Development of a home-based Computer Assisted Arm Rehabilitation (hCAAR) device for upper limb exercises in stroke patients

by

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The candidate confirms that the work submitted is his own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

Chapter 2 is based on work from a jointly-authored publication in Journal of Rehabilitation Medicine. The paper is as follows: Systematic review of outcome measures used in the evaluation of robot-assisted upper limb exercise in stroke. Sivan M, O'Connor RJ, Makower S, Levesley M, Bhakta B. Journal of Rehabilitation Medicine 2011; 43(3): 181-9. Dr Sivan identified the clinical studies and outcome measures, categorised the outcome measures and wrote the paper. Dr O'Connor and Miss Makower identified outcome measures and edited the paper. Professor Levesley and Professor Bhakta conceptualised the systematic review, identified the clinical studies and edited the paper.

Chapter 3 is based on work from a jointly-authored publication in Assistive Technology. The paper is as follows: Investigating the International Classification of Functioning, Disability and Health (ICF) framework to capture user needs in the concept stage of rehabilitation technology development. Sivan M, Gallagher J, Holt R, Weightman A, Levesley M, Bhakta B. Assistive Technology 2014; 26(3): 164-173**.** Dr Sivan conceptualised the study, conducted the user interviews and wrote the paper. Mr Gallagher and Dr Weightman suggested ideas for user interviews, assisted in user interviews and edited the paper. Dr Ray Holt, Professor Levesley and Professor Bhakta suggested ideas for user interviews and edited the paper.

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Contributions

This research has been carried out by a team that has included members from the Academic Department of Rehabilitation Medicine (the main author (MS), Sophie Makower, Rory J O'Connor and Bipinchandra Bhakta) and the Department of Mechanical Engineering (Justin Gallagher, Ray Holt, David Keeling and Martin Levesley) from the University of Leeds.

The main author's contributions, which are fully and explicitly indicated in the thesis, have been writing the research protocol, obtaining approvals from the Research Ethics Committee (REC), Research and Development (R&D) and the Medicines and Healthcare Products Regulatory Agency (MHRA), the screening and recruitment of participants, conducting and recording user interviews, helping with development of levels for the computer games, conducting the feasibility study, helping device installation in homes, kinematic and clinical outcome measurements, maintaining research site files and data collection, clinical advice to users on adverse events, undertaking the statistical analysis of the data and writing the thesis.

The contributions of other members of the research team have been as follows: Justin Gallagher wrote the software program and control algorithms for the device, designed and helped manufacture the device, helped install the devices in homes, attended to all the device technical problems during the study period, undertook the kinematic outcome measurements and helped undertake statistical analysis of the data. Sophie Makower undertook clinical outcome measurements in the post-use and final assessments. David Keeling helped undertake the kinematic outcome measurements in the absence of Justin Gallagher. Rory J O'Connor reviewed the clinical outcomes, supervised the main author after the retirement of Bipinchandra Bhakta and reviewed the thesis. Martin Levesley supervised the author throughout the project, supervised the manufacture of the device, helped with obtaining regulatory body approvals, helped install the devices at homes and reviewed the thesis. Bipinchandra Bhakta was the principal investigator, supervised the author throughout the project, helped with obtaining approvals from the regulatory bodies, secured research grants and reviewed the thesis.

List of publications/presentations arising from this thesis

Review article

Sivan M, O'Connor RJ, Makower S, Levesley M, Bhakta B. Systematic review of outcome measures used in the evaluation of robot-assisted upper limb exercise in stroke. Journal of Rehabilitation Medicine 2011; 43(3): 181-9.

Original article

Sivan M, Gallagher J, Holt R, Weightman A, Levesley M, Bhakta B. Investigating the International Classification of Functioning, Disability and Health (ICF) framework to capture user needs in the concept stage of rehabilitation technology development for stroke patients. Assistive Technology 2014; 26(3): 164-173.

Research letter

Sivan M. Interpreting effect size to estimate responsiveness of outcome measures. Stroke 2009; 40(12); e709.

Oral presentations

Sivan M, Gallagher J, Makower S, O'Connor R, Levesley M, Bhakta B. Home Based Computer Assisted Arm Rehabilitation (hCAAR) robotic system for upper limb therapy after stroke, A feasibility study. Presented at the Society for Research in Rehabilitation (SRR) meeting, Feb 2014, London, United Kingdom (UK).

Sivan M, Gallagher J, Holt R, Weightman A, Levesley M, Bhakta B. The "ICF Core Set for stroke" as a useful template to capture user needs during development of arm rehabilitation technology. Presented at the British Society of Rehabilitation Medicine (BSRM) and SRR joint meeting, July 2011, Newcastle-under-Lyme, UK.

Sivan M, O'Connor RJ, Makower S, Levesley M, Bhakta B. Using the ICF to systematically review outcomes used in the evaluation of robot assisted upper limb exercise. Presented at the SRR meeting, July 2010, Sheffield, UK.

Original article accepted for publication

Sivan M, Gallagher J, Makower S, Keeling D, Bhakta B, O'Connor RJ, Levesley M. Home-based Computer Assisted Arm Rehabilitation (hCAAR) robotic device for upper limb exercises after stroke. Results of a feasibility study in home setting. Journal of NeuroEngineering and Rehabilitation.

Original article submitted for publication

Sivan M, Gallagher, Holt R, Bhakta B, O'Connor RJ, Levesley M. Employing the International Classification of Functioning, Disability and Health (ICF) framework to capture user feedback in the design and testing stage of development of home-based arm rehabilitation technology.

Abstract

Home-based robotic technologies may offer the possibility of self-directed upper limb exercise after stroke as a means of increasing the intensity of rehabilitation treatment. The aim of this research project was to develop and evaluate a robotic device hCAAR that can be used independently at home by stroke survivors with upper limb weakness. The project had two stages: Stage 1, hCAAR development using a user-centred design process; Stage 2, A feasibility clinical study in the home setting.

Stage 1: Nine stroke survivors with upper limb weakness and six healthcare professionals were involved in the concept and design stages of device development. hCAAR consists of a powered joystick with a computer interface, which is used to direct the movement of the upper limb to perform therapeutic movements as directed by tasks on the screen. hCAAR also provides controlled assistance when the user's voluntary upper limb movement is insufficient to complete the prescribed task.

Stage 2: In the feasibility study, 19 participants (stroke survivors with upper limb weakness) were recruited and 17 participants used hCAAR in their homes for eight weeks. No serious adverse events were reported. All 17 participants were able to use the device independently. A statistically significant improvement was observed in the kinematic and clinical outcomes. Three participants showed clinically significant improvement in all clinical outcomes. Five participants reported improvement in functional ability in daily activities. Participants, family members and therapists were satisfied with the usability of hCAAR in the home setting.

This research project also demonstrated that the International Classification of Functioning, Disability and Health (ICF) Comprehensive Core Set for stroke provides a useful basis to structure interviews to gather feedback from end-users and healthcare professionals in different stages of the rehabilitation device development.

In summary, hCAAR is a home-based rehabilitation robotic device that can be independently used by stroke survivors with upper limb weakness and has the potential to improve upper limb movement and function.

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List of Abbreviations

A0	Baseline assessment
A1	Post-use assessment
A2	Final follow-up assessment
ACRE robot	ACtive REhabilitation robot
ADL	Activities of Daily Living
ADRM	Academic Department of Rehabilitation Medicine
AMAT	Arm Motor Ability Test
AMES	Assisted Movement with Enhanced Sensation
ARAMIS	Automatic Recovery Arm Motility Integrated System
ARAT	Action Research Arm Test
ARM Guide	Assisted Rehabilitation and Measurement Guide
AS	Ashworth Scale
BATRAC	Bilateral Arm Training with Rhythmic Auditory Cueing
BB	Bipinchandra Bhakta
BBT	Box and Block Test
BdF	Braccio di Ferro
BFIAMT	Bilateral Force Induced Isokinetic Arm Movement Trainer
BI	Barthel Index
CAHAI	Chedoke Arm and Hand Activity Inventory
CIMT	Constraint Induced Movement Therapy
CMSA	Chedoke McMaster Stroke Assessment
CRT	Charterhouse Rehabilitation Technologies
DOF	Degrees of Freedom
EMG	Electromyogram
EQ-5D	European Quality of Life – 5 Dimensions
FAT	Frenchay Arm Test
FIM motor	Functional Independence Measure motor subscale
fMRI	Functional Magnetic Resonance Imaging
FM-UE	Fugl-Meyer Upper Extremity motor subscale
GMC	General Medical Council
hCAAR	Home-based Computer Assisted Arm Rehabilitation
HEXORR	Hand Exoskeleton Rehabilitation Robot

HWARD	Hand Wrist Assistive Rehabilitation Device
Hz	Hertz
ICF	International Classification of Functioning, Disability and Heath
ICIDH	International Classification of Impairments, Disabilities and Handicap
ID	Identification
iPAM	Intelligent Pneumatic Arm Movement
IT	Information Technology
IQR	Inter-quartile range
JG	Justin Gallagher
L-Exos	Light Exoskeleton
MAL	Motor Activity Log
MAS	Modified Ashworth Scale
MCID	Minimal Clinical Important Difference
MEMOS	MEchatronic system for Motor recovery after Stroke
MFT	Manual Function Test
MHRA	Medicines and Healthcare Products Regulatory Agency
MIME	Mirror Image Movement Enabler
MIT	Massachusetts Institute of Technology
ML	Martin Levesley
mm	Millimetre
Motor AS	Motor Assessment Scale
MRC	Medical Research Council
MS	Manoj Sivan
MSS	Motor Status Score
NCMRR	National Centre for Medical Rehabilitation Research
NeReBot	Neuro Rehabilitation Robot
NHPT	Nine Hole Peg Test
NHS	National Health Service
NSA	Nottingham Sensory Assessment
R&D	Research and Development
REC	Research Ethics Committee
REHAROB	REHabilitation ROBotic

RH	Raymond Holt
RMA	Rivermead Motor Assessment
RJOC	Rory J O'Connor
ROC curve	Receiver Operating Characteristic curve
ROM	Range of Motion/Movement
SD	Standard Deviation
SCT	Star Cancellation Test
S-E	Shoulder Elbow
sec	Seconds
SF-36	Short Form (36) health survey
SIS	Stroke Impact Scale
SM	Sophie Makower
TCT	Trunk Control Test
TUG	Timed Up and Go
UCD	User Centred Design
UL	Upper Limb
VAS	Visual Analogue Scale
WHO	World Health Organization
WMFT	Wolf Motor Function Test

Chapter 1: Introduction

Stroke is a major public health problem with an annual incidence estimate of 15 million people worldwide [1], between 200 and 300 per 100,000 people in Europe [2] and around 130,000 in the United Kingdom (UK) [3]. Globally, it is the third leading cause of mortality (after coronary heart disease and cancer) and results in 5 million deaths annually [4]. Stroke is the leading cause of adult onset disability worldwide, and annually, leads to 5 million people developing long-term disability and dependency [1, 2, 4]. In the UK, the estimated direct and indirect costs of stroke care are £ 9 billion a year, accounting for approximately 5% of the total National Health Service (NHS) costs [3]. With a progressively ageing population and improved stroke survival rates, the number of survivors with disability is expected to increase in the coming decades.

Stroke is defined as acute neurological dysfunction of vascular origin with rapid onset of symptoms according to the affected regions of the brain [5]. Depending on the location and severity of the stroke, stroke survivors can experience problems such as motor weakness, sensory disturbances, communication difficulties, visual disturbance, cognitive difficulties, reduced mobility or difficulty in performing daily activities.

1.1 The ICF framework

The last century has witnessed various conceptual models describing the relationship between diseases and their functional consequences. The initial models that described disability as an attribute of the individual (medical model, original Nagi model) faced criticism from societies of individuals with physical impairments and led to the development of models that describe disability being related to the environment (social model of disability) [6, 7]. The recent models (Modified Nagi model, International Classification of Impairments, Disabilities and Handicap ICIDH, National Centre for Medical Rehabilitation Research NCMRR model, International Classification of Functioning, Disability and Health ICF) depict the interaction better by linking disability to the person-environment relationship [8-11]. The

World Health Organization's (WHO) ICF framework is the most widely accepted model and used officially in more than 190 countries [7].

The ICF [11] provides a useful framework to understand the impact of the condition on the individual and helps plan rehabilitation interventions to improve function and reduce disability. The domains of the ICF framework are as below:

(a) Body functions and structures: Functions refers to physiological functions of body systems including psychological function. Structures are anatomical parts or regions of the body and their components. Impairments are problems in body function or structure.

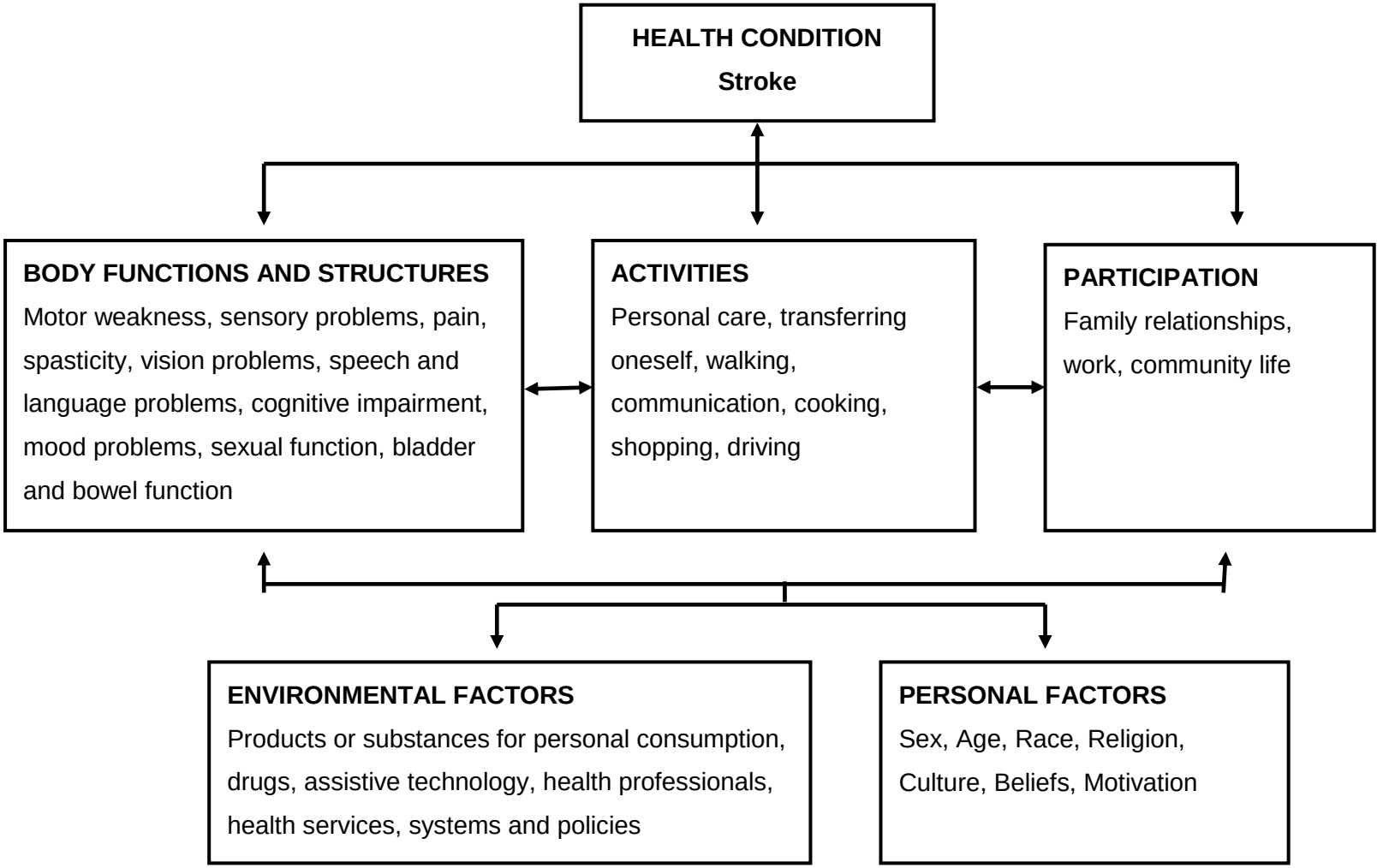
(b) Activity: Activity refers to the execution of a task by an individual. Limitations of a task are defined as difficulties an individual might experience in completing a given activity.

(c) Participation: Involvement of an individual in a life situation. Restrictions to participation describe difficulties experienced by the individual in a life situation or role.

(d) Contextual factors: These include the personal and environmental factors that influence the relationships between the different components.

Figure 1 shows some examples of the impact of stroke on survivors in the different domains of the ICF framework.

Figure 1. Examples of the impact of stroke on stroke survivors using the WHO ICF framework



1.2 Upper limb weakness after stroke

The incidence of stroke survivors experiencing some degree of paresis of the upper limb at the onset has been reported to be between 70 and 85% [12, 13]. The incidence is reported to be lower (48%) in dedicated acute stroke units including thrombolysis [14]. Only 20% to 56% of survivors regain complete functional use of the affected upper limb in spite of therapeutic intervention at 3 months [15-18]. Recovery of upper limb function is generally slower and less complete than return of mobility. This is partly due to the complexity of movement required for upper limb function [19, 20]. Motor recovery has been shown to be the most influential factor in determining well-being one year after stroke [21] and hence the emphasis of rehabilitation interventions is to improve upper limb function and reduce long-term disability [18]. A meta-analysis of prognostic variables related to upper limb recovery after stroke found initial upper limb impairment or function to be the most significant clinical predictive variable for upper limb recovery [22]. Age, sex, lesion size, time since stroke, side of stroke, handedness, upper limb sensation and comorbidities all had either no association or inconclusive evidence for any association with upper limb recovery [22].

The term “arm” is often used in stroke rehabilitation literature and layperson terms to represent the “upper limb”. The use of the term “arm” in this thesis means the “upper limb”, unless specified as the arm section of the upper limb.

1.3 Motor learning principles and post-stroke upper limb rehabilitation

The neuroanatomical basis of motor recovery after stroke in the early stages comprises resolution of the neurogenic shock with reduction of oedema, and in the later stages neural reorganisation or brain plasticity [23]. Plasticity is the capacity of the brain to modify its structure or function in response to brain damage or learning [24]. This property of the brain allows motor relearning to occur in response to engagement either in therapy or by resuming activities in virtual reality or in the real world.

The two-stage model of skill acquisition proposed by Gentile et al. suggests a) an initial stage of learning where the individual learns the basic movement patterns needed to achieve the goal and identify components of the environment important to the task (explicit learning) and b) a later stage of learning where the individual learns to improve motor efficiency and movement flexibility (implicit learning) [25, 26].

Three stages of skill acquisition have been proposed by other authors: a) skill acquisition, b) skill retention and c) transfer of skills [23, 27]. Skill acquisition is the initial practice of a new skill; for example, using the hemiplegic upper limb to reach and grasp a glass in a sitting position in a therapy session. Skill retention is the ability to demonstrate skill in the same task after a break during which the task is not practised. Transfer of skills is the ability to perform a task similar to the practised task but in a different context; for example, reaching and grasping a jacket in a standing position in the real world. The skills acquired need to progress from closed skills (where the performer can start and stop at any time because the regulatory features of environment remain constant) to open skills (where the performer needs to conform to the dynamic changes and challenges in the environment [28]. Rehabilitation interventions promote skill acquisition, retention and transfer by promoting practise of closed and open skills.

Rehabilitation therapies differ in the amount of practice, the types of tasks, the training schedule and the feedback given to the individual. The evidence available for the effectiveness of the duration and intensity of practice suggests there is a dose-response for therapy, as observed in constraint-induced movement therapy (CIMT), even though some authors argue that task specificity is more important than intensity of practice. Motor tasks practised in their entirety [29] are believed to be more effective than those broken up into separate parts, for example reach and grasp practised as a single task is more effective than practicing reach alone [23, 30]. Also, in a treatment session, variability within the task practised makes it more effective than constant repetition of same task in terms of retention and transferability of the skill [31-34]. Feedback within these interventions can be gained as a) internal or task-intrinsic feedback gained through sensory, visual

and auditory experiences related to the task or b) extrinsic augmented feedback by the therapist or the system delivering the intervention that can be verbal, visual or physical. It is well established that these feedback strategies enhance skill acquisition in practice [23].

Upper limb rehabilitation interventions can be broadly categorised as impairment-based upper limb ability training, CIMT, bilateral training, electromyogram (EMG)-triggered neuromuscular stimulation, virtual reality-based rehabilitation and interactive robotic therapy [35]. Upper limb ability training is designed for individuals with mild upper limb weakness and aims to improve movement characteristics such as handgrip, coordination, tracking and wrist-finger speed. Traditional CIMT aims to overcome learned non-use by restraint of the less-affected upper limb for 90% of waking hours and massed practice of the affected upper limb for at least 6 hours a day [36]. Modified CIMT involves training of affected upper limb for 30 minutes – 2 hours/day and restraint of unaffected upper limb for less than 6 hours a day [37]. Modified CIMT has been shown to be more effective than conventional physiotherapy in improving upper limb movement and function in a recent meta-analysis [38]. Bilateral training involves practising simultaneous synchronous and asynchronous activities with both upper limbs. It is believed to enhance stimulation of the damaged cerebral hemisphere through enhanced interhemispheric inhibition [39, 40]. The current evidence is inconclusive in terms of superiority over conventional physiotherapy or unilateral upper limb training [41].

EMG-triggered neuromuscular stimulation is used for individuals with severe weakness and involved triggering muscle contractions when EMG activity in the muscle reaches a chosen threshold [42]. Virtual reality-based rehabilitation simulates the real world using a human-machine interface so that three-dimensional real life activities can be practised, it is used by the individual with or without the assistance of technology to help movement [43, 44]. Interactive robotic therapy provides repetitive assistive therapy to the affected upper limb in a varying and engaging environment. It aims to improve basic movement patterns and helps the acquisition of skills, which could be transferred to real world functional activities. The usability of robotic

therapy spans varying degrees of upper limb impairment and can be used to augment any of the above therapies or used on its own.

1.4 Robotic technology for upper limb rehabilitation

Novel robotic technology provides repetitive meaningful tasks, greater intensity of practice, stimulating and engaging environments for users and alleviates the labour-intensive aspects of hands-on conventional physiotherapy. There are a number of complex robotic devices that have been developed over the years to assist upper limb exercises in rehabilitation; these include the Massachusetts Institute of Technology (MIT-Manus), Mirror Image Movement Enabler (MIME), Bi-Manu-Track, Assisted Rehabilitation and Measurement (ARM) Guide, ARMin, GENTLE system and intelligent Pneumatic Arm Movement (iPAM) [45, 46]. The characteristic features of these devices and the clinical studies examining the use of these devices by stroke patients are summarised is described in Table 1.

1.4.1 User-centred design approach in device development

User-centred design (UCD) is a technique that focuses on users' needs, and designs according to these needs [47, 48]. UCD is an iterative process; its key principles include: a) using the work practices of the user to control the development, b) the active involvement of the users' representatives early and continuously throughout development, c) the requirement for the development to undergo many iterative cycles to come up with the requirements of the users, d) the early and continuous creation of prototypes to visualise and evaluate ideas and e) the involvement of interdisciplinary teams in the development process [49, 50].

Table 1. Overview of existing robotic devices tested in upper limb rehabilitation after stroke

Robot	Country	Upper limb (UL) joint movements	Modes	Tested in environment/ supervision	Total pts.	Nature of patients tested	Effect on UL movement	References
MIT-Manus	USA	Shoulder and elbow (wrist in additional module)	Assistive Resistive Passive	Research centre and Hospital/ Therapist	> 300	Subacute and chronic	Improvement in UL movement and strength at shoulder and elbow	[51-58]
MIME	USA	Forearm (pronation/ supination)	Active assist Bimanual Passive	Research centre and Hospital/ Therapist	> 100	Subacute and chronic	Improvement in UL movement kinematics, strength	[59-62]
Bi-Manu-Track	Germany	Forearm and wrist	Active assist Active resist Passive	Research centre/ Therapist	> 100	Subacute and chronic	Improvement in wrist and finger power and UL function, reduction in spasticity	[63-67]
NeReBot	Italy	Shoulder and elbow	Passive Active assist	Hospital/ Therapist	> 50	Subacute	Improvement in shoulder and elbow strength and UL movement	[68, 69]
ARMin (Exoskeleton)	Switzerland	Shoulder, elbow and wrist	Passive Active assist	Research centre/ Therapist	> 40	Chronic	Improvement in UL movement and ADL ability	[70-72]

Robot	Country	Upper limb (UL) joint movements	Modes	Tested in environment/ supervision	Total pts.	Nature of patients tested	Effect on UL movement	References
REO system	Israel	Shoulder and elbow	Active assist Passive	Research centre/ Therapist	> 40	Subacute and chronic	Improvement in UL movement	[73-75]
BATRAC	USA	Shoulder and elbow	Active	Research centre/ Therapist	> 30	Chronic	Improvement in shoulder and elbow movement, range and power	[76, 77]
REHAROB	Hungary	Shoulder and elbow	Passive	Research centre/ Therapist	> 30	Subacute and chronic	Shoulder and elbow movement improved and reduction in spasticity	[78, 79]
GENTLE	UK	Shoulder and elbow	Active Active assist Passive	Research centre/ Therapist	20	Chronic	Improvement in shoulder and elbow movement and range	[80]
BFIAMT	Taiwan	Shoulder and elbow	Active Passive	Research centre/ Therapist	20	Chronic	Improvement in UL movement kinematics	[81]
ARM-Guide	USA	Shoulder and elbow	Active Active assist	Research centre/ Therapist	19	Chronic	Improvement in UL kinematics	[82]
BdF	Italy	Shoulder and elbow	Active assist	Research centre/ Therapist	14	Chronic	Improvement in UL movement kinematics	[83, 84]

Robot	Country	Upper limb (UL) joint movements	Modes	Tested in environment/ supervision	Total pts.	Nature of patients tested	Effect on UL movement	References
ARAMIS (Exoskeleton)	Italy	Shoulder, elbow and wrist	Passive Active assist Active	Hospital/ Therapist	14	Subacute	Improvement in UL movement and function	[85]
HWARD	USA	Wrist and finger	Active assist	Research centre/ Therapist	13	Chronic	Improved movement of wrist and fingers	[86]
HapticKnob	Singapore	Forearm and hand	Active assist	Research centre/ Therapist	13	Chronic	Improved UL movement and hand function	[87]
Haptic Master	Netherlands	Shoulder, elbow, wrist and hand	Active assist	Research centre/ Therapist	11	Chronic	Improvement in UL movement and function in daily activities	[88]
ACRE	Netherlands	Shoulder and elbow	Active assist	Research centre/ Therapist	10	Subacute	Improvement in UL movement	[89]
L-Exos (Exoskeleton)	Italy	Shoulder and elbow	Active assist	Research centre/ Therapist	9	Chronic	Improvement in UL movement and kinematics, reduction in spasticity	[90]

Robot	Country	Upper limb (UL) joint movements	Modes	Tested in environment/ supervision	Total pts.	Nature of patients tested	Effect on UL movement	References
RUPERT (Exoskeleton)	USA	Shoulder, elbow, forearm and wrist	Active assist	Research centre and home/ Therapist	8	Chronic	Improvement in UL movement kinematics	[91, 92]
AMES	USA	Wrist and fingers	Active assist	Home/ Self	8	Chronic	Improvement in wrist and finger strength and range	[93]
Reha-Digit	Germany	Fingers	Passive	Research centre/ Therapist	8	Subacute	Reduction in spasticity, no change in strength	[94]
MEMOS	Italy	Shoulder and elbow	Passive Active assist Active	Research centre/ Therapist	8	Chronic	Improvement in strength and range in shoulder and elbow	[95]
Amadeo	Austria	Fingers	Passive Active assist	Hospital	7	Subacute	Improvement in UL movement and function	[96]
HEXORR (Exoskeleton)	USA	Fingers	Active assist	Research centre/ Therapist	5	Chronic	Improvement in range of finger movement	[97]
REHA-SLIDE	Germany	Shoulder, elbow and wrist	Passive	Research centre/ Therapist	2	Subacute	Improvement in UL movement and strength	[98]

Involvement of users in medical device technology development has been shown to influence the safety, usability, quality, cost, and clinical effectiveness in the target group [99-101]. Groups such as the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) in the UK promote the process of user involvement by developing formal methods for evaluating users perspectives and engaging the community in technology development [102].

Only a few upper limb rehabilitation robot studies in the current literature report on the actual UCD process undertaken in the development of the devices [50, 103]. There is a need for the research team to include multidisciplinary members, understand the engagement methods, explore the breadth of feedback content and undertake multiple iterative cycles to develop robotic devices that are fit for purpose.

1.4.2 Principles of robot mechanical design

Based on the mechanical structure of the robot, two categories are recognised: end-effector based robots and exoskeleton-based robots [104]. End-effector based robotic devices contact the user's limb only at its most distal part; for example, MIT-Manus and MIME. Exoskeleton-based devices have a structure that mirrors the skeletal structure of users' upper limb and support the range of movements of each joint; for example, ARMin and RUPERT. Exoskeleton-based devices use a more complicated algorithm and need adjustment of their segments to the user's upper limb length so that the joints of the device match those of the user. They are cumbersome to put on and take off but provide better stability to limb movements and promote a larger range of motion of the limb at multiple joints [71]. Some robotic devices, such as ArmeoSpring, use a combination of both approaches [105].

The actuator(s), or motor(s), drives the assistance force provided by the robot to the limb movement. It is generally located in the constrained part of the robotic device to reduce the weight and inertia of the moving part of the device. Most of the actuators of robotic devices are electric [104]. Some devices have pneumatic actuators which are lighter and have lower impedance than their electric counterparts, such as iPAM [106], Pneum-

WREX [107] and RUPERT [92]. A third category of hydraulic actuators (powered by hydraulic energy using oil) is being tested in some newer devices [108].

A robotic device can promote either three-dimensional movement or movement in one plane. Most of the robotic devices listed in Table 1 allow movement in three dimensions; for example, GENTLE, ARMin and NeReBot. The planar robots allow movement of the distal piece attached to the limb in one plane only. The original version of MIT-Manus is a planar device but with the addition of the anti-gravity module it allows movement in two planes [109]. The BdF planar device allows the working space to be changed between horizontal and vertical planes [83]. ARM Guide is a planar device where the forearm slide angle can be adjusted to enable working in multiple workspace regions [82]. A planar robot is less complex and easier to build, which reduces the cost of the device [104].

The total number of axes of movement allowed by the device in different joints is referred to as the Degrees of Freedom (DOF) of the robotic device. The planar device MIT-Manus has two DOF. The end-effector robotic devices (as listed in Table 1) that provide movement only to the proximal joints (shoulder and elbow) of the upper limb have lower DOF. The exoskeleton-based robots generally have higher DOF, as they allow movements in different planes. The robots for finger or hand rehabilitation have higher DOF, the hand exoskeleton developed in the Technical University has 20 DOF [110]. The higher number of DOF increases the complexity of the algorithm used by the system and makes the device more expensive and needs assistance from therapists for use [104].

1.4.3 Principles of robotic exercise therapy

An assistive robotic system can sense the movement or force of the user, use that information to make decisions and plan subsequent motion or output, and provide force feedback to the user via actuators (motors) in the system [46]. The movements generated by robots are gross movements such as reaching, bilateral training, fine hand skills, activities of daily living or a combination of these movements. The system may also provide audio,

visual and proprioceptive feedback to the user that makes the movements more interactive and engaging.

1.4.3.1 Gross movement training

A typical robotic system aims to shape the reaching movement towards the target. The user is required to move their arm to reach the target endpoint. The robotic system (attached to the arm) contributes to make the movement efficient and complete the task. It can passively move the upper limb towards the endpoint (passive mode), provide extra force to help complete the task (active assistance), resist force applied by the user to the robot (active resistance), or assist in the direction of the movement and redirect strayed movements towards the target (active constraint). Not all robotic systems have all these modes (Table 1). The GENTLE robotic system can operate in three modes (passive, active assistance, active resistance) and a clinical study in chronic stroke participants observed that the active mode was more beneficial than the other modes in improving upper limb movement [80]. The force-feedback function of MIT-Manus assists movement in the direction appropriate for task completion and has been shown in several studies involving acute and chronic stroke subjects to produce improvement in upper limb movement [51, 111].

1.4.3.2 Bilateral robotic training

The understanding of cortical reorganisation and motor recovery, particularly the understanding of bihemispheric plasticity after stroke has led to the development of therapy that simulates the bilateral movement of the paretic and nonparetic upper limbs at the same time. The belief is that bilateral training enhances the interhemispheric motor cortex disinhibition and facilitates cortical overflow from the undamaged hemisphere [81, 112]. This is contrary to the principles of constraint therapy where the unaffected upper limb is deliberately constrained and the affected upper limb is intensively exercised. However, both therapies promote intensity and repetition of meaningful movements. The current evidence is still inconclusive whether bilateral therapy is superior to unilateral therapy in terms of motor recovery [113].

Some robotic devices are able to provide bilateral symmetrical upper limb training to [59, 77, 81, 83]. In subacute and chronic stroke patients, robots delivering bilateral therapy, such as BFIAMT [81], BATRAC [77], MIME [59] and BdF [83] have showed improved upper limb movement kinematics and function. MIME device can provide both unilateral and bilateral therapy where the device assists the paretic upper limb to move in a mirror fashion to movement of the unaffected upper limb. In a sample of subacute stroke patients, Lum et al. found bilateral therapy improved function but was not superior to unilateral therapy [60].

1.4.3.3 Robotic training for fine hand skills

In the latest versions of the robotic devices MIT-Manus and GENTLE, there are additional modules to address distal muscle movements in their latest versions [29, 114]. The Hand Wrist Assistive Rehabilitation Device (HWARD) is a robot built specifically to improve hand grip/release and wrist movements in a real time virtual environment [86]. Rutgers Master II-ND glove is a robotic system that applies force to fingers and helps promote movement in the fingers and maintain the range of movement [115]. Clinical studies of these devices with stroke survivors have shown improvements in finger movement kinematics and hand function [86, 116].

1.4.3.4 Robotic training for Activities of Daily Living (ADL)

One of the criticisms of most end-effector robotic systems is that the hand is holding the handle of the robotic arm while performing reaching movements and is not engaged in grasping and manipulating objects as it would be in daily activities. The ARMin robot is an exoskeleton robot that supports the movement of the arm leaving the hand free to perform daily activities in a virtual reality three-dimensional environment. The hand would not be able perform the activities without the support of the robotic device. A study involving chronic stroke subjects using ARMin showed improvements in motor function but no significant change in their perceived-change in ability in daily activities [70]. Timmermans et al. used a Haptic Master robot to guide upper limb movement with the free hand actively training in daily activities and found that robot training improved functional ability in daily activities [88];

however, the effect was however not superior to video-instructed task-oriented conventional training.

1.4.3.5 Feedback to the user

Most robotic devices involve performing reaching tasks to play games on a computer screen. Some devices involve reaching and manipulating things in the real (Haptic Master) or virtual environments (ARMin) [70, 88]. Robotic devices control force feedback to the user either using the impedance control approach (where movement is measured and the force feedback adjusted such as MIT-Manus and most robotic devices) or using the admittance control approach (where the force exerted by the user is measured and the movement displacement adjusted; for example, iPAM). Haptic devices interact with the user through the sense of touch and are able to adjust assistive forces based on the force applied by the user; for example, the T-WREX exoskeleton device [117]. As well as assisting the upper limb movement, the feedback provided to the user can be visual, tactile, audio, electrical or a vibratory stimulation [104].

1.4.4 Comparison of robotic therapy and conventional therapy

A meta-analysis of randomised controlled studies investigating robotic therapy versus usual care, conventional therapy or electrical stimulation showed a significant improvement in upper limb movement with robot therapy, measured using the Fugl Meyer – Upper Extremity [FM-UE] outcome measure [118]. There was however no significant improvement in activities of daily living (ADL) when compared to control therapy, measured using the Functional Independence Measure (FIM). The review included nine randomised controlled studies with a combination of proximally acting robots (such as MIT-Manus, MIME) and distally acting robots (such as Bi-Manu-Track). The authors recommended future studies to consider specific outcome measures (kinematic analysis of upper limb movement) and subsections of outcome measures (proximal and distal subsection of FM-UE) to capture the real effects on proximal or distal muscles. Functional outcome measures such as the Action Research Arm Test (ARAT) or the Wolf Motor

Function Test (WMFT) were recommended, as they are more sensitive than the FIM for this type of intervention [118].

A later systematic review of 11 randomised controlled studies investigating six robotic devices (providing unilateral therapy only) drew two important conclusions (a) when robot therapy and conventional therapy are matched in duration and intensity, there was no significant difference in motor recovery, strength, motor control and activities of daily living between the robot therapy and conventional therapy groups; and (b) when robot therapy is used as an additional therapy to regular conventional therapy, the gains are significantly higher in the combination group and these gains remain significant at an 8-month follow-up [119]. The authors suggested that robotic devices could be used to fill the gap in provision of intense therapy caused by therapist resource constraints in most rehabilitation settings. They observed that most devices were planar robots (two-dimensional) designed for proximal therapy and lacked the function-based approach and future research should focus on these aspects of robot therapy.

1.4.5 Cost-effectiveness of robotic therapy

An economic analysis of robotic technology is difficult as most clinical studies recruit small numbers, involve a heterogeneous group of participants and there is often no uniform outcome of intervention across participants (except for use of FM-UE). The cost-effectiveness of robotic therapy when compared to intensive comparison conventional physiotherapy has been analysed in only one study so far [120]. A multicentre study (the VA robotic study) studied the cost-effectiveness of the MIT-Manus in 127 participants across four sites. The cost of the robotic device was $ 230,750 with additional maintenance costs ($15,000 per year). With a life-span of 5 years, the cost of the robot per one-hour session was estimated to be $20. The cost of therapist time was $120 for robot therapy (15 min of therapist contact time per session) and $218 for a 60 min session of conventional therapy. The total average cost per person over the 12-week treatment period including travel costs was $5152 for robot therapy and $7382 for conventional therapy. The study based on clinical outcomes concluded that robot therapy did not

demonstrate superior cost-effectiveness but did demonstrate similar cost-effectiveness [53, 120]. This demonstrates that robotic therapy has the potential to address the shortage of therapist manpower in healthcare services.

1.4.6 Home-based robot technology and telerehabilitation

Common features of most robotic systems (Table 1) are that they are complex, are deployed within a hospital or research centre setting and need therapist supervision in therapy sessions. Patients need to travel to hospital or to a research centre to access robotic therapy. Some patients are unable to do this due to transport costs, lack of carer support or severe disability after stroke. In current healthcare systems, including the NHS, the inpatient rehabilitation length of stay for patients with stroke is decreasing with increasing emphasis being placed on community-based rehabilitation. Home-based conventional physiotherapy is effective but can be resource-limited due to therapist availability and is generally provided only for a fixed period after stroke (generally up to 6 months post-stroke). Home-based robotic therapy is an attractive alternative option but has a number of technical and clinical challenges to overcome.

The technical challenges of home-based robotic therapy are to make the technology safe to be deployed and usable in a home setting. The footprint of the device needs to be acceptable to the patient, family and carers. The user should be able to easily set-up and use the device without the therapist being present for each session. The user would need access to engineering support for technical issues and would need to be remotely supervised by a therapist to ensure appropriate therapy is being delivered. The clinical challenges are many; the technology needs to be able to match conventional physiotherapy principles and provide the relevant therapy to the user. There is a risk of dehumanisation of the rehabilitation therapy if there is little interaction with the therapist and other patients. The therapy will need to address personal functional needs and will need to be tailor-made for each individual user.

There have been a few devices developed to provide home-based robotic upper limb rehabilitation for stroke patients. RUPERT is a wearable exoskeleton robot that helps direct the upper limb to perform functional activities in a three-dimensional virtual reality [92]. It has been tested in the home setting in two chronic stroke subjects with improvement in the accuracy and smoothness of their movements [92]. The impact on daily activities was not reported. The exoskeleton needs to be fitted to the user's upper limb by the family member or carer. The acceptability of the device needs to be tested in a larger heterogeneous sample of stroke subjects in a home setting.

Johnson et al. [121] developed an upper limb stroke therapy suite (intended for home use) consisting of affordable hardware platforms, such as the force-reflecting joystick (Therajoy) and wheel (TheraDrive) working on a customisable universal software platform (UniTherapy). A sample of 16 chronic stroke subjects with mild to moderate upper limb weakness tried the system; simultaneous EMG recording of the upper limb muscles demonstrated that the robot therapy can be personalised in terms of the muscles targeted or activated by using a choice of joystick and wheel tasks. The system also has the ability to accurately track movement kinematics that can be useful to monitor progress. The system is yet to be tested in a clinical study in a home setting.

The Java therapy system is based on wrist exercises using a low-cost commercial force feedback joystick connected to a customised computer program of therapeutic activities available on the web [122]. The system has been designed for home use and the therapy can be monitored remotely by a therapist using a low-cost web camera and teleconferencing software. One stroke survivor used the system for a 12-week period and showed improvements in movement speed and movement control. The low-cost system (estimated to cost $240 for the joystick, upper limb rest, splint and base) received high satisfaction scores from the user and his carer. This is yet to be tested in a larger clinical study in the home setting.

Wood et al. have developed a simple 'Palanca' sliding lever device used to play an electronic ping-pong game on the computer and have shown improvement in the functional abilities of four stroke subjects after using the

device [123]. This feasibility study was conducted in the research centre and showed that the low-cost device helped maintain high level of interest, motivation and enjoyment in therapy. A larger scale study in the home setting is being planned.

