**Title**

Neurofeedback for Indigenous children with complex PTSD in out of home care: A pre-post experimental trial

* Version 1, dated 25/06/2022

**Project Team Roles & Responsibilities**

* Dr Beth Mah, The University of Newcastle, Consultant Child and Adolescent Psychiatrist, Wandiyali; Chief Investigator
* Mr Jai Kilroy, Wandiyali, cultural guidance; Research Investigator
* Mr Wade Mahoney, Wandiyali, cultural guidance; Research Investigator
* Dr Mirjana Askovic, Chair of Biofeedback Certification International Alliance, Director of the Australian Neurofeedback Institute, Neurofeedback program coordinator, NSW STARTTS, PhD candidate- University of Sydney; Associate investigator
* Ms Karliya Sams, Wandiyali, Aboriginal Honours Psychology graduate employed as Behaviour Support Worker. Experience in ensuring treatments and interpersonal interactions are culturally appropriate; Associate Investigator
* Dr Sejla Murdoch, Deputy Director of Australian neurofeedback Institute, experienced mentor of neurofeedback for traumatised children; Associate Investigator
* Mrs Alikki Russell, Immediate Past Chair of Biofeedback Certification International Alliance Co-Director of The Hummingbird Centre in Newcastle. This psychology centre provides neurofeedback treatment for those exposed to trauma; Associate Investigator
* Mr Christophe Lefevre, Hunter Medical Research Institute, Biostatisician; Associate Investigator

**Resources**

This project has acquired adequate funding from the Hunter Children’s Research Foundation and Wandiyali are providing salary in kind support. The combination of these two funding sources will allow the project to occur to completion.

**Background**

In NSW, despite Aboriginal and Torres strait Islander persons (hereafter respectfully, Aboriginal) making up 3% of the population, 39% of children in Out of Home Care (OOHC) are Aboriginal [1]. Rates of complex Post-traumatic Stress Disorder (cPTSD) have been found to be extremely high in non-Aboriginal children in foster care at 22.8% [2]. A recent randomised controlled trial using neurofeedback treatment found impressive improvements in PTSD symptoms, internalizing, externalizing, other behavioural and emotional symptoms, and significantly improved the executive functioning of non-Aboriginal children aged 6–13 years with severe histories of abuse and neglect who had not significantly benefited from any previous therapy [3]. Neurofeedback is a specific form of biofeedback which utilises brain electrical activity recorded in real time as participants play a computer game that reflects the status of their EEG activity and provides visual ‘rewards’ for shifting into calmer or more focused EEG patterns [3]. Wandiyali is a Newcastle based Aboriginal organisation currently case-managing approximately 140 Aboriginal children in OOHC, many of whom struggle with trauma related issues and difficulty accessing effective trauma informed treatment [4]. Wandiyali executive members have requested this trial occur within their organisation.

**Aims:** To assess improvement in cPTSD symptoms in Aboriginal children in OOHC after treatment with neurofeedback. To assess improvement in the child’s self-concept, academic, social and personal functioning and the foster carer’s stress levels and confidence in parenting their foster child.

**Expected outcomes:**

This project will deliver and evaluate neurofeedback treatment, an evidence based therapy to a new and highly vulnerable population not yet studied. Additionally, specialised neurofeedback treatment training and supervision will occur for three current Wandiyali employees (two of whom are Aboriginal).

In the interim period, this project will allow for continuing treatment for all other Wandiyali managed children in OOHC, and for clients of other Wandiyali services such as Family Preservation Services, receiving referrals from Department of Communities and Justice to prevent removal of Aboriginal children from their biological parents. Neurofeedback will be offered to these clients after the project’s completion.

**Project Design:**

Research Project Setting: This single site trial will be based at Wandiyali, Aboriginal Community and Children’s service in Elermore Vale, NSW. Wandiyali have requested this study occur for the Aboriginal children in OOHC that they have by proxy parental rights for.

Participants: 30 children will be recruited from Wandiyali Out of Home Care service. Children will be included if they are Aboriginal, aged 6-17, have experienced at least one interpersonal traumatic event such as abuse or neglect and have clinically significant cPTSD. Children will be excluded if they have a known history of epilepsy, or head injury; if they have received neurofeedback treatment in the past 5 years; if they are currently prescribed a benzodiazepine; or if there has been a serious suicide attempt in the previous six months. Ideal sample size will be determined by mid-point analysis of results. The project will continue to recruit thereafter to ensure ideal sample size is recruited, currently calculated as *n*=30.

