the reaction time to the cue (Fig. 1). Movement acceleration is sampled at a range of 1 to 10 Hz and summed as

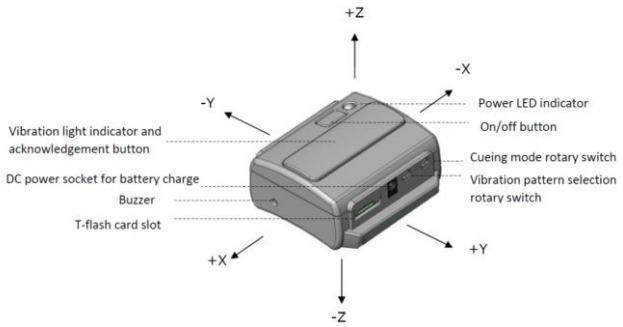

Fig.1. The cueing wristwatch device

a raw count over a user-specified epoch time period that varies from 1 second to 60 minutes. In this study, the device was set to vibrate at 10-minute intervals with a 5-second on/off vibration pattern; acceleration was sampled at 5 Hz and a 2-second recording epoch time was used. The device, which is operated by a rechargeable battery, has a recording capacity of up to 72 continuous hours of use. There is a micro-SD card in the device for both data download and programming. A notebook computer can download and display the movement of the arm and cueing data from an date and time point. This is to provide the therapist and patient with feedback information during the follow-up.

F. Procedures

After group allocation, patients followed the instructions of the research assistant to receive the interventions of the study group. Participants were requested to record whether they have received any upper limb therapy during usual care on their daily activities log sheet. Usual care was face-to-face therapy provided by an occupational therapist, physiotherapist, as arranged by the hospitals or themselves, in public or private outpatient centers elsewhere. Evaluations were conducted on four measurement occasions: within three days before discharge, immediately after completion of the 4-week intervention, and at the 8-week and 12-week follow-ups. The interventions in this study were delivered immediately post hospital discharge.

Apart from usual care, patients in both the experimental and sham groups were required to wear wristwatch devices on the affected arm for three consecutive hours daily during the daytime, for a total of four weeks (Fig. 2). The patients were told they should wear the device for three consecutive hours, either in the morning or afternoon session, they had to make sure the wearing time did not coincide with their outpatient rehabilitation sessions or other kinds of training received. Upon every signal, patients in the experimental group were required to repeat customized arm movements five times, tailored by an occupational therapist. These movements were on a graded level of difficulty based on patients' levels of upper extremity functioning in the FTHUE [17] and chosen with reference to their functional levels that had been reported in our preliminary study [11]. Patients in the sham group would wear the sham device, the only difference being that no vibration was emitted from the device, leading to no cue for arm movements, although they were taught the same upper extremity movements. Patients in both experimental and

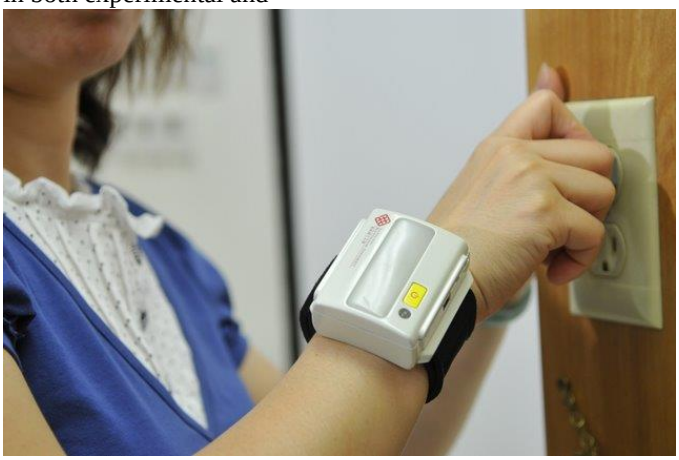

Fig. 2. The patient is wearing the wristwatch device in activities of daily living

sham groups were notified that the device would record data relating to how long they had worn it and how frequently they had used their affected arm; therefore, they were encouraged to use their more affected upper extremities as much as possible in their daily activities. In the event that some patients might forget the device operation and movements, a manual showing how to use the wristwatch (turning on/off, charging the battery, pressing the acknowledgment button, proper response to the signal emitted, and related movements) with explanatory photographs, was distributed to them. A research assistant made a regular weekly follow-up telephone call to participants in the experimental and sham groups to ensure safety use of the device, but only serious accidents or adverse events will be specifically reported. The assistant also visited them at the end of the second week to focus mainly on downgrading or upgrading the customized movements assigned to them, according to their updated arm conditions. At the end of the fourth week the assistant visited again to download the data from the device. An extra home visit was only made if a participant required extra feedback on their arm performance or advice on monitoring with the wristwatch device. No intervention was implemented for patients allocated to the control group, with only usual care scheduled by either the hospitals or themselves. The occupational therapists and research assistants had received an one-hour basic training about the study protocol, delivery of the upper extremity

therapy programme, and monitoring the device retrieved data.

