#### Alleviating anxiety in patients prior to MRI

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#### Radiography

DOI: 10.1016/j.radi.2017.10.001

Published: 01/05/2018

Peer reviewed version

Cyswllt i'r cyhoeddiad / Link to publication

Dyfyniad o'r fersiwn a gyhoeddwyd / Citation for published version (APA): Tugwell, J. R., Goulden, N., & Mullins, P. (2018). Alleviating anxiety in patients prior to MRI: A pilot single-centre single-blinded randomised controlled trial to compare video demonstration or telephone conversation with a radiographer versus routine intervention. *Radiography*, 24(2), 122-129. https://doi.org/10.1016/j.radi.2017.10.001

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Alleviating anxiety in patients prior to MRI: A pilot single-centre singleblinded randomised controlled trial to compare video demonstration or telephone conversation with a radiographer versus routine intervention J.R. Tugwell, N. Goulden, P. Mullins

#### **Introduction**

Patients undergoing magnetic resonance imaging (MRI) often experience fear and anxiety prior to and during scanning. This could result in early termination of scan and indirectly affect image quality in terms of motion artefacts. In addition anxiety is known to increase respiratory rate, peristalsis and fluid flow, all potentially having detrimental effects on image quality.<sup>1,2</sup> It is reported that up to 37% of patients undergoing an MRI scan experience moderate to high levels of anxiety.<sup>2,3</sup>

For this reason, there has been much research testing different interventions to reduce anxiety, early termination and motion artefact, and to improve patient experience. However, the majority of previously explored interventions have either been time consuming, difficult to implement into practice, or very costly. Psychological interventions such as cognitive behavioural therapy<sup>1,4,5</sup> sedation<sup>6,7</sup> and mock MRI <sup>8,9</sup> are very protocol driven, and do not consider the individual needs of each patient. In addition, the majority of these trials have focused on paediatric patient as oppose to adult patients, however the psychological needs between these two cohorts of patients would differ significantly. Patients have been found to have diverse informational needs<sup>10</sup> which supports the importance of an intervention that is flexible and caters for all patients. Patients also tend to have limited knowledge regarding diagnostic procedures with the main source of information being family and friends.<sup>10,11</sup> In addition, over half of patients do not know the type of investigation they will receive when attending the radiology department.<sup>11</sup> This limited information about the procedure decreases a patients perceived level of control and increases their fear and uncertainty.<sup>12</sup>

Additional written information has been a common method explored to better inform patients and to reduce anxiety prior to MRI, but there are mixed views regarding this intervention.<sup>2,13</sup> Video demonstration on the other hand has been found in many studies to be an effective method to improve the level of patient satisfaction prior to various medical procedures and to help reduced anxiety.<sup>14,15,16</sup> A randomised controlled trial recently explored the use of a DVD prior to patients undergoing an MRI. This study demonstrated that the intervention effectively alleviated psychological distress related to the scan which lead to decreased motion artefacts and increased scan completion rate.<sup>17</sup> There are however a few limitations that need to be considered within the study: the use of closed questions for patient response, which did not allow patients to elaborate on their experience fully; and the inclusion of a range of mixed scanning protocols which all may affect anxiety differently.

The current project set out to evaluate the use of two different interventions that **better inform** patients prior to an MRI scan with the intention of eliminating any misconceptions they may have regarding the scanning procedure. The primary aim of this study is therefore to establish whether a video demonstration or a telephone conversation with a radiographer can reduce anxiety prior to the scan.

#### **Method**

#### <u>Design</u>

This study was a pilot single-centre single-blinded randomised controlled trial (RCT) to compare the use of video demonstration, or a telephone conversation with a radiographer, versus routine intervention, to alleviate anxiety in patients prior to undergoing MRI. Patients were randomised to either one of two interventions or a third control group: 1. Online video clip (in addition to standard appointment letter and information); 2. Telephone conversation with a radiographer (in addition to standard appointment and information); 3. Standard appointment letter with information. Patients were asked to complete a validated anxiety questionnaire prior to and after receiving the intervention and also were asked to complete a post scan survey regarding their entire experience. Motion artefacts for acquired images were also assessed.

Ethical approval was obtained from the Wales Research Ethics Committee 5 (REF 14/WA/1233).

