**Too tired to recover:**

**Evaluation of a post-stroke fatigue management guideline**

**Investigative team:**

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**Introduction:**

*Background:* **Fatigue negatively impacts rehabilitation outcomes** including participation in therapy, return to work (Nadarajah & Goh, 2015), and adherence to home exercise programs (Ploughman et al., 2015). The prevalence of post stroke fatigue may be as high as 70% (Hawkins et al., 2015), **and is a disabling and persistent issue** (Nadarajah & Goh, 2015) (Walsh, Galvin, Loughnane, Macey, & Horgan, 2015). Fatigue is conceptualised as having mental, physical, and emotional components. Mental fatigue refers to the inability to sustain a mental effort over a long period of time (Nadarajah & Goh, 2015) and impacts around 62% of people with post stroke fatigue (Muina-Lopez & Guidon, 2013). However, **mental fatigue has not received much attention in the literature until recent years** (Levitin, 2014)**.** It is urgent that fatigue be thoroughly addressed in order to improve engagement with and long-term outcomes of stroke rehabilitation. **A targeted approach to reducing mental fatigue could substantially increase rehabilitation adherence and improve recovery.**

While fatigue is recognised as an important barrier to rehabilitation, there remains insufficient evidence to inform treatment of post stroke fatigue (Hinkle et al., 2017, Wu et al., 2015). The Australian National Stroke Foundation (NSF) guidelines do not yet differentiate the different types of fatigue in its recommendations. **As it stands, clinicians have no reference when it comes to treatment planning for fatigue.**

In the absence of a clinical guideline for post stroke fatigue, **a general fatigue guideline for common modifiable causes of fatigue would be helpful in rehabilitation.** A guide may also reduce the practice of fatigued clients being discharged due to reduced performance. **To improve perseverance during rehabilitation, more mental fatigue therapies are required.** These tools would aim to promote relaxation and rests but also address other strategies for mental fatigue, such as reducing multitasking, distractions, and decision making.

**To address the gaps identified through review of the scientific literature and a recent service evaluation, a general fatigue management guideline, and two novel mental fatigue therapies were developed** (see appendix)**.** The guideline was designed to be used by a range of health professionals (i.e. occupational therapists, physiotherapists) to facilitate uptake and use in team-based treatment planning. An innovative client education resource was also developed (see appendix) to fill the gap for mental fatigue and was designed to engage clients with attention and memory deficits. These tools have been piloted and refined through feedback and it is anticipated they will be effective in allowing patients to regain control over their energy choices. Due to the complexity of fatigue aetiology, the new therapy guideline is multifactorial and multidisciplinary. Importantly, this guideline promotes the expanded scope of OT to manage mental not only physical fatigue. It is formatted in an innovative mind map format to be engaging for staff and to remain relevant by using internet hyperlinks. The use of technology in clinical practice is becoming increasingly attractive to health professionals and service users alike as it enhances usability, providing an alternative approach for provision of information and delivery of rehabilitation. **Our project aims to evaluate the effectiveness of a new suite of clinical tools at reducing post stroke mental fatigue and review the usefulness of the fatigue management guideline for rehabilitation staff.**

*Rationale:*This study will be the first to date, to evaluate the effectiveness of a novel fatigue management guideline for reducing post stroke mental fatigue. This innovative approach incorporating education and newly developed clinical tools will be a step toward enhanced management of mental fatigue in practice.

**Aim:**

The aim of this pilot study is twofold: 1) to evaluate the effectiveness of a novel fatigue management guideline for reducing mental fatigue and improving outcomes in adults post stroke; 2) to evaluate the usefulness of a novel fatigue management guideline for enhancing management of mental fatigue in clinical practice. We hypothesise that:

i. Patients who engage in active treatmentwill show significant reduction in mental fatigue compared with standard care.

ii. Patients who engage in active treatment will have significantly greater self-efficacy for daily living, and quality of life outcomes compared with patients receiving standard care.

iii. Patients who engage in active treatment(including education and use of the matrix and routine tools) will perceive it to be beneficial.

iiii. Therapists who use the fatigue management guideline will perceive it to be useful in enhancing their management of mental fatigue in clinical practice.

**Method:**

*Study design:* An exploratory randomised controlled trial (RCT) with two conditions: an active fatigue management (including education and use of newly developed clinical tools) and a standard care group.