Procedure: Pre-post experimental design is the chosen methodology to ethically provide the highest level of evidence to answer the project’s primary research question: “To assess improvement in cPTSD symptoms in Aboriginal children in OOHC after treatment with neurofeedback”. A randomised controlled design was considered but rejected due to the population of children receiving current services from Wandiyali being too symptomatic. These symptoms are already putting their foster placements and schooling at risk of break-down. The study design will attempt to improve upon the findings of Rogel et al. by increasing the number of training sessions.

After ethics approval, enrolment will be considered by an initial screening conversation with the child’s Wandiyali caseworker (who hold parental rights by proxy from the Minister for Families, Communities and Disability Services). The caseworker will seek agreement from the child and their foster-carer. Baseline cPTSD score will be established to confirm inclusion. Participants will complete baseline outcome measures then commence neurofeedback treatment (NFT). NFT will consist of 32 sessions over 24 weeks. The aim will be to provide 24 sessions in 12 weeks and then 8 sessions over the following 8 weeks. An extra 4 weeks have been built into the protocol to add flexibility given the global COVID-19 pandemic and the possible need to re-arrange health care appointments at short notice. Both groups will complete outcome measures after half the total number of sessions has been completed (at 8-10 weeks), again at completion (20-24 weeks) and finally at 4 weeks follow up (24-28 weeks). See Figure 1.

NFT will be performed with an *EEGer system* with *A202 amplifier* (Neurofeedback International Academy, Victoria, Australia) with the impedance of all electrodes kept at under 15 kΩ and placed according to the international 10/20 system. A NFT specific assessment will be completed including a ‘mini-map’ and initial site of training will be as per Dr Susan Othmer’s protocol guide [5]. The mini-map will be repeated at midpoint and completion.  
The frequency of reward and inhibit bands will be set after assessment of the posterior dominant rhythm (PDR); this will also be individualised and guided by expert supervisors’ input co-investigators and NFT clinicians from the Australian Neurofeedback Institute. The software allows for insertion of culturally appropriate images, or even the child’s own drawings. Adjustments to the protocol will be based on caregiver and child reports and clinical judgment. All carers will receive standard NFT psychoeducation and will be guided to encourage their children complete regular home based relaxation practice. Their feedback regarding symptoms for the 48 hours after treatment will be incorporated into treatment planning as is standard for this model of care. Fidelity of treatment will be guided by expert supervisors.

Outcome measures and methods of data gathering:  
***Demographic data and past history of trauma*** will be established as was collected in Rogel et al’s study [3]. Wandiyali case workers will complete this as they have access to greater details of the participant child’s early childhood experiences of trauma prior to coming into care from the Department of Community and Justice referral.

