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RESEARCH

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Telerehabilitation using a 2-D planar arm rehabilitation robot for hemiparetic stroke: a feasibility study of clinic-to-home exergaming therapy

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Abstract

Background We evaluated the feasibility, safety, and efficacy of a 2D-planar robot for minimally supervised home-based upper-limb therapy for post-stroke hemiparesis.

Methods The H-Man, end effector robot, combined with web-based software application for remote tele-monitoring were evaluated at homes of participants. Inclusion criteria were: strokes > 28 days, Fugl-Meyer Motor Assessment (FMA) > 10-60/66, presence of a carer and absence of medical contraindications. Participants performed self-directed, minimally supervised robotics-assisted therapy (RAT) at home for 30 consecutive days, after 2 therapist-supervised clinic on-boarding sessions. Web-based compliance measures were: accessed sessions of > 20 min/day, training minutes/day and active training hours/30 days. Clinical outcomes at weeks 0, 5 (post-training), 12 and 24 (follow-up) consisted of FMA, Action Research Arm Test (ARAT) and WHO-Stroke Specific Quality of Life (SSQOL). To estimate immediate economic benefits of the home-based robotic therapy, we performed cost-effectiveness analysis (CEA), followed by budget impact analysis (BIA).

Results Altogether, all 12 participants completed Home-RAT without adverse events; 9 (75.0%) were males, mean (SD) age, 59.4 years (9.5), median (IQR) stroke duration 38.6 weeks (25.4, 79.6) baseline FMA (0–66) 42.1 ± 13.2, ARAT (0–57) 25.4 ± 19.5, SSQOL (0–245) 185.3 ± 32.8. At week 5 follow-up, mean (SD) accessed days were 26.3 days ± 6.4, active training hours of 35.3 h ± 14.7/30 days, or ~ 6 days/week and 77 training minutes ± 20.9/day were observed. Significant gains were observed from baseline across time; ΔFMA 2.4 at week 5 (FMA 44.5, CI 95% 39.7–49.3, $p < 0.05$) and ΔFMA 3.7 at week 24 (FMA 45.8, CI 95% 40.5–51, $p < 0.05$); ΔARAT 2.6 at week 5 (ARAT 28.0, CI 95% 19.3–36.7, $p < 0.05$), and ΔARAT 4.8 at week 24 (ARAT 30.2, CI 95% 21.2–39.1, $p < 0.05$). At week 5 follow-up, 91% of participants rated their overall experience as satisfied or very satisfied. Incremental CEA observed savings of -S$144/per cure over 24 weeks, BIA—potentially 12% impact reduction over five years.

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Conclusions This study demonstrates the feasibility, acceptability, safety, clinical efficacy, and cost-effectiveness of a home-based, web-enabled telemonitored carer-supervised robotics-aided therapy.

Trial registration: NCT05212181 (https://clinicaltrials.gov).

Keywords Telerehabilitation, Tele-monitoring, Stroke, Robotics-assisted therapy, End effector robot, Upper limb, Cost-effectiveness

Introduction

Stroke is a disorder characterized by significant impairment of sensorimotor and cognitive functions. Globally, stroke is the second-leading cause of death, accounting for 11.6% of total deaths and the third-leading cause of death and disability combined, accounting for 5.7% of total disability-adjusted life years (DALYs) [1].

In particular, hemiparetic weakness is common after stroke [2, 3], affecting 70–80% of stroke survivors. In terms of upper extremity (UE) motor function, only 10–20% of stroke survivors achieve complete or useful upper limb recovery [4, 5]. Thus, stroke should be regarded as a long-term condition requiring continuing support [6].

Stroke rehabilitation aims to maximise functional independence and improve the patient's quality of life through a combination of reduction of impairment and learning of compensatory motor strategies [7]. Greater functional independence in the patient leads to reduced caregiver burden, better quality of life and potentially lower costs of care [8]. Current evidence in stroke rehabilitation emphasises the need for repetitive, intensive and adaptive task-specific UE training to facilitate motor relearning and neuroplasticity [9, 10].

Upper-limb Robotics-Assisted Therapy (RAT) can deliver task-specific, repetitive, intensive UE exercises safely with comparable clinical outcomes and improved neuroplasticity [11–13]. Current studies on RAT and dose-matched conventional therapy show comparable effects on improving motor outcome with high levels of safety and acceptability, with reduced supervision of therapist. [14–17]. Thus, RAT provides a potential solution to provide quality-ensured upper limb intensive therapy and decrease therapists' workload [12, 18].

The development of table-top, portable, simple to use, upper limb end effectors has afforded innovative, effective, low-cost solutions comparable to more complex exoskeletal robots. A typical model is the current device tested, a 2-dimensional planar end effector robot which is a portable, low-cost commercial model with haptic handle. (www.articares.com) (Fig. 1a) This was combined with a web-based telerehabilitation platform and clinically applied as a potential innovation to extend clinic RAT and circumvent barriers such as scheduling, limited access from pandemic-related lockdowns, through decentralized and minimally supervised home-based therapy [14, 19–22].

It had also long been assumed that stroke patients reach a plateau in their recovery within 6 months of their

(a) (b)

Fig. 1 H-Man upper-limb rehabilitation robot. **a** Robot and graphic interface for exergames. **b** Study participant training at home with the H-Man

stroke, however, several studies challenge this assumption. A proportion of interventions delivered > 6 months post-stroke demonstrated a positive benefit for individuals in the chronic stage of stroke [23]. Ward et al. reported results of a clinic-based UE rehabilitation programme consisting of 90 h over 3 weeks, for chronic stroke survivors (median time 18 months post-stroke) with severe UE disability (mean Fugl-Meyer-Motor Assessment (FMA) score 26/66), who achieved clinically significant gains of 42% in motricity and 50% gains in motor function, which persisted for 6 months [24, 25].

These findings suggest that given the length of time needed for post-stroke UE recovery in relation to motor and functional benefits, substantial provisions should be made for post-hospitalisation rehabilitation to be continued for months to years after the initial stroke. However, challenges remain in matching therapy provision to optimise recovery or neuroplasticity in the poststroke subacute to chronic phase, in large part related to healthcare resource limitations and various barriers. For example, a 2014 Singaporean study found that, in general, post-hospital rehabilitation attendance was low [26]. While 87.1% of the patients viewed rehabilitation as beneficial, overall longitudinal attendance rate fell from 100% as inpatient to 20.3% at 3 months, 9.8% at 6 months, 6.3% at 9 months and 4.3% at 12 months. Reasons for this included physical and social barriers, which were high initially, but decreased with time, while the prevalence of financial and perceptual barriers increased with time [26].

Home-based training and telerehabilitation combined with technology deployment at home or nursing facilities are various methods which can increase therapy delivery without over-burdening healthcare manpower. [19, 22, 27]. Also, home-based therapy combined with telerehabilitation and technology are potential methods to optimise therapy intensity and circumvent traditional barriers to access, such as transportation, scheduling and staff availability [19].

Telerehabilitation (TR) for stroke rehabilitation has emerged as a feasible way to deliver various services asynchronously or simultaneously, thus prolonging, or intensifying hospital or clinic-based treatments without concomitant strain on healthcare resources and circumventing physical barriers or clinic scheduling. Stroke patients who completed home-based telerehabilitation achieved outcomes equal to or better than those from conventional care during the first 3 months of stroke. Home-based self-managed UE therapy can also be regarded as another method for extending UE rehabilitation beyond the clinic. A systematic review by Westlake et al., showed largely equivalent efficacy between clinic and purposely designed, self-managed UE home programmes [27–30].

A large randomised controlled trial (RCT) of 124 subacute and chronic strokes with moderate to severe UE impairment established that 36 h of 70 min each of telerehabilitation, combining computer games with and without supervision, was non-inferior to dose-matched clinic-based rehabilitation, with both groups achieving 7.86–8.36 FMA gains after 6 weeks of training [31]. Reports involving minimally- or un-supervised home-based actuated robot aided training with asynchronous therapist monitoring are sparse, hence this novel therapeutic approach requires further study to determine its feasibility, safety and efficacy and role in stroke rehabilitation.

However, development of medical robotic devices suitable for home-based use still lags with respect to other technologies involved in telerehabilitation such as digital telecommunications and virtual reality. There is a need for less complex and user-friendly robotic systems designed specifically for non-clinical environments [32]. However, most commercially available robots for rehabilitation usually have large dimensions and are complex and costly to operate, which makes them suitable only for clinical settings. Consequently, to-date, there are few publications pertaining to minimally supervised or unsupervised telerehabilitation at home involving RAT.

Hence, this pilot study aimed to evaluate the feasibility, safety, and efficacy of carer-minimally supervised RAT using a portable arm robot, H-Man (Articares Pte Ltd, Singapore) within homes of patients, supervised by carers (i.e., family members or untrained paid helpers,) supported by a web-based platform and remote telemonitoring. For this study, we termed H-Man and web-based platform as "Home-RAT". Analysis of the experimental data involved both longitudinal assessment of standardised outcome measures and patient-reported outcomes. Secondary outcomes evaluated included the cost-effectiveness and budget impact of Home-RAT.

The innovations of this study fall into four main categories: user acceptance, initial training effectiveness, asynchronous interaction with the clinician and clinical efficacy.

The study's hypothesis was that telerehabilitation using a carer-minimally supervised portable robot at home for 30 days and clinic remote telemonitoring by occupational therapists (OT) would be feasible to achieve the following outcomes:

i. 75% of sample achieving an active day defined as any log-in of > 20 min/day continuously.
ii. < 10% drop out rate of enrolled participants during the 30-day robot-assisted home training period.
iii. < 10% of participants' adverse events related to robotics-assisted therapy such as arm pain, shoul-

der pain, increased spasticity on clinically measured scales by independent assessors.

Materials and methods

A prospective, pilot, feasibility trial of hemiparetic stroke patients with independent outcomes assessment and longitudinal follow up for 24 weeks was conducted in a single ambulatory centre, with affiliations to a tertiary inpatient rehabilitation unit. The goal of this study was to determine the feasibility, safety, and acceptability of implementing a clinic-to-home rehabilitation pathway using RAT, deploying a portable, 2D planar end-effector robot designed for upper-limb therapy, focused on training shoulder and elbow flexion and extension (Fig. 1a). The system provides smart physical human–robot interaction (haptics) in partial substitution of physical interaction with a therapist, coupled with remote telemonitoring via a web-based software (www.articares.com) (Fig. 1b).

Hardware

The upper-limb rehabilitation robot employed in this study is shown in Fig. 1a. H-Man is a portable, planar end-effector device designed to help train arm movements, and is essentially a powered, cable-driven differential mechanism [33].

The mechanism design provides the following advantages:

- High back drivability: Back drivability refers to the ease with which the user can move the handle in the absence of motor actuation. Compared to other robot designs, the inertia and friction felt by the user's hand when moving the handle are minimal. In this way, the user concentrates on performing the training tasks rather than overcoming the resistance of the mechanism. The device's high back drivability also eliminates the need for feedback control, which in turn guarantees the robot's contact stability. This makes H-Man inherently safe for manual interaction with the user.
- Optimal workspace dimensions: The workspace of H-Man on the horizontal plane is 334.5 mm x 350 mm which defines all possible positions of the handle. The total footprint of the device is 665 mm x 620 mm x 105 mm.

H-Man can provide end-effector forces of up to 23 Newtons in any specified direction of the planar workspace to collaborate in the rehabilitation task. Previous clinical studies with Home-RAT can be found in [14, 20, 33].