The Assisted Movement with Enhanced Sensation (AMES) device provides assistance to uniaxial flexion and extension movements of the wrist (and fingers) or ankle joint. The device also provides vibration sensation to the antagonist muscle-stretching tendon when the agonist muscle is performing the desired action to provide somatosensory feedback during movement. The device provides visual feedback on the torque exerted by the user. A study of upper limb exercises in the home setting, involving eight chronic stroke participants, showed improvements in the strength and range of movement in the wrist and fingers after six months of home use. The effect on functional abilities of the upper limb was not reported. During the home-use period, three participants needed additional training with EMG feedback in the research laboratory as they could not generate adequate torque to be able to use the device. The system lacks variation in tasks that can affect long-term usage (engagement in therapy) and this needs to be explored in a larger sample of patients [93].

1.4.6.1 Future research in home-based robotic technology

Micera et al. have put forward a simple hierarchical system of classifying robotic devices for upper limb rehabilitation after stroke 1) Exoskeleton devices with greater range of movement and complex design suited for use in hospitals and research laboratories for users with severe disability, and 2) Operational devices which are less complex, end-effector and suitable for use by users with moderate disability [95]. The operational devices group can be further sub-classified as a) Class 1 devices that have low mechanical friction, high back-driveability, fine tuned visco-elastic properties and high cost that can be used in the laboratory setting and b) Class 2 devices that have a simple mechanical structure, compensation of inertia/friction, no back-drivability and low cost to be used in telerehabilitation settings at home. From our review of robotic devices tested in clinical

settings, there is a plethora of exoskeleton and Class 1 devices that have been manufactured and tested. However, there is an obvious paucity of Class 2 devices that have been tested in the home setting. Future research clearly needs to explore the challenges of making low-cost home-based robots that are simple, acceptable and effective in improving upper limb function. The number of people needing upper limb rehabilitation post-stroke is increasing worldwide and there is growing emphasis of moving rehabilitation resources to community settings and peoples' homes.

1.4.7 Conceptual models for assistive technology outcomes research

Various models exist that help assessment of assistive technology in terms of matching to the users needs, measuring impact on user and predicting usability. The Human Activity-Assistive Technology (HAAT) model [124], the ICF-AT model [125] and the Matching Person and Technology (MPT) model [126] are some of the popular models in the current literature. These models offer descriptive frameworks to explore the complex relationship between assistive technology, personal traits and environmental factors that determine the usage and impact of the technology. These models have been primarily utilised for assistive technology outcome assessment, but their use can potentially be extended to providing basis for user involvement in device development.

1.5 Project objectives

The purpose of this project is to develop and undertake preliminary evaluations of a low-cost restorative rehabilitation robotic system that assists stroke survivors to undertake independent upper limb exercises at home. The project has two stages: Stage 1, Developing the home-based Computer Assisted Arm Rehabilitation (hCAAR) device development using a user-centred design process; Stage 2, A proof of concept clinical feasibility study of hCAAR in people with upper limb weakness after stroke.

1.5.1 Stage 1: hCAAR device development

The objective of the user-centred design process is to understand user needs and involve them in the different stages of device development. Stroke survivors with upper limb weakness (end-users) and healthcare professionals providing therapy to stroke survivors (professional users) are both involved in this process. Feedback is gathered in the concept, design and testing stages of hCAAR development.

1.5.2 Stage 2: Feasibility study

The objective of the feasibility study is to test whether hCAAR can be safely used in a home setting with minimal supervision and whether using the device improves upper limb movement and function. Stroke survivors with upper limb weakness will use the device for upper limb exercises in their homes for 8 consecutive weeks. Kinematic and clinical outcome measures will be used to capture movement characteristics and functional abilities to indicate efficacy. Qualitative feedback is used to indicate acceptability (for example, how it looks, how it fits into the home environment, quantity of use) and impressions (for example, efficacy, future developments to the device).

Chapter 2: Systematic review of the outcome measures used in robot-assisted exercise studies and using the ICF framework to select outcome measures

The landscape of upper limb rehabilitation technology has been changed by the advent of robotic devices that have been evaluated in clinical studies with stroke participants. A meta-analysis of randomised controlled studies showed a significant improvement in upper limb motor function but no significant change in ADL function with upper limb robotics [118]. The failure to achieve a significant effect on real life activities may relate to either the lack of impact of the intervention, or the poor responsiveness of the outcome measures used in the studies, or both. Larger robot studies are needed to confirm or refute the findings of the smaller scale robot studies done so far. It is also vital that appropriate outcome measures are used in these larger and more expensive studies.

There is no consensus on the combination of outcome measures that should be used in robot studies. Most published clinical studies have used FM-UE to enable comparisons to be made between studies and pooling of data for meta-analyses. In the past, there was greater emphasis on measuring change at the impairment level (by kinematic assessment or impairment-based rating measures) than measuring change at the activity level. Clinical studies published recently have incorporated outcomes that reflect day-to-day activities. There is limited literature describing how to select outcome measures based on the nature of the intervention and the patient's clinical features.

The ICF could be used as a framework to analyse the content of outcome measures and to develop a system that enables the selection of appropriate outcomes in a study. Although the domains described in the ICF conceptual framework of health condition, i.e., body functions (and structures), activities and participation, and personal and environmental factors, are related, they do not necessarily have causality between them, making measurement of all the domains necessary [127]. This implies that

outcomes capturing these different domains need to be included in future robot studies.

The aims of this chapter are a) to identify and evaluate outcome measures currently used in robot studies b) to determine selection criteria for outcome measures in robot studies and c) to select suitable outcomes for the hCAAR feasibility study.

2.1 Methods

A systematic review of outcomes used in robot studies was undertaken in three stages.

2.1.1 Identify outcome measures used in robot studies in stroke patients

The first stage was a search of the MEDLINE, EMBASE, CINALH, PUBMED and PsychINFO databases to identify relevant robot studies. These databases were selected because published robot clinical studies are captured in searches of these databases. The keywords used were: stroke, upper limb, arm, rehabilitation, motor, recovery, robot, computer, training, therapy, physiotherapy, function and study. From the initial search, all abstracts were reviewed. The inclusion criteria for this review were

1. Study involved participants with diagnosis of a stroke.
2. Study involved at least 10 participants.
3. Upper limb exercise assisted by a robot device. For the review, a robotic device was defined as any technology that has the ability to assist upper limb movement for therapeutic exercises.
4. At least one outcome measure used in the study.

Studies of robot devices involving only healthy volunteers and those with fewer than 10 participants were excluded. The reason for having the number of participants as one of the criteria was to facilitate an appraisal of the performance of the outcome measure utilised in the study.

This stage was primarily undertaken by the main author MS. The authors SM, ML and BB also searched databases and cross-referenced with MS search list to ensure all relevant studies had been identified.

2.1.2 Classify outcome measures using the ICF framework

In the second stage of this systematic review, the individual items within each identified outcome measure were categorised into the one of ICF domains based on their ICF code. The ICF online database of codes was used to identify the most suitable code. Based on the distribution of the items, each outcome measure was then categorised as representative of one of the ICF domains.

This stage was primarily undertaken by the author MS. The author ROC checked the ICF codes for items and categorisation of outcomes to the different domains.

2.1.3 Evaluate measurement properties of outcome measures

The third stage of the systematic review involved a search of the same databases, which were used in first stage, to identify clinical studies involving stroke participants that described the measurement properties of the identified outcome measures. The keywords used were: the name of the outcome measure, stroke, validity, reliability, questions, items, consistency, minimal clinically important difference (MCID), responsiveness, floor effect, ceiling effect and agreement. Standard criteria were used to define and classify the measurement properties of reliability, validity, responsiveness and acceptability for the outcome measures (Table 2). These criteria are widely used in outcome measure research [128, 129]. A measurement profile for each outcome measure was constructed based on the evidence for the different properties.

Participants were considered being in the *subacute* stage of recovery if within 6 months of their stroke and the *chronic* stage if more than 6 months since their stroke.

This stage was undertaken by the authors MS. The author ROC ensured the standard criteria were used appropriately to construct the measurement profile for the outcome measures.

Table 2. Definition and standards for the evaluation criteria

Criterion	Definition	Standard
Reliability	Reproducibility is the extent to which the same results are obtained on repeated administrations of the same questionnaire by same person (test-retest) or different people (inter-rater). Internal consistency assesses the homogeneity of the scale's items [128].	Reproducibility (test-retest or inter-rater) - *Intraclass correlation coefficient or kappa value* - excellent or high > 0.75, moderate 0.4 – 0.74 and poor < 0.40 [128, 130]. Internal consistency – *Cronbach's α* excellent > 0.8, adequate 0.70 – 0.79 and low < 0.70 [129, 131].
Validity	The extent to which the scale measures what it intends to measure. Content validity is extent to which the measure is representative of the conceptual domain. Criterion validity (concurrent, convergent, predictive) is the degree to which the measure correlates with a gold standard. For most of the functional scales, there is no gold standard, so construct validity is used. Construct validity is determined by examining the hypothetical relationship between the measure and other similar measures [128].	*Correlation coefficient value (r)* – excellent > 0.60, adequate 0.3 – 0.6 and poor < 0.3 [129] *ROC analysis – Area under curve (AUC)* excellent > 0.9, adequate 0.7 – 0.9 and poor <0.7 [132].

Criterion	Definition	Standard
Responsiveness	The ability of the instrument to accurately detect changes which have occurred over time [133]. Minimal clinically important difference (MCID) - The smallest difference in the scores in the domain of interest that patients perceive as beneficial or that would be clinically meaningful Floor and ceiling effects - The extent to which scores cluster at either the bottom or the top of the scale range	Change in score - The *effect size* is calculated by the observed change in score divided by the standard deviation of baseline score. Large > 0.8, Moderate 0.5-0.8 and small < 0.5 [134, 135]. Other methods: *Standardised Response Mean*, *ROC analysis – area under curve*, *Statistical significance p value*, *Correlation values* of observed change compared to change in other scales MCID - described as a score value Floor and ceiling effects - Expressed as *percentage of the number of scores* clustered at bottom / top. Excellent 0%, Adequate <20%, poor > 20% [129].
Acceptability	Respondent burden - Is the length and content of scale acceptable to the intended participants (participants with disability)? Administrative burden - How easy is the tool to administer, score and interpret? Cost implications?	Respondent burden - Excellent: Brief (< 15 min) and acceptable, Adequate: either longer or some problems of acceptability. Poor: both lengthy and problems of acceptability [129]. Administrative burden - Excellent: scoring by hand, easy to interpret, Adequate: computer scoring, obscure interpretation, Poor: costly and complex scoring/ interpretation [129].

2.2 Results

2.2.1 Outcome measures used in robot studies

The initial search yielded 642 articles. After reading the abstracts and applying the inclusion criteria, 36 studies were identified as suitable for inclusion in the review. Table 3 summarises the outcome measures used in these studies. The most common outcome measure used was the Fugl Meyer- Upper Extremity (motor section) that was recorded in 33 studies. The outcome measures that were used in at least 10 studies were the Ashworth Scale/Modified Ashworth Scale, Medical Research Council and Functional Independence Measure. Each of the remaining outcome measures was used in less than seven studies in total. Kinematic measures that require separate motion capture system to calculate upper limb movement characteristics while the user performs standard reaching tasks were used in three studies. Kinematic variables derived from the robotic device were reported in three studies.

2.2.2 Classification of outcome measures using the ICF framework

Most of the items of each outcome measure corresponded to an ICF code and were matched to the relevant ICF domain (Table 4). A few items did not correspond to any ICF category and were described as “not yet categorised”. A few examples of such items are “feel you are a burden” and “control life as you wish”. These items correspond to the “personal factors” domain of the ICF framework, which is not yet categorised.

Figure 2 summarises the classification of all the outcome measures into the different ICF domains of body function, activity, participation and contextual factors. The majority of the outcome measures represented the body function or structure domain, followed in order of decreasing frequency by the activity domain, then the participation domain and finally the contextual factors domain.

Table 3. Outcome measures used in robot studies (in the order of total number of patients involved in studies with each named robot and then year of publication)

Robot device	Study year	n	Type of patients	FM-UE	AS/ MAS	MRC	FIM	Kinematic measures	Robot measures	Others	References
MIT Manus	2011	62	Chronic	+						WMFT, SIS	[58]
	2010	127	Chronic	+	+					WMFT, SIS	[53]
	2009	20	Chronic		+					MSS, ROM, VAS (pain)	[54]
	2008	47	Chronic	+							[57]
	2008	30	Subacute	+		+	+			MSS, FM – pain	[55]
	2005	12	Chronic	+						AMAT	[136]
	2003	20	Subacute	+	+	+				MSS	[52]
	2000	56	Subacute	+		+	+			MSS	[56]
	1997	20	Subacute	+		+	+				[51]

Robot device	Study year	n	Type of patients	FM-UE	AS/ MAS	MRC	FIM	Kinematic measures	Robot measures	Others	References
Bi Manu track	2012	20	Chronic	+			+			ABILHAND, MAL	[67]
	2011	18	Chronic	+		+				ABILHAND, MAL	[66]
	2008	54	Subacute	+	+	+				BBT	[65]
	2005	44	Subacute	+	+	+					[64]
	2003	12	Chronic		+					RMA, Patient impressions	[63]
MIME	2011	54	Subacute	+	+	+	+			WMFT	[62]
	2006	23	Subacute	+		+	+			MSS	[60]
	2002	27	Chronic	+			+	Reach extent		BI, Muscle power MVC	[59]
	2000	21	Chronic	+							[61]
ARMin	2014	77	Chronic	+	+				Mean strength	Grip strength, MAL, WMFT, SIS	[70]

Robot device	Study year	n	Type of patients	FM-UE	AS/ MAS	MRC	FIM	Kinematic measures	Robot measures	Others	References
NeReBot	2007	35	Subacute	+	+	+	+				[68]
	2007	24	Subacute	+		+	+			MSS	[69]
Reo system	2011	19	Chronic	+	+		+			VAS (pain), BBT, FAT, ABILHAND, EQ-5D, VAS (satisfaction)	[75]
	2009	14	Chronic	+	+		+			VAS (pain), BBT, FAT, ABILHAND, EQ-5D	[74]
	2008	10	Subacute	+						MFT, Patient satisfaction	[73]
BATRAC	2004	21	Chronic	+						WMFT, fMRI, Grip strength	[76]
	2000	14	Chronic	+						WMFT, Grip strength	[77]
REHAROB	2007	30	Mixed	+	+		+			RMA, ROM, VAS (patient acceptance), VAS (pain)	[79]
Haptic Master	2014	22	Chronic	+						ARAT, MAL, EQ-5D, SF-36	[88]

Robot device	Study year	n	Type of patients	FM-UE	AS/ MAS	MRC	FIM	Kinematic measures	Robot measures	Others	References
GENTLE	2008	20	Chronic	+	+					ROM, Motor AS, SCT, VAS (pain), NSA	[80]
BFIAMT	2007	20	Chronic	+	+			Peak speed, Time, Jerk	Push-pull strength	FAT, Grip strength	[81]
ARM Guide	2006	19	Chronic					Range, Smoothness, Path length	Stiffness Range Velocity	CMSA	[82]
ARAMIS	2012	14	Subacute	+			+				[85]
Haptic Knob	2011	13	Chronic	+	+					Motor AS, NHPG, Grip strength, VAS (pain), Patient satisfaction scale	[87]
HWARD	2008	13	Chronic	+	+					ARAT, NHPT, BBT, SIS	[86]
BdF	2009	10	Chronic	+	+				Force, time, error		[84]
ACRE	2007	10	Subacute	+						Patients and therapists impressions	[89]

Table 4. ICF categorisation of items

ICF code	Assessment	FM- UE	MSS	ARAT	CMSA	WMFT	Kinematics	BI	FIM motor	CAHAI	AMAT	RMA arm	Motor AS	MAL	ABILH-AND	SIS	SF-36	EQ5D
b710	Shoulder movements	+	+			+	+					+	+					
b710	Elbow movements	+	+			+	+					+	+					
b710	Pronation/supination	+	+			+						+	+					
b710	Wrist movements	+	+			+							+					
b710	Finger movements	+	+															
b730	Power	+	+		+		+											
b735	Tone				+								+			+p		
b735	Spasticity				+													
b1470	Speed	+			+		+											
b7651	Tremor	+					+											
b7651	Jerk						+											
b7602	Coordination	+			+													

ICF code	Assessment	FM- UE	MSS	ARAT	CMSA	WMFT	Kinematics	BI	FIM motor	CAHAI	AMAT	RMA arm	Motor AS	MAL	ABILH-AND	SIS	SF-36	EQ5D
b750	Reflexes	+			+													
b280	Pain				+												+p	+p
b7305	Posture				+							+						
b130	Energy or drive																+p	
b152	Anxiety																+p	+p
b152	Depression															+p	+p	+p
b152	Concentrate															+p		
b175	Problem solving															+p		
b144	Memory															+p		
b399	Name objects correctly															+p		
b4552	Fatiguability																+p	
d4459	Contribution to bilateral activity									+	+							
d440	Grasp	+	+	+		+						+						

ICF code	Assessment	FM- UE	MSS	ARAT	CMSA	WMFT	Kinematics	BI	FIM motor	CAHAI	AMAT	RMA arm	Motor AS	MAL	ABILH-AND	SIS	SF-36	EQ5D
d440	Pinch		+	+														
d440	Grip			+		+						+				+p		
d4401	Grip glass to pour water			+						+				+p				
d4400	Pick and lift objects			+		+					+	+	+				+p	
d440	Open jar									+	+				+p	+p		
d440	Dial number									+	+					+p		
d3352	Draw line									+								
d2102	Put toothpaste on brush									+					+p			
d5201	Brushing/ caring for teeth													+p				
d2102	Cut putty									+	+	+			+p			
d2100	Zip up zipper									+					+p			
d2101	Dry back with towel									+								
d2101	Clean eyeglasses									+								

ICF code	Assessment	FM- UE	MSS	ARAT	CMSA	WMFT	Kinematics	BI	FIM motor	CAHAI	AMAT	RMA arm	Motor AS	MAL	ABILH-AND	SIS	SF-36	EQ5D
d540	Put on shirt										+							
d5400	Do buttons									+				+p	+p			
d430	Carry bag									+				+p		+p		
d5402	Putting on footwear													+p				
d2101	Hammering a nail														+p			
d2101	Threading a needle														+p			
d2101	Peeling potatoes/onions														+p			
d2101	Cutting/Filing one’s nails														+p			
d2101	Wrapping gifts														+p			
d2101	Shelling hazelnuts														+p			
d2101	Opening a pack of chips														+p			
d2101	Spreading butter on bread														+p			
d2100	Washing hands													+p	+p			

ICF code	Assessment	FM- UE	MSS	ARAT	CMSA	WMFT	Kinematics	BI	FIM motor	CAHAI	AMAT	RMA arm	Motor AS	MAL	ABILH-AND	SIS	SF-36	EQ5D
d5400	Buttoning up trousers														+p			
d2101	Opening mail														+p			
d2101	Stack checkers					+												
d2100	Flip cards over					+												
d550	Hand to mouth/eating			+				+	+		+		+	+p				
d4400	Pick up and hold pencil											+	+	+p				
d145	Write on paper												+	+p				
d4400	Pick up paper											+						
d2101	Pat a cake											+						
d2101	Tie shoelace										+					+p		
d2101	Tie bow											+						
d2100	Wipe spilled water										+							
d2100	Operate light switch										+			+p				

ICF code	Assessment	FM- UE	MSS	ARAT	CMSA	WMFT	Kinematics	BI	FIM motor	CAHAI	AMAT	RMA arm	Motor AS	MAL	ABILH-AND	SIS	SF-36	EQ5D
d2100	Operate door handle										+			+p		+p		
d2100	Turn key in lock					+								+p				
d5202	Comb hair								+		+		+	+p				
d540	Grooming							+	+		+			+p				
d510	Bathing							+	+							+p		+p
d540	Dressing							+	+							+p		+p
d530	Toileting							+	+							+p		+p
d530	Bowel							+	+							+p		+p
d530	Bladder							+	+							+p		
d420	Transfer				+			+	+					+p		+p		
d4103	Supine to sitting				+													
d4104	Sit to stand				+								+	+p				
d450	Walk				+			+	+				+			+p	+p	+p

ICF code	Assessment	FM- UE	MSS	ARAT	CMSA	WMFT	Kinematics	BI	FIM motor	CAHAI	AMAT	RMA arm	Motor AS	MAL	ABILH-AND	SIS	SF-36	EQ5D
d4551	Stairs				+			+	+							+p	+p	
d640	Vacuum, laundry, gardening															+p	+p	
d6200	Shopping															+p	+p	
d860	Managing finances															+p		
d839	Study																	+p
d840	Work															+p		+p
d920 *	Enjoy life															+p		
d710	Social activities																+p	
d920	Recreational activities															+p	+p	+p
d9308	Religious/spiritual activities															+p		
d760	Role in family															+p		
d6605	Ability to help others															+p		
*	Feel you are a burden															+p		

ICF code	Assessment	FM- UE	MSS	ARAT	CMSA	WMFT	Kinematics	BI	FIM motor	CAHAI	AMAT	RMA arm	Motor AS	MAL	ABILH-AND	SIS	SF-36	EQ5D
*	Control life as you wish															+p		
*	Pt. perceived health state																+p	+p
*	Pt perceived recovery															+p		
	References	[137, 138]	[139]	[140]	[141]	[142]	[143, 144]	[145]	[146]	[147]	[148]	[149]	[150]		[151]	[152]		[153]

ICF code b	Body function/structure
ICF code d	Activity and participation
*	As yet unclassified (personal factors)
+	Assessed in the outcome measure
+ p	Patient perceived
	Not assessed in the outcome measure

Figure 2. ICF categorisation of outcome measures

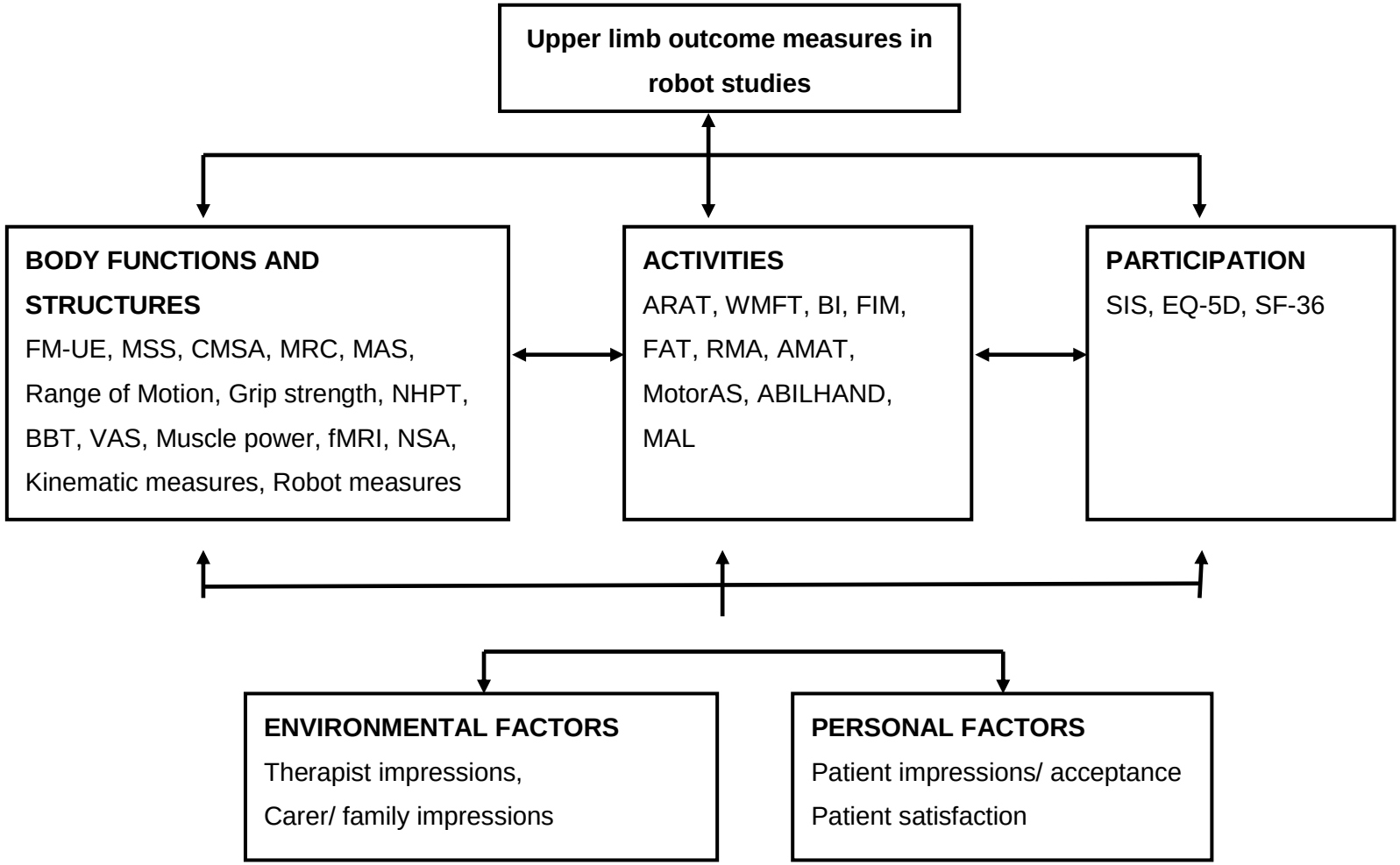


Table 5. Psychometric properties of 'body function' outcome measures

Characteristics	FM-UE	MSS	CMSA	MAS	MRC	Kinematics	Grip strength	NHPT	BBT
Time taken (min)	20	n/a	60	varies	varies	varies	< 1	2	1
Number of items	33	29	6	1	1	varies	1	1	1
Options per item	3 point	6 point	7 point	6 point	6 point	varies	timed	timed	timed
Score range	0 - 66	0 - 82	6 - 42	0 - 5	0 - 5	varies	varies	varies	varies
Test-retest reliability	+++	+++	n/a	++	n/a	+++	+++	n/a	n/a
Inter-rater reliability	+++	+++	+++	++	+++	n/a	+++	+++	+++
Construct validity	+++	+++	+++	+	n/a	++	n/a	+++	+++
Responsiveness	++	n/a	n/a	n/a	n/a	+++	n/a	n/a	n/a
MCID	7	n/a	n/a	n/a	n/a	n/a	2.9kg	32 sec	6 / min
Floor effect	adeq	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Ceiling effect	adeq	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Burden	adeq	adeq	poor	adeq	adeq	adeq	nil	nil	nil
References	[128, 137, 138, 141, 154-164]	[139]	[141, 165, 166]	[167-177]	[178-180]	[143, 144, 181, 182]	[183-185]	[183-186]	[185, 187]

Scoring criteria as defined in Table 1: +++ High / Excellent; ++ Moderate; + Low / poor; n/a – not applicable (evidence not available yet); adeq - adequate (acceptable) floor / ceiling effect / burden; poor - poor (unacceptable) floor / ceiling effect / burden; nil - Minimal / no burden

Table 6. Psychometric properties of 'activity' and 'participation' outcome measures

Characteristics	BI	FIM motor	ARAT	WMFT	CAHAI	AMAT	RMA arm	FAT	Motor AS	ABILHAND	SIS Partic.	EQ5D	SF-36
Time taken (min)	10 - 15	20	10	10 - 12	25	45	20	3	20 - 30	n/a	n/a	2 - 3	10
Number of items	10	13	19	15	13	17	15	5	9	23	8	5	36
Options per item	2 - 4	7	4	6	7	6	2	2	7	3	5	3	2-6
Score range	0 - 100	13 - 91	0 - 57	0 - 75	13 - 91	0 - 85	0 - 15	0 - 5	0 - 54	logit	0 - 100	0 - 1	0 - 100
Test-retest reliability	+++	+++	+++	+++	n/a	+++	+++	+++	+++	n/a	+++	+++	++
Inter-rater reliability	+++	+++	+++	+++	+++	+++	n/a	+++	+++	+++	n/a	n/a	n/a
Construct validity	+++	+++	++	+++	+++	n/a	++	n/a	+++	++	+++	++	++
Responsiveness	++	++	++	++	+++	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
MCID	16	11	6	12	6.3	n/a	3	n/a	n/a	n/a	n/a	n/a	n/a
Floor effect	poor	n/a	poor	poor	n/a	n/a	n/a	poor	n/a	n/a	n/a	adeq	adeq
Ceiling effect	poor	adeq	poor	poor	n/a	n/a	n/a	poor	n/a	n/a	n/a	adeq	poor
Burden	nil	adeq	adeq	adeq	adeq	poor	adeq	nil	adeq	adeq	nil	adeq	adeq
References	[145, 156, 188-195]	[194, 196-201]	[140, 162-164, 182,	[142, 162, 204-208]	[147, 209]	[148, 159, 210]	[149, 211-216]	[184, 217, 218]	[150, 158, 219]	[151, 220]	[152, 221-223]	[153, 224, 225]	[226-229]

2.2.3 Measurement properties of outcome measures

The evidence for the important measurement properties such as the number of items, the time taken to complete, reliability, validity, responsiveness, MCID, floor effect, ceiling effect and administrative burden are summarised in Table 5 and 6.

Some of the measurement properties are yet to be investigated in stroke populations and are indicated as “n/a” in the tables. CAHAI was included in the analysis as it is an outcome measure developed from CMSA and it is an activity-based measure. It is also reported to be more responsive than ARAT [209]. CAHAI was included as it had the potential to be one of the measures for the hCAAR feasibility study and the analysis of its measures when compared to other measures would be useful in making an informed decision on measures for the feasibility study.

2.3 Discussion

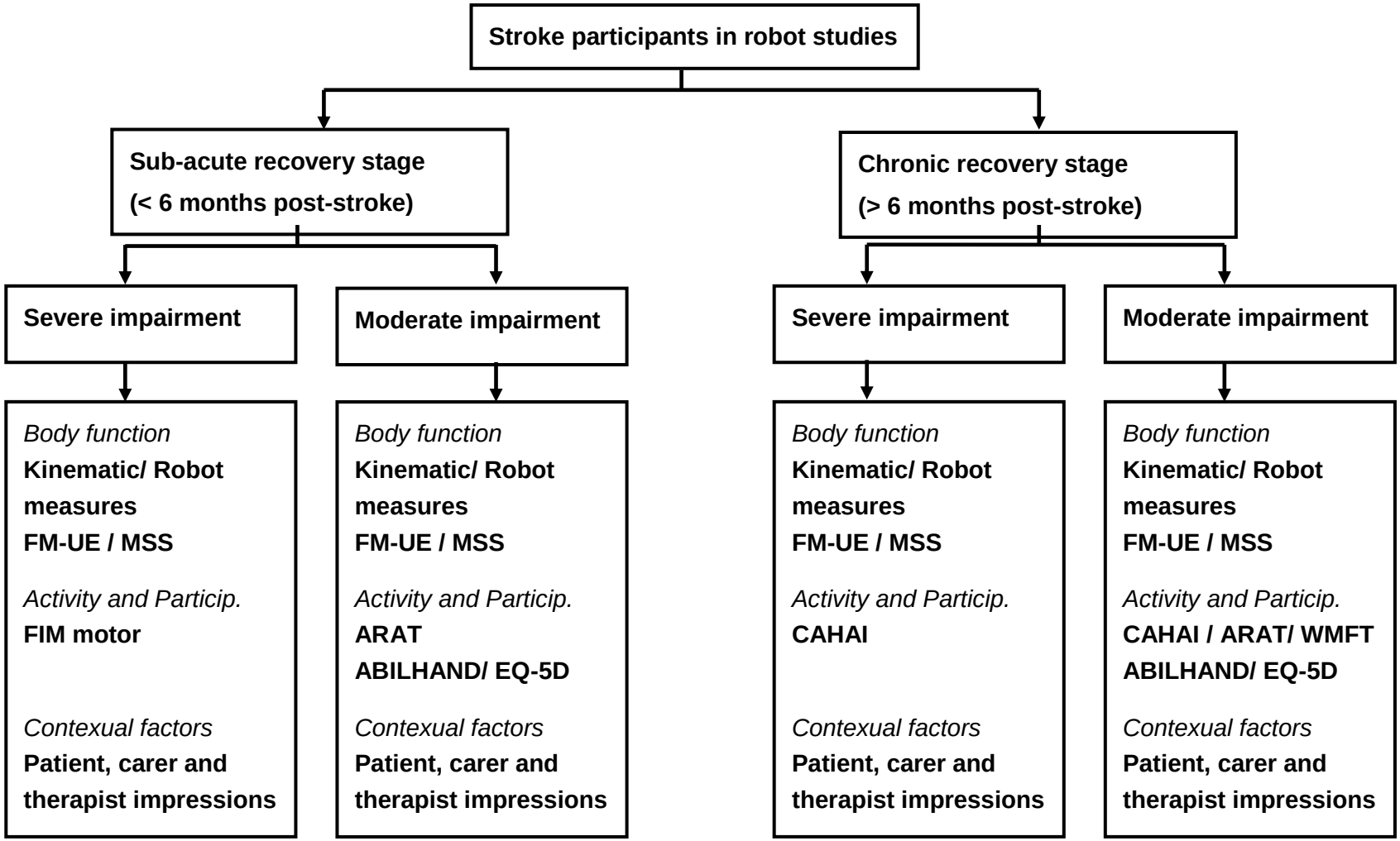
The knowledge of the severity of impairments does not allow an accurate prediction of the limitation in activities and participation experienced by the individual, due to the varied interplay between these domains and the influence of contextual factors. Such differences may also be seen in relation to the effects of any intervention (e.g. change at the body function level does not necessarily translate into change in the other domains, e.g. activity or participation). The selection of outcome measures is therefore crucial in the design of robot studies and should aim to capture the changes in all the aspects of the health condition (in this case, stroke). Using the ICF to describe the outcome measure content should enable researchers to compare the different outcomes measures and select the most appropriate ones for any clinical study. Appraising the measurement properties may allow targeting of the most appropriate outcome measure to the study participants.

2.3.1 Using the ICF framework to select outcomes for future studies

Published reports of robot studies indicate that a criterion to categorise the study participants would be useful to target the interventions. The ‘severity of impairment’ and ‘time since stroke’ are two important variables to be considered for devising such a criterion. Some studies have considered FM-UE scores of less than 20 or 25 to indicate severe impairment and more than 20 or 25 as moderate impairment [59, 76]. In acquired brain injury studies, participants are considered as being in the *subacute* stage of recovery if within 6 months since the event and *chronic* stage if more than 6 months [59, 63, 81, 230]. Time since stroke has been used to indicate speed of recovery during rehabilitation. Based on the variables of severity and time since stroke, we can therefore conceptualise participants for robot studies as belonging to four categories (Figure 3).

The first category includes severely impaired participants in the subacute stage of recovery. Outcome measures with minimal floor effects will be needed for these participants to be able to discriminate the scores of individual participants. Kinematic measurement and the FM-UE or MSS would be appropriate body function outcome measures for this group. Kinematic measures captured with external equipment can be time consuming and require the relevant expertise and resources. Kinematic measures captured by the robotic device are easier to record and need to be included in the analysis of the effects of the intervention. The FM-UE scale has been used for almost all the robot studies so far and has been shown to be responsive for this group of participants. Even though the FM-UE is not as responsive as kinematic or robotic measures, it allows comparison across robot studies and meta-analysis of the available data from different robot studies. Among the activity measures, the FIM motor subscale or CAHAI are suitable activities for use in this category. ARAT has a large floor effect and hence would not be the best activity measure for this group.

Figure 3. Proposed algorithm for selection of the outcome measures based on patient characteristics and ICF domains



Severe impairment : Fugl-Meyer < 20 ; Moderate impairment : Fugl-Meyer > 20

The second category includes participants with moderate impairments in the subacute stage of recovery. These participants require outcome measures with minimal ceiling effects to be able to discriminate between score changes observed in individual participants. Kinematic measurement and the FM or MSS are again suitable body function outcome measures for this group. Among the activity measures, the ARAT and WMFT might be limited by their ceiling effects. ABILHAND and CAHAI would be suitable activity measures and EQ-5D would be a suitable participation measure for this group.

The use of FM-UE, FIM motor subscale or BI is limited by their moderate responsiveness in the third category of participants, those with severe impairments in the chronic stage of recovery after stroke. Kinematic or robotic measures would be ideal body function measures. The MSS scale even though it was developed for the reason to be more responsive than FM-UE, has not been extensively researched in the stroke population and some of its measurement properties are still not known (Table 5). ARAT and CAHAI would be the preferred activity measures. ARAT may be limited by its floor effects when compared to the CAHAI. CAHAI has not been used in robot studies so far. EQ-5D would be a suitable participation measure.

The final category of moderately impaired participants in the chronic stage will need outcome measures with high responsiveness and acceptable ceiling effects. Kinematic or robotic measures would be ideal body function measures to capture the small changes with intervention. The ARAT or WMFT or CAHAI would be suitable activity measures along with ABILHAND as a patient-reported measure. The use of EQ-5D or SF-36 would be a suitable participation measures, SF-36 would be limited by its poor ceiling effect when compared to EQ-5D. The floor and ceiling effects of SIS are not yet known.

Economic evaluations should be considered as an important part of any large scale clinical investigation of robot-assisted exercise. Therefore when designing the study, it is important to include the use of a health utility measures and health resource utilisation questionnaires within the context of robot studies. The EQ-5D can be used for economic evaluations as well. One

robot study involving chronic participants did not observe any statistically significant improvement in EQ-5D scores although statistically significant improvements were found in the FM-UE and FIM motor scores [74]. It is possible that the EQ-5D has lower responsiveness than the FM-UE and FIM motor. The responsiveness of EQ-5D in stroke participants is currently unknown. Other measures such as the Northwick Park Dependency Scale (NPDS) that capture dependency and provide an estimate of the care cost savings through the reduction in dependency for physical assistance should be considered [231]

Personal and environmental factors have a huge influence on any intervention in rehabilitation. Patient, carer and therapist perceptions of robot-assisted exercise are important outcome measures to allow design iteration and gain information on satisfaction with the delivery of robot-assisted therapy relating to the look and feel of the system [63]. Achievement of personalised goals can be used to capture changes following intervention at an individual level (e.g. Goal Attainment Scale, Canadian Occupational Performance Measure) [232]. These are suitable for individual person monitoring but are not appropriate for group analysis and have poor measurement properties [233, 234], which limits their usefulness in robot studies.

The selection of outcome scores also depends on the type of intervention in terms of whether it is aimed at proximal or distal upper limb muscle groups. The effects are believed to be generalised in the subacute stage, whereas they are specific to the trained muscles in the chronic stage of recovery [52, 59, 64, 68, 89]. The three hand function tests (grip strength, NHPT and BBT) are quick to administer and may be suitable for studies where the intervention is directed at distal limb and hand function. The hand-based robot HWARD study showed a greater increase in BBT and NHPT scores when compared to proximal shoulder and elbow scores, FM-UE and ARAT [86].

One aspect of recovery, which is neglected in robot studies, is the measurement of change in the perceptual (sensory) function arising as a result of robot-assisted upper limb exercise. Perceptual function is a vital part

of normal movement and evidence suggests that recovery of functional motor ability is dependent on intact sensation, spatial awareness and attention. Interactive robot-assisted sensori-motor training may improve perceptual deficits or potentially confound the benefits that might be identified in robot studies. Only one robot study used a sensory assessment tool as one of the outcome measures [80]. The extent of sensory impairment did not seem to influence the overall benefit from robot-assisted therapy in this study. Changes in the perceptual function need to be further researched in robot studies.

We propose that at least four suitable outcome measures covering the different domains of ICF domains could be considered as essential to understand the effects of robot-assisted exercise on movement and functional use of upper limbs in daily activities and the impact on various aspects of health. Apart from the factors mentioned in the algorithm in Figure 3, other factors that should be considered in selecting outcome measures are the type of intervention that the robot provides (proximal, distal or both) and the resources required (e.g. trained healthcare professionals for clinical and kinematic measures, external optical tracking equipment to record movement patterns in simple tasks). This selection will also depend on the outcome measures the team is already used to and have a commitment to use in terms of the purchase license.

The future of robot-assisted upper limb exercise will be influenced by accurate capture and interpretation of the observed effects. This approach based on the ICF framework should help in identifying and selecting appropriate outcome measures for any robot studies [235]. The main limitation of this review is that we have analysed in detail only those outcome measures that have been used in previous robot studies. CAHAI was the only external outcome measure included as it had been developed based on CMSA, which has been used in robot studies. This does not necessarily mean that outcome measures not previously used in robot studies are not suitable for use in future robot studies. However, this review provides an approach based on the ICF for selection of outcome measures, which should

enable the researchers to apply this approach to any outcome measure they wish to explore in future studies.

2.3.2 Selection of outcomes for the hCAAR feasibility study

For the hCAAR device, participants and therapists will be involved throughout the various stages of device development based on the principles of user-centred design. Once the device is ready to be tested in a clinical setting (home), the participants recruited to the study are likely to be those with moderate impairment and in the chronic stage of recovery after stroke. The participants likely to be recruited will be those who have been discharged to the community and are attending stroke rehabilitation clinics, hence are likely to be in the chronic stage of recovery. As this is a home-based robot with limitations to its size and the power of the actuators, only participants with moderate impairments are likely to be able to use the system to performed assisted movements with their affected upper limb. The outcome measures that will be suitable for the feasibility study include (a) Body function measures: optical tracking device kinematic measurements during standard reaching tasks, robot kinematic measures, MRC, MAS and FM-UE (b) Activity and Participation measures: ARAT, CAHAI and ABILHAND and (c) Contextual factors: Participant, family, carer and therapist impressions of the device.

