# RESEARCH PROTOCOL

## Coaching individuals with a neurological condition to use the SMART Arm to drive their recovery

## INVESTIGATORS AND AFFILIATIONS


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This project has received no financial support from SMART Arm Pty Ltd, the commercialization entity for the SMART Arm device. The device to be used in this project is the property of James Cook University. Ruth Barker is a part of the inventor team of the SMART Arm device. JCU and NAPHL are shareholders in SMART Arm Pty Ltd, the company that is in the process of commercialising the SMART Arm.


## INSTITUTIONS AND ADDRESSES WHERE THE RESEARCH WILL TAKE PLACE

This research will be conducted at Community Rehab nQ, 16 Ryan St, Belgian Gardens Q 4810. It is anticipated that data analysis will be carried out at James Cook University, Cairns Campus.

## BACKGROUND

Upper limb recovery after stroke and other neurological conditions is notoriously poor (Houwink, Nijland, Geurts, & Kwakkel, 2013) (Kong, Chua, & Lee, 2011) (Welmer, Holmqvist, & Sommerfeld, 2008). An innovative intervention, the SMART Arm, was developed to enable people with moderate to severe upper limb paresis undertake intensive task-oriented training, to promote arm and hand recovery. Twelve hours of SMART Arm training over a four week period has been shown to significantly reduce arm impairment and improve arm activity in people with arm dysfunction resulting from stroke (Barker, Brauer, & Carson, 2008; Hayward, Barker, Carson, & Brauer, 2014). National Stroke Guidelines 2010 suggest that the greatest benefits from SMART Arm training are likely to occur if training is of a high volume, occurs daily, and is integrated into use of the affected arm in everyday tasks (National Stroke Foundation, 2010).

The SMART Arm has been designed to enable individuals with a neurological condition, particularly stroke, to practice independently, *without* a clinician present, so that they are able to drive their own recovery and continuously achieve the intensity of practice required to recover in the long term. At Community Rehab nQ (CRnQ) however, there has been a tendency for SMART Arm training to occur *with* a clinician present. A possible explanation is that the basic SMART Arm train-the-trainer course focuses on providing the clinician with the skills to set-up the individual with a neurological condition on the SMART Arm, provide training, progress their practice and integrate their practice into everyday tasks. Little attention has been given to clinicians coaching individuals with a neurological condition to carry out all aspects of training themselves. Hence, the need for a SMART Arm advanced train-the-trainer course has been identified. The focus of this course needs to be on coaching the individual with a neurological condition to set-up, practice, progress optimally and use their arm in everyday tasks either independently or with a significant other to help them.

The potential benefits of clinicians undertaking this advanced train-the-trainer course is that individuals with neurological conditions will be taught how to work independently, to maximise volume and quality of practice and hence, maximize arm recovery after stroke, brain injury or other neurological conditions. This approach has particular relevance and application in regional, rural and remote NQ where access to rehabilitation services may be limited and the need to 'drive your own recovery' is critical.

## AIM

The aim of this project is to design and evaluate an advanced SMART Arm train-the-trainer course, for Occupational Therapists, Physiotherapists and Rehab Assistants, focused on coaching individuals with a neurological condition to set-up, practice and progress optimally, either independently, or with only a significant other to help them.

Objectives of the research are to:

1. Determine requirements for a SMART Arm Advanced Training Course
2. Develop a SMART Arm Advanced Training Course and corresponding Capabilities Assessment Tool
3. Pilot SMART Arm Advanced Training with clinicians who use the SMART Arm at CRnQ
4. Evaluate the SMART Arm Advanced Training Course and make recommendations for refinement.

The expected research outcomes will include a SMART Arm Advanced Training Course and corresponding Capabilities Assessment Tool designed for use by clinicians who will offer SMART Arm Training as part of their rehabilitation service. In addition, Occupational Therapists, Physiotherapists and Rehab Assistants at CRnQ will have received SMART Arm Advanced Training and will have been assessed as capable, by trainers and individuals with a neurological condition.