Robotic intervention (exergames)

Therapy sessions with Home-RAT involved the participant performing a series of game-like training exercises or 'exergames' provided by the robot's software. The exergame's graphic user interface provides the user with a virtual manual task to execute, such as capturing fish in a pond, serving meals to customers, etc. The Home-RAT interacts physically with the user by exerting controlled forces on the handle. Depending on the type of task, these forces can either help the user in completing the required movements or create a challenge, such as adding resistance or introducing perturbations**.** In some games, the control software features an adaptive component that automatically adapts the intensity of the therapy to the patient's current level of recovery. Tables 5 and 6 in Appendix 1 present a summary of the exergames employed in this study.

Exergames were prescribed by an OT and tailored to each participant's needs; working towards prescribing exergames to improve arm coordination, strength and/or agility. Agility was defined as the average speed of point-to-point movements.

The exergame's levels of assistance, resistance or perturbation are adjusted in the robot software based on the patient's kinematic performance metrics. The metrics are computed from the sensor data (specifically handle position data) generated by the robot during the patient's previous training exercises.

As the exergaming interface was in development during the pilot trial and initially commenced with 3 exergames, halfway into the study period, a further 5 exergames were added by the software developers. Consequently, we assigned participants to 2 groups for participation evaluation; Group 1 consisted of 6 participants (P01-P06) who trained with 3 different exergames at home. We refer to these as exergames E_1. (Appendix 1, Table 5). Group 2 also consisting of 6 participants (P07-P012; group 2). For the trials with group 2 we incorporated a new set with an additional 5 exergames; we refer to these as exergames E_2 (Appendix 1, Table 6). Thus, group 2 trained with a total of 8 exergames at home (Appendix 1, Table 6).

Remote monitoring software

The H-Man is controlled by a software application called the CARE Platform [34]. The software features a remote monitoring component capable of linking up the supervising clinician with one or several patients receiving robotic therapy in their homes (Fig. 2). In compliance with the institution's Medical Devices and Operational Technology Security (MDOTS) [35], no personal identifiers (name, identity numbers, addresses) were stored in the robot or web-based platform which was not

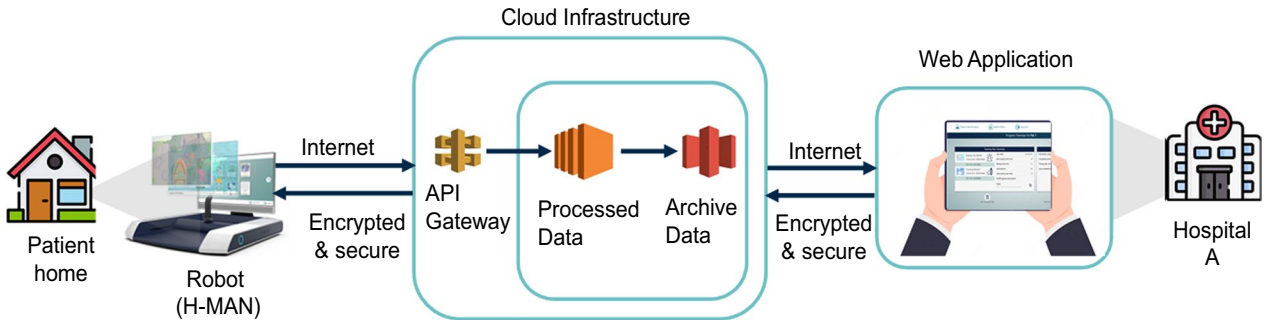


Fig. 2 Schematic illustration of H-Man and web platform architecture. Motion and performance data are generated from each training session with the robot. Data collection is performed by the software application (CARE Platform installed in the robot's PC). Only non-identifiable (non-PII) data are collected from the user. The bulk of the data consist of robot motion data and performance data generated during training. Data are uploaded in encrypted form to a secure cloud-based server. Data can be accessed remotely by registered users (for example the supervising clinician) by means of a web-based software application

connected with the healthcare institution's network and H-Man robot external USB ports were disabled.

The software's communication framework featured encrypted transmission of training data from Home-RAT to a secure database, and generation of data analysis and progress reports, allowing remote access by clinicians with secure log in passwords to view and manage participants' therapy schedules and generate reports remotely.

Study setting

The study was conducted from 3 March 2022 to 1 September 2023 at the Tan Tock Seng Hospital, Clinic for Advanced Rehabilitation Therapeutics (TTSH-CART) in Singapore, an ambulatory rehabilitation facility providing comprehensive medical rehabilitation consultations and multi-disciplinary rehabilitation therapies, incorporating various rehabilitation technologies (e.g., robot-aided therapies, virtual reality training, neuromuscular electrical stimulation etc.). TTSH CART is directly linked to Tan Tock Seng Hospital (TTSH) Rehabilitation Centre, a 95-bed inpatient tertiary rehabilitation unit providing acute inpatient neurorehabilitation programs.

Study participants

The majority of participants had completed inpatient rehabilitation at TTSH Rehabilitation Centre and were recruited consecutively according to the following study inclusion criteria; first-ever clinical stroke (ischaemic or hemorrhagic) confirmed by admitting doctors and CT, CT angiography or MRI brain imaging, aged 21–90 years, duration of > 28 days post-stroke, upper limb motor impairment measured with Fugl-Meyer Motor Assessment scale (FMA) scale between 10 and 60/66 [25], presence of stable home situation and a carer to supervise home-based RAT, Montreal Cognitive Assessment (MoCA) score > 21/30 and ability to understand purpose of research [36].

The study's exclusion criteria were: non-stroke related causes of arm motor impairment, severe aphasia, medical conditions incompatible with research participation such as uncontrolled medical illnesses (hypertension or diabetes, ischaemic heart disease, congestive heart failure, bronchial asthma, severe / untreated depression, agitation, end stage renal/liver/heart/lung failure, unresolved cancers, anticipated life expectancy of < 6 months, inability to tolerate sitting continuously for 60 min, local factors potentially worsened by intensive robot-aided arm therapy and computer-based training: active seizures within 3 months, spasticity of Modified Ashworth Scale grades > 2 skin wounds, shoulder, arm pain visual analogue scale > 5/10, active upper limb fractures, arthritis, fixed upper limb flexion contractures, hemi anesthesia of affected limb, severe visual impairment or visual neglect affecting ability to interact with the H-Man user interface, history of dementia, severe depression or behavioural problems, absence of a reliable carer to provide supervision during home training. Pregnant and or lactating females were also excluded.

Study protocol and ethics statement

Institutional ethical approvals were obtained by the National Healthcare Group, Domain Specific Review Boards (NHG-DSRB 2021/00156) prior to participant recruitment and study procedures. The study was conducted in accordance with the Declaration of Helsinki, which governs ethical principles for medical research involving human subjects. All participants signed written informed consent prior to enrolment. The study was registered with www.clinicaltrials.gov (NCT: 05212181) [37].

Retrospective data related to participants' demographic, acute stroke characteristics and individualised

billed cost data were extracted from institutional electronic medical records. All other clinical or robotic metric data were prospectively collected.

The protocol for the home-based training and follow-up is shown schematically in Fig. 3. Following eligibility screening and signed informed consent, 2 clinic onboarding (Visits V1, V2 occurred before and after, T0 respectively, for baseline outcomes) sessions of 90 min each were conducted within a week by an OT for both the participants and their appointed carer. This was followed by a single home visit (Visit V3) by the vendor to deliver and set up the H-Man at the participants' homes. Simultaneously, an OT was present at this home visit for appropriate interfacing of the participants to Home-RAT, reinforcement of Home-RAT training, safe operations, and handling of the robot. From the next day, Home-RAT was commenced for 30 consecutive days. The Home-RAT was then retrieved from the participants' homes.

At week 5 (Visit V4, T1), participants returned to the clinic for 1 session of clinic-based OT. Follow-up assessment sessions using standardised outcome measures were conducted in the clinic on weeks 5 (T1), 12 (T2) and 24 (T3) (Fig. 3). All T0-T4 assessments and up to 10 remote telemonitoring sessions were conducted by an independent experienced OT, not involved in V1-2 interventions.

Description of in-clinic phase

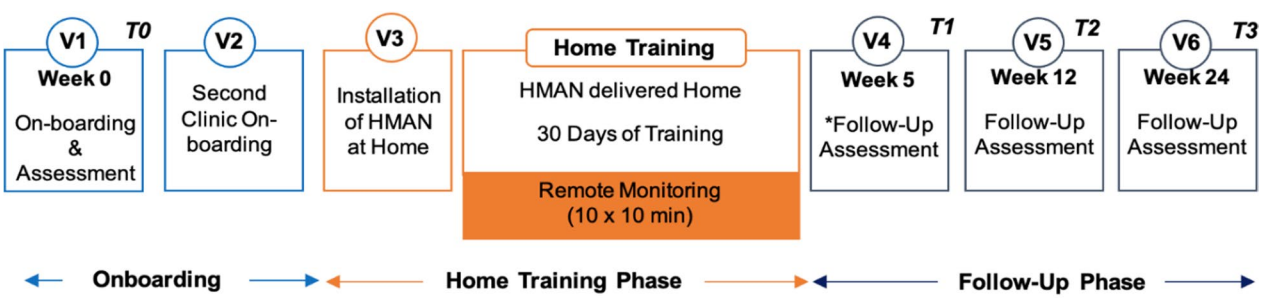
Following screening and informed consent, each participant was assigned a unique research identifier code, which was used in data collection forms, the clinic and home robots and a web-based platform to identify participants. Participants were then assessed at baseline by an OT using the above outcome measures (T0, visit 1), followed by 2×90-min clinic onboarding sessions (V2-V3) at TTSH-CART. The main purposes were to introduce participants to Home-RAT training, familiarise participants to the various exergames, training schedules and progression and to train their carers on proper operational handling, safety aspects and progression of training on the Home-RAT. Particular attention was paid to proper trunk posture and positioning in height-adjustable chairs with appropriate hemiplegic shoulder positioning and hand straps to the robotic handle as needed.

Subsequently, visit 3 occurred at the participants' homes with the concurrent delivery and installation of the Home-RAT by the vendor and training set up by CART OT over 90 min (Fig. 3). The goal of this visit was to ensure continuity of ergonomic positioning of the participant, which was previously established during the prior 2 clinic onboarding sessions; also, supervision or manual assistance from carers or next of kin as needed for proper positioning at the Home-RAT or for turning on /off and adjustment of controls; and revision of safety and trouble-shooting protocols by participants and carers. Participants were given contact numbers to short message or contact OTs or vendor in case of physical or technical difficulties respectively. A paper record was also provided for manual logging of dates, start and end times of each of the training sessions as a consistency counter-check against the web-based cloud data.

Home training phase

Participants were instructed to perform daily home-based Home-RAT training for the next 30 days, starting at 20–30 min per session daily and progressing with rest breaks as needed to 60 min/day at the end of the first week and further increasing to 120 min daily in distributed sessions by the end of the second week. OTs did not perform synchronous tele-monitoring facing the participants during the 30-day home training phase.

Remote asynchronous tele-monitoring via the web-based cloud platform was performed by OTs in the clinic for 10 min each, up to 10 sessions over 30 days (i.e., 2–3 times per week). This involved accessing the cloud data and participants' performance (log-in duration, dates, times via a graphical interface). The first remote monitoring session occurred 24 h after visit 3



Legend: V: Visit, T: Time point from recruitment* Included 1 clinic OT session for functional training

Fig. 3 Protocol for the study

(delivery and set-up of Home-RAT) and proceeded as per protocol at 2-3x/week up to 10 sessions/30 days. Telephone calls or short messaging from OTs to participants/carers were on an as-needed basis, when the following situations were encountered: absence of web-based cloud activity noted for > 24 h initially, intermittent, or poor compliance (i.e., irregular, or infrequent log-in < 20 min each time) or failure to progress training duration to 60 min/day by day 14/30 days.