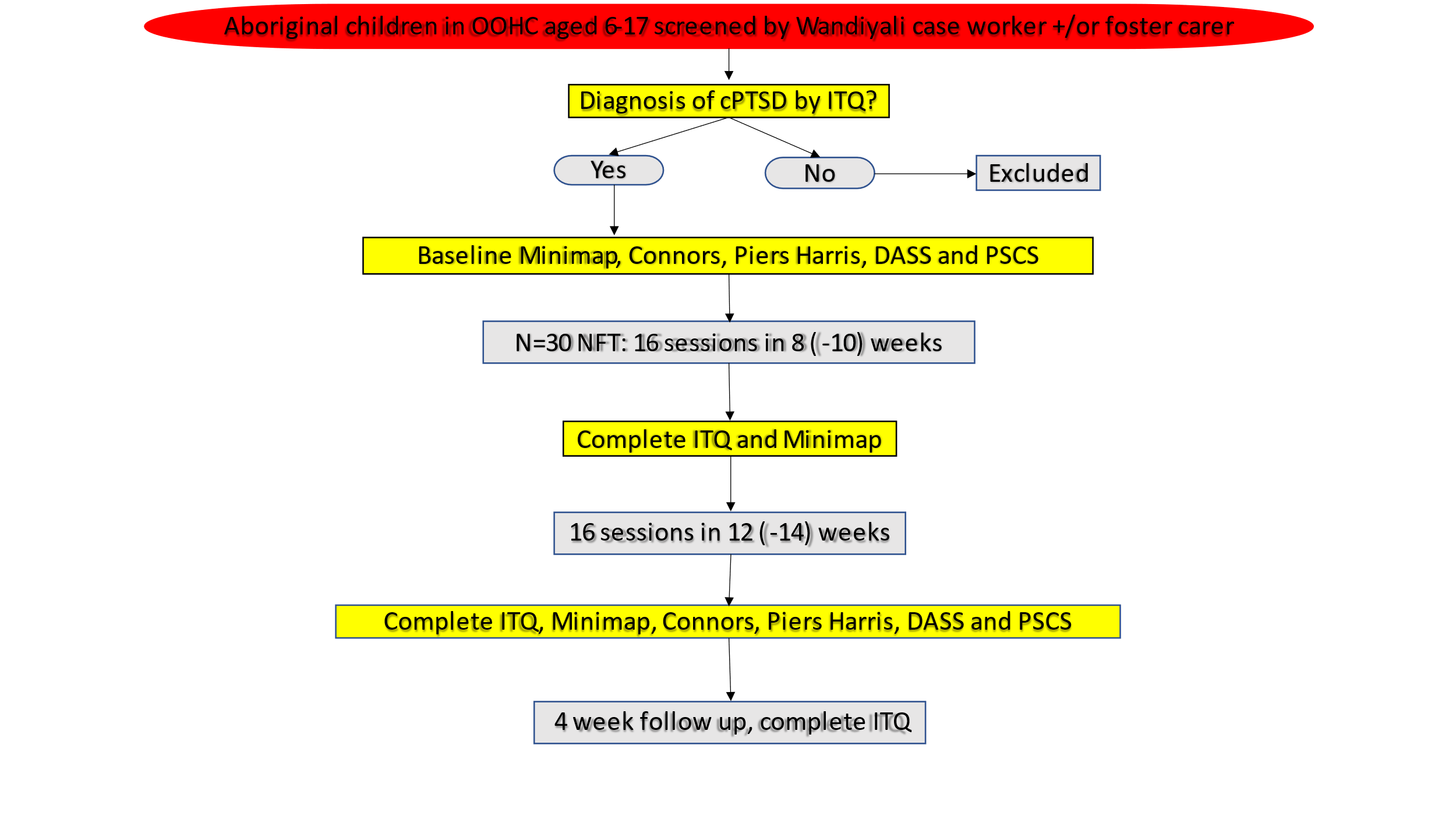
***cPTSD* *diagnosis at baseline and* *symptom severity*** will be established using the International Trauma Questionnaire [6]. The subscale ‘Disturbances in Self Organisation’ (DSO) which measures Affective Dysregulation, Negative Self-Concept, and Disturbances in Relationships will be used, as most children in OOHC experienced their trauma too young to score in clinical range for classic PTSD domains of re-experiencing and avoidance. The questionnaire has been validated for use in populations of children in foster care [2]. The scale will be completed by the child with the assistance of foster carer, case worker or none as desired by the child.   
***Child academic and peer function***will be measured using the Connors Parent and Teacher Assessment Short Form- 3rd Edition [7]. This 45 (for parents) or 41 (for teachers) item survey establishes centile scores for the domains of inattention, hyperactivity and impulsivity, learning problems, defiance and aggression and peer relations. The assessment has frequently been used for monitoring the impact of treatments for school aged children.   
***Child self-concept*** will be explored using the Piers-Harris Self-concept Scale, Third Edition which has been developed for children aged 6 and over [8]. The survey consists of 58 self-report items requiring only yes or no answers by the child. Subscales capture the domains of behavioural adjustment, freedom from anxiety, happiness and satisfaction, intellectual and school status, physical appearance and attributes as well as social acceptance.

***Foster carer confidence*** will be assessed using the Parenting Sense of Competence Scale [9]. This self-report scale of 17 items offers multiple choices to answer questions related to feelings, thoughts and motivation for parenting related issues.

***Foster carer stress*** will be measured by the Depression Anxiety and Stress Scale (DASS) [10]. This 21 item self-report survey captures symptoms in three psychological domains as subscales (depression, anxiety and stress symptoms).

***Change in EEG*** will be assessed by comparing the theta to beta ratio at CZ (10/20 International system site) eyes open extracted from the ‘Minimap’ at baseline, midpoint and completion [11]. The Minimap is a standard neurofeedback assessment tool which measures the amplitude of varying frequencies of brain waves at three midline sites with both eyes open and closed. Norms exist for children both under and over the age of 10 years [12].

