CONFIDENTIAL

Enhancing rehabilitation services for Aboriginal Australians after brain Injury: Healing Right Way

Version: 5
Date: 3rd November 2020

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STUDY ACKNOWLEDGMENT/CONFIDENTIALITY

By signing this Protocol, the Site Investigator acknowledges and agrees:

The Protocol contains all necessary details for conducting the study. The Investigator will conduct this study as detailed herein, in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirements, and will make every reasonable effort to complete the study within the time designated.

The Protocol and all relevant information will be made available to all personnel who participate in the conduct of this study.

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The conduct and results of this study will be kept confidential. The results of this study may be published. Upon completion of the Study it is the intention of the parties to prepare a joint publication regarding or describing the Study and all the results there from and both parties shall co-operate in this regard. Where it is the intention of Edith Cowan University to file for a patent or other intellectual property right protection, publication may be deferred at the option of Edith Cowan University for up to 12 months from the date of completion of the proposed joint publication to allow Edith Cowan University to make all filings it deems appropriate.

Investigator Signatory:

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	Signature:
	Date:

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1 Abbreviations and definitions of terms

ABIC	Aboriginal Brain Injury Coordinator
AE	Adverse Event
ACTRN	Australasian Clinical Trial Registry Number
ALO	Aboriginal Liaison Officer
ANOVA	Analysis of Variance
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRCT	Cluster Randomised Control Trial
CST	Cultural Security Training
CT	Computed Tomography
CTRA	Clinical Trial Research Agreement
DSMC	Data Safety Monitoring Committee
eCRF	Electronic Case Report Form
ECU	Edith Cowan University
EQ-5D-3L	European Quality of Life – Five dimensions – 3 Level version
FIM	Functional Independence Measure
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GEE	Generalised Estimating Equations
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IMPACT	International Mission for Prognosis and Analysis of Clinical Trials in TBI
IP	Intervention Package
LLOQ	Lower Limit of Quantification
MCSI	Modified Caregiver Strain Index
MRI	Magnetic Resonance Imaging
mRS	Modified Rankin Score
NCWA	Neurological Council of Western Australia
NHMRC	National Health and Medical Research Council
QALYs	Quality Adjusted Life Years
QoL	Quality of Life
SAE	Serious Adverse Event
SD	Standard Deviation
TIA	Transient Ischemic Attack
TIDieR	Template for Intervention Description and Replication
TGA	Therapeutic Goods Administration
VAS	Visual Analogue Scale

2 Protocol Synopsis

Study Title:	Enhancing rehabilitation services for Aboriginal Australians after brain injury.
Protocol Number:	ECU 2017
Trial Registration	TBA
Development Phase:	Phase 3
Indication:	Aboriginal Patients following brain injury
Study Intervention	The intervention consists of two components: i) Cultural Security Training for hospital staff surrounding brain injury, including culturally appropriate educational and treatment resources, ii) The introduction of an Aboriginal Brain Injury Coordinator at each site. The Coordinator will see the participants in hospital and up till 26 weeks post injury, providing education, support, liaison, and advocacy services to the participants and their families. A stepped wedge cluster randomised control trial (CRCT) design will be used, with individual healthcare sites functioning as clusters. Twenty-six weeks of baseline control data will be obtained prior to implementation of the intervention, which will be introduced sequentially to all sites at 26-week intervals. Sites will be randomised at the beginning of the project to determine the sequencing of the introduction of the intervention period.
Total number of Participants:	312
No. Centres:	Eight acute care hospitals (4 metropolitan and 4 regional) will participate in the study.
Study Duration:	Anticipated recruitment over 4 years Participant involvement is 26 weeks duration
Objectives of the Study:	Objectives are to: 1. improve delivery of rehabilitation services to Aboriginal people post-brain injury (stroke and

	traumatic brain injury) 2. improve overall health outcomes for the above population 3. conduct an economic evaluation to support the business case for funding new rehabilitation services which will contribute to the planning and sustainability of future services if the Intervention is determined to be cost-effective 4. explore the acceptability of the intervention from the perspectives of the health professionals and the Aboriginal participants involved, and to utilise this information to assist in interpretation and translation of findings
Study Hypotheses:	***Primary hypothesis*** H1. Compared to usual care, implementation of the proposed intervention package (IP) will result in an at least 15 point higher score on the Euro QOL–5D-3L VAS at 26 weeks post injury ***Secondary hypotheses:*** H2a. Compared to usual care, implementation of the IP will result in significant improvement in service delivery at 12 and 26 weeks post injury as related to increased occasions of service H2b. Compared to usual care, implementation of the IP will result in significant improvement in service delivery at 12 and 26 weeks post injury as related to increased compliance with minimum process of care indicators H3. Compared to usual care, implementation of the IP will result in significant improvement in neurological disability (Modified Rankin Scale) and independence (Functional Independence Measure) at 12 and 26 weeks post injury H4. Compared to usual care, implementation of the IP will result in significantly reduced carer burden (Modified Caregiver Strain Index) and less brain injury survivor anxiety and depression (Hospital Anxiety and Depression Scale) at 12 and 26 weeks post injury. H5. The culturally sensitive IP will be more cost-effective (additional benefits gained will justify additional costs for delivering the intervention; may lead to potential cost-offsets from less severe disease) than usual care at 12 and 26 weeks post injury H6. The IP will be acceptable to health professionals and Aboriginal participants and their families, and the role

	of the Aboriginal Brain Injury Coordinator a feasible one
Primary Outcome measure	Blinded assessment of the Euro QOL–5D-3L VAS score at 26 weeks post brain injury.
Secondary Outcome measures	Clinical service provision (rehabilitation services provided), Compliance with minimum process of care indicators at 12 and 26 weeks post injury, Modified Rankin Scale at baseline, 12 and 26 weeks post injury, Functional Independence Measure ^{TM} at baseline, 12 and 26 weeks post injury, Hospital Anxiety Depression Scale at baseline, 12 and 26 weeks post injury, Burden of care (Modified Caregiver Strain Index) at 12 and 26 weeks post injury, Resource utilisation at 12 and 26 weeks post injury. *Process evaluation data* - Questionnaires measuring hospital staff satisfaction with cultural security training and attitude change following both completion of face to face and online training. - Participant questionnaires measuring satisfaction with Aboriginal Brain Injury Coordinator service at 26 weeks. - Interviews with a sub-section of participants (n=10) exploring participants' satisfaction with Aboriginal Brain Injury Coordinator service at 26 weeks - Bi-annual Partner meetings incorporating feedback on the Aboriginal Brain Injury Coordinator service interviews with Aboriginal Brain Injury Coordinators at the completion of their contracts surrounding their experience of the role.
Study Design:	Stepped wedge cluster randomised controlled trial. Parallel process evaluation as per the TIDieR checklist.
Eligibility Criteria (Inclusion and Exclusion)	Aboriginal participants with a newly documented brain injury to be identified, recruited, and first assessment completed within six weeks of onset. ***Inclusion criteria****:* Identification as Aboriginal (from medical file or through self-identification via personal communication with staff) ≥Age 18 years

	Acute ischaemic or haemorrhagic stroke defined as "an acute episode of focal dysfunction of the brain lasting longer than 24 hours, or of any duration if imaging (CT or MRI) shows focal infarction or haemorrhage relevant to the symptoms" [1] Acute traumatic brain injury defined as 1) a head trauma severe enough to cause traumatic brain injury and causing neurological symptoms (including headache and nausea) lasting at least 1 week and 2) at least one of the following: loss of consciousness for at least 1 minute, posttraumatic amnesia for at least 30 minutes, neurological symptoms (excluding headache and nausea) during the first 3 days after the injury, or neuroradiological findings suggesting traumatic brain injury (e.g., skull fracture, intracerebral hemorrhage)[2] Neurological deficit present as reflected in NIHSS > 0 Able to benefit from rehabilitation as determined by the medical and allied health team within the first six weeks post injury. ***Exclusion criteria**:* Transient Ischaemic Attack (TIA) defined as "focal dysfunction of less than 24 hours duration and with no imaging evidence of infarction"[1] Glasgow Coma Scale severity score <8 Concurrent progressive neurological disorder(s) Pre-existing clinical diagnosis of dementia with patient fulfilling ICD 10 criteria for dementia Documented current psychosis For palliative care and not likely to survive to primary endpoint i.e. 26 weeks Participation in other intervention trial.
Study Procedures:	Eligible Aboriginal patients will be invited to participate in the study. During both the control and intervention periods at each site, participants will be assessed as soon as possible but within a maximum of six weeks post injury to hospital, and at 12 and 26 weeks post injury. During both the control and intervention periods at each site, service delivery data will also be collected. Sites will have a minimum 26 week control period, with commencement of the intervention at two sites following the initial 26 week period. A further two sites will commence intervention every 26 weeks thereafter. The intervention will consist of cultural security training surrounding brain injury for hospital staff, and the

	introduction of an Aboriginal Brain Injury Coordinator who will meet the participant whilst in hospital and follow up for 26 weeks with consultation, advocacy and support.
Safety Parameters/analysis:	Adverse events and serious adverse events will be collected for all participants. An independent safety monitoring committee will review all events on a regular basis and will report safety issues to the management committee. The committee will advise if the trial needs to be stopped if there is clear evidence of benefit or that the intervention is causing harm to participants.
Sample Size Determination:	We will require a total of 312 participants to detect a difference of 15 points on the EuroQoL-5D VAS with 80% power at the 5% significance level.

3 Introduction

The problem

The incidence of brain injury in Aboriginal Australians is significantly higher than in non-Aboriginal Australians, with stroke occurring up to three times more frequently, at a younger age, and being three times as likely to result in being dependent at hospital discharge.[3] Traumatic brain injury (TBI) after assault occurs 21 times more frequently[4], and head trauma accounts for 31% of all injuries requiring hospitalisation.[5] Motor, communication, sensory, and cognitive deficits all adversely affect quality of life in the long term, including employment status and prospects, family relationships, social participation, and typically resultant depression.[6,7] Currently, there is little ongoing engagement between Aboriginal brain injury survivors and mainstream hospital based rehabilitation services, with complex service pathways to navigate following hospital discharge, particularly in rural areas.[8] This unmet burden results in considerable suffering for brain injury survivors, their families, and communities. The burden of poor service delivery results in continuing challenges and additional costs to the health system reflected in management of immediate and subsequent chronic care issues and repeated hospitalisations.[9,10]

Specific care issues

Fewer Aboriginal people than non-Aboriginal people are admitted to stroke units.[11] When Aboriginal patients are admitted to stroke units, allied health assessments are conducted later than for non-Aboriginal patients.[11] Additionally, the majority of health professionals feel under-prepared to work with Aboriginal patients in a culturally secure manner[12,13] and few people are seen for issues specifically related to brain injury in Aboriginal Community Controlled Health Services.[14] Coffin's work in an earlier study of stroke survivors in Geraldton also highlighted gaps in services and under-confidence of health professionals working with Aboriginal patients.[15]

Our Western Australian -based research team, through the *Missing Voices* project[16] and a previous pilot study,[14] was the first to investigate this issue across the state. This work involved an in depth epidemiological examination of the extent of acquired communication disorders (ACD) following brain injury[17] and investigation into the experiences of individuals with ACD as well as health providers.[18.19] We were the first to develop a screening tool for acquired communication disorders after brain damage in Aboriginal populations.[20] Through interviewing brain injury survivors, their families, and a range of Aboriginal and non-Aboriginal health service providers, *Missing Voices* found that survivors and their families wanted more services, and found the transition from hospital to home difficult. Many felt they received little information on how to live with the brain injury in the longer term, including what services and funding were available to meet their ongoing needs. Our extensive file audit in *Missing Voices*, combined with interview data, also revealed that lack of coordination between services was a major issue and while in hospital, few people saw an Aboriginal Health Liaison Officer or an interpreter when English was not their first language. Aboriginal brain injury survivors are more likely to suffer from multiple and serious co-morbidities than non-Aboriginal survivors, and are more likely to live in very remote and socioeconomically disadvantaged areas in WA. As a result, they are more likely to be admitted to regional or district hospitals as emergency admissions.[17] Difficulties associated with subsequent transfers to unfamiliar metropolitan hospitals away from country, compound the situation. Patients are distanced from families who struggle to find the resources to travel to visit their relative while at the same time maintaining often complex family situations at home.