2.4 Limitations

The limitation of this review is that it includes only those outcome measures, which have been used in robot studies so far. This does not necessarily mean that outcome measures not used in robot studies are not suitable for use in future studies. However, this review provides a system for selection of outcome measures, which should enable the researchers to apply these criteria to the outcome measures they wish to explore in future studies. The future of robot-assisted upper limb rehabilitation exercises after stroke will be influenced by accurate analysis and interpretation of the observed effects. This can be accomplished by using the most appropriate outcome measures.

2.5 Conclusions

In conclusion, there is so far no consensus on the outcome measures that must be used in robot-assisted upper limb exercise clinical studies. A unique approach has been proposed in this chapter to assist researchers in selecting outcome measures in the design of future robot studies. A basket of outcome measures covering all domains of the ICF framework is crucial as it is important to measure change in each domain. The selection of outcome measures should also be based on the focus of the intervention, severity of upper limb weakness, time since stroke and the psychometric properties of the outcome measures. The outcome measures for the hCAAR feasibility study have been selected based on the above approach.

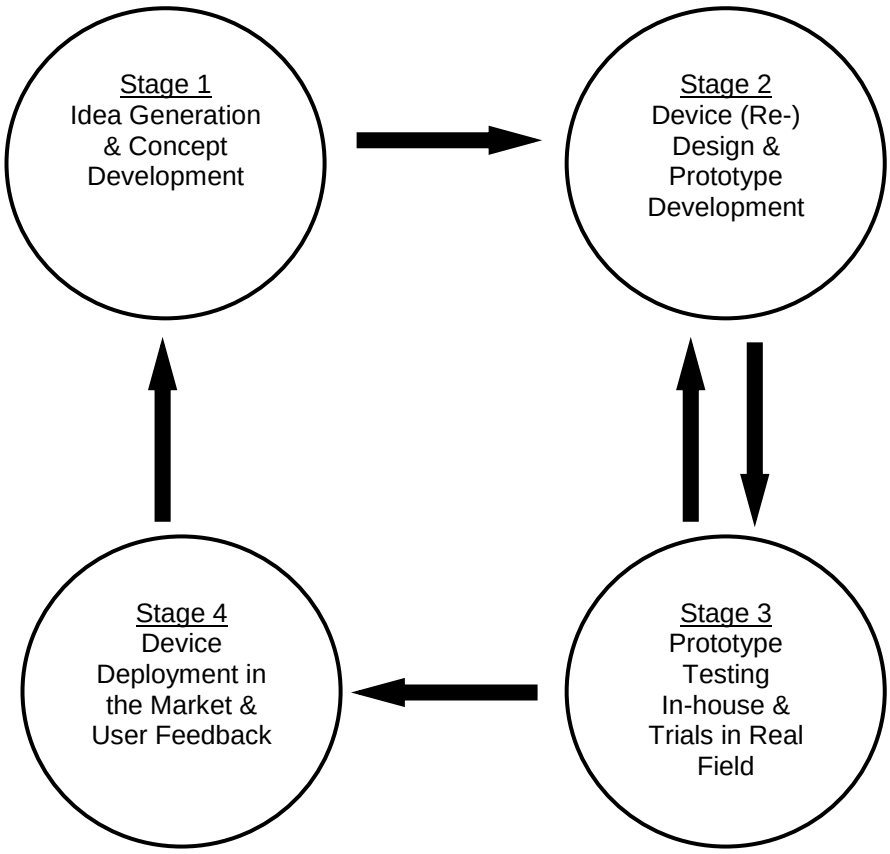
Chapter 3: User-centred design process for developing hCAAR

The success of any medical device depends on how well it matches the purpose intended by the healthcare professional and the needs and expectations of the individual being investigated or treated. This makes the perspectives of both patients and healthcare professionals paramount in the development process of medical device technology. It is now well established that the needs of users (patients and healthcare professionals) should drive product development, rather than technological and commercial pressures, and that users should be involved early in device development [236]. The involvement of users at the initial stages is associated with devices with higher market usability [237], improved equipment safety and efficiency [238], higher chances of successful user use [239] and overall reductions in development time and costs [240, 241]. This has also led to an increased regulatory requirement of user involvement in device development [242].

The involvement of users can be considered at various stages of device development from the stage of idea generation to the final stage of market deployment. Current literature supports the concept that users needs should drive product development, not technology and commercial pressure and that users should be involved in all stages of device development [236]. Models of medical device lifecycle stages have been described by Cooper and Kleinschmidt (13 stages) [243], Rochford and Rudelius (12 stages) [244] and World Health Organisation (seven stages) [245]. A recent comprehensive model proposed by Shah et al. comprises of four stages in the rehabilitation assistive technology development process: Concept, Design, Testing and Deployment [246] (Figure 4). Early involvement of different types of users in the concept and design stages can facilitate the development of technology with improved usability, higher customer satisfaction and reduced modification costs and time in comparison to involving users later in the device lifecycle [101, 247].

The concept stage starts with idea generation and includes technical, financial and commercial assessment [101, 246]. The design stage involves product development from (re)design to prototype development. The testing stage starts with prototype testing in-house and includes studies in the field. The deployment stage includes product marketing, launch and use in the field [101, 246].

Figure 4. Medical device technology development: for a device new to market (Reproduced from Shah et al. 2009) [230].



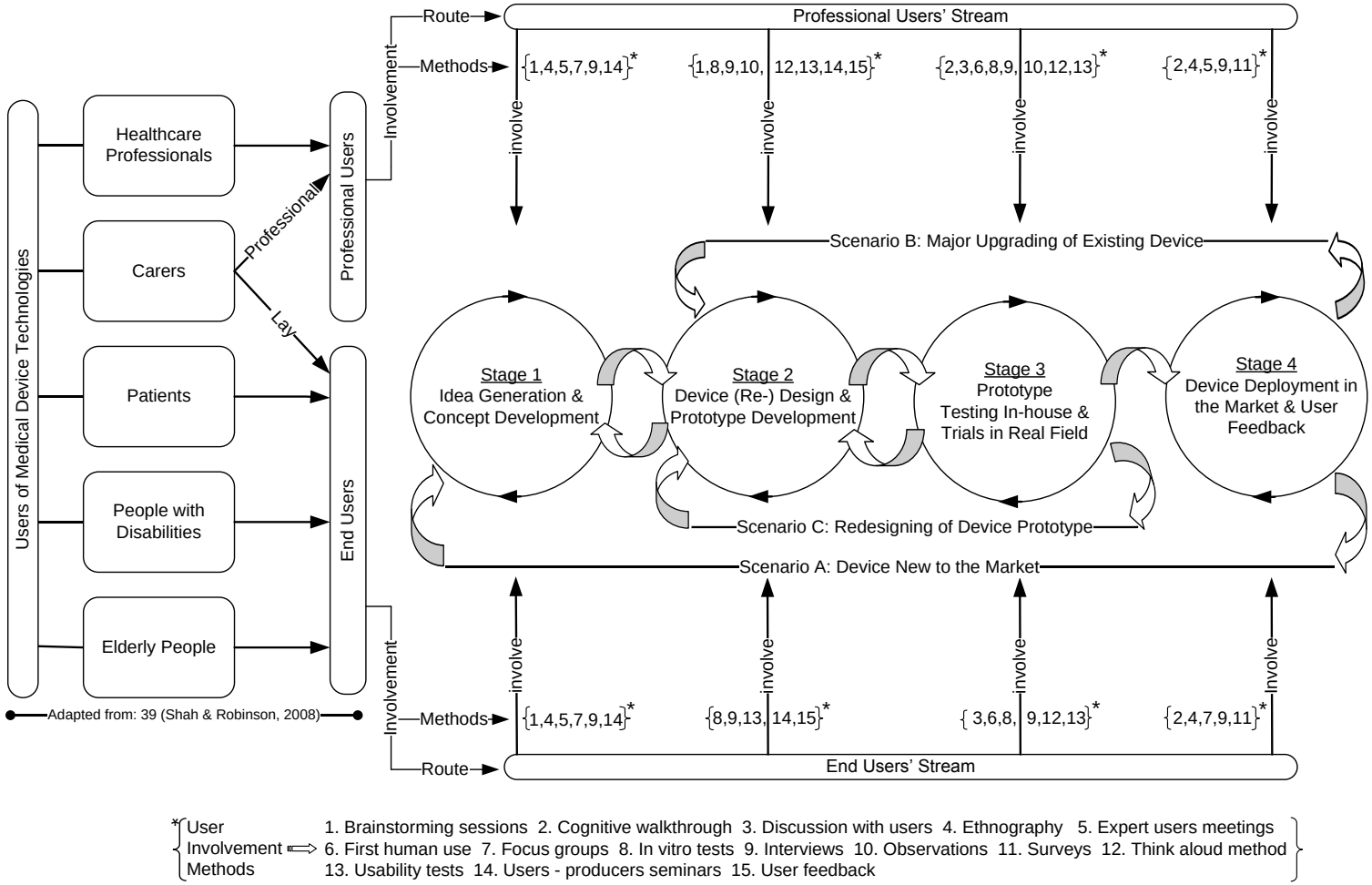
International Organization for Standardization 9241-210:210 set out the international standard for user-centred design, and specified six principles for user-centred design: that it is based on explicit understanding of users, tasks and environments; that users are involved throughout development; that design is driven by user-centred evaluation; that the process is iterative; that the design must address the whole user experience; and that the design team should include multidisciplinary skills and

perspectives. It also set out an iterative process for user-centred design, which involves understanding and specifying the context of use; specifying user requirements; producing design solutions; evaluating the design against the user requirements and iterating as necessary until the user requirements are satisfied [248].

There are a variety of direct and indirect methods that can be used to involve users throughout the device development process (Figure 5). Usability tests, interviews and questionnaire surveys are the most commonly used methods across all stages of device development [101]. The methods, which are most useful in the concept stage are brainstorming sessions, ethnography, user meetings, interviews, focus groups and seminars [246]. In user-centred design literature, there are currently no sufficiently detailed models described to help researchers understand their target population's needs in the concept stage.

The Cambridge "design exclusion calculator" developed based on the disability follow-up survey of 1996/97 [249], is used to give an estimate of the number of people in a population who would be excluded by a particular design and helps researchers to develop more inclusive designs [250]. The calculator is based on seven impairments disabled people might have: locomotion, reach, dexterity, vision, hearing, communication and intellectual function. This model could be used to help design technology for stroke survivors but the above impairments do not provide the breadth of factors that help to understand this population. This model does not take into account extended functional activities; personal factors, such as sex, race, ethnicity, interests and motivation; and environmental factors, such as therapy resource, carers and vocation. Cook and Hussey's Human Activity Assistive Technology (HAAT) Model also provides a process for structuring considerations of users' needs in prescribing and designing assistive technology to place them in the context of a given activity, environment and level of ability [251].

Figure 5. Theoretical framework for involving users in the medical device technology development process: streams, methods and stages (Reproduced from Shah et al. 2009) [230].



One framework that is commonly used in the health sciences to understand and capture the different aspects of any health condition is the World Health Organization's ICF. The ICF classifies the health condition into domains of body structure/functions, activities, participation, and the personal and environmental factors relevant to each individual [11]. This framework is internationally accepted and used extensively in research. Researchers have developed disease-specific ICF Core Sets for specific health conditions such as rheumatoid arthritis, multiple sclerosis and stroke. The Comprehensive ICF Core Set categories for stroke put forward by an international consensus group is widely used in stroke-related research (Appendix A) [252].

We undertook the process of user involvement and feedback in all the stages of device development. The concept and prototype design stages of device development are described in this chapter and user feedback from testing stage is described in Chapter Six. We have investigated the usefulness of the stroke-specific Comprehensive ICF Core Set to guide researchers in understanding user needs in all the stages of developing hCAAR.

The aims of the home-based Computer Assisted Arm Rehabilitation (hCAAR) user-centred design process described in this chapter are:

1) To understand user needs and expectations of a home-based upper limb rehabilitation device (concept stage).

2) To determine whether the ICF framework can be used as a template to understand user needs in the concept stage of the development of technology.

3) To get feedback on the device prototype (design stage) and develop the definitive hCAAR device which could then be tested in a feasibility study.

4) To provide a description of the definitive hCAAR device.

3.1 Methods

The user-centred design study had approval from National Research Ethics Committee (REC) and the local Research and Development (R&D) departments.

3.1.1 Sample

Stroke survivors with upper limb movement difficulties and who were attending local NHS stroke rehabilitation out-patient clinics were recruited to this study. The participants needed to have some voluntary movement in the affected upper limb and have no cognitive or speech difficulties to be able to engage in interviews. The nature of the study was explained to them by the researcher MS and they were given the patient information sheet, and, if interested in the study, were given a further appointment in the Charterhouse Rehabilitation Technologies (CRT) laboratory for the team to obtain their written informed consents.

Healthcare professionals (physiotherapists and occupational therapists) involved in the care of individuals with stroke were identified from local stroke rehabilitation services. The nature of the study was explained to them by the researcher MS and they were given the healthcare professional information sheet, and, interested healthcare professionals were invited to the CRT laboratory for the team to obtain their written informed consents.

The users in the context of this study were considered in two groups: end-users and professional users. The “end-user” group comprised of stroke survivors with upper limb weakness (including those with communication difficulties, visual impairments, mobility problems and varying degrees of upper limb weakness) and their carers. In the “professional user” group, physiotherapists and occupational therapists experienced in assessing and treating stroke survivors were included.

3.1.2 Interview process (concept stage)

All participants were offered a mutually convenient time to attend for face-to-face interviews undertaken by the main author MS. The aim of interviews was to understand users’ perspectives and expectations of robotic

technology (to provide upper limb exercises) in a home setting and the barriers to such technology. The research team (two clinicians and four engineers) initially identified the broad interview topics by brainstorming ideas and discussion in research team meetings. The topics were based on previous experiences in the user-centred design process [103, 253] and the existing literature on the development of assistive technology for upper limb rehabilitation [254, 255]. The interviews were comprised predominantly of open-ended questions based on the interview checklist of topics prepared by the research team. The nature of the interviews allowed the discussion to deviate from these topics to those that were identified by the end-users' relevant to the technology design. Written notes were taken by MS during the interviews. There was no audio or video recording undertaken.

For the interview format and the content of the questions, patients and their carers were considered as the 'end-user' group (Appendix B: Patient interview topics checklist). Physiotherapists and occupational therapists were considered as the 'Healthcare professionals' group (Appendix C: Healthcare professional interview topics checklist). End-users and healthcare professionals were asked questions on the intensity and type of upper limb therapy that patients receive after stroke, the home upper limb exercises, functional goals, the role of technology to provide upper limb exercises, Information Technology (IT), computer skills, and the perceptions of home-based technology and its comparison with hands-on conventional physiotherapy.

3.1.3 Extracting interview concepts

ICF linking rules have been developed to link health measures and interventions to the ICF framework. These rules were initially published in 2002 [256] and later updated in 2005 [257]. The authors suggested identifying meaningful concepts within items and responses of measures and linking to the most precise ICF category. Meaningful "concepts" are those that describe the health condition, the person, functional activity or any of the environmental factors. For example, consider the statement/item "Pain doesn't prevent me from walking any distance". Two different meaningful concepts can be identified in this statement, "pain" and "walking".

Meaningful concepts referring to “quality of life” are assigned “Not definable- quality of life”. If a meaningful concept is not contained in the ICF and is clearly a personal factor, it is assigned “personal factor”. If a meaningful concept is not contained in the ICF and is not a personal factor, it is assigned “not covered”. If the meaningful concept refers to a diagnosis or a health condition, it is assigned “health condition” [257].

Based on the above linking rules, meaningful concepts were extracted from our interview topic questions and responses.

3.1.4 Matching interview concepts to the ICF Core Set for stroke

The interview concepts, which resulted from the semi-structured interviews were matched to the categories within the Comprehensive ICF Core Set for stroke. The Core Set has 130 categories in total, which comprise 46 categories from the body function and structure domain, 51 categories from the activities and participation domain, and 33 from the environmental factors domain [252]. The personal factors domain has no categories as yet.

The process of extracting interview concepts and matching them to ICF categories as proposed by Cieza et al. [257] can be explained with the following example from our interviews.

a) The participants were asked *“Describe the home arm exercises you do (end-users) / prescribe (professional users)”.* The two meaningful concepts which can be extracted from the question are – “home setting” and “arm exercises”.

b) A sample end-user response was *“I have private physical therapy at home performing squeezing exercises with the affected hand, wheel hand cycling and working with weights”*. A sample professional user response was *“Lack of motivation and cognitive problems could contribute to poor compliance with home exercises”*. The meaningful concepts that can be extracted from above two responses are – “private therapy”, “fine hand skills”, “stretching exercises”, “strengthening exercises”, “motivation”, “cognitive problems” and “compliance”.

c) The extracted concepts are linked to one or more of the Comprehensive ICF Core Set categories, which convey the same meaning

Home setting – e210 “Physical geography”;
Private therapy – e580 “Health services, systems and policies”;
Cognitive problems – b110 “Consciousness functions”, b114 “Orientation functions and others.

3.1.5 Prototype (design) stage feedback

Our research team has successfully developed a dual-user assistive joystick system (K005) for use by children with cerebral palsy in schools (Figure 6) [258]. Based on our understanding of user needs in the concept stage, we chose to use the K005 device as a prototype to develop hCAAR. The aim of this stage (design stage) was to enable us to make the necessary modifications to the prototype and develop the definite hCAAR device that will be tested in the feasibility study.

Figure 6. K005 robotic device designed for children with cerebral palsy

The users were introduced to the prototype design (K005 system) and feedback was gathered on what a single user hCAAR system for home use should look like. Feedback was obtained on the hardware and software

components of the prototype system using user interviews. The feedback from these interviews was further explored in the research team meeting to inform the final design of the hCAAR system.

3.2 Results

Nine stroke survivors with residual arm weakness, and six experienced physiotherapists and occupational therapists in neurological practice were enrolled in the user-centred design process. We will refer to stroke survivors as “end-users” in this thesis.

3.2.1 End-users

The time since stroke ranged from 1 year to 3 years. Five participants had left side weakness and four had right side weakness. Five participants had weakness in their non-dominant arm and four in their dominant arm. Five participants had problems with speech and language, four of them had word finding difficulty (expressive dysphasia) and one had problems with articulation (dysarthria). All participants had problems with weakness in the affected arm, five of them had stiffness (spasticity) and three of them had problems with sensation in the affected arm. Four participants had experienced problems with vision (field defects) after stroke, which had improved by the time of recruitment. One participant had visual inattention on the affected side at the time of recruitment. Three participants had mild to moderate pain in the affected arm; one of them had previously received an injection in the shoulder area in the past for pain and all three were on analgesic medication for pain. Pain limited the range of movements in their arms. One participant had cognitive problems in areas of short-term memory since the stroke. Two participants reported ongoing problems with their mood since the stroke. None of the participants was in employment.

3.2.2 Healthcare professionals

The six healthcare professionals enrolled in the user-centred design process all had at least five years of experience of working with individuals with stroke. Four of them were physiotherapists and two were occupational therapists. Four of them provided therapy in both inpatient and outpatient

settings. Two therapists provided therapy in community settings. All of them were involved in providing and advising home-based arm exercise programs for their patients with stroke.

3.2.3 Interview results (concept stage)

The interview topic results were grouped as comments made by the end-user group and the healthcare professional group. Similar comments made by more than one individual are reported in third person in this Chapter. Individual comments are reported as direct quotes (using quotation marks and italics).

3.2.3.1 Therapy received after stroke

3.2.3.1.1 End-user group

All participants (nine) felt that there was a need for continuing therapy at home once inpatient and outpatient therapy had finished. Participants on average received 3-4 sessions of 45-min long physiotherapy sessions per week while they were inpatients after stroke. Following discharge from hospital, outpatient or community-based rehabilitation therapy varied from one session per week to four sessions a week and continued up to 12 weeks.

All participants felt they would benefit from additional therapy for their arm movement difficulties:

> *“I felt I needed more therapy for my arm but did not receive it in the long term.”*
>
> *“There was more emphasis on walking (lower limb function) than upper limb exercises in the initial therapy after stroke.”*
>
> *“NHS resources are limited and the waiting time for outpatient therapy is long.”*
>
> *“I wish to perform more arm exercises and want to improve arm function for better performance in daily activities and better quality of life”.*

3.2.3.1.2 Professional user group

All six healthcare professionals agreed that there was a gap between acute/subacute therapy and long-term therapy after stroke in the current NHS.

"The waiting list for outpatient therapy could be up to 6 months from the time of accepting a referral."

Up to 3 months to 2 years after stroke was reported as the time period when maximal recovery of arm function was likely to occur, although all professionals indicated that there is continued recovery even beyond this period, depending on the type and intensity of the therapy received by patients.

"There is scope for change up to 5 years post-stroke."

"Additional therapy would result in improved recovery of functional arm movement".

3.2.3.2 Types of arm exercise

3.2.3.2.1 Professional user group

All healthcare professionals commented that their therapy plans are personalised to individual patient goals. The interventions are targeted at maintaining a pain-free passive range of arm movement and improving arm weakness.

"The intensity of community therapy is based on the initial assessment, the patients can be considered in three categories: high need (therapy three times in a week), moderate need (twice in a week) and low need (once a week). The sessions are one hour each."

"Distraction and stimulation techniques are used for visual sensory inattention or neglect. "

"Patients are advised to exercise within their pain-free range of movement".

3.2.3.3 Home exercises

3.2.3.3.1 End-user group

All participants had been given home-based arm exercises by their therapists, which involved passive stretching exercises and active involvement in daily activities of living.

"I use hand beads for fine hand control exercises and also baking."

Seven participants were no longer practicing home exercises on a regular basis

"I did not continue doing home exercises after few months as lost motivation."

"I have private physical therapy at home performing squeezing exercises with my affected hand, wheel hand-cycling and working with weights".

Two participants occasionally went to the gym and worked with cross-trainer exercise machines and lifted weights.

3.2.3.3.2 Professional user group

Prescribed home exercises were based on the functional daily activities goals in discussion with patients.

"The exercise program includes stretching and sensitisation exercises as well as trunk stabilisation and balance exercises to optimise arm movement."

"Digital photos of exercises are given to patients to remind them how to do the exercises".

Patients varied in their compliance with home exercises.

"A compliance rate of one-third of the recommended amount of exercises is acceptable."

"Lack of motivation and cognitive problems after stroke could contribute to poor compliance."

"I recommend patients to do arm exercises (on top of their daily activities) for at least 15 minutes every day".

3.2.3.4 Functional activity goals

3.2.3.4.1 End-user group

All participants did not use their affected arms as much in daily activities as much as before stroke. They had developed compensatory strategies to perform daily tasks.

"I lift the kettle with my unaffected arm now."

"I use the affected arm only to hold things in place while the unaffected arm does most of the activity".

The participants wanted to improve their ability to use their affected arm in daily activities, such as combing their hair, washing, dressing, cooking, and eating with a knife and fork.

"I want to improve my writing."

"I want my affected arm to be less tight while doing activities."

"I want to get back to swimming and driving a manual car (currently driving an automatic car)".

3.2.3.4.2 Professional user group

The healthcare professionals directed therapy based on individual's functional activity goals and encouraged patients to use their affected arms as much as possible in daily activities and as early as possible after stroke.

"Therapy is tailored to patients' needs."

3.2.3.5 Use of technology at home for arm therapy

3.2.3.5.1 End-user group

Two participants have used the Wii video game console for entertainment and therapy at home.

"I use my unaffected arm to operate the Wii remote device as the affected arm does not have sufficient strength to operate the device. I play golf, tennis and bowling with my son."

"I like the competitive element of Wii games".

3.2.3.5.2 Professional user group

The healthcare professionals sometimes recommend use of the Wii for arm therapy in selected patients

“It depends on the type of arm impairment and availability of the equipment. It can be engaging and can augment the intensity of arm therapy.”

“Computer gaming exercise may be an adjunct to conventional treatments if chosen appropriately and based on individual clinical assessments”.

3.2.3.6 IT skills and computer games

3.2.3.6.1 End-user group

All participants had either used computers in the past or currently use them on a regular basis. They described their IT skills as basic and used the computer for Internet browsing, shopping and emails. Seven participants had laptops, one had a desktop computer, and two had both a laptop and a desktop computer. One participant did not have a computer at home. Seven participants’ family members or carers had basic computer skills and could use computers for Internet browsing, shopping and email.

Three participants have previously played computer games, such as card games, street game, formula one car racing games, darts and Chinese checkers with their families.

“I would like to play computer games based on golf, bowling and tennis.”

“Games based on Soduku or shopping would be interesting.”

“Games based on space (asteroids) or word building (scrabble) would be good”.

3.2.3.6.2 Professional user group

The healthcare professionals felt computer games might keep some patients interested.

“Not all would find using a computer easy and interesting, especially the elderly patients and those with cognitive problems.”

"The nature of games that will engage patients will vary between individuals, depending on sex, vision problems, interests and previous experience".

3.2.3.7 Individual's perceptions on the role of arm rehabilitation technology in the home setting

3.2.3.7.1 End-user group

All participants believed that using a home-based technology aimed at arm exercises would help them perform more arm exercises. They felt it would give them more independence in their rehabilitation program and motivate them to engage more in the exercise program.

"It (rehabilitation technology device) *can improve one's concentration and thinking ability."*

"It can improve hand-eye coordination and fine skills."

"It would have been ideal if it were available straightaway when I was discharged from hospital after my stroke."

"It might give me a purpose to get out of bed and use the device every day".

Seven of the participants preferred to use the technology on an individual basis at home.

"I prefer using it on my own as feel I would become conscious of my problems when using such devices in front of other people."

"Competition is good but not with able-bodied people."

"I do not like stroke clubs and resource centres".

Two participants also preferred to use the technology in a multi-user setting with other individuals. They were interested in the idea of a collaborative approach where one could play with another individual remotely via an Internet connection.

"Using such technology in hospital setting would benefit us (patients) early after stroke."

3.2.3.7.2 Professional user group

All healthcare professionals supported the idea of having technology that could help individuals perform arm exercises in their homes.

“Such technology could improve thinking ability and cognition”.

Most healthcare professionals (five) felt that patients would prefer using such technology both on an individual basis and in a multi-user approach in community centres and stroke clubs.

“Patients are generally motivated in groups but some patients could become self-conscious and threatened in a group.”

“Younger people like competition.”

“ Elderly patients might not be keen on technology.”

“There might be some potential difficulties installing the device in community centres, like with the maintenance of the device, the transport facilities for patients to get to the centres and the inability to access the device when facilities were closed”.

3.2.3.8 Comparison of arm rehabilitation technology to conventional hands-on physiotherapy

3.2.3.8.1 End-user group

All participants stated that the technology would provide them with additional therapy to their physiotherapy and would benefit the eventual recovery of their arm function. They stated that home-based technology could increase their ability to perform arm exercises independently in their free time.

“Home technology might save time going to hospitals and would help me undertake therapy when my child (2 yr old) is asleep.”

“Using computer games could increase my concentration and thinking ability that has been affected by the stroke.”

“I am unsure if playing computer games could be used to provide useful exercises for arm recovery.”

“I would not know whether the correct exercises were being undertaken using the technology as they would not be supervised by professionals”.

3.2.3.8.2 Professional user group

All healthcare professionals felt that technology can augment hands-on physiotherapy after stroke.

“It might provide intensity to the exercise program and encourage patients to perform exercises when not being supervised.”

“It might empower the patient by increasing independence.”

“It can increase engagement and have a positive impact on cognitive function.”

“It might be cheaper, convenient and flexible (in terms of taking breaks within sessions when tired)”.

Four healthcare professionals stated a major drawback would be the lack of ability to monitor the patient performance and quality of movements undertaken.

“It might be difficult to correlate device movements to the functional relevant daily activity movements.”

“One concern is the huge costs involved in developing such technology and whether it is cost-effective in the long run”.

3.2.3.9 Expectations of the home-based arm rehabilitation device

3.2.3.9.1 End-user group

The participants (seven) wanted the device to be simple and easy to use with a footprint suitable for installation in a home setting.

Participants wanted the device to be deployable in a living room (three participants) or kitchen (two participants) or bedroom (four participants). All these four participants’ bedrooms were first floor rooms with a staircase as the only route to the rooms.

“It should be a tidy piece of equipment.”

“It has to be easily moveable and portable.”

“The device must be safe especially electrical faults.”

“Hope there will be access to engineers to fix any technical issues that arise”.

3.2.3.9.2 Professional user group

All healthcare professionals felt the device should be safe and easy to set-up and use. They suggested the device should be compact and easily installable in the home setting.

Two healthcare professionals stated that the system should have options to individualise exercise programs depending on patient' deficits and needs.

"The technology must be simple, appealing and motivating for the patients."

"The computer tasks must be meaningful and functionally relevant based on the principles of motor relearning. The device should help maintain the range of movement and improve strength in the weak arm."

"I like the idea of ability of the device to provide assistance when the user is unable to complete the task with the affected arm."

"It would be difficult to engage some elderly people who are not used to computers and games."

"Hygiene issues must be considered while designing and delivering devices to people's homes."

"Patients must have access to engineers and healthcare professionals who have knowledge about the technology".

3.2.4 Extracting interview concepts

Meaningful concepts extracted from each interview topic questions and responses/discussions with end-users and healthcare professionals are listed in Table 7. In cases of duplication of concepts, they are listed only once in the table.

3.2.5 Matching interview themes to the ICF Core Set for stroke

Concepts linked to the most relevant ICF Core Set category(s) are shown in Table 8. Two concepts were assigned as related to "health condition", 14 concepts were assigned to "personal factor" and one concept was assigned "not covered".

Table 7. Meaningful concepts extracted from the interviews

Interview topic	**Concepts emerging from the discussions**
Demographic characteristics	Age, gender, type/time of stroke, side of weakness, dominant side, speech and language skills, vision, stiffness, weakness, sensation, pain, cognitive problems, mood, employment
Therapy and exercises	Duration of exercises, intensity of exercises, walking, upper limb specific exercises, time since stroke, NHS resources, daily activities, quality of life, personal goals
Home exercises	Home setting, private therapy, fine hand skills, stretching exercises, strengthening exercises, endurance exercises, sensitisation exercises, balance, compliance, motivation, cognitive problems
Functional activity goals	Use of affected arm, writing, daily activities, combing hair, washing, dressing, cooking, eating, swimming, driving
Home technology	Playing games, engagement, intensity of therapy, personal choice, leisure interests
IT skills and computer games	Computer use, owning a computer, playing games, cognitive skills, gender, vision, interest, experience
Individual perception	Concentration, thinking, coordination, fine skills, time since stroke, purpose in life, competition, motivation, social life, age, community resources
Comparison between technology and hands-on physiotherapy	Therapy principles, cognitive skills, independence, supervision by professionals, cost, maintenance
Expectations from home-based device	External look of device, expectations of users/ professionals/friends/family carers, motivation, assistance, safety, hygiene, engagement, meaningful exercises

Table 8. Interview concepts and matched ICF Core Set categories

Interview concept	**ICF Core Set category**
Type/time of stroke	Health condition
Side of weakness	Health condition
Dominant side	Personal factor
Speech and language problems	b167, b330
Weakness	b730
Stiffness	b735
Involuntary movements	b755
Sensory function problems	b260, b265, b270
Pain	b280
Vision problems	b210
Inattention	b140
Memory problems	b144
Cognition problems	b164
Mood problems	b152
Employment	d850, d855
Therapy/ exercises	d210, d220, d230, e580
Duration of exercises	b455
Walking	d450
Upper limb exercise	d440, d445
Daily activities	d230, d430, d510, d520, d530, d540, d550
National Health Service (NHS) services	d580
Quality of life	Not definable
Intensity of exercises	b740
Fine hand skills	b440
Home setting	e210
Private therapy	e580
Strengthening exercise	b730
Stretching exercise	b710
Sensitisation exercise	b270
Endurance	b740
Balance	b770

Compliance	Personal factor
Motivation	Personal factor
Cognitive problems	b110, b114, b117, b140, b144, b152, b156, b164, b167, b172, b176
Usage of affected arm	Not covered
Washing	d510, d530
Dressing	d540
Cooking	d630
Eating	d550
Combing hair	d520
Writing	d170
Swimming	d920
Driving	d475
Playing games using technology	d210, d220
Engagement	b140
Intensity of therapy	b740
Personal choice	Personal factor
Leisure interests	d920
Computer usage	e115
Owning a computer	e165
Gender	Personal factor
Interest	Personal factor
Experience	Personal factor
Concentration	b140
Thinking ability	b164
Coordination	b755
Purpose in life	Personal factor
Competition	Personal factor
Motivation	Personal factor
Social life	e325
Age	Personal factor
Community health resources	e575, e580
Independence	Personal factor
Supervision by professionals	e355, e360
Cost	e165

Convenience	Personal factor
External look of device	e150, e155, personal factor
Expectations of friends, family, staff	e410, e420, e425, e440, e450, e455
Engagement	Personal factor
Assistance	e115
Hygiene	e150, e155
Safety	e150, e155

3.2.6 Interview results - prototype (design) feedback

3.2.6.1 Hardware

3.2.6.1.1 End-user group

All participants liked the look of the prototype device and were satisfied with the likely final footprint of the hCAAR device and felt it would be deployable in their homes. They identified in their homes the exact rooms they would prefer the device to be installed if they were part of the feasibility clinical study. We realised that some participants would prefer to use the device in rooms on the first floor. We had to design the device in such a way that it could be dismantled sufficiently to enable it to be taken upstairs and assembled in the desired location. We had to make the computer screen and joystick height adjustable to accommodate the different heights and builds of participants. We realised the keyboard was occupying too much space and some participants found it cumbersome; it needed to be replaced with a smaller keypad.

Two participants were using considerable trunk movements to move the joystick and had to be instructed to try to bring the desired movement more from the arm while keeping their trunk rested against the back of the chair. We incorporated this aspect of usage to be checked in the weekly telephone communication with the participants in the feasibility study. While observing patients use the device, we identified a need for separate design for right arm use and left arm use to enable participants to operate the safety button with the unaffected arm while using the joystick with the affected arm.

3.2.6.1.2 Professional user group

Two therapists suggested the need to vary the joystick height and position depending on the handedness and height of the user. This suggestion was incorporated in the design modifications.

"The system could have an adjustable screen and joystick, which could be moved up, so that the patient could perform tasks in a standing position. This would simulate some of the arm exercises that could be performed in a standing position. This can be challenging to the user and improve the individual's balance as well".

The research team discussed this suggestion and it was felt that this modification would increase the size of the device and make it less appealing for the home setting.

"The joystick handle could be set-up in a horizontal or semi-horizontal position to suit patients who have lost supination range at their forearm".

The research team felt that that the planned vertical handle design would encourage patients to regain the lost range of supination movement in the forearm and would more closely resemble the anatomical positions used in most daily tasks.

"Could the handle incorporate pronation/supination and finger movements to work on distal muscles as well?"

As part of their ongoing research in developing rehabilitation robotic systems for arm rehabilitation, the research team had already developed additional modules to promote distal movements of pronation/supination and hand movements. However, they felt that for this device (hCAAR), adding additional modules again increased the size of the device and would make it less acceptable to users in a home setting.

Two therapists felt that a drawback of the device is that it facilitates movements in one plane only.

"The device would be less appealing to those with mild weakness and those who can do more complex tasks."

“I feel rotation movements in the shoulder while performing the joystick movements would encourage maintain range of movement at the shoulder joint.”

The research team acknowledged that hCAAR would appeal most to those with moderate impairment or deficits after stroke.

3.2.6.2 Software

3.2.6.2.1 End-user group

All participants liked the concept of therapy based on joystick movements. They appreciated the joystick assisting their arm movements and felt the movements were easier in the assistance mode. They liked the idea of scores being displayed on the screen after each game which gave them an indication of their performance. Two participants could not recognise from the display whether their performance was getting better or was the same, which prompted us to change the score display format.

3.2.6.2.2 Professional user group

The therapists liked the idea of being able to adjust the assistance to the system based on individual deficits and the ability of the device to help individuals complete tasks on the screen. They also appreciated the concept of the assistance adjusting automatically based on individual performance. This variation is important to keep robot assistance to the minimum and encourage the user to actively perform the movements. We changed the assistance algorithm based on this feedback.

Two therapists were interested in knowing whether the system could track individual performance (in terms of movement kinematics) and give feedback to the user as the therapy progresses. We felt this was a good suggestion and planned to incorporate this in future versions of the device. For this study, we planned to get feedback on simple display of previous best scores and then make changes to feedback methods in future version.

“It would be interesting to analyse the effect on tone (spasticity) after using the device.”

“The long-term benefits of using the device must be analysed”.

3.2.6.3 Games

3.2.6.3.1 End-user group

All participants enjoyed the games on the prototype system and were interested in using the games in a clinical study. They were shown four game concepts: van, river, chase and puzzle. Two participants found the animation aspect of the game more suited for children than adults. This prompted us to include four more games with similar themes but without the animated characters.

3.2.6.3.2 Professional user group

The therapists agreed that the movements being generated by the system were functionally relevant, though restricted to one plane. Most of the functional daily activities involve reaching movements and the system was generating mainly reach and retrieve movements. One therapist suggested having a library of levels for the computer games, and have them set-up in an increasing order of difficulty. We adapted this suggestion to create a library of levels, with levels becoming progressively harder and involving a larger range of movement for the shoulder.

> *"Different kind of games would suit different patients depending on extent of spasticity and motor weakness. One could use games (such as chase and puzzle) that enable range of movement if spasticity was the predominant problem and use games (such as river and van) that enable precision of movement when user has low tone and more weakness".*

The research team used this suggestion to personalise therapy with hCAAR in the feasibility study.

> *"Having a level of unpredictability in games adds to the cognitive demand on the patients*".

The levels of games were designed to introduce unpredictability and complexity as levels progressed. The researcher MS designed the levels of games and helped the researcher JG with writing the code for the levels of the games.

“Games based on planning a day, using the shopping trolley, managing accounts, doing puzzles, crosswords, Soduku, Scrabble or word formation, could be cognitively challenging to patients.”

“Virtual games based on daily activities would be functionally relevant”.

Three therapists felt that playing games can become boring for some patients in the long run and felt that some patients may fatigue easily playing demanding computer games.

The suggestions of creating more challenging games based on users’ leisure interests and creating virtual games based on daily tasks is challenging and would require extensive resources because the games, once created, need to be designed in a way that they have functional relevance to everyday tasks. They then need to be linked to the joystick movement and assistance algorithm of the device. These ideas will be considered when developing the future versions of the device.

3.2.7 Description of final hCAAR system

3.2.7.1 Hardware components

The hardware components of the device consist of a Personal Computer (PC) allowing interaction between the user and the computer software (Figure 7). The interface equipment consists of a joystick handle linked to a chassis. The chassis allows the handle to move within a set workspace relative to the user, which is set to maximise the therapeutic exercise workspace. The exercise workspace can be adjusted if needed both physically or through software depending on the progress of the person. The motion of the device is limited to a two-dimensional plane at the central attachment point of the joystick.

The interface device has a system of motors and pulleys that provides assistance to (or alternatively resistance to) the motion of the joystick handle. Sensors within the handle and chassis allow tracking of the handle position and the force applied. This creates a position control loop, which can be changed in real time to make the handle move to different positions in the exercise workspace. Within the chassis a controller, motor and gear system

enable force feedback from the software to guide the position of the handle. A system of sensors (potentiometers on the bearing joints) is used to track the position of the handle and any other inputs into the PC, such as the force applied to the handle and button switches. All of the above components are covered by purpose-built panels and set-up in a moveable trolley system.

Figure 7. hCAAR device

There is an additional handle switch connected to the computer that is meant to be operated by the good arm while playing the computer game (Figures 8 and 9). An emergency stop button in the system enables the user to disconnect the motor assistance to the joystick in case of emergency. The device is purpose-built for use on one side only so that the joystick handle is operated by affected/impaired arm and the unaffected arm is able to operate the switch and keypad. The unaffected arm can be used to operate the emergency button if needed. The equipment was tested for reliability and physical and electrical safety by the School of Mechanical Engineering using University of Leeds standards.

