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Author(s): Julie Bernhardt, Kathryn Hayward, Gert Kwakkel, Jane Burridge, Michael O'Sullivan, Andrew Clarkson, Matthew McDonald, Matthew Jeffers, Steve Cramer, Janice Eng, Marion Walker, Marie-Louise Bird, Karen Borschmann, and Dale Corbett

**Consensus-based core recommendations from the second Stroke Recovery and Rehabilitation Roundtable**

Julie Bernhardt PhD [1]
Kathryn S Hayward PhD [2]
Gert Kwakkel PhD [3,4]
Jane H Burridge PhD [5]
Michael J O'Sullivan PhD [6]
Andrew N Clarkson PhD [7]
Matthew W McDonald PhD [8,9]
Matthew S Jeffers MSc [8,9]
Steven C Cramer MD [10]
Janice J Eng PhD [11,12]
Marion F Walker PhD [13]
Marie-Louise Bird PhD [11,12]
Karen Borschmann PhD [1]
Dale Corbett PhD [8,9]
For the SRRR II Collaboration

[1]Centre for Research Excellence in Stroke Rehabilitation and Brain Recovery, Florey Institute of Neuroscience and Mental Health, The University of Melbourne, Heidelberg, Australia
[2]Centre for Research Excellence in Stroke Rehabilitation and Brain Recovery, Florey Institute of Neuroscience and Mental Health, Department of Physiotherapy, The University of Melbourne, Heidelberg, Australia
[3]Amsterdam UMC, Vrije Universiteit Amsterdam, department of Rehabilitation Medicine, Amsterdam Neurosciences and Amsterdam Movement Sciences, The Netherlands.
[4]Department of Neurorehabilitation, Amsterdam Rehabilitation Research Centre, Reade, The Netherlands.
[5]School of Health Sciences, Faculty of Environmental and Life Sciences, University of Southampton, Southampton, UK
[6]UQ Centre for Clinical Research, Faculty of Medicine, University of Queensland, Brisbane, Australia

[7]Department of Anatomy, Brain Health Research Centre and Brain Research New Zealand, University of Otago, Dunedin, New Zealand
[8]Department of Cellular and Molecular Medicine, University of Ottawa, Canada
[9]Canadian Partnership for Stroke Recovery, University of Ottawa, Canada
[10]Depts. Neurology, Anatomy & Neurobiology, and Physical Medicine & Rehabilitation, University of California, Irvine, USA
[11]Department of Physical Therapy, The University of British Columbia, Vancouver, Canada
[12]GF Strong Rehabilitation Research Laboratory, The University of British Columbia, Vancouver, Canada
[13]School of Medicine, University of Nottingham, Nottingham, UK

Corresponding author:
Julie Bernhardt, Florey Institute of Neuroscience and Mental Health, The University of Melbourne, 245 Burgundy St, Heidelberg, VIC, 3084, Australia.
julie.bernhardt@florey.edu.au. Ph: +61 3 9035 7000
@AVERTtrial

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## Introduction

The Stroke Recovery and Rehabilitation Roundtable (SRRR) meetings bring together an international group of preclinical and clinical researchers along with statisticians, methodologists, funders and consumers, to develop consensus-based core-recommendations for effective treatments for stroke recovery and to support best-evidence uptake in rehabilitation practice. We aim to complement, not replicate, the work of other collaborations. The breadth and ambition of stroke recovery and rehabilitation research requires synergistic collaborative work. The SRRR community is aligned in the search for life-changing recovery treatments, complementing what is currently available during the hyperacute phase.

The first SRRR (SRRR I, 2016) was a major international collaborative effort that set the scene for a new direction in recovery research. SRRR I focused on translation of preclinical evidence into human discovery trials (1); recovery biomarkers to provide knowledge of therapeutic targets and prognosis in human stroke (2); intervention development, monitoring, and reporting standards (3); and standardized measurement for motor recovery trials (4). The impact of SRRR I continues to grow (see Figure 1).