At the end of 30 days, the Home-RAT was retrieved from participants' homes by the vendor.

Follow-up phase

These consisted of 3 clinic visits of 60–90 min each (visits 4–6, or T1,2,3). These included 1 session of independently rated outcome measures and functional retraining by OT at week 5 (T1, visit 4), and 2 further follow up outcome measures, assessed by OT at weeks 12 (T2, visit 5), and weeks 24 (T3, visit 6). At T1, visit 4, functional retraining was performed prior to T1 outcome assessment, this consisted of limb ranging and mobilisation followed by guided practice of reach coordination and grasp/release functions utilising neuro-facilitatory handling techniques such as the Bobath Concept and Neurodevelopmental Treatment, with Task-oriented Training [38, 39]. At T3 and T4 follow-up points, we documented which participants had concomitant rehabilitation interventions, however, the exact amounts or intensity of upper limb training or interventions, were not documented in line with institutional ethical regulations due to electronic medical records outside of study protocol and site.

Participants were discharged from the study at week 24 upon completion of all study interventions and outcome measures.

Outcome measures

Therapy plan: adherence

Primary outcomes of participants' adherence with the therapy plan, were defined in two ways. Firstly, we defined as an "active day" any day within the 30-day therapy programme in which a participant training was logged into the robot's software for at least 20 min. Secondly, we defined "active hours/30 days" or "active minutes/day", the total time spent, removing idling time of the robotic handle. These were counter checked against participants 'manual logs filled out during home RAT training.

Patterns of participant usage per day according to date and time stamped on the web application.

Participant subjective ratings

Patient reported outcome measures (via standard questionnaire), where participants rated on a Likert scale [40] of 1–5, with 1 being strongly disagree and 5 being strongly agree on their home-based experience with Home-RAT. The questions (1–7) were as follows:

1. It is easy to learn how to use the system.
2. The set-up was comfortable.
3. The training was easy to complete at home.
4. The training was not boring.
5. The training was useful for exercising my arm.
6. The home robot training should be part of standard therapy.
7. I am overall satisfied with the performance of the robotic system.

Standardised clinical outcomes

The following secondary efficacy and health-related quality of life (Hr-QOL) outcomes were measured T0,1,2,3 by an independent, experienced OT assessor not involved in training visits 1–3. These were done to assess the durability of any gains over 24 weeks (follow-up period of 19 weeks).

- Upper extremity (UE) Fugl-Meyer Motor Assessment (FMA) is a widely used quantitative measure of motor impairment to evaluate upper-limb recovery [25]. Its scores range from 0 being the minimum to the maximum score of 66 points and is divided into UE including shoulder-elbow, and coordination and speed (0–42) and distal wrist-hand scores (0–24).
- Action Research Arm Test (ARAT) is a 19-item observational measure of upper-extremity performance score and score ranges from 0 being the minimum to the maximum score of 57 points. [41, 42]. It consists of 4 sub-tests (grasp, grip, pinch, and gross movement). Each task performance is rated on a 4-point scale ranging from 0 (no movement) to 3 (normal movement). The subscale ranges for each subtest are; grasp (6 items, 0–18), grip (4 items, 0–12), pinch (6 items, 0–18) and gross movement (3 items, 0–9). Scores from each task are summed, with a minimum total score of 0 to a maximum score of 57 [41, 42].
- Affected hand grip strength was measured using Jamar Dynamometer (kg) using the mean reading of 3 attempts [43].
- The Stroke Specific Quality of Life Scale (SSQOL), an instrument intended to measure the quality of life specific to stroke patients [44]. The instrument

consists of 49 items within 12 domains such as family roles, self-care, and mobility. Each item is scored on a 5-point Likert scale [40] from 1–5, with a minimum total score of 49 and a maximum of 245. Higher scores imply higher QOL.

Safety data

In terms of participant safety monitoring, these included clinical measures of hemiparetic limb spasticity of shoulder adductors, elbow flexors, wrist and finger flexors using the Modified Ashworth Scale scores (MAS) [45] and shoulder/arm visual analogue scale pain scale (VAS 0–10) at rest for T0,1,2,3. [46] (Appendix 3, Tables 8, 9).

All participant demographic and clinical data were collected and managed on the REDCap electronic tool hosted at the National Healthcare Group [35].

Statistical analysis

As this was a pilot feasibility trial, formal statistical power calculation was not performed. A minimum sample size of 10 was planned and factoring in a ~ 20% drop out rate (~ 2 subjects), the total sample size was 12. All eligible patients were consecutively screened and recruited. Modified intention to treat analyses was performed [47]. A normality test (Shapiro Wilk p value was > 0.05) was performed for all the main outcome variables. All variables were found to be normally distributed, except for ARAT at week 24, whereby, skewness and kurtosis tests conducted for ARAT at week 24 showed a skewness of -0.0242 indicating a nearly symmetric distribution and kurtosis value of 1.253 suggesting a less peaked distribution and has lighter tails, indicating that data points are more evenly spread around the mean compared to a normal distribution. Overall, these values suggested that the distribution is approximately normal, which is generally acceptable for conducting parametric tests. We then analysed differences for main outcome variables between T0-T1, T0-T2 and T0-T3.

In our analysis, we employed a mixed random effect modelling procedure for all pre-specified outcomes (FMA total, ARAT Total and SSQOL), following the standard univariate and multivariate stepwise backwards regression analysis technique.

In this standard procedure, the first step was to conduct a univariate analysis to identify putative predictor variables associated with the outcome measures. A significance threshold $p \leq 0.1$ was used in this stage in order not to miss any potentially clinically important predictors.

In the multivariate analysis, the final fitted models were constructed using multivariate backward stepwise regression procedures. The known clinically important variables are forcefully adjusted in the model. The final statistical significance remained conventionally defined as $p \leq 0.05$.

Age, nature of the stroke (Haemorrhagic and Infarct/Ischemic), duration of stroke, affected side of stroke (right, left & both), frequencies of home-based exercise (captured via cloud data) were forcefully adjusted in the multivariate model. The inclusion of these covariates, despite the lack of statistical significance in the univariate analysis, was motivated by their known clinical relevance and potential to influence the outcomes.

Initial exploratory analysis employed the paired t-test to determine the changes in the mean scores of outcome variables over time using paired t-test.

Final adjusted clinical effect sizes for FMA referring to intervention of COT, RAT at clinic and RAT at home (using Home-RAT) were calculated using multivariate mixed random effect models with unstructured covariances and sandwich regressor (Robust Variance) option to take into account for quantifying heterogeneity within subject variability for repeatedly measured FMA scores over time; unstructured covariance matrix which provide a flexible framework for modelling the correlation structure of the data, while the sandwich estimator helped to correct for any potential misspecification of the covariance matrix.

The final independent variables included in the multivariate model were: (1) nature of the stroke, classified as infarct, haemorrhagic, (2) recurrence of stroke (classified as yes or no), (3) side of the stroke (classified as right, left, or both), (4) intensity of training (measured as total days trained per month). (Refer to Appendix 5 Table 15).

The level of statistical significance for all tests was set at two-sided $p < 0.05$.

Cost-effectiveness analysis (CEA)

The CEA [48] was conducted based on societal (stroke survivors' and hospital's) perspectives. The time horizon of the analysis was set at ~ 24 weeks in line with the study duration. In this initial analysis, we quantified and compared the costs of each intervention at the follow up (week 24), COT, RAT at clinic and RAT at home (using Home-RAT) and their corresponding effectiveness measures, such as clinical FMA outcomes. Cost data for COT, RAT at clinic were retrospective, billed data for each participant where available. RAT at home billed data was collected prospectively for all 12 participants. All costs were estimated in Singapore dollars (S$). Details on the estimation of healthcare and non-healthcare related medical costs for all interventions are provided in Appendix 2.

FMA scores for COT and RAT at clinic were obtained from an earlier conducted randomised clinical trial (RCT) in 2018 at the same clinic as the current study [14]. With reference to this study by Budhota et al., we

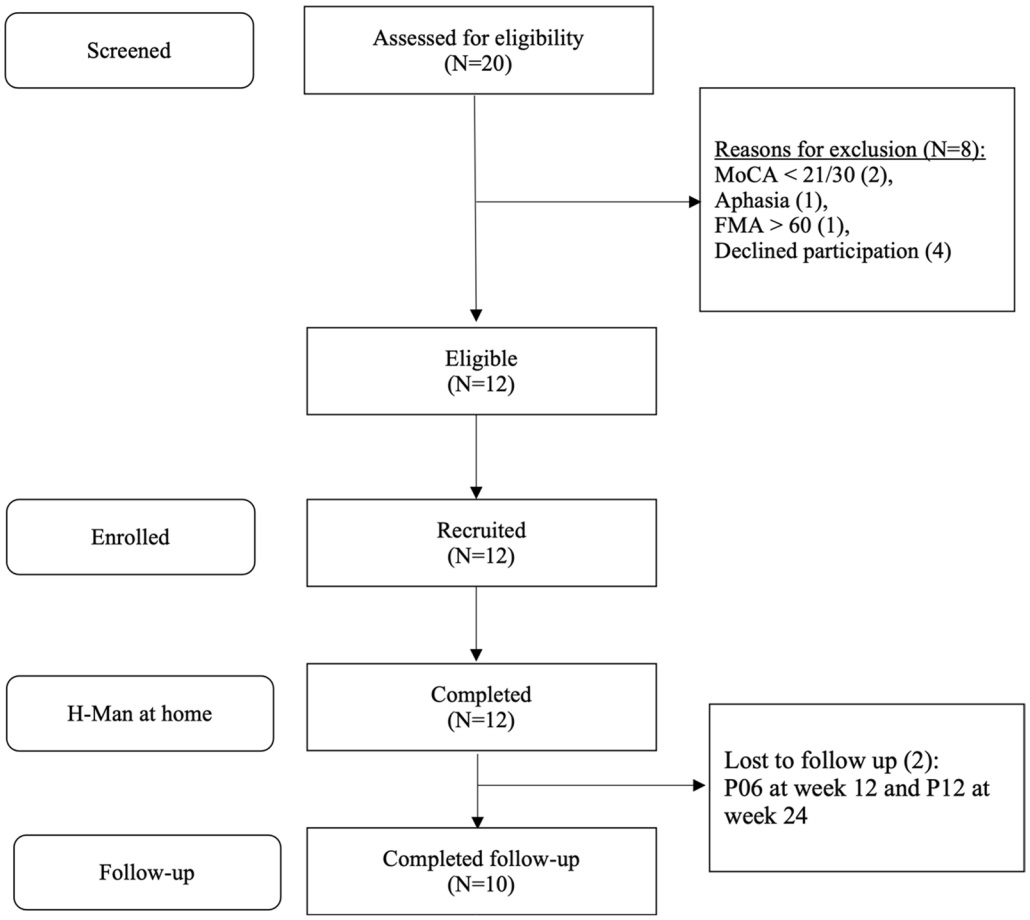


Fig. 4 Participant recruitment flow diagram

provide a summary of the comparison groups' baseline characteristics, intervention and follow up, which were used for CEA. The non-inferiority RCT design was used in the first laboratory prototype of Home-RAT to compare 2 intervention groups: (i)18×90-min sessions over 6 weeks, thrice weekly, of in-clinic supervised RAT (60 min of H-Man and 30 min of COT per session) with (ii) duration-matched in-clinic 90 min per session, thrice weekly, supervised COT by OT.