Data were collected from the pre-assessments on the participants' demographic characteristics — trial center, name, address, contact telephone number, gender, age, education, affected arm, dominant arm, type of stroke, time from onset to treatment, lesion site(s), and destination after discharge. Information was also collected on the vibratory sensation on the wrist (measured by Bio-Thesiometer, Bio-Medical Instrument Company, Newbury, Ohio, USA), unilateral neglect (measured by Conventional subtests, Behavioral Inattention Test, BIT) [22], MMSE [19], and MAS on elbow flexor/extensor and wrist flexor/extensor [18]. The primary outcomes were laboratory-based assessments for arm functions, including the Fugl-Meyer Assessment-Upper Extremity Score (FMA-UE) [23], ARAT [24], and Box and Block Test (BBT) [25]. The secondary outcomes were daily activity scales, including the Functional Independence Measure (FIM) [26], self-reported questionnaire Motor Activity Log (MAL) (including the Amount of Use scale (AOU) and Quality of Movement scale (QOM)), indicating how often and how well patients used their affected arm in daily life [27], as well as the kinematic data recorded by the built-in accelerometer in the wristwatch. Evaluations were conducted at pre-treatment (0 week), post-treatment (4-week), with 8-week, and 12-week follow-ups. The exceptions were that MAL was only implemented post-intervention and at follow-up assessments, and kinematic data were recorded during the 4-week intervention. These kinematic data included the mean movement acceleration in X, Y, and Z directions over the 3-hour wearing period. The movement amount was then calculated using the ratio of number of movements detected by the accelerometry divided by the whole wearing/logging period.

G. Statistical Analysis

Once patients had been allocated to a group and had started to receive the related intervention, they were included for intention-to-treat data analysis. They could drop out during intervention or at follow-up evaluations. The method of 'last observation carried forward' (LOCF) was used for the dropouts provided that the missing data rates were not over 10%, otherwise mixed effects models were used [28]. Analysis of covariance (ANCOVA) was used to determine the time and group interaction effects, with the group as the between-subject factor, and baseline performances in arm functioning as classified by the levels of FTHUE as covariates, followed by post-hoc analysis if needed. In terms of only extracted movement amounts from the wristwatch device were obtained in the experimental and sham groups, mixed factors ANOVA was used to analyze the difference between groups, with group as between-subject factor and time as within-subject factor. For the experimental and sham groups, partial correlation was used to investigate the relationship between movement amounts and other assessments by controlling for the baselines of motor impairments. Type I error of $p < 0.05$ was treated as a significant difference and an adjusted value of '0.05/n' after Bonferroni correction, where 'n'=2 was the number of primary hypothesis tests. All the data were analyzed in IBM SPSS statistics version 23.

III. RESULTS

A total of 3,953 stroke patients were screened in four hospitals over 1.5 years; 84 eligible patients who met the selection criteria were successfully recruited and randomized into three groups — experimental, sham, and control groups with 32, 25, and 27 patients, respectively (Fig. 3). Most patients did not fulfill the inclusion criteria due to reasons of recurrent stroke or bilateral hemispherical involvement, readmission to acute care for surgery or other medical reasons such as fracture or cardiac problems, receiving Botox injections, or not meeting upper extremity functional level. Six patients recruited were not followed up with pre-assessment and randomization due to an occurrence of swine influenza and winter surge epidemics during the initial study period. Five of the 84 participants dropped out for various reasons; in the experimental group (n=3): one moved away from the town, one was readmitted to hospital because of a hip fracture, and another claimed the intervention interrupted his daily life; in the sham group (n=1): one patient moved away; and in the control group (n=3): one

