STUDY PROTOCOL

The effectiveness of community neurorehabilitation for persons with an acquired brain injury: protocol for a systematic review [version 1; peer review: 1 approved with reservations]

Eileen Mitchell1-3, Nicola Philips1,2,4, Elayne Ahern1,2,5, Grainne McGettrick4, David Mockler2, Kyle Fitzpatrick1,2, Dominic Trepel1,2

1Global Brain Health Institute (Trinity College Dublin | University of California, San Francisco), Dublin, Ireland
2Trinity College Dublin, the University of Dublin, Republic of Ireland, Dublin, Ireland
3Queen's University Belfast, Belfast, UK
4Acquired Brain Injury, Dublin, Ireland
5University of Limerick, Limerick, Ireland

Abstract

Background: Acquired brain injury (ABI) refers to any type of brain damage after birth. ABI from either traumatic or non-traumatic origin is a leading cause of death and long-term disability globally. The impact of an ABI can be cognitive and/ or physical, greatly affecting their ability to function independently. With a lack of specialist inpatient rehabilitation facilities and services many of these survivors reside within the community either alone, with family or in residential facilities. Up-to-date evidence is required to indicate which forms of community rehabilitation are most effective in improving cognitive and physical outcomes for survivors. This systematic review aims to explore the clinical effectiveness of community neuro-rehabilitation services for persons living with an ABI.

Methods: A systematic review of relevant electronic databases will be undertaken to identify eligible published randomised controlled trials. The PRISMA statement will be used to guide the systematic review. From running the initial search, we aim to submit the paper for publishing within 6 months. This process will be completed using Covidence software. Two reviewers will independently screen the search results and select studies using pre-defined selection criteria, extract data from and assess risk of bias for selected studies.

Discussion: This systematic review will aim to explore the clinical effectiveness of community neuro-rehabilitation services for persons with an ABI. It plans to review and synthesize the current best available evidence base. A goal of this study is to positively inform
ongoing service development within a quality framework.

**Systematic review registration:** PROSPERO CRD42020148604
(26/02/2020)

**Keywords**
Acquired Brain Injury, Community, Neuro-rehabilitation, Systematic Review

**Corresponding author:** Eileen Mitchell (emitchell09@qub.ac.uk)

**Author roles:** Mitchell E: Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; Philips N: Writing – Original Draft Preparation, Writing – Review & Editing; Ahern E: Data Curation, Project Administration, Writing – Review & Editing; McGettrick G: Supervision; Mockler D: Investigation, Methodology, Project Administration; Fitzpatrick K: Investigation, Methodology; Trepel D: Supervision

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Background

Acquired brain injury (ABI) is an umbrella term describing any injury sustained to the brain since birth. The Royal College of Physicians and the British Society for Rehabilitation Medicine (2003) define ABI as an inclusive category that embraces acute (rapid onset) brain injury of any cause, including brain injuries sustained traumatically (traumatic brain injury; TBI) such as following a road traffic accident; or damage acquired non-traumatologically following surgery, brain illness, toxic or metabolic insult, or most commonly, stroke. ABI from either traumatic or non-traumatic origin is a leading cause of death, disability, and high healthcare costs globally. Brain injuries of a traumatic nature (TBI) are estimated to cost €33 billion in direct and indirect costs across Europe. In addition to the long-term effects of ABI on an individual, the costs borne by society are substantial, encompassing pre-hospital care, emergency, hospitalisation, outpatient rehabilitation, and indirect losses due to lost workplace production. Of the overall burden of neurological disorders, ABI accounts for over half of all disability-adjusted life years lost and nearly 70% of all related deaths. Prevalence rates for TBI estimate 55.5 million cases, while the incidence of TBI has increased over time reflecting growth in the size of the population but also accounting for an aging population. This makes TBI, and more broadly, ABI, a pressing public health concern. With an ever-increasing unmet rehabilitative need, it makes the requirement for suitable services ever more pressing. At the World Health Organisation (WHO) Rehabilitation 2030: a call for action, calls for coordinated and collaborative global action for rehabilitation services generally.