Figure 8. A left-hand device being used

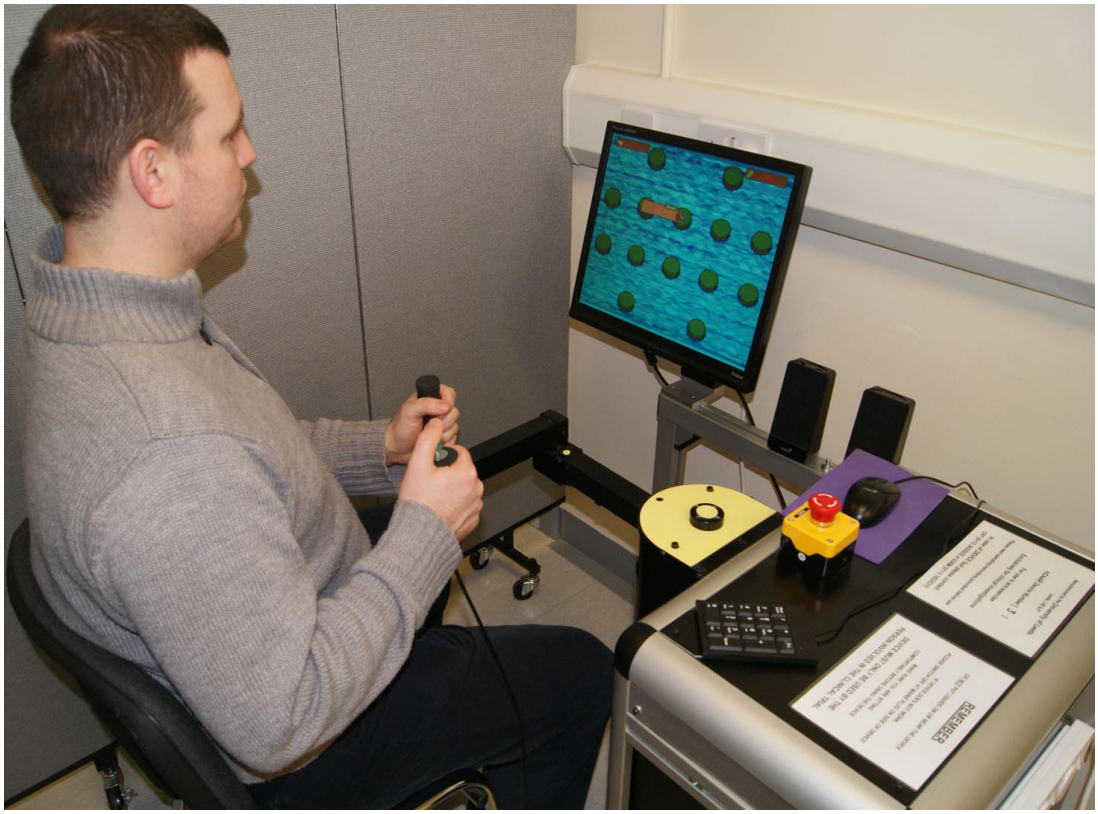


Figure 9. The affected arm holds the joystick and the good arm operates the switch and emergency button (when needed)

3.2.7.2 Software components

The computer program includes a base “software platform” for underlying functions and a set of activity-based tasks that will be used to direct and control the exercises. Software components include the following key points:

- Data acquisition and interface device inputs. Inputs are important for moving elements of the activity relative to the handle position, also data acquisition is accurate enough to control the position of the handle in a safe way.
- Multimedia including graphics and sound. Libraries within the software produce images on the PC monitor using the available graphics cards, and produce sound through the PC sound card operates the user interface.
- Statistical data tracking. Storing measurements of the usage, assistance level, and other important data that can be used in the evaluation of the user’s performance.
- Interactive software. The key feature is computer games/interactive activities that engage users in using the device.
- Local Area Networking, Client/Server networking can be incorporated within a laboratory setting but this was not part of the clinical evaluation in this project. The aim in the future is to develop the software platform that will enable multi-user interactive exercises on a local network or through the internet.

The system hosts a database storing user information including:

a The times of login and duration of time used.

b The duration of assessment exercises and game play.

c The number of attempts at various games/exercises and the number of levels completed within each game.

d The accuracy of the position of the handle during assessment and game play.

e The improvement in a user’s performance improved over time.

The software also measures the number of hits in the assessment exercise. The assistance levels adjust according to the performance in the assessment exercise. As the user performance increases, the assistance levels decrease by the set algorithm of the software. The computer screen provides visual and auditory feedback of the target location and the movement of the joystick. The baseline clinical examination and computer assessment exercise allows the initial exercise parameters (duration, nature of games, game levels and assistance level) to be set.

There are two operational modes for the device:

- Active nonassist – the movement is performed completely by individual's own effort with no assistance/resistance offered by the device. This mode is used for the assessment exercise prior to game play.
- Active assisted bimanual mode – the individual initiates the movement and is aided by the device towards the goal. The joystick directed movement on the monitor can complete the task only when accompanied by the action of a switch device controlled by the unaffected arm. This mode is used during game play.

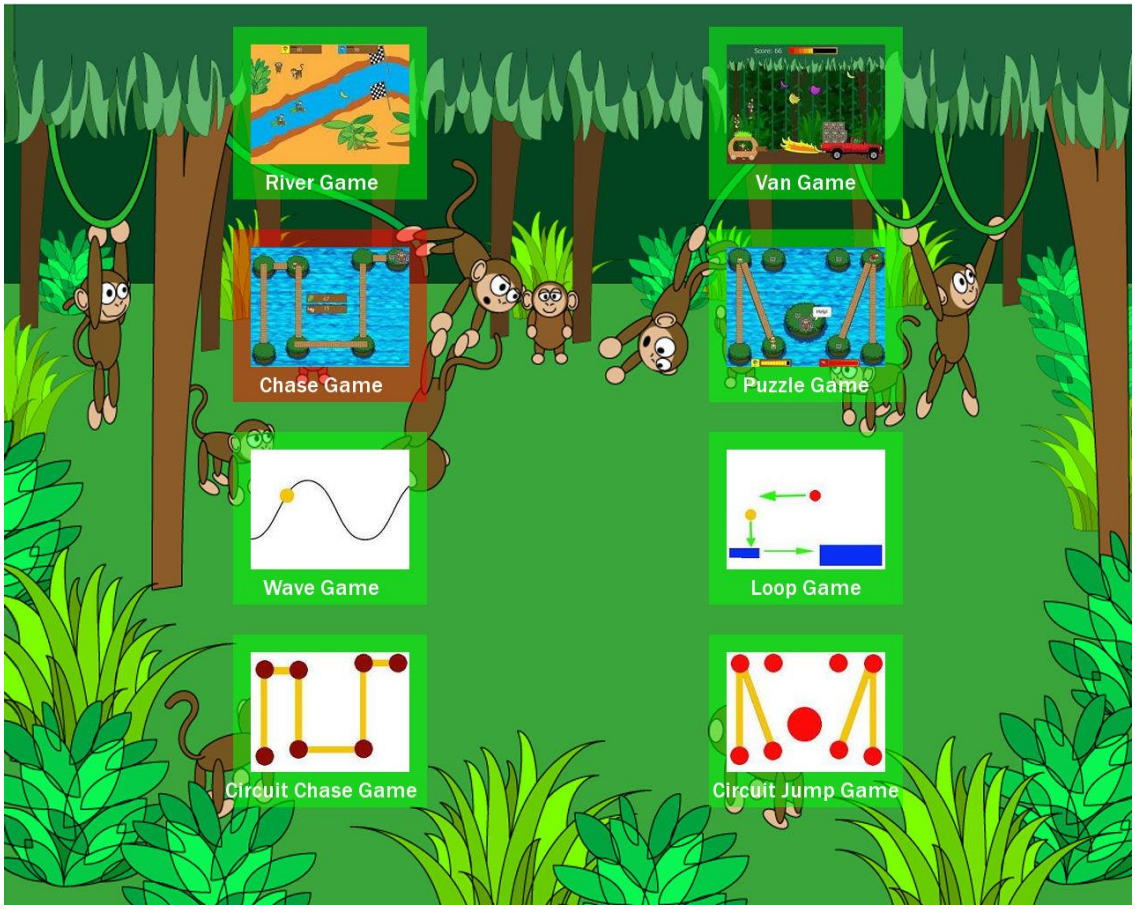
3.2.7.3 Computer games

There are eight computer games that were designed to provide arm exercises to the participant (Figure 10). Each game involves a series of linear movements within the monitor workspace to be performed by moving the joystick using the affected arm. The characters have to be moved to the target and the switch device pressed by the unaffected arm to complete each component task within the game. Four games have animated characters to provide more fun while performing tasks and four games do not have the animated characters. Each game is based on a series of movement steps on the screen.

The river game and the wave game: In the river game, the user must guide the monkey image to follow the path of a river stream. The user collects bananas along the way by clicking the switch with the unaffected arm. The assistive force helps keep the monkey along the river path. The score is based on number of bananas collected. The wave game is similar to the river game without the animated figures of monkeys and bananas.

The van game and loop game: In the van game, the monkey has to move up and down and collect the bananas being fired by the van. The monkey also has to avoid flames coming from the back of the van to avoid losing points. The assistive force keeps the monkey image along the expected path. The loop game is similar to the van game without the animated figures of monkeys and bananas.

Figure 10. hCAAR games menu



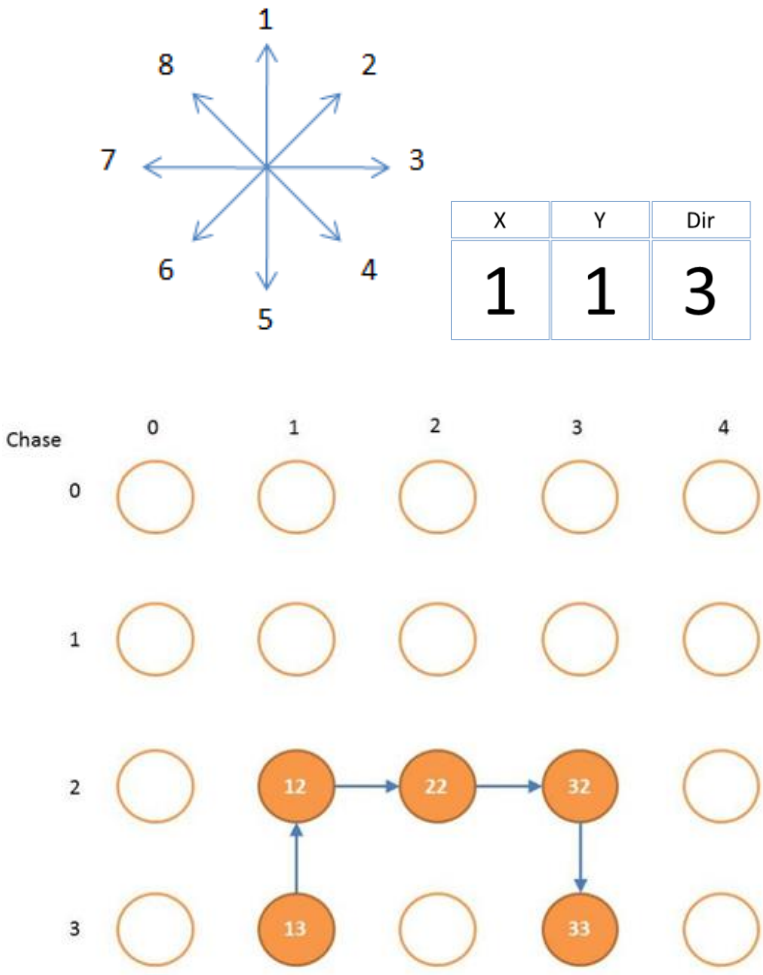
The chase game and circuit chase game: In the chase game, the monkey has to follow the bridge paths between the islands and reach the target. The assistive force keeps the monkey image along the bridge path. The time taken to complete the task determines the score. The circuit chase game is similar to the chase game without the animated images.

The puzzle game and circuit jump game: In the puzzle game, the user must press the switch to open the bridges, reach the target and release the caged monkey. If the image falls in the water, points are lost. The assistive force keeps the monkey image along the path. The circuit jump game is similar to the puzzle game without the animated images.

3.2.7.3.1 Game level generation

In order to maintain engagement and promote progression of arm use, every game has different levels arranged in a hierarchical order of difficulty. The river game was based on a combination of sine waves. The earlier levels start with a simple design but in the higher levels, the sine waves become more frequent and taller. The chase and puzzle games were based on a 5 x 4 grid of islands and connecting bridges. The series of steps in each level were created from a series of three numbers representing the position on the grid and the intended direction of movement. The first number represents the x-axis position, the second number is the y-axis position and the third number is the direction of movement in the grid. For example, the path in Figure 11 could be created from the following sequence: 131, 123, 223, 325, 330. The direction of '0' represents the end of the sequence.

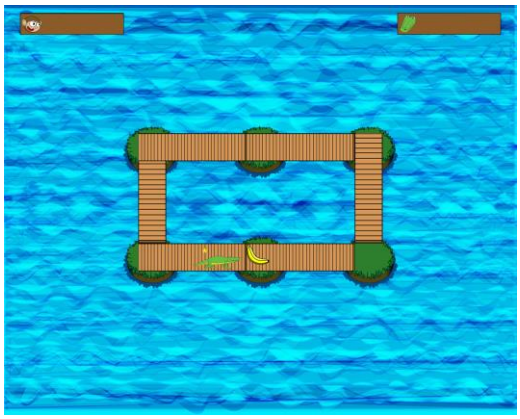
Figure 11. Example chase game level generation



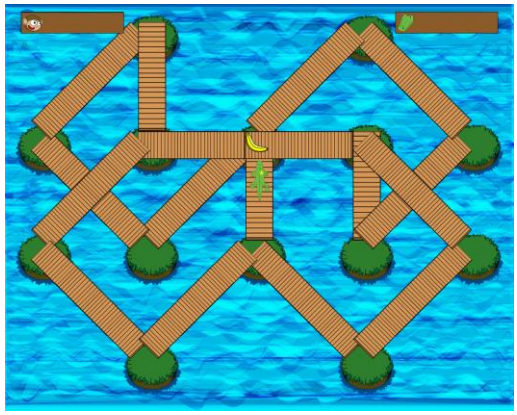
Each game has 75 built-in levels designed to provide a hierarchical order of difficulty in terms of the number of movement steps and the extent of workspace used. For example level 1 of the chase game has a small workspace of approximately 4 x 2 inches on the screen whereas level 75 has a workspace of approximately 6 x 6 inches on the screen (Figure 12). The range of movement the shoulder and elbow go through while performing level 75 is greater than the range used in level 1. This makes the levels progressively difficult and more challenging to the user.

Figure 12. Chase game levels

Chase game level 1

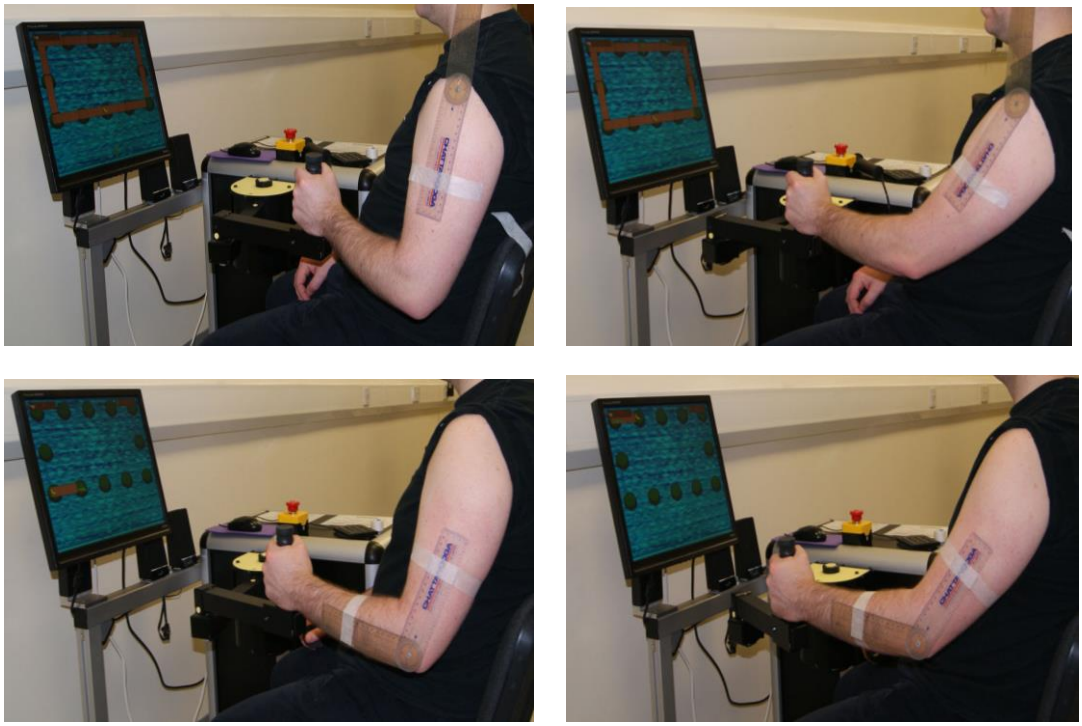


Chase game level 73



Level 1 in the above example involves 12 movements restricted to a 4x2 inch space on the monitor that can be performed with a limited range of movement in the shoulder and elbow. Level 75 is more complex; it involves a total of 40 movements and is spread over a 6 x 6 inch space on the monitor and will need a greater range of movement in the shoulder and elbow. We roughly estimated the range of movements the shoulder and elbow go through in the sagittal plane while moving the character from bottom of screen to the top of screen (three upward movements) (Figure 13). The elbow angle changed from 110 to 135 degrees of extension and the shoulder angle changed from 3 to 30 degrees of flexion.

Figure 13. Shoulder and elbow ranges of movements in the sagittal plane during reaching movements

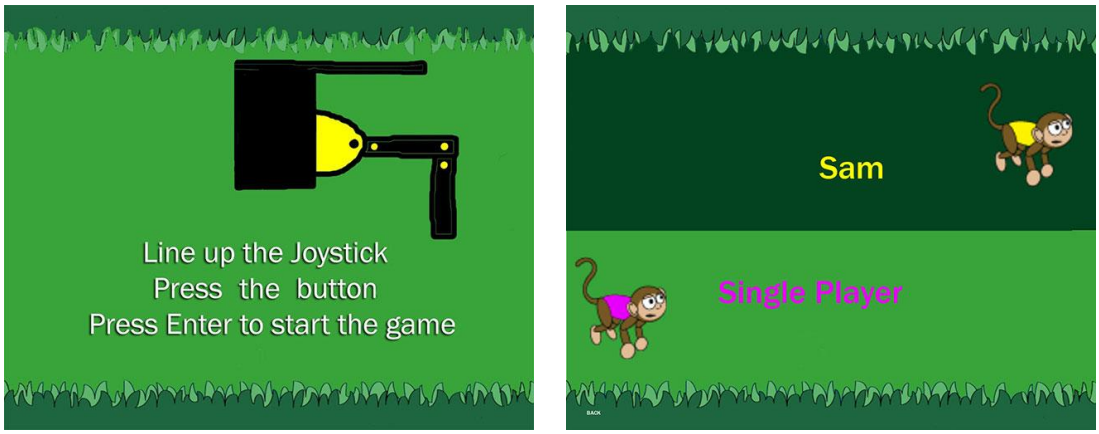


3.2.7.4 System menus

Figure 14 shows the system menus and how the games are played. Interactions with the menu are through a push switch held in the unaffected hand of the user.

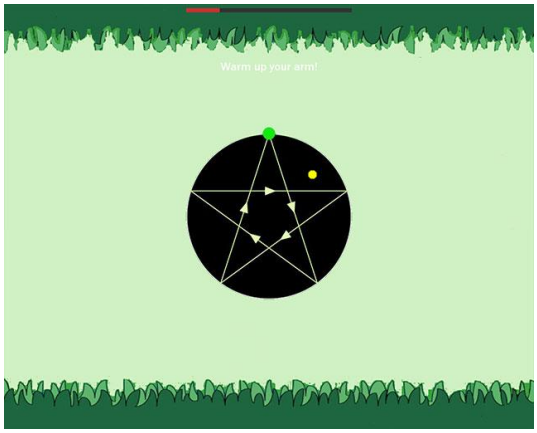
Figure 14. System menus for playing games

(a) Align the joystick **(b) Player confirmation**



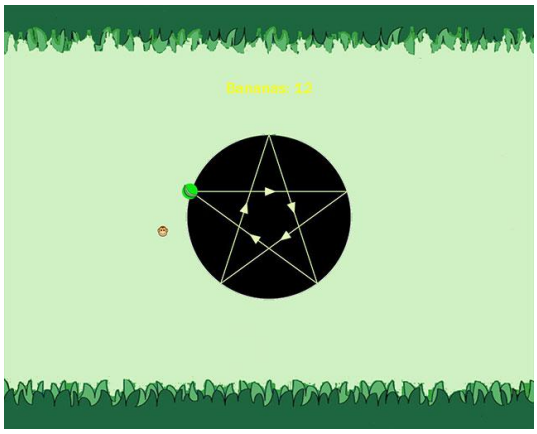
(c) Warm-up instructions

(d) Warm-up routine



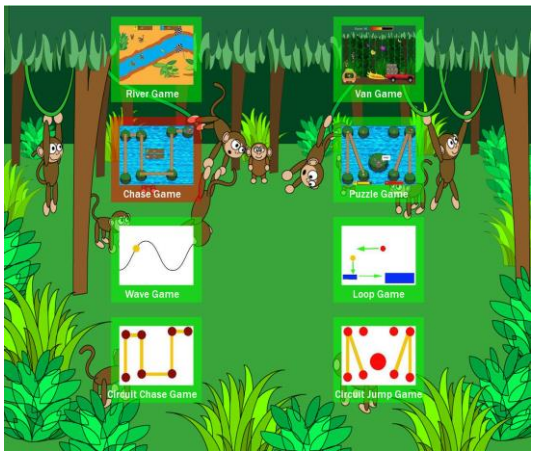
(e) Assessment instructions

(f) Assessment task



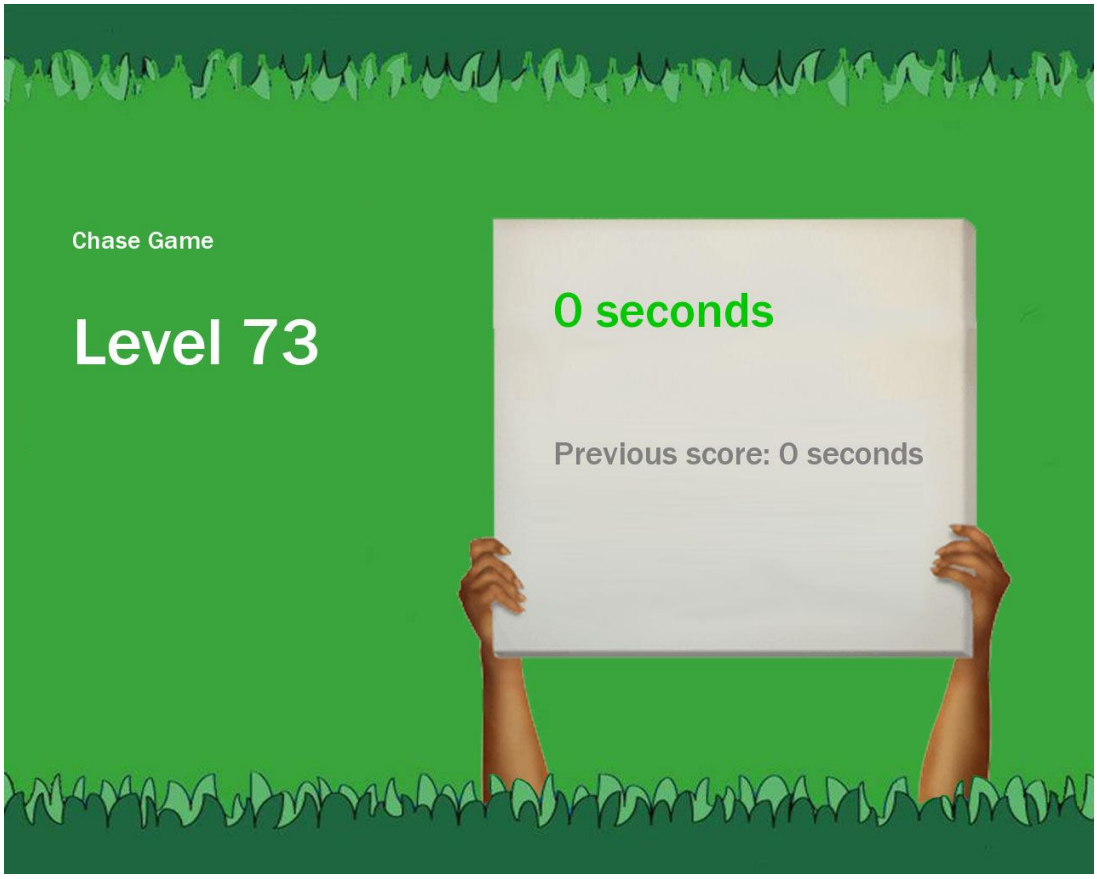
(g) Assessment well done

(h) Games menu



After each level of game played, the performance score comes up on the screen with a comparison with the previous score on that level which gives an indication of the individual's performance (Figure 15).

Figure 15. Sample score display



3.3 Discussion

Three aspects of user-centred design have been undertaken in this study. Firstly, the users' needs and expectations of a home-based robotic device were explored. Secondly, the interview concepts were matched to the Comprehensive ICF Core Set categories and found that the Comprehensive ICF Core Set serves as a template for researchers to understand user needs and expectations in the concept stage of device development. The matching of interview concepts of other stages (design and testing) of device development to the Comprehensive ICF Core Set categories will be described in Chapter Six. Thirdly, we have successfully developed a definitive device ready to be tested in a clinical setting.

3.3.1 Concept stage of user-centred design

Involving users early on in the technology development process will lead to improved technology design, which will lead to a greater likelihood of usability, adherence to treatment protocols both within clinical studies and in routine use, and the subsequent adoption of the technology by the health services. The interviews in this user-centred design study provided valuable insights into the problems faced by individuals after stroke and the current status of upper limb rehabilitation therapy. It is clear that different patients have different needs in their daily lives, and it is important for upper limb exercises to be based on functional needs and often patients require higher intensity than they are currently receiving. Unfortunately, long-term therapy in the NHS is limited and there is a lack of long-term continued motivating therapy in the home setting for patients after a stroke.

The interviews highlighted two potential gaps in the therapy services provided in the period after discharge from hospital: the first gap occurs immediately after discharge from acute hospital treatment, while waiting for input from community rehabilitation services, and the second gap is after discharge from community rehabilitation services until long-term continuing outpatient therapy is organised. The second gap can vary widely in length as some users do not receive any long term continuing outpatient physiotherapy. These gaps in upper limb therapy services could potentially be covered by therapy delivered by technology to meet patients' needs in the long run. Such therapy needs to be novel, intense and based on functional activities.

Home technology has been welcomed with enthusiasm by both end-users and therapists who feel it might augment hands-on conventional physiotherapy and increase the practice intensity. It might also motivate end-users to engage in therapy and give them more independence and control in their rehabilitation programs. Technology can provide variety and feedback which are key principles of motor leaning after stroke [259]. The Wii video games console is currently being used in homes by some patients and is also being recommended by therapists for upper limb exercises after stroke. The Wii system is, however, limited by the lack of physical assistance to upper

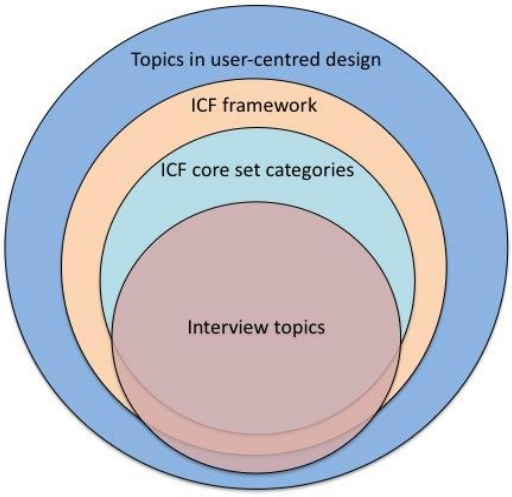
limb movement, hence individuals who have significant weakness in their arms are unable to use this technology. It does not provide feedback specific to stroke survivors and it could exacerbate their conditions due to the unrestrained movement it allows.

The perception of end-users and therapists is that any technology developed to aid recovery needs to be simple, easy to use and safe. End-users preferred to use the arm rehabilitation device on their own in their homes, rather than using it with others in a centre. One drawback that has been highlighted by the end-users and therapists is how to monitor performance and movement patterns while using the device in the home setting.

3.3.2 Matching of interview concepts and ICF Core Set categories

The matching of the concept stage interview concepts with the ICF Core Set categories showed that most concepts were covered within these ICF Core Set categories. Some interview concepts related to the personal factors domain in ICF, but as yet there are no “personal factor” categories described yet in the Comprehensive ICF Core Set. The overlap of topics can be represented in a schematic diagram (Figure 16).

Figure 16. Concepts in the user-centred design process in the concept stage of device development



This implies that researchers can use the ICF framework/Core Set for stroke as a tool to understand the critical problems/needs of individuals with stroke. This will help in the development of an inclusive technology that meets these needs and caters to the target population. Some examples from each ICF domain are discussed below.

Some “body function” factors, such as the side affected by the stroke can be crucial in informing the design of the system. We considered this aspect in designing a home-based exercise technology that can be adjusted for right or left upper limb use to make it efficient in terms of usability and acceptability to the user. Also, visual inattention or neglect are common in left-sided stroke and language problems are common in right-sided stroke. Recognising the types of visual inattention and field defects these users could have, we designed an adjustable monitor screen to suit individuals with specific deficits. Keeping the display and user login instructions simple was most important to enable those with language and cognition impairments to use the technology. Stroke survivors can experience pain in the affected upper limb and assessing the impact this has on technology usage and vice-versa, enabled us to advise participants on the device usage time and develop tailor-made or personalised therapy within the range of pain-free movements.

Understanding the ICF “activity and participation” factors such as functional daily activities, will help us design games or tasks that replicate those desired activities and make the technology more meaningful and functionally relevant to the user. The ICF “environmental factors”, such as home environment, physical space available for device, appearance of device, carer support, perceptions and opinions of people (including professionals) around the individual has a major influence on the individual’s progress and usage of technology. We have ensured these needs are catered to with the hCAAR device. This is likely to increase the acceptability and usage of the device.

Finally, the ICF “personal factors” are arguably the most important factors that can determine the success of any technology. These include the individual’s perception of the technology, self-efficacy and belief in the

therapy, computer skills, motivation, interest, experience and liking for the technology. These factors could determine how much the technology will appeal to or motivate the individual and will determine the extent of engagement of the individual. We aim to capture these aspects of device utility in the feasibility clinical study.

3.3.3 The hCAAR device

The hCAAR device is a simple low-cost end-effector planar robotic that helps to improve the range of movement at the shoulder and elbow with the hand moving in a single horizontal plane. The evidence base in the current literature is mainly around the complex exoskeleton (such as ARMin) and complex end-effector devices (such as MIT-Manus and MIME) with a paucity of clinical studies on simple low-cost end-effector robotic devices that can assist arm exercises. hCAAR has the potential to fill this void in the current literature.

hCAAR is potentially deployable in the home setting and could be used by individuals with stroke in a minimally-supervised environment. The joystick handle is adjustable, and so is the computer screen to accommodate the different heights of users and their vision problems post-stroke. The device is purpose-built for one side use to allow the user the safety of being able to operate the emergency switch easily with the unaffected upper limb. The trolley has been designed in such a way that all hardware fits in a compact space and the footprint of the device is as small as possible; the device has a pleasing external look. The final dimensions of the device are approximately 90cm by 60cm, which are similar to the dimensions of some common household equipment, such as fridges and washing machines. Panels cover most of the hardware and give it a look that is acceptable for all users to have the device in their homes.

The inclusive design methodologies of the hCAAR ensure that a wide spectrum of individuals will be able to set-up and use the system. Individuals with impairments such as language deficits, speech problems, visual field defects or inattention, mild to moderate pain in the affected upper limb, varying degrees of upper limb weakness and stiffness and mild cognitive problems should be able to independently use the device. The nine

participants who were involved in the development process had a wide range of the above deficits and they were all able to set-up and use the device independently in the research laboratory.

The hCAAR device provides reach and retrieve movements to the affected upper limb using the joystick. The predominant movements replicated by the games are shoulder flexion and extension, shoulder rotation, and elbow flexion and extension, which all are functionally relevant movements for daily activities. Reaching is the predominant movement required in most daily activities as reflected in the Barthel index where reaching is required in more than 50% of tasks in the outcome measure [260]. Reaching involves a complex interplay of shoulder flexion and elbow extension and is influenced by the residual power, stiffness and range of motion in these two major joints. The therapists were satisfied with these movements being replicated by the prototype device even though the movements were restricted to a single plane. There was concern that the computer games might not appeal to everyone equally, or that they would become less engaging in the long run. The computer games were designed to incorporate different levels that progressively become harder as the performance improves. The device has the facility to personalise the exercise program based on extent of weakness, range of movement and amount of stiffness (spasticity) in the affected upper limb.

The assistance factor of the hCAAR device is an important feature that enables individuals to complete therapy tasks. The device also adjusts the assistance provided to upper limb movement based on individual performance so that the patient is encouraged to use more of their own effort to perform the movements, rather than depending on the assistance of the device. As the upper limb function and performance improves, the assistance drops accordingly to facilitate increased participation of the individual in the task. This matches the general approach adopted by therapists in conventional hands-on physiotherapy where the individual is initially helped by therapist to perform movement but as the individual improves, they are promoted to perform tasks independently.

The assistance feature differentiates the device from other technology-based therapy devices such as the Wii. The assistance level of hCAAR can be adjusted to suit the residual power in the user's upper limb. The assistance also auto-adjusts based on the user's performance so that there is an element of challenge for the user while playing the games. This approach has been used to good effect in other robots such as MIT-Manus, MIME and GENTLE [52, 60, 80, 111]. These robotic systems can be operated in three different modes: active assist (assists user's active movement), active non-assist (no assistance to user's active movement) and passive (all movement done by the robot) [261]. In robot studies, the active-assist therapy has been shown to be superior to the other modes [80, 86]. hCAAR can operate only in two modes: active assist and active non-assist. It cannot operate in passive mode as the actuators are not as powerful as the other lab-based robotic devices. This is the compromise that had to be made to keep the device simple and suitable for home installation and use.

The hCAAR games generate uniplanar reach and retrieve movements and lack the three-dimensional aspects of functional tasks. The ADLER, RUPERT and ARMin devices are robotic devices that promote the upper limb to do real world tasks [70, 92, 262]. The ARMin robot can provide therapy in three modes: mobilisation (passive mode), games (active-assist) and training for ADL (active or active-assist) [70]. However these devices are too complex to be used in home settings and use of the device needs assistance from a helper or therapist. The levels of games can be individualised based on the available range of motion and ability of the user, similar to the approach used by other robots [74, 91].

hCAAR incorporates the concept of bilateral therapy as the unaffected upper limb operates a switch to complete tasks in game play. The task of operating the switch is however a minor task and its contribution to overall motor recovery is debatable. The current literature is still inconclusive as to whether bilateral therapy is superior to unilateral therapy [113]. The involvement of the other upper limb predominantly for symmetric movements is promoted by the robot devices such as MIME, BdF and BFIAMT [60, 81, 83]. However, the criticism of this approach has been that most daily

activities are asymmetrical in nature. Therefore hCAAR aims to provide asymmetrical bilateral therapy but whether operating a switch is adequate contribution to motor tasks is debatable.

3.4 Limitations

There are some limitations to this user-centred design study. Firstly, a relatively small sample of end-users and healthcare professionals were included for the interviews. There is, however, no established literature in user-centred design on what the minimum sample size should be involved in such a process. The aim in this sampling technique was to cover the main impacts stroke has on the individual and additional information would be obtained from the healthcare professionals.

Secondly, regarding the ICF Core Set linkage, the meaningful concepts are ideally linked to the most precise third-level ICF categories as per the ICF linking rules [257], but we have linked them only to the second-level categories available in the Comprehensive ICF Core Set. The aim of this experiment was only to explore whether ICF provides a useful template for the user-feedback process and not to test the accuracy of the linking process. Hence the linking to the available categories is justified.

Finally, the hCAAR device has its limitations. The device has the potential to provide exercises to only the proximal muscles of the upper limb. Current literature suggests that benefits from exercises to proximal muscles do not extend to distal muscles in the chronic stage of recovery. However any additional attachment/ module to carry out distal movement for the upper limb is likely to make the device bigger and more complex, defeating the concept of keeping it simple, compact and usable in home setting.

3.5 Conclusions

A user-centred design development process involving stroke survivors with upper limb weakness and healthcare professionals has resulted in the development of hCAAR. The Comprehensive ICF Core Set provides a useful template to structure content of user-feedback methods in the device development process.

Chapter 4: Methodology of the hCAAR feasibility study

The aims of the home-based Computer Assisted Arm Rehabilitation (hCAAR) feasibility study were to a) To investigate whether the hCAAR device could be deployed and used independently in a home setting by individuals with upper limb weakness after stroke b) To investigate the impact of hCAAR on affected upper limb movement and usage using clinical and kinematic outcome measures and c) To capture feedback from participants and therapists on device deployment and usage during the study (the testing stage of the device development life cycle).

The aims of this chapter are to describe the study design including the outcome measurements, statistical analysis and research governance. The results of the study will be described in Chapters 5 and 6.

4.1 Study design

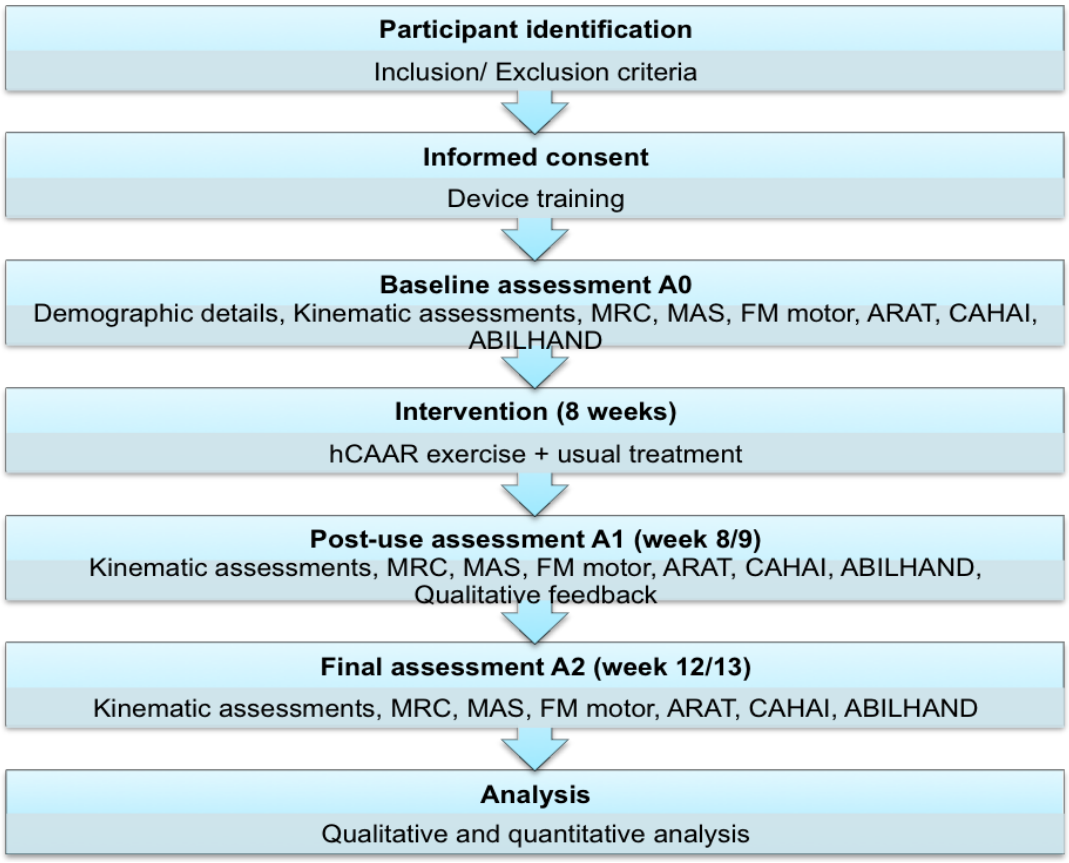
This was a pilot open label cohort phase 2 clinical study as defined by the Medical Research Council (MRC) Guidelines on Complex Interventions [263] for a new restorative rehabilitation robotic device, hCAAR. The study involved 8 weeks of home upper limb exercise using hCAAR for stroke survivors with residual upper limb weakness. This was not a randomised control study, all consented participants received the hCAAR system to undertake home exercises in addition to their usual treatments. The usual treatment varied between individual participants and involved treatments such as NHS community physiotherapy, private physiotherapy or self-exercise.

The study plan is as shown in Figure 17.

4.1.1 Sample population

Stroke survivors who were admitted to stroke rehabilitation inpatient services or were attending outpatient clinics within the Leeds Teaching Hospital NHS Trust and the Leeds Primary Care Trust were screened for suitability for the study.

Figure 17. Feasibility study flow-diagram



4.1.2 Inclusion and exclusion criteria

The inclusion criteria for the feasibility study were:

- Age more than 18 years.
- Diagnosis of ischaemic or haemorrhagic stroke at least 1 month prior to inclusion and either discharged from acute hospital or being planned for discharge to community care.
- Residual weakness of an upper limb.
- Some voluntary upper limb movement to allow the participant to perform the hCAAR tasks. Participant in a sitting position must be able to actively move the affected hand, rested on table, by at least 15cm.

The exclusion criteria were:

- Significant pain in the affected upper limb.
- Significant limitation in the range of motion of the affected upper limb.
- Cognitive impairment affecting capacity to consent.
- Sensory impairment affecting ability to use the hCAAR system.
- Significant medical co-morbidities such as uncontrolled epilepsy.

4.1.3 Recruitment

The clinicians delivering stroke rehabilitation within the Leeds Teaching Hospital NHS Trust and the Leeds Primary Care Trust assessed participants' suitability and gave them information on the study. These clinicians also passed on details of potential participants to the researchers. The clinicians within the research team explained the study further to interested potential participants, gave them the study information sheet and consent form and allowed a cooling off period of at least 24 hours for them to make their decision on participation.