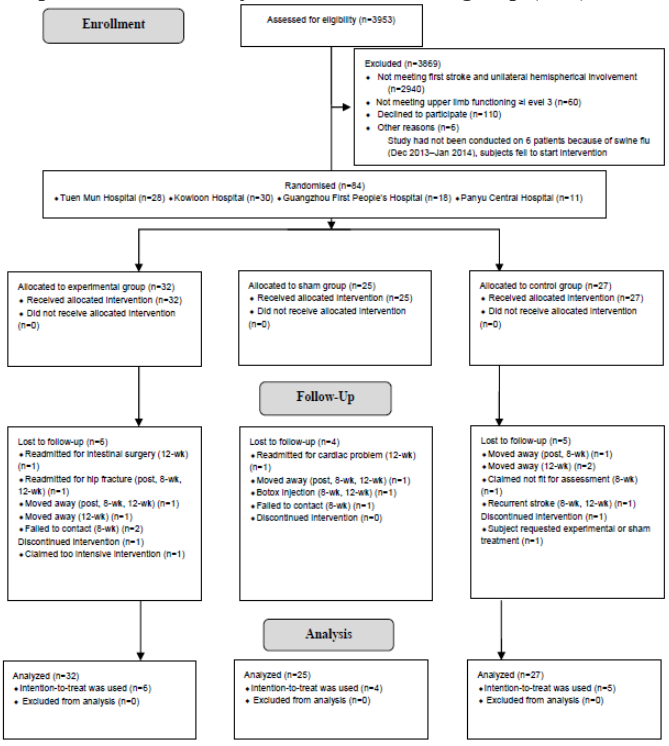

Fig. 3. CONSORT diagram of subjects throughout the study

patient refused to be in the control group and requested to be moved to the experimental or sham intervention. Other than one patient dropped out of the experimental group complaining the device was not useful, no major adverse events or complaints of discomfort were reported in the above treatments. Some patients failed to receive follow-up assessments after intervention because they lost contact, temporarily moved away, or suffered a recurrent stroke (experimental group (n=6), sham group (n=4), and control group (n=5)) (Fig. 3). The

overall missing data rate was 10.7% (36/336; experimental=16, sham=7, control=13) (Fig. 3), therefore, all 84 patients were included in the data analysis based on intention-to-treat and the method of 'LOCF' was conducted for the missing data. The baseline characteristics and primary and secondary outcomes are shown in Table 1. There were no significant differences between the three groups in terms of demographic and baseline characteristics (Table 1). Partial correlation analysis showed that overall movement amount made by the participants of the experimental and sham groups presented significant correlation with the improvements in ARAT between pre and post (0.341, p=0.028), pre and 8-week (0.303, p=0.034), and pre and 12-week (0.291, p=0.042) when the baseline of ARAT was controlled, however, there was no significant correlation with other assessment outcomes. Therefore, baseline performances of ARAT were used as the covariates for repeated ANOVA measures.

Results of the mixed factors ANOVA showed that, after the 4-week intervention, there were significant within-group improvement in the three groups, and performances continued to improve until the 12-week follow-up (Table 2). The accelerometry data extracted from the wristwatch device revealed that the movement amount made by the patients in the experimental group was significantly higher than that in the sham group (12.52% (SD 4.49) vs 9.41% (SD 3.88)) (p=0.011, $\eta 2$=0.351) (Fig. 4). Fig. 5 shows a summary of performance changes in the three groups across the 12 weeks. The self-reported AOU of the MAL showed that patients in the experimental group used their affected arm more frequently than those in the sham and control groups at post-treatment, 8-week and 12-week follow-ups, although no significant differences could be found among the groups (p=0.587). Table 2 shows that throughout 12-week there was a significant difference in the main effect of group in ARAT (p=0.008, $\eta 2$=0.339) with moderate effect size reported (effect size F between 0.25 to less than 0.4) and also a significant 2-way interaction between group*time (p<0.01). Further subgroup analysis showed that significant improvement was found in both the experimental and the control groups (p<0.001 and p=0.017 respectively) but not in the sham group (p=0.118). Multiple comparisons using Bonferroni correction showed patients in the experimental group achieved significantly better improvement in ARAT than the sham group (p=0.019, mean difference=6.283, 95% CI 0.815-11.752) and the control group (p=0.035, mean difference=5.767, 95% CI 0.299-11.235), but the difference between the sham and control groups was not significant. By using the power analysis software, G*power, Cohen's d between the experimental and sham groups was 0.288, and Cohen's d between the experimental and control groups was 0.227. Further post-hoc analysis by Bonferroni showed that there was significant difference in change score pre-post (p=0.021), pre to 8-week (p=0.038) and pre to 12-week (p=0.021) between the experimental and sham groups, as well as pre to 12-week (p=0.016) and 8-week to 12-week (p=0.019) between the experimental and control groups.