Healthcare workers reported similar issues, but from the service provider perspective. General Practitioners, Speech Pathologists and Aboriginal Health Workers all commented on a lack of a) coordination and communication between health service providers, b) accessible information regarding brain injury rehabilitation and c) culturally appropriate therapy resources.[18,19] Many felt ill-equipped to work with Aboriginal families due to lack of confidence in what was culturally appropriate to discuss, how to structure family meetings, and knowledge of linguistic and cultural customs in general. Many felt rehabilitation and services were not always wanted by Aboriginal brain injury survivors.

The current project will translate the findings of both previous studies across WA and will test the impact of a research-informed *culturally secure*[21] intervention model for Aboriginal people with brain injury in WA. This will occur in partnership with WA Department of Health services and Aboriginal Community Controlled Health Services, as well as national policy-makers. The project addresses the systemic challenges identified in our research using existing resources where possible, and developing a site and service specific sustainable evidence-based approach. Due to the chronic nature of consequences of brain injury, the proposed intervention package follows a Chronic Care Model (CCM)[22] demonstrated to be successful in the management of other chronic conditions, incorporating specific components related to brain injury. This clinically oriented model aims to reshape the ambulatory care system into one characterised by multi-disciplinary team involvement, continuity and integration of care, proactivity, flexibility, and self-management, all aimed at preventing complications and improving quality of life. This project will also increase workforce capacity by employing Aboriginal Community Nurses/Health Workers as Aboriginal Brain Injury Coordinators in the management of brain injury survivors. It will facilitate a more integrated, collaborative and culturally secure response to brain injury between hospital, rehabilitation, and community services (both 'mainstream' and Aboriginal community controlled). This model can then be applied nationally. The project is aligned with Priority 4 of the WA Health Strategic Intent 2015 – 2020[23] and adheres closely to the NHMRC Roadmap II.[24]

4 Objectives

The aims of this stepped-wedge cluster randomised controlled trial (CRCT) are to:

1. improve delivery of rehabilitation services to Aboriginal people post-brain injury (stroke and traumatic brain injury)
2. improve overall health outcomes for the above population
3. conduct an economic evaluation to support the business case for funding new rehabilitation services which will contribute to the planning and sustainability of future services if the intervention is determined to be cost-effective
4. explore the acceptability of the intervention from the perspectives of the health professionals and the Aboriginal participants involved, and to utilise this information to assist in interpretation and translation of findings.

4.1 Primary hypothesis

H1 Compared to usual care, implementation of the proposed intervention package (IP) will result in an at least a 15 point higher score on the Euro QOL–5D-3L[25] VAS at 26 weeks post injury.

4.2 Secondary hypotheses:

H2a Compared to usual care, implementation of the IP will result in significant improvement in service delivery at 12 and 26 weeks post injury as related to increased occasions of service.

H2b Compared to usual care, implementation of the IP will result in significant improvement in service delivery at 12 and 26 weeks post injury as related to increased compliance with minimum process of care indicators.

H3 Compared to usual care, implementation of the IP will result in significant reduction in disability (Modified Rankin Scale – mRS[26]) and greater independence (Functional Independence Measure - FIM^{TM} [27]) at 12 and 26 weeks post injury.

H4 Compared to usual care, implementation of the IP will result in significantly less carer burden (Modified Caregiver Strain Index[28]) and less brain injury survivor anxiety and depression (Hospital Anxiety and Depression Scale[29]) at 12 and 26 weeks post injury.

H5 The culturally sensitive IP will be more cost-effective (additional benefits gained will justify additional costs for delivering the intervention; may lead to potential cost-offsets from less severe disease) than usual care 26 weeks post injury.

H6 The IP will be acceptable to health professionals and Aboriginal participants and their families, and the role of the Aboriginal Brain Injury Coordinator is a feasible one.

5 Study Design

Design: A stepped wedge cluster randomised control trial (CRCT) design[30] will be used, with pairs of healthcare sites functioning as clusters. Each metropolitan hospital will be paired with a regional hospital. The pairing will be broadly based on existing stroke pathways linking the hospitals. Twenty-six weeks of baseline control data will be obtained prior to implementation of the intervention, which will be introduced sequentially to all sites at 26-week intervals. Control data will continue to be collected at each site until the intervention commences. The intervention will continue within each cluster until the last clusters have received the intervention for a 52 week period.

Figure 1: Stepped wedge design

Jan-Jun'17	Jul-Dec'17	Jan-Jun'18	Jul-Dec'18	Jan-Jun'19	Jul-Dec'19	Jan-Jun'20	Jul'20-Jul'21
Project Set-up including ethics, staff recruitment	Sites 7&8	Sites 7&8	Sites 7&8	Sites 7&8	Sites 7&8	Sites 7&8	Analysis & Feedback Write up
	Sites 5&6	Sites 5&6	Sites 5&6	Sites 5&6	Sites 5&6	Sites 5&6	
	Sites 3&4	Sites 3&4	Sites 3&4	Sites 3&4	Sites 3&4	Sites 3&4	
	Sites 1&2	Sites 1&2	Sites 1&2	Sites 1&2	Sites 1&2	Sites 1&2	

*Dark Shaded area = baseline control observational data collection; Light Shaded area = intervention underway

Due to the complex nature of the intervention i.e. multiple components, broad site base (including very different local contexts across sites), potential contamination across sites due to movement of some patients from rural to metropolitan hospitals, and potential clinical changes throughout the intervention period (e.g., changes of staff, changes in local organisation of services), a process evaluation[31] will be undertaken alongside measurement and analysis of the intervention and primary outcomes as per the TIDieR checklist.[32]

5.1 Recording Control and Intervention periods

Based on site randomisation, all clusters will collect control data until notified of the commencement of the Intervention period by the central team. Distinction of control and intervention periods for each site will be recorded using REDCap[33] data recording system (see Section 17).

6 Study Setting

Eight acute hospital sites across Western Australia will participate in the study. These include four Perth metropolitan sites (Sir Charles Gairdner Hospital, Royal Perth-Bentley Hospital, Fiona Stanley-Fremantle Hospital, St John of God Midland Hospital) and four regional sites (Broome Hospital, Kalgoorlie Hospital, Geraldton Hospital and Hedland Health Campus, Port Hedland). Transfer across hospitals within WA is anticipated, and 'step-down' rehabilitation sites will be involved (ethics approval obtained) for participant follow-up but not recruitment.

7 Study Population

Aboriginal people ≥18 years of age, admitted for acute stroke and/or traumatic brain injury to hospital in each of the intervention sites will be recruited.

7.1 Number of participants

The number of Aboriginal participants with brain injury required for this study is 312.

7.2 Inclusion and Exclusion Criteria

Participants will be identified, recruited, and will participate in first assessment within 42 days of brain injury.

7.2.1 Inclusion criteria:

- Identification as Aboriginal (from medical file or through self-identification via personal communication with staff)
- ≥Age 18 years
- Acute ischaemic or haemorrhagic stroke defined as "an acute episode of focal dysfunction of the brain lasting longer than 24 hours, or of any duration if imaging (CT or MRI) shows focal infarction or haemorrhage relevant to the symptoms"[1]
- Acute traumatic brain injury defined as 1) a head trauma severe enough to cause traumatic brain injury and causing neurological symptoms (including headache and nausea) lasting at least 1 week and 2) at least one of the following: loss of consciousness for at least 1 minute, posttraumatic amnesia for at least 30 minutes, neurological symptoms (excluding headache and nausea) during the first 3 days after the injury,

or neuroradiological findings suggesting traumatic brain injury (e.g., skull fracture, intracerebral haemorrhage)[2]

- Neurological deficit present as reflected in NIHSS[34] > 0
- Able to benefit from rehabilitation as determined by the medical and allied health team within the first six weeks post injury.

7.2.2 Exclusion criteria:

- No TIA defined as "focal dysfunction of less than 24 hours duration and with no imaging evidence of infarction"[1]
- Glasgow Coma Scale (GCS)[35] severity score <8
- Concurrent progressive neurological disorder(s)
- Pre-existing clinical diagnosis of dementia with patient fulfilling ICD 10 criteria for dementia
- Documented pre-existing psychosis
- For palliative care and not likely to survive to primary endpoint i.e. 26 weeks
- Participation in other intervention trial

8 Site Randomisation

Sites will be randomised at the beginning of the project to determine the sequencing of the introduction of the intervention period.

It is anticipated that numbers of participants recruited in metropolitan sites may be higher than in regional sites due to potential transfer of patients to tertiary metropolitan hospitals for early treatment post injury. In order to minimise potential differences in participant numbers across steps in the wedge, one metropolitan and one regional site (cluster) will be paired prior to randomisation, then these pairs of sites will be randomised. Sites will be assigned to a particular intervention commencement time through the use of computer-generated sequence of random numbers. The process will allocate sites to one of four commencement periods (see Figure 1).

9 Participant Recruitment

All Aboriginal patients admitted to participating hospital sites who meet the study criteria (Section 7.2) will be approached to participate by the investigator. If the person agrees for their name to be given to the clinical trial team, a team member will preferably see the person in hospital within two days of referral in order to further discuss the project and obtain written informed consent. If, however, the person is discharged before the baseline assessor is able to attend in order to gain consent and complete an assessment or the baseline assessor cannot attend the hospital in person due to hospital or patient-related restrictions, the assessor will telephone them, to see if they would be interested in hearing more about the project/being involved. If the person agrees, the assessor will then see the person at their home, mutually agreed location or will contact via telephone/telehealth facility in order to further discuss the project, obtain consent, and complete the baseline assessment. Project information will be given to the patient in hard copy, digitally or verbally based upon whether it is safe and feasible for a baseline assessor to visit the patient in person and the patient's access to electronic and digital communication platforms including email and telehealth programs. Patients will give their consent to participate either in wet-ink writing; via

electronic or digital signature or verbally. In the latter scenario the baseline assessor will read aloud information from the Participant Information and Consent Form to provide the patient with project information. The patient's verbal decision will be recorded in the CRF at the recruiting hospital. The patient will then be sent a copy of the study's information sheet. In the case of the investigator not having had the opportunity to approach the person whilst in hospital, the investigator will telephone them, to see if they would be interested in hearing more about the project/being involved. If the person agrees for their name to be given to the clinical trial team, the baseline assessor will then see the person at their home, mutually agreed location or will contact via telephone/telehealth facility in order to further discuss the project, obtain informed consent, and complete the baseline assessment and processes will proceed as above. The informed consent process will involve the use of 'aphasia friendly' information to accommodate patients with communication disorders, those with other cognitive issues typically associated with brain injury, and those with limited literacy skills. The process will also involve a relevant interpreter as needed. In the case of patients with a decision making disability who are incapable of providing consent, we will apply a Research Decision Maker consent pathway. Within this study, exclusion on the basis of inability to give consent would discriminate against individuals with severe brain injury, as the intervention provides additional client and family support and monitoring, rather than being a specific activity based or pharmaceutical intervention.

