Author’s response to reviews

Title: Evaluation of a targeted, theory-informed implementation intervention designed to increase uptake of emergency management recommendations regarding adult patients with mild traumatic brain injury: results of the NET Cluster Randomised Trial

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Professor Gregory Aarons, Ph.D.
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Dear Professor Aarons,


Thank you for considering our paper for possible publication with Implementation Science. I am pleased to submit a revised manuscript for your consideration.

We would like to thank the reviewers for their questions; we feel they have improved our manuscript and we hope our response addresses their concerns. Our point-by-point response to the reviewers’ comments follows:

Reviewer # 1

1. This manuscript describes a cluster-randomized trial of 24 Australian emergency departments to test the effect of interventions designed to improve the care of patients who present with minor head injury. The investigators employed a variety of techniques to support implementation based largely on a multifaceted approach including opinion leaders and educational interventions as well as tailored approaches designed to address barriers. The methodology is comprehensive and robust and compliant with CONSORT although not entirely clear to me is if CONSORT for cluster-randomized trials was explicitly followed.

Response: Thank you for this observation. In the text of the first paragraph of the methods section, we now provide a link to additional File 3: NET-Trial CONSORT checklist, which indicates the sections in the manuscript where each of the items in the CONSORT extension for cluster randomised trials is addressed.

2. The study's primary outcome was the use of a post trauma amnesia scale which is designed to be completed while in the emergency department and should serve as a guide to safe discharge. Other outcomes relate to the "appropriate" use for CT scanning and the provision of discharge information related to head injury. The primary outcome seems to have been extracted by retrospective chart review and there was long-term patient
interviews comparing patients seen in control and intervention sites. The primary outcome reported at two months was positive in comparison to controls but still somewhat disappointing with less than 20% uptake. The other interventions were essentially negative including long-term patient outcomes. The study was conducted in 2013. This study demonstrates some of the challenges associated with achieving successful implementation in the context of a cluster-randomized trial. Despite a well-developed intervention the findings were disappointing. I think the paper is informative although a few areas merit concern. It is unclear from the manuscript, beyond a note that these interventions were suited to the Australian context, why repeat completion of the PTA was deemed as such an important piece of evidence to translate. If there is a lack of compelling evidence for the importance of the intervention one can appreciate how uptake was disappointing.

Response: In the trial protocol, we included a table outlining the three key recommendations, their relevance to managing this patient group, as well as the evidence underpinning the recommendations and the size of the gap between recommended and actual practice. Given this information is available in the protocol, and to limit the word count of this paper, we chose not to additionally include this information in the current manuscript. However, we do agree that readers of the current paper should be directed to this information and so we now refer to Table 1 of the trial protocol (additional file 1) in the second paragraph of the ‘Introduction’ section.

3. The findings around appropriateness of CT use are difficult to follow and by the authors' own admission were not readily measurable. The manuscript refers to expected rates of CT use but these seem high if in fact a validated instrument for true minor traumatic brain injury were used.

Response: Table 2 lists the outcomes and their definitions and includes descriptions of our CT outcomes; 1. CT scan-clinical criteria (CT) - defined as: a CT scan was provided in the presence of a risk factor that justified the scan (age 65 or older; GCS<15; amnesia; suspected skull fracture; vomiting and coagulopathy).

2. CT scan (all) – defined as: a CT scan was provided or not.

The appropriateness of the CT scanning decision (outcome 1) was not easily determined from the retrospective audit data due to an incomplete data set (often information regarding whether particular clinical criteria were present or absent was missing from the notes). This meant that, we were only able to determine whether a CT was justified for the cohort of patients where we had (some) data on clinical criteria (i.e. when one or more of the criteria that would justify a scan were noted ‘present’); however, we were not able to determine whether a scan was appropriately denied (as this would require no data was missing; and all criteria had to be scored ‘absent’). We have now clarified the reason why we were unable to measure ‘appropriate denial’ in the discussion section.

Given the difficulties around this CT measure, we decided post-hoc to include a second measure – CT scan (all), which provides crude CT rates per ED. This additional outcome was included so
that we would have a measure of the impact of the intervention on CT scanning across all patients, and not only the subset for whom risk criteria were recorded. Given hospitals were randomly assigned to intervention groups, we would expect that the case-mix of participants would be similar across groups, and therefore that comparing CT-scan rates for all patients would yield an unbiased estimate of intervention effect (this additional measure and reasons for inclusion has been described in additional file 2).

This ‘crude rate’ was 44% for control patients at follow-up and 50% for intervention patients. Although it is difficult to get an exact estimate of the percentage of patients in our study we would expect to receive a CT scan, due to differences in study population, definitions, and criteria used in our study compared with published studies, we compared our findings with percentages reported in other studies studying one or various rules (e.g. external validation studies). In these studies, percentages were calculated by dividing the number of mTBI patients in whom the decision rule was positive divided by the total of number of mTBI patients. These studies typically reported rates of 50 to 70%, although higher and lower percentages have also been reported. For example, a number of these studies included the Canadian CT Head rule and estimated that – if this rule would be followed- 53% (Stein 2009), 58% (Foks 2018) and 59.9% (Tan 2018) of mTBI patients in their study population would get scanned. Hence, we concluded that, potentially, this points to the fact that there was only modest scope for improvement for this recommendation. We have now clarified some of these details in the text.