IV. DISCUSSION

This study has shown that a 4-week intervention of RTM treatment could induce patients, with subacute stroke who have recently been discharged from hospital, to move their affected arm more frequently in daily life than those patients who received sham or control treatments. More importantly, this frequent use could elicit a more functional recovery of the hemiplegic arm, either of lower or higher arm functioning, as assessed by the ARAT. Apart from the statistical significance, change scores of 12-17 in the ARAT [29] and 9-10 in the FMA-UE [30] were considerable as minimal clinically important differences (MCID). In the present study, an ARAT change score of 10-19 from post-assessment through follow-up was found in the experimental group, compared to 2-5 in the sham and 4-5 in the control group. There was also a change in the FMA-UE score from 5-9 in the experimental group versus 3-5 in the sham and 4-5 in the control. This shows that RTM treatment was able to bring about a more clinically important improvement in these two primary outcomes for subacute stroke patients after hospital discharge.

However, other functional outcomes were disappointing, and the self-reported amount of use and quality of movement of the arm and overall functional independence might have no significant advantage after RTM. The findings should be interpreted with cautions as unilateral accelerometer might not be useful to reflect actual arm functions in daily activities [21]. The subacute stage of stroke may explain also this outcome as there was spontaneous improvement over the upper extremity in individual patients.

RTM treats patients in a less aggressive manner and deals with some of the shortcomings of CIMT mentioned in previous studies [4, 9, 31], for example, affecting bimanual performance, cosmetic appearance, narrowed beneficial population, risk of losing balance, and intensive supervised therapy [2, 6]. It is a simpler method for a self-administered, low cost, community-based treatment that can be used as an alternative treatment or as a supplement to CIMT for the hemiplegic upper extremity [16]. This study has an impact as current evidence-based approaches rely upon an increase in direct contact therapy time which can lead to increase manpower and high equipment cost.

In this study, we found patients who received RTM showed a more significant movement amount recorded by the wristwatch device than those in the sham group, and the partial correlation analysis showed significant relationship between movement amounts and improvements in ARAT. The results of the AOU and the FMA were superior in the experimental group than in the sham and control groups, although a significant difference was not reached. This phenomenon might be due to the reason that the ARAT is a test that was designed to measure upper extremity functions among individuals after stroke [32]. The BBT is a simpler measure of gross manual dexterity for a wide range of populations including stroke whereas the FMA was the measure used to evaluate hemiplegic upper extremity impairment [32]. The repetitive, progressive, customized arm movement, individually tailored by the occupational therapist for patients during RTM, was task-specific in nature which might lead to improvement on hand functions rather than on

impairments [33]. In this study, all 3 groups showed improvement on BBT, but group differences were not differentiated by the BBT, perhaps because the measurement is simply a single task – transporting the blocks from one compartment of a box to another compartment, without evaluating different movement strategies such as the use of different grasps and grips. This interpretation is consistent with the significant findings of the ARAT in this study, where more improvement was noted in fine motor skills, and RTM seems more promising on distal hand function. In this study, the FIM and MAL were used to assess the patients' overall functional performance and use of their affected arm in daily life. The reason for the non-significant differences of these two scales among the three groups might include that patients could compensate the loss of function in their hemiplegic upper extremity by using the non-affected arm, and that the real life performance was not solely a function of upper extremity capacity but dependent on other factors such as motivation, health behaviors, and environmental support [34].

This study has some limitations. Patients with subacute stroke immediately after discharge from the hospital were always very busy with their regular follow-ups in outpatient training in the hospital or elsewhere. This might have lowered their interest in RTM and reduced their compliance in wearing the wristwatch, and although participants were randomly allocated to one of the three groups, this confounding effect was equal among the groups. Since the participants were not wearing the device at specific times of day, this might have made a difference on the effect of RTM training. Second, we did not apply the accelerometer (inside the device) to patients in the control group, so we could not compare the difference of the amount of arm use and movement amounts between the two groups with the control. Third, the experimental and sham groups also benefited from additional time via home visits compared to the control group. Finally, in this study, we recruited participants from both Hong Kong and Guangzhou, the usual care is different in these two places — patients in Hong Kong would generally be discharged earlier and receive regular follow-up outpatient training while patients in Guangzhou would receive a longer length of stay in the hospital for rehabilitation, hence, they would have less opportunity to receive follow-up rehabilitation after inpatient discharge, and this might affect the outcomes of usual care.