Participants can be recruited to the study at any time within six weeks post injury.

10 Study Assessment and Procedures

In this study, 'baseline' refers to both individual participant status and the status of services provided at each site during the Control period i.e. before the intervention period commences. As part of the stepped-wedge project design, the length of service baseline (i.e. usual care control period, where intervention has not been introduced) will vary across sites depending on when they are randomised to receive the intervention. Those sites receiving the intervention in 2018 will have shorter control periods than those not receiving interventions until 2019.

10.1 Screening

All Aboriginal stroke and traumatic brain injury patients over the age of 18 admitted to hospital will be screened for inclusion in the study as per the eligibility criteria outlined in section 7.2. Those screened by the investigator and deemed not eligible for the study will be entered into a screening log, which outlines the reason for non-inclusion in the study.

10.2 Participant Assessment Schedule

10.2.1 Baseline Assessments

Assessors trained in the use of all assessment tools will collect all patient related data. Required study assessments are outlined in Appendix 1 – Schedule of Assessments.

Individual baseline data will preferably be collected on the same day as consent (or within 2 days if recruited over a weekend) from participants who meet all inclusion criteria and have provided consent. The assessment will be completed within 42 days of injury. The assessments completed at baseline will be: modified Rankin Score (mRS),[26] Functional Independence Measure (FIM™),[27] Hospital Anxiety Depression Scale.[29]

Baseline data collection will include the collection and documentation of:

1) Demographic details including age, gender, languages spoken, language group, residence location (metro/rural/remote), premorbid employment, Aboriginal or Torres Strait Islander status, living arrangements at the time of admission
2) Details related to brain injury type (stroke vs traumatic brain injury), and pathological sub-types of each (stroke: ischaemic vs haemorrhagic; TBI: closed, penetrating, blast, crush - as per IMPACT core data set[36]), hemisphere(s) involved, first or recurrent/subsequent injury, and severity as determined by the National Institutes of Health Stroke Scale[34] (for the post stroke participants) and the Glasgow Coma Scale[35] (for the post traumatic brain injury participants). Cause of the TBI i.e. road traffic incident vs violence will also be recorded.
3) Past medical history, brain injury history and comorbidities.
4) The assessment tasks should be completed in a single session. If the participant is unable to complete assessment tasks in a single session, they must be completed on the same day if possible (i.e. over a morning and afternoon session). If this is not possible, the assessments should take place on consecutive days. Protocol deviations will be recorded if assessment sessions are not completed on the same day or if sessions are completed later than the due date +/- 7 days.

10.2.2 Week 12 (84 days post injury +/- 14 days) follow up visit

The participants will be followed up at their place of residence, in the hospital or Aboriginal Medical Service clinic as convenient for the participant, or by phone/telehealth facilities as appropriate by a blinded assessor. The assessment tasks should be completed in a single session. If the participant is unable to complete assessment tasks in a single session, they must be completed on the same day if possible (i.e. over a morning and afternoon session). If this is not possible, the assessments should take place on consecutive days. Protocol deviations will be recorded if assessment sessions are not completed on the same day or if sessions are completed later than the due date +/- 14 days.

During this visit, the modified Rankin Score (mRS),[26] Functional Independence Measure (FIM™),[27] Modified Caregiver Strain Index[28] and Hospital Anxiety and Depression Scale[29] will be re-administered, as well as the EuroQol-5D-3L.[25] See Appendix 1 for details.

At this visit the participant and/or their carer will be asked about their general health to determine if there have been any adverse events since their last visit.

As part of the economic analysis and as part of general service data (see Section 10.4 below), data will be collected for all patients at this visit regarding inpatient and outpatient rehabilitation related sessions (rehabilitation specialist, allied

health sessions). In addition, hospital length of stay, cost of transfer from rural to metro sites, private services used up to 12 weeks post onset (rehabilitation services, allied health sessions), cost of travel associated with patient accessing services, rehabilitation costs of medical/allied health specialists visiting patients in their homes/remote communities, number of associated services required e.g., respite care, cost of current Aboriginal Liaison Officer services, specialist ABIC services, cost of interpreter services. Also costed will be carers' and brain injury survivors' loss of income or household productivity impacts. A record of pre-event (stroke or ABI) services use will also be captured to account for service use that is only applicable to the current condition.

As part of the process evaluation, a brief questionnaire will be completed with the assistance of the assessor, focusing on hospital experiences and brain injury related services to date. Another questionnaire surrounding the services of the ABIC as relevant to the intervention period will also be administered. However in order to maintain blinding of the main assessor, another independent assessor will administer this questionnaire

10.2.3 Week 26 (182 days – 14 days / + 28 days follow up visit

The participants will be followed up at their place of residence, in the hospital or Aboriginal Medical Service clinic as convenient for the participant, or by phone/telehealth facilities as appropriate by a blinded assessor. The assessment tasks should be completed in a single session. If the participant is unable to complete assessment tasks in a single session, they must be completed on the same day if possible (i.e. over a morning and afternoon session). If this is not possible, the assessments should take place on consecutive days. Protocol deviations will be recorded if assessment sessions are not completed on the same day or if sessions are completed later than the due date – 14 days / +28 days.

During this visit, the modified Rankin Score (mRS),[26] Functional Independence Measure (FIM^{TM}),[27] Modified Caregiver Strain Index[28] and Hospital Anxiety and Depression Scale[29] will be re-administered, as well as the EuroQol-5D-3L.[25]

At this visit the participant and or their carer will be asked about their general health to determine if there have been any adverse events since their last visit.

As part of the economic analysis and as part of general service data (see Section 10.4 below), data will be collected as per the 12 week visit for all patients at this visit regarding inpatient and outpatient rehabilitation related sessions (rehabilitation specialist, allied health sessions) occurring between the 12-26 week period (see previous Section 10.2.2).

As part of the process evaluation, a brief questionnaire will be completed with the assistance of the assessor, focusing on hospital experiences and brain injury related services to date. Another questionnaire surrounding the services of the ABIC as relevant to the intervention period will also be administered. However in order to maintain blinding of the main assessor, another independent assessor will administer this questionnaire. Individual interviews with a sub-section of participants (n=10) exploring participants' satisfaction with the Aboriginal Brain Injury Coordinator service will be conducted at 26 weeks

10.3 Assessment details

10.3.1 The Euro QOL-5D-3L[25]

The Euro QOL–5D-3L developed by the Euroquol group, has two sections: the EQ-5D descriptive system which measures the health-related dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression on a 3 point scale, and the EQ visual analogue scale (EQ VAS) – a vertical where the endpoints are labelled 'Best imaginable health state' and 'Worst imaginable health state'. It has been used with stroke and traumatic brain injury survivors,[37,38] validated in many different countries and cultural settings, and can be administered by face to face or telephone interview, or as a self-or proxy mail out.

The Euro QOL-5D-3L will be completed at 12 and 26 weeks post injury.

10.3.2 Modified Rankin Scale[26]

The mRS is a scale commonly used for measuring the degree of disability or dependence in the daily activities of individuals post-stroke. The mRS has an administration time of approximately 5 minutes. The scale contains 7 points from 0-6, ranging from perfect health without symptoms to death.

The mRS will be administered at baseline and at 12 and 26 weeks post injury. It is validated for administration by telephone as well as face to face. All assessors will hold formal training certificates in the use of this tool.

10.3.3 Functional Independence Measure™[27]

The FIM™ is a basic indicator of level of disability, and measures changes in a patient's functional abilities. It consists of 18 items, grouped into 2 subscales - motor (13 items) and cognition (5 items). Each item is scored on a 7 point scale, which ranges from 1-7. On the scale, 1 represents total dependence in a particular functional skill and 7 represents complete independence.

The total score for the FIM motor subscale (the sum of the individual motor subscale items) ranges from 13 to 91.

The total score for the FIM cognition subscale (the sum of the individual cognition subscale items) ranges from 5 to 35.

The total score for the FIM instrument (the sum of the motor and cognition subscale scores) will be a value between 18 and 126.

The FIM™ will be administered at baseline and at 12 and 26 weeks post injury. It is validated for administration by telephone as well as face to face interview, and by proxy.

All assessors will hold formal training certificates in the use of this tool.

10.3.4 Modified Caregiver Strain Index[28]

The Modified Caregiver Strain Index is a 13-item questionnaire administered to carers and concerns burden of care-giving. Carers are required to respond with 'yes, on a regular basis' (=2 points), 'yes, sometimes' (=1 point) or 'no' (=0 points). Test instructions indicate that any positive answer may indicate a need for intervention in that area. A total score of 7 or higher indicates a high level of stress.

The Modified Caregiver Strain Index will be administered at 12 and 26 weeks post injury.

10.3.5 Hospital Anxiety and Depression Scale[29]

The Hospital Anxiety and Depression Scale is a 14 item questionnaire designed to measure anxiety and depression in a general medical population and takes between 2-5 minutes to complete. There are seven items for anxiety and seven for depression and the two areas are scored separately. There is a 4 point scale for each. For both areas, scores that are less than 7 are considered 'non-cases.' Scores between 8-10 are considered mild, 11-14 = moderate, and 15-21 = severe.

The Hospital Anxiety and Depression Scale will be administered at baseline, 12 and 26 weeks post injury.

10.4 Service data

Site data will be collected with respect to services delivered to each participant for six months during the control and intervention periods. This data will consist of:

- Occasions of service per allied health discipline (Physiotherapy, Occupational Therapy, Speech Pathology, Social Work, Dietetics; Clinical Psychology/ Neuropsychology; Prosthetics/Orthotics; Therapy Assistant; inpatient and outpatient)

The data will be collected through a medical file review process and through access to hospital administrative data systems as needed.

In addition, *Minimum Process of Care Indicators* will capture data on whether key processes of care occurred while the patient was in hospital and/or within 26 weeks of injury.

The data collection will:

- involve extraction of relevant data from medical file (audit process)
- be undertaken by an independent blinded auditor
- include hospital sites at which patients were admitted for the index admission and any related contiguous admission or related admission
- will include inpatient and hospital notes
- be audited cumulatively i.e. they will be checked for occurrence across the 26 week follow up period
- note the timing of items with reference to the index admission will be recorded
- occur at 6 month intervals

The Minimum Processes of Care are the following:

- patient assessed by allied health within 48 hours of admission
- Aboriginal Liaison Officer involved during inpatient stay
- language noted in medical file
- interpreter used if Aboriginal language is participant's primary language
- telephone or face to face contact with family made by any allied health staff during inpatient stay
- Aboriginal brain injury educational resource provided during inpatient stay
- inpatient allied health service provided (any discipline)
- discharge plan developed with patient and family at family conference

- outpatient allied health service provided (any discipline)

In the case of participants returning from a metropolitan hospital to a regional/rural/remote location:

- verbal contact made by the metropolitan hospital with local rural service provider (hospital and local Aboriginal Medical Service)
- discharge report from metropolitan hospital sent to rural service provider (hospital and local Aboriginal Medical Service)

10.5 Resource utilisation and valuation of costs

A standardised protocol ensuring uniform data collection will be used to calculate resource use in participants during the control and intervention phases of this study. Details of all services used will be collected, by the blinded assessor, for all participants until 26 weeks post injury.