The impact of an ABI can be physical and/or cognitive, greatly affecting an individual’s level of function in a myriad of psychosocial or occupational domains, either temporarily or permanently. Thus, the magnitude of impairment can be classified as either mild, moderate, or severe ABI. It often leaves the survivor with an acquired disability that they and their family must adapt to, with little or no preparation. It is estimated that 35,000 people in Ireland between the ages of 16–65 are living with an ongoing disability resulting from ABI (approx. 7.25 persons for every 1000). The number of persons experiencing an ABI greatly exceeds the available rehabilitative services in Ireland, hence many ABI survivors reside in the community with varying access to community-based neurorehabilitation, families struggling to cope and inappropriate placements in nursing homes. This situation is not unique to Ireland, with the need only set to increase due to global health, demographic trends and ageing population.

Neurorehabilitation involves a multidisciplinary approach to assessing individual needs to best help the individual to regain and optimise function, while preventing further deterioration. The ability to support an individual with ABI in the community would allow for increased service capacity and reduce waiting lists, but also help ensure optimal outcomes during recovery.

It is reported internationally that community-based neurorehabilitation services are not adequately supported, with access to vital services often dependent on geographical location. This coupled with a trend of shortening hospital inpatient stays places an increased reliance on community services, showing the need to investigate how to best meet the ongoing rehabilitation needs of people with ABI. In Ireland, the 2019 Neurorehabilitation Implementation Framework outlined specific issues pertaining to long waiting lists, this included limited access to specialist neurorehabilitation services, alongside a scarcity of community-based neurorehabilitation. Consequently, the lack of neurorehabilitation services has been acknowledged to account for the inappropriate use of beds in acute hospitals, with similar findings being reported internationally. Acquired Brain Injury Ireland and other stakeholders have advocated to prioritise the implementation of neurorehabilitation services embedded in a policy framework and supported by evidence-based data that verifies improved outcomes for individuals with ABI.

A Cochrane review of 19 studies on multidisciplinary rehabilitation for ABI amongst adults of working age demonstrated that, for those with moderate to severe ABIs, intensive neurorehabilitation showed earlier gains, whilst timely rehabilitation was better than delayed treatment. This review also concluded that following acute services, community-based neurorehabilitation is necessary for the patients’ ongoing needs and goals, yet there is limited evidence for such community-based services, as only 3 relevant studies were identified. A review by Doig et al. (2010), inclusive of 17 studies, demonstrated that community-based or home-based rehabilitation showed at least equivalent outcomes, and often superior outcomes, when compared to outpatient clinic settings (e.g. day hospital). Albeit, the majority of studies included a stroke population which may limit the generalisability of findings, but this nevertheless supports efforts to increase the provision of neurorehabilitation services for ABI in the community context.

Neurorehabilitative services overall aim is to help the individual achieve optimal function in interaction with their environment. Resultantly, the use of outcome measures tend to be quite heterogeneous, including but not limited to consciousness, motor and sensory function, cognition, occupational functioning, community integration, and independence in daily activities. Without a core outcome data set the variation in outcome measures across the literature limits the potential of additional analysis and hinders the ability to draw conclusive therapeutic recommendations. Kwakkel et al. (2017) provide progress in this area by providing recommendations of standardized measurements during stroke recovery. These recommendations, to keep validity across stroke trials, are limited to the stroke population and not the wider ABI population. This is an area warranting further development.