Figure 1: Trial flowchart



Notes: cPTSD=complex post-traumatic stress disorder; DASS=Depression Anxiety and Stress Scale; ITQ=International Trauma Questionnaire; Mini-map=EEG assessment of amplitude of brain waves; NFT=neurofeedback treatment; OOHC=Out of Home Care; PSCS= Parenting Sense of Competence Scale

Consent:

Consent will be gained from numerous sources. Participant children, aged 6-13, are too young to legally give written consent; their verbal agreement will be sought at each step of the project. Timing and reason for redaction of child verbal consent will be recorded and reported on. After this, the intervention will not recommence without the participant’s case worker, foster carer or both advocating for the child that they wish to recommence participating in the project. For all children unable to give their own consent, signed consent will be gained from both foster carer as well as an appropriately appointed delegate from the Department of Communities and Justice.

Written consent will be sought from participant children aged 14-17. It will be made clear to participant children as well as their foster carers that not consenting to participate in the project will not affect the ongoing care and service that they receive from the Wandiyali Out of Home Care service.

Data management:

All data for this project will be stored in REDCap via the CIA’s affiliation with the Hunter Medical Research Institute (HMRI). Only members of the research team will have access to this data. Appropriate REDCap training will be completed utilising HMRI’s suite of digital resources. All data collected will remain non-identifiable and will be used only for analysis to answer the research questions this project seeks to establish. However, if any data collected indicates any child protection risk for any participant, this will be reported as per mandatory reporting guidelines (guided both the Children and Young Persons (Care and Protection) Act 1998 No 157 and the Children’s Guardian Act 2019 No 25). The following Wandiyali policies will be adhered to by the research team: Wandiyali ATSI child protection policy (Resolution number 121212402, dated 1.6.18), Wandiyali Casework Manual, 5.1 Record Keeping (Resolution number 121212432, dated 1.10.18) and the Wandiyali Out-of-Home Care Policies and Procedures document (Resolution number 121212427, dated 1.10.18). Participants and their carer will be advised about their confidential and de-identified data being stored on a highly secure, cloud based digital system.

*REDCap introduction*: Data for the project will be collected in REDCap (Research Electronic Data Capture), a secure web-based database system. REDCap is a purpose-built software application for the conduct and management of medical research surveys and case report forms for clinical trials. This application was developed by Vanderbilt University, with collaboration from a consortium of institutional partners (https://www.project-redcap.org).

REDCap has been widely disseminated for local use at more than 3,600 institutes in 131 countries. Close to 1 million people use REDCap worldwide. REDCap provides an intuitive user interface that streamlines database development and improves data quality through structured data entry and real-time validation rules (with automated data type and range checks). REDCap also provides easy data monitoring with audit trails, data history and data resolution workflows. REDCap’s survey capabilities are a powerful tool for building and managing online surveys and data collections. The research team can create and design surveys and data collection forms in a web browser and engage participants using a variety of notification methods (e.g. email, SMS and phone calls).

*REDCap Security*: The REDCap application is hosted locally on HMRI secure servers (https://redcap.hmri.org.au/) which are both physically and virtually secured. Data is stored on a user-based password protected server located in a locked room on the premises of HMRI with closed-circuit television (CCTV) surveillance. HMRI has 24-hour security personnel that monitor CCTV and swipe-card access. Swipe-card access permissions are restricted to authorised personnel. The REDCap application provides role-based access with authentication details encrypted in transit and storage. All communication between clients and the servers utilise HTTPS via Secure Socket Layer encryption (SSL (HTTPS) 256 bit secure channel). The HMRI data centre offers cold disaster recovery. HMRI backs up the REDCap server to disk daily and backups are stored both onsite and offsite, to enable a restore from major problems such as a database or server corruption. This backup and restore function is tested at least annually.

At a project level, a REDCap user with designated project permissions can export a complete copy of the research project (metadata and data) and store this backup as per approved ethical protocol. Access to each project’s data is limited to the project owner, their nominated project team and HMRI authorised support staff. Each user can have their rights and permissions customised for each project, restricting their access to individual forms, data exports and/or reports. To maintain, support and test systems, users with Administrator access in REDCap have the capacity to access all data housed within their instance of REDCap. Within HMRI, Administrator access is limited to authorised HMRI staff with either a specialised IT or database management skill set. HMRI IT and HMRI REDCap Administrator staff understand the importance of and maintain confidentiality of all data housed within the HMRI REDCap instances. In REDCap, user authentication for logging into REDCap requires a Username/Password combination. All database edits and data entries completed by each user (including REDCap Administrators) are logged in the project’s audit trail. REDCap supports flagging of identifiable data. This can prevent the inadvertent release of sensitive data and supports the censoring of identifiable data from members of the team who do not require access.