As noted above, the following data will be collected for all patients: hospital length of stay, ambulance transfers, emergency hospital visits, inpatient and outpatient rehabilitation related sessions (rehabilitation specialist, allied health sessions), general practice services, bush medicine services, therapy aids and equipment and any informal care by family or friends. In addition, for the purposes of this analysis specifically, cost of transfer from rural to metro sites, private services used up to 26 weeks post brain injury (rehabilitation services, allied health sessions), cost of travel associated with patient accessing services, rehabilitation costs of medical/allied health specialists visiting patients in their homes/remote communities, number of associated services required e.g., respite care, cost of current Aboriginal Liaison Officer services, specialist ABIC services, cost of interpreter services. Also costed will be carers' and brain injury survivors' loss of income or household productivity impacts. A record of pre-event (stroke or ABI) services use will also be captured to account for service use that is primarily applicable to the current condition.

Two methods will be used to collect resource use information. First, as noted above, the eCRF will capture brain injury related therapy activity including amount and discipline of therapy received. Second, a participant interview will capture changes to employment and services utilised as a result of the brain injury including: length of acute hospital stay; discharge destination; inpatient and outpatient rehabilitation; hospital readmissions; GP visits; community and health care service use; medication use (including medication prescribed after the stroke for anxiety and depression); allied health therapies; respite and informal care services; and changes to participant and carer employment; and any aids/devices provided. The additional costs of providing the interventions (program-related costs) will also be estimated as part of the Economic Evaluation.

Resource utilisation information will be used to estimate the cost effectiveness of both the cultural training and the implementation of the ABIC (see section 12.5). In brief, cost description analyses of each comparator group to 26 weeks will be detailed. Cost items will be valued for the reference year 2020. Where prices in 2020 are unavailable, adjustment to the real price will be made using the published health sector specific deflator/inflators. Incremental cost-effectiveness ratios or the net difference in costs and outcomes will be calculated for the intervention group relative to the control group. Sensitivity and uncertainty (probabilistic multivariable [Monte-Carlo simulated])

analyses to account for variability in point estimates will be performed to assess the robustness of results.

10.6 Safety Assessments

At all visits, participants will be assessed for possible Adverse Events (AEs). All ongoing SAEs should be followed through to stabilisation or recovery. AEs that are possibly, probably or definitely attributable to the intervention will be reported via the eCRF as they occur (between consent and 26 weeks post brain injury). The investigator and designated study personnel will monitor each participant for AEs during the study.

AEs that meet the criteria for serious, are considered Serious Adverse Events (SAEs) and will be reported for the duration of the project. The investigator or designee will ask the participant non-leading questions in an effort to detect adverse events, important medical events and serious adverse events. Refer to section 13 of this protocol for detailed explanation.

11 Study intervention

As with the control periods, the intervention periods will vary across sites, with some sites having 2.5 years, and some having 1 year in total. This will depend on site randomisation. The intervention will consist of two components – i) Cultural Security Training (CST) for hospital staff, and ii) introduction of an Aboriginal Brain Injury Coordinator (ABIC) at each site employed for one day/week.

11.1 Description of interventions

11.1.1 Cultural Security Training of hospital staff

The CST will involve training of 20 health professionals at each site (nursing, medical and allied health staff). It will involve 3 hours face-to-face time delivered in person where possible or live via on-line platforms if constrained by extraordinary circumstances (such as hospital quarantine as per COVID-19 context), followed by 3 hours online focusing on issues surrounding brain injury. The face to face sessions will be co-facilitated by a local cultural security trainer and a member of the research team. The training will be undertaken to suit the individual site with alternative delivery sessions being one three hour block or 3 x 1 hour sessions and will be completed within a 3 week period. The online modules will constitute approximately 3 hours of study. This component must be completed within 3-4 weeks of completion of the face to face component. administered by Edith Cowan University

The training will be offered at each site every 6 months to address the issue of changing/rotating staff.

Details of the CST are outlined in the Intervention Protocol.

11.1.2 Aboriginal Brain Injury Coordinator

An Aboriginal person will be employed for one day/week at each of the project sites as an Aboriginal Brain Injury Coordinator (ABIC). The ABIC will see the participants in hospital and up till 26 weeks post injury onset and provide

education, support, liaison, and advocacy services to the participants and their families.

A minimum qualification of a Certificate 3 in a relevant health or community care subject of study will be required. Qualifications and experiences as an Enrolled or Registered Nurse or in Aboriginal Health Work will be highly desirable.

The ABIC will receive 12 hours of training from the Neurological Council of Western Australia (NCWA) and the research team. Each ABIC will be located either in the hospital, the local community controlled Aboriginal Medical Service (AMS), or offices of the NCWA as part of their community neurological nursing service, depending on the preference of each site. This person will be supported by the local AMS, the NCWA community nursing service, and the research project manager.

The ABIC will visit the person if admitted locally to hospital, and follow up with the person and their family at home/aged care facility for 26 weeks thereafter. In cases of transfer between sites in the study, the ABIC at the site of recruitment will be the primary contact with the participant. Follow up of participants will occur through phone or telehealth contact as agreed upon. However, if the ABIC services have commenced at the place to which the participant is transferred, then the local ABIC will see the participant there. Conversely, if there is no ABIC service at the site of recruitment, the participant will not receive ABIC services even if they are transferred to a hospital region where ABIC services have been introduced, as they are technically part of the control period of the original site.

Further detail of the ABIC's role is outlined in the Intervention Protocol.

Any deviation from the prescribed protocols will be reported as a protocol deviation.

11.2 Recording of interventions

11.2.1 Cultural Security training:

The dates of training, numbers in attendance, characteristics of attendees in terms of discipline, years professional experience, gender, age and ethnic background will be recorded in a databaseby the research team member involved in the site-training.

11.2.2 Aboriginal Brain Injury Coordinator

The activities of the Aboriginal Brain Injury Coordinator that involve direct and indirect contact with participants will be recorded in the e-CRF.

Details to be recorded include: the date of the activity; nature (direct or indirect); modality of direct contact (in-person; telephone; video-conference); location of the participant during contacts; location of ABIC during contacts; the specific activities that occurred (assessment of needs; counselling; goal setting; attending appointments with participant; education to patient and family; making referrals, advocacy, liaison with social services; attendance at multi-disciplinary meetings; consultation with healthcare providers). When the

activity relates to direct participant contact, either face to face or via telephone/ video-conference the length of the session should be recorded.

The ABIC will also make clinical notes relevant to care coordination activities with the participant in a participant specific file that is identified by a participant number and which will be kept in a locked cabinet at the ABIC's workplace (either the offices of the NCWA or the Aboriginal Medical Service). These files will also contain an action plan; documented goals; documents related to referrals made; written correspondence with health and support services. The contents of these files will be sent to the recruiting site for storage in the CRF at the recruiting site, at completion of the intervention period.

11.3 Intervention integrity

Detailed information regarding the implementation of the CST and the ABIC role is essential to record whether these components are delivered as planned.

The following components of each aspect of the intervention will be recorded for intervention integrity purposes.

11.3.1 Cultural Security Training

Dates of training, adherence to content, staff attendance and face to face completion of the training will be recorded by the research team member involved in the site-training. Completion of the online training component will be recorded on the secure website containing the online materials

11.3.2 Aboriginal Brain Injury Coordinator (ABIC)

Completion of training of the ABIC will be recorded.

To ensure the ABIC role is implemented as prescribed, Redcap data entry related to the ABIC role will be monitored on a monthly basis. Feedback will be provided to the ABIC if data is missing or prescribed activities have not been performed. These monitoring activities will occur in conjunction with ongoing clinical supervision by NCWA and ECU. See further details in the Intervention Protocol

12 Process evaluation

As well as data related to intervention integrity, data will be collected that will enable evaluation of potential causal and overall contextual factors related to the outcomes of the study, as recommended by MRC[34] and as included in the TIDieR checklist[31]. As the nature of the intervention is complex i.e. interacting components, careful monitoring of implementation and contextual factors, including those related to organisational attitudes, hospital staff, brain injury survivors, and ABICs will be undertaken.

12.1 Cultural Security Training

Factors related to the impact of the CST including *staff satisfaction* with training, and *perceived usefulness* of training will be measured through evaluation questionnaires.
A questionnaire examining staff satisfaction with and impact of the face to face training will be completed at the end of the face to face training (see Appendix 2). An online

questionnaire examining satisfaction with and impact of the online training specifically as well as reflection on the overall program will be undertaken by staff at the completion of the online component (see Appendix 3).

As well as the Minimum Processes of Care Indicators monitored as part of the main secondary data collection (see Section 10.4), a brief questionnaire will be undertaken with all Aboriginal participants at 12 and 26 week post discharge that will incorporate ratings of their hospital and general rehabilitation service experiences in terms of cultural security (see Appendix 4). This data will provide information on how services were received – which parts worked well and which parts might need to be further improved.

12.2 Aboriginal Brain Injury Coordinator

The implementation of the ABIC will be monitored through the data collected as described in Section 11.2.2. In addition, a brief questionnaire surrounding the Aboriginal participants' perceptions regarding the usefulness of the ABIC support will be completed at 12 and 26 weeks (see Appendix 5). Individual interviews with a sub-set of participants (n=10) exploring participants' satisfaction with the Aboriginal Brain Injury Coordinator service will be conducted at 26 weeks by an independent interviewer.

The ABICs will also be interviewed either during or at the completion of their employment in order to gain their reflections and perspective on the role (see Appendix 6). Informal interviews with NCWA and AMS personnel working with the ABIC will be undertaken to record attitudes and context relevant to implementation of this service. All documentation will be coded and qualitatively analysed to identify themes/issues that arise. Any deviation from the prescribed treatment protocol will be documented, along with reasons and context as part of the process evaluation.

Individual characteristics of the ABICs will be recorded in order to estimate potential effects of personal characteristics including age, gender, language group, qualifications and previous experience in health settings. Primary location of the ABIC will also be recorded e.g. regional vs metropolitan, AMS vs NCWA-based in order to gauge effects of geographical context.

Recruitment and turnover of ABIC staff will also be recorded.

12.3 Hospital and community context

Ongoing descriptive information will be collected at each site related to the specific hospital context e.g. general staffing levels, staff turnover, policy changes, accreditation processes occurring. This information will be collected by the Project Manager through informal discussions with key staff, and through regular Partner meetings (4 per year) where the general progress of the trial will be discussed, along with any such factors perceived to be influencing service delivery at the site. Content of these meetings will be recorded in detailed meeting minutes. In addition, the Project Manager will collect contextual information specific to the local community e.g. community activities available beyond formal hospital services e.g. yarning groups, social groups, location of AMSs within regions involved.