Leveraging momentum, SRRR II addressed targets identified at SRRR I as well as new areas for consensus (*Figure 1,* (5)). For example, while motor recovery was a logical target for early consensus building, the need for consensus around definitions, measurement and research priorities related to cognitive domains was evident (Theme 1, SRRR II). After establishing recommendations for core outcomes for motor recovery trials in SRRR I, improving our approach to measuring recovery and brain repair, not just functional change, was an important next step. This required recommendations for standardization of kinematics

to measure alterations in the quality of movement that accompanies motor system changes (Theme 2). In search for life-changing recovery treatments that are rigorously developed and tested, Theme 3 focused on how we build better recovery trials in the future. Theme 4 tackles the challenge of getting evidence-based treatments into practice (delivering what we know works). In this paper, we summarise the approach taken to build consensus, and the key outcomes of each theme including their consensus recommendations (6-9), which have been co-published in International Journal of Stroke and Neurorehabilitation and Neural Repair.

*< Please insert figure 1 here>*

**Methods**

The SRRR II management group held monthly meetings from January 2018 until June 2019. All core working group members were invited by March 2018 and working groups subsequently established broader advisory groups. Each theme undertook a structured approach to consensus building and recommendation development. Part of this process included a face-to-face meeting of core participants (n=38) in Saint-Saveur, Canada in October 2018. A summary of the approach taken by each theme is presented in Table 1.

**Table 1: Approach to consensus building for each Theme.**

| Theme | Approach to consensus building |
|---|---|
| Cognitive impairment after stroke (9) | • Development of a core working group with expertise in clinical stroke, non-human models of stroke, human and animal neuroimaging, neuropsychology, the neurobiology of language and cognitive rehabilitation.<br>• Structured survey sent to core (n=9) and wider advisory group (n=6) members. From this, a list of major challenges was defined, and transformed into an agenda for the working group meeting.<br>• Future directions for cognitive recovery research were mapped out. |
| Standardized measurement of quality of upper limb movement after stroke (7) | • Survey design and distribution to core (n=5) and advisory (n=8) group members<br>• Analysis of the results of the survey<br>• Face-to-face discussion<br>• Draft recommendations developed and distributed to the core and advisory group for feedback |
| Improving how we develop recovery trials (6) | • Development of core working group members with expertise in clinical trials development and conduct, preclinical models of stroke, biomarkers, behavioural motor training and adjuvant therapies.<br>• Consultation with core (n=12) and consultant (n=11) groups to identify ‘knowledge units’, which if addressed could |

| | |
|---|---|
| | advance trial design. Information gathered through web-based survey and video-recorded meetings.<br>• Prioritisation of evaluation criteria to make a judgment about importance of and confidence with available evidence to make GO, NO-GO decisions using graph theory-based voting system.<br>• Conceptualisation of SRRR Trials Development Framework (SRRR-TDF).<br>• Face-to-face application of SRRR-TDF to exemplar (upper limb recovery trial).<br>• Development of exemplar, including collation of evidence, summary of issues and recommendations. |
| Moving knowledge into practice (8) | • Establish core working group (n=10) with international advisory group (n=18).<br>• Review literature and develop criteria for prioritisation.<br>• Survey health practitioners and people with stroke and their care-partners.<br>• Consolidate categories of topics.<br>• At face-to-face meeting to prioritise, vote to retain or exclude topics. Rank ordering not done.<br>• Inductive approach to group topics into domains. |

**Theme 1: Cognitive impairment after stroke**

Previous international guidelines highlighted the lack of evidence on specific approaches for rehabilitation of cognitive function (10). Therefore, a major goal of the cognitive working group was to develop consensus on definitions and research priorities to identify major knowledge gaps, including alignment of preclinical and clinical research, in post-stroke cognition (9).