A larger emphasis on rehabilitation for cognitive, behavioural, psychological and social domains has been recommended following long-term outcomes of individuals with TBI; the physical and vocational rehabilitation of these participants was deemed successful in light of the fact that neurorehabilitation programmes tend to more so incorporate physical and occupational therapy. Physical and cognitive outcomes are
frequently used to assess intervention effectiveness for ABI as these are common deficient areas following ABI, are modifiable factors that can be targeted during rehabilitation, and are relied upon for day-to-day activities\textsuperscript{20,21}. Thus, addressing cognitive and physical functioning in a multidisciplinary approach may be integral to ensuring transfer to psychosocial domains. Many reviews to date have tended to focus on physical\textsuperscript{22,23} or cognitive outcomes\textsuperscript{24,25} following ABI suggesting benefits for function, albeit the variance owing to differences in age, type of injury, and treatment content/delivery cannot be overlooked. Few of these reviews have focused on community-dwelling individuals with ABI (self-management programs)\textsuperscript{23}, but to the best of our knowledge, no reviews have exclusively considered a multidisciplinary approach for ABI in the community context. Considering the service needs reported by individuals within the first year of recovery from ABI\textsuperscript{26,27} a focus on the continuity of care into the community is paramount.

In comparison to previous literature that has largely assessed single discipline neurorehabilitation and summarised findings across inpatient and community-based contexts, the aim of this review is to determine the effectiveness of multidisciplinary community-based neurorehabilitation for individuals with ABI, which include cognitive or physical functioning outcomes as either primary or secondary outcomes. The objectives are: (a) review RCTs pertaining to community-based rehabilitation for ABI provided by a multidisciplinary team of healthcare professionals to improve physical and/or cognitive function, relative to usual care; (b) determine how the content and delivery of community-based neurorehabilitation relates to improvements in cognitive and/or physical function following ABI, (c) make recommendations for the provision and outcome evaluation of community-based neurorehabilitation services.

**Methods/design**

We will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline for this review (see Figure 1). In accordance with the PRISMA-P guidelines, this protocol was submitted to the International Prospective Register of Systematic Reviews in November 2019. The protocol

![Figure 1. PRISMA Flow diagram.](image-url)
has been reported according to the PRISMA-P (2015) checklist (see reporting guidelines). The reviewers will be using Covidence software\textsuperscript{28} to operationalise the review process, EndNote X9.3.1\textsuperscript{29} (to compile library), Revman 5 (to prepare reviews)\textsuperscript{30} and Stata 15 (for advanced statistical analysis)\textsuperscript{31}.

Types of participants

The review will include randomized controlled trials (RCT’s) of adults who have survived an ABI and are currently living in the community. Persons under the age of 18 years old will not be included due to brain development not being fully mature before this age, therefore being unable to rule out natural development versus recovery. Please see Table 1. As the review is investigating clinical effectiveness of therapy delivered in the community, all levels of ABI will be included in order to establish and evaluate all the available evidence. If appropriate a sub-group analysis will be completed in accordance with age group or severity of injury. ABI severity is individual to the person and is dependent on location and extent of the injury, they are commonly described as mild, moderate or severe.

Types of interventions

For the purpose of this review, neurorehabilitation is defined as rehabilitation provided to persons with an ABI\textsuperscript{32}. This rehabilitation is aimed at reducing disability, preventing deterioration and helping people regain and maximise their functional potential by setting meaningful goals\textsuperscript{32}. Principles of stroke rehabilitation, which falls under the umbrella of ABI, are detailed by Langhorne, Bernhardt & Kwakkel (2011) including; goal setting; high intensity practice, increased therapy or intervention; multi-disciplinary team care and task specific training\textsuperscript{32}. It is widely accepted that for neurorehabilitation to be effective it needs to be timely, in the correct setting and by the required health professional\textsuperscript{33}. For the purposes of this review, a neurorehabilitation intervention will also be defined as any non-surgical or non pharmacological intervention provided to persons with a diagnosis of ABI. These interventions will be delivered or overseen by allied health professionals in a community setting. For the purpose of this review, community settings will include the home, out-patient clinics, day hospitals and any setting which is not in-patients. We will not include interventions primarily addressing problems related to communication, swallowing or medical management of an ABI.