13 Adverse Events (AE) and Serious Adverse Events (SAE)

The investigator is responsible for the detection and documentation of events meeting the criteria and definition of an adverse event as detailed below (AE) or a serious adverse event (SAE) as provided in this protocol. During the study, when there is a safety evaluation, site staff will be responsible for detecting AEs and SAEs, as detailed in this section of the protocol.

13.1 Definition of an Adverse Event (AE)

An Adverse Event (AE) is any untoward medical occurrence in any participant involved in the study. It does not necessarily have to have a causal relationship to the study intervention. However, for the purposes of this study, only those events which are possibly, probably or definitely attributable to the intervention will be noted.

Examples of an AE **include**:

- Exacerbation of a chronic or intermittent pre-existing condition including either an increase in frequency and/or intensity of the condition.
- New conditions detected or diagnosed after involvement in the study even though it may have been present prior to the start of the study.

Examples of an AE **do not include** a/an:

- Medical or surgical procedure (e.g. endoscopy, appendectomy); the condition that leads to the procedure is an AE.
- Situations where an untoward medical occurrence did not occur (social and/or convenience admission to hospital).

13.2 Definition of a Serious Adverse Event (SAE)

A serious adverse event is any AE that:

a) results in death

b) is life threatening

Note: The term 'life-threatening' in the definition of 'serious' refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event, which hypothetically might have caused death if it were more severe.

c) requires hospitalisation or prolongation of an existing hospitalisation.

Note: In general, hospitalisation signifies that the participant has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or out-patient setting. Complications that occur during hospitalisation are AEs. If a complication prolongs hospitalisation or fulfils any other serious criteria, the event is serious. When in doubt as to whether 'hospitalisation' occurred or was necessary, the AE should be considered serious.

Hospitalisation for elective treatment of a pre-existing condition that did not worsen from baseline is not considered an AE.

d) results in disability/incapacity, or

Note: The term disability means a substantial disruption of a person's ability to conduct normal life functions. This definition is not intended to include experiences of relatively minor medical significance such as uncomplicated headache, nausea, vomiting, diarrhoea, influenza, and accidental trauma (e.g. sprained ankle) which may interfere or prevent everyday life functions, but do not constitute a substantial disruption.

e) is a congenital abnormality / birth defect.

Medical and scientific judgement should be exercised in deciding whether reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation, but may jeopardise the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These should also be considered serious. Examples of such events are invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalisation, or development of drug dependency or abuse.

The investigator will exercise his or her medical and scientific judgement in deciding whether an abnormal laboratory finding or other abnormal assessment is clinically significant.

13.3 Time Period, Frequency, and Method of Detecting AEs and SAEs

All SAEs will be recorded from the time of consent until the final follow up visit at week 26.

Other adverse events possibly, probably, or definitely attributable to the intervention will be recorded from the time of consent until the final follow up visit at week 26.

Each participant will be monitored regularly by the site investigator and study personnel for events occurring throughout the study. During the period in hospital, the site investigator will enquire about AEs by asking the following non-leading questions:

"How are you feeling?"

At subsequent scheduled intervals participants will be asked:

"Since you were last asked, have you felt unwell or different from usual?"

13.4 Recording of AEs and SAEs

When an AE/SAE occurs in hospital, it is the responsibility of the investigator to review all documentation (e.g. hospital progress notes, laboratory, and diagnostic reports) relative to the event. The investigator will notify the Project Manager and will record all relevant information regarding an AE/SAE in to the CRF. There may be instances when copies of medical records for certain cases are requested. In this instance, all participant identifiers will be blinded on the copies of the medical records prior to submission to the Sponsor.

For each reportable event, start and stop dates, action taken, outcome, intensity and relationship to study treatment (causality) will be documented. If an AE changes in frequency or intensity during a study, a new entry of the event must be made in the eCRF.

The investigator will attempt to establish a diagnosis of the event based on signs, symptoms, and/or other clinical information. In the absence of a diagnosis, the individual signs/symptoms should be documented.

All details of any treatments initiated due to the adverse event should be recorded in the participant's notes and the eCRF.

13.5 Prompt Reporting of SAEs to the Sponsor

Once an investigator or assessor becomes aware that an SAE has occurred in a study participant, he/she will immediately notify the sponsor by contacting the Project Manager via telephone. The SAE form must be completed as thoroughly as possible with all available details of the event, signed by the investigator (or appropriately qualified designee), and sent to the Project Manager within 24 hours of first becoming aware of the event.

If the investigator does not have all information regarding an SAE, ***he/she will not wait to receive additional information before notifying the Project Manager*** of the event and completing the form. The form will be updated when additional information is received.

The blinded assessor will always provide an assessment of causality at the time of the initial report as described in Section 13.6.2, "Assessment of Causality".

In accordance with local IEC requirements, the investigator must also notify their Ethics Committee of any SAEs according the guidelines of the Ethics Committee.

Those adverse events that are **CAUSALLY** related to the study treatment, **AND** that are both **SERIOUS** and **UNEXPECTED** – see section 9.8.3) are subject to expedited reporting to the independent Data Safety Monitoring Committee (DSMC).

The investigator, and others responsible for participant care, should institute any supplementary investigations of serious adverse events based on their clinical judgement of the likely causative factors. This may include seeking further opinion from a specialist in the field of the adverse event. If a participant dies, any post-mortem findings may be requested by the Sponsor.

13.6 Evaluating AEs and SAEs

13.6.1 Assessment of Intensity

The investigator will make an assessment of intensity for each AE and SAE reported during the study. The assessment will be based on the investigator's clinical judgement and assigned to one of the following categories:

Mild: An event that is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.

Moderate: An event that is sufficiently discomforting to interfere with normal everyday activities.

Severe: An event which is incapacitating and prevents normal everyday activities.

An AE that is assessed as severe should not be confused with an SAE. Severity is a category utilised for rating the intensity of an event; and both AEs and SAEs

can be assessed as severe. An event is defined as "serious" when it meets one of the pre-defined outcomes as described in Section 13.2 "Definition of an SAE".

13.6.2 Assessment of Causality

The blinded assessor is obligated to assess the relationship between study treatment and the occurrence of each AE/SAE. The blinded assessor will use clinical judgment to determine the relationship. Alternative causes, such as natural history of the underlying diseases, concomitant therapy, other risk factors, and the temporal relationship of the event to the treatment period will be considered.

The causal relationship to the study treatment assessed by the blinded assessor should be assessed using the following classifications:

Not Related	In the Assessors opinion, there is not a causal relationship between the study product and the adverse event.
Unlikely	The temporal association between the adverse event and study treatment is such that the study treatment is not likely to have any reasonable association with the adverse event.
Possible	The adverse event could have been caused by the study treatment.
Probable	The adverse event follows a reasonable temporal sequence from the time of study treatment, abates upon discontinuation of treatment and cannot be reasonably explained by the known characteristics of the study participant's clinical state.
Definitely	The adverse event follows a reasonable temporal sequence from the time of study treatment start or reappears when study treatment is reintroduced.

13.6.3 Assessment of Expectedness

Expected	An adverse event, the nature or severity of which is consistent with the clinical condition of the participant.
Unexpected	An adverse event, the nature or severity of which is not consistent with the clinical condition of the participant.

13.7 Follow-up of AEs and SAEs

After the initial AE/SAE report, the investigator is required to proactively follow each participant and provide further information to the sponsor for all ongoing events.

All AEs and SAEs documented at a previous visit/contact and are designated as ongoing, will be reviewed at subsequent visits/contacts.

All AEs and SAEs will be followed until resolution, until the condition stabilises, until the event is otherwise explained, or until the participant is lost to follow-up.

New or updated information will be recorded on the originally completed SAE form, with all changes signed and dated by the investigator. The updated SAE form should be resent to the Sponsor.

14 Participant Completion and Discontinuation

14.1 Participant Completion

Participants have completed the study when the final follow up visit at week 26 is complete and all data pertaining to this visit has been submitted to the study Sponsor.

14.2 Participant Withdrawal

Participants will be withdrawn from the study if they withdraw consent to continue, or if it is determined that involvement in the trial poses a health or safety risk to the participant.

Data collected up until the time of withdrawal will be used in analysis unless otherwise requested by the participant.

Withdrawn participants will not be replaced.

14.3 Early Termination of the Study

The study may be terminated prematurely by the principal investigator or his/her designee and the sponsor if:

- The number and/or severity of adverse events justify discontinuation of the study
- New data become available which raise concern about the safety of the study treatment, so that continuation might cause unacceptable discomfort to participants.

In addition the sponsor reserves the right to discontinue the trial prior to inclusion of the intended number of participants, but intends only to exercise this right for valid scientific or administrative reasons.

After such a decision, the investigator must contact all participating participants within two weeks, and written notification must be sent to the Ethics Committee.

15 Electronic Case Report Form (eCRF)

An electronic Case Report Form (eCRF) will be completed for each study participant summarising all clinical screening and study data. Participants will only be referred to in the eCRF by their participant number and initials in order to retain participant confidentiality.

The completed eCRFs will be submitted to the Sponsor as soon as practical after completion and review. A copy of each completed eCRF will be printed and retained by the investigator at the recruiting site for at least 7 years from the end of the study and according to local regulations.

All data entered on the eCRF will have supporting source data located at the study site in the participant's research record. Data allowed to be recorded directly in to the eCRF (i.e. no prior written or electronic record of data), will be discussed and documented with the Sponsor at the commencement of the trial.

16 Data Analysis and Statistical Considerations

16.1 Hypotheses

Primary hypothesis

H1 Compared to usual care, implementation of the proposed intervention package (IP) will result in an at least 15 point higher score on the Euro QOL–5D-3L VAS at 26 weeks post injury

Secondary hypotheses:

H2a Compared to usual care, implementation of the IP will result in significant improvement in service delivery at 12 and 26 weeks post injury as related to increased occasions of service

H2b Compared to usual care, implementation of the IP will result in significant improvement in service delivery at 12 and 26 weeks post injury as related to increased compliance with minimum process of care indicators

H3 Compared to usual care, implementation of the IP will result in significant improvement in neurological disability (Modified Rankin Scale) and independence (Functional Independence Measure) at 12 and 26 weeks post injury

H4 Compared to usual care, implementation of the IP will result in significantly reduced carer burden (Modified Caregiver Strain Index) and less brain injury survivor anxiety and depression (Hospital Anxiety and Depression Scale) at 12 and 26 weeks post injury

H5 The culturally sensitive IP will be more cost-effective (additional benefits gained will justify additional costs for delivering the intervention; may lead to potential cost-offsets from less severe disease) than usual care at 12 and 26 weeks post injury.

H6 The IP will be acceptable to health professionals and Aboriginal participants and their families, and the role of the Aboriginal Brain Injury Coordinator a feasible one.