The baseline FMA and ARAT of both intervention groups were similar; FMA (RAT group) 40.3 (SD 9.3) vs FMA (COT group) 35.9 (SD 11.7), $p > 0.05$; and ARAT (RAT group) 26.6 (SD 16.6) vs ARAT (COT group) 18.9 (SD 15.6), $p > 0.05$. The baseline FMA and ARAT values (RAT intervention group) were comparable with the current study's baseline values of FMA 42.1 (SD 13.2) and baseline ARAT 25.4 (SD 19.5) [14]. The duration of follow up was similar for Budhota et al. and current study, at 24 weeks after baseline measurements.

Adjusted clinical effect sizes for FMA referring to COT, RAT at clinic and RAT at home were calculated using multivariate mixed random effect models and clinically important variables were adjusted in the models (more details in Sect. 2.8.4). CEA was carried out using model-based, estimated individual predicted clinical effect sizes, and healthcare, non-healthcare costs, and total costs for 3 unique treatment pathways.

Incremental Cost-Effectiveness Ratio (ICER) was calculated using the following formula (1):

$$ICER = \frac{\left(Cost\ of\ New\ Intervention - Cost\ of\ Comparator\right)}{\left(Effectiveness\ of\ New\ Intervention - Effectiveness\ of\ Comparator\right)} \quad (1)$$

Table 1 Baseline individual demographic and clinical characteristics (N = 12)

Participant no (P-n)	Group	Age (Years)	Sex/race	Time since stroke (weeks)	Stroke subtype	FMA/66	ARAT/57	HGS (affected) /kg	Dominant hand trained (Y/N)	SSQOL/245	COT (Y/N)*
001	1	75	M/Chinese	89.1	Infarct	15	3	6.2	Y	173	N
002	1	52	M/Burmese	501.0	ICH	33	12	6.2	Y	184	N
003	1	54	M/Chinese	51.1	Infarct	46	24	13.4	Y	197	Y
004	1	56	F/Japanese	177.4	Infarct	36	6	5.9	N	155	Y
005	1	58	M/Chinese	13.4	Infarct	53	38	6.9	N	237	Y
006	1	63	M/Indian	38.3	Infarct	46	22	8.5	Y	177	Y
007	2	54	F/Chinese	41.6	Infarct	53	48	8.2	N	221	Y
008	2	50	M/Chinese	33.6	ICH	52	45	10.3	N	122	N
009	2	76	F/Chinese	22.3	Infarct	56	55	11.2	Y	214	Y
010	2	46	M/Chinese	38.9	Infarct	31	4	3.4	N	200	Y
011	2	62	M/Chinese	32.1	Infarct	56	43	8.4	N	196	Y
012	2	67	M/Caucasian	23.1	ICH	28	5	5.4	Y	147	N

M Male, *F* Female, *ICH* Intracerebral Haemorrhage, *FMA* Fugl Meyer Assessment scale score, *ARAT* Action Research Arm Test, *HGS* Hand Grip Strength, *SSQOL* Stroke specific Quality of Life, *COT* conventional occupational therapy

*concomitant COT during study period

The ICER indicates the additional cost incurred to attain an additional unit of effectiveness with the new intervention when compared to the alternate choice or comparator.

Budget impact analysis (BIA)

The BIA [49] aimed to estimate the potential impact of increased uptake of a new intervention (RAT at home) compared to the current model—only COT. BIA used Singapore's national perspective and a five-year time horizon. To estimate the annual number of stroke survivors eligible for post-stroke rehabilitation, we used national statistics reported by the Singapore Stroke Registry [50] and the Ministry of Health data [51].

Results

Participants and study

Altogether, 12 participants were enrolled from an initial sample of 20 outpatients. Figure 4 shows the participant recruitment flow diagram. All 12 (100%) participants completed initial on-boarding phase of 3 visits (V0-3) and 30 days of minimally supervised Home-RAT training without adverse events or training-related side effects such as shoulder/arm pain, increased arm spasticity or cybersickness. Ten out of 12 participants (83.3%) completed the 24 weeks study while 2 out of 12 (16.7%) were lost to follow-up during the follow-up phase (P06, P12).

Table 1 shows the 12 individual participants' baseline data. Altogether, there were 9 (75%) males and the mean (± SD) age 59.4 (± 9.5) years with an equal number of right (6) and left (6) hemiplegic participants. All participants were in chronic phase of stroke, with considerable variation in the individuals' time after stroke—median duration 38.6 weeks (IQR 25.4, 79.6). It was also noted that 8/12 (66.7%) participants had concomitant COT as part of usual standard therapy over 24 weeks.

The baseline total FMA score was mean (SD) 42.1 (± 13.2) with subtotal FMA (proximal) of 28.9 (± 6.5) and subtotal FMA (distal) of 13.2 (± 7.0). Mean (± SD) total ARAT (0–57) was 25.4 (± 19.5) while subtotal ARAT scores were 8.1 (± 7.1) grasp, 5.6 (± 4.7) grip, 5.5 (± 6.8) pinch and 6.3 (± 1.8) gross. This indicated a chronic population with moderate to severe poststroke arm motor impairment.

Mean (± SD) hemiplegic hand grip strength was 7.8 (± 2.8) kg, SSQOL (0–245) 185.3 (± 32.8) (See Appendix 3 for baseline spasticity).

Follow-up phase and safety data

During the 19-week follow-up phase, 2 out of 12 participants (16.7%) were uncontactable (P06, P12).

Two participants (P005, P010) encountered minor equipment malfunctions, rectified expediently with replacement robots. Two (P001, P008) had software malfunctions, rectified virtually. Mean VAS pain score showed no change across time points T0–T3 (Table 13), and no appreciable increase in clinical spasticity using total (summated) Modified Ashworth Scale (MAS) between T0 to T3 were observed (Appendix 3, Tables 8, 9).

Training compliance obtained from web-based platform data

Training time, compliance with training plan and training patterns

In this study, we defined "active days" as days in which a participant trained at home and logged into the CARE platform at least once for 20 min. The number of active days per participant (mean, ± SD) was 23.0 (± 7.9) for Group 1(trained with 3 home exergames), 29.7 (± 0.8) for Group 2 and 26.3 (± 6.4) for the combined groups over a total of 30 days (Fig. 5a). Notably, Group 2 (trained with 8 home exergames), reported ~ 100% compliance with the goal of daily training during the 30-day intervention period.

The total training time (mean, ± SD) defined as "active hours" per participant during the home trials, removing robotic idling (non-training) time over 30 days, was 28.4 (± 15.1), 42.2 (± 11.6), 35.3 (± 14.7) hours for Group 1, Group 2, and combined groups respectively (Fig. 5b).

On active daily minutes, the participants averaged (± SD) 68.9 (± 21.4), 85.3 (± 23.4), and 77.1 (± 23.0) total minutes of training for Group 1, Group 2, and the combined groups respectively (Fig. 5c). There was a sizable proportion of training sessions exceeding 60 min/day of training, with Group 2 averaging ~ 90 min of training daily. Usual COTS is capped at 60 min/session in our healthcare institution.

No participant reached the advised training duration limit of 120 min/day.

Participants in both groups divided their training into ~ 2 or more sessions per day (Fig. 6a). Robotic non-training or idling time, for example, pausing to decide which game to use next, or simply resting, was also documented. Comparing groups 1 and 2, 20% less non-training time was documented in group 2, with an overall total of 22% of training time spent idling (Fig. 6b).

Figure 7 shows the training time per week per participant for each group. Participants in Group 1 showed a steady decline in training time from week to week, with mean weekly hours reduced by 52% from week 1 to 4. Group 2 participants, on their part, essentially maintained a consistent duration of training hours from week to week.

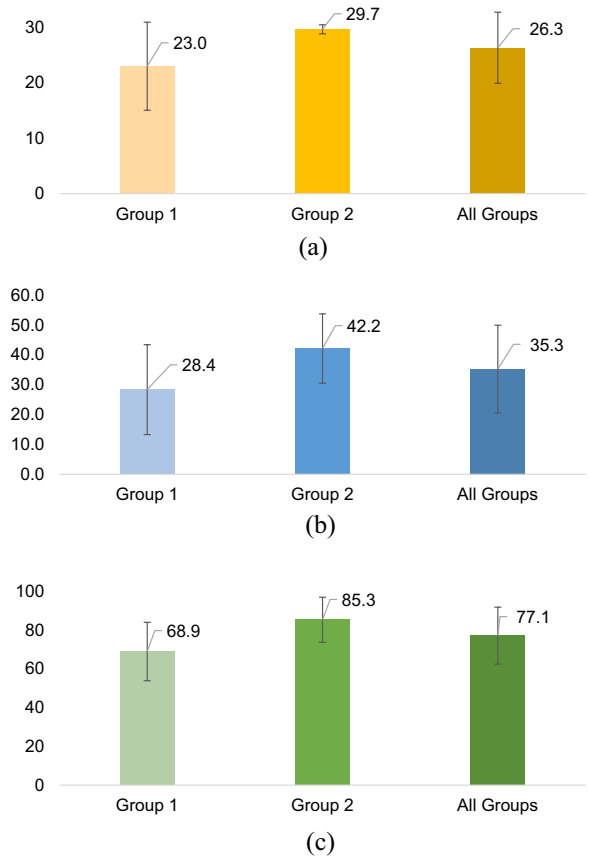


Fig. 5 Participants' compliance with the training plan (mean, ± SD) represented as **a** Total active days per participant (out of 30) **b** Total active hours (out of 30) **c** Duration of active time per day (minutes)

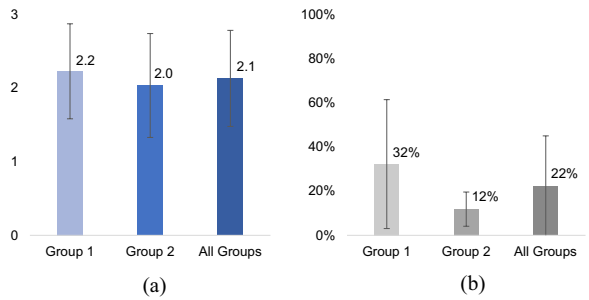


Fig. 6 Patterns in the participants' home-based training (mean, ± SD). **a** Number of training sessions per active day. **b** Percentage of non-training time per session

Figure 8 shows the participants' self-reported outcomes. In general, all 12 participants felt that the exergames was easy to learn, 10/12 were overall quite or well satisfied with the overall experience and deemed it to be useful with a comfortable setup; and 4/12 opined that the exergames could be boring. Overall, 75% (9/12) desired that Home-RAT to be part of their standard treatment. Individual comments recorded participants' positive feedback of training at home and motivation related to virtual reality games while some negative feedback was related to robot dimensions, software glitches and stress of training intensity (see Appendix 4 for individual recorded comments from participants).

Clinical outcomes summary

For each participant, the clinical outcomes were measured via assessments post-trial on weeks 5, 12 and 24. Table 2 provides a summary of the clinical outcomes.

Fugl-Meyer Assessment (0–66). Significant FMA gains were observed across all timepoints and sustained beyond training phase to week 24 (Fig. 9); ΔFMA of 2.4 at week 5 (FMA 44.5, 13.9, $p = 0.02$), from baseline (FMA 42.1, 13.2), ΔFMA 4.3 at week 12 (FMA 46.4, 14.6, $p = 0.004$) and ΔFMA 3.7 at week 24 (FMA 45.8, 14.1, $p = 0.02$).

In terms of individual ΔFMA compared with baseline T0, a minimal detectable change (MDC) of > 5.25 was observed in 2/12 participants at T1, 4/12 at T2, and 3/12 at T3. For the minimal clinical important difference (MCID) FMA range 4.25–7.25 compared with baseline T0, this was observed in 3/12 of participants at T1, 7/12 at T2, and 3/12 at T3.