The fact that cognition is multi-dimensional and hierarchical, creates difficulties for interventional research and building consensus around standardized assessment tools. As a consequence, the group decided that there was inadequate evidence to support formal consensus for trial methodology. However, there is an urgent need to define major priorities for research in post-stroke cognition to advance the field. There are a number of working groups engaged in defining cognitive impairments for vascular cognitive impairment (VCI) around the world. As such, this group focused primarily on the setting of stroke recovery and rehabilitation (process of care) trials. To build on our understanding of cognitive impairments and explore basic mechanisms of plasticity and repair, a bed-to-bench approach was adopted. This entails incorporating key aspects of human cognitive impairments (e.g., chronicity of impairment, executive dysfunction) and assessment in preclinical models. This is an important step in building a two-way interactive pipeline between preclinical and clinical research, which was viewed as central for cognitive recovery research and a core component of the working group's mission.

In order to move cognitive rehabilitation forward it is essential to understand how distributed neural networks, including interactions between remote regions, subserve different cognitive domains, (9, 11). Moreover, strokes that affect cognition frequently span multiple domains

resulting in complex cognitive impairments that can often occur weeks or months after stroke. Since cognitive impairments are a major determinant of quality of living (QoL) after stroke, our view is that assessment of cognitive function must meet predefined criteria for evaluation in all trials and observational studies of stroke recovery (see, McDonald et al., 2019 Table 2). More longitudinal studies (both animal and human) with clinically relevant outcomes are needed to fully understand the evolution of post-stroke cognitive impairment and the associated mechanisms (e.g. brain connectivity changes) contributing to recovery. Such information is necessary to plan rational, biologically driven intervention trials. From such studies, sensitive cognitive biomarker readouts should be determined that can be implemented in Phase II and III trials.

**Box 1: Cognitive consensus recommendations**

*Observational studies and trials*

1. All clinical intervention studies and trials should include evaluation of cognition across multiple domains.
2. Cognitive function should be evaluated at study enrolment and as an outcome measure (secondary if not primary).
3. Wherever possible, studies should include evaluation of other behavioural aspects that are associated with cognition and important for quality of life: e.g. mood, apathy, fatigue, anxiety, sleep.
4. Strategies to limit selection bias and selective attrition should be standard in clinical studies. Selection based on language deficits should require formal language assessment, and adjust test administration for aphasic patients when possible (eg using Supported Conversation (12)). Reports should state who were excluded and why.
5. Preclinical research should utilise models that reproduce common, clinically relevant cognitive deficits, using a battery of tests sensitive to multiple domains.

*Developmental priorities*

1. Measures of cognitive functioning better adapted to the needs of trials
2. Parallel studies of cognitive functioning across multiple domains, with long follow up periods, in clinical and preclinical research to facilitate translation
3. Identification of biomarkers for processes and epochs of recovery (identification of targets for intervention).
4. Greater use of cognitive paradigms that translate between clinical and preclinical research (supported by standards for selection, execution and reporting of tests).

| | |
|---|---|
| **5.** | Preclinical models should incorporate age, sex, cardiovascular and metabolic comorbidities. |

**Theme 2: Standardized measurement of quality of upper limb movement after stroke.**

Clinical trials and observational studies have failed to effectively explore the association between recovery of movement quality and upper limb capacity. Consequently, the distinction between behavioural restitution and compensation is poorly understood. There is therefore an urgent need to reach a consensus (13) on how to measure quality of movement in stroke recovery and rehabilitation trials to understand what patients learn and how they improve their upper limb capacity early post stroke. At the SRRR II consensus meeting, three key research questions were posed by the metric task force on the use of metrics for measuring the quality of movement: 1) Which performance assays of the paretic upper limb should be used to address questions about the quality of upper limb movement execution at the ICF level of body function? 2) Which functional task(s) should be recommended to measure quality of upper limb movement execution at the ICF level of activities? 3) Which types of technology (e.g., optoelectronic, electromagnetic movement tracking systems) should be recommended for measuring movement during performance assays and functional tasks? (7) At the impairment level, we recommended four performance assays (i.e., 2D planar standardized reaching movement, finger individuation, grip strength and precision grip). For the functional task we recommended using a standardized 3D-drinking task at activity level that addresses body function and activity respectively. We agreed that, given the current maturation of the technology and algorithms to generate metrics, *only* high speed and high-resolution digital optoelectronic systems should be used to measure kinematics during the performance assays and the functional task. In contrast, wireless wearables including 2D and

3D-IMU's, as well as Kinect or other optical systems are deemed currently inadequate for measuring the quality of movement.