16.2 Outcome Measures

Data collection point (***Time post injury)***	**Baseline** (***0-4 wks)***	**1** (***12wks)***	**2** (***26wks)***
Demographic data	X		
Injury data	X		
Site Usual Care data		X	X
Modified Caregiver Strain Index		X	X
mRS	X	X	X
FIM™	X	X	X
HADS	X	X	X
EuroQoL-5D-3L		X	X
Resource Utilisation		X	X
Process of care indicators		X	X
Participant satisfaction		X	X
Staff satisfaction	X		

16.2.1 Primary Outcome Measure

The ***Primary outcome measure*** is the Euro QOL–5D-3L which will be administered at 6 months post symptom onset. It is hypothesised that in improving rehabilitation service delivery in terms of culturally secure practices, that health outcomes will also be improved for Aboriginal people. While the service delivery aim is the obvious prerequisite aim in this context, a QoL measure was chosen as the primary outcome measure, as improvement in general QoL is the ultimate goal of rehabilitation, rather than simply improvement in service delivery. The notion of QoL captures a more holistic picture of outcome, consistent with an Aboriginal view of health and is more meaningful than simply an impairment-based outcome. The EQ-5D,[25] developed by the Euroquol group, measures the health-related dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. It has been used with stroke and traumatic brain injury survivors,[37,38] validated in many different countries and cultural settings, and can be administered by face to face or telephone interview, or as a self-or proxy mail out. It is used in the Australian Stroke Clinical Registry, as well as other stroke registries,[39] hence can be used for international comparison.

16.2.2 Secondary Outcome Measures

These relate to the further health outcomes of stroke severity (modified Rankin Score), functional independence (Functional Independence Measure -FIM™), burden of care (Modified Caregiver Strain Index), anxiety and depression (Hospital Anxiety and Depression Scale) and clinical service provision (Minimum Process of Care Indicators). Clinical service provision will be recorded for the six month period following patient admission. Data collected will include inpatient rehabilitation related sessions and out-patient service use up to six months post onset (rehabilitation specialist, allied health sessions), place where services are provided, including allied health/medical specialists visiting patients in their homes/remote communities. All constitute contributors to QoL and as such are important components for study. As part of a process evaluation, participant satisfaction will be measured through questionnaires administered either face to face or by phone/telehealth facility. Staff satisfaction

will be measured through questionnaires administered both face to face and online.

16.3 Sample Size

Sample size was estimated using GPower 3.1,[40] and adjusted for the design effect of the stepped-wedge design using the method described in Woertman et al.[41] Based on the literature,[42] the mean difference between stroke and non-stroke populations on the Euro QOL–5D VAS is approximately 25 points with a standard deviation of 25. We anticipate that the intervention will result in an improvement of 15 points on the Euro QOL–5D VAS (with a standard deviation 25). This equates to a medium-large effect size of d=0.6. GPower estimated that we would require a total of 90 participants to detect this difference with 80% power at the 5% significance level. To adjust for the design effect, we assumed a conservative intraclass correlation of 0.08. After adjusting for the design effect for a 4-step stepped-wedge design with one baseline measurement and one follow-up measurement, we estimate that we will need to recruit 13 patients at each site in every time period. This equates to a total sample size of 312 patients.

16.4 Statistical Analyses

The primary analysis will be performed on an intention to treat basis with each participant allocated to the site at which he/she was originally recruited.

16.4.1 Primary outcome analysis

The primary hypothesis (H1) will be analysed using a mixed effects linear regression model, which controls for the effects of secular trends over time. The model will be designed to assess the effect of the intervention on Euro QOL–5D-3L VAS score at 26 weeks post injury. Differences in baseline characteristics will be included in the model.

16.4.2 Secondary outcomes analyses

A mixed effects logistic regression model will be used to assess the impact of the intervention on the odds of achievement of the minimum processes of care [H2a]. The outcome variable will be a binary variable: minimum processes of care received by patient in the first 26 weeks post brain injury versus minimum processes of care not received by patient in the first 26 weeks post brain injury. Time will be included as a fixed effect in the model to control for the effects of secular trends. Site will be included as a random effect in the model.

A linear mixed effects regression model will be used to assess the impact of the intervention on the occasions of service [H2b]. The outcome variable will be the count of the occasions of service in the first six months post brain injury. Type and severity of the brain injury will be controlled for in the model. Time will be included as a fixed effect in the model to control for the effects of secular trends. Site will be included as a random effect in the model.

To examine the secondary outcomes of effects of the intervention on stroke/TBI disability and independence after injury [H3], the mRS score will be dichotomised into good outcome (mRS 0-2) and poor outcome (mRS 3-6). A logistic generalized linear mixed model will be developed to assess the impact

of the intervention on mRS at baseline, 12 and 26 weeks after injury. Within-cluster effects will be controlled for in the model and deviations from the protocol caused by changes in care site will be included as random effects.

A longitudinal linear mixed model will be used to assess the impact of the intervention on carer burden [H4]. The outcome variable will be the Modified Caregiver Strain Index at 12 and 26 weeks post brain injury. Type and severity of the brain injury will be controlled for in the model. Time period will be included as a fixed effect in the model to control for the effects of secular trends. Site will be included as a random effect in the model.

A longitudinal linear mixed model will be used to assess the impact of the intervention on anxiety and depression [H4]. The outcome variable will be the Hospital Anxiety and Depression Scale at 12 and 26 weeks post brain injury. Type and severity of the brain injury will be controlled for in the model. Time period will be included as a fixed effect in the model to control for the effects of secular trends. Site will be included as a random effect in the model.

1. Safety

Adverse events are expected to have a Poisson or negative binomial distribution. The distribution will be examined and the appropriate regression models will be used to compare counts of serious adverse events between conditions. Logistic regression will be used to compare binary adverse events (e.g. death). Risk ratios will be adjusted as per primary analysis with age, and mRS included as covariates.

2. Demographics

Baseline demographic characteristics will be tabulated. Between condition differences in continuous/ordinal measures will be assessed using one-way ANOVA or the Kruskal-Wallis test. Chi-square tests will be used to assess differences in categorical variables.

3. Blinding

All assessors will be independent of the researchers involved in the intervention or the trial. However, assessors in rural areas will most likely be aware of whether their local hospital is in intervention or control phase. Therefore it is not possible to blind the assessors, patients or most investigators on whether the patients received intervention or not. However, follow-up assessors will be blinded to the baseline assessment of any given participant. All analyses will be carried out by a statistician who is blinded to the randomization of sites and allocation of individual patients to intervention or control. Assessor blinding will be examined according to CONSORT[43] guidelines at 12 weeks. The James blinding index[44] will be used to assess the effectiveness of the blinding.

4. Post hoc analyses

The relationship between amount of services received, baseline stroke and traumatic brain injury severity and recovery are likely to be part of post hoc analyses given their clinical relevance.

5. Interim analyses

The DSMC will review interim data for adverse events and serious adverse events. The DSMC will use the Haybittle-Peto boundary with a difference of at least 3 standard errors in the analysis of serious adverse events (e.g. death

from all causes, aspiration pneumonia within the first 50 days post injury) needed to justify halting, or modifying the study before the planned completed recruitment. There will be no interim analyses for efficacy.

16.5 Economic Analysis

The economic analyses will provide important evidence in facilitating translation of this research into practice and policy. Very little economic evidence exists related to rehabilitation services post stroke or traumatic brain injury. **Reliable evidence to drive redistribution of scarce healthcare resources to accommodate the service delivery gap** in meeting Aboriginal health needs following brain injury is urgently needed.

Cost description analyses of each comparator group will be detailed using a decision-analytic model. All costs will be valued in 2020 dollars. Where prices in 2020 are unavailable, adjustment to the real price will be made using the published health sector specific deflator/inflators. Intervention delivery costs will also be accounted for as part of the intervention group. The incremental costs and benefits of the intervention (i.e. Quality Adjusted Life Years [QALYs] gained derived from EQ5D results) compared to control will be determined and expressed as a ratio by dividing by the net benefits for the outcomes of interest. Sensitivity and uncertainty (probabilistic multivariable [Monte-Carlo simulated]) analyses to account for variability in point estimates will be performed to assess the robustness of results. The intervention will be judged cost-effective if the incremental cost per QALY gained is <$50,000 (i.e., the willingness-to-pay threshold). Cost-effectiveness Acceptability Curves will also be generated to provide a plot of the probability that the intervention is cost-effective as a function of willingness to pay. This method provides a measure of magnitude and uncertainty of cost-effectiveness, expressed as a probability statement meaningful to policy makers.

17 Data Management

Data will be collected and managed using REDCap electronic data capturing tool hosted at Florey Institute of Neurosciences and Mental Health, 245 Burgundy Street, Heidelberg, Victoria 3084, Australia. REDCap (Research Electronic Data Capture) is a secure, web based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

The platform complies with regulatory requirements such as the FDA Code of Federal Regulations Title 21 CFR part 11 (electronic records). The system is developed, deployed and maintained according to industry guidelines and standards that apply to computerized systems in healthcare, including audit trails, electronic signatures and documentation for software and systems.

At the end of the trial following the data base lock, the data base will be provided to the sponsor for statistical analysis. Statistical analysis will be done by University of Technology, Sydney.

Data related to hospital services will be collected from existing hospital databases and stored on a separate database at ECU.

Qualitative data (questionnaires and interview data) related to the Cultural Security Training and ABIC services will also be kept in a separate database at ECU.

Participant outcome data may be contributed to brain injury outcome projects and used in secondary analyses for future student research (Honours, PhD projects) and other collaborative projects All shared data will be non-identifiable. New case numbers will be assigned to existing trial participant numbers for any third party use. Only participants for whom consent has been obtained will be included in any shared data base. The data for participants who did not sign the consent form outlining the sharing of data will not be used for this purpose.

18 Monitoring and Quality Assurance

18.1 Protocol compliance

The Project Manager and Data & Operations Manager will provide project management for this study. They will supervise the conduct and progression of the trial, and monitor site compliance with study procedures and completion of the Case Report Forms (CRFs). Site visits will include thorough review of medical records, comparison with source documents, and observation and discussion of the conduct of the study with the Investigator.

The organisation, monitoring, supply of study materials and quality assurance of the present clinical study is the responsibility of the Sponsor and the Project Manager.

In order to ensure the accuracy of data, direct access to source documents by the representatives of both the Sponsor and regulatory authorities is mandatory. Anonymity of the participant will be maintained at all times. The Sponsor reserves the right to terminate the study for refusal of the Investigator/Institution to supply source documentation of work performed in the study.

18.2 Curriculum Vitae and Other Documentation

In order to comply with regulatory requirements in some countries, all investigators signing the Protocol and all trial staff should provide a current, signed and dated Curriculum Vitae (CV) to be filed by the Sponsor. The CV should include name, title, occupation, education, research experience and present and former positions. A Staff Signature List at each site will also be required.

18.3 Aboriginal Reference Group

An Aboriginal Reference Group will guide the research throughout to ensure that the study is conducted according to principles of cultural security[21] and in line with the NHMRC Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.[45] It will guide the project and provide advice to the researchers regarding participant recruitment, relevant human and practical resources (e.g., interpreters), community feedback from the project, and general cultural and ethical issues involved. They will also provide input into study translation. The Reference Group will meet twice per year.

19 Investigator Responsibility

Except where the Main Investigator's signature is specifically required, it is understood that the term 'investigator' as used in this Protocol and on the CRFs refers to the Main Investigator or an appropriately qualified member of the staff that the Main Investigator designates to perform specified duties of the Protocol. The Main Investigator is ultimately responsible for the conduct of all aspects of the study at their particular site.

