

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

This paper was submitted to the JECH but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Subjective discomfort in children receiving 3T Magnetic Resonance Imaging and experienced adults' perspective on children's tolerability of 7T: a cross-sectional questionnaire survey
AUTHORS	Chou, I-Jun; Tench, Christopher; Gowland, Penny; Jaspan, Tim; Dineen, Rob; Evangelou, Nikos; Abdel-Fahim, Rasha; Whitehouse, William; Constantinescu, Cris

VERSION 1 - REVIEW

REVIEWER	Frank MacMaster University of Calgary, Canada
REVIEW RETURNED	08-Aug-2014

GENERAL COMMENTS	<p>First, the idea of examining tolerability of MRI in children, youth, and adults is very important.</p> <p>That said, I do have some concerns.</p> <ol style="list-style-type: none">1. "To establish the possible discomfort perceived by children participating in 7 Tesla (T) magnetic resonance imaging (MRI)" - But the children were on in the 3T. Please correct. You did not conduct a study of tolerability of 7T in children.2. The idea of the adult's best guess as to how children would react may not be useful. In my experience, adults underestimate the performance abilities of children in MRI studies. If anything, this report may reduce the likelihood of children participating in high field studies without sufficient evidence.3. Would an adult know if they were in a 7T vs. a 3T (or even a 1.5T) unless they were told? If you expect it to be more difficult, people will expect more difficulties.4. The main risks of high field include dizziness, vertigo, nausea, peripheral nerve stimulation, and the perception of a metallic taste. In your findings the only one to have a real impact was dizziness. The cold and noise are common regardless of field strength.
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	<p>5. "general discomfort" is too vague to be useful.</p> <p>6. Does "service evaluation" allow for publishing the results? Is your ethics board OK with that? I know it varies from place to place. Please clarify.</p> <p>7. For the noise, was there an effect of what protocols were used? Some are more annoying than others.</p> <p>8. Why was image quality only assessed for so few scans?</p>
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REVIEWER	Stavros Michael Stivaros University of Manchester and Royal Manchester Children's Hospital. - United Kingdom.
REVIEW RETURNED	21-Aug-2014

GENERAL COMMENTS	<p>I have great sympathy for this paper which I think would be a valuable addition to the paediatric specific neuro-imaging literature. Specifically of benefit to ethics committee review panels. In addition, it helps to define specific child specific concerns when designing social stories for children's MRI acclimatisation. This is becoming more and more important as we move towards non-sedated/anaesthetised multi-parametric physiological imaging in this age group. I have some reservations regarding the translational adult 7T findings to children, but the authors have clearly dealt with this limitation in the manuscript. I also think that access to the questionnaires particularly benefits the readership in this instance particularly with regard to future protocol planning.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer Name Frank MacMaster
 Institution and Country University of Calgary, Canada
 Please state any competing interests or state 'None declared': None

First, the idea of examining tolerability of MRI in children, youth, and adults is very important.

That said, I do have some concerns.

1. "To establish the possible discomfort perceived by children participating in 7 Tesla (T) magnetic resonance imaging (MRI)" - But the children were on in the 3T. Please correct. You did not conduct a study of tolerability of 7T in children.

Answer:

Thank you for the correction.

In page 2 – Abstract and page 4 – beginning of 3rd paragraph, we revised the manuscript as follows:
 “To explore the possible discomfort perceived by children participating in 7 Tesla (T) magnetic resonance imaging (MRI) research”

2. The idea of the adult's best guess as to how children would react may not be useful. In my experience, adults underestimate the performance abilities of children in MRI studies. If anything, this report may reduce the likelihood of children participating in high field studies without sufficient

evidence.

Answer:

The general experiences of children in high-field scans have, as yet, not been published to the best of our knowledge. Our data support their fair tolerability in 3T scanners. Our report was not to discourage recruitment of younger children in 7T MRI, but to promote higher vigilance in this vulnerable group.

3. Would an adult know if they were in a 7T vs. a 3T (or even a 1.5T) unless they were told? If you expect it to be more difficult, people will expect more difficulties.

Answer:

This is an interesting question, which can also eliminate some bias derived from knowing the field difference. Unfortunately, we did not address this specifically.

4. The main risks of high field include dizziness, vertigo, nausea, peripheral nerve stimulation, and the perception of a metallic taste. In your findings the only one to have a real impact was dizziness. The cold and noise are common regardless of field strength.

Answer:

Our sample size is not big enough to distinguish the difference of dizziness between 3T and 7T field strengths. These discomforts are common and we did find greater general discomfort in 7T than in 3T system.

5. "general discomfort" is too vague to be useful.

Answer:

We agree "general discomfort" is vague, but representing general scanning experience compositing lots of elements, such as the noise, the temperature, the light, the space, the comfort of lying for a long time, the loss of contact of people, and the desire not to move inside the scanner. "General Discomfort" is a global subjective evaluation by the people who were scanned. It gives us their overall appreciation of the experience.

6. Does "service evaluation" allow for publishing the results? Is your ethics board OK with that? I know it varies from place to place. Please clarify.

Answer:

Thank you to point out this important issue. The method and pilot data of this service evaluation are part of the ethics approved study protocol (REC 13/EM/0080) in the chapter of USER AND PUBLIC INVOLVEMENT. The data collected from these children, young people, and their parents /carers were completely anonymized, as you can see that the supplementary questionnaires do not include any confidential data, such as name, date of birth, or hospital number. We have considerable experience in pre-protocol consumer involvement, which is itself required by the research ethics committee, for our future research study.

In page 6 - 1st paragraph, we revised the manuscript as follows:

"Anonymized data from children undergoing clinical 3T MRI scans came from an ongoing service evaluation exercise performed in the MRI Department at the Nottingham University Hospitals NHS Trust, for which the ethics committee approved as a pre-protocol exercise.

7. For the noise, was there an effect of what protocols were used? Some are more annoying than others.

Answer:

The scanning protocols may have effect on the noise production according to literature on 3T and lower field strength. Unfortunately, the audiometry measurement at 7T system has not been reported because of the difficulty of locating the metallic apparatus directly within its bore, where the magnetic field is intense. Subjective feelings can be reported by experienced users.

8. Why was image quality only assessed for so few scans?

Answer:

The image quality analysis was done retrospectively and there were only 29 research MRI data traceable in a linked anonymized method.

In page 13 – image quality section, we revised the manuscript as follows

“In total, linked anonymized brain images of 29 adult patients were available to be examined retrospectively.”

Reviewer Name Stavros Michael Stivaros

Institution and Country University of Manchester and Royal Manchester Children's Hospital. - United Kingdom.

Please state any competing interests or state 'None declared': None Declared

I have great sympathy for this paper which I think would be a valuable addition to the paediatric specific neuro-imaging literature. Specifically of benefit to ethics committee review panels. In addition, it helps to define specific child specific concerns when designing social stories for children's MRI acclimatisation. This is becoming more and more important as we move towards non-sedated/anaesthetised multi-parametric physiological imaging in this age group. I have some reservations regarding the translational adult 7T findings to children, but the authors have clearly dealt with this limitation in the manuscript. I also think that access to the questionnaires particularly benefits the readership in this instance particularly with regard to future protocol planning.

Response:

Thank you very much to see our efforts to contribute paediatric neuro-imaging field.