4.1.4 Consent

Potential participants interested in participating in the study were given a user meeting appointment at the Charterhouse Rehabilitation Technologies (CRT) laboratory at the University of Leeds. This facility is on the ground floor with full access for wheelchair users and easy access to the disabled toilet facilities. In the meeting, potential participants had the opportunity to see the device and ask the researchers further questions. If they were willing to proceed, written consent was recorded. If the participant was able to provide fully informed consent but was unable to sign or otherwise mark the consent form, provision for completion of the consent form by a family member was made. Every participant had the right to decline to take part in the study at any time without giving reasons and without prejudicing any further treatment.

4.1.5 Sample size

The feasibility study planned to recruit 20 participants (stroke survivors with residual upper limb weakness). A sample of this size was deemed sufficient to indicate the practical aspects of using the device and indicate the potential for the benefits of the device. This sample size is sufficient to indicate the trends in change in upper limb movement and function, if any, from use of the hCAAR. The study will also provide data to develop methods for a larger- scale phase 3 randomised control study in the future.

4.1.6 Intervention

Five hCAAR devices were available for use in the study. Up to four devices could be used at a given time during the study period. The device was set-up in the participant's home by the research team. Participants were asked to use the device as much as they wanted during the 8-week period. The general recommendation was for at least half an hour of exercise every day for at least five days every week. This was based on robotic therapy time recommended in other robot studies [118, 261]. The participant's usual medical and rehabilitation treatment continued as part of their routine care and was not altered due to participation in the study.

4.1.7 Device installation/ deinstallation

Within the first week after the baseline assessment, members of the research team visited the participant's home at a mutually convenient time to set-up hCAAR. The researchers explained the process of using the device with the participant (and family member or carer if available). A device user instruction booklet with the contact telephone numbers of the researchers was given to the participant. Participants could contact the research team at any time during the study period if they were concerned about any aspect of using the device. The researcher MS contacted the participant by telephone once every two weeks to check the participant's progress and to discuss any queries the participant might have. At the end of week 8, members of the research team visited the participant's home to retrieve the system.

4.2 Outcomes

The outcome measures selected for the feasibility study were based on the systematic approach proposed in Chapter 2. The outcome measures captured the different domains of the ICF framework (a) Body function measures: Optical tracking device kinematic measurements during standard reaching tasks, MRC, MAS and FM-UE (b) Activity and Participation measures: ARAT, CAHAI and ABILHAND and (c) Contextual factors: Participant, family, carer and therapist impressions of the device during and after the 8-week home use of the device.

4.2.1 Measuring quality of voluntary upper limb movements

Measurement of voluntary upper limb movement using kinematic analysis was undertaken while performing a standardised reaching task similar to that reported in the current literature [264]. A suite of Optotrak and Optokat systems installed in the CRT laboratory was used to record variables of upper limb movement characteristics such as movement time, path length and jerk.

4.2.1.1 Optotrak system

The Optotrak (Certus) system comprises of a position sensor/camera mounted on the roof and a system control unit connected to a computer. The ceiling-mounted position sensor/camera captures signals from the markers/diodes (Figure 18). These signals are sent to a system control unit that calculates the position of marker as 3 coordinates (x,y and z) and sends the 3D raw data of marker position to the host computer for further analysis.

4.2.1.2 Optokat

Optokat provides a method of standardising the performance task so that variables can be compared within assessments for the same participant and between all participants. It comprises a standard moveable frame with a chair and a start and end point for the tasks (Figure 19). The four corners of the frame, seat position, start and end point are attached with infrared radio emitting diodes. The participant sat in a standard position in front of the touch screen monitor so that they could reach towards the stimuli along a para-sagittal plane (this reduced the number of joint-level degrees of freedom required during the movement to two: one at the shoulder and one at the elbow). Markers were attached to the upper limb either as a single marker (shoulder and elbow) or a group of markers known as rigid-body markers (wrist, mid-arm and trunk) (Figure 20). Rigid-body markers enables the system to detect a combination of three markers from the rigid body (Cartesian coordinate system) to detect the three-dimensional movement of the limb segment.

Figure 18. The position sensor of the Optotrak system mounted on the ceiling picks up the marker signals (*research team member in picture*)

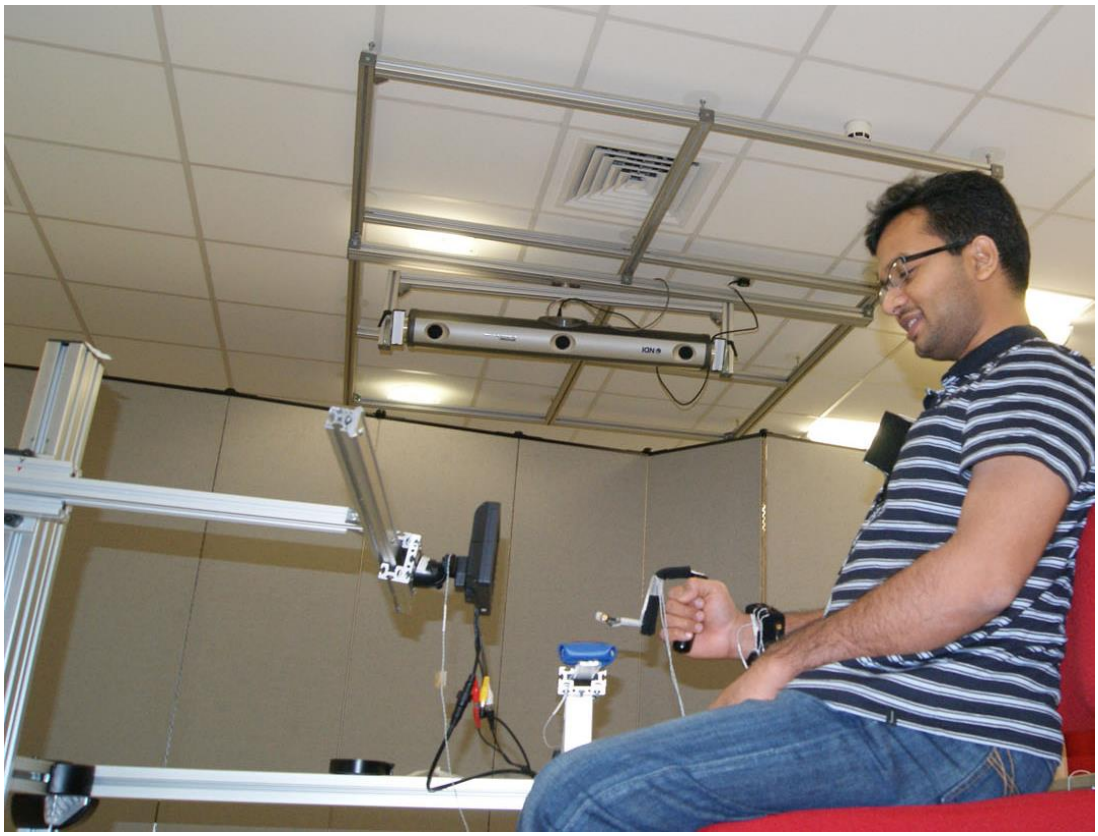


Figure 19. The frame, seat, start position and target of the Optokat system

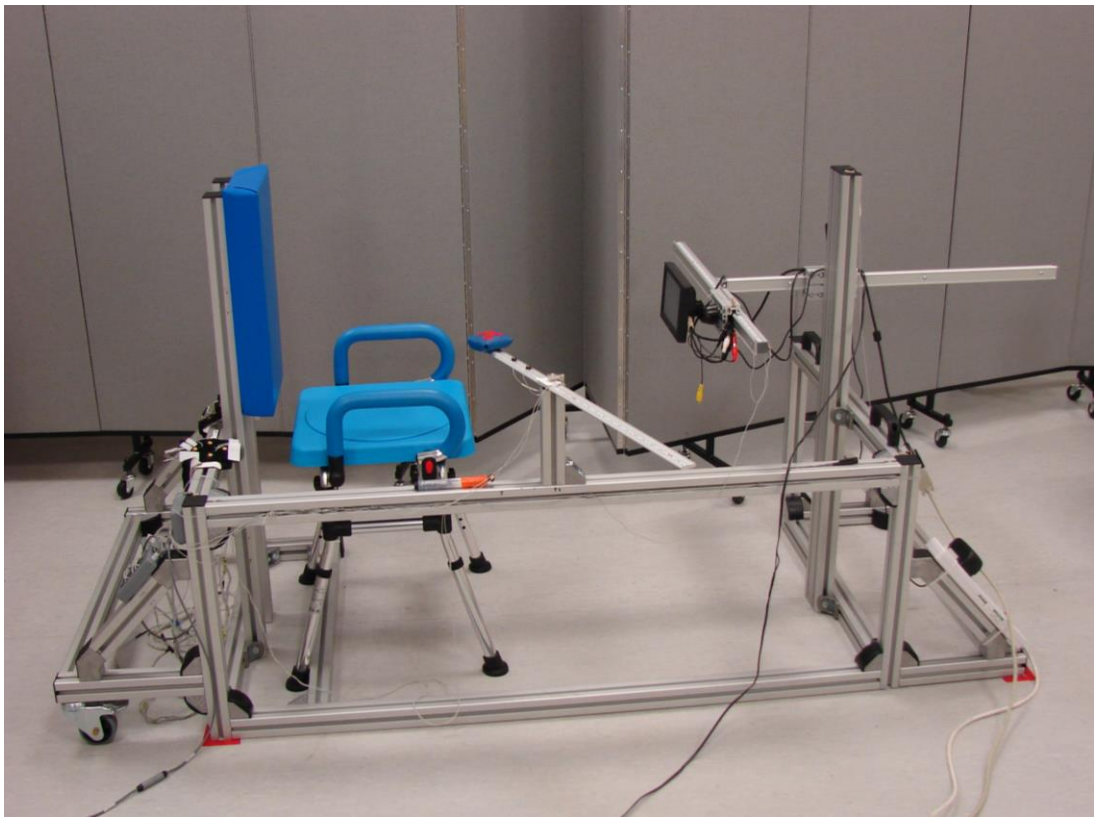
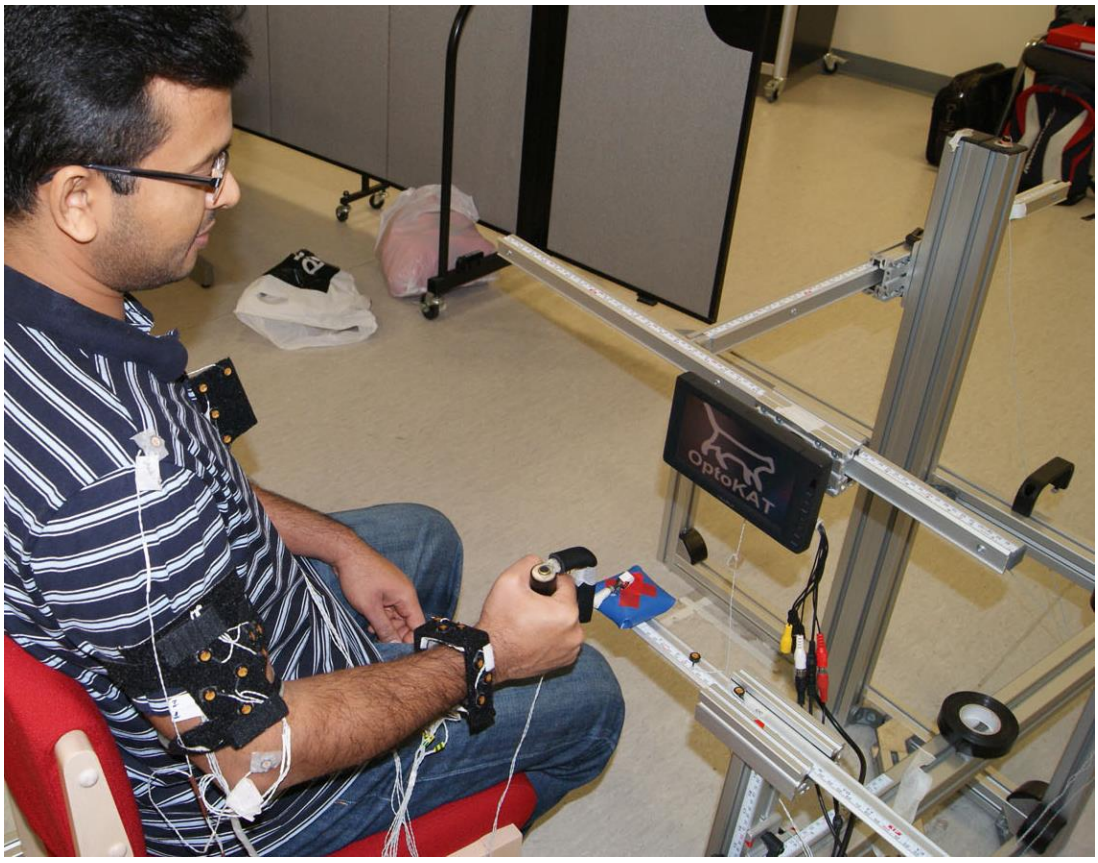


Figure 20. Single markers for shoulder, elbow and stylus; rigid-body marker for mid-arm and wrist (*research team member in picture*)

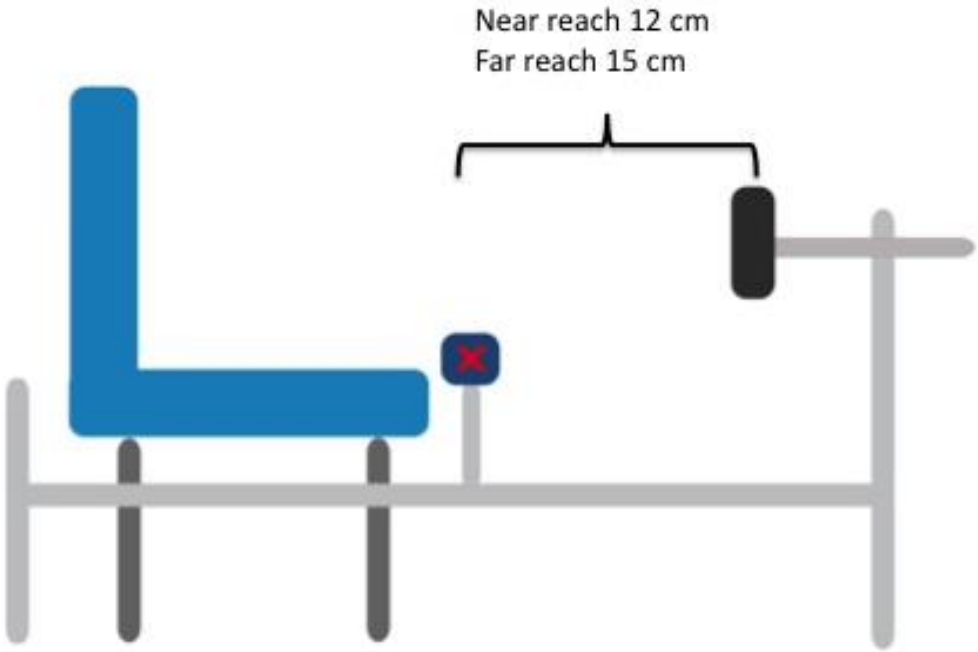


4.2.1.3 Standardised tasks

The study began with the participant holding a handle with the stylus positioned at the start point (Figure 20). In start position, the elbow angle was at approximately 90 degrees, forearm in a midprone/neutral position and the wrist in a neutral position. An auditory signal (which corresponds to the initialisation of data collection) indicated that the participant should start the movement. The participant was instructed to aim towards the switch picture on the screen quickly and accurately, with the goal being to press the switch on the screen with the stylus. On touching the target, there was a bulb image displayed and an auditory signal indicating the end of the task.

The first task was a calibration task where the participant had to hold the stylus at the start position for 10 seconds. The system recorded the reference position of the markers. The second task was reaching a near reach target 120mm away from the start position (Figure 21). Five trials were performed with the near reach target and the software checked that all the required variables had been recorded. The third task was a far reach task with the target moved 30mm further away so that the target distance was 150mm away from the start position. Five repeated trials at this target were performed and the software checked that the data had been converted to the required variables.

Figure 21. Near reach and far reach tasks



4.2.1.4 Extracting kinematic variables

Data were collected for 4000ms at 100Hz, then stored for subsequent offline analysis and filtered using a dual-pass Butterworth second order filter with a cut-off frequency of 16Hz (equivalent to a fourth order zero phase lag filter of 10Hz). Following this operation, the tangential speeds of the infrared

radio emitting diodes were computed and the onset and offset of the movement was estimated using a standard algorithm (the threshold for movement onset and offset was 50mm/s). The software generated kinematic data in terms of (upper limb reaching) movement time, path length and normalised jerk. The definitions for these variables are as follows:

4.2.1.4.1 Movement time (MT)

This is the time taken to complete the task of reaching from the start position to the target on the screen. It is expressed in seconds (sec) [181]. It reflects the overall speed of a movement, as a faster movement would result in shorter movement time [81].

4.2.1.4.2 Pathlength (PL)

This is the distance taken to reach the target on the screen from the start position. It is expressed in millimetres (mm). It gives an indication of the path taken for the near reach and far reach tasks that had standard distances (between start and end points) maintained across the assessments. A reduction of path length would indicate a straighter path taken for completion of the task and hence improvement.

4.2.1.4.3 Normalised jerk (NJ)

Jerk is the rate of change of acceleration during movement and is a measure of the smoothness and efficiency of the movement. A reduction in the jerk value indicates smoother and more efficient reaching movement [144, 265]. As jerk varies with movement time and distance travelled during the movement, normalising the quantity in time and distance gives the NJ value. NJ is a dimensionless number that allows movements of different durations and lengths to be compared [266].

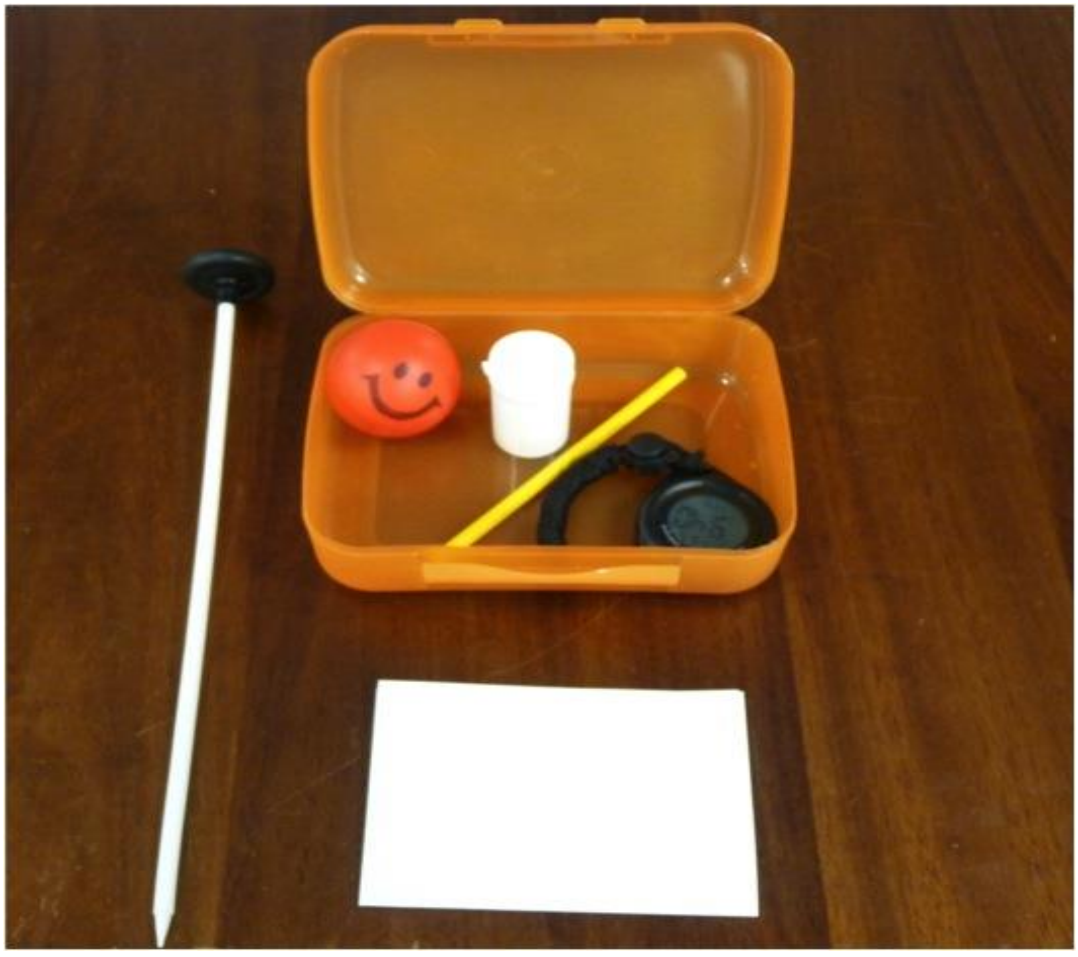
4.2.2 Measuring clinical/ functional outcomes

The clinical outcome measures used were FM-UE, ARAT, MRC, MAS, CAHAI and ABILHAND.

4.2.2.1 Fugl Meyer motor - Upper limb section (FM-UE)

The FM-UE was used to measure the movement ability of the affected upper limb. It is a validated upper limb measure with score ranging from 0 – 66 points [137]. Each of the 33 items are scored on a 3-point ordinal scale 0=cannot perform, 1=performs partially, 2=performs fully. The kit used for scoring comprised a tendon reflex hammer, a rubber ball, a folded A4 size paper, a cylinder, a pencil and a stopwatch (Figure 22). The participant was asked to undertake a series of motor tasks such as lifting the upper limb up, gripping the cylinder, etc. Each movement was scored on the 3-point scale depending on participant's ability. This test took approximately 20 minutes to complete.

Figure 22. FM-UE kit



4.2.2.2 Action Research Arm Test (ARAT)

The ARAT was used to measure grasp, grip, pinch and gross movements. It is a validated upper limb measure with 19 items scored on a 4-point scale: 0=no movement to 3=normal movement. The kit used comprised a standard ARAT table 92cm x 45cm x 83cm high, with a shelf of 93cm x 10cm, positioned 37cm above the main surface of the table; a chair (46cm seat height) with a back rest and no arm rests; wooden blocks of 2.5, 5, 7.5 and 10cm^3; a cricket ball 7.5cm in diameter; two alloy tubes: one 2.25cm in diameter x 11.5cm long, the second one 1.0cm in diameter x 16cm long; a washer; two plastic glasses; a marble 1.5cm in diameter; a ball bearing 6mm in diameter; and a stopwatch (Figure 23). This test took approximately 10 minutes to complete.

Figure 23. ARAT kit

4.2.2.3 Modified Ashworth Scale (MAS)

The MAS was used to measure spasticity (muscle stiffness) in the paretic arm. Spasticity in the shoulder abductors/ adductors/ flexors/ extensors, elbow flexors/ extensors, wrist flexors/ extensors and finger flexors/extensors in particular was recorded. The 6-point ordinal scale 0-4 was scored as: 0= No increase in muscle tone, 1= Slight increase in tone with minimal resistance at end of range, 1+= Slight increase in tone with minimal resistance through range, 2= More marked increase in tone through the range and passive movement easy, 3= Considerable increase in tone and passive movement difficult, 4= Affected part rigid [167, 267]. The MAS scores of all muscles were summated to get a total MAS score in order to compare scores before and after intervention. This test took approximately 5 minutes to complete.

4.2.2.4 Medical Research Council (MRC) scale

The MRC scale was used to record muscle power in the different muscle groups of the paretic arm. The 0-5 ordinal measure of muscle power was scored as: 0= No movement, 1= Palpable contraction but no visible movement, 2= Movement but only with gravity eliminated, 3= Movement against gravity, 4= Movement against resistance but weaker than normal, 5= Normal power [268]. The MRC score of shoulder flexion/ extension/abduction, elbow flexion/ flexion, pronation/ supination, wrist flexion/ extension and finger flexion was recorded. The scores were added to give a total MRC scale that was used to compare scores before and after intervention. This method of adding scores to give a total motor power scale is described in the literature [55].

4.2.2.5 The Chedoke Arm and Hand Activity Inventory (CAHAI)

The CAHAI version 13.0 was used to capture functional ability in daily activities. It has 13 real life functional tasks (Table 4) scored on a 7-point scale to give a score ranging between 13 and 91 [147]. The criteria used for scoring: 1 = Total assist (weak UL <25% of effort), 2 = Maximum assist (weak UL =25-49% of effort), 3 = Moderate assist (weak UL =50-74% of

effort), 4 = Minimal assist (weak UL >75% effort), 5 = Supervision, 6 = Modified independence and 7 = Complete independence.

The equipment comprised of height adjustable table, chair/wheelchair without armrests, dycem, 200g jar of coffee, push-button telephone, 12 inch/ 30cm ruler, A4 size paper, pencil, 2.3L plastic pitcher with lid filled with 1600 ml water, 250 ml plastic cup, wash cloth, wash basin (24.5cm in diameter, height 8cm), pull-on vest with five buttons (one side male & one side female), buttons (1.5cm. in diameter, 7cm apart), bath towel (65cm x 100cm), 75ml toothpaste with screw lid, toothbrush, dinner plate (heavy plastic, 25cm in diameter), medium resistance putty, knife and fork, 27inch/67cm metal zipper in polar fleece poncho, eyeglasses, handkerchief, plastic 38L container (50 x 37 x 27cm), plastic grocery bag holding 4lb/2kg weight (Figure 24). This test took approximately 20 minutes to complete.

Figure 24. CAHAI kit

Item 13 of the measure involved carrying a carry bag with 2kg weight up stairs. This was performed on staircase adjacent to the CRT laboratory in University of Leeds. All participants were risk-assessed prior to performing this task. This item was not performed for participants who were not using the stairs independently at home.

4.2.2.6 ABILHAND

The ABILHAND was used to capture participant perception of performance in actual daily life activities. It is a self-reported questionnaire with 23 items (Table 4) that relate to daily life activities. The participant is asked to estimate the difficulty in performing each activity using a 4-point scale : not applicable, 0= impossible, 1= any difficulty or 2= easy [151]. The scale has also been validated based on the Rasch model and gives an interval measure of manual ability. The responses were entered in to an online computer program (http://www.rehab-scales.org/abilhand-rasch-analysis-chronic stroke.html) that gave the score in logits. This test took approximately 5 minutes to complete.

4.2.2.7 Qualitative feedback

MS gathered qualitative feedback on hCAAR from all participants (in the study) and a community physiotherapist involved with these participants using semi-structured interviews. The feedback from participants was gathered at the post-use assessment stage. A separate appointment was arranged with the community physiotherapist to gather feedback on the device. The details of topics covered in these interviews and responses are described in Chapter Six.

4.2.2.8 Device data

The hCAAR device recorded the total amount of usage at home. It recorded the time spent in the assessment exercise and the duration of each game played in each session. The data were retrieved from the hCAAR device at the end of the 8 weeks of home use.

4.2.3 Assessment schedule

All baseline and follow-up assessments were undertaken in the CRT laboratory in Worsley Building, University of Leeds.

4.2.3.1 Baseline assessment (A0)

Baseline assessments were undertaken within one week of the home installation of the device (week 0). Demographic data recorded included age, sex, date and type of stroke, affected side and clinical signs and symptoms of stroke, past medical history and medications. Researchers MS and Justin Gallagher (JG) carried out the kinematic assessment. MS assessed the clinical outcome measures. The participant was shown how to use the device and allowed to independently set-up and use the device. The user instructions manual was given to the participant for reference. A complete baseline assessment typically lasted around 2.5 hours. This included comfort breaks and refreshments.

4.2.3.2 Post-use assessment (A1)

Assessment A1 was carried out just after completion of the 8-week usage period (week 8/9). MS captured the participant and carer impressions of the device in semi-structured interviews. MS and JG did the kinematic assessments. Sophie Makower (SM) (research physiotherapist) assessed the clinical outcome scores. On two occasions, when SM was unable to attend due to sickness or leave, MS did the clinical assessments. A complete A1 assessment took on average took 2.5 hrs to complete. This included comfort breaks and refreshments.

4.2.3.3 Final follow-up assessment (A2)

Assessment A2 was undertaken four weeks after assessment A1 (week 12/13). This corresponded to 4 weeks after stopping use of the device. MS and JG did the kinematic assessment. SM assessed the clinical outcome scores. MS assessed the clinical outcomes on one occasion when SM was unable to attend the appointment due to leave. A2 assessments took on average took 2 hrs each to complete. This included comfort breaks and refreshments.

4.2.4 Assessor training and blinding

SM is a neurophysiotherapist with extensive experience of working with stroke patients and outcome measures related to upper limb function after stroke. SM also has experience of using outcomes in research studies in stroke rehabilitation. SM and MS were involved in a critically appraisal of all the available outcomes used in robot studies (Chapter 2) [235]. For the hCAAR feasibility study, the research team selected outcomes based on this systematic review. SM and MS practised the selected outcome measures on each other and with healthy volunteers (research colleagues) for at least 6 months prior to start of the study to ensure consistency of scoring between them.

MS assessed the clinical scores in assessment A0. SM was not aware of the baseline assessment scores while assessing participants in A1 and A2. If doubts on scoring arose during testing, they discussed those items between themselves after completion of assessment (without disclosing participants number) and reached a consensus on the score to be given. SM assessed the clinical outcomes while MS conducted the user feedback interviews in the same appointment at A1. Such a blinding of assessments was planned to minimise the assessor bias of knowing the pre-use scores and being influenced by a participant's impression of the intervention.

4.3 Drop-outs

If a participant had consented to the study but could not eventually proceed to use the device, for any reason such as inadequate power in the upper limb to use the device, lack of space at home to install the device, medical problems, such participants were recorded as drop-outs from the study. Every participant had the right to withdraw at any stage during the study. If a participant started using the hCAAR device and subsequently developed any medical problems or personal problems, either the participant or the research team could decide to withdraw hCAAR use temporarily on clinical grounds. If any participant failed to attend an appointment in the laboratory, a subsequent meeting was arranged. If they failed to attend the

subsequent appointment as well, it was counted as “DNA (*did not attend*)” and assessment data was recorded as “missing” or “not available”.

4.4 Analysis

4.4.1 hCAAR usage

Total usage time for each participant time was recorded in terms of time spent on the warm-up exercise, assessment exercise, and the time spent in playing games.

4.4.2 Kinematic variables

The output of the Optotrak software was saved as an Excel file that was extracted to a master Excel file. The software provided data on movement time, peak speed, time to peak speed, path length, path length ratio, peak elbow angle and peak trunk angle. The best three trials for each task (near reach or far reach) were selected based on the shortest movement time (and selected by path length if the movement time was the same for any two trials). The selection of the three best trials enabled the minimising of the bias of variation in the individual initiating the movement on the start command and dealing with distractions during the command. The mean and median of these three trials were calculated to give the average variable value for that assessment. Percentage changes for A1-A0, A2-A0 and A2-A1 were calculated. The minimal clinically important difference (MCID) values of the kinematic variables are not yet known in the current literature.

4.4.3 Clinical/ Functional outcome measures

FM-UE, ARAT, total MAS, total MRC, CAHAI and ABILHAND scores were calculated adding item values using Microsoft Excel. A1-A0, A2-A0 and A2-A1 changes were calculated. To determine clinical significance, MCID values of outcome measures were used if already described in the literature (Table 9). MCID is defined as the smallest difference in score in the domain of interest that patients perceive as beneficial or that would be clinically meaningful. For the ABILHAND score, whose MCID has not yet been validated, this was arbitrarily set as 10% as suggested in the literature [269, 270].

Table 9. Clinically significant change values for clinical outcome measures

Outcome score	Total maximum score	MCID value	Reference
FM-UE	66	7	[128, 164]
ARAT	57	6	[164, 182]
CAHAI	91	7	[209]
ABILHAND	46	5	(10% rule)
Total MAS	40	N/A	
Total MRC	50	N/A	

4.4.4 Statistical analysis

All the statistical analyses were carried out in Microsoft Excel and IBM SPSS version 22 software packages. The calculations of mean, median, standar deviation (SD) and inter-quartile range (IQR) and drawing the chart figures were done in Microsoft Excel. The median and IQR were the preferred measurements for average values to analyse the results in this study. The mean and SD values were used to compare the results in this study with other studies in the literature that have reported only mean average values. Non-parametric tests for calculating data significance levels were done using SPSS. A non-parametric Friedman's test was used to detect the significance of the three related samples A0, A1 and A2. If this test showed statistical significance, a Wilcoxon post-hoc analysis was used to test for significance between two related samples such as A0A1, A0A2 or A1A2. The significance levels for these tests were set at $p = 0.05$. SPSS was also used to do multiple regression analyses to test the relationships between independent variables such as baseline score, age, time since stroke and device usage; and the dependent variable, change in outcome measure.

4.5 Research governance

4.5.1 Ethical approval

The project (including feasibility study) had approval from the Research Ethics Committee (Ref 09/H1313/25) and the Research and Development (R&D) departments of Leeds Teaching Hospitals NHS Trust (LTHT) and Leeds Community Healthcare (NP/0058). The Medicines and Healthcare Products Regulatory Agency (MHRA) approved the use of the device in the feasibility study (Ref CI/2011/0026).

4.5.2 Safety reporting

The feasibility study adhered to the guidance provided by the Department of Health's Research Governance Framework for Health and Social Care (Second edition, 2005).

An adverse event was defined as any untoward medical occurrence in a participant which does not necessarily have a causal relationship with the device and can include any unintentional, unfavourable clinical sign or symptom and any new illness or disease or the deterioration of existing disease or illness. Potential hCAAR related adverse events were identified as:

- Pain in the affected/unaffected upper limb while using the joystick.
- Fall from chair while using the hCAAR system.
- Worsening of upper limb impairment (muscle stiffness or loss of power).
- Fatigue, tiredness.

A serious adverse event was defined as "any untoward medical occurrence or effect that results in death or is life-threatening or requires inpatient hospitalisation or prolongation of existing hospitalisation or results in persistent or significant disability or incapacity and may require medical or surgical intervention to prevent one of the outcomes listed above".

Any medical problems encountered during the project were addressed by physicians MS and BB who have experience in dealing with stroke patients in a rehabilitation settings. An analysis of the possibility of recurrence of such an event was made and the decision on the safety of the patient to continue

in the study was made. MS was responsible for the maintenance of log of medical adverse events. The principal investigator (BB) had the coordinating responsibility for reporting serious adverse event to the MHRA, REC and the R&D departments.

A device-related event was defined as technical problems with the device or events related to usage of the device needing intervention by the research team. The technical complications related to the device were documented and addressed by engineers in the research team JG and ML. MS and JG were responsible for maintenance of the log of device-related events.

4.5.3 Data handling and storage

Informed consent from participants was sought to record personal details including name, date of birth, postcode, address and telephone numbers to facilitate follow-up by the research team. All data collection forms were coded with a study number that included their initials as participant identifiers. In addition, all participants (a) consented for access to their medical records by the GMC registered medical researchers (BB, MS) or from the regulatory authorities, where it was relevant to study participation; (b) consented for the data collected in the study to be used to evaluate safety and develop new research. The original consent form was retained in the Investigator Site File, a copy of the form was given to the patient. Any new information when became available that was relevant to the safety or well-being of the participant, was notified to the existing participants by the medical researchers (BB, MS) and detailed in an updated patient information booklet and consent documentation.

At the end of the study, all de-identified research data was archived on a secure University server, and password protected with access by the principal investigator. Following authorisation from the Sponsor, arrangements for confidential destruction will be made in the future. All information collected during the course of the project has been kept strictly confidential. Information is held securely on paper and electronically at the CRT lab and the Academic Department of Rehabilitation Medicine (ADRM) and complies with the 1998 Data Protection Act. The documents contained, or which have been contained, in the study master file will be retained for 5

years from the conclusion of the project as per the Medicines for Human Use (Clinical Studies) Amendment Regulations 2006 - sections 18 and 28 [271].

4.5.4 Quality control/ assurance

A project management group comprising research team members (BB, MS, ML, JG, RH, SM, RJOC) oversaw the running of the whole project. The project was conducted to MRC Good Clinical Practice Consolidated Standards of Reporting Studies (CONSORT), and the Mental Capacity Act 2007 in England and Wales and Adults with Incapacity Act 2000 in Scotland. The University/NHS R&D departments had access to all the project documents stored in the ADRM through request to researcher BB. Sponsor representatives or regulatory authorities had to request permission from the Chief Investigator BB for monitoring of research data.

Chapter 5: Results of the hCAAR feasibility study

This chapter aims to a) provide descriptive characteristics of the participants b) analyse aspects of the device installation and usage in the study c) summarise the results of kinematic and clinical outcomes d) perform grouping of participants to explore trends in the changes observed and e) look at the influence of the predictive variables on the outcomes.

5.1 Descriptions of the participants and their device usage

Nineteen participants were recruited to the study. After recruitment, two participants could not use the device in their homes and dropped out of the study. Seventeen participants completed 8 weeks of hCAAR home use.

5.1.1 Drop-outs

5.1.1.1 Participant ID number 12

This participant liked the device and was able to use device independently in the research laboratory. All initial assessments (A1) were completed satisfactorily. On the day of the deployment, the participant had reassessed his home situation (in view of some relatives living in his house for holiday) and felt there was inadequate space in his house to accommodate the device for the period of the study. He requested postponing his participation by few months. This participant was considered as a drop-out from this study as the project had been completed by then.

5.1.1.2 Participant ID number 15

This participant was deemed to be eligible for participation during screening but after consent and clinical examination, was unable to move the joystick to complete tasks even using the full assistance mode of the device. Hence, this participant could not continue in the study. This participant's details were passed on to other researchers working on a research centre-based robot iPAM that can be used by individuals with severe weakness of the upper limb.

5.1.2 Demographics

The demographic information for the 17 participants (who used device in homes) at the time of starting device use is shown in Table 10.

Table 10. Participants' demographics

Baseline characteristics	**Participants (n=17)**
Mean age in years (SD)	56.4 (11.5)
Sex	
Male	14
Female	3
Mean time since stroke in months (SD)	24.8 (17.8)
Type of stroke	
Infarction	13
Haemorrhage	4
Side of weakness	
Right dominant	9
Right non-dominant	0
Left non-dominant	8
Left dominant	0
Other impairments	
Expressive dysphasia	6
Pain in affected upper limb	3
Visual inattention	1
Employment	
Not in employment before stroke	14
Gave up employment since stroke	3
Employed	1

The device usage descriptions, details of additional physiotherapy, device usage, clinical observations, adverse events and device-related events for these 17 participants are described in the below sections.

5.1.3 Additional physiotherapy received during hCAAR use

Twelve participants received no additional physiotherapy during the 8-week period of the study. Three participants received community hands-on physiotherapy for 4 weeks during the study period. This therapy involved two

1-hour sessions per week for 4 weeks. Two participants went to the gym at least once a week and did a variety of aerobic, strengthening and endurance exercises.

Four participants had received advice on some additional home exercises by the researcher MS during the course of the study. Three of them had received shoulder mobilisation exercises for shoulder pain (both related and unrelated to joystick use) and one of them was given advice on wrist mobilisation and strengthening exercises for wrist pain associated with use of the joystick.

5.1.4 Device set-up and usage descriptions

The device was installed in the participants' homes in various different locations both on the ground floor or the first floor (Figure 25). Ten participants had the device in their living rooms, four in the bedroom (first floor), two in the dining room and one in the conservatory. The research team (MS, JG and ML) did not encounter any difficulties in installing the device in these locations.

Figure 25. hCAAR installed in the bedroom of a participant

After installation and retraining on the user instructions, 13 participants did not experience any difficulty in logging in and using the device independently during the entire 8-week device-use period. Two participants required help from family members during the first one week to log in and initialise the joystick, but were able to play games independently once the joystick was initialised. These two participants became fully independent in using the device after one week. Two other participants required help from family members to log in and initialise the joystick for two weeks before becoming fully independent in the using the device.

Participants' generally preferred, or aimed, to use the device for three to four times a week for 15-20 minutes per session during the 8-week usage period. Three participants used the device during the weekend as well. One participant could not use the device for almost the entire study period because of personal problems (total usage 12 min). Three participants were unable to use device for more than two weeks during the 8-week period due to unexpected travel and illness. One participant had a 5-year old son who would not let the participant concentrate on game play when he was around. This participant could use the device only at times when the son was asleep and consequently the usage time was affected.

5.1.5 Clinical observations and adverse events

All clinical adverse events during the device-use period were managed by the clinicians in the research team (MS and BB). None of the clinical adverse events needed hospital admission or external clinician intervention. One participant had a fall (and sustained a neck of femur fracture) after completing the home use and the device had been retrieved from the home. This adverse event was deemed to be unrelated to the study. This participant needed hospital admission to manage her hip fracture and could not attend her final assessment (A2) in the research laboratory. Other clinical observations and clinical adverse events that occurred during the device-use period are listed in Table 11.