Each investigator will comply with the local regulations regarding clinical trials and the Investigator responsibilities outlined in the ICH GCP guidelines.[46]

20 Study Report

At the conclusion of the study the findings will be published in peer review journals and at relevant conferences.

The final study report will be prepared by the executive management team with input from relevant sub committees. Results of the study will also be provided to participants via the research staff at each site. A lay summary of the results will be made available for this purpose.

21 Administrative Procedures

21.1 Ethical Considerations

The monitoring and safety guidelines are outlined in the Monitoring Guidelines for the study. This study will be carried out according to the Declaration of Helsinki, the NHMRC National Statement on Ethical Conduct in Research Involving Humans (1999) and the Notes for Guidance on Good Clinical Practice as adopted by the Australian Therapeutic Goods Administration (2000) (CPMP/ICH/135/95), the ICH GCP Guidelines,[46] and the National Health &Medical Research Council (NH&MRC) Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003).[45]

21.2 Ethical Review Committee

The Protocol will be submitted for approval to the appropriate Ethics Committees, and written approval obtained, before volunteers are recruited and participants are enrolled. The investigators will receive all the documentation needed for submitting the present Protocol to the Ethics Committee. A copy of the respective approval letters will be transmitted to the Sponsor before starting the study. The composition of the Ethics Committee will also be provided. If approval is suspended or terminated by the Ethics Committee, the investigator will notify the Project Manager immediately.

It is the responsibility of the investigator to report study progress to the Ethics Committees as required or at intervals not greater than one year.

The Main Investigator, or his/her delegate, will be responsible for reporting any serious adverse events to the Ethics Committee as soon as possible, and in accordance with the guidelines of the Ethics Committee.

21.3 Informed Consent

Before recruitment and enrolment into the study, each prospective participant will be given a full explanation of the nature and purposes of the study. They will also receive a copy of the Participant Information to review and where consent has been gained verbally, a copy of Participant Information will be posted to the participant afterwards. . As noted in Section 9 above, this will be 'aphasia friendly' in format to accommodate patients with communication disorders, those with other cognitive issues typically associated with brain injury, and those with limited literacy skills. Relevant interpreters will be utilised where required. Once the essential study information has been provided, and the Investigator is assured that the participant understands the implications of participating in the study, the participant will be asked to give consent to participate in the study by giving their consent to participate either in wet-ink writing; via electronic or digital signature or verbally. In the latter scenario the baseline assessor will read aloud from the Participant Information and Consent Form to provide the patient with project information. The patient's verbal decision will be recorded in the CRF at the recruiting hospital. Consent forms shall be signed and dated by the appropriate parties. A notation that informed consent has been obtained will be made in the participant's medical file.

In the case of patients who are incapable of providing consent, a Research Decision Maker (RDM) will be approached to consent on their behalf, with a determination provided by an Independent Medical Practitioner (IMP), as per the *Guardianship and Administration Amendment (Medical Research) Act 2020.* Exclusion of brain injury survivors on the basis of inability to give consent discriminates against individuals with severe brain injury in this case, as the intervention provides additional client and family support and monitoring, rather than specific activity based or pharmaceutical intervention.

A family member/carer of the brain injury survivor will also be approached to participate in the project in their own right to provide data related to carer burden specifically. This family member/carer will be over the age of 18 years (and identified via the 'next of kin' details in hospital records and/or via further discussion with the patient's family and/or discussion with the patient's medical team). The family member/carer may also be the RDM for the purpose of enrolment of the participant with a brain injury, but in some circumstances the family member/carer participant may be different to the RDM.

The process for obtaining a family member/carer's informed consent in regard to participating in their own right will be undertaken as per the same process described above for the participant.

In obtaining the informed consent of an RDM, all steps required as part of the Research Decision Maker Consent Pathway will be followed. Where an RDM cannot be physically present with the Researcher, the process outlined above for obtaining consent by verbal or digital means will be undertaken.

The completed consent forms will be retained by the Investigator and a copy will be provided by the Investigator to the participants.

21.4 Notification of Primary Care Physician

With the consent of the patient, it is the local investigator's responsibility to notify the primary care physician of the participant's participation in the study. A letter will be

sent to the physician stating the nature of the study, treatments, expected benefits or adverse events.

21.5 Investigator Indemnification

The study is being conducted subject to the 'Guidelines for Compensation for Injury Resulting from Participation in a Company-sponsored Clinical Trial' published by the Medicines Australia. Edith Cowan University will reimburse participants for costs of medical care that occur as a result of complications directly related to participation in this study.

21.6 Financial Aspects

The conduct of the study is subject to the clinical trial research agreement (CTRA) between Edith Cowan University and the participating sites.

21.7 Protocol Amendments

No changes (amendments) to the Protocol may be implemented without prior approval from the Sponsor and the appropriate Ethics Committee. If a Protocol amendment requires changes to the Informed Consent Form, the revised Informed Consent Form, prepared by the Investigator, must be approved by the Ethics Committee.

Once the final Protocol has been issued and signed by the investigator and the authorised signatories, it shall not be informally altered. Protocol amendments are alterations to a legal document and have the same legal status.

It is the responsibility of the investigator to submit any amendment to the Ethics Committee for their approval and written approval must be obtained prior to implementation of the amendment.

21.8 Protocol Compliance

The instructions and procedures specified in this Protocol should be followed at all times. Should there be questions or consideration of deviation from the Protocol, clarification will be sought from the Project Manager. Any participant that deviates from the Protocol, may be ineligible for analysis and thereby compromise the study.

The nature and reasons for the Protocol deviation shall be recorded in the CRF.

The investigator and designees will comply with all applicable federal, state and local laws.

21.9 Archives: Retention of Study Records

All source documents, CRFs and trial documentation will be kept by and are the responsibility of the Investigator for the appropriate retention period as stipulated by local regulations. Electronic de-identified data may be kept indefinitely to allow comparisons with future studies in this developing area of research.

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APPENDIX 1: Schedule of Assessments

Assessment	Baseline **Between Day 2 and Day 28 post injury**	12 Weeks	26 Weeks
		Week 12 **12 weeks post injury** **+/- 7 days**	**Week 26** **26 weeks post injury** **+/- 14 days**
Screening/Eligibility	**X[1]**		
Consent	**X[2]**		
Demographics	**X[2]**		
Past medical History	**X[2]**		
Brain injury subtypes	**X[2]**		
NIHSS	**X[2]**		
GCS	**X[2]**		
mRS	**X[2]**	**X[3]**	**X[3]**
FIM™	**X[2]**	**X[3]**	**X[3]**
Modified Caregiver Strain index		**X[3]**	**X[3]**
Hospital Anxiety and Depression Scale	**X[2]**	**X[3]**	**X[3]**
EuroQol-5D-3L		**X[3]**	**X[3]**
Allied health OOS		**X[5]**	**X[5]**
Minimum processes of care		**X[4]**	**X[4]**
Resource Utilisation		**X[3]**	**X[3]**
Adverse Events		**X[3]**	**X[3]**
SAEs		**X[3]**	**X[3]**

X^1 = Person screening the participant
X^2 = Trained Baseline Assessor
X^3 = Blinded Assessor
X^4 = Blinded file auditor
X^5 = Blinded data extractor

Euroqol

Figure 1: EQ-5D-3L

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care

I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

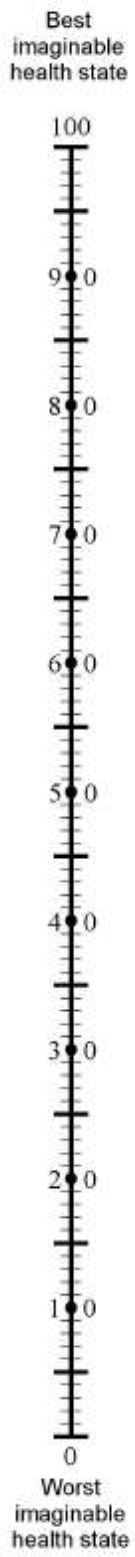
Anxiety/Depression

I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked **100** and the worst state you can imagine is marked **0**.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Modified Rankin Scale

Note: the modified Rankin scale is to be assessed based on the participants symptoms **to the current Brain Injury event.**

This score must be ASSESSED by a person Certified for the modified Rankin Scale

		Fill ONE box only
0 -	**No symptoms at all** The participant should be unaware of any new limitations caused by the stroke, however minor.	☐
1 -	**No significant disability despite symptoms; able to carry out all usual duties and activities** The participant has some symptoms as a result of the stroke, whether physical, cognitive (e.g., affecting speech, reading, writing; or physical movement; or sensation; or vision; or swallowing; or mood)- but can continue to take part in all previous work, social and leisure activities. The crucial question to distinguish grade 1 from grade 2 (below) may be 'Is there anything that you can no longer do that you used to do until you had the stroke? As a guide, an activity that was undertaken more frequently than monthly could be regarded as a 'usual' activity.	☐
2 -	**Slight disturbance; unable to carry out all previous activities, but able to look after own affairs without assistance** The participant will be unable to undertake some activity that was possible before the stroke (e.g., driving a car, dancing, reading, or working) but is still able to look after him/herself without the help from others on a day to day basis. Thus, the participant can manage dressing, moving around, feeding, toileting, preparing simple meals, shopping, and travelling locally without needing assistance from anyone else. Supervision may not be necessary. This grade assumed that the participant could be left alone at home for periods of a week or more without concern.	☐
3 -	**Moderate disability; requiring some help, but able to walk without assistance** At this grade, the participant is independently mobile (using a walking aid or frame if necessary) and can manage dressing, toileting, feeding etc but needs help from someone else with more complex tasks (e.g., someone else may need to undertake the shopping, cooking, cleaning, and will need to visit the participant more often than weekly to ensure that these activities are completed). The assistance can be advisory rather than physical e.g., a participant who needs supervision or encouragement to cope with financial affairs would be in this grade.	☐
4 -	**Moderately severe disability; unable to walk without assistance, unable to attend to own bodily needs without assistance** The participant requires someone else to help with some daily tasks, whether walking, dressing, toileting, or eating. This participant will be visited at least once and usually twice or more times daily, or must live in proximity to a carer. To distinguish grade 4 from grade 5 (below), consider whether the participant can regularly be left alone for moderate periods during the day.	☐
5 -	**Severe disability; (usually) bedridden, incontinent, and requiring constant nursing care and attention** Someone else will always need to be available during the day and at times during the night, though not necessarily a trained nurse.	☐

Functional Independence Measure™

Name: _____ Date of birth: _____
Date of assessment: _____ Date of motor accident _____
Hospital/unit: _____
Method of administration: ☐ Direct observation ☐ Interview with: _____

Area	Score	Is score due to the brain injury?	Explain reasons for giving this score
SELF CARE			
1.Eating		☐ Yes ☐ No	
2.Grooming		☐ Yes ☐ No	
3.Bathing		☐ Yes ☐ No	
4.Dressing– Upper Body		☐ Yes ☐ No	
5.Dressing– Lower Body		☐ Yes ☐ No	
SPHINCTER CONTROL			
6.Toileting		☐ Yes ☐ No	
7.Bladder management		☐ Yes ☐ No	
8.Bowel management		☐ Yes ☐ No	
Self care subtotal			
TRANSFERS			
9.Transfers: Bed/ Chair/Wheelchair		☐ Yes ☐ No	Mode: W– Walk C- Wheelchair B- Both