Cognitive rehabilitation involves engaging broad domains, abilities and everyday processes, which are applied in basic and abstract ‘real-world’ situations and settings in order to address functioning and performance in respect to an individual’s goals\textsuperscript{34}. Cognitive rehabilitation can include but is not exclusive to cognitive training, cognitive retraining, cognitive remediation, cognitive processing, brain training, executive functioning training, memory training, cognitive recovery and cognitive endurance.

Physical rehabilitation aims to enhance and restore physical function to help improve independence and quality of life. These include training methods aimed at improving an individual’s ability to complete activities of daily living with more independence\textsuperscript{35}. Physical rehabilitation can include but is not exclusive to motor function, motor ability, physical training, physical recovery, balance, physical ability and physical independence.

The review will include studies that involve the provision of neuro-rehabilitation interventions addressing functioning, specifically relating to cognitive and/or physical domains. A rehabilitative programme will be considered as neurorehabilitation if it was described as such by the authors, or if it included a description of programme components that adhered to the rehabilitation principles set out by Langhorne, Bernhardt & Kwakkel (2011) detailed above, with the overall aim to restore or maximise function\textsuperscript{32}. Neurorehabilitative input may be received from an individual health professional or an interdisciplinary/ multidisciplinary team.

Comparators

As the reviewers aim to investigate the clinical effectiveness of neuro-rehabilitation interventions, the studies must include an experimental group of therapy being compared to usual care, attention control, or waitlist control. Usual care is a term used in real world studies to describe the full spectrum of patient care services\textsuperscript{36}.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>1 Adults (&gt;18 years of age) currently living in the community with an acquired brain injury</td>
<td>Participants who have a diagnosis of a degenerative neurological condition or congenital neurological diagnosis.</td>
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<tr>
<td>2 Assesses the effectiveness of Neuro-rehabilitation</td>
<td>Paediatric population (&lt;18 years)</td>
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<tr>
<td>3 Is community based</td>
<td>Studies which are inpatient based.</td>
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<tr>
<td>4 Randomised controlled trial (RCT) with control group of usual care, waitlist control or attention control.</td>
<td>Single arm trial (no comparator)</td>
</tr>
<tr>
<td>5 Reported on at least one of the following outcomes: cognitive function or physical function, assessed using a reliable and valid scale</td>
<td>Studies where participants are in receipt of therapies that were not neuro-rehabilitative focused.</td>
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Types of outcome measures
ABI’s, dependent on the site and severity of injury, have the potential to impact cognitive and physical domains as well as many other areas such as behavioural, environmental, psycho-social and communicative. Cognitive and physical abilities are imperative for an individual to maintain independence in everyday functional tasks. Therefore, our primary outcome will be a measure of function specifically relating to physical or cognitive abilities, as assessed using valid and reliable scales. Outcomes will focus on data pre and post intervention.

Functional outcomes for both cognitive and physical function can include (but are not limited to) the following, as informed by the core outcome sets for traumatic brain injuries and outcomes frequently used in stroke rehabilitation:

Cognitive functional outcomes can measure cognition, memory and/or attention. These domains may be measured by the following outcome measures; Rey Auditory Verbal Learning Test (RA VLT), Trail Making Test (TMT), processing speed index from Wechsler Adult Intelligence Scale (WAIS)-III or WAIS-IV.

Physical function outcomes can measure motor function, self care activities, balance, activities of daily living (ADL’s and personal activities of daily living (PADL’s). These domains may be measured by the following outcome measures; Bartel index, modified Rankin Scale, Rivermead Mobility Index, Action Research Arm Test, Berg Balance Scale, Functional Independence measure (FIM) motor subscale, Wolf Motor Function Scale, 2-Minute Walk Test, 5-Minute Walk Test.

Where relevant, secondary outcomes focusing on the broader domains of function such as social interaction, improved participation, and psychosocial adjustment will also be extracted from included studies.