Table 11. Clinical observations and adverse events

Number of participants	**Clinical observations/ Clinical adverse events**	**Actions taken**	**Result**
One	Wrist pain when uses joystick for more than 10 min particularly while playing higher-level games	Advised to play lower level games, reduce duration of session, use a wrist splint and do wrist stabilising and strengthening exercises.	Reduction in wrist pain
Three	Shoulder pain. Two participants reported an increase in shoulder pain with device usage. One of them was noted to be sitting with back unsupported in the chair and had excessive wrist flexion while holding the joystick. The third participant had long-standing shoulder pain unrelated to device usage.	All three participants had shoulder impingement syndrome on clinical examination. They were advised on shoulder strengthening and range of motion exercises. One participant was advised on sitting back against the chair and holding joystick handle with the wrist in a neutral position during game play.	Shoulder pain improved with exercises
One	Injured finger with bruising while trying to stretch fingers to hold the handle of the joystick	Advised on slow stretching of fingers prior to holding handle. Also received botulinum toxin injection to finger flexors as routine planned treatment unrelated to this study.	No further injury while gripping joystick

Number of participants	Clinical observations/ Clinical adverse events	Actions taken	Result
One	Reported scapula becoming more prominent in affected upper limb (has had the prominence since stroke)	Reassured and advised on scapular stabilisation exercises.	No further worsening of prominence
Four	Could not use device as expected due to personal problems or medical problems (such as chest infections) unrelated to device usage	None. Research team not made aware of personal problems by the participants during the study period.	Usage improved once medical problems were resolved
Two	Low mood. One participant due to chronic ill health and other participant due to family member being unwell.	Reassurance.	n/a
One	Painful thumb and index finger in the affected hand, reported to be not related to device usage.	Found to have osteoarthritis of small joints in these fingers. Advised to use topical analgesia.	Good relief of symptoms with topical analgesia
One	Episodes of dizziness during study period, reported to be unrelated to device use. Lacked motivation to use device.	Dizziness symptoms resolved with adjustment of his regular medications. Needed lot of encouragement from participant's wife to use the device.	Needed encouragement from wife throughout study period

5.1.6 Device-related events

All device-related events were managed by the research engineers in the research team (JG and ML) and did not need any external professional engineering input. Two joysticks needed to be changed as they became noisy and jerky in movement. Six participants encountered joystick calibration/initialising problems that led to them losing track of the joystick position on the screen while starting game play. This was resolved with a home visit by the engineer JG and additional training on initialising the joystick; the participants picked this up easily after one training session at home.

5.1.7 Device usage time

The mean device usage time during the 8-week study was 520 min (range 12 min – 1468 min, SD 381 min). The median usage time was 433 minutes (IQR 250 – 791 min). One participant could not use the device beyond 12 min due to personal problems.

5.1.8 Outcome measure assessments

The clinical and kinematic measurements were successfully undertaken in the research laboratory at the A0, A1 and A2 assessment points as described earlier. The A1 assessments could not be done on one participant (ID number 07) and A2 assessments could not be done on another participant (ID number 05) as they did not attend their appointments. A complete set of assessments at all three assessments points, A0, A1 and A2, for kinematic, FM-UE, ARAT, CAHAI and ABILHAND was available for 15 participants in total.

5.2 Summary of kinematic and clinical outcome scores

Data were available for 17 participants who completed 8 weeks of device use. A summary of kinematic and clinical outcome scores for each participant is described in Appendix D. The data from two participants (ID numbers 05 and 07) were not included in the analysis as there were no assessments done at one of the assessments points for each of them. The descriptive statistics for the remaining 15 participants are shown in Tables 12-17.

The kinematic scores at A1 in the far reach task showed statistically significant changes in movement time and path length ($p<0.05$) (Table 14). The percentage improvement in the median movement time at A1 was by 19%, path length improved by 15% and jerk improved by 19% (Table 13). The improvements (except path length) were maintained at the final assessment (A2) suggesting that the improvements were retained one month after using the device (Table 13).

All the clinical score improvements at A1 were statistically significant when compared to baseline scores ($p<0.05$) (Table 17). The average FM-UE score in this study showed a median improvement of one point at A1 (post-use assessment). The median gain in other clinical scores at A1 were 3 points in the ARAT score, 5.5 points in CAHAI, 3 points in ABILHAND, 1.5 points in the total MAS score and 2 points in the total MRC (Table 16). All the improvements were maintained at the final assessment (A2) suggesting the gains were retained at one-month follow-up.

Table 12. Kinematic variable scores at three assessment points and percentage change in scores (mean and standard deviation)

Kinematic variable	Baseline A0 Mean (SD)		Post-use A1 Mean (SD)		Final A2 Mean (SD)		A1 – A0 % change Mean (SD)		A2 – A0 % change Mean (SD)		A2 – A1 % change Mean (SD)	
	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach
Movement time	**0.48** (0.20)	**0.66** (0.33)	**0.42** (0.16)	**0.48** (0.17)	**0.37** (0.11)	**0.46** (0.11)	**- 5** (37.3)	**- 19** (33.8)	**- 16** (29.9)	**- 21** (27.2)	**- 7** (29.1)	**2** (20.3)
Path Length	**154.00** (51.42)	**188.53** (49.5)	**141.31** (39.45)	**164.70** (38.35)	**126.01** (18.28)	**161.05** (20.75)	**- 5** (22.2)	**- 9** (24.9)	**- 11** (28.0)	**- 11** (17.1)	**- 6** (24.9)	**0** (14.3)
Normalised Jerk	**393.20** (173.01)	**453.83** (179.15)	**276.79** (114.59)	**385.62** (149.56)	**282.35** (144.82)	**349.68** (93.06)	**- 17** (50.1)	**- 4** (59.0)	**- 20** (43.6)	**- 14** (43.2)	**16** (64.5)	**- 1** (33)

Movement time – in sec

Path Length – in mm

Normalised Jerk – no units

n/a – not applicable

Table 13. Kinematic variable scores at three assessment points and percentage change in scores (median and Inter-quartile range)

Kinematic variable	Baseline A0 Median (IQR)		Post-use A1 Median (IQR)		Final A2 Median (IQR)		A1 – A0 % change Median (IQR)		A2 – A0 % change Median (IQR)		A2 – A1 % change Median (IQR)	
	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach
Movement time	**0.43** (0.38 – 0.51)	**0.53** (0.48 – 0.63)	**0.41** (0.32 – 0.49)	**0.44** (0.37 – 0.55)	**0.33** (0.29 – 0.43)	**0.44** (0.42 – 0.55)	**-10** (-30.5 – 3.5)	**-19** (-39.5 – -11)	**-9** (-37.5 – 0.5)	**-20** (-42.5 – -8.5)	**-8** (-26 – 12.5)	**2** (-11 – 9.5)
Path Length	**132.85** (122.18 – 172.03)	**187.12** (148.89 – 212.35)	**127.80** (112.83 – 154.22)	**155.95** (140.40 – 180.41)	**125.66** (111.56 – 135.50)	**165.94** (140.23 – 179.23)	**-4** (-15 – -1)	**-15** (-19.5 – -4.5)	**-7** (-21 – -3.5)	**-11** (-23 – -4.5)	**-**3 (-16 – 2.5)	**4** (-4.5 – 5)
Normalised Jerk	**370.38** (301.71 – 405.46)	**447.75** (350.22 – 488.43)	**258.17** (227.38 – 283.43)	**388.65** (289.28 – 468.57)	**233.26** (193.63 – 308.34)	**363.64** (307.53 – 391.89)	**-23** (-55.5 – 1)	**-19** (-29 – 4.5)	**-34** (-44.5 – -21.5)	**-20** (-42 – -1)	**-7** (-31 – -48.5)	**-7** (-23.5 – 13)

Movement time – in sec

Path Length – in mm

Normalised Jerk – no units

Table 14. Statistical significance values for the kinematic variables

Kinematic variable	Significance A0A1A2		Significance A0A1		Significance A0A2		Significance A1A2	
	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach	Near reach	Far reach
Movement time	**0.105**	**0.006**	**n/a**	**0.036**	**n/a**	**0.008**	**n/a**	**0.460**
Path Length	**0.011**	**0.015**	**0.112**	**0.061**	**0.011**	**0.027**	**0.140**	**0.650**
Normalised Jerk	**0.038**	**0.091**	**0.069**	**n/a**	**0.023**	**n/a**	**1.000**	**n/a**

Table 15. Clinical outcome scores at three assessment points and change in scores (mean and standard deviation)

Outcome measure	Baseline A0 Mean (SD)	Post-use A1 Mean (SD)	Final A2 Mean (SD)	A1 – A0 Mean (SD)	A2 – A0 Mean (SD)	A2 – A1 Mean (SD)
FM-UE	**28.5** (9.8)	**31.1** (8.9)	**31.2** (8.7)	**2.5** (3.4)	**2.6** (5.0)	**0.1** (2.9)
ARAT	**26.4** (19.9)	**30.2** (18.9)	**31.1** (20.1)	**3.8** (3.9)	**4.7** (6.1)	**0.9** (3.9)
CAHAI	**48.8** (21.7)	**55.3** (20.1)	**58.8** (18.8)	**6.6** (4.7)	**10** (9.5)	**3.4** (5.8)
ABILHAND	**18.2** (9.3)	**22.5** (10.1)	**23.8** (8.9)	**4.3** (5.5)	**5.6** (5.3)	**1.3** (3.2)
Total MAS	**11.0** (5.0)	**9.1** (4.7)	**8.5** (4.5)	**- 1.9** (1.5)	**- 2.5** (2.6)	**- 0.6** (2.1)
Total MRC	**36.2** (4.6)	**39.1** (1.3)	**39.6** (1.5)	**2.9** (4.2)	**3.4** (4.4)	**0.5** (1.2)

Table 16. Clinical outcome scores at three assessment points and change in scores (median and inter-quartile range)

Outcome measure	Baseline A0 Median (IQR)	Post-use A1 Median (IQR)	Final A2 Median (IQR)	A1 – A0 Median (IQR)	A2 – A0 Median (IQR)	A2 – A1 Median (IQR)
FM-UE	**29** (19.5 – 36.5)	**32** (28.5 – 35.5)	**30** (28 - 36)	**1** (1.0 – 4.0)	**1** (-1.0 – 4.5)	**0** (-1.0 – 4.5)
ARAT	**23** (9.5 – 44.5)	**31** (16 – 46.5)	**33** (11.5 - 49)	**3** (1.0 – 4.0)	**4** (1.0 – 5.5)	**0** (-2.0 – 2.0)
CAHAI	**47.5** (33.3 – 65.8)	**55** (42.5 – 71.8)	**62** (48.5 – 68.8)	**5.5** (4.3 – 8.5)	**10** (2.3 – 13.5)	**3** (0 – 6.75)
ABILHAND	**17** (11.5 – 24.5)	**24** (16.5 - 31)	**22** (18 – 31.5)	**3** (1 - 5)	**5** (1.0 – 8.5)	**0** (-0.5 – 4.0)
Total MAS	**12** (7.5 – 14.5)	**9.5** (5.5 – 12.5)	**7.5** (5.5 - 11)	**-1.5** (-2.5 – -0.5)	**-2** (-3.5 – -1)	**-1** (-2.0 – -1.0)
Total MRC	**38** (34.5 – 39.3)	**40** (38.5 - 40)	**40** (40 - 40)	**2** (0 – 3.25)	**2** (1.0 - 4)	**0** (0 – 1.0)

Table 17. Statistical significance values for the clinical outcome measures

Outcome measure	Significance A0A1A2	Significance A0A1	Significance A0A2	Significance A1A2
FM-UE	**0.028**	**0.009**	**0.094**	**0.964**
ARAT	**0.000**	**0.001**	**0.007**	**0.306**
CAHAI	**0.000**	**0.001**	**0.002**	**0.050**
ABILHAND	**0.000**	**0.004**	**0.001**	**0.154**
Total MAS	**0.000**	**0.001**	**0.004**	**0.344**
Total MRC	**0.000**	**0.011**	**0.005**	**0.202**

5.3 Grouping of participants

The inter-quartile ranges for the kinematic and clinical scores suggest a wide distribution of values. Therefore to perform further analysis of the data, the participants were divided into three groups based on the magnitude of the observed changes in relation to the Minimal Clinically Important Difference (MCID) values of the clinical measures and the uniformity of the changes across the different clinical measures. The criteria used to categorise the participants are shown below in Table 18 (MCID values FM 7; ARAT 6; CAHAI 7 and ABILHAND 5). Kinematic variables were not considered for the categorisation, as the MCID values for kinematic variables are not yet established.

Table 18. Categorisation of participants based on changes in scores

Group	**Criteria**	**Participant ID number**	**(n)**
I	MCID changes in all clinical measures FM, ARAT, CAHAI and ABILHAND	8,10 and 13	3
II	MCID change in at least one of the clinical measures FM, ARAT, CAHAI or ABILHAND	1, 2, 3, 9, 11, 14, 18 and 19	8
III	MCID change in none of the clinical measures FM, ARAT, CAHAI or ABILHAND	4, 6, 16 and 17	4

The rationale for grouping of participants was three-fold: one, to identify the participants (Group I) about whom one could be reasonably confident that they had improved clinically in functional ability; two, to analyse whether the kinematic variables follow the same trends as observed with clinical outcomes within these three groups i.e., best improvement in Group I, moderate improvement in Group II and mild or no improvement in Group III; and three, whether there are any trends within the four individual clinical outcomes in terms of their responsiveness.

5.3.1 Kinematic variables

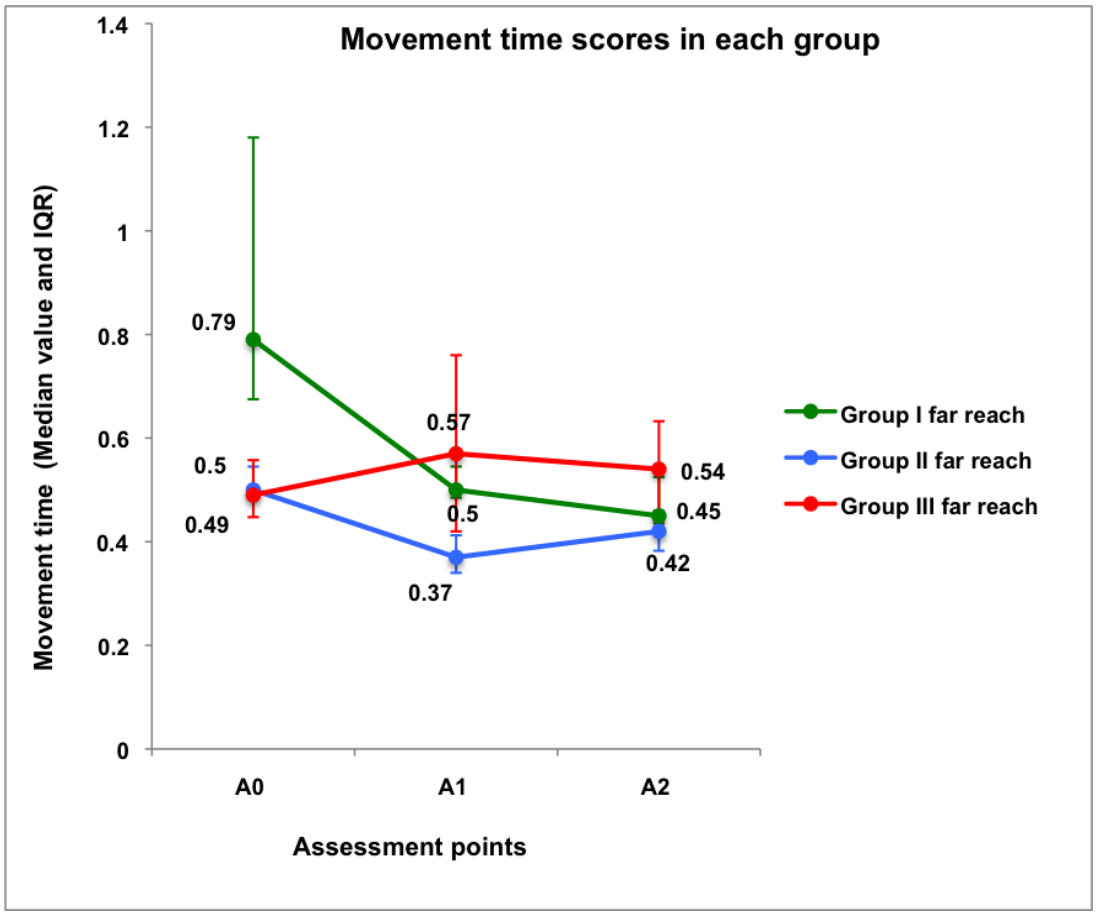
5.3.1.1 Movement time

The median movement time at A1 decreased more in Group I as compared to Group II, whereas it was increased in Group III (Table 19 and Figure 26).

Table 19. Movement time scores (median and IQR) in each group

Mov. Time (Far reach) (sec)	A0		A1		A2	
	Median	IQR	**Median**	IQR	**Median**	IQR
Group I	**0.79**	0.67 - 1.18	**0.5**	0.48 - 0.54	**0.45**	0.43 - 0.52
Group II	**0.5**	0.49 - 0.55	**0.38**	0.35 - 0.42	**0.42**	0.38 - 0.46
Group III	**0.49**	0.45 - 0.56	**0.57**	0.42 - 0.76	**0.54**	0.44 - 0.63

Figure 26. Movement time scores (median and IQR) in each group



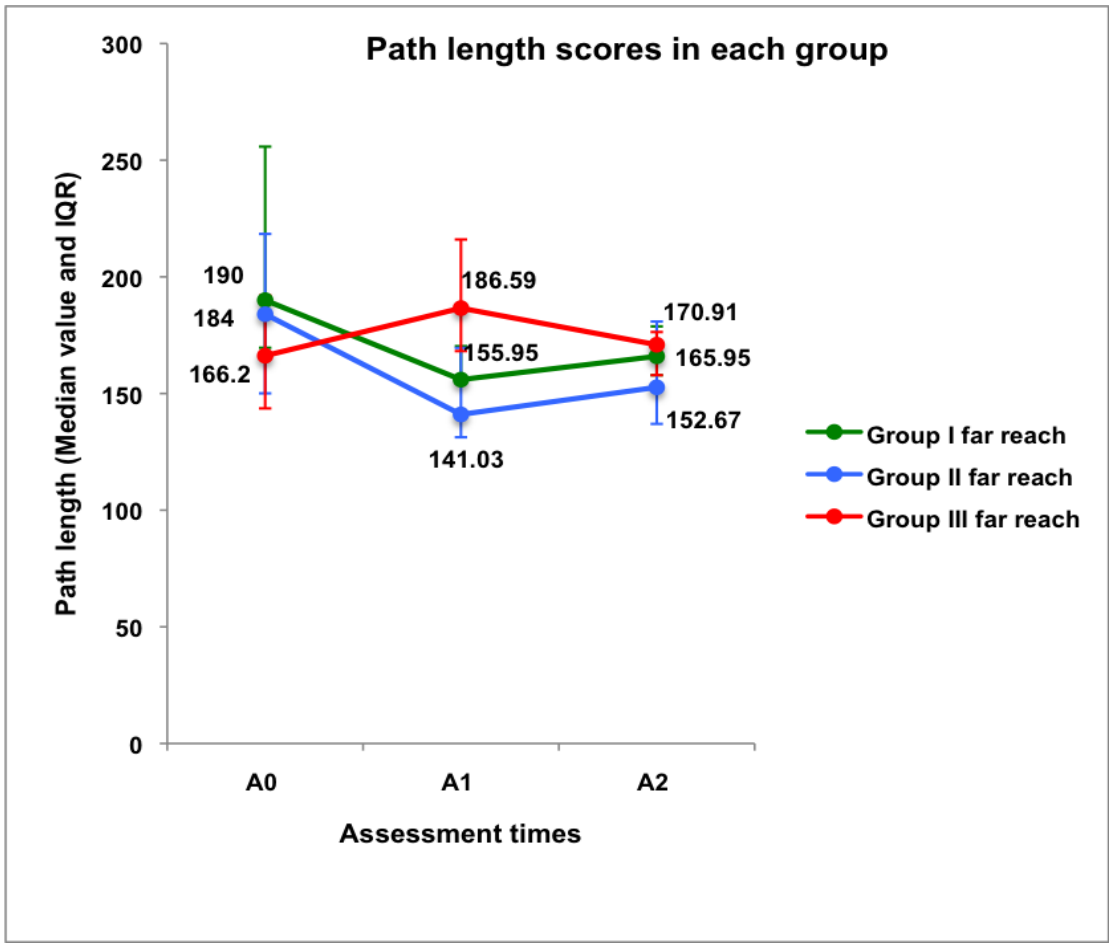
5.3.1.2 Path length

The path length had decreased in both Groups I and II by a similar extent, whereas it had increased in Group III (Table 20 and Figure 27).

Table 20. Path length scores (median and IQR) in each group

Path length (Far reach) (mm)	A0		A1		A2	
	Median	IQR	**Median**	IQR	**Median**	IQR
Group I	**190**	169.0-255.8	**155.95**	154.5-170.3	**165.95**	157.8-178.8
Group II	**184**	150.1-218.4	**141.03**	131.2-169.5	**152.67**	137.0-180.9
Group III	**166.2**	143.6-192.0	**186.59**	168.2-216.0	**170.91**	157.9-176.3

Figure 27. Path length scores (median and IQR) in each group



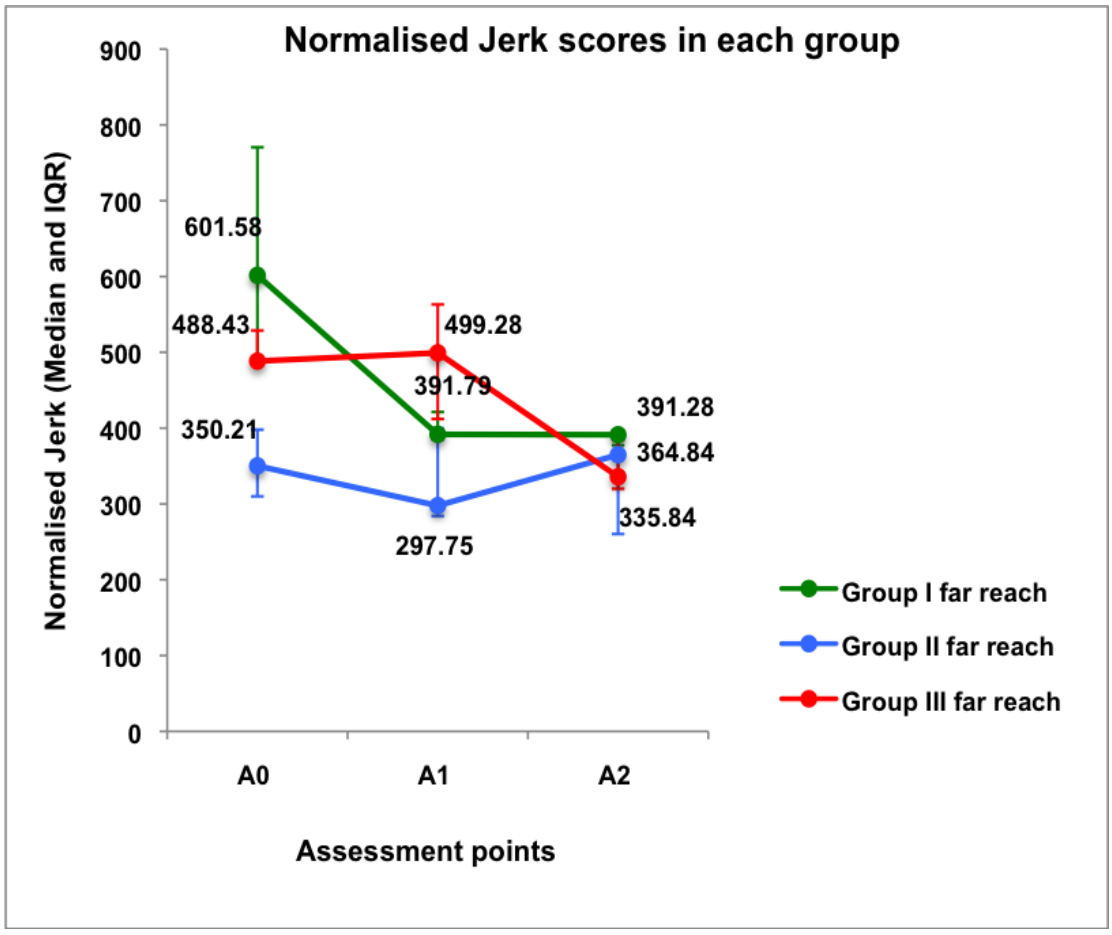
5.3.1.3 Normalised Jerk

The median jerk had decreased most in Group I followed by Group II and there was slight increase in Group III, keeping with the trend observed in movement time and path length (Table 21 and Figure 28).

Table 21. Jerk scores (median and IQR) in each group

Jerk	A0		A1		A2	
Far reach	**Median**	IQR	**Median**	IQR	**Median**	IQR
Group I	**601.58**	490.3 - 770.5	**391.79**	385.4 - 421.3	**391.3**	377.5 - 391.9
Group II	**350.21**	310.0 - 398	**297.75**	284.1 - 399.8	**364.84**	260.3 - 396.5
Group III	**488.43**	486.8 - 528.8	**499.28**	412.1 - 563.1	**335.84**	320.0 - 383.9

Figure 28. Jerk scores (median and IQR) in each group



5.3.2 Clinical outcome measurements

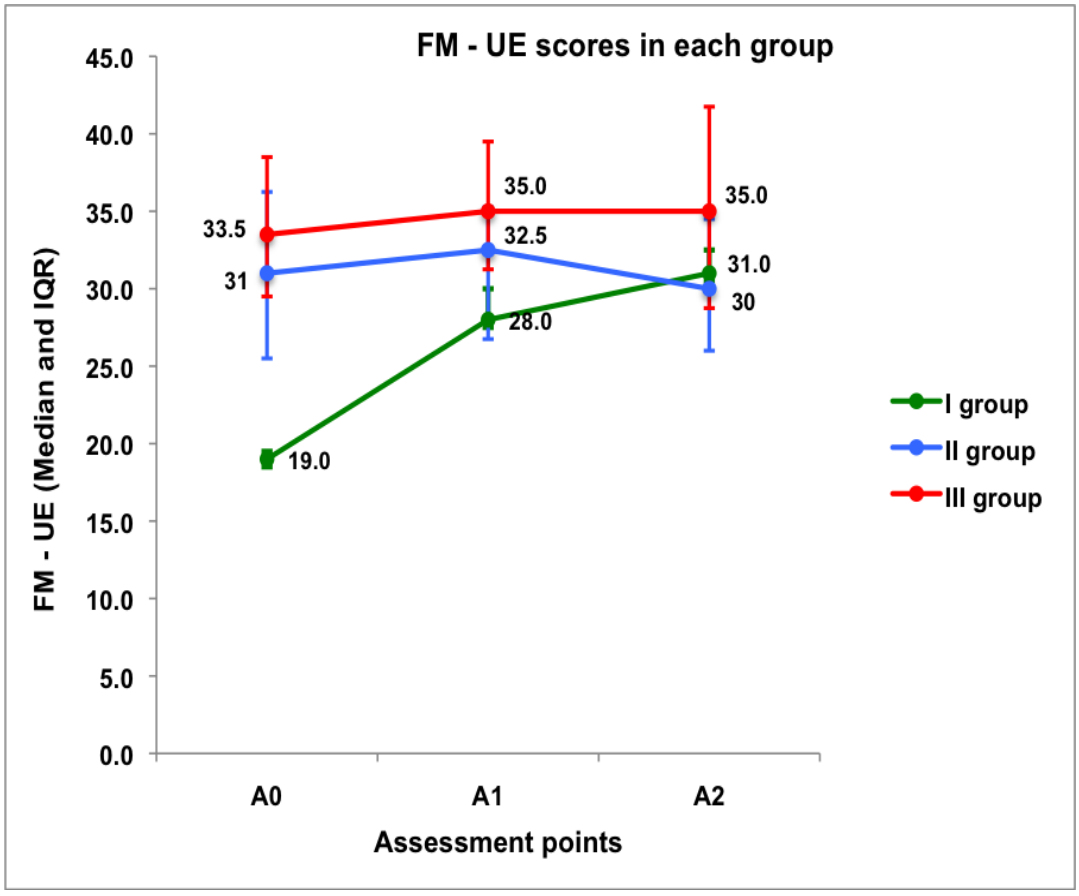
5.3.2.1 Fugl Meyer – Upper Extremity (motor)

The median and inter-quartile range of the FM - UE (motor) score for each group at the A0, A1 and A2 assessments is shown in Table 22 and Figure 29. Group I showed an improvement of 9 points at A1 and further improvement by 3 points between A1 and A2. Groups II and III showed only marginal increase of 1.5 points at A1.

Table 22. FM-UE scores (median and IQR) in each group

	A0		A1		A2	
FM - UE	**Median**	IQR	**Median**	IQR	**Median**	IQR
Group I	**19**	18.5 - 19.5	**28**	26.0 - 28.5	**31**	29.5 - 31.5
Group II	**31**	25.5 - 36.2	**32.5**	26.7 - 35.2	**30**	26.0 - 34.5
Group III	**33.5**	29.5 - 38.5	**35**	31.2 - 39.5	**35**	28.7 - 41.7

Figure 29. FM-UE scores (median and IQR) in each group



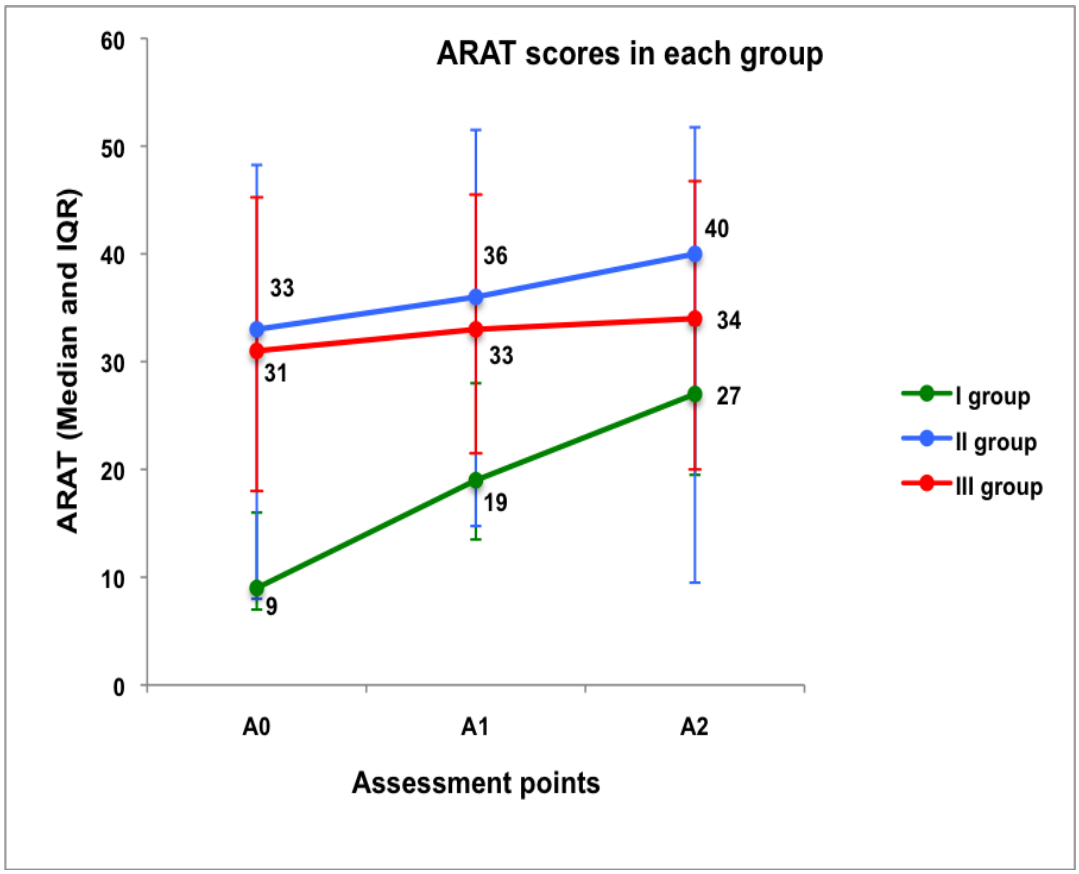
5.3.2.2 Action Research Arm Test

The median ARAT score for Group I showed an improvement of 10 points at A1 and further improvement of 8 points between A1 and A2 (Table 23 and Figure 30). The improvements in Groups II and III at A1 were only 3 and 2 points, respectively, and were similar to the trends seen with the FM-UE scores.

Table 23. ARAT scores (median and IQR) in each group

ARAT	A0		A1		A2	
	Median	IQR	**Median**	IQR	**Median**	IQR
Group I	**9**	7.0 – 16.0	**19**	13.5 – 28.0	**27**	19.5 - 33.5
Group II	**33**	8.0 - 48.2	**36**	14.7 - 51.5	**40**	9.5 - 51.7
Group III	**31**	18.0 - 45.2	**33**	21.5 - 45.5	**34**	20.0 - 46.7

Figure 30. ARAT scores (median and IQR) in each group



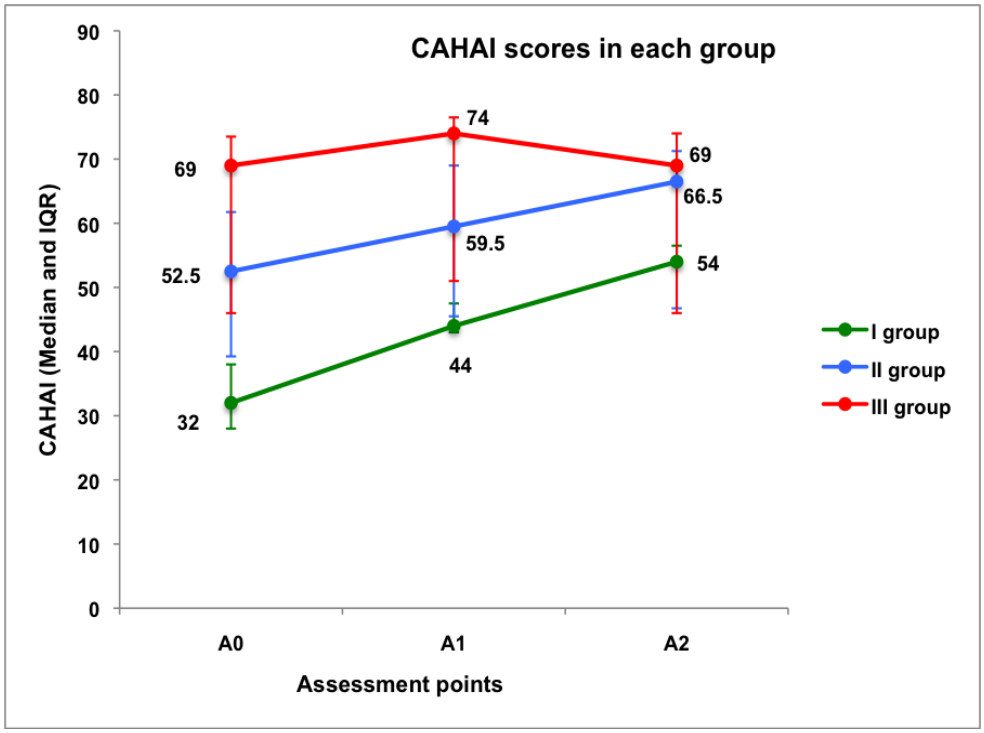
5.3.2.3 Chedoke Arm and Hand Activity Inventory

The median CAHAI score for Group I showed an improvement of 12 points at A1 and further improvement of 10 points between A1 and A2 (Table 24 and Figure 31). Group II score improved by 7 points at A1 and a further 7 points between A1 and A2. This trend for Group II was not observed with FM-UE and ARAT scores. This suggests the higher responsiveness of CAHAI when compared to FM-UE and ARAT in this study. Group III showed an improvement of 5 points at A1 and a drop of 5 points between A1 and A2. This trend is similar to the trends seen in kinematic variables (movement time, path length and jerk) for Group III. This suggests the CAHAI score matches the trend seen in kinematic measurements better than FM-UE and ARAT.

Table 24. CAHAI scores (median and IQR) in each group

CAHAI	A0		A1		A2	
	Median	IQR	Median	IQR	Median	IQR
Group I	**32.0**	28 - 38	**44.0**	43 - 47.5	**54.0**	53.5 - 56.5
Group II	**52.5**	39.2 - 61.7	**59.5**	45.5 - 69	**66.5**	46.7 - 71.2
Group III	**69.0**	46 - 73.5	**74.0**	51 - 76.5	**69.0**	46 - 74

Figure 31. CAHAI scores (median and IQR) in each group



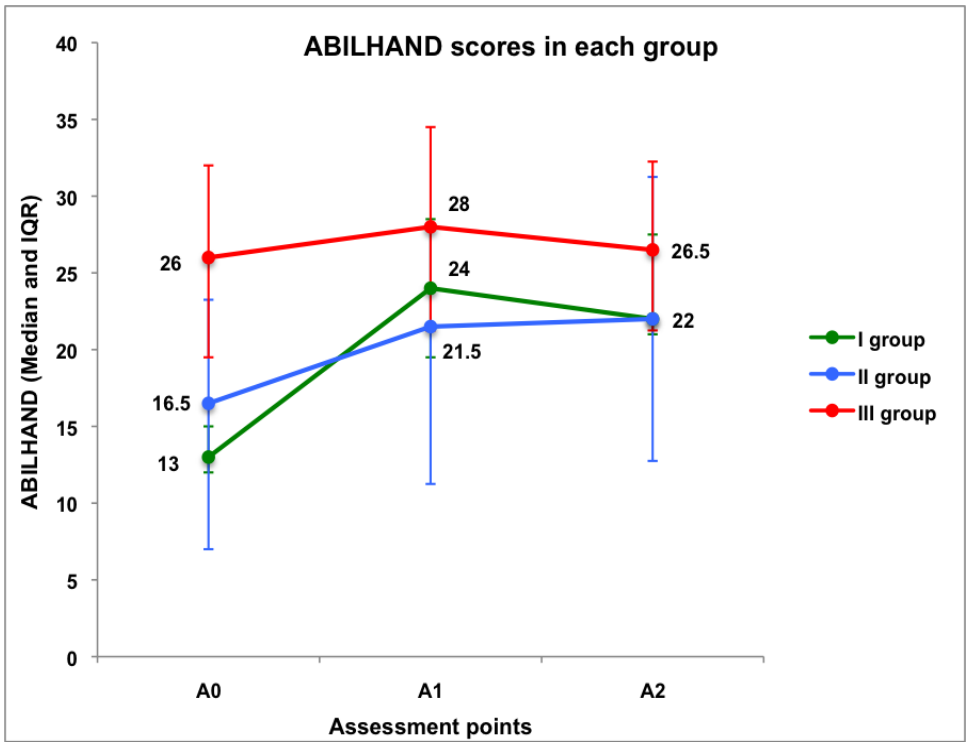
5.3.2.4 ABILHAND

The median ABILHAND score for Group I showed an improvement of 11 points at A1 (Table 25 and Figure 32). Group II also showed a considerable improvement of 5 points at A1. This trend is similar to CAHAI and unlike the trends with FM-UE and ARAT scores. The improvement in Group III was only a marginal 2 points at A1. This suggested ABILHAND behaved similar to CAHAI in changes between A0 and A1. The two scores ABILHAND and CAHAI however showed divergent trends in changes between A1 and A2.

Table 25. ABILHAND scores (median and IQR) in each group

ABILHAND	A0		A1		A2	
	Median	IQR	**Median**	IQR	**Median**	IQR
Group I	**13.0**	12.0 – 15.0	**24.0**	19.5 - 28.5	**22.0**	21.0 – 27.5
Group II	**16.5**	7.0 - 23.0	**21.5**	11.25 – 28.0	**22.0**	12.75 - 31.0
Group III	**26.0**	19.5 – 32.0	**28.0**	21.25 - 34.5	**26.5**	21.0 – 32.0

Figure 32. ABILHAND scores (Median and IQR) in each group



5.4 Relationships between variables and outcomes

The multiple regression analysis, using the independent variables of age, time since stroke, device usage time and baseline scores, and dependent variable of change in scores, revealed no significant predictive relationships for age, time since stroke and device usage time. The baseline clinical scores (ABILHAND logit scores), particularly the A0 scores for far reach task, seem to be the only variable which approached significance levels for predictive relationship with change in scores (Pearson coefficient exceeding 0.50 and significance value of 0.058). The output of regression analysis is summarised in Table 26.

Table 26. Regression analysis between variables and outcomes

	Pearson correlations			**Multiple regression coefficients - Significance**		
	A1 MT-near change	**A1 MT-far change**	**A1 ABILH. change**	**A1 MT-near change**	**A1 MT-far change**	**A1 ABILH. change**
Age	0.30	0.01	0.36	0.13	0.62	0.62
Time since stroke	0.37	0.25	0.27	0.24	0.81	0.55
Device usage	- 0.11	- 0.03	0.46	0.47	0.34	0.98
A0 MT-near	- 0.43	n/a	n/a	0.19	n/a	n/a
A0 MT-far	n/a	0.36	n/a	n/a	0.82	n/a
A0 ABILH.	n/a	n/a	- 0.50	n/a	n/a	0.06

5.5 Discussion

The feasibility study recruited 19 participants, of which 17 participants completed the 8 weeks of hCAAR home use. Two participants could not use the device and dropped out of the study: one of them did not have the minimal active movement required to move the joystick: and the other participant could not accommodate the device at home. This highlights that the most important prerequisites to use hCAAR are having a minimum voluntary movement in the upper limb and having a home environment suitable for device installation.