ARAT (0–57). Similarly, significant, and modest ARAT gains were observed across time and sustained beyond training phase to week 24 (Fig. 10); ΔARAT 2.6 at week 5 (ARAT 28.0, 20.3 $p = 0.03$), from baseline (ARAT 25.4, 19.5, $p = 0.04$), and ΔARAT 4.8 at week 24 (ARAT 30.2, 21.6, $p = 0.004$).

In terms of individual ΔARAT compared with baseline T0, MDC Δ3-7 was observed in 4/12 participants at T1, 4/12 at T2 and 6/12 at T3, while MCID changes of Δ5.7 ARAT were observed in 3/12 at T1, 3/12 at T2 and 3/12 at T3.

WHO-SSQOL (0–245): Significant gains were observed only from week 0 to 24 (Fig. 11); ΔWHO-SSQOL 17.2 at week 24 (WHO-SSQOL 202.4, 28.5, $p = 0.008$) from baseline (WHO-SSQOL 185.3, 32.8). Changes from week 5 to baseline ΔWHO-SSQOL 5.2 (SSQOL 190.4, 31.4, $p = 0.15$) and week 12 to baseline and ΔWHO-SSQOL 6 (SSQOL 191.7, 32.4, $p = 0.25$) were not statistically significant.

See Appendix 3, Tables 8, 9, 10, 11, 12, 13, 14 for MAS, FMA, ARAT, HGS (affected), WHO-SSQOL, VAS pain respectively.

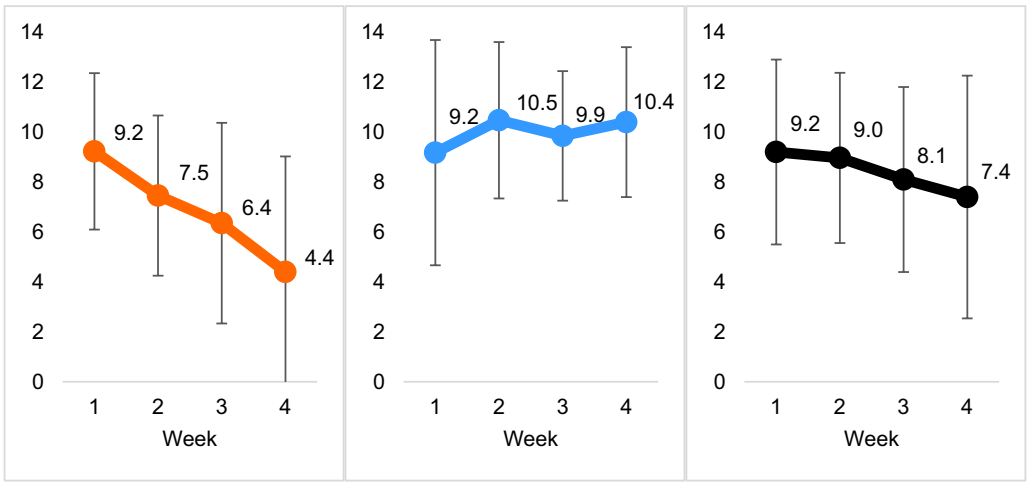


Fig. 7 Patients' total training time per week (mean ± SD). **a** Group 1. **b** Group 2. **c** All groups

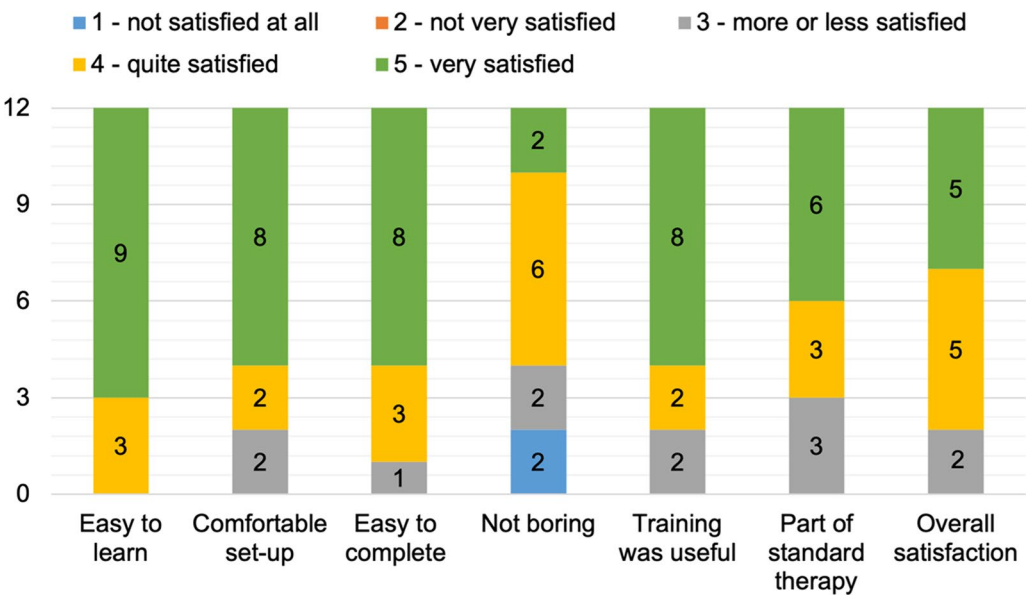


Fig. 8 Participants reported outcome measures at Week 5 (post-training) (N = 12)

Table 2 Summary data of clinical outcomes by timepoint

Variables, Mean (SD)/time point	T0 Week 0	T1 Week 5	T2 Week 12	T3 Week 24
FMA/66	42.1 (13.2)	44.5 (13.9)	46.4 (14.6)	45.8 (14.1)
ARAT/57	25.4 (19.5)	28.0 (20.3)	28.2 (20.7)	30.2 (21.6)
HGS (Affected) (kg)	7.8 (2.8)	8.6 (2.2)	9.3 (2.3)	10.4 (3.8)
SSQOL/245	185.3 (32.8)	190.4 (31.4)	191.7 (32.4)	202.4 (28.5)

FMA Fugl Meyer Assessment scale score, *ARAT* Action Research Arm Test, *HGS* Hand Grip Strength, *SSQOL* Stroke specific Quality of Life

Health-economic outcomes summary

Cost savings were observed for (S$ 2,416.9) Home-RAT compared to (S$ 3,191.0) COT (control) ($p > 0.05$) and (S$ 3,282.1) RAT in clinic. This was mainly related to the lower mean healthcare cost of Home-RAT. Table 3 describes the breakdown costs for each intervention.

Clinical outcome—the adjusted predicted mean (± SD) values of FMA for Home-RAT, COT, and RAT at clinic were 45.8 (± 14.1), 40.4 (± 11.6) and 45.3 (± 11.4), respectively.

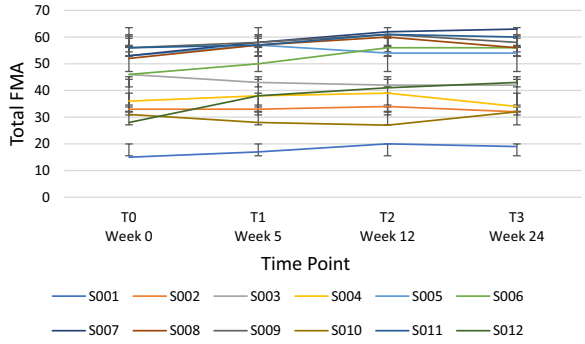


Fig. 9 Changes in total FMA by time point comparing week 0–24 (N = 12). Mean and SD are shown

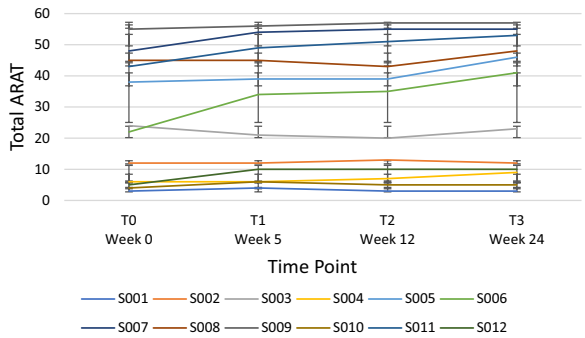


Fig. 10 Changes in total ARAT by time point comparing week 0–24 (N = 12). Mean and SD are shown

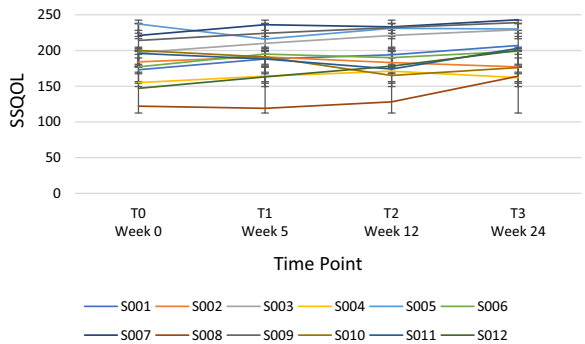


Fig. 11 Changes in SSQOL by time point comparing week 0–24 (N = 12). Mean and SD are shown

As shown in Fig. 12, CEA comparing Home-RAT with COT demonstrated a positive incremental effect of ΔFMA + 5.4 with a negative incremental cost-effectiveness ratio (ICER) of S$ -143.73 per cure. These results indicated that Home-RAT was cost-effective.

In Singapore, assuming a national perspective, with an annual 4% increase in stroke cases [50], a first-year survival rate of 75% [52] and referral for rehabilitation services of 47.2% [51], the cost of using only COT by 19,842 stroke survivors could reach S$ 63,316,616 over five years. As shown in Table 4, a stepwise increase in uptake of RAT at home could reduce the annual budget impact from 5 to 19%, on average, 12% of the total cost [Appendix 2].

Discussion

General summary of study outcomes, feasibility, safety, usability data and sample characteristics

Findings from this pilot study demonstrate preliminary feasibility, acceptability, safety, clinical efficacy, and cost-effectiveness of a web-enabled telemonitored carer-supervised RAT at home using a 2D planar end effector robot, H-Man. There were no major hardware/software malfunctions which majorly disrupted home training and comparisons with manual logged data and cloud data were largely similar. No participants dropped out due to any major adverse events or increases in pain or spasticity.

In terms of "active days" observed, this was aggregated at 87.7% (26.3/30 days adherence) for the entire sample (groups 1 & 2) with a mean of 77 min /day, on ~ 26/30 days of active exergaming (i.e., exceeding the primary outcome goals set at the commencement of the study. This exceeds clinical scheduled intensity of 60 min twice weekly for clinic-based RAT by 4 times.

This was the first time Home-RAT was deployed in home settings with carer supervision. Study inclusion criteria were purposively broad (FMA 10–60) to allow a wide range of UE impairment levels to be trained. Our lower FMA inclusion limit was 10 points less than Budhota et al.'s which described the first RCT for in-clinic H-Man training using FMA 20–50) [14] and the lowest FMA was 15. Our sample's baseline FMA scores were comparable to that of the telerehabilitation (TR) groups of a large RCT on post stroke TR (our 42.1 vs Cramer et al.'s 42.8) [31].

COT was provided only once during the 5-week training period for functional training, as the main purpose of the study was to evaluate feasibility and acceptance of Home-RAT with telemonitoring platform, patterns of self-driven practice at home, clinical efficacy and cost-effectiveness. It was also noted that 8/12 (66.7%) participants had concomitant COT as part of usual standard therapy over 24 weeks and this was not disrupted during the 24-week study duration.