Search methods for identification of studies
A comprehensive systematic literature search will be conducted in the following databases: EMBASE, MEDLINE, PsycINFO, CINAHL, Cochrane Library, Web of Science. Included studies will be restricted to those published from 1st January 2010 to 31st December 2019, and available in English. This time frame has been selected to include the growing interest in neuro rehabilitation in the last decade and to generate sufficient data for analysis.

Search terms will include a combination of the following: Neurorehabilitation AND Acquired Brain Injury AND Community.

Full search terms are available as extended data.

Data extraction and management
The aforementioned search keywords will be used to conduct the search on the previously listed search engines with references compiled in a library on the reference management software (EndNote). Duplicates will then be removed. Titles of studies will be screened independently by two review authors to identify studies that potentially meet the inclusion and exclusion criteria outlined above. The filtered articles will then be screened by their abstracts. The full text of these potentially eligible studies will be retrieved and will be independently assessed for eligibility by two review team members. Any disagreement between reviewers regarding study eligibility will be resolved through discussion and consensus, while a third reviewer will be sought for final decision if consensus is not met. A standardised form will be used to extract relevant data from the included studies. Data to be extracted will include context, participants, study design, intervention description, outcome measure used to assess physical/cognitive functioning, findings and quality of the study. The Covidence software will be utilised to streamline and standardise this process, this will make the systematic review efficient and transparent. Table 2 gives an overview of the data to be extracted from eligible papers.

<table>
<thead>
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<th>Table 2. Suggested data to be extracted from eligible papers.</th>
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<td>Publication details</td>
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<tr>
<td>Methods</td>
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<td>Population</td>
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<td>Neurorehabilitation</td>
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<tr>
<td>Comparator</td>
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<td>Outcomes</td>
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Assessment of risk of bias

We will follow the Cochrane Collaboration tool for assessing risk of bias for randomised trials as outlined in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions and use the version 2 of the Cochrane risk-of-bias tool (Rob 2.0) for randomized trials\cite{38}.

Data synthesis

A narrative data synthesis will be conducted for all included studies describing patient/rehabilitation characteristics, choice of comparator group, outcome measures, and follow-up assessment points, if applicable. If a sample of studies are deemed sufficiently consistent to enable the pooling of results, they will be synthesised for a meta-analysis using RevMan software. Outcomes will be broadly classified into 2 domains, either cognitive or physical; within these domains similar outcome measures will be grouped (e.g. Berg Balance Scale, assessing balance, will be categorised within the physical domain). At minimum of 2 studies will be required for meta-analysis of any subdomain. Cohen’s $d$ effect size will be calculated as the standardised mean difference between the neurorehabilitation group and comparator group in the cognitive/physical outcome measure at post-treatment, divided by the pooled standard deviation. Inverse-variance weighted, random effects modelling will be conducted to generate a weighted mean effect size and confidence intervals. Effect sizes will be described in accordance with the recommended cut-offs, $>0.20 = $ small, $>0.50 = $ medium, $>0.80 = $ large\cite{39}. Heterogeneity will be analysed using the $Q$ statistic chi-squared $\chi^2$ test, with the I$^2$ index used to quantify the percentage of variability across the studies. If heterogeneity is significant ($p < 0.10$ alpha level, as recommended by Cochrane;\cite{39}), then appropriate moderator or subgroup analyses will be conducted to determine the explanatory potential of patient/rehabilitation characteristics on the effectiveness of neurorehabilitation.

This study will aim to conduct a quantitative synthesis with combined results to produce a single measure using a random-effects model unless there are few trials (2 or less)\cite{39}, in which case we will use a fixed effect model. If there is substantial heterogeneity, then results will not be combined and a narrative summary will be completed. A risk of bias assessment of included studies will be summarized in a table and results and implications will be critically discussed.

Dissemination of information

The findings of this systematic review will be disseminated through peer-reviewed publication. Additionally, findings will be presented at both national and international conferences and via a Public and Patient Involvement group of adults living with an ABI.

Study status

The original search was conducted in March 2020 and a second updated search was conducted in January 2021 respectively. We have completed the initial screening process and are in the process of currently beginning to data extract information from selected studies.