The FM-UE score can be used to predict the participant's ability to use hCAAR. The participant with an FM-UE score of 6/66 could not complete the computer tasks even with full assistance and hence had to drop out of the study. The range of FM-UE scores for the seventeen participants who completed the home use of hCAAR was 12 – 43. The participant with lowest FM-UE score in this group (12/66) was able to use the device. A FM-UE score of 12 could, therefore, be reasonably considered as the minimum score to be able to use hCAAR. This, however, cannot be considered as the definite minimum score for usability as there were no participants with a baseline FM-UE score between 6/66 and 12/66 in this study. The participant with FM-UE score of 6/66 had an ARAT score of 0 and CAHAI score of 16. The ARAT score of 0 emphasises the floor effect of this outcome measure and indicates that it cannot be used to screen participants for hCAAR use.

There were no serious adverse events during the study. One participant injured a finger of his unaffected hand while trying to open his spastic fingers to hold the joystick handle. Training on gradual hand opening and spasticity management (a botulinum injection) enabled this participant to successfully use the device. Two participants developed shoulder pain, and another wrist pain that were deemed to be related to device usage. The rest of the clinical events listed in Table 11 are unrelated to device usage. Rest, avoiding the painful range of movement and optimising the position of the trunk and upper limb proved to be successful approaches to manage these symptoms. These events suggest the need for periodic clinical review during hCAAR use.

The changes in outcome scores seen in this study are comparable to those seen in previous robot studies. The mean improvement in FM-UE score in this study was 2.5 points; this change is similar to changes ranging from 2.8 to 5.3 that have been reported in previous robot studies [56, 59, 66, 77, 81, 272]. The median improvement in ARAT score in the hCAAR study was 3 points; this is less when compared to a 9 point change in median improvement reported in one previous HapticMaster robot study [88]. The mean ABILHAND logit score improved by 0.56 in the hCAAR study, that is higher when compared to the observed change of 0.25 logits in one robot study involving Bi-Manu-Track device [66]. There was a 19% reduction in mean movement time in the hCAAR study whereas a 35% reduction in mean movement time was observed in a group of participants with chronic stroke in a BFIAMT robot study [81].

The changes in spasticity and strength are also similar to other robot studies. The median total MAS scored showed a reduction of 1.5 points at post-use assessment A1. Similar reductions in spasticity scores has been observed in previous Bi-Manu-Track and BFIAMT robot studies [64, 81]. Whether the reduction of spasticity helps in improving movement and functional ability is unknown and cannot be inferred from these studies. Muscle strength measured using the total MRC showed a 2-point increase in median score A1 that was maintained at A2. A previous study using MIT-Manus showed an increase of 5 points in total MRC score and a study with Bi-Manu-Track showed an improvement by 20 points [56, 64]. However, these studies however involved subjects in the subacute recovery stage. The only study involving chronic subjects showed an average change of 0.4 points per muscle group [66]. Some authors have observed that the improvement in muscle strength with robot therapy does not necessarily correlate to gains in functional ability [70, 273].

There was a statistically significant ($p<0.05$) improvement in the mean clinical outcome scores at A1 and this improvement was retained at final assessment A2, one month after using the device. The improvements, however, did not reach clinical significance (observed gains at A1 were below the MCID values for the outcomes: 1 point in FM-UE; 3 points in ARAT; 5.5

points in CAHAI; and 3 points in ABILHAND). This was not the case when individual participant results were analysed. Some participants did show clinically significant improvements in their scores. This prompted a grouping of the participants based on change in scores in relation to MCID values of the clinical outcomes.

Participants were considered in three groups. A group of three participants (Group I) had achieved clinically significant improvement in all the four clinical scores FM-UE, ARAT, CAHAI and ABILHAND. This suggests that these three participants had a level of improved upper limb function that was noticeable to them. This was confirmed in the qualitative interviews described in the next Chapter (Chapter 6). In another group of eight participants (Group II), the improvements reached clinical significance in some but not all four clinical outcomes. The disparity in the changes in the outcomes can be due to two reasons: the outcome measures have different psychometric properties (particularly responsiveness); and they represent different ICF domains. The chances that all nine of these participants would have noticeable improvements in function is less likely than for group I participants. The third group of four participants (Group III) did not demonstrate clinically significant improvements in any of the outcomes. One would assume that none of these four participants would have noticeable change in upper limb function. This was confirmed in the user qualitative interviews described in the next Chapter (Chapter 6).

Previous studies have also demonstrated that not all participants in any robot study experience similar responses to the intervention [60, 80]. In the GENTLE robot study, a group of seven out of the 20 chronic stroke participants showed clinically significant improvement across all outcome measures [80]. The reason for using MCID values to categorise participants in the hCAAR study was to be certain about the interpretation of the clinical improvements. Interestingly, the group of three participants in this (hCAAR) study who showed clinically significant improvements in the four clinical outcomes, FM-UE, ARAT, CAHAI and ABILHAND, also reported significant changes in their upper limb function in the user-feedback interviews.

The kinematic scores also showed statistically significant improvement in movement time and path length scores at A1 ($p<0.05$). When kinematic measurements at the three assessment points for the three groups were plotted, the following was observed: Group I had steep upward slopes indicating larger improvement; Group II had less steep upward slopes suggesting smaller improvement; and Group III showed flat or downward slopes suggesting no improvement or deterioration respectively. This suggest the kinematic measurements responded in similar fashion to clinical outcome measures in this study.

The device seemed to be most suitable for individuals with moderate arm weakness. This median baseline FM-UE score of participants was 29 (range 12-43). The individuals with severe weakness might not be best suited to use the device as suggested by the one drop-out from the study (with an FM-UE of 6/66). Participants with mild weakness might not find the device useful as they need to practice complex three-dimensional functional movements, which hCAAR is unable to provide.

Among the participants with moderate weakness, the ones with lower baselines scores seem to have better gains from device use. The median baseline FM-UE score was lowest in group I (19 points) and this group showed better gains than other two groups II (baseline FM-UE 31 points) and III (baseline FM-UE 33.5 points). This trend was also observed with ARAT, CAHAI, ABILHAND and kinematic measurements. This is also supported by the regression analysis that showed that A0 baseline ABILHAND logit score was the only variable to approach predictive significant relationship ($p = 0.06$) with change in score value (A1-A0). This finding is supported by some other robot trials where individuals with moderate impairments (score of 15 – 40 on FM-UE score) improved more than those with severe weakness of the upper limb [52, 60, 80, 111, 261, 272, 274].

There was a lack of a significant predictive relationship between time since stroke and the improvement in outcomes. The mean time since stroke for Group I participants (who had the greatest clinical improvement) was 11.8 months. It is an encouraging finding that hCAAR therapy can lead to clinically significant improvements in individuals in the chronic stages after stroke. It

was difficult to compare the effect of hCAAR between subacute and chronic stages after stroke as most of the participants in the study were in the chronic stage. There were only four participants who were in the sub-acute stage (within 6 months post-stroke) and their outcome varied: only one was in Group I (best clinical improvement); two were in Group II (some clinical improvement); and one in Group III (no clinical improvement). A similar finding has also been observed in a larger study involving 38 chronic stroke participants who used the ARMin robot for 8 weeks [70]. The authors of the ARMin trial performed a post-hoc analysis stratified by age, hand dominance and time since stroke and did not find any significant relationships between these variables and the gains.

The hCAAR study did not reveal the expected dose-response relationship. There was no significant correlation between device usage time and the gains observed. None of the previous robot studies was able to stratify data based on device usage as all the studies were based in hospitals or research centres with all participants receiving the same duration of robot therapy. This dose-response relationship needs to be explored in future studies. It is difficult to standardise the usage in a minimally supervised home environment, where the user is in charge of the usage time. However a minimum usage time can be recommended in future studies.

The usage time in the hCAAR study was considerably lower than that of most previous robot studies. The mean usage of hCAAR in this study was 520 min (range 12 min – 1468 min) during the 8-week period. This is lower than the usage time reported in other studies, which involved usage time of 900 to 2160 min spread over 4 – 12 weeks [53, 70, 74, 79, 81]. It can be argued that hCAAR usage time might have been sub-therapeutic and that could explain why no dose-response relationship was seen. Previous robot studies have also identified that there is no advantage of robotic therapy at a low utilisation [80, 82, 118, 275]. One trial comprising 9 hours [540 min] of conventional functional retraining did not show any benefit in chronic stroke subjects with moderate upper limb impairment [275]. The study by Higgins et al. however, does not report whether a subgroup of participants showed improvement in upper limb function.

The improvements seen at A1 in this study are sustained at the 1-month follow-up at A2. Previous robot studies suggest that improvement in chronic subjects is maintained for up to 3 months [64, 93, 276]. Robotic therapy in chronic stroke shows faster gains when compared to intensive conventional physiotherapy, but only while using the device and the gains become similar to intensive conventional physiotherapy in the long term (6 months) [53, 70]. It is encouraging to find that the short- and long-term effects of robot therapy are similar to intensive conventional physiotherapy. The long-term retention effects of robot therapy beyond 6 months need to be further researched.

5.6 Limitations

There are some limitations to this feasibility study. Firstly, the small sample of participants limits the generalisation of the results on efficacy. The aim of the feasibility study was primarily to test whether the robot device could be used safely in a minimally supervised home setting. The efficacy data shows the potential for therapeutic effect in some participants and this needs to be explored in future hCAAR studies.

All the participants were independently mobile with or without the use of walking aids. None of the participants was dependent on a wheelchair for mobility. None of them needed assistance with transferring to and sitting in the chair. It is difficult to predict whether participants needing assistance for chair transfers would use and accept hCAAR in their home setting unless this was tested in future studies.

This study had a greater number of male than female participants (14:3) and greater number of middle aged than elderly participants. Only three participants were above 65 years of age and only one participant was above 70 years of age. This limits the assumptions we could make on whether hCAAR would be equally usable by females and elderly people. However, this study included one female participant who was 81 years of age and who had never used a computer in her life before. She needed some supervision from family members to use hCAAR at first but became independent thereafter and completed the study with reasonable usage time in the 8-week

period (461 min). She became interested in computers during the course of the study and her family were considering getting her a computer for use in future. This example suggested that the device has the potential for use by elderly patients.

This study lacked multiple baseline assessments to estimate ongoing natural recovery. From the spontaneous recovery studies reported by Duncan et al., we know that the recovery pattern tends to plateau after 3 or 6 months, depending on the severity of the stroke [277]. In this study, most of the patients were in the chronic phase of recovery (mean time since stroke 24.8 months; median 26 months) and there was a definite improvement in outcomes scores at A1 followed by a plateau or slight dip in improvement at A2. This improvement pattern suggests that the observed changes are due to hCAAR use in the intervention period and also suggests that with the aid of rehabilitation treatments, motor improvements can occur beyond the 6 months post-stroke period.

5.7 Conclusions

The feasibility study has demonstrated that individuals with moderate upper limb weakness after stroke can safely use hCAAR in a home setting. The use of the device led to statistically significant improvements in kinematic and clinical outcomes. Three participants showed clinically significant improvements in all the four clinical outcomes FM-UE, ARAT, CAHAI and ABILHAND.

Chapter 6: User feedback from the hCAAR feasibility study

6.1 Introduction

The restorative rehabilitation assistive technology development process can be considered in four stages: Concept, Design, Testing and Deployment [246]. The concept stage starts with idea generation and includes technical, financial and commercial assessment [101] [246]. The design stage involves product development from (re) design to prototype development. The testing stage starts with prototype testing in house and includes studies in the real field. The deployment stage includes product marketing, launch and use in the real field [101] [246]. The concept and design stages of hCAAR were considered in Chapter 3. This chapter deals with the testing stage of hCAAR. A brief summary of the user involvement methods already described in detail in Chapter 3 is summarised in this section.

There are a variety of direct and indirect methods used to involve users throughout the device development process. The methods, which can particularly be used in the testing stage are user discussion, interviews and usability tests [246]. There are no sufficiently detailed models so far described in user-centred design literature that describe which aspects of user requirement need to be covered in these user involvement methods.

One framework that is commonly used in health sciences to understand and more fully capture the different aspects of any health condition is the World Health Organization's ICF. The ICF classifies health condition into domains of body structure/functions, activities, participation, personal and environmental factors related to the individual [11]. This framework is internationally accepted and used extensively in research. Researchers have developed disease-specific ICF Core Sets for specific health conditions such as rheumatoid arthritis, multiple sclerosis and stroke. The Comprehensive ICF Core Set categories for stroke put forward by an international consensus group is widely used in stroke related research [252].

This chapter will describe the user feedback from testing stage of hCAAR i.e, the feasibility study in the home setting. We have also investigated the usefulness of the stroke-specific Comprehensive ICF Core

Set to guide researchers in capture user feedback in the testing stage of device development.

The aims of the hCAAR user-centred design process in the feasibility study (testing stage of device development) described in this chapter are:

1) To obtain feedback on hCAAR usability and efficacy from end-users involved in the feasibility study and healthcare professionals

2) To investigate whether the ICF framework can be used as a template to obtain user feedback in the testing stage of technology development.

6.2 Methods

6.2.1 Sample

Seventeen participants from the feasibility study (end-users) provided feedback on hCAAR. The two participants who did not complete the home use of the device were not included in the feedback process. One of them had inadequate voluntary movement in her upper limb and the other felt there was no adequate space at home for the device. These two participants chose to drop out from the study.

One neuro-physiotherapist (professional user) from the community stroke rehabilitation team agreed to provide feedback. This was the only therapist involved in providing treatment (usual treatment) to three participants enrolled in the study. Therefore only one therapist could be involved in the feedback process. The recruitment and consent process is as described in chapter 3.

6.2.2 Stage I. Interview process

All participants were offered a mutually convenient time to attend for face-to-face interviews with the researcher MS. The aim of interviews was to understand users' experience of using or observing the usage of hCAAR, and obtain users' perspectives and suggestions on the future development of the technology. The research team initially identified the broad interview topics by brainstorming ideas and discussion in research team meetings. The topics were based on previous experiences of the user-centred design process [103, 253] and existing literature on the development of assistive

technology for upper limb rehabilitation [254, 255]. The interviews comprised of predominantly open-ended questions based on the checklist of topics prepared by the research team. The interviews allowed the discussion to deviate from these topics to those that were identified by users based on their experience of using the technology. The interviews were recorded in writing by the researcher MS.

The checklists used in the end-user group interviews and the professional user interview are described in Appendix E and Appendix F. The topics covered included device hardware, device software, exercises, effects on upper limb movement and activities, personal views and views of family members and professionals involved in the participants' care. The researcher MS was blinded to the changes in clinical outcome measures while conducting these interviews at the A1 assessment. Researcher SM was performing the clinical outcome measures during the same appointment.

6.2.3 Stage II. Extracting interview concepts

The identification of meaningful concepts within outcome measure items and their responses, and the linking of the concepts to most precise ICF categories were initially published in 2002 [256] and later updated in 2005 [257]. Meaningful "concepts" are those that describe the health condition, person, functional activity or any of the personal or environmental factors. For example, consider the statement/item "Pain doesn't prevent me from walking any distance". Two different meaningful concepts can be identified in this statement, "pain" and "walking".

Meaningful concepts referring to "quality of life" are assigned "Not definable - quality of life". If a meaningful concept is not contained in the ICF and is clearly a personal factor, it is assigned "personal factor". If a meaningful concept is not contained in ICF and is not a personal factor, it is assigned "not covered". If the meaningful concept refers to a diagnosis or a health condition, it is assigned "health condition" [257].

Meaningful concepts were extracted from the hCCAR testing stage interview topic questions and responses based on the above ICF linking rules.

6.2.4 Stage III. Matching interview concepts to ICF Core Set

The meaningful concepts extracted from the semi-structured interviews were matched to the categories within the Comprehensive ICF Core Set for stroke [252]. The Core Set has 130 categories in total, which comprise of 46 categories from the body function and structure domain, 51 categories from activities and participation domain and 33 from the environmental factors domain [252]. The personal factors domain has no categories as yet.

The process of extracting interview concepts and matching them to ICF categories can be illustrated with the following example from our interviews.

a) The participants were asked *"Comment on the arm exercises or therapy delivered by the device"* One meaningful concept that can be extracted from the question – "arm exercises".

b) A sample end-user response was *"The hand was closed while performing reaching movements which is not in keeping with exercises suggested by the physiotherapists"*. A sample professional user response was *"The device has the ability to provide repetitive movement, engage person and motivate".* The meaningful concepts that can be extracted from the above two responses are – "hand movements", "reaching movements", "physiotherapist suggestion", "repetition", "engagement" and "motivation".

c) The extracted concepts are linked to one or more of the Comprehensive ICF Core Set categories, which convey the same meaning:

Arm exercises – d210, d220 (Undertaking simple/ multiple tasks)

Hand movements – d440, d445 (Fine hand use, hand and arm use)

Reaching movement – d210 (Undertaking simple task)

Physiotherapist suggestion – e455 (views of professionals)

Repetition/ Practice – Not covered

Engagement – b140 (Attention function)

Motivation – Personal factor

6.2.5 Stage IV. Comparing participant feedback with outcome measure changes

The user perspectives of the impact of intervention were subsequently matched to the clinical outcome measures to observe for any relationship between them.

6.3 Results

6.3.1 Stage I. Interview results

The interview topic results were grouped as comments made by the end-user group and those made by the healthcare professional. Similar comments made by more than one individual are reported in the third person in this Chapter. Individual comments are reported as direct quotes (using quotation marks and italics).

6.3.1.1 Hardware

6.3.1.1.1 End-user group

Sixteen participants were satisfied with the footprint and transportability of the device and felt it did not take up too much space in their homes. One participant felt the device took up too much space at home.

> *"If the device was smaller it could be easily moved from one room to another within the house"*
>
> *"The device took up considerable space in our small kitchen and needs to be smaller than its current size*"

All participants were satisfied with the external look and manufacture of the device.

> "*My three dogs have chewed away cables of devices in the past, but this device was placed in the corner and there were no exposed cables, so there were no particular problems."*

Ten participants had the device installed in their living room, four in the bedroom (first floor), two in the dining room and one in the conservatory.

Thirteen participants used their dining chairs to sit on while using hCAAR. Four participants did not have suitable chairs in their homes and

were provided with standard straight-back chairs from our research laboratory along with the device.

"I used a dinner chair to start with but was not comfortable and changed it to a bar chair and found it better."

"I kept leaning forwards while using the device. Could there be an option of having a "seat belt" to minimise trunk movement?"

"The position and angle of the arm should be similar each time the device is used and hence the chair could be made part of the system. The chair could be set-up in a standard position each time its used."

Fourteen participants did not experience any difficulties with the device joystick. Two participants had problems with noisy joysticks that needed to be replaced during the study.

"My hand kept slipping from the joystick. May be having a strap to hold the hand in place while holding the joystick could be tried?"

6.3.1.1.2 Professional user

"I am impressed with this device. I am not sure whether the device could be made smaller, as one of the users found the device took up considerable space in his kitchen. This participant was also leaning forward while using the joystick. He needed constant reminding to sit in the recommended position while using the device. There must be clear instructions for users that the individual needs to sit with the back against the backrest of the chair and the arm should be in the normal resting position by the side of the body"

6.3.1.2 Software

6.3.1.2.1 End-user group

Fourteen participants were satisfied with the assistance levels set for the hCAAR joystick. Of these, three participants felt the assistance provided by the joystick was not noticeable and felt their arms were actively performing most of the movements on their own while playing the games. Three participants felt the assistance was insufficient for their abilities and arm power.

“The assistance is the key concept of the device to help people with greater disability”

Twelve participants liked the score display idea and felt the display of scores after each game helped them keep track of their previous scores and motivated them to try to better their previous scores. Five participants reported they did not pay much attention to their previous performance scores.

“I wonder whether the device could display graphs to show my performance over a time period.”

Twelve participants felt some of the games became repetitive and less interesting after a while. They felt their usage would have been better if the device had more interesting games. Three participants liked the concept of the levels becoming progressively harder as that kept them interested in using the device. Three participants suggested developing games based on sport such as football or golf.

“I liked the puzzle and chase game in particular as the higher levels were interesting and complex.”

“I liked the concept of the levels progressively becoming harder.”

“The current games are pretty mind numbing. They need to be developed further.”

“The graphics in the van game were all right but rest of the games were very basic.”

“I would suggest games based on tennis and space invaders could be tried.”

“Games based on shopping baskets and crossword puzzles would be nice.”

“I did not like the river game and the loop game. The chase and puzzle games were okay.”

“I liked the chase and puzzle games as they had graphics (crocodile, monkey) and interesting levels. I did not like other games as they lacked speed and challenge.”

“The van game was complex and I found releasing the banana (and avoiding the flame at the same time) difficult.”

“A game based on crosswords would be good.”

Six participants had problems with joystick calibration/initialising and required additional training by the research team.

6.3.1.2.2 Professional user

“The concept of telerehabilitation could be developed which would help communication with the user, monitor progress and make users aware of their progress. This could also enable remote monitoring of the user’s position while using the device. Unsupervised exercise in some individuals might lead to unhelpful patterns.”

6.3.1.3 Therapy/Exercises

6.3.1.3.1 End-user group

All participants liked the concept of therapy based on computer games. Four participants had suggestions for future versions of the device.

“The joystick promotes arm movement only in few directions. I wonder whether there could be more movements, like the arm going round”

“The movements generated are restricted to a single plane. The hand is closed while performing reaching movements, this is not in keeping with the exercises suggested by the physiotherapists. They teach that the hand needs to be open while reaching the target.”

“Good for certain movements like moving sideways and forwards. Could further developments include the joystick moving in other directions, and could hand and finger movement could be included?”

“I wondered whether the arm activity would stimulate brain areas controlling speech”

6.3.1.3.2 Professional user

“The device has the ability to provide repetitive movements, engage the user, motivate the user and measure performance which is good. It does not replicate all required movements. Ideally, one would expect to work on hand opening and closing while performing reaching movements. The concept of bimanual involvement is good to see.”

6.3.1.4 Impact on arm movement and function

6.3.1.4.1 End-user group

As a result of using the device during the 8-week study period, five participants felt there was an improvement in power and movement ability in their affected arms. The remaining 12 participants did not notice any improvement in arm power and ability.

"My hand is opening more and gripping things better."

"I feel more confident in moving the affected arm."

"I am generally more aware of my weak arm now."

All five participants who noticed improved power in their arms reported that they were using the affected arm more in daily activities and there was an improvement in functional ability in everyday tasks

"I am zipping up my coat using both hands, which I could not do before."

"*I am using the weak arm more in daily activities including washing up, peeling potatoes, carrying things, squeezing toothpaste, etc."*

Four participants felt their affected arm was less stiff since using hCAAR.

Two participants reported improvements in mood since they started using the device.

"The device gave me a sense of purpose in life, something I looked forward to every day when I got up."

6.3.1.4.2 Professional user

"I was involved with three patients using the device but our (community stroke team) follow-up finished before the end of the hCAAR pilot study, so I never got to formally assess the response specific to the hCAAR therapy. I know one participant was definitely getting better and benefited from having the device at home."

6.3.1.5 Individual perception

6.3.1.5.1 End-user group

All participants liked the concept and purpose of the device.

"This is a very good device."

"I would have benefited more if I had used it more frequently and my shoulder pain had not restricted usage of the device."

"Multi-player modes would be more engaging to people."

"It (the device) is interesting and motivates me to do more exercises at home."

"I had some initial problems with understanding the technology but once I got into routine use (of the device), it became easy to use."

"I got bored using the device. Going to the gym suits me more as I meet other friends and do a variety of exercises."

"*I am motivated as a result of using this device to do more exercises."*

"This is a good idea to encourage (arm) movement."

Twelve participants felt the games need to be made more interesting and challenging to increase the device usage. Three participants suggested the device was more suited for individuals with greater weakness in their arms than theirs. Two participants commented they were motivated to use the device as they were participating in a research study.

"Please put my name down for future studies involving such devices."

"I appreciate the efforts put in by you all (researchers) in designing the device."

Three participants suggested the device should be used in the early period after stroke. Two participants felt the device motivated them to do more exercises at home. Two participants felt they could not use the device as much as they wanted due to various reasons (such as illness and personal problems). These participants felt they would have derived greater benefit had they used the device more. Two participants were interested in buying the device if it were available commercially. Three participants commented that they would be interested in buying the device provided the games were improved.

Four participants felt the device could be used in stroke centres. Two participants would like to use the device in multi-player settings in community centres whereas all other 15 participants preferred to use the device on their own in a home setting. Two participants commented they would be more comfortable using it with people who had similar disabilities rather than playing in front of non-disabled people.

6.3.1.5.2 Professional user

"The device provides independence to the individual to engage in therapy and can be used in addition to hands-on therapy from a therapist. For the future research study, there could be two arms of a controlled study - hCAAR + standard physiotherapy versus standard physiotherapy in a larger sample of users with appropriate outcome measures."

6.3.1.6 Family and therapist perception

Family members (wives/partners/sons/daughters) of seven participants expressed their satisfaction with the device and felt the device had been very useful to the participants.

"It is a brilliant concept for arm exercises."

"The device could improve thinking as well."

"It is a good concept for encouraging arm movement."

"Such devices should be available early after stroke."

"His arm movement has improved and he uses the arm more in everyday activities. The device has given him hope and kept him occupied at home. He used to get easily get frustrated with the lack of therapy particularly lack of speech and language therapy. The device might be good for his brain activity as well."

"I liked the idea of this device. He is moving his arm better than before. We are interested in buying such a device if available on the market."

"His arm feels less tight now since using the device. I massage the arm on a regular basis and can tell the difference. I feel the device

increases ones independence and is good for brain function and thinking ability."

"*The device has helped improve his arm movement and has kept him occupied. The device provides the option of doing exercise at home whenever he wants to do exercise. He doesn't need to depend on a therapist."*

"I am impressed with the device and feel the device could have had a better effect on his arm movement if he had used it more often. The device should be part of the physiotherapy program, particularly early after stroke. The warm-up and assessment exercises could be quicker or bypassed so that one could start using the games straight after logging in to the device. I would suggest improving the games in future like: *car around a track, electric loop buzzer game, horse racing with jumping (grand national), hurdle racing, archery target, basketball shooting, demolition game (blow things up, crane with ball), paintball game (good for colours), fox hunt (chasing through woods, etc), boats on water, battleships."*

"*The login procedure needs to be made simple so that the person can go straight to games after switching on the computer. Games could be based on word formation from letters."*

"The device has good potential and would have made a big difference to him if it had been available early after stroke. Our close friends have liked the device and the concept."

"We have noticed him using the arm more towards the end of the study period."

"My private therapist was satisfied with the movements being performed while using the device and encouraged me to use the device as much as possible. He suggested that any movement is good movement after a stroke."

"The device took up significant space in the kitchen and we would not wish to have such a device at home in the future."

6.3.2 Stage II. Extracting interview concepts

Meaningful concepts extracted from each interview topic questions and responses/discussions with the end-users and the healthcare professional are listed in Table 27. Where there are duplication of concepts, they are listed only once in the table.

Table 27. Meaningful concepts extracted from the interviews

Interview topic	**Concepts emerging from discussions**
Hardware	Home setting, space, technology, computer use, personal view, assistance at home, comfort, hand grip
Software	Playing games, computer game, personal choice, engagement, motivation, telerehabiltation
Exercises/ Therapy	Upper limb exercises, duration and intensity of exercises, tolerance, reaching movement, hand grip/ movements, compliance, health service, sport
Impact	Arm movement, sensation, power, tone, spasticity, pain, functional activity, daily activities, cognition, mood, speech, language, performance at work, leisure interests, quality of life, personal goals, confidence, purpose in life
Individual perception	Knowledge, time after stroke, social skills, cost
Family and therapist views	Views of family members, views of professionals, Independence, frustration, effort

6.3.3 Stage III. Matching interview concepts to the ICF Core Set for stroke

Table 28 shows the concepts linked to the most relevant ICF Core Set category or categories. Eleven concepts were assigned to “personal factor”, one concept as “not covered” and one concept was assigned “not definable”.

Table 28. Interview concepts and matched ICF Core Set categories

Interview concept	**ICF Core Set category**
Personal view	Personal factor
Geography	e210
Technology	e115
Comfort	Personal factor
Computer use	e115
Handgrip/hand movements	d440, d445
Assistance	e340
Body position	d410
Playing game	d920
Engagement	b140
Motivation	Personal factor
Telerehabilitation /health services	e580
Training/ practice	Not covered
Upper limb exercises	d210, d220
Duration of exercises	b180
Intensity of exercises	b740
Tolerance	Personal factor
Reaching movement	d210
Compliance	Personal factor
Sport	d920
Arm movement	d210, d220
Sensation	b265, b270
Power	b730
Tone/spasticity	b735
Pain	b280
Functional activity	d210, d220
Daily activity	d230, d420, d430, d475, d510, d530, d540, d550, d630, d640
Cognition	b140, b144, b164
Mood	b152
Speech	b330
Language	b167
Work/employment	d845

Leisure interests	d920
Quality of life	Not definable
Personal goals	Personal factor
Confidence	Personal factor
Purpose in life	Personal factor
Knowledge	b126
Social relationships	d750
Views of family members	e410
Views of professionals	e455
Independence	Personal factor
Frustration	Personal factor
Effort	Personal factor
Cost/affordability	e165

6.3.4 Stage IV. Comparing participant feedback with objective outcome measure changes

The changes in clinical outcome scores (reported in Chapter 5) for the five participants who reported significant change in their arm movement in their interviews were analysed. Three of these five participants belonged to Group I (clinically significant changes in all the four outcomes FM-UE, ARAT, CAHAI and ABILHAND). The other two participants belonged to Group II where some clinical outcomes improved by clinically significant levels. The other six participants of Group II (who had clinically significant improvement in some outcomes) did not report improvement in the user feedback interviews. The four participants of Group III (who did not have clinically significant improvement in any of the clinical outcomes) did not report any improvement in the feedback interviews.

In their interviews, four participants had reported a reduction in arm stiffness after using the device. The total MAS score in each of these four participants showed a reduction by at least 2.5 points at A1. Conversely, there were two participants who showed considerable reduction in their total MAS score (2.5 points in one participant and 3.5 points in the other) but neither of them reported any noticeable reduction in arm stiffness in their interviews.

The two participants who reported improved mood while using the device were among the four participants who had used the device most during the feasibility study. One of these two participants did not show clinically significant improvement in any of the clinical outcomes and was categorised in to Group III (clinical significant change in none of the clinical outcomes). The other participant belonged to Group II and showed clinically significant changes in CAHAI and ABILHAND.

Family members of seven participants reported an improvement in either the arm range of motion, power, stiffness, involvement in daily activities or functional ability. These participants included the five participants who had themselves reported improved arm movements in the interviews. The two remaining participants belonged to Group II where there was clinically significant improvement in some outcome measures.

6.4 Discussion

6.4.1 The hCAAR device feedback (testing stage)

Only a few robot studies in the current literature report on patient and therapist impressions of the device in the study. This could be related to either restrictions on length of the publication or lack of user-centred design approach or separate publication on user feedback on the device. The reported measures in some studies are user satisfaction of device [74, 96, 117], compliance [74], content of therapy [73, 117], functional impact [73, 87, 96, 117] and therapist views [89]. The ACRE robot study reports on the actual design modifications made in the device based on user feedback from patients and therapists [89].

hCAAR was generally well accepted by users and their families or carers in their home environment in this study. Out of the recruited 19 participants, 17 participants were able to use the device on their own in their homes. Out of these 17 participants, two participants with greater disability in certain aspects (one with severe spasticity and other with severe dysphasia) needed some additional help and training from family members for two weeks prior to becoming independent. The usability of hCAAR by people with

greater physical, language and cognitive ability needs to be explored in future studies.

The transportability, footprint and external look of the device were found to be satisfactory and appreciated by users and carers. hCAAR has been successfully transported and installed in various locations (in both the ground floor and the first floor) in homes. The members of the research team did not encounter any difficulties in installing and retrieving the devices at these locations. Some of the participants' suggestions and the resulting discussions in the research team and their outcome is summarised in Table 29.

The levels in the hCAAR games were designed to provide a hierarchical order of difficultly to the user. The range of motion of the shoulder and elbow increases with the higher levels of each game. This approach allowed hCAAR to be used by a wide range of users. However some users with mild upper limb weakness did not find the games challenging enough for their level of ability (even at the advanced levels of the game). This highlights that the current planar hCAAR device is more suitable for those with moderate to severe weakness.

The hCAAR device can deliver active assist and active non-assist modes of therapy. The clinician can adjust the assistance based on the available power in the user's upper limb. All the participants in the feasibility study were on active assist mode and the device could alter the assistance level based on the performance of the user. None of the participants reached a zero assistance level during the study period, despite three participants feeling that they received no assistance from the device; this suggests all the participants needed some assistance to complete the tasks in the games.

Table 29. Participants' suggestions and research team discussions

Number of participants	**Suggestion**	**Discussion by research team**	**Action**
One	Device taking up considerable space in the kitchen	Further reduction is challenging to achieve; in fact, if target population were to include people with severe upper limb weakness, device likely to be bigger to accommodate attachments	None
One	Having a standard chair. And standard instructions on sitting position and position of arm while using device	Standard user instructions already mention these aspects of usage	User instructions to be made more clear in future instructions guide. Standard chair to be made integral part of device in future
One	Web-based camera to enable monitoring of therapy	Would enable tele-rehabilitation and monitor usage and progress	To be considered for future version of the device
One	Additional attachments like straps to hold hand on the joystick	Optional attachment to secure hand on to joystick would be useful when users have minimal voluntary hand control	To be considered for future version of the device
Six	Problems with joystick initialisation and double-clicking of switch	Joystick position when initializing needs to be clarified in the user instructions. Use of keypad instead of the switch to initialise might simplify the process	To be considered for future version of the device
Twelve	Games need to be made more interesting and challenging. Games based on functional activities and games suggested	Games design was restricted by available resources and expertise in designing hCAAR specific games that could be linked to the joystick movement	Games need to be further developed with including experts in this area and explore possible link up with commercial gaming.
One	Device could display performance over a period of time	Results and performance over a period of time need to included in the device feedback	Software update in the future version of the device

The professionals involved in the design and testing stage feedback interviews have appreciated the bimanual aspect of hCAAR therapy. The key underlying principle of bilateral therapy is to stimulate the motor area of the unaffected upper limb that is believed to have a modulating effect on the affected side motor cortical area. This was the basis for introducing the switch button in hCAAR for the unaffected upper limb. It is difficult to evaluate whether the activity of the unaffected upper limb in the hCAAR device was adequate to contribute to the functional gains seen in this study. This will need to be explored in future studies.

he need to remotely monitor the user during hCAAR therapy has been highlighted in the interviews. The remote therapist would have the advantage of being able to collect data without travelling and minimising the time used for each user, which can be substantial when home visits need to be done across a large geographic area. This is an aspect that needs to be the focus of future research.

In this study, the concept of the hCAAR has appealed to users and there were no drop-outs once users started using the device (there were two drop-outs prior to home use). When asked whether users preferred to use hCAAR at home or in a public place, most (15) participants preferred to use the device on their own in their homes. Two individuals expressed views that they became self-conscious when using the device in the presence of non-disabled or more-able individuals in a group. This suggests hCAAR should continue to be tested in home settings in future trials.

hCAAR gave the participants control and independence in their therapy needs, which two participants highlighted in the interviews. The user has the advantage of using the device when needed and can fit the therapy around their other commitments. The ability of using the device independently means they do not need to depend on a helper for their therapy.

hCAAR seemed to motivate some of the participants. Two participants stated that their mood had improved since using the device and they were among the most active users. One participant expressed a desire to be part of the next clinical study of the device. Two participants reported that being

part of a research study in itself motivated them to use the device. This encourages the research team to explore whether the motivation element of the therapy can be increased in future iterations of the device as it has been shown that motivation drives use of the device.

Participants' carers, families, relatives and friends seemed to be generally enthusiastic about the hCAAR device and were pro-active in suggesting future developments. This included feedback on both the hardware and software (games). They provided help and encouragement to the participants. The carers/families of seven participants had noticed improvement in upper limb movements and function and attributed these improvements to the device. This included two participants who had not noticed improvement themselves and their clinical scores confirmed the family perceived gains.

6.4.2 Matching of participant feedback with objective clinical measures

The matching of individual participant's perceived impact to objective clinical measures has not been undertaken in any robotic study in the current literature. Participants' and carers' perspectives compare well to the clinician-scored outcome measures in the hCAAR study. This lends more weight to the interpretation of the observed changes in the outcome measures. However some participants did not report any benefit in spite of the improvements observed in the outcome measures. This raises the possibility that the actual clinically significant values of the outcome measures might be much higher than the MCID values reported in the literature. The other possibility is that participants did not realise the improvements that had occurred. This was particularly observed in two participants where the family members reported more usage of the upper limb when participants themselves did not notice any improvement.

6.4.3 Matching of interview concepts and ICF Core Set categories

Finally, matching of the interview concepts to the Comprehensive ICF Core Set categories showed that most concepts were covered within the ICF Core Set. This suggests that researchers can use the Comprehensive ICF

Core Set for stroke as a tool to structure the content of their various methods of gathering feedback in the testing stage of technology development. Some interview concepts relate to the personal factors domain in ICF, which are yet to be categorised in the Comprehensive ICF Core Set and need to be considered in addition to the Core Set categories when using this approach. It has already been demonstrated that this approach can be used in the initial stages (concept and design stage) of understanding users' needs (Chapter 3).

6.4 Limitations

There are several limitations to this user-centred design process. Firstly, a relatively small sample of end-users and only one healthcare professional were included in the interviews. Only therapists providing conventional therapy to the participants alongside the device usage could be included in this process, hence only one therapist could be involved. The feedback received in the process was sufficient to give the researchers a flavour of user perspectives and the practical implications of using a home-based robotic device. The end-users did not include those who are not independently mobile and those with severe disability, which limits the generalisability of the results on acceptability and usability of the device.

The lack of researcher/therapist video monitoring meant we did not monitor users' positions when they were using the device. Ideally the device would be used as an adjunct to conventional therapy and there would be monitoring of hCAAR usage either by the attending therapist or by a remote supervision. This interaction would help encourage users to use the device for the full recommended usage time.

The range of games available limited the device usage. The usage time was below the recommended levels and users suggested improving the content and nature of games to suit their interests and needs. The games will need to be updated in future hCAAR studies to explore whether this aspect of the system can improve motivation and engagement of the user and lead to increased usage.

Finally, ideally, meaningful concepts should be linked to the most precise third-level ICF category as per the ICF linking rules [257] but we only linked them only to the second-level categories available in the Comprehensive ICF Core Set. The aim of this experiment was to explore only whether the ICF Core Set provides a useful template for user-feedback process and not to test the accuracy of the linking process. Hence the linking to the available second-level categories of the Comprehensive ICF Core Set is justified.

6.5 Conclusions

Seventeen stroke survivors with upper limb weakness have used the hCAAR device with minimal supervision. The device has been well accepted by users and family members in a home setting. Five participants reported a perceived therapeutic effect of hCAAR therapy. The participants and a healthcare professional have been involved in gathering useful feedback on the device that informs the future modifications needed in the device. The ICF framework provides a useful template to structure the content of user-feedback methods in device development.

Chapter 7: Conclusions and future directions

This research project aimed to develop a home-based robotic device to aid stroke survivors with upper limb weakness undertake upper limb exercises. In addition the project explored the feasibility of using the robotic device in the home setting and assessed its effects on upper limb function. This final chapter will present an overview of the results of this research, analyse the findings in the context of the current literature, discuss the limitations of this research and explore the potential research questions arising from the work described in this thesis.

7.1 Summary of research findings

Chapter 1 provided an overview of restorative rehabilitation robotic technology for upper limb rehabilitation exercises after stroke. Robotic technology has the potential to provide repetitive training of meaningful tasks in a stimulating and engaging environment. Previous studies involving upper limb robotic devices have demonstrated that robotic therapy can be as effective as intensive conventional physiotherapy, and can be used to overcome lack of resources in today's healthcare services. Most of the robotic devices tested so far have been used in hospital or research centre settings. Very few home-based devices are described in the current literature. There are clinical and technical challenges to overcome in the development of a technology that is acceptable to, and usable by, this population. There was an identified need to develop and test a home-based robotic device that can be used by stroke survivors either independently or under minimal supervision.

The future of any novel robotic device depends on its usability and its impact on upper limb function. An accurate measurement of its efficacy is a difficult task because of the moderate responsiveness of the outcome measures used in robot studies. So far there is a lack of consensus on the outcome measures that should be used in robot studies. In Chapter 2, all the outcome measures that have been used in all previous (upper limb) robot studies were systematically reviewed. They were categorised based on the ICF framework domains and a new algorithm for the selection of outcome

measures was proposed. Based on this algorithm, a combination of kinematic and clinical outcome measures was selected to be used in the feasibility study involving the home-based robotic device.

In Chapter 3, the user-centred design process to develop hCAAR was explored. Nine individuals with upper limb weakness after stroke and six healthcare professionals were involved in the semi-structured interviews. User needs and expectations were analysed and incorporated into the design of the device. The user-feedback interview content was mapped to the ICF Core Set categories to demonstrate the usefulness of the ICF framework template in the design and testing stage of device development process. The hardware and software components of hCAAR enable the individual to undertake assisted reach and retrieve movements with the hand (end-effector) moving in a single horizontal plane. The device provides therapeutic movements to the shoulder and elbow group of muscles of the affected upper limb. The unaffected upper limb also contributes to the computer tasks by operating a separate switch during game play.