## METHODS

Overview

A sequential mixed methods design will be utilised with a sample of 40 individuals with a neurological condition and 10 clinicians working at CRnQ. Throughout the study period, all participating individuals with a neurological condition that are identified as potentially benefitting from SMART Arm training will be invited to participate in the study. If consent is given, they will undertake SMART Arm training as part of their rehabilitation program. All CRnQ physiotherapists, occupational therapists and rehabilitation assistants will be invited to participate in the study. If consent is given, they will deliver SMART Arm training for the participating individuals with a neurological condition, as part of their practice.

Phase I of the study will involve development and administration of a quantitative and qualitative survey questionnaire to determine requirements for SMART Arm Advanced Training. Survey questionnaire development will be drawn from established SMART Arm clinical guidelines as well as recent findings in the scientific literature. The newly developed survey will be administered with participating individuals with a neurological condition and clinicians who have respectively participated in, or delivered, SMART Arm training at CRnQ. In order to verify and interpret survey findings, two focus groups will be conducted, one with a selection of individuals with a neurological condition and one with clinicians, all of whom will have previously completed the survey. Focus groups will be audiotaped and transcribed verbatim and a simple descriptive analysis of the data undertaken.

Phase II of the study will involve development and piloting of the SMART Arm Advanced Train-the Trainer Course materials and corresponding Capability Assessment Tool and will be based on Phase I outcomes. All participating clinicians will undertake the new Train-the-Trainer Course. Immediately following the course participating clinicians will complete the Capability Assessment, with respect to their own capability. Results will be collated and feedback provided, to clinicians as a group, and advice provided on areas for improvement. Three months and six months later, clinicians will complete the Capability Assessment Tool again. In addition, those individuals with a neurological condition that have participated in SMART Arm training during the period following delivery of the Advanced Training course will complete the Capability Assessment (with respect to clinicians capability) at the three month and six month time-point. At each time-point, group feedback on collated results will be provided to clinicians and advice given to address areas for improvement. Following the six-month time-point, outcomes of the capability assessments will be collated and used to refine the Train-the Trainer Course.

Recruitment Processes

*Participants – individuals with a neurological condition*

An estimated forty individuals with a neurological condition aged over 15 years whose arm function has been reduced as a result of the neurological condition, and that receive a service from Community Rehab nQ during the study period, will be invited to participate in the study. Identification of those individuals who meet the eligibility criteria will occur within the comprehensive assessment at their first appointment with CRnQ, or, at any time during their Rehabilitation Program. Once identified, they will be approached by one of the Occupational Therapists and Physiotherapists at CRnQ and provided with an explanation of the study and an information sheet outlining the objectives of the research, all requirements of participation, as well as potential benefits and risks of their participation. If time limits the clinician' s ability to fully explain what is involved or if the potential participant has further questions, the CRnQ Research Assistant (CS) or Research Lead (RW) will provide the information required. All potential participants will be made aware that they will not be able to use the SMART Arm device if he or she is not a participant in the study.

If individuals would like to participate, they will be asked to sign an Informed Consent form. If they are physically unable to write but do have the capacity to understand and consent, their legal guardian will be asked to sign on their behalf. If they have cognitive or linguistically based communication limitations, a potential participant's capacity to consent will be determined by the Speech Pathologist and Occupational

Therapist working with them as part of their regular rehabilitation program. Legal guardians, of the person with a neurological conditions who is eligible to participate but does not have the capacity to consent, will be approached by the CRnQ Research Assistant, provided with an explanation of the study and an information sheet. As appropriate, the Speech Pathologist will speak with the eligible participant in the presence of their legal guardian to provide an appropriately modified explanation of the study and requirements for participation. The legal guardian will be asked to sign the informed consent form to enable the person with the neurological condition to participate in the study. Evidence that they are the legal guardian must be provided.