The consensus we achieved (Box 2) on measuring the quality of movement is imperative, to three aspects of understanding. Firstly, for stroke recovery and rehabilitation trials, and secondly to enable meaningful interpretation of neuroimaging studies (e.g. fMRI, DTI). Specifically, only by relating quality of movement and neural images is it possible to distinguish neural changes associated with behavioral restitution from compensatory strategies. This granularity of behavioral measurement is the only way that neuroimaging can make a useful contribution to neurorehabilitation (14, 15). Thirdly, standardization of kinematic measurement protocols will allow pooling of participant data, thereby increasing sample size aiding meta-analyses of published trials, more detailed exploration of recovery profiles, the generation of new research questions with testable hypotheses, and development of new treatment approaches focused on impairment. These consensus statements will serve as a blueprint for capturing recovery of the lower limb using kinetics and kinematic measures.



**Box 2: Measurement consensus recommendations**

1. By lack of current consensus, there is an urgent need to measure quality of movement in stroke recovery and rehabilitation trials to understand what patients learn and how they improve their upper limb capacity early post stroke.
2. We recommend using the principles derived from motor control as a framework for measuring quality of movement.
3. We recommend measuring the standardized 2D-reaching assay, finger individuation, pinch- and grip strength for assessment of assessment of behavioural restitution.

4. We recommend using the standardized 3D-reach-to-grasp drinking task for measuring recovery of upper limb capacity (see (7) for full details).
5. The recommended 2D-reaching assays and 3D-drinking task should be measured repeatedly at fixed times post stroke concomitant with the recommended clinical measurements of outcome.
6. We strongly recommend that only high-resolution digital optoelectronic systems be used to measure both performance assays and functional tasks. Only people who have the expertise and access to these technologies should therefore conduct quality of movement assessment.

**Theme 3: Improving how we develop recovery trials**

Stroke recovery treatments that set the field on a radical new path are critically needed (16). The SRRR II Next Trials working group (6) aimed to address the challenge of how we develop the next generation of stroke recovery trials to be both rigorous and aspirational to produce game-changing stroke recovery treatments. We propose the SRRR-TDF to guide development of stroke recovery treatment trials, which incorporates recommendations from SRRR I (2-4, 16, 17) and decision analysis science. Stroke recovery trials in any treatment domain (speech and language, motor, cognition) require critical thinking and evidence gathering to appropriately inform decisions about whether to proceed with or hold off running a comparative effectiveness trial (i.e., the GO, NO-GO decision). This framework includes review of the evidence (preclinical and clinical), rating both the importance and confidence with available evidence to inform the start of the GO, NO-GO decision process. Where there is insufficient knowledge to proceed, research methods and earlier phase trial designs that can fill the knowledge gap need to be prioritised *before* proceeding to a Phase III

recovery trial. This framework complements existing guidelines for complex intervention development (18, 19).

We use the term “knowledge units” to refer to important areas for consideration in trial development. From our process of consultation and prioritisation we identified five (5) knowledge units: HOW MUCH treatment, WHAT is an effective intervention (and the active ingredients), WHO to treat, and WHEN treatment is best delivered. These considerations apply to behavioural treatments, the current cornerstone of rehabilitation approaches. They also apply to ADJUVANT treatments, defined here as those treatments (e.g., drugs, non-invasive brain stimulation) that aim to modify the effect of a primary behavioural intervention.