Discussion

Persons with ABI undergo a wide range of experiences and outcomes dependent on their social situation, location and extent of injury\cite{38,40,41}. In Ireland, due to a lack of specialist inpatient facilities the majority of these survivors reside within the community either independently, with family or in residential facilities\cite{40}. It is not currently clear what the most clinically effective interventions for this population of clients is. The results of this systematic review will summarize the available evidence regarding the clinical effectiveness of neurorehabilitation focusing on interventions in the community addressing cognitive and physical outcomes.

Data availability

Underlying data

No data are associated with this article.

Extended data


This project contains the following extended data:
- Additional file 1 – Search strategy .docx (Search strategy for the database searches in {MEDLINE, Embase, and CENTRAL})

Reporting guidelines


Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

References


Kim-Huong Nguyen
Centre for Health Services Research, The University of Queensland, Herston, Qld, Australia

Overall, the research topic is an important one, and the method for systematic review is appropriate. The proposed process and research plan is sufficient for a protocol paper. I look forward to reading the full review.

I only have a few minor comments.

1. "With an ever-increasing unmet rehabilitative need, it makes the requirement for suitable services ever more pressing. At the World Health Organisation (WHO) Rehabilitation 2030: a call for action, calls for coordinated and collaborative global action for rehabilitation services generally." Does this refer to rehab in general or rehab for ABI? It is unclear for me here.

2. "This situation is not unique to Ireland, with the need only set to increase due to global health, demographic trends and ageing population." It is unclear for me why global health or demographic trends will increase ABI. I can see why the demand-supply situation is a problem in Ireland and most places, but it is possibly of lack of resource, and priority toward ABI rather than global health or demographics. I suggest the authors consider revising this. A few examples outside Ireland about the similar situations will be useful. And if the authors want to highlight the pressing need for research around this area, there is need much stronger evidence (which I don't think is hard to find, and some is already mentioned - around the cost of illness of TBI etc. and disability burden - the immediate previous paragraph).

3. "Neurorehabilitation involves a multidisciplinary approach to assessing individual needs to best help the individual to regain and optimise function, while preventing further deterioration. The ability to support an individual with ABI in the community would allow for increased service capacity and reduce waiting lists, but also help ensure optimal outcomes during recovery." Is neuro-rehab often delivered in a tertiary facility? Or depends on the country? Is community-based neuro-rehab a new thing - or always there but under-utilised?
Maybe there should be a bit more explanation of the settings where neuro-rehab is often delivered? In tertiary - do you know the estimated cost? In community - do you know how much cheaper it might be? Might not be available I guess - but it is an important economic question if you want to elevate the the necessary of community-based neuro-rehab.

4. "A Cochrane review of 19 studies on multidisciplinary rehabilitation for ABI amongst adults of working age\textsuperscript{16} demonstrated that, for those with moderate to severe ABIs, intensive neurorehabilitation showed earlier gains, whilst timely rehabilitation was better than delayed treatment."
   This seems obvious - timely rehab is better than later - I am curious "how much better" - is there anything in the Cochrane review about the "size" of the "betterness"?

5. If the criteria is "adults living in the community" - you imply that the community-based neuro-rehab is not applicable for people living in facilities - even these facilities are not tertiary or specialised in neuro-treatment? If neuro-rehab is effective for people who live in the community then maybe they are applicable for those who live in "home-care facilities" (not necessarily nursing home).

6. Maybe in the paragraph starting with "For the purpose of this review, neurorehabilitation is defined as rehabilitation provided to persons with an ABI", you should include the cognitive and physical rehabs in the definition - such as 'neuro-rehab is...' - and including both cognitive and physical rehab. They are mentioned below, but feel disconnected.

7. "Search terms will include a combination of the following: Neurorehabilitation AND Acquired Brain Injury AND Community." I suggest the authors provide a table with the search terms and results for each databases. This is important for reproducibility.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Economics, evaluation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.