Sample baseline characteristics

In terms of participants' ages, our mean age of ~ 60 years was a decade younger than Singapore's mean age of stroke of 69.8 years, with a predominant younger stroke population with only 2/12 aged > 65 years [50], but of similar age at study to the cohort studied by Cramer et al. (our 60 years vs Cramer et al.'s 62 years) [31]. A higher

Table 3 Mean healthcare, non-healthcare cost, and total cost of clinic-based conventional occupational therapy (COT), RAT at clinic and Home-RAT (N = 11 because one participant did not have retrospective clinical data)

Mean (SD) S$	COT matched toRAT at clinic (Control)	RAT at clinic	Home-RAT (Current research intervention)
Total (A + B)	3,191.04 (1,258.50)	3,282.14 (1,386.05)	2,416.92 (253.26)
(A) Healthcare costs	2,826.12 (1,173.91)	2,917.22 (1,312.51)	2,187.61 (262.62)
Programme cost	2,826.12 (1,173.91)	2,917.22 (1,312.51)	2,050.39 (232.71)
Telemonitoring cost	0.00	0.00	137.22 (83.99)
(B) Non-healthcare costs	364.92 (125.34)	364.92 (125.32)	229.31 (53.56)
Waiting time	0.00	0.00	29.53 (55.20)
Transportation	364.92 (125.34)	364.92 (125.32)	92.03 (35.30)
Home related furniture	0.00	0.00	107.75 (30.75)

S$ Singapore dollar

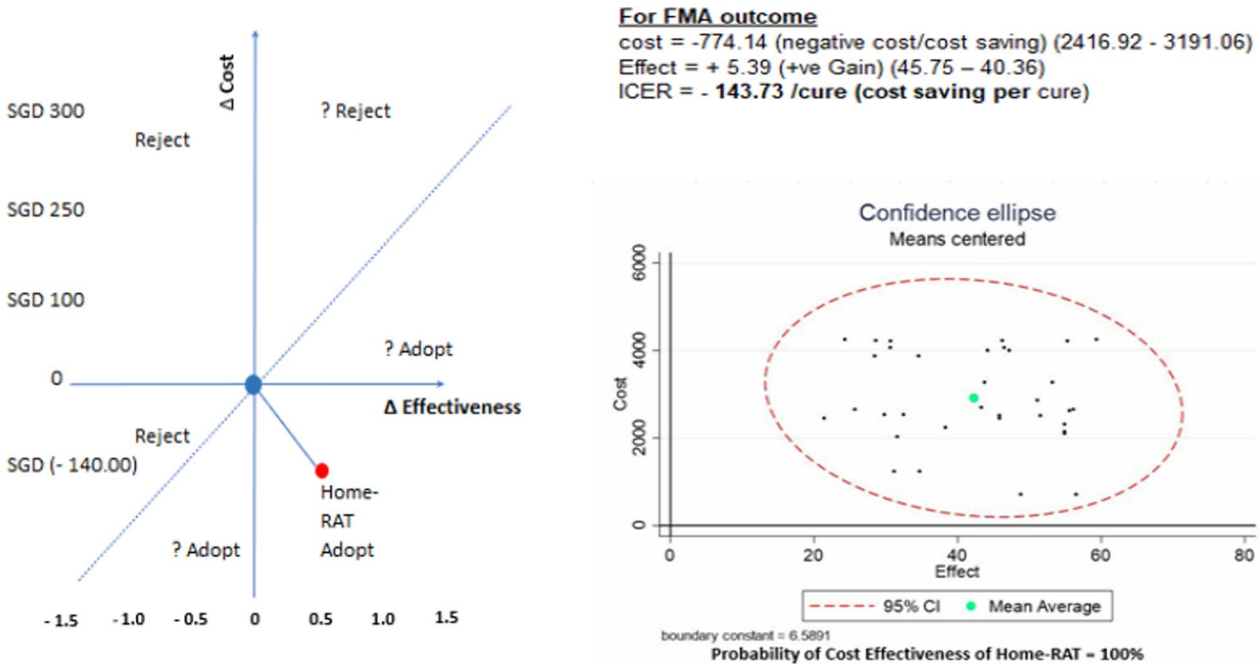


Fig. 12 Cost-effectiveness analysis (CEA) comparing Home-RAT (current research intervention), RAT at clinic and COT. CEA shows that Home-RAT dominates over COT

proportion of haemorrhagic strokes (25%) was noted in comparison to global proportions at 10–15%, typical of Asian stroke demographics [1]. In addition, the chronicity of stroke and wide variation in stroke durations with a median time from stroke of 38 weeks and 25% < 24 weeks, were similar to other studies [19, 31]

Summary of safety data

With regards to safety data, this was satisfactory, as all 12 (100%) participants completed 30 days of Home-RAT training with 0% dropouts and no adverse events possibly related to RAT, such as /shoulder pain or increased shoulder/elbow spasticity. This was explained by meticulous attention paid to proper trunk and arm positioning preserving shoulder biomechanics during onboarding and home training and provision of passive arm supports as needed and intelligent haptic forces feedback to prevent excessive arm effort. Notably, post-training satisfaction score recorded > 83% (10/12) of overall satisfaction score as quite or very satisfied. Individual participant feedback

Table 4 Budget impact analysis of the implementation of Home-based Telerehabilitation over five years in Singapore

Year	First year stroke survivors	Eligible stroke survivors	Only clinic-based COT (control)	Combined use home-RAT and COT			Budget impact (Combined use of home-RAT and COT vs use of only COT)	
			Users of COT (%)	Total cost (S$)	Users of home-RAT (%)	Total cost (S$)	Total cost difference	Total (%) difference
2024	7,761	3,663	100	11,688,780	733 (20)	11,121,659	−567,120	5
2025	8,072	3,810		12,157,862	1,143 (30)	11,273,043	−884,819	7
2026	8,395	3,962		12,642,900	1,981 (50)	11,109,369	−1,533,532	12
2027	8,731	4,121		13,150,276	2,885 (70)	10,917,172	−2,233,104	17
2028	9,080	4,286		13,676,797	3,429 (80)	11,022,495	−2,654,303	19
Sum	42,038	19,842		63,316,616		55,443,738	−7,872,878	

gave opportunities for further technology and delivery improvements. This finding was similar to Cramer et al.'s study of 124 patients who reported < 2% of adverse events in the telerehabilitation group, all unrelated to the study interventions [31].

Regarding the performance of the H-Man robotic platform, this was overall robust and reliable, with 2/12 hardware issues, solved by delivery of a replacement robot, and 2/12 self-limiting software issues; both did not appreciably delay training in the 4 participants.

Summary of objectives

In terms of the primary objectives, these exceeded initial set objectives of > 75% compliance. Through performance generated on cloud data, compliance at home was 87.7% with self-directed exergaming, occurring on a mean of > 26 /30 days, 6 days per week and a mean duration of 77 min daily. This average intensity (~ 30.3 h/month) far exceeded the current centre's standard in-clinic intensity of 8-hourly sessions/month by ~ fourfold. Notably, group 2 participants (n = 6), who were able to access a total of 8 exergames compared to 3 for group 1, recorded 96.7% (29/30 days) adherence. The level of adherence (averaging 92.2% for group 1 & 2) was comparable to a large study by Cramer et al. (98.3%), where 50% of the delivered telerehabilitation sessions were supervised by professionals [31].

Telerehabilitation for stroke rehabilitation

Technology considerations for robotics-aided TR at home

Since the mid-90's to 2000, there has been a surge of TR to address population-level issues in stroke care, such as the reduction of hospitalisation stay and costs through various TR services such as videos, online educational materials or instructions, or supervised training via TR and RAT combined with TR. For the latter, several critical factors are needed for successful implementation, such as reliable internet connections for accessing cloud data, secure web-based portals to allow telemonitoring by healthcare professionals, low-cost, non-complex, portable devices with interactive sensing and gaming devices. Important features for TR incorporating RAT training devices include platforms or delivery systems which enhance engagement rather than discourage, automate delivery and progression of exercise intensity progression, adapt and assess real time performance [53]. Remote human factors such as prompt attention and encouragement ensure that patients remain supported during TR [54].

Few upper limb robotic systems have been developed for use as home-based TR devices. Previous reports of simple distal portable and passive limb robots such as Hand Mentor devices [55] and SCRIPT passive orthosis [56] have been described, focusing on usability and participant feedback for further improvements. These devices are passive wrist and hand orthosis, without active generation of forces or control of moments.

Guillen-Climent et al., reported a safety and usability study of 9 subacute and chronic stroke patients using an unactuated robotic system with a software system based on interactive gaming, the MERLIN, for daily arm and hand rehabilitation for 3 weeks, including 2 weeks at home with 50% (3x/week for the second week) of the time under supervision [19]. Self-directed movements of the wrist were needed for patients and games included assessment and training content, in total 7 games, including online games and word or puzzle games, challenging both UE motor abilities and cognitive abilities [19]. Moderate observable gains in mean total ΔFMA 4.0 at 3 weeks post-intervention, including 2 weeks at home, was observed and high satisfaction scores using objective usability and assistive aid assessment scales, indicating that home-based technology was feasible and safe with

high participant motivation. This benchmark for home-based robotic training is comparable to largest ΔFMA at 4.3 at week 12 follow up of our sample with variations in the proportion of clinic vs home training durations between our study with Guillen-Climent et al.

RAT and TR clinical efficacy

In the first clinical study on H-Man utilising a 2-arm RCT design with combinatory OT, Budhota et al., demonstrated over 24 weeks, FMA gains of Δ4.2, at lower limit of MCID, after 18 h over 6 weeks of in-clinic training [14]. Clinical efficacy of these results was similar to lab versions of the H-Man previously used: ΔFMA 4.2 H-Man at clinic [14] vs ΔFMA 3.7 (current Home-RAT) at week 24 follow-up with similar arm impairment inclusion criteria, albeit this pilot study did not incorporate COT during the month-long training phase. Overall, these treatment gains in clinic or home are comparable with ΔFMA ranges of 2.8–4.0 for various RAT in-clinic trials using including end-effector upper limb RAT [15–17, 57, 58].

Over 24 weeks of follow-up, gains in ΔFMA were sustained over baseline. However, we could not totally ascribe these gains to be solely due to H-Man training as a concomitant low-intensity standard COT was ongoing in 8/12 (66.7%) participants.

Cramer et al., demonstrated that the efficacy of upper limb home-based telerehabilitation (TR) to be comparable to in-clinic therapy with non-inferior results, noting that both TR at home and in clinic therapy groups achieved minimal clinically important difference (MCID) in ΔFMA, exceeding 7 points [31]. In this study, 124 patients were randomised to 2 groups of either TR or clinic-based matched therapy, combining unsupervised and supervised via computer games and dose and duration-matched in-clinic therapy, 70 min 6 days per week [31]. Our study participants achieved lower ΔFMA 4.2 at week 12 and ΔFMA 3.7 at week 24, compared to Cramer et al., (ΔFMA > 7) despite similar baseline FMA and similar training intensity of 70 min, 6 days per week. Individually, 3/12 (25%) of our sample achieved MCID gains at week 24 (follow up T3) for FMA Δ4.25 at least, and ARATΔ5.7, in particular 6/12 (50%) of the sample at week 12 (T2) achieved MDC (Δ3-7) for ARAT.

We postulate that this disparity could be explained by differences in home technology used (actuated robot ours, vs computer games, Cramer et al.), duration of chronicity post stroke (38 weeks, ours vs 18 weeks Cramer et al.). More importantly, a vital factor in the difference in clinical efficacy could be related to the lack of combinatory directly- supervised OT with technology deployment, as 50% of 18 TR home sessions in Cramer et al., were directly supervised and 50% were not in comparison to our home technology deployment which was care-supervised and remotely therapist-monitored.