We applied the SRRR-TDF to an exemplar trial (upper limb recovery). The core working group drew on systematic reviews, preclinical experiments and clinical trials in our evidence summaries. It was not our intention to conduct a rigorous systematic review of primary literature for each knowledge unit; although doing so would be justified in a real-world scenario. We found that the evidence for most knowledge units is currently inadequate to support a late phase upper limb recovery trial. This indicates that additional, earlier phase trials are needed to address priority gaps. From this work, we developed eight recommendations (Box 3).

In summary, rigorous appraisal of the evidence that underpins essential knowledge units is needed in developing a trial will ultimately lead to fewer, but better, trials progressing to Phase III.

**Box 3: Next trials consensus recommendations**

1. Researchers interested in developing comparative effectiveness recovery trials in any domain (speech and language, motor, cognition etc) should apply the SRRR-TDF when developing trials, ensuring that all 'knowledge units' have been considered in the process to inform GO, NO-GO decisions.
2. When there is insufficient evidence to support a decision (i.e., NO-GO), the researcher should proceed to fill this knowledge gap. This may prompt an earlier phase design(s), potentially followed by a feasibility study to inform the trial that will answer the primary question, i.e., does the intervention work?
3. Funders of stroke research need to support earlier phase programs of research that aim to develop evidence to inform critical knowledge units in stroke recovery. These programs should be prioritised above large Phase III trials that do not have sufficiently strong biological evidence of effect or have positive findings from a single pilot trial. If progress is warranted, recommendations for intervention detailing, monitoring and reporting from the SRRR I should be followed (3).
4. HOW MUCH: To report dose, future trials should report all elements of dose (including repetitions, duration, intensity) and dose schedule, from all arms of the trial. Threshold doses for effectiveness need to be determined (20-22).
5. WHAT: Effective training is likely to comprise several elements. Studies that aim to optimise promising treatments and use fine grained behavioural outcomes are required. These may identify active ingredients for further testing.
6. WHO: Hypothesis-driven studies to identify reliable and valid assessments that distinguish biological subgroups, and responses to treatment are needed across both preclinical and clinical. Current potential stratification approaches need further testing

in trials.

7. WHEN: Complete clinical trials that enrol patients based on days post stroke, in epochs that are time-linked to our current understanding of the neurobiology of recovery. Greater focus on enrolling patients earlier post stroke is needed given the strength of preclinical evidence.
8. ADJUVANTS: Clinical and preclinical researchers should jointly design studies to systematically test if training combined with an adjuvant is better than training alone. Careful phasing and reporting of trials is needed.

**Theme 4: Moving knowledge into practice**

The Knowledge Translation group of SRRR II (8) brought together experts with an international perspective to gain consensus about priorities for implementing practice change in the area of stroke rehabilitation. Firstly, the group determined the criteria on which the prioritization process would be based on from the literature and consensus. This forms the first recommendation of the group; health system managers looking to implement new practices should choose practices with a *high level of research evidence* that provide *meaningful impact to stroke survivors* and are *feasible* while considering how this will influence the delivery of services in the local *health system* context. These criteria are transferable to other clinical areas and may be used by other researchers.

Input from health care providers (n=502) and patients (and their families) (n=112) from over 28 countries informed the recommendations (Box 4) as they are the ultimate end-users as those delivering the treatment and those receiving the treatment. Several areas that were deemed high priority for practice change can be addressed by redesigning health services

with minimal new costs. For example, improving communication processes for providing patient centred services or interdisciplinary care was identified to improve the coordination of services. Increasing the intensity of physical rehabilitation was identified across multiple professions (nurses, physical therapists, occupational therapists and speech language pathologists) to improve patient outcomes. Screening and assessment for dysphagia, depression and cognition was prioritized because these have well-established protocols that are not consistently adopted into practice. Increasing the use of established clinical practice guidelines and upskilling of staff were also priorities. Both health care providers and people with stroke identified family support and caregiver training as well as self-management strategies as high priority to implement. In particular, social isolation was a frequent concern from consumers, and healthcare providers should be aware of how to assess social isolation and implement social support interventions. Of note, the topic of fatigue was frequently raised by consumers but was not included as an implementation priority, but rather a topic requiring more primary research.