V. CONCLUSION

This study addresses the emerging concept of an affordable, low-cost technology where a 4-week RTM home-based treatment could prompt an increase in affected upper extremity movement and therapy practice in stroke patients following subacute discharge. Future studies may focus on the cost-effectiveness of RTM as an innovative rehabilitation approach on the hemiplegic upper extremity after stroke, with the use of real-time wireless data communication between patients and therapists, as well as using motion detection in RTM rather than pure repetitive intermittent cueing. Nowadays, the commercial wearable device is becoming popular. We therefore suggest that, the RTM concept be implanted in commercial wearable devices, such as smart watches, so that more patients may benefit from tele-rehabilitation.

TABLE 1
BASELINE CHARACTERISTICS OF THE INTENTION-TO-TREAT POPULATION

	Experimental group (n=32)	Sham group (n=25)	Control group (n=27)	*p*
Gender				0.783[a]
Male	25 (78%)	20 (80%)	23 (85%)	
Female	7 (22%)	5 (20%)	4 (15%)	
Age (years)	59.19 (11.25)	60.44 (10.38)	63.11 (10.27)	0.368[b]
Stroke type				0.298[a]
Ischemic	21 (66%)	21 (84%)	20 (74%)	
Hemorrhagic	11 (34%)	4 (16%)	7 (26%)	
Time since onset (days)	47.75 (21.93)	61.08 (41.26)	53.67 (41.16)	0.368[b]
Education				0.999[a]
Illiterate	2 (6%)	2 (8%)	2 (7%)	
Primary	14 (44%)	9 (36%)	13 (48%)	
Secondary	12 (38%)	13 (52%)	6 (22%)	
College and above	4 (13%)	1 (4%)	6 (22%)	
Affected side				0.287[a]
Left	16 (50%)	15 (60%)	19 (70%)	
Right	16 (50%)	10 (40%)	8 (30%)	
Dominant side				0.872[a]
Left	2 (6%)	1 (4%)	2 (7%)	
Right	30 (94%)	24 (96%)	25 (93%)	
Living site				0.126[a]
Home	27 (84%)	23 (92%)	24 (89%)	
Old-age home	5 (16%)	2 (8%)	3 (11%)	
MMSE (score 0–30)	26.33(3.31)	26.87(3.20)	27.17(3.00)	0.729[b]
Vibratory sensation (volts)				
More affected wrist	17.43 (10.46)	18.92 (16.28)	18.92 (16.63)	0.602[b]
Less-affected wrist	11.23 (5.07)	11.67 (8.71)	14.91 (10.99)	0.228[b]
MAS (score 0–4)				
Elbow extensor	0.33 (0.66)	0.31 (0.66)	0.31 (0.57)	0.959[a]
Elbow flexor	0.47 (0.59)	0.55 (0.55)	0.45 (0.63)	0.787[a]
Wrist extensor	0.08 (0.30)	0.00 (0.00)	0.00 (0.00)	0.193[a]
Wrist flexor	0.31 (0.59)	0.24 (0.44)	0.24 (0.53)	0.912[a]
BIT				
Letter cancellation (score 0–40)	35.81 (2.79)	36.40 (3.67)	35.63 (3.40)	0.602[b]
Star cancellation (score 0–54)	53.03 (3.20)	51.48 (4.50)	52.07 (4.02)	0.329[b]
Line bisection (score 0–9)	8.77 (0.50)	8.80 (0.41)	8.56 (1.09)	0.322[b]
Lesion site				
Frontal lobe	6 (13%)	7 (16%)	4 (10%)	
Parietal lobe	4 (9%)	6 (14%)	4 (10%)	
Temporal lobe	5 (11%)	4 (9%)	4 (10%)	
Occipital lobe	4 (9%)	0 (0%)	1 (2%)	
Insular lobe	0 (0%)	2 (5%)	1 (2%)	
Basal ganglia	23 (29%)	14 (33%)	15 (37%)	
Brain stem	4 (9%)	5 (12%)	5 (12%)	
Thalamus	6 (13%)	2 (5%))	3 (7%)	
Internal capsule	1 (2%)	2 (5%)	0 (0%)	
Cerebellum	0 (0%)	0 (0%)	1 (2%)	
Other sites	2 (4%)	1 (2%)	3 (7%)	
FTHUE (score 1–7)	5.06 (1.46)	5.36 (1.60)	5.15 (1.66)	0.809[a]
FMA-UE (score 0–66)	52.03 (13.95)	51.24 (16.74)	50.78 (17.59)	0.975[b]
ARAT (score 0–57)	34.00 (17.84)	36.12 (21.84)	35.96 (22.59)	0.909[b]
BBT	19.00 (14.66)	21.74 (17.16)	18.15 (15.53)	0.692[b]
FIM (score 0–126)	109.91 (9.48)	109.52 (10.82)	107.70 (11.87)	0.836[b]