*Recruitment:*40 adults who have a diagnosis of stroke will be recruited through the Metro North Hospital and Health Service (MNHHS) Community Based Rehabilitation Teams (CBRT). New referrals to the service will be consecutively tracked by CBRT members across four sites; namely Chermside, Redcliffe, North Lakes and Caboolture. A researcher will conduct an initial eligibility screen based on intake information and suitable patients will be informed about the study and invited to participate. The researcher will liaise with team leaders who attend all case reviews to ensure all suitable candidates are approached about the study. Inclusion criteria are: a) diagnosis of stroke; b) aged over 40 years; c) able to communicate in English; d) fatigue issues identified on care plan. Exclusion criteria are: a) pre-morbid major psychiatric or neurological disorder; b) significant visual impairment; or c) significant hearing impairment; d) severe aphasia or other communication disorder including difficulty reading or understanding written information; e) severe cognitive impairment.Eligible respondents who provide informed consent will be randomised to receive either active fatigue management or standard care. A random number generator will be used to allocate participants to treatment group. Opaque envelopes containing each concealed allocation will be sequentially drawn by therapists administering treatment at each site.

*Assessment:* Routine assessment, for approximately 1hr on each occasion, will be conducted at baseline and post-intervention (10 weeks). All assessments will be conducted in the client’s home or local Community Health Centre. Risk assessments will be conducted as per Queensland Health policy prior to visiting participants in the community. A trained assessor blinded to participants’ intervention condition will collect disease and demographic data and administer well-established, validated measures used routinely in practice on a Queensland Health tablet. Fatigue impact will be measured using the Multidimensional Fatigue Symptom Inventory – Short Form (MFSI-SF). Self-efficacy will be measured using the Daily Living Self-efficacy Scale (DLSES). Cognitive function, depression, and quality of life will be measured using the Montreal Cognitive Assessment (MoCA), Depression and Anxiety Severity Scale (DASS-21), and Short Form Health Survey of the Medical Outcomes Study (SF-36), respectively. Qualitative feedback will be sought from patients regarding their experiences around clinical tool usage and the fatigue management guideline at post intervention.

*Intervention:*One-on-onetreatment will be carried out by a qualified occupational therapist in the MNHHS Community Based Rehabilitation Team for a 10 week intervention period. Participants enrolled in the treatment arm will benefit from incorporation of new clinical tools in therapy, including the routine tool, matrix tool, and mental fatigue client education booklet (see appendix). A matrix was developed to help clients consciously prioritise activities and decisions to avoid excessive multitasking and decision making. This tool would refer them to external memory strategies to reduce the cognitive load on the brain. A routine tool was developed that uses daily habits to promote breaks, relaxation, and plans for optimal energy use. The electronic routine tool was developed with drop down lists to increase the speed and convenience for therapists to develop customisable daily routines. It provides the option to monitor client’s adherence to habits (Gardner, Lally & Wardle, 2012; Lally, Van Jaarsveld, Potts & Wardle, 2010) to ensure that goals are realistic and achievable in a 10 week timeframe, giving them the best chance of increasing willpower (Neal, Wood & Drolet, 2013) and self-efficacy. Participants that are identified as having high levels of depression or anxiety on the DASS-21 will be supported but eh CBRT Social Worker and referred to a Psychologist as needed (see depression and anxiety handout in appendix). It is not anticipated that the fatigue management intervention will cause participants any distress or discomfort. Patients randomly assigned to standard care will not receive education about fatigue or focus on mental fatigue in therapy but may receive some compensatory strategies for cognitive or fatigue symptoms that are considered within the realm of routine practice. 

*Data collection:*

1) 40 adults with a stroke diagnosis will be recruited through MNHHS CBRT, with new referrals tracked by CBRT members across 4 sites. A researcher will meet regularly with the CBRT and utilise a shared secure spreadsheet to record all referrals (de-identified) and provide opaque envelopes for random assignment of eligible participants.

2) Allocated intake therapists will conduct initial eligibility screens based on intake information and invite suitable patients to participate, obtaining verbal consent for an independent researcher to contact them and keep a record on the shared spreadsheet of consenting eligible participants, and those who were not eligible or did not wish to be contacted.

3) Once verbal consent is provided, the researcher will schedule and conduct initial appointments to provide patients with a participant information sheet (see appendix) and gain written informed consent using the consent form (see appendix), then conduct pre-intervention assessments with the participant. Assessments will be conducted face-to-face for 1 hour at baseline and at post intervention, at the client’s home or local community health centre, by the researcher blinded to treatment condition.