#### **Patients**

Patients were first time attending outpatient adults awaiting an MRI scan of their head, lumbar spine or heart on a Philips Achieva 1.5T scanner. From reported literature<sup>1,3</sup> and local clinical experience, the examination with the highest incidence of patient anxiety and premature termination is head scan. Examinations of the spine also have a high incidence of anxiety and premature termination. Cardiac patients have not yet been explored in the literature, however it is one of the longest lasting MRI scans. Patients were excluded if they were inpatients, were not able to communicate in English or Welsh, deemed to lack capacity to consent or were under the age of eighteen. Patients were also excluded if they required contrast or intended to take benzodiazepines prior to the scan. These were deemed to be confounding factors that could influence the level of anxiety experienced by the patients. A sample size calculation was completed to ensure that the study would be adequately powered to detect a meaningful difference in levels of anxiety between groups. This included allowances for predicted sample attrition and non-response across the duration of the study. Our assumption was that anxiety levels between patients receiving an intervention as oppose to routine preparation would reduce by approximately 25%. From this estimation, a total sample size of 90 would have 80% power to detect this reduction in patient's anxiety level, allowing for 20% attrition. Two hundred and thirty patients were invited to participate with a patient information sheet, consent form and a pre intervention anxiety questionnaire sent in their appointment letter. These patients were then called to determine whether they wanted to participate and subsequently randomised into the trial.

Randomisation to the study was achieved by secure web access to a remote randomisation system from NWORTH CTU at Bangor University. The randomisation was performed by dynamic allocation to protect against subversion while ensuring that the trial maintained good balance to the allocation ratio of 1:1:1 both within the stratification variable and across the trial.<sup>18,19</sup> Patients were stratified by areas scanned and gender.

#### **Interventions**

#### Control group

The control group received the standard information letter sent to all MRI patients prior to an appointment. This contains the appointment letter, the safety questionnaire and an A4 bilingual single sided sheet with information regarding basic technical details, safety issues and in general what to expect from the scan (see appendix 1)

#### Intervention group 1

Intervention one consisted of a short video clip made specifically for this study using actors to illustrate the most important events occurring during the MRI procedure. The video visually demonstrates what the MRI machine looks like, how it works, examples of the noise generated and what is required of them during the scan. It is approximately a four minute clip commencing with arrival at reception all the way through to departing the department and

obtaining results. A link was available on the patient information sheet of all eligible patients however only those randomised into the video group were provided with a password. If patients did not have internet access, they had the opportunity to watch the video clip in the waiting room prior to their scan. The content of the video clip was chosen after discussion with MRI staff and previous patients to ensure all important and useful information was covered.

#### Intervention group 2

The second intervention was a telephone conversation prior to the MRI scan. This was an informal but semi-structured information session over the telephone where the radiographer provided patients with relevant information, answered questions and reassured them about any worries they may have prior to the procedure. Once randomised to this group, the patient and researcher arranged a suitable date and time for the telephone conversation to happen ensuring that the pre intervention anxiety questionnaire had already been completed prior to that time. The essential aspects of the telephone conversation were to develop a trusting relationship with the patient whilst encouraging them to express any worries whilst offering support and eliminating any misconception they may have regarding the scan.

#### **Outcome Measures**

#### State-Trait Anxiety Inventory (STAI)

The pre and post anxiety was assessed using the validated state-trait anxiety inventory (STAI) questionnaire. Patients were asked to complete this at home before receiving any intervention, then again in the MRI waiting room pre scan. This questionnaire is a self reported psychometric test that has been used in several previous MRI studies<sup>1,2,17,20</sup> and proven to be a valid tool for screening patients who may be unable to tolerate the scan prior to attendance.<sup>13</sup>

#### Image Quality

Image quality was assessed by two qualified MRI radiographers, blinded to the patient's intervention group. Assessment of image quality was based on the presence and severity of motion artefacts similar to previous literature.<sup>2,17,21</sup> The images were graded by an overall statement of: *'no motion artefacts', mild motion artefacts', 'moderate motion artefacts', 'significant motion artefacts'*. Patients undergoing cardiac scans where excluded from this

analysis as it is a scan of a moving structure acquired during either gated or breath-hold sequences.

#### Patient satisfaction post scan questionnaire

All patients completed a post scan satisfaction questionnaire to evaluate the entire MRI experience (See appendix 1). This questionnaire was designed to address specific aspects of the MRI experience using five closed questions and four open ended questions (which are to be analysed in a separate paper). The first four questions were closed questions, with the fifth question exploring reasons behind patient's anxiety, if any, giving them the option to specify reasons other than the options provided. As this was a self-designed non-validated questionnaire, it was piloted by four patients and two radiographers to ensure clarity and readability of the questions.

#### Statistical analysis

Data were entered into SPSS-PC for Windows with the STAI anxiety levels pre and post intervention analysed using analysis of covariance (ANCOVA). The post intervention STAI was assessed with covariates STAI pre intervention, group, gender, area scanned, age and duration of scan. The data and residuals from the model were not normally distributed, therefore a natural logarithm transformation was applied to the data.