Data are number (%) or mean (*SD*). [a]Chi-square; [b]One-way ANOVA. Time since onset=the time from stroke onset until the time of wearable placement. ARAT=Action Research Arm Test. BBT=Box and Block Test. BIT=Behavioral Inattention Test. FIM=Functional Independence Measure. FMA-UE=Fugl-Meyer Assessment Upper Extremity Score. FTHUE=Functional Test for Hemiplegic Upper Extremity-Hong Kong version. MAS=Modified Ashworth Scale. MMSE=Mini-mental State Examination.

Table 2. Comparison of performances within/between groups throughout 12-week

	Experimental group (n=32)				Sham group (n=25)				Control group (n=27)				$p^{\#}$	p^{*}	η^2
	Pre	Post	8-week	12-week	Pre	Post	8-week	12-week	Pre	Post	8-week	12-week			
FMA-UE	52.03(13.95)	57.19(12.29)	58.63(11.64)	59.16(12.21)	51.24(16.74)	54.60(15.54)	56.20(15.59)	56.64(15.58)	50.78(17.59)	54.37(15.53)	55.48(15.53)	55.26(16.00)	0.291	0.322	0.173
proximal	35.59(6.32)	37.94(5.72)	38.28(5.66)	38.38(6.23)	34.04(8.75)	35.52(8.08)	36.84(7.96)	37.16(7.98)	34.19(9.22)	35.93(7.93)	36.37(7.93)	36.33(8.53)	0.646	0.460	0.105
distal	16.44(7.93)	19.25(7.21)	20.34(6.32)	20.78(6.19)	17.20(8.66)	19.08(7.97)	19.36(7.96)	19.48(7.92)	16.59(8.67)	18.44(8.00)	18.81(8.00)	18.93(7.83)	0.239	0.189	0.187
ARAT	34.00(17.84)	44.78(17.50)	47.13(16.11)	49.22(16.22)	36.12(21.84)	38.96(22.60)	40.80(22.50)	41.28(22.76)	35.96(22.59)	40.32(21.59)	41.68(21.42)	40.76(21.94)	0.008	0.000	0.339
BBT	19.00(14.66)	28.34(17.38)	31.44(17.55)	34.31(17.90)	21.74(17.16)	28.78(19.20)	32.96(21.33)	36.66(23.28)	18.15(15.53)	24.69(16.44)	27.28(17.58)	28.43(20.60)	0.357	0.333	0.158
FIM	109.91(9.48)	117.84(6.05)	121.38(4.76)	122.22(4.23)	109.52(10.82)	117.40(8.18)	119.56(7.64)	120.96(7.16)	107.70(11.87)	113.33(11.60)	117.15(11.34)	117.37(11.56)	0.169	0.328	0.210
MAL															
AOU	NA	2.72(1.53)	3.09(1.64)	3.19(1.57)	NA	2.34(1.50)	2.51(1.52)	2.91(1.43)	NA	2.26(1.61)	2.94(1.84)	3.02(1.77)	0.587	0.416	0.122
QOM	NA	2.42(1.46)	2.56(1.43)	2.81(1.31)	NA	2.48(1.30)	2.67(1.31)	3.05(1.25)	NA	2.28(1.12)	2.56(1.19)	2.87(1.25)	0.908	0.922	0.055

$p^{\#}$-between groups. p^{*}-interaction effect time× group. η^2-between groups effect size.
AOU=Amount of Use scale. ARAT=Action Research Arm Test. BBT=Box and Block Test. FIM=Functional Independence Measure. FMA-UE=Fugl-Meyer Assessment Upper Extremity Score.. MAL=Motor Activity Log. NA=not available. QOM=Quality of Movement scale.