4) Eligible participants will be randomly assigned to active treatment or standard care (20 per condition) via concealed envelopes to be drawn by therapists administering treatment. Therapists will conduct one-on-one treatment over a 10 week intervention period. Participants will be free to withdraw from the study or re-negotiate their participation at any time without it affecting their access to care through the service.

*Outcomes of interest:*

The outcomes of interest are:

1. Level of mental fatigue compared with patients receiving standard care.
2. Self-efficacy for daily living and quality of life outcomes compared with patients receiving standard care.
3. Patients’ level of satisfaction with fatigue management tool usefulness.
4. Therapists’ level of satisfaction with clinical utility of fatigue management guidelines.

*Statistical analysis:*

De-identified data will be stored securely for a minimum of 7 years as per Queensland Health guidelines on-site at a Metro North Hospital and Health Service, with copies storedin the secure UQ Research Data Management (RDM) System. Statistical analyses will be conducted to compare the treatmentgroup with standard care using repeated measures ANOVA. Intention to treat analysis will be used. Missing data will be examined to determine if missing completely at random and multiple imputation implemented if required. An alpha level of .05 will be set for statistical significance. A minimum of 36 participants are required to achieve power of .90 to detect a medium effect size (f = .25; G\*Power 3). This pilot will recruit 40 post stroke patients (20 per condition).

*Ethical considerations:*

Full ethics review is sought via the Human Research Ethics Committee in the Metro North Hospital and Health Service. Informed consent will be obtained from all participants.

*Financial considerations:*

Personnel

Two Research Assistants (RAs), Kim Doussin and Sarah Davies are required to assist the Chief Investigators (CIs) Hannah Gullo and Anthony Walsh in the administration of the project, recruitment of participants (4hrs/wk for 9mths = 144hrs), and predominately collection of assessment data (160hrs). Specifically, the RAs will be responsible for carrying out the pre- and post-assessments, which will take approximately one hour (+ one hour travel time) per participant for 40 individuals enrolled in the pilot study (2 Assessments/participant \* 2hrs \* 40 participants = 160hrs). The RAs will be trained in recruitment and assessment procedures (10hrs) and work alongside, and under routine supervision of, the CIs. The RA will also help with tasks such as data synthesis and analysis in the final phase of the project (24 hrs/wk for 3mths = 288hrs) toward a future grant application and publication. Kim and Sarah are both registered occupational therapists and are considered suitably qualified for the role.

Maintenance

This study involves evaluation of a novel fatigue management guideline, which is accessible via hyperlink and would be facilitated through tablet use. Administration of the novel patient education booklet and clinical tools would also be enhanced through technology. Four iPads have already been obtained by the Community Based Rehabilitation Teams and are available for use in the study by therapists at each site. However, 2 iPads are required for the research assistants to facilitate project coordination and collection of data, as well as entry into the Qualtrics data system for ease of collation and analysis. One has been obtained through in-kind contribution of the School of Health and Rehabilitation Sciences, UQ and another through the Faculty of Health and Behavioural Sciences and Metro North Hospital and Health Service Research Collaboration Seeding Grant.

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| Casual Research Assistant [project coordinator and blind assessor]  (HEW 5, Level 1) 602 hours @ $42.69/hr + 30% on-costs | $34,411 |
| Apple iPad Pro 10.5-inch 256GB Wi-Fi + Cellular | $1,329 |

The approved activity budgetand funding amount of $35,750 for this project will be financed through the collaboration seeding grant and administered by the Community, Indigenous and Subacute Services, MNHHS.

*Study timelines:*

Permission has been sought from the Director of the CBRT and staff have received information on the new fatigue management guideline through inservice and team meetings. Occupational therapy staff are on board and eager to trial the assessment and intervention tools across four sites making recruitment to this clinical trial highly feasible. It is anticipated the trial will gain substantial interest based on the team’s previous experience recruiting people who have had a stroke. Use of a usual care comparison rather than waitlist control will reduce the timeframe to completion and ensure that treatment is not withheld from patients. If the novel fatigue management approach is found to be superior to standard care, it will be embedded into practice within the CBRT service and participants will have access to ongoing care through their community health centres. With over 80 older stroke patients being referred through the CBRT service (according to *AROC data*) each year we would aim to recruit 2/3 of patients to account for ineligibility and drop-out.

**Dissemination of findings:**

The current project would formally evaluate the effectiveness and usefulness of the new fatigue management guideline for rehabilitation staff. This evaluation will allow for dissemination of the resources to other rehabilitation services and lead to ongoing opportunities for future research. It is anticipated that the results of this evaluation will be published in an appropriate peer-reviewed journal.

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