A meta-analysis by Toh et al., on home-based UE rehabilitation on stroke survivors found home-based rehabilitation to be more effective in improving hemiplegic upper limb function (SMD 0.28, $p < 0.001$) than in-clinic conventional therapy [59]. On the contrary, results from robotic studies, favoured their control groups that used the "no technology" home exercises programme after treatment but not at follow-up. Comparing home-based robotic-powered assisted interventions with clinic controls, these had modest effects, likely due to the low duration, intensity, and limited number of exercises of these RAT (3 exercises) compared to COT (34 exercises) [59]. Again, this reinforces the importance of RAT design for use in remote locations from close supervision, in promoting adherence through motivational strategies, large numbers of virtual reality varied exercises and affordable cost.

RAT and TR economic evaluation

CEA established RAT at home, using H-Man as a cheap and clinically effective option compared to the alternatives, COT, and RAT at clinic. RAT at clinic, compared to COT, incurred higher costs, as the intervention cost included fully OT-supervised sessions and additional robot costs. In concordance with these, a RCT conducted by Fernandez-Garcia et al. showed that a fully supervised mode of RAT at clinic is not a cost-effective option compared to COT [60]. Therefore, RAT at clinic would not represent a preferred mode for therapy delivery in future. On the other hand, RAT at home, where device rental scheme was employed, compared to COT, reduced healthcare cost by 24%, which was possible by decreasing the need for an OT's presence during therapy sessions. Lower healthcare cost and higher clinical gains made H-Man at home more cost-effective than comparators. However, the findings of our CEA differed from the study by Adie et al. [61]. In their analysis, based on an RCT, authors concluded that home-based TR was not a cost-effective option compared to the self-administered Graded Repetitive Arm Supplementary Programme (GRASP). Adie et al.'s unfavorable health-economic results for home-based TR could be attributed to the selection of GRASP—a cost-free comparator (control) and the use of a commercial gaming console as a new intervention, which might not have adequate capabilities for rehabilitation purposes.

Furthermore, our cost outcomes were comparable with previous studies investigating cost of RAT at home [62, 63]. Like those studies, our results showed that the major

costs were saved through decreased therapist's presence during therapy provision. However, in our study, (24%) total cost reduction with Home-RAT compared to clinic-based COT was lower than the findings of (65%) Housley et al. [62] and (44%) Lloréns et al. [63]. This could be explained by large differences in estimated non-healthcare costs, such as transportation cost. In the case of Singapore, transportation costs were minimal and had a negligible effect on overall cost savings with Home-RAT; While other studies reported 75% [62]–88% [63] of total cost reduction due to decreased transportation with a robot at home.

In Singapore, over a five-year span, if by the end of the fifth year, 80% of stroke survivors use RAT at home, it could potentially yield annual cost savings of 19%. However, it is essential to note that the actual cost savings of a novel approach would be contingent upon the number of individuals referred to RAT at home. Thus, uptake rates would require further validation and scrutiny by the stakeholders.

Study limitations

We highlight the following limitations: the small sample size due to the objectives of a pilot trial and the absence of a control intervention arm of either standard COT or clinic-based RAT. A small sample size did not provide enough statistical power to detect differences in economic outcomes. Objective evaluation of system usability and motivational scales were not used. Also, retrospectively collected cost data for RAT at clinic and COT did not represent actual incurred cost; rather, it was estimated based on current attended sessions and estimations were also calculated for transportation and waiting time.

Data on health outcome measures (SSQOL) for RAT at clinic and COT groups were not available to estimate health utilities. Hence, we performed CEA using clinical outcomes (FMA).

Conclusions

We were able to demonstrate a feasible pilot trial for home-based robot-aided rehabilitation TR using telemonitoring with a high level of safety, acceptability with modest sustained gains in upper extremity FMA, comparable with other home-based passive robotic devices; with lower healthcare costs through reductions in numbers of clinic visits and preliminary positive cost effectiveness. Considering the non-inferior outcomes of RAT either in clinic or via TR compared with COT, the ability to reduce healthcare costs and positively impact productivity provides evidence-based solutions to under-resourced healthcare systems. Hence, our findings need to be duplicated and further well-designed randomised controlled trials combining in-clinic COT with home-based robot-aided TR conducted, to compare clinical efficacy, cost effectiveness, types of devices and sustainability from all stakeholders; i.e. patients, practitioners, payors and society.

Furthermore, the presence of cloud computed data facilitates a deeper understanding of dose–response relationships in home-based RAT due to higher numbers of multiple data points per day compared with weekly clinic-based therapy. Detailed analyses of willingness to pay, levels of acceptance amongst healthcare providers, patients and administrators are also needed to evaluate levels of adoption.

Appendix

Appendix 1

Exergames

Tables 5 and 6 present a summary of the exergames employed in this study.

Appendix 2

Cost data sources and model inputs—methodology

Total, healthcare and non-healthcare cost components comparing COT and RAT at clinic were computed based on participants' retrospective billed clinical programme costs during the study duration.

Healthcare costs included onboarding and outcomes/telemonitoring by OT, home visits, H-Man at home rental and supporting furniture.

Non-healthcare costs included participants' and carers' transport, clinic waiting & payment time, carer home supervision time directed towards providing care for patient either during clinic COT or home RAT TR, the latter would include the use of home-related utilities and Wi-Fi [66, 67].

Healthcare costs

Healthcare costs for COT and RAT at clinic were estimated based on therapy sessions performed at TTSH CART, which was obtained from retrospective billed cost per individual patient (2021–2022), where available (11 participants in a RAT at clinic at group had retrospective data). COT in clinic sessions were matched with RAT at clinic for parity. See Table 3.

Healthcare medical cost for H-Man at home was derived by combining the cost of a single (90-min) home visit by an OT and fixed monthly rental of the H-Man device and furniture (where needed).

Table 5 Haptic exergames employed in E_1: groups 1 and 2

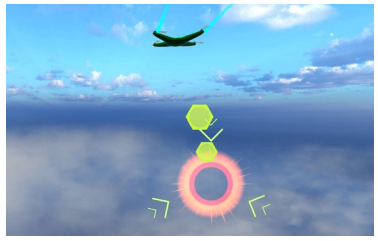
Game	Description	Physical intervention	Objectives	Image
1. Explore the world	The player has to move the cursor through a series of target points on the screen in order to reveal a hidden picture	The game evolves from providing assistance to providing perturbation using the spectral arc length (SPARC) metric to quantify movement smoothness [64]	Coordination	
2. Fishing	Fish appear swimming toward the bottom of the screen at random intervals. The player's task is to catch as many fish as possible (one at a time) with a net	None	Agility	
3. Drone	The player controls a drone to capture targets appearing at random locations on the screen	A viscous haptic field creates a resistive and/or perturbation forces proportional to the drone's speed	Strength	

Table 6 Haptic exergames employed in E_2: group 2 only

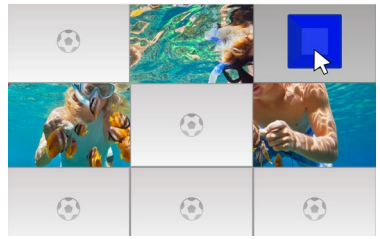
Game	Description	Haptic intervention	Objectives	Image
4.Restaurant	The player has to serve dishes to customers by moving the dish along a conveyor belt to make it reach the customer	Viscous haptic field	Arm reach	
5.Flower Shop	The player has to bring potted plants to the customers. Motor challenge consists of avoiding collisions. Cognitive challenge consists of recalling the items ordered and the sequence of customers arrival	Errorless motor learning [65]: a high-viscosity field surrounding the virtual objects reduces the chances of a collision "Errorful" motor learning: haptic perturbations increase the chances of collisions	Coordination/Memory	
6.Race car	The player drives a car along a closed track, attempting to overtake other cars while avoiding obstacles on the track	Resistance or perturbation	Coordination	
7.Matching pairs	The player is presented with an array of tiles. Picking a tile momentarily reveals a geometric figure underneath. The player tries to pick two tiles with matching figures. The goal is to guess all figure pairs with the least number of moves. Haptic intervention provides strength training simultaneously	Resistance or perturbation	Memory/strength	

Table 6 (continued)

Game	Description	Haptic intervention	Objectives	Image
8.Music	The screen shows an array of graphic objects, each of which produces a unique sound when touched. The game presents the player with a sequence of sounds. The task is to reproduce the sequence by "playing" the objects. Haptic intervention provides strength training simultaneously	Resistance or perturbation	Memory/strength	

Table 7 Budget impact analysis (BIA)

	Parameter	Value	Source
a	Individuals affected by stroke at the start point	8846 in 2019	[50]
b	Annual mean incremental rate of stroke incident	4%	[50]
c	First-year post-stroke survival rate	75%	[52]
d	Percentage of stroke survivors referred to **C**onventional **O**ccupational **T**herapy **(COT)**	47.2%	[51]
e	Total mean cost of COT in clinic	S$ 3, 191	Our study
f	Total mean cost of home-based **R**obot-**A**ssisted **R**ehabilitation **(RAT)** and **T**ele**r**ehabilitation **(TR)**	S$ 2, 417	Our study
$g_{1\text{-}5}$	Annual rate of COT users in a clinic	$_{1–5}$ = 100%	Assumption
$h_{Rat\&Tr1\text{-}5}$	Annual rate of home-based RAT and TR users over 5 years	$_1$ = 20%; $_2$ = 30%, $_3$ = 50%, $_4$ = 70%, $_5$ = 80%	Assumption
$h_{Cot1\text{-}5}$	Annual rate of COT users in a clinic over 5 years	$_1$ = 80%, $_2$ = 70%, $_3$ = 50%, $_4$ = 30%, $_5$ = 20%	Assumption

(1) **Total annual cost of monotherapy of COT =** $(a+a\times b)\times c\times d\times e\times g_{1\text{-}5}$
(2) **Total annual cost of new model** $=(a+a\times b)\times c\times d\times e\times h_{Cot1\text{-}5})+((a+a\times b)\times c\times d\times f\times h_{Rat\&Tr1\text{-}5})$
(3) **Incremental annual cost for 5 years =** Total cost of a new model over 5 years—Total cost monotherapy of COT over 5 years

Non-healthcare costs

Non-healthcare costs for COT in clinic and RAT at clinic consisted of (i) transportation costs estimated based on the distance from individuals' homes to the clinic, using standard fares for public and private transportation in Singapore; (ii) caregiver time (waiting time) to provide either clinic-based COTs or Home-RAT, and (ii) resources needed for devices' home deployment. The caregiver time-related cost of Home-RAT was estimated for 5 in-clinic non-therapy visits and home-based assistance during home usage of the device.

The salary rates were derived from respective data sources for each type of caregiver [68, 69]. The transportation cost of Home-RAT included the cost of commuting for 5 in-clinic non-therapy visits (estimated identically to COT and RAT at clinic, the monthly rent of home space [70] to accommodate the device and the bill for electricity consumed by the device (estimates provided by the developer). See Table 7.

Table 8 Baseline individual spasticity scores by Modified Ashworth Scale (MAS)* by arm region (N = 12)

Participant No	Modified Ashworth Scale (MAS)			
	Shoulder	Elbow	Wrist	Fingers
001	1	1	2	2
002	1	1.5	2	1.5
003	0	1	1	1.5
004	0	2	2	1.5
005	0	1	1	1
006	0	1	0	0
007	0	1	0	0
008	0	1	1	0
009	0	1	1	1
010	0	1	0	1
011	1	2	2	1.5
012	0	2	2	1.5

*MAS 1 + was assigned with numerical value of 1.5 to allow computation)

Appendix 3

Baseline characteristics and clinical variables

See Tables 8, 9, 10, 11, 12, 13, and 14.