If the potential participant is less than 18 years old, assessment of their vulnerability and capacity to consent will be done by the Social Worker who is involved in their care. The legal guardian of the younger person will be approached by the CRnQ Research Assistant, provided with an explanation of the study and an information sheet. As appropriate, the Social Worker will speak with the younger person in the presence of their legal guardian to provide an appropriately modified explanation of the study and requirements for participation. The younger person will be asked to sign a consent form for individuals under 18 years old. Their legal guardian will also be asked to sign the regular consent form on their behalf. Evidence that they are the legal guardian must be provided. A younger person will not be invited to participate in the focus group discussion.

Individuals with a neurological condition who agree to take part in the study will be required to a) undertake SMART Arm training under the guidance of one or more of the participating clinicians; b) complete a survey questionnaire OR a Capability Assessment with respect to the clinicians performance as their trainer or coach. Those individuals who participate prior to provision of the Advanced Training Course for clinicians will complete a survey and may participate in a group discussion. Those who receive SMART Arm training after clinicians have undertaken the advanced training will be asked to assess the clinicians' capabilities using the Capability Assessment Tool.

*Participants – Clinicians*
All occupational therapists, physiotherapists and rehabilitation assistants working at CRnQ will be invited to participate in the research. The CRnQ Research Assistant and Research Lead will conduct a group session with all potential clinician participants in which they will provide them with an explanation of the study, an information sheet and invited them to participate. Clinicians who would like to participate, will be asked to sign an Informed Consent form. Clinicians who participate in the study will all have the capacity to consent.

Clinician participants who agree to take part in the study will be required to a) complete a survey; b) participate in a group discussion; c) undertake the SMART Arm advanced train-the-trainer course; and d) complete a Capability Assessment regarding their own performance.

Data collection

Information collected from participating individuals with a neurological condition will include:
1) Participant characteristics - age, gender, neurological condition, date of onset/diagnosis, level of arm dysfunction (Motor Assessment Scale–Upper Limb Items 6, 7 8. (Carr, Shepherd, Nordholm, & Lynne, 1985)
2) Survey questionnaire responses
3) Focus group transcriptions
4) Capability assessments of participating clinicians

Information collected from participating clinicians will include:
1) Participant characteristics - age, gender, profession, years of experience in neurological rehabilitation
2) Survey questionnaire responses
3) Focus group transcriptions
4) Capability self-assessments

Occupational Therapists or Physiotherapists, assigned to the care of an individual with a neurological condition, will complete the Motor Assessment Scale Upper Limb Items 6,7,8. This information will be used to define the level of arm dysfunction at baseline, not to monitor progress.

The Research Assistant will collect all participant demographics once informed consent has been provided; distribute all survey questionnaires and capability assessment tools; assist participants to complete the questionnaires and assessments as required; and collate survey and capability assessment responses. The Speech Pathologist will assist those with cognitive or linguistically based communication limitations as required and the Social Worker will assist younger persons as required.

The Principal Investigator, who leads the SMART Arm expert panel, will conduct the focus groups (with research assistant as observer); analyse focus group transcriptions; design and conduct the Train-the-Trainer course; provide feedback to clinician participants based on the capability assessments; and refine the Train-the-Trainer Course and Capability Assessment tool.

Data Analysis

*Survey questionnaires*

Quantitative survey data will be collated and areas of weakness identified, with respect to Stroke Guidelines and SMART Arm Clinical Guidelines. Qualitative survey data will be collated and a simple descriptive analysis of the data will be undertaken. This information will be used to select the content and mode of instruction used within the Train-the –Trainer Course.

*Focus group discussions*

Focus group discussions will be audiotaped and transcribed verbatim and a simple descriptive analysis of the data undertaken. This information will be used also to select the content and mode of instruction used within the Train-the –Trainer Course.

*Capability Assessments*

Capability Assessments will be collated and areas of weakness identified at each time-point. This information will be used to address gaps in training or to strengthen existing components of the training.