Chapter 4 described the feasibility study materials and methods. Nineteen participants were recruited to undertake a clinical study involving 8-week home use of hCAAR. The study outcomes involved a combination of a) body function measures: kinematic measurements using the Optotrak and Optokat systems, MAS, MRC and FM-UE; b) activity-based measures: ARAT, CAHAI, ABILHAND; and c) personal, family and therapist impressions using semi-structured interviews. The kinematic and clinical outcome assessments were undertaken in the research laboratory at three points: baseline A0, post-use A1, and one month follow-up A2. The user-feedback interviews were conducted at A1. The statistical and clinical significance of the results were determined. Movement time and ABILHAND logit scores were used in multiple regression analyses to test the relationships between the predictive variables and the outcomes.

The feasibility study results described in Chapter 5 demonstrated that stroke survivors with upper limb weakness could safely use hCAAR in home settings. Two participants could not use the device in the home setting: one of them had severe upper limb weakness and was unable to generate active

movements to complete tasks even using at full assistance of the system. The other participant could not accommodate the device in his home and withdrew from the study. Seventeen participants completed the home use of the device for 8 weeks. A full set of kinematic and clinical assessments at all the three assessments points A0, A1 and A2 were available for 15 participants in total.

There was a statistically significant improvement in clinical and kinematic outcomes at A1 when compared to A0. The median improvement of clinical scores at A1 was 1 point in the FM-UE score, 3 points in the ARAT score, 5.5 points in CAHAI, 3 points in ABILHAND, 1.5 points in the total MAS score and 2 points in the total MRC. The kinematic scores showed a median improvement of 19% in movement time, 15% in path length and 19% in jerk scores at A1 in the far reach task. The clinical and kinematic improvements (except path length) were maintained at A2 suggesting the improvements were retained for 1 month after the use of hCAAR finished. Three participants showed clinically significant improvement in all the four clinical outcomes FM-UE, ARAT, CAHAI and ABILHAND.

Chapter 6 described the user-centred design qualitative feedback on hCAAR from the participants of the feasibility study and the healthcare professional involved with three participants in the study. The device was well accepted by users and family members in their home settings. Five participants and family members of seven participants reported a beneficial therapeutic effect of hCAAR therapy. Their qualitative feedback was comparable to the clinical outcome measure changes observed in the study. The users feedback on the device will inform the future modifications needed in the device. The matching of interview concepts to ICF Core Set categories confirmed that the ICF framework provides a useful template to structure the content of user-feedback methods in the testing stage of the device development process.

In summary, the research described in this thesis has led to the development of a robotic upper limb rehabilitation exercise device hCAAR that can be safely used in a home setting by stroke survivors with upper limb weakness. The feasibility study demonstrated the potential for the therapeutic

effect of improving upper limb movement and function. hCAAR is being re-designed and a larger scale clinical study is planned in the future.

7.2 Discussion

This research demonstrates that the hCAAR robotic device can be used safely in a home setting. Most of the previous robot studies have been conducted in research centres or hospitals and have had a therapist present with the patient in each treatment session. This is the first clinical study of its kind (excluding clinical case studies) in the literature in which the participants used a robotic device on their own in their homes with minimal supervision from healthcare professionals.

There is currently a paucity of home-based robotic devices that have been proven to be safe and able to be used independently by individuals with upper limb weakness. The spectrum of robotic devices in the current literature includes a) complex exoskeleton robotic devices that can carry out three- dimensional movement of the upper limb (such as ARMin) b) complex end-effector devices with low friction and high back-drivability (such as MIT-Manus) and c) simple low-cost planar devices with no back-drivability that can be used in home settings. Most of the robotic device research so far has been focused on developing and testing complex exoskeleton and complex end-effector devices. There is, however, an increasing need for simple low-cost robotic devices for home use. The stroke survivor population is expanding and there is an increased emphasis on moving rehabilitation resources from acute settings to the community. Resources in the community are however limited and time constrained. hCAAR has shown the potential to fill this gap in therapy resources for stroke survivors.

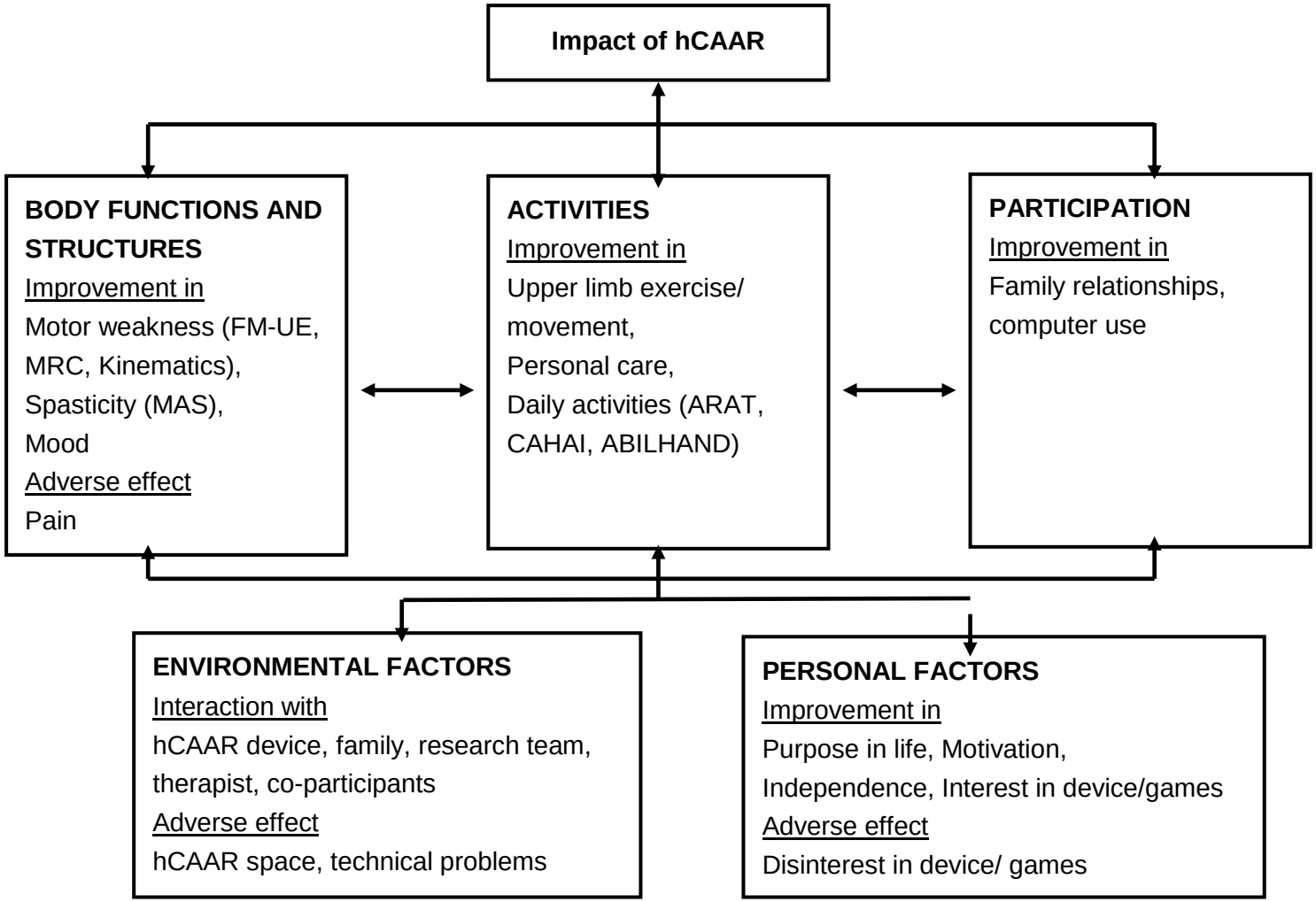
The musculoskeletal adverse events (shoulder pain, wrist pain) noted in this study are comparable to those seen in other robot studies [70]. General advice on the appropriate positioning of upper limb, rest, and using the available pain-free range of movements is the standard approach adopted in these studies. These musculoskeletal problems are also encountered in conventional therapy as well and similar management approaches are used.

The hCAAR study showed statistically significant improvement in two functional activity-based outcome measures CAHAI and ABILHAND, and at least five participants reported changes in functional activities. This is contrary to findings in the systematic review of robot studies that did not find evidence of changes in functional activities (based on changes in the FIM score) [118]. Two reasons could be identified for this finding; first, CAHAI and ABILHAND are more responsive measures than the FIM motor in upper limb motor recovery; and second, previous robot studies do not often include patient impressions of the impact of interventions as outcomes.

The hCAAR feasibility study demonstrated significant changes across all the domains of the ICF framework for stroke. A diagram with some examples of the changes in the various domains of the ICF framework is shown in Figure 33. The changes across the different outcome measures are not necessarily highly correlated as they represent different domains of the ICF framework. The different domains of ICF framework i.e., body function, activities, participation, personal and environmental factors, are related but do not have a causal relationship between them. The correlations between the outcome measures representing different domains are, therefore, at best, only moderate [278]. This emphasises the fact that measurement of change must occur across the different domains of ICF.

Most robot studies so far have involved high-cost complex devices with therapists being involved in delivering each session of robot therapy. The only large-scale economic analysis study involving the MIT-Manus robotic device concluded that there was no increased cost-effectiveness with robot therapy when compared to intensive conventional therapy [120]. The cost of the robotic device was $ 230,750 with additional maintenance costs ($15,000) and cost of therapist time ($120 for 15 min of therapist contact time per session) [120]. The cost of the hCAAR device is much lower (approx 5000 GBP) compared to this and there is no therapist time involved for each session. A cost-effectiveness analysis in comparison to conventional therapy needs to be done in future hCAAR studies in the home setting.

Figure 33. WHO's ICF framework diagram showing examples of the impact of hCAAR



7.3 Limitations

The user-centred design process had limitations. Users were involved in the initial stages but not every user feedback was incorporated in the final hCAAR device. The suggestion of movements being made more functional incorporating distal movements is difficult to include in a low-cost device for home use. The suggestions for games to be based on daily activities or sport could not be easily adapted as the resources available to create software programmes linked to the assistive joystick were limited in this study. The linking of interview concepts to ICF Core Set categories in this thesis was a retrospective exercise and future studies should use the Core Set categories to plan the interviews and explore the limitations and advantages of this approach.

hCAAR therapy is limited by the nature of the device. It is a planar robot providing exercises only to the proximal muscles of the upper limb. The current literature suggests that the benefits to proximal muscles from exercises do not extend to the distal muscles in the chronic stage of recovery. The device was designed with home use in mind and there was a need to keep the device as simple as possible. The provision of additional attachments/modules might provide additional therapy to distal muscles, but would make the device bigger and more complex making it less appealing for home use.

The concept of bilateral therapy has been incorporated in hCAAR; its actual contribution to motor recovery in this study is, however, inconclusive. Evidence on the amount and type of involvement of the unaffected limb in bilateral therapy is lacking. Most robotic devices promoting bilateral therapy such as MIME, BATRAC, BFIAMT, provide symmetrical bilateral therapy and one robot study did not show any benefit of bilateral therapy over unilateral therapy [60]. It is difficult to establish whether the activity of the unaffected upper limb had any role in the gains observed in the hCAAR study.

There was no mandatory minimum recommended usage time planned for this study. Even though participants were advised to use the device for at least 30 min every day for five days a week, the device software did not provide feedback on usage time to the participants during the study period. Lack of such reminders could have influenced device usage time in the study. Several participants suggested that the games lacked complexity and did not match their preferences. This could be one of the reasons for the low device usage time when compared to other robot studies.

Participants in the hCAAR study, even though they had a wide range of impairments, did not include individuals with significant visual field defects, severe language impairments, or those with severe mobility limitations. The selection of participants was influenced by the nature of the study in which the participants needed to be able to attend the research laboratory (using their own transport) for the introduction to the device and the outcome score assessments. Future hCAAR studies must include individuals with greater disability and older individuals to test usability in these population groups. Suitable outcome measures need to be chosen so that they can be completed at homes and avoid participants having to visit the research laboratory for the assessments.

The sample size of the feasibility study was not large enough to derive any definite conclusions on the efficacy of hCAAR therapy. The feasibility study however showed that some participants did benefit and the trends in changes between A0, A1 and A2 suggested the changes observed in this study were due to hCAAR usage. This suggests the therapy provided by the device has the potential to improve upper limb function and the actual effect size needs to be further explored in a larger sample of participants.

7.4 Future directions

It is believed that robotic therapy could fill the gap caused by resource constraints by providing intense practice of useful movements [119, 279]. The findings in various robot studies that robotic therapy can be as equally effective as intensive conventional physiotherapy support this view [53, 70]. The professionals involved in the hCAAR user-centred design process see the future of hCAAR as a useful adjunct to conventional therapy in the community. Community therapy in the current NHS is constrained, with many patients unable to get the intensity of therapy they need. The concept of telerehabilitation with robotic devices has been tried in only a few studies so far [93, 280]. hCAAR has shown the potential to provide such therapy in the future.

hCAAR, even though has been developed with stroke survivors in mind, can be used in other conditions resulting in upper limb weakness. Acquired brain injury (traumatic and non-traumatic), high cervical spinal cord injury, multiple sclerosis, and muscular dystrophy are some conditions where there is scope for using hCAAR to improve upper limb movement. For future research, it might be prudent to establish the efficacy of hCAAR in a larger stroke survivor population before exploring its use in other conditions.

7.4.1 Device modifications

The games of hCAAR need further development. The type of movements generated by the games will be limited by the planar nature of the device. However the content of the games could be improved and made more interesting and engaging. They could be based on the user's leisure interests, on sport, puzzles, word formation etc. Having a wider range of games will provide more options to the user. The drawback of planar movement can be overcome by extending the exercise prescription to include real life functional tasks in addition to the standard hCAAR therapy.

The performance feedback options should include giving feedback to the user over the entire usage time period and the option of a therapist remotely providing additional professional feedback using a webcam. The

device software could also prompt the user on usage time and encourage the user to meet the recommended usage time.

7.4.2 Research study design

7.4.2.1 Patient selection

hCAAR therapy needs to target individuals with moderate severity of upper limb weakness, i.e., a score between 15 and 40 on the FM-UE score. These individuals, particularly the individuals with scores between 15 and 30 are likely to engage the most and reap the most benefit from hCAAR therapy, as observed in the feasibility study. Individuals with severe weakness (FM-UE score less than 12 in this study) will experience difficulty in using the current version of the device even in full assistance mode. These individuals would also need additional support to hold up their upper limbs against gravity. Individuals with mild weakness (more than 40 FM-UE score) will have reasonable active upper limb movement and hCAAR might not be sufficiently challenging and appealing enough for them. They need the more complex functional tasks that are very well provided in conventional physiotherapy.

hCAAR therapy can be used in the subacute and chronic stages of recovery after stroke. In the current healthcare services, there seems to be gaps in the availability of therapy of sufficient intensity and duration in both the subacute and chronic stages of recovery. hCAAR can complement conventional physiotherapy and increase the intensity of practice of upper limb exercises. It also provides independence in ones own therapy and has the advantage of providing long-term therapy in people's homes.

7.4.2.2 Study design

A controlled study in a home environment is needed to compare a combination of hCAAR therapy and intensive conventional therapy with intensive conventional therapy alone. Such a comparison has already been done for complex hospital-based robotic devices. A crossover study can also be considered where every participant is assured the advantage of additional hCAAR therapy.

Multiple baseline assessment prior to study recruitment will ensure there is estimation of ongoing natural recovery prior to starting hCAAR

therapy. A previous robot study used a cut-off of 3 points difference in FM-UE scores between baseline assessments as an exclusion criterion to ensure that natural recovery did not influence the outcome [70]. This approach is needed in future hCAAR studies, particularly with participants in the subacute stage of recovery.

The long-term effects of hCAAR therapy needs further research. The feasibility study showed retention of gains at 1 month after stopping the use of hCAAR, but long-term benefits to upper limb function are unknown. Follow-up assessments at 6 months and 1 year will help understand the long-term benefits, such assessments have rarely been done in previous robot studies [281].

7.4.2.3 Intervention

The true efficacy of intervention will be known only when the device usage time improves in future studies. The total therapy time in a future study needs to exceed at least 1200 min, which is approximately 30 min therapy per session each day, 5 days a week for 8 weeks. The device software could prompt the user to meet the recommended therapy time. Remote connection to a therapist via the web will help monitor the therapy, maintain motivation and provide professional feedback to the user.

7.4.2.4 Outcomes

The hCAAR feasibility study had a carefully selected combination of outcome measures spanning the different domains of the ICF framework. FM-UE is the most commonly used outcome measure in robot studies and must continue to be used in future studies to enable comparison and meta-analysis of the data. Kinematic measurements using optical tracking mechanisms in a research laboratory is time consuming, resource intensive and needs participants to attend the laboratory for assessments. The robotic device records joystick movement characteristics and can provide assessment of some kinematic variables such as movement time, path length and jerk. These measures can be used instead of external kinematic assessments using optical tracking equipment.

ARAT is a standard activity measure that is gaining popularity in stroke rehabilitation research studies. The kit is transportable, does not need to be cleaned prior to use and the tests can be completed in the home setting. The only problem with this outcome measure is its floor effect, and its poor discrimination between participants at baseline, which means it cannot be used as a screening measure. Both ABILHAND and CAHAI are activity measures and were found to be similarly responsive in this study. ABILHAND is a patient-reported outcome and can be completed without needing any equipment. CAHAI, however, needs a standard kit and involves a considerable amount of cloth used in various items. The cloth material needs cleaning prior to each use and this could limit its use in large samples of participants. A combination of ARAT and ABILHAND seems to be the most sensible combination of activity measures for future use.

Measures to capture changes at the participation level (or health-related quality of life level) such as EQ-5D or SF-36 were not included in this study as this was not felt necessary at the stage of testing feasibility of hCAAR use. These measures will need to be considered in future larger scale studies. This needs to be combined with participant, family and carer qualitative feedback on usability and impact on upper limb function, as was done in the feasibility study. The user feedback was via semi-structured interviews in this study. The use of Likert scales for structured feedback is an alternative option that could be considered in the future.

7.5 Summary

In conclusion, a home-based restorative rehabilitation robotic device hCAAR has been developed using a user-centred design process that involved stroke survivors, carers and healthcare professionals. The hCAAR feasibility study was the first clinical study of its kind reported in the literature; in this study, 17 participants used the robotic device independently for eight weeks in their own homes with minimal supervision from healthcare professionals. Statistically significant improvements were observed in the kinematic and clinical outcomes in the study.

In the future, the hCAAR games could be improved and the feedback the device provides to the user on their results and performance needs to be developed. Internet linkage to a remote therapist to monitor the therapy and provide professional feedback must also be considered. A future clinical study would need to explore the use of hCAAR in a larger, more heterogeneous sample of participants in the home setting. A study design comparing the combination of conventional therapy and hCAAR with conventional therapy alone needs to be explored. A combination of outcome measures that span the domains of the ICF framework needs to be included in any future study.

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Appendix A. The Comprehensive ICF Core Set for stroke

Table 30. Comprehensive ICF Core Set for stroke (Reproduced from Geyh et al. 2004) [236]

International Classification of Functioning, Disability and Health (ICF) – categories of the component body functions included in the Comprehensive ICF Core Set for stroke

Code	Category title
b110	Consciousness functions
b114	Orientation functions
b117	Intellectual functions
b126	Temperament and personality functions
b130	Energy and drive functions
b134	Sleep functions
b140	Attention functions
b144	Memory functions
b152	Emotional functions
b156	Perceptual functions
b164	Higher-level cognitive functions
b167	Mental functions of language
b172	Calculation functions
b176	Mental function of sequencing complex movements
b180	Experience of self and time functions
b210	Seeing functions
b215	Functions of structures adjoining the eye
b260	Proprioceptive function
b265	Touch function
b270	Sensory functions related to temperature and other stimuli
b280	Sensation of pain
b310	Voice functions
b320	Articulation functions
b330	Fluency and rhythm of speech functions
b410	Heart functions
b415	Blood vessel functions

b420 Blood pressure functions
b455 Exercise tolerance functions
b510 Ingestion functions
b525 Defecation functions
b620 Urination functions
b640 Sexual functions
b710 Mobility of joint functions
b715 Stability of joint functions
b730 Muscle power functions
b735 Muscle tone functions
b740 Muscle endurance functions
b750 Motor reflex functions
b755 Involuntary movement reaction functions
b760 Control of voluntary movement functions
b770 Gait pattern functions

International Classification of Functioning, Disability and Health (ICF) – categories of the component body structures included in the Comprehensive ICF Core Set for stroke

Code Category title
s110 Structure of brain
s410 Structure of cardiovascular system
s720 Structure of shoulder region
s730 Structure of upper extremity
s750 Structure of lower extremity

International Classification of Functioning, Disability and Health (ICF) – categories of the component activities and participation included in the Comprehensive ICF Core Set for stroke

Code Category title
d115 Listening
d155 Acquiring skills
d160 Focusing attention
d166 Reading
d170 Writing

d172 Calculating
d175 Solving problems
d210 Undertaking a single task
d220 Undertaking multiple tasks
d230 Carrying out daily routine
d240 Handling stress and other psychological demands
d310 Communicating with – receiving – spoken messages
d315 Communicating with – receiving – non-verbal messages
d325 Communicating with – receiving – written messages
d330 Speaking
d335 Producing non-verbal messages
d345 Writing messages
d350 Conversation
d360 Using communication devices and techniques
d410 Changing basic body position
d415 Maintaining a body position
d420 Transferring oneself
d430 Lifting and carrying objects
d440 Fine hand use
d445 Hand and arm use
d450 Walking
d455 Moving around
d460 Moving around in different locations
d465 Moving around using equipment
d470 Using transportation
d475 Driving
d510 Washing oneself
d520 Caring for body parts
d530 Toileting
d540 Dressing
d550 Eating
d570 Looking after one’s health
d620 Acquisition of goods and services
d630 Preparing meals
d640 Doing housework
d710 Basic interpersonal interactions
d750 Informal social relationships

d760 Family relationships
d770 Intimate relationships
d845 Acquiring, keeping and terminating a job
d850 Remunerative employment
d855 Non-remunerative employment
d860 Basic economic transactions
d870 Economic self-sufficiency
d910 Community life
d920 Recreation and leisure

International Classification of Functioning, Disability and Health (ICF) – categories of the component environmental factors included in the Comprehensive ICF Core Set for stroke

Code Category title

e110 Products or substances for personal consumption
e115 Products and technology for personal use in daily living
e120 Products and technology for personal indoor and outdoor mobility and transportation
e125 Products and technology for communication
e135 Products and technology for employment
e150 Design, construction and building products and technology of buildings for public use
e155 Design, construction and building products and technology of buildings for private use
e165 Assets
e210 Physical geography
e310 Immediate family
e315 Extended family
e320 Friends
e325 Acquaintances, peers, colleagues, neighbours and community members
e340 Personal care providers and personal assistants
e355 Health professionals
e360 Health-related professionals
e410 Individual attitudes of immediate family members
e420 Individual attitudes of friends

e425 Individual attitudes of acquaintances, peers, colleagues, neighbours and community members
e440 Individual attitudes of personal care providers and personal assistants
e450 Individual attitudes of health professionals
e455 Individual attitudes of health-related professionals
e460 Societal attitudes
e515 Architecture and construction services, systems and policies
e525 Housing services, systems and policies
e535 Communication services, systems and policies
e540 Transportation services, systems and policies
e550 Legal services, systems and policies
e555 Associations and organizational services, systems and policies
e570 Social security services, systems and policies
e575 General social support services, systems and policies
e580 Health services, systems and policies
e590 Labour and employment services, systems and policies

Appendix B. Patient interview topics checklist – concept stage of device development

Table 31. End-user interview topics checklist - concept stage

Time of stroke, type of stroke, weak side
Dominant side
Motor/sensory problems
Vision/speech/cognitive problems/seizures
Perception problems – Inattention/neglect
Pain and its impact on activities
Mood
Employment, medications, other medical problems
Therapy received as inpatient/outpatient
Home exercises – characteristics
Impression on therapy received and expectations
Reasons for not getting needed therapy
Usage of weak arm in bilateral activities
Compensatory strategies to perform ADL
Functional goals
Support available for performing exercises at home
Cost of technology and affordability
Concept of computer-based device in home - impressions
Suitability of home setting
Suggestions on features of home device
Home computer
Computer usage/experience/skills
Experience of computer games
Leisure interests – games based on interests and engagement
Experience of using technology-based device for exercises – e.g., Wii
Belief/impressions about technology for arm exercises
Independence and control in therapy program
Advantages and drawbacks of technology based exercises when compared to conventional hands-on physiotherapy
Preference of environment for usage of technology
Any other comments/suggestions

Appendix C. Healthcare professional interview topics checklist – concept stage of device development

Table 32. Professional user interview topics checklist - concept stage

Therapy received by stroke patients as inpatients – characteristics
Outpatient therapy – characteristics/ duration/ intensity etc.
Criteria for outpatient therapy
Home exercises program - characteristics
Compliance of patients with home exercises
Impressions on duration and intensity of therapy for affected arm
Optimal time period for maximum recovery
Therapy based on computer games - impressions
Design spec. of such technology
Exercises for neglect/ perception problems
Exercise recommendations if pain in the affected arm
Exercise recommendations for stiffness in the affected arm
Advice given to patients on involving weak arm in bilateral activities
Therapy based on functional activities – Impressions/ recommendations
Functional activities targeted
Beliefs/Impressions about technology delivering arm exercises
Independence of patients in rehabilitation program
Drawbacks of technology over conventional hands-on physiotherapy
Home-based computer device for arm exercises - impressions
Features of such a device
Exercise preferences – individual/ group for technology-based exercises
Deployment in community centres such as stroke club

Appendix D. Clinical and Kinematic measurements of individual participants

Participant ID 1

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 1 are shown in the tables below. The scores improved across most clinical outcome measures and all three kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 1)

	A0	A1	A2	A1 – A0	A2 – A0
FM-UE	33	33	30	0	- 3
ARAT	37	41	47	4	10
CAHAI	51	60	65	9	14
ABILHAND (Logit score)	22 (- 0.008)	25 (0.263)	32 (1.199)	3	10
Total MAS	12	8.5	11	- 3.5	- 1
Total MRC	34	NA	40	NA	6

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 1)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.46	0.50	0.25	0.27	0.26	0.30	-45	-47	-44	-40
PL	205.44	218.00	150.41	132.16	125.66	138.09	-27	-39	-39	-37
NJ	186.21	260.39	56.72	122.14	143.33	149.87	-70	-53	-23	-42

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement

Participant ID 2

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 2 are shown in the tables below. CAHAI, ABILHAND and MRC improved at A1 and were maintained at A2. The kinematic parameters improved except for jerk in the far reach task.

Table. Changes in clinical outcome scores (participant ID 2)

	A0	A1	A2	A1 – A0	A2 – A0
FM-UE	12	12	11	0	- 1
ARAT	0	1	0	1	0
CAHAI	16	19	26	3	10
ABILHAND (Logit score)	7 (- 2.322)	18 (- 0.635)	17 (- 0.769)	11	10
Total MAS	15.5	15	16.5	- 0.5	1
Total MRC	33	37	35	4	2

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 2)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.35	0.44	0.29	0.40	0.33	0.41	-15	-9	-4	-8
PL	185.92	241.31	127.80	173.09	130.12	180.69	-31	-28	-30	-25
NJ	414.03	200.06	213.84	551.41	199.87	445.01	-48	176	-52	122

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement

Participant ID 3

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 3 are shown in the tables below. Most clinical measures showed improvement with improved performance of kinematic parameters (with the exception of the far reach task at A2).

Table. Changes in clinical outcome scores (participant ID 3)

	A0	A1	A2	A1 – A0	A2 – A0
FM-UE	36	33	34	- 3	- 2
ARAT	52	53	56	1	4
CAHAI	54	59	68	5	14
ABILHAND (Logit score)	12 (- 1.329)	13 (- 1.247)	12 (- 1.407)	1	0
Total MAS	6	5.5	5.5	- 0.5	- 0.5
Total MRC	39	39	40	0	1

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 3)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.4	0.5	0.27	0.33	0.3	0.52	-31	-34	-24	4
PL	128.43	164.94	123.57	145.52	120.56	182.81	-4	-12	-6	11
NJ	355.54	381.41	270.93	294.39	187.38	384.15	-24	-23	-47	1

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement

Participant ID 4

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 4 are shown in the tables below. Kinematic measurements show deterioration of most parameters in both near reach and far reach tasks.

Table. Changes in clinical outcome scores (participant ID 4)

	A0	A1	A2	A1 – A0	A2 – A0
FM-UE	30	32	29	2	- 1
ARAT	20	24	24	4	4
CAHAI	30	NA	46	NA	16
ABILHAND (Logit score)	15 (- 0.511)	19 (- 0.462)	19 (- 0.377)	4	4
Total MAS	8.5	NA	6.5	NA	- 2
Total MRC	37	NA	40	NA	3

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 4)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.36	0.44	0.49	0.70	0.41	0.62	34	60	13	43
PL	112.03	138.63	108.49	197.02	111.28	165.94	-3	42	-1	20
NJ	308.80	488.81	502.32	715.66	604.40	517.88	63	46	96	6

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 5

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 5 are shown in the tables below. Only A1 assessment results were available; these show improvements in the clinical scores at A1 that did not match with the variable changes of the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 5)

	A0	A1	A2	A1 – A0
FM-UE	32	36	-	4
ARAT	20	32	-	12
CAHAI	44	59	-	15
ABILHAND (Logit score)	12 (- 1.428)	17 (- 0.539)	-	5
Total MAS	13	6	-	- 7
Total MRC	31	40	-	9

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 5)

	A0		A1		A1 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**
MT	0.40	0.47	0.42	0.47	7	0
PL	143.66	158.88	116.91	137.93	-19	-13
NJ	252.76	383.55	324.40	317.93	28	-17

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 6

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 6 are shown in the tables below. The clinical scores improved by marginal amount across all outcome measures and are accompanied by increase in all kinematic parameters in both near reach and far reach tasks at A1 and A2.

Table. Changes in clinical outcome scores (participant ID 6)

	A0	A1	A2	A1 – A0	A2 – A0
FM	37	38	41	1	4
ARAT	42	42	44	0	2
CAHAI	78	79	79	1	1
ABILHAND (Logit score)	35 (1.962)	36 (2.151)	36 (2.510)	1	1
Total MAS	14.5	9.5	7.5	- 5	- 7
Total MRC	38	40	40	2	2

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 6)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.35	0.45	0.34	0.36	0.33	0.38	-2	-19	-7	-16
PL	124.11	145.29	119.07	144.25	109.13	133.67	-4	-1	-12	-8
NJ	715.49	648.92	182.15	189.53	260.12	339.30	-75	-71	-64	-48

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 7

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 7 are shown in the tables below. Only A2 results were available; these show marginal improvement in the clinical scores but deterioration of the kinematic parameters movement time and path length.

Table. Changes in clinical outcome scores (participant ID 7)

	A0	A1	A2	A2 – A0
FM	32	-	36	4
ARAT	37	-	37	0
CAHAI	44	-	46	2
ABILHAND (Logit score)	16 (- 0.826)	-	19 (- 0.194)	3
Total MAS	10	-	9	- 1
Total MRC	42	-	43	1

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 7)

	A0		A2		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**
MT	0.57	0.64	0.80	0.74	40	16
PL	145.96	175.94	191.33	192.86	31	10
NJ	294.48	386.52	130.27	312.10	-56	-19

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 8

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 8 are shown in the tables below. The results suggest significant improvements of clinical and kinematic scores at both A1 and A2.

Table. Changes in clinical outcome scores (participant ID 8)

	A0	A1	A2	A1 – A0	A2 – A0
FM	19	24	31	5	12
ARAT	9	19	27	10	18
CAHAI	24	44	59	20	35
ABILHAND (Logit score)	11 (- 1.496)	15 (- 0.777)	20 (- 0.046)	4	9
Total MAS	16	N/A	10.5	N/A	- 5.5
Total MRC	31	N/A	39	N/A	8

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 8)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	1.15	1.57	0.49	0.59	0.27	0.60	-57	-63	-76	-62
PL	303.33	321.62	174.04	184.65	97.49	191.59	-43	-43	-68	-40
NJ	370.38	601.58	393.99	450.88	216.76	392.50	6	-25	-41	-35

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 9

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 9 are shown in the tables below. The results suggest small improvements in clinical scores and in most of the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 9)

	A0	A1	A2	A1 – A0	A2 – A0
FM	42	43	44	1	2
ARAT	53	54	54	1	1
CAHAI	80	81	81	1	1
ABILHAND (logit score)	29 (1.958)	31 (2.001)	34 (2.065)	2	5
Total MAS	2	1	0	- 1	- 2
Total MRC	40	40	41	0	1

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 9)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.40	0.46	0.44	0.38	0.27	0.42	8	-17	-32	-9
PL	175.78	203.05	156.80	168.35	133.07	181.37	-11	-17	-24	-11
NJ	267.92	326.57	258.17	433.11	205.52	351.20	-4	33	-23	8

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 10

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 10 are shown in the tables below. The results suggest improvements in clinical scores and most of the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 10)

	A0	A1	A2	A1 – A0	A2 – A0
FM	20	29	32	9	12
ARAT	23	37	40	14	17
CAHAI	44	51	54	6	10
ABILHAND (logit score)	13 (- 0.324)	33 (1.915)	33 (2.359)	20	20
Total MAS	15.5	15	13.5	- 0.5	- 2
Total MRC	35	37	39	2	4

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 10)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.55	0.79	0.41	0.47	0.31	0.42	-26	-40	-43	-47
PL	131.49	190.00	133.39	152.98	111.84	149.74	1	-19	-15	-21
NJ	396.88	379.00	226.41	391.79	263.08	363.64	-43	3	-34	-4

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 11

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participants eleven are shown in the tables below. The results suggest improvements in clinical scores and in most of the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 11)

	A0	A1	A2	A1 – A0	A2 – A0
FM	15	17	20	2	5
ARAT	2	5	5	3	3
CAHAI	37	41	47	4	10
ABILHAND (Logit score)	5 (- 2.849)	6 (- 2.603)	13 (- 1.335)	1	8
Total MAS	14.5	12	13	- 2.5	- 1.5
Total MRC	31	37	40	6	9

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 11)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.49	0.61	0.48	0.37	0.65	0.44	-1	-39	33	-28
PL	93.97	143.38	99.08	114.61	155.86	133.62	5	-20	66	-7
NJ	339.00	461.85	270.12	388.65	233.26	378.49	-20	-16	-31	-18

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 13

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 13 are shown in the tables below. The results suggest improvements in clinical scores and in most of the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 13)

	A0	A1	A2	A1 – A0	A2 – A0
FM	18	28	28	10	10
ARAT	5	8	12	3	7
CAHAI	32	42	53	10	21
ABILHAND (logit score)	17 (- 0.582)	24 (0.410)	22 (0.127)	7	5
Total MAS	18.5	14.5	10.5	- 4	- 8
Total MRC	25	40	40	15	15

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage change in kinematic parameters (participant ID 13)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.43	0.56	0.28	0.50	0.43	0.45	-35	-11	-2	-20
PL	132.85	149.20	107.24	155.95	129.68	165.95	-19	5	-2	11
NJ	610.27	939.37	228.34	379.03	353.59	391.28	-63	-60	-42	-58

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 14

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 14 are shown in the tables below. The results suggest improvements in most clinical scores and most of the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 14)

	A0	A1	A2	A1 – A0	A2 – A0
FM	29	32	28	3	- 1
ARAT	10	18	11	8	1
CAHAI	56	65	68	9	12
ABILHAND (Logit score)	27 (0.888)	31 (1.700)	31 (1.745)	4	4
Total MAS	11	9.5	7.5	- 1.5	- 3.5
Total MRC	38	40	40	2	2

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 14)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.54	1.30	0.53	0.62	0.49	0.58	-2	-52	-9	-56
PL	149.98	219.58	200.95	187.74	141.83	162.98	34	-14	-5	-26
NJ	294.61	447.75	258.87	301.12	399.50	433.65	-12	-33	36	-3

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 16

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 16 are shown in the tables below. The results suggest small improvements in some clinical scores and in some of the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 16)

	A0	A1	A2	A1 – A0	A2 – A0
FM	43	44	44	1	1
ARAT	55	56	55	1	0
CAHAI	69	74	69	5	0
ABILHAND (Logit score)	31 (1.418)	34 (1.662)	31 (1.057)	3	0
Total MAS	7.5	5.5	6	- 2	- 1.5
Total MRC	40	40	40	0	0

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 16)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.40	0.53	0.36	0.44	0.42	0.46	-10	-18	3	-14
PL	160.35	206.70	151.63	176.17	162.67	175.89	-5	-15	1	-15
NJ	390.01	483.22	500.36	512.30	257.71	282.67	28	6	-34	-42

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 17

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 17 are shown in the tables below. The results suggest small improvements in clinical scores at A1 but these are not maintained at A2. The kinematic parameters show variable results.

Table. Changes in clinical outcome scores (participant ID 17)

	A0	A1	A2	A1 – A0	A2 – A0
FM	28	29	28	1	0
ARAT	12	14	8	2	- 4
CAHAI	23	28	23	5	0
ABILHAND (Logit score)	21 (- 0.141)	22 (- 0.008)	22 (0.088)	1	0
MAS	13	12.5	10	- 0.5	- 3
MRC	36	39	40	3	4

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 17)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.52	0.64	0.92	0.94	0.43	0.67	78	48	-18	5
PL	168.28	187.12	241.50	273.02	137.92	177.76	44	46	-18	-5
NJ	734.81	488.05	240.02	486.26	586.63	332.39	-67	0	-20	-32

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 18

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 18 are shown in the tables below. The results suggest small improvements in most clinical scores and in some of the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 18)

	A0	A1	A2	A1 – A0	A2 – A0
FM	29	30	30	1	1
ARAT	29	31	33	2	4
CAHAI	40	47	46	7	6
ABILHAND (Logit score)	7 (- 2.322)	3 (- 2.930)	8 (- 2.109)	- 4	1
Total MAS	9.5	8.0	5.5	- 1.5	- 4
Total MRC	39	40	40	1	1

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 18)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.29	0.53	0.46	0.47	0.37	0.42	57	-11	27	-21
PL	117.87	150.57	113.15	128.50	109.80	133.33	-4	-15	-7	-11
NJ	127.49	349.40	253.62	283.90	174.89	279.12	99	-19	37	-20

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Participant ID 19

The total scores for the clinical outcome measures and kinematic parameters at three assessment points for participant ID 19 are shown in the tables below. The results suggest improvement in most of the clinical scores and in all the kinematic parameters.

Table. Changes in clinical outcome scores (participant ID 19)

	A0	A1	A2	A1 – A0	A2 – A0
FM	37	42	39	5	2
ARAT	47	51	51	4	4
CAHAI	79	85	85	6	6
ABILHAND (Logit score)	21 (- 0.141)	27 (0.888)	27 (0.888)	6	6
Total MAS	4	1.5	4	- 2.5	0
Total MRC	40	40	40	0	0

FM-UE	Fugl Meyer Upper Extremity motor subscale
ARAT	Action Research Arm Test
CAHAI	Chedok Arm and Hand Activity Inventory
MAS	Modified Ashworth Scale
MRC	Medical Research Council
	Improvement
	Deterioration

Table. Percentage changes in kinematic parameters (participant ID 19)

	A0		A1		A2		A1 - A0 % change		A2 - A0 % change	
	Near reach	**Far reach**	**Near reach**	**Far reach**	**Near reach**	**Far reach**	**NR**	**FR**	**NR**	**FR**
MT	0.48	0.51	0.34	0.35	0.24	0.28	-30	-32	-50	-45
PL	120.24	148.57	112.51	136.54	113.29	142.36	-6	-8	-6	-4
NJ	386.61	351.03	295.92	284.16	149.16	203.99	-23	-19	-61	-42

MT	Movement Time
PL	Path Length
NJ	Normalised Jerk
NR	Near Reach
FR	Far Reach
	Improvement
	Deterioration

Appendix E. Participant interview checklist (feasibility study)

Table 33. Participant interview topics checklist (feasibility study)

ID
General views about the device
Suggestions for improvements
Hardware
Views on computer/ joystick/ chair/ seating/ height
Size of the device
Room in which device installed
Problems encountered while using the device at home
Used independently/ help needed
Software
Views on assistance provided by joystick
Games
Score display after game
Suggestions for developing games in the future
Exercise
Views on the concept of therapy based on games
Usage
Suggestions
Impact
Change in arm movement ability/ROM/sensation/pain/stiffness
ADL/functional ability/employment
Personal goals
Mood and cognition
Others
Using device at home alone vs. multi-user mode
Views of friends, family, carers about the device
Views of therapists/ professionals about the device
Others views on impact on arm movement/ function
Use in community (stroke centre etc)
Commercial aspect of the device

Appendix F. Healthcare professional interview checklist (feasibility study)

Table 34. Healthcare professional interview topics checklist (feasibility study)

ID
Involved with ? participants using device
General views about the device
Suggestions for improvements
Hardware
Views on computer/joystick/chair/seating/height
Size of the device
Problems encountered while patients using the device at home
Suggestions for the future
Software
Views on assistance provided by the joystick
Games
Score display after game
Suggestions on developing games in the future
Exercise
Views on the concept of therapy based on games
Therapy delivered by device
Concept of bimanual therapy
Usage/ compliance
Suggestions
Impact
Change in arm movement/ROM/sensation/pain/stiffness
ADLs/functional ability/personal goals
Mood and cognition
Others
Views on single user at home / multi-user mode in community
Commercial aspect of device
Future research – trial design
Patient selection
Time after stroke