Table 9 Total spasticity scores by Modified Ashworth Scale (MAS) by time point (N = 12)

Participant No	Total Modified Ashworth Scale (MAS) score			
	T0 Week 0	T1 Week 5	T2 Week 12	T3 Week 24
001	6	4	5.5	6
002	6	5	5	4
003	5	5.5	6	7
004	3.5	4	4	4.5
005	5.5	5.5	5	3.5
006	3	1	1	1
007	1	1	1	1
008	1	1	1	2.5
009	2	1	1	1
010	3	2.5	6.5	5
011	2	3.5	2	2
012	6.5	4.5	5	4

*MAS 1 + was assigned with numerical value of 1.5 to allow computation of all regions to arrive at a total MAS score)

Appendix 4

Summary of participant subjective feedback

Participant feedback at week 5.

i. It is good that I can be able to do it on my own time without needing to travel for therapy.
ii. It is good that my therapist can support from afar without any need for a home visit.
iii. I am able to feel resistance and tone strength.
iv. I enjoy the racing car game.
v. I enjoy fishing and explore the world game.
vi. I like the pictures from explore the world and want to get more points for fishing and drone games.

Participant suggestions or improvements at week 5.

i. System occasionally hangs, there were certain game glitches, brush would freeze occasionally, and I am unable to move it – had to resort to using another hand to push.
ii. Graphics quality could be improved.
iii. I prefer to have a scoring system to indicate my performance and could add graded increase in game difficulty.
iv. I had to pull the handle very hard as there was too much resistance.
v. Smaller dimension would be better – table is too big, and my arm keeps hitting the edge of the device.
vi. Intensity of exercise required for 30 days might be overwhelming – tough to integrate exercises with full programme.
vii. Duration was too long, and it was tiring, games were also repetitive without any music or sound.

Appendix 5

Summary of univariate and multivariate statistical values

See Tables 15, 16.

Table 10 Total and subset FMA scores across timepoints (N = 12)

Participant no	FMA Scores											
	T0 (Week 1)			T1 (Week 5)			T2 (Week 12)			T3 (Week 24)		
	Shoulder elbow	Wrist hand	Total	Elbow	Wrist hand	Total	Shoulder elbow	Wrist hand	Total	Shoulder elbow	Wrist hand	Total
001	14	1	15	16	1	17	17	3	20	17	2	19
002	26	7	33	26	7	33	26	8	34	27	5	32
003	30	16	46	29	14	43	28	14	42	29	13	42
004	28	8	36	30	8	38	30	9	39	29	5	34
005	36	17	53	35	22	57	36	18	54	34	20	54
006	29	17	46	34	16	50	36	20	56	35	21	56
007	34	19	53	37	21	58	41	21	62	41	22	63
008	32	20	52	36	21	57	37	23	60	35	21	56
009	35	21	56	36	22	58	38	23	61	35	23	58
010	25	6	31	25	3	28	24	3	27	29	3	32
011	36	20	56	38	19	57	39	22	61	39	21	60
012	22	6	28	27	11	38	28	13	41	29	14	43
Mean	28.9	13.2	42.1	30.8	13.8	44.5	31.7	14.8	46.4	31.6	14.2	45.8
SD	6.5	7.0	13.2	6.5	7.6	13.9	7.3	7.5	14.6	6.4	8.3	14.1

Table 11 Total ARAT scores across timepoints (N = 12)

Participant no	Total ARAT Scores			
	T0 (Week 1)	T1 (Week 5)	T2 (Week 12)	T3 (Week 24)
	Total	Total	Total	Total
001	3	4	3	3
002	12	12	13	12
003	24	21	20	23
004	6	6	7	9
005	38	39	39	46
006	22	34	35	41
007	48	54	55	55
008	45	45	43	48
009	55	56	57	57
010	4	6	5	5
011	43	49	51	53
012	5	10	10	10
Mean	25.4	28.0	28.2	30.2
SD	19.5	20.3	20.7	21.6

Table 12 Mean hand grip strength scores across time points (N = 12)

Participant no	Hand Grip Strength (kg) (Affected)			
	T0 (Week 1)	T1 (Week 5)	T2 (Week 12)	T3 (Week 24)
	Average	Average	Average	Average
001	6.2	5.6	7.1	5.9
002	6.2	7.6	7.2	7.4
003	13.4	9.8	8.9	8.3
004	5.9	5.5	6.2	5.6
005	6.9	8.1	9.6	9.3
006	8.5	9.5	14.0	18.4
007	8.2	9.5	9.2	11.1
008	10.3	11.9	11.1	16.0
009	11.2	12.1	12.1	12.2
010	3.4	8.9	7.6	9.9
011	8.4	8.5	10.6	10.3
012	5.4	6.0	7.7	10.0
Mean	7.8	8.6	9.3	10.4
SD	2.8	2.2	2.3	3.8

Table 13 Total WHO-SSQOL scores across timepoints (N = 12)

Participant no	WHO-SSQOL scores			
	T0 (Week 1)	T1 (Week 5)	T2 (Week 12)	T3 (Week 24)
	Total	Total	Total	Total
001	173	188	194	207
002	184	191	183	177
003	197	210	221	229
004	155	164	171	162
005	237	216	231	230
006	177	195	190	199
007	221	236	233	243
008	122	119	128	164
009	214	224	232	239
010	200	191	165	176
011	196	188	174	203
012	147	163	178	200
Mean	185.3	190.4	191.7	202.4
SD	32.8	31.4	32.4	28.5

Table 14 VAS Pain scores across timepoints (N = 12)

Participant no	VAS Pain score			
	T0 (Week 1)	T1 (Week 5)	T2 (Week 12)	T3 (Week 24)
	Total	Total	Total	Total
001	0	0	0	0
002	0	0	0	0
003	0	0	0	0
004	0	0	0	0
005	0	0	0	0
006	2	0	0	0
007	0	0	0	0
008	0	0	0	0
009	4	0	0	0
010	0	0	0	0
011	0	0	0	0
012	2	0	1	0

Table 15 Univariate analysis of factors associated with outcomes (FMA Total, ART Total and SSQOL Scores) mixed random effect model

	Outcome: FMA total				Outcome: ARAT total				Outcome: SSQOL			
	Unadjusted regression coefficients	95%	CI:	P Value	Unadjusted regression coefficients	95%	CI:	P Value	Unadjusted regression coefficients	95%	CI:	P Value
Age												
Aged < 64	Ref:				Ref:				Ref:			
Aged ≥ 65	−9.14	−30.04	11.77	0.392	−6.92	−37.48	23.65	0.657	5.53	−28.37	39.42	0.749
Gender												
Gender (Male)	Ref:				Ref:				Ref:			
Gender (Female)	8.86	−6.31	24.03	0.252	14.42	−14.58	43.41	0.33	20.53	−20.75	61.81	0.33
Dur of stroke												
≤ 24 weeks	Ref:				Ref:				Ref:			
> 24 weeks	−7.19	−21.42	7.03	0.322	−9.64	−36.30	17.02	0.479	−22.42	−58.49	13.65	0.223
Side of the stroke												
Right	Ref:				Ref:				Ref:			
Left	−8.44	−24.18	7.29	0.293	−13.30	−37.65	11.05	0.284	−18.68	−50.75	13.38	0.253
Both	6.10	−5.51	17.71	0.303	6.45	−14.63	27.53	0.549	29.15	4.59	53.71	0.02
Type of stroke												
Infarct	Ref:				Ref:				Ref:			
Haemorrhage	−3.25	−18.48	11.98	0.676	−7.81	−31.59	15.98	0.52	−39.25	−69.19	−9.31	0.01
Recurrence of stroke												
No Recurrence	Ref:				Ref:				Ref:			
Yes Recurrence	9.98	−3.25	23.20	0.139	17.33	−0.46	35.11	0.056	−7.43	−37.26	22.41	0.626
TOT_days_trained_mth	0.00	−1.29	1.30	0.994	1.00	−0.25	2.25	0.115	0.00	−1.29	1.30	0.994
Involvement of upper limb	9.46	−5.03	23.95	0.201	14.38	−7.10	35.85	0.189	23.54	−6.89	53.98	0.129
Weeks (0/Baseline)	Ref:				Ref:				Ref:			
5	2.42	0.38	4.46	0.02	2.58	0.31	4.85	0.026	5.17	−1.87	12.21	0.15
12	4.33	1.35	7.32	0.004	2.75	0.08	5.42	0.043	6.42	−4.58	17.42	0.253
24	3.67	0.53	6.81	0.022	4.75	1.55	7.95	0.004	17.17	4.42	29.91	0.008

Table 16 Adjusted effect size estimates by time point for FMA total, ARAT total and SSQOL scores changes (multivariate mixed random effect model)

	Outcome: FMA total				Outcome: ARAT total				Outcome: SSQOL			
	Adjusted effect size (Coefficients)	95%	CI:	P Value	Adjusted Effect Size (Coefficients)	95%	CI:	P Value	Adjusted effect size (Coefficients)	95%	CI:	P Value
Visit (week)												
Baseline (Week 0)					Ref:				Ref:			
Week—5	2.42	0.38	4.46	0.02	2.58	0.31	4.85	0.026	5.17	−1.87	12.21	0.15
Week—12	4.33	1.35	7.32	0.004	2.75	0.08	5.42	0.043	6.42	−4.58	17.42	0.253
Week—24	3.67	0.53	6.81	0.022	4.75	1.55	7.95	0.004	17.17	4.42	29.91	0.008
Nature of the stroke												
Infarct					Ref:				Ref:			
Haemorrhage					−56.91	−98.89	−14.92	0.008	−27.60	−50.21	−4.98	0.017
Recurrence of stroke	Ref:											
Recurrent stroke (No)	−50.86	−78.11	−23.61	< 0.0001	Ref:				Ref:			
Recurrent stroke (Yes)	23.28	16.76	29.81	< 0.0001	32.56	18.13	46.98	< 0.001	−75.09	−107.53	−42.65	0
Side of stroke												
Right	Ref:				Ref:				Ref:			
Left	41.81	26.24	57.39	< 0.0001	40.22	14.42	66.02	0.002	39.38	4.23	74.53	0.028
Bilateral	4.46	−2.84	11.75	0.231	3.02	−14.08	20.11	0.729	8.23	−10.45	26.92	0.388
Intensity of training												
TOT days trained per month	3.76	2.62	4.91	< 0.0001	3.85	2.13	5.56	< 0.001	2.44	0.46	4.42	0.016

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Author contributions
Author contributions i. Ethical approval KSGC, WBC, PLO. ii. Device provision, technical support, cloud data and monitoring: GAO, AH, MM. iii. Study concept, design: KSGC, PLO, CWKK, LWK, KHG. iv. Clinical trial screening, recruitment, tele monitoring: PLO, TKP, CYN, WBC. v. Participant safety monitoring: PLO, TKP, CYN, WBC. vi. Data analysis, clean up, tables, figures: LWK, KHG, WBC, TS, MM, SK, JAML. vii. Health Economics Analysis: TS, LWK, KHG, HJC, SK. viii. Manuscript Preparation: GAO, KSGC, LWK, KHG, TS Equal contribution: GAO, KSGC, TS, LWK, KHG All authors have reviewed and agreed on the final version of the manuscript.

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Availability of data and materials
These data sets (anonymised) will be made available on request.

Declarations

Ethics approval and consent to participate
Institutional review board approvals were obtained from National Healthcare Group (NHG 2021/00156). All participants gave written informed consent.

Consent for publication
Participant gave written consent for image in Fig. 1B.

Competing interests
KSGC and CWKK both declare interests that they were not involved in participant screening, informed consent, participant recruitment, data analysis nor data safety monitoring due to their co-sharing royalties from H-Man co-development. AH declares interest as co-founder and CEO of the company leading the development of H-Man and was not involved in the concept, conduct of trial, data monitoring or analysis of results. The following authors have no competing interests: GAO, PLO, TKP, CYN, LWK, KHG, WBC, JAML, MM, TS, SK, HJC.

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