A number of system level changes were prioritized in this consensus process which could improve quality of life as well as service efficiencies. Health system managers should prioritize changes that support early access to services and transitions in care, especially back to the community. While it is recognized that health care shortfalls may impact the ability to provide new resources, two areas were identified to provide the most impact. Increasing staff numbers and especially staff who have expertise in managing people with stroke, as well as access to technology were identified as resources that were essential to enhance rehabilitation.

While interventions with a strong evidence base were prioritized, research is still required to determine the best ways to change practice in different contexts. Therefore, funders have an important role to play in supporting this knowledge translation research. Funding agencies can use recommendations provided to prioritize funding for maximum impact.

**Box 4: Moving knowledge into practice consensus recommendations**

1. When identifying treatments to move to stroke rehabilitation practice consider the research evidence, personal impact, feasibility and system impact.
2. Interventions that are ready to be implemented include those which improve interdisciplinary care, screening (i.e., for dysphagia, depression and cognition), intensity of rehabilitation and support for families and caregivers. The use of clinical guidelines and education can support these initiatives.
3. System level changes should prioritize early access to rehabilitation and support transitions in care, especially into the community.
4. Health care funding should be directed to increasing the number of staff, especially those with stroke specific expertise, and improving access to technology. Knowledge translation research funding is needed to determine the best ways to improve uptake of research evidence into clinical practice in stroke rehabilitation.

## Conclusion

The Stroke Recovery and Rehabilitation Roundtables have served to unite people who are committed to progressing stroke recovery and rehabilitation science and practice, and interested in building strong, international partnerships to accelerate change. We hope that researchers, clinicians and academics in the field of stroke recovery, together with funding bodies and journal editors, will join us in pursuing and promoting the goals outlined here (6-9) and in our previous recommendation papers (1-4, 16), and support our vision for change. We believe the next step is to grow a broader international alliance of clinicians, researchers, consumers and other stakeholders from across the world, who can work together to action these and other recommendations. Collective action will serve to accelerate progress in this exciting, but relatively neglected field. As a group, we remain optimistic that alignment of our efforts will yield important discoveries, and better implementation of effective treatments that will ensure people affected by stroke achieve optimal recovery and quality of life. We invite interested parties to join us.

**DECLARATIONS:**

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Figure 1: Development of Stroke Recovery and Rehabilitation Roundtables (SRRR I and II), and International Stroke Recovery and Rehabilitation Alliance (ISRRA). Reproduced with permission, Bernhardt et al., 2019 International Journal of Stroke;14:450-456.

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# Stroke Recovery and Rehabilitation Roundtable (SRRR)

**Purpose: An international collaboration to create a pathway to accelerate development and implementation of breakthrough treatments for stroke recovery**

## SRRR1*

**Enhancing alignment preclinical** and clinical pipeline

**Biomarkers** of recovery; motor, sensation, language and cognition

**Development, monitoring and reporting** of stroke rehabilitation research

**Standardised measurement** of sensorimotor recovery

Identified gaps

## SRRR2*

**Cognitive impairment** after stroke

Standardised measurement of **quality of upper limb movement**

Improving how we **develop recovery trials**

**Moving knowledge into practice**

Leverage momentum

## ISRRA

- To create a 'go-to' place for researchers interested in recovery
- Identify funding priorities for stroke recovery research
- Create working groups that continue to drive momentum to support the stated purpose and goals
- Identify new targets for consensus building

## Goals

1. Identify critical **knowledge gaps**
2. Build **capacity, leadership and networks**
3. Setting new standards through **consensus** building
4. **Identifying target activities to accelerate discovery**

***Impact at 9 December 2019 for SRRR1 & SRRR2: 42,139 downloads across International Journal of Stroke & Neurorehabilitation and Neural Repair.**