TABLE 2
COMPARISON OF PERFORMANCE WITHIN/BETWEEN GROUPS THROUGHOUT 12-WEEK

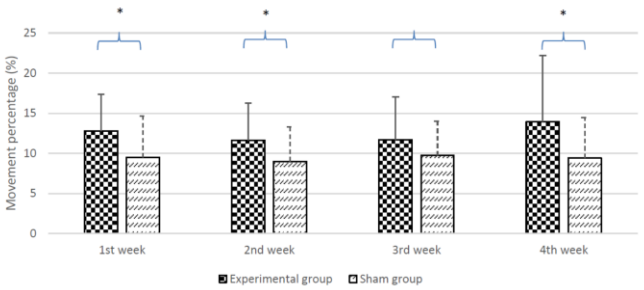

Fig. 4. Movement amount made by the patients in the experimental and sham groups recorded by the wristwatch during the 4-week intervention. *p<0.05. Error bars are standard deviations. Mixed factors ANOVA indicates significant difference between groups (p=0.011).

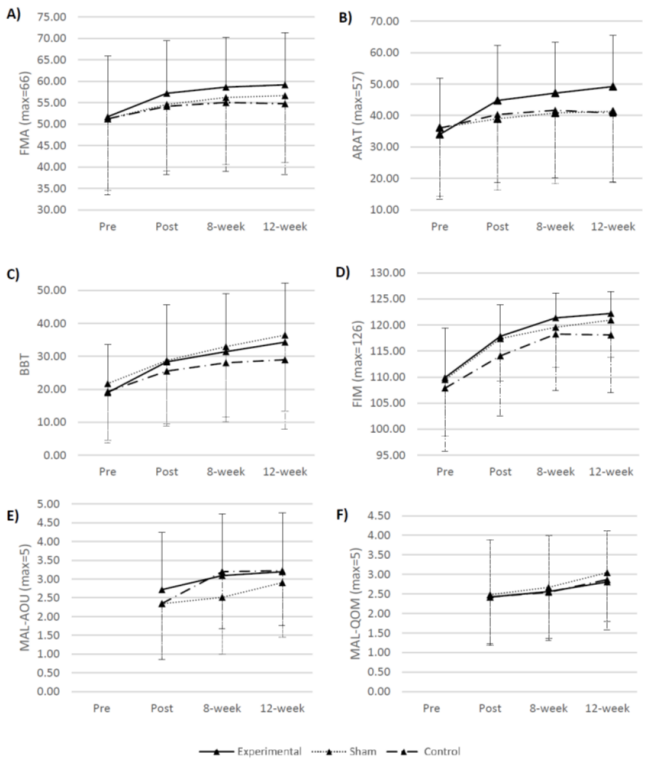

Fig. 5. Performance changes of three groups in 12 weeks
(A) FMA-UE - Fugl-Meyer Assessment Upper Extremity Score. (B) ARAT - Action Research Arm Test. (C) BBT - Box and Block Test. (D) FIM - Functional Independence Measure. (E) MAL-AOU - Amount of Use scale, Motor Activity Log. (F) MAL-QOM - Quality of Movement scale, Motor Activity Log. Error bars are standard deviations. Repeated measure ANOVA indicates significant difference between groups while baseline set as covariance (B).

APPENDIX - LIST OF ABBREVIATIONS

ANCOVA - Analysis of covariance
ANOVA - Analysis of variance
ARAT - Action Research Arm Test
AOU - Amount of use
BBT - Box and Block Test
BIT - Behavioral Inattention Test
CIMT - Constraint-Induced Movement Therapy
FIM - Functional Independent Measure
FMA - Fugl-Meyer Assessment

FMA-UE -Fugl-Meyer Assessment upper extremity subscale
FTHUE-HK- Functional Test for Hemiplegic Upper Extremity – Hong Kong Version
LOCF - Last observation carried forward
MAL - Motor Activity Log
MAS - Modified Ashworth Scale
MCID - Minimal clinically important differences
MMSE - Mini-mental Status Examination
QOM - Quality of Movement
SCW-V2 - Sensory cueing watch version 2
RTM - Remind-to-Move

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DECLARATIONS

The authors disclose competing interests in patents of SCW-V2 (US patent: US-2010-0160834-A1 and China patent: 200910175541.7).

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