Statistical analysis:  
To assess the impact of NFT on ITQ scores, the data will first be visualised to observe and compare score distributions with histograms and boxplots. Score trajectories over time will also be described with spaghetti-plots. Statistical significance of mean differences between any time points will be estimated using the paired t-test. With 30 subjects, if the effect size was at least 0.55, we would have 80% power to declare that the mean of the paired differences is significantly different from zero (i.e. two sided p-value < 0.05). Next, piecewise multilevel growth curve modelling (GCM) [13] will be conducted to examine change in DSO trauma-related symptoms through the course of treatment (individual DSO sub-scores of ITQ). Multilevel GCMs have become the standard for analysing psychotherapy outcome data because of several advantages such as the capacity to handle missing data and unbalanced information, efficient and modelling flexibility [14]. This approach is recommended by the Institute of Medicine (2001) for small clinical trials to maximize data use while obtaining reliable and valid results. Modelling and model fitting and evaluation will be implemented using mixed-effect linear model regression with the R Statistical Package lme4 [15]. Piecewise growth modelling [14] examined change during treatment and during follow-up. Two time variables were included in the analyses: The primary time begins at zero (baseline assessment) and increased by one for subsequent assessments; and a variable coded zero for all the assessments that occurred during treatment and coded one for the follow-up assessment. For the estimation of the impact of treatment (NFT vs. WL), a dummy-coded treatment variable will provide a predictor of the effects of treatment on time parameters. This model produces three coefficients: The regression intercept represents baseline scores; the first-time parameter for changes during treatment; and the second time parameter for the difference in rate of change during treatment and during the follow-up period.

**Results, Outcomes and Future Plans**

Given this project has been planned with the intention of improving the results established by Rogel et. Al [3], this project is highly likely to generate results of interest to participants, their carers, organisations tasked with child protection goals as well as the international child trauma and mental health field. All participants including their foster carers will be asked at the consent stage of the project, if they wish to receive a summary of the results of the study at its completion. These will be provided in lay person’s terms, via mail or email as per participant preference. Additionally, community consultation has resulted in a desire that de-identified results be shared in the newsletter which is accessible to all foster carers looking after children managed by Wandiyali. The results provided will be de-identified between group changes in outcome measures. In addition to this, it is highly likely that the results of individual outcome measure results would be valuable to the child’s carer to inform the school or future providers of mental health care. Again, this will be offered to participant families at the consent stage of the project. Foster carers will indicate their preference for receiving results for their individual child in written or verbal form which will be provided by the lead research team psychiatrist. If desiring verbal format the foster parent will be asked if they wish their child’s caseworker, casework manager or Wandiyali carer support officer present when these are presented to them.

Community consultation has occurred regarding broader dissemination of results. This consultation has resulted in a decision to disseminate to an international peer reviewed journal.

Plans for dissemination and publication of project outcomes:

Dissemination of findings will be completed by publication/s in peer reviewed journals and presentations at conferences; the track record of the CIs indicates this is highly likely to be successful. The research team has strong relationships with policy related organisations. These include:

* The Australian Neurofeedback Institute [16] has an impressive list of collaborating organisations, all dedicated to dissemination of findings, increasing access to this important treatment modality and influencing funders.
* Wandiyali [4] has a very close relationship with Department of Communities and Justice and frequently influence them to fund new pilot programs to improve child protection outcomes for Aboriginal families.

Follow up research:

Future research may include applying NFT to varying other client groups receiving current services from Wandiyali. These include foster carers (frequently under extreme stress), Aboriginal and Torres Strait Islander adults with alcohol and other drug issues or parents referred to our family preservation services (with current child protection risks).

This project will provide NHMRC Level III-2 evidence. Future projects will be competitive for external funding with the provision of this project’s pilot data. These projects will also be exceptionally competitive based on addressing a population and clinical problem that is a high priority for many external funding bodies:

* Aboriginal persons
* reducing the removal of Aboriginal children
* improving intergenerational trauma
* improving the life trajectory for Aboriginal children in OOHC
* mental health research
* research for Aboriginal persons by an Aboriginal organisation
* culturally appropriate research

Other potential uses of the data at the end of the project:

Collection of data establishing any change from the EEG assessment to post treatment ‘mini-map’ may be used to explore any correlation with change in primary and secondary outcome measures.

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