4. Finally the authors may want to speculate as to whether the results achieved were warranted based on the effort invested and if their implementation strategy merits replication. A recurrent theme of many of these trials is that the change expected seems to be largely imposed by the research team rather than growing organically as something patients and providers feel they need. Was this a reason for most departments declining the study?

Response: We agree with the reviewer that the question ‘does this intervention merit replication’ is an important point to discuss. A companion paper of the current paper, which reports the results of the economic evaluation conducted alongside the trial, and which has also been submitted to Implementation Science, has been looking at this question in detail.

We now include some reflections on the above in our manuscript. We have expanded the sentence regarding the fact that ultimately, health service providers interested in implementing this intervention should decide what size of improvement would be important enough in their setting to justify any increase in costs associated with adopting the intervention. The economic evaluation that was conducted alongside this trial considered the trade-off between the net costs of the implementation intervention and improvements in clinical practice and health outcomes. The authors conclude that, as delivered in the trial, the balance of costs and outcomes from the
implementation intervention is unlikely to be acceptable to providers and fund-holders. Full results and further reflections on this can be found in Mortimer et al (62).”

Further, we are currently drafting a manuscript that will report the process evaluation of the trial. This will report findings from interviews with staff, and questionnaires, on (perceived) success of implementation and factors influencing implementation. In addition, in this manuscript we will reflect on the reasons of why EDs declined participation, including feasibility of implementation. Of the ED Directors who provided us with a reason for declining (either following the initial invitation or during a later stage of the process, but before randomisation; N=61), the most commonly mentioned reason (N=48; often several reasons mentioned per site) was the lack of capacity to participate in the trial (e.g. short staffed, not enough time to perform required tasks in relation to data collection and/or intervention delivery – in some cases due to other research already running in the department). Five sites reported that mTBI wasn’t on their priority list (e.g. due to already having pathway in place or seeing very few of these patients).

Reviewer #2

Thank you for the opportunity to review this manuscript, which will be of interest to readers who are planning to improve emergency department practice based on behaviour change interventions. This is a well written manuscript and a comprehensive account of the effectiveness study, including a full account of the study's limitations. A few minor observations that might be considered by the authors:

1. Re recruitment to the study, whilst it is acknowledged that self selection was a limitation, “I wasn't entirely clear from the text in the manuscript [lines 205-207] how the ED director's consent to be involved in an either/or intervention played through in terms of how those sites were then allocated to an intervention [without referring to a supplementary file] - adding a little more detail here would be helpful - perhaps with clearer linkage to the minimisation approach.

Response: No EDs withdrew following randomisation. The process of randomisation is described in the randomisation section, and we have added a sentence to indicate that ED directors (and other trial stakeholders) had no ability to influence the allocation to groups. The additional sentence reads ‘The allocation of EDs to intervention groups was undertaken externally to preclude any potential influence in the allocation by trial staff, study investigators, or study participants (i.e. ED directors).’

2. With respect to the intervention - I appreciate the content of the intervention is in a supplementary file and the development reported elsewhere, but it would be helpful to know within the text of the manuscript what the underlying theory/theories were about the intended mechanisms of action of the interventions.

Response: This work will be discussed in more detail in a future process evaluation paper, however, we acknowledge that further detail would be helpful in the current paper so that the
reader can better understand how the intervention components were hypothesised to operate. We have therefore added information in two ways:

First, in the ‘intervention section’, we have incorporated information on the process used to identify the barriers and facilitators and theoretical frameworks underpinning this work, as well as the process of intervention development. This section now reads:

Intervention

The method of development of the intervention has been reported elsewhere [22]. In brief, prior to designing the intervention, we conducted interviews to identify the clinical and organisational factors that may influence implementation of the three recommended practices [23, 24]. The content of the intervention was designed to target the important factors identified through the interviews. Both the interviews and the intervention design process were guided by two theoretical frameworks in a complementary manner [22]. The first of these, the Theoretical Domains Framework (TDF), is grounded in psychological theories of clinical behaviour change [31]. The second, the Model of Diffusion of Innovations in Service Organisations, was developed from an organisational perspective [32]. Next, intervention components were identified and operationalised. Behaviour change techniques were identified that were most likely to bring about change for each clinical practice using sources that link techniques to the theoretical domains of the TDF [33-35]. In addition, the literature was consulted to identify intervention components that might be effective in targeting or taking into account organisational factors that were identified through the interviews [32, 36-39]. Finally, evidence on the effectiveness of interventions designed to improve healthcare delivery [40, 41], and information derived from the interviews regarding practicalities and feasibility of proposed intervention components was considered.

Table 1 presents an overview of the delivery of intervention components, and Additional file 5 provides further details on the content and rationale for including each component.

Second, we have replaced the table in Additional file 5 with a table that not only includes the description of the intervention components, but also shows the rationales/reasoning underpinning the intervention elements/content.

3. lines 444 - cost is mentioned, but there is no economic analysis reported in this manuscript. I appreciate that the process evaluation findings will be the subject of a further manuscript, but it is a shame that the reader does not get at least a hint of some of the explanation behind the findings...

Response: We have added a reference to the paper presenting the results of our economic evaluation (which has been submitted to Implementation Science as a companion paper to the current manuscript) and we include the conclusion of this paper in the current manuscript (please see response to point 4 of reviewer #1).