## CONDITIONS OF PARTICIPATION (e.g. withdrawal)

Participants will be informed that their agreement or refusal to participate in the study will not affect their relationship with their clinicians or the services they receive. If they consent to participate in the study they will maintain the right to withdraw at any stage and will not be required to state a reason for doing so. Their decision to withdraw will also not affect their relationship with clinicians or the rehabilitation services they receive. The potential participant will be made aware however, that they will not be able to use the SMART Arm device if he / she is not a participant in the study.

## BENEFITS

SMART Arm training enables individuals with a neurological condition who have arm paresis to undertake intensive and repetitive task-oriented practice that would not be possible otherwise. This research will serve to maximise the benefits gained from SMART Arm training. This research will result in the production of user- informed and evidence-based advanced train-the-trainer course materials and capability assessments. As the process for TGA approval is currently underway, these resources will be available for implementation as soon as the SMART Arm is commercially available. It is anticipated therefore, that individuals with a neurological condition, will be provided with advanced SMART Arm coaching which in turn, will provide them with the opportunity to drive their own recovery without clinician support and achieve greater recovery than would otherwise have been possible.

The process and outcomes of this research will improve clinical practice at Community Rehab nQ which in turn, has the potential to improve outcomes for individuals with a neurological condition. This study will also establish the feasibility of coaching individuals with a neurological condition to use the SMART Arm independently, so that they may continue to drive their recovery in the long term.

RISKS

Risks of harm or discomfort for participants in this study is extremely low. There have been no adverse events identified when SMART Arm training has been provided in all previous trials including those conducted at CRnQ. In addition, clinicians at CRnQ have been trained to provide SMART Arm training for individuals with neurological conditions, thereby minimising risks of harm or discomfort. Conversely, it is likely that individuals with a neurological condition will benefit from participation in this study on the basis that SMART Arm training has previously been shown to improve arm function more than usual care alone. However, there is no guarantee that participants will directly benefit from this intervention.

Participation in survey and focus groups is unlikely to caused any distress or harm and is likely to lead to improved coaching of individuals with a neurological condition which in turn, could lead to greater arm and hand recovery than would have been possible otherwise.

As there is little or no risk associated with participation in the study, and there is a potential benefit of SMART Arm training, the potential benefits of participating in this study far outweigh the risks.

Monitoring

All three investigators will monitor the progress of the trial through regular audits of the process for notification regarding an eligible participant, the process for informed consent, collection and storage of data. Although unlikely, adverse events will be reviewed immediately following the event. Any safety concerns will be discussed by all investigators and advice sought from the SMART Arm expert panel, if deemed appropriate. The Principal investigator will be responsible for reporting any adverse events or safety concerns.

BENEFITS, SIGNIFICANCE, OUTCOMES

If demonstrated to be effective in training clinicians to be capable coaches, the SMART Arm train-the-trainer course is likely to lead to improved outcomes in the short term and continued recovery in the long term, for individuals with neurological conditions.

**Security and confidentiality**

Information collected for, used in, or generated by, this project will not be used for any other purpose. As the information pertains to individuals other than the researchers, confidentiality will be maintained. Individual participant's results will not be recorded in their personal medical records. Survey questionnaires and capability assessments collected during the study will be stored on paper data collection sheets in a locked filing cabinet in the office of the Research Lead. Data collected will be entered and stored electronically on a password-protected computer. Study investigators will have access via the password. Data stored electronically will be de-identified. Data stored at the completion of this project will be non-identifiable. This data will be retained for a period of 10 years after completion of the study, after which time data in paper format will be shredded and computer files will be deleted.

**Dissemination of findings**

A report will be disseminated to participants at the completion of the study. An abstract will be submitted for presentation of the results in an oral presentation at a relevant national or international scientific conference. A manuscript will also be submitted to an appropriate peer reviewed journal.

## REFERENCES


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