Area	Score	Is score due to the brain injury?	Explain reasons for giving this score
10.Transfers: Toilet		☐ Yes ☐ No	
11.Transfers: Bath/Shower		☐ Yes ☐ No	
LOCOMOTION			
12.Walk/ Wheelchair		☐ Yes ☐ No	Mode: W– Walk C- Wheelchair B- Both
13.Stairs		☐ Yes ☐ No	
Mobility subtotal			
Area	**Score**	**Is score due to the brain injury?**	**Explain reasons for giving this score**
COMMUNICATION			
14.Comprehension		☐ Yes ☐ No	Mode: A – Auditory V - Visual C - Both
15.Expression		☐ Yes ☐ No	Mode: V – Vocal N - Non-vocal B - Both
SOCIAL COGNITION			
16.Social interaction		☐ Yes ☐ No	
17.Problem solving		☐ Yes ☐ No	
18.Memory		☐ Yes ☐ No	
Cognition subtotal			

Area	Score	Is score due to the brain injury?	Explain reasons for giving this score
FIM™ TOTAL SCORE			

Administered by:_____ **FIM™** credentialed: ☐ Yes ☐ No
Signature:_____ Date of assessment: _____

FIM™ LEVELS

No helper
7 Complete Independence (Timely, Safely)
6 Modified Independence (Device)

Helper – Modified Dependence
5 Supervision (Subject = 100%)
4 Minimal assistance (Subject = 75% or more)
3 Moderate assistance (Subject = 50% or more)

Helper – Complete Dependence
2 Maximal assistance (Subject = 25% or more)
1 Total assistance (Subject less than 25%)

Modified Caregiver Strain Index

Directions: Here is a list of things that other caregivers have found to be difficult. Please put a checkmark in the columns that apply to you. We have included some examples that are common caregiver experiences to help you think about each item. Your situation may be slightly different, but the item could still apply.

	Yes, On a Regular Basis=2	Yes, Sometimes =1	No=0
My sleep is disturbed (For example: the person I care for is in and out of bed or wanders around at night)			
Caregiving is inconvenient (For example: helping takes so much time or it's a long drive over to help)			
Caregiving is a physical strain (For example: lifting in or out of a chair; effort or concentration is required)			
Caregiving is confining (For example: helping restricts free time or I cannot go visiting)			
There have been family adjustments (For example: helping has disrupted my routine; there is no privacy)			
There have been changes in personal plans (For example: I had to turn down a job; I could not go on vacation)			
There have been other demands on my time (For example: other family members need me)			
There have been emotional adjustments (For example: severe arguments about caregiving)			
Some behavior is upsetting (For example: incontinence; the person cared for has trouble remembering things; or the person I care for accuses people of taking things)			
It is upsetting to find the person I care for has changed so much from his/her former self (For example: he/she is a different person than he/she used to be)			
There have been work adjustments (For example: I have to take time off for caregiving duties)			
Caregiving is a financial strain			
I feel completely overwhelmed (For example: I worry about the person I care for; I have concerns about how I will manage)			

[Sum responses for "Yes, on a regular basis" (2 pts each) and "yes, sometimes" (1 pt each)]

Total Score =

Hospital Anxiety and Depression Scale

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

APPENDIX 2: Face to Face CST Training Evaluation Questionnaire

Thank you for supporting this research by attending the face-to-face training session(s) run at your workplace. Your involvement and engagement in this professional development training is most appreciated. Please take a few minutes to complete the questions below.

General Information:

Your professional discipline			Your gender		M	F
Your level of professional experience	< 1 year	1-5 yrs	5-10 yrs	10-20 yrs	20-30 yrs	>30 yrs
Years of brain injury (stroke/TBI) experience	< 1 year	1-5 yrs	5-10 yrs	10-20 yrs	20-30 yrs	>30 yrs
Name of your workplace					Date of training	
Names of your presenters						

Please indicate how this training was presented for you:

As a single 3 hour session?			
As three 1 hour sessions? (Please tick those you attended)	Session 1	Session 2	Session 3

Please tick the box that best reflects your view of the specific aspects covered in this course:

	Very useful	**Quite useful**	**Neutral**	**Not very useful**	**Not at all useful**	**Other** (see below – space for comments)
Knowledge of local cultural issues delivered by a local Aboriginal cultural security trainer						
Explanations of *cultural security* and how they apply to my workplace						
Explanations of *clinical yarning* and						

how this can be applied in my workplace						
The use of case scenarios of Aboriginal people with acquired brain injury to support learning						
The opportunity to consider the cognitive, behavioural, and communication impairments which commonly occur after stroke or traumatic brain injury						
The focus on practical strategies, good communication skills, and culturally secure *relationships* with Aboriginal patients and families						
Experiential learning and the opportunity to reflect on working with Aboriginal patients and families						
Having the time to *team-build* with colleagues						
Having the time to consider the policies or ***reconciliation action plan*** for my workplace						
An opportunity to develop best practice principles in my workplace						

Please tick the box that best reflects your view of the impact of this course:

	A lot	**A little**	**Somewhat**	**Not at all**	**Other** (see below – space for comments)
It has been **useful** in relation to my team's work or individual practice					
It will make a **difference** to the way I work with					

Aboriginal patients and families.					

If you answered *other* or would like to comment further on any aspects of the course, please do so here:

Thank you!

APPENDIX 3: Online Cultural Security Training Evaluation Questionnaire

Thank you for supporting this research by both attending the previous face-to-face training session(s) run at your workplace and doing the online training (link url). Your involvement and engagement in this professional development training is most appreciated. This questionnaire will focus on your feedback on the online modules and your reflections on this professional development overall. Please take a few minutes to complete the questions below.

General Information (complete or circle as appropriate)

Your professional discipline			Your gender		M	F
Your level of professional experience	< 1 year	1-5 yrs	5-10 yrs	10-20 yrs	20-30 yrs	>30 yrs
Years of brain injury (stroke/TBI) experience	< 1 year	1-5 yrs	5-10 yrs	10-20 yrs	20-30 yrs	>30 yrs
Name of your workplace						
Approximate time spent completing online modules	1 hour		2 hours		3 hours	
Having time between the face-to-face and online training	Helpful for reflection and applying the experiences and information to practice		Neutral		Not helpful for reflection and applying the experiences and information to practice	
Access to the site through ECU's Health*Info*Net	Easy access		Difficult to access		Comment:	
Quality of the site developed for this training on ECU's Health*Info*Net	High quality information, presentation and links		Poor quality information, presentation and links		Comment:	
Importance of certificate of completion	Very important		Neutral		Not important	

Please tick the box that best reflects your view of the specific aspects covered in the online modules

	Very useful	**Quite useful**	**Neutral**	**Not very useful**	**Not at all useful**	**Other** (see below – space for comments)
Section on "learning from my patients"						
The use of case scenarios of Aboriginal people with acquired brain injury to support learning						
	Very useful	**Quite useful**	**Neutral**	**Not very useful**	**Not at all useful**	**Other** (see below – space for comments)
Opportunities to view video clips of people's experiences						
Quiz questions to reinforce learning						
Section on "learning from my colleagues"						
Having scenarios and video clips of people's experiences						
Practical strategies, and a *framework* for working with Aboriginal patients and families						
Thinking through practices for: admission, assessment, family involvement, collaborative goal planning, ongoing referrals, discharge planning (please comment more specifically below if you wish).						
Section on "systemic practices"						
Having the time to consider the policies or ***reconciliation action plan*** for my workplace						
Following suggested **links** to other relevant resources						

An opportunity to develop best practice principles in my workplace						

Please tick the box that best reflects your view of the impact of this course

	Strongly agree	**Agree**	**Neutral**	**Disagree**	**Strongly disagree**	**Other** (see below space for comments)
Both the face-to-face and online aspects of this training have been generally **useful** in relation to my team's work or individual practice						
This training has made a **positive difference to my attitude** towards working with Aboriginal patients and families with brain injury.						
This training has made a **positive difference to my skills/knowledge** in relation to working with Aboriginal patients with brain injury and their families.						
The training was helpful in addressing the specific issues for **managing brain injury** for Aboriginal patients and families						
This was helpful in promoting stronger working practices with **Aboriginal Liaison Officers and/interpreters**						
The overall training will make a **difference to the way I communicate/yarn** with Aboriginal patients and families.						
The overall training will make a **difference** to the systems in my workplace						

for Aboriginal patients and families.						

If you answered *other* or would like to comment further on any aspects of the course, please do so here:

Thank you!

APPENDIX 4: Aboriginal Participant Questionnaire: Hospital Services

Tell us what you think about…

Being in hospital and then coming home

Tick the box you think is right for you…

	Yes – it was good 	In the middle 	No – it was not good 
Looking back… how I was looked after in hospital			
How staff yarned with me and answered my questions			
How staff talked with my family			
How staff planned for what I wanted when I left hospital			
Receiving the information I needed			
Getting therapy if I needed it			
Preparing me for keeping busy and seeing friends			

Anything else you want to add?

_____

_____

_____

_____

_____

_____

_____

Thank you for telling us how it has been for you.

APPENDIX 5: Aboriginal Participant Questionnaire: Aboriginal Brain Injury Coordinator Service

Tell us what you think about…

Being with your *Aboriginal Brain Injury Coordinator*

Tick the box you think is right for you…

	Yes – I agree. Good 	**In the middle** 	**No – I don't agree. Not good** 
This person has helped me understand **what was going on while I was in hospital**			
This person has helped me get what I needed **when I left hospital**			
This person has **helped my recovery**			
This person has helped my **family**			

Anything else you want to add?

_____

_____

_____

_____

_____

_____

_____

Thank you for telling us how it has been for you.

APPENDIX 6: Aboriginal Brain Injury Coordinator Interview Schedule

Topics and related questions for semi-structured interview for the Aboriginal Brain Injury Coordinators

- Tell us a little about your role in this project.
    - What did you do?
- What did you think about your training?
    - Did you get enough training?
    - What was the most beneficial aspect of your training?/ Comment on the usefulness or relevance of a) orientation b) training c) clinical supervision
    - Is there information/ training you feel would have been useful to receive to help you in your ABIC role? If so, what additional information/ training would you have liked to receive?
- Did the role meet your expectations of what it would be?
- What things, if any, helped you achieve what you wanted to do in your role?
- What things, if any, got in the way of your ability to achieve what you wanted to do in your role?
- Do you feel you were able to help your participants to access rehabilitation services?
    - If so, how did you help them? What did you do that made a difference to them?
    - If not, what were the main things that prevented this?
- What parts of the ABIC service did you feel the participant found the most useful?
- How would you explain your role to someone outside of the project?
- What advice would you give to a service that was looking to employ Aboriginal Brain Injury Coordinators?
- What was your experience of being based at the Neurological Council of WA/Aboriginal Medical Service? Can you comment on:
    - your ability to perform your role in a way that reflected the needs of your Aboriginal participants
    - your own feelings of cultural safety in the workplace
    - what you think makes a workplace feel comfortable for Aboriginal staff
- What was your experience of working with the staff at the hospital e.g. medical team, ALOs, allied health team?
- What was your most memorable moment during your work as a Brain Injury Coordinator?
- Do you have anything you'd like to add/share?