Lay Summary of a Completed Research Project

| CCR No and Study Title: | CCR4362  
A randomised controlled trial comparing the accuracy and acceptability of closed-face and open-face thermoplastic immobilisation shells in cranial radiotherapy.  
REC: 15/WS/0182, amendment AM1705/04 |
|-------------------------|------------------------------------------------|
| CI and Sponsor names:   | CI: Dr Liam Welsh  
Sponsor: The Royal Marsden Hospital |
| Study opening date:     | 9/11/2015  
Study closing date:      | 12/10/18 |
| Proposal and Objectives:| Thermoplastic shells are used to help patients to stay still and maintain the required position for receiving radiotherapy to the head and/or neck to assure accurate treatment delivery. The shells currently in use within the RMH radiotherapy department cover the whole face, and as a result have the potential to cause anxiety and distress, particularly to claustrophobic patients.  
The study will test the accuracy and acceptability of using open faced shells compared to using the standard ‘closed face’ shells for patients receiving cranial radiotherapy.  
The aim of this trial is to improve the patient experience of cranial radiotherapy by means of open-face immobilisation shells, without compromising setup accuracy and reproducibility.  
Primary Objective:  
i. To determine if open-face shells provide equivalent (non-inferior) setup accuracy and reproducibility compared to closed-face shells  
Secondary objectives:  
ii. To determine patient acceptability and tolerability for both types of shell  
iii. To determine the magnitude of intra-fraction motion (stability) for both types of shell  
iv. To compare the satisfaction of both patients and radiographers with the fabrication and use of each type of shell for radiotherapy treatment  
v. To compare the efficiency of open and closed face shells in terms of time required for initial moulding and patient setup in both the pre-treatment (RT planning) and treatment delivery settings. |
**Main Findings:**

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<tr>
<td>I.</td>
<td>The set up accuracy and reproducibility of the open-face shell was found to be either equivalent or non-inferior to the closed-face shell.</td>
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<td>II.</td>
<td>There was no significant difference between the shells in terms of patient experience. There was a significant correlation between pre-existing claustrophobia-related anxieties and patient experience, i.e. patients with higher scores for pre-existing anxieties had lower scores for positive patient experience, regardless of which shell was used.</td>
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<td>III.</td>
<td>There was no significant difference between shells for intra-fraction motion (stability).</td>
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<td>IV.</td>
<td>There was no significant difference between shells in terms of radiographer experience.</td>
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<td>V.</td>
<td>There was no significant difference between the efficiency of the shells in terms of shell fabrication time or treatment time.</td>
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**Implications for practice/future research:**

- The department can confidently offer patients the use of the open-face shell design for cranial radiotherapy, without compromising on the stability and reliability of the shells used.
- We plan to conduct departmental audits of the open-face shell using 3D imaging in relation to stereotactic radiosurgery.

**Dissemination Plan:**

- Submission of manuscripts on a) shell stability and accuracy and b) patient perception and experiences.
- Poster/oral presentations at national conferences.
- Oral presentation within Radiotherapy department.