Motion artefact ratings were analysed using a chi-squared test, and agreement on motion artefact ratings between the two observers was assessed using the intra-class correlation coefficient (ICC). Descriptive statistics were also used to reflect upon some of the outcomes.

The data for the MRI satisfaction questionnaire were also analysed. Questions one to four were analysed using a chi-squared test in order to test for differences in the frequency of responses in the different groups. Answers to questions five were tabulated for descriptive purposes.

#### **Results**

Patient's recruitment and retention details are demonstrated in Figure 1 and Table 1.

There were 89 eligible patients who were randomised and consented into the trial, however only 74 completed the entire trail. There were instances during randomisation/pre scan period where three patients did not watch the video, and had therefore received the same intervention as the control group. Additionally, three control group patients received more information over the telephone then is standard practice, and therefore received the same as the telephone call group. These six patients were still analysed as they did not breach protocol however two separate analyses were conducted. The first analysis is based on intention to treat analysis (ITT) where patients were analysed in the group they were initially randomised to. The second analysis is based on per protocol (PP) where these six patients discussed above were analysed in the intervention group they <u>actually</u> received.

There was no significant difference in age (t(87)=0.73, p=0.47) or STAI pre intervention when comparing patients who completed the study and those who completed the pre visit only. There was no significant difference in the proportion of group (chi-square(2)=1.332, p=0.514) or gender (chi-square(1)=0.107, p=0.744). There was a significant difference in the proportion of area scanned (chi-square(2)=10.439, p=0.005) (Table 2 and 3)

#### **STAI questionnaires**

An ANCOVA was computed for all three groups. The results of this ANCOVA are presented in Table 4.

There was a significant effect of group in the per protocol analysis (p=0.004), but not the ITT analysis (p=0.169). These results are for those patients who completed the study. Post intervention STAI scores were imputed for the patients who did not complete the study, based on the per protocol data. The median and range of F and p for 'Group' were 6.8 [5.7, 7.7] and 0.002 [0.001, 0.005] respectively.

Further ANCOVAs were computed to assess for differences between each pair of groups. There was a statistically significant reduction in the adjusted STAI post intervention in the video group compared to the control group (p=0.001) also there was a statistically significant reduction in the adjusted STAI post intervention in the telephone call group compared to the control group (p=0.015). When comparing the video group and the telephone call group there was no statistically significant difference (p=0.419).

#### **Motion artefacts**

The Intra Class Correlation (ICC) for both observers within this study was 0.81 (p<0.001) demonstrating an excellent inter- observer agreement when grading motion artefact (reference). No statistically significant difference was observer between the three groups (chi-square=5.910, p=0.206 for observer 1 and chi-square=1.870, p=0.760 for observer 2) on a per protocol analysis. (Table 3)

#### **MRI Satisfaction questionnaire**

For question 1 on how anxious patients were prior to scan, there was no significant difference between the groups in the per protocol analysis (chi-square(6)=3.154, p=0.789) or the ITT analysis (chi-square(6)=3.213, p=0.782).

For question 2 on how well the pre scan information alleviated worries, there was no significant difference between the groups in the per protocol analysis (chi-square(6)=10.642, p=0.100) or the ITT analysis (chi-square(6)=10.722, p=0.097).

For question 3 on how well the pre scan information prepared patient of what to expect, there was a significant difference between the groups in the per protocol analysis (chi-square(6)=18.504, p=0.005), and in the ITT analysis (chi-square(6)=17.348, p=0.008). In the per protocol analysis there was a significant difference between the control group and the telephone call group when multiple comparisons are accounted for (chi-square (3) =11.234, p=0.011). The reason for this is that in the control group patients tended to select the less favourable responses, mostly "*As expected*", whereas the telephone call group selected more favourable responses, mostly "*Better than expected*" with some "*Considerably better*". See Figure 2.

For question 4 on the patients overall MRI experience there was no significant difference between the groups in the per protocol analysis (chi-square(6)=7.056, p=0.316) or the ITT analysis (chi-square(6)=5.855, p=0.440).

Question 5 aimed to explore the reasons behind the patient's anxiety, if any. On this question, 48.6% of patients selected *"I wasn't anxious"* which means that the remaining 51.4% were anxious for some reason (Table 5).

In addition, question 5 was coded as 0 if "*Not anxious*" and 1 for all other anxiety reason in order to test for a difference in the mean STAI score pre intervention. The STAI scores pre intervention are significantly lower in those who selected "*Not anxious*" compared to one of the answers indicating anxiety (t=-5.94, p<0.001), demonstrating consistency between the STAI scores and the answers to question 5 on the MRI satisfaction questionnaire.

#### **Discussion**

The results of this study demonstrated that the use of a telephone conversation with a radiographer or an online video link detailing what to expect when having an MRI scan in comparison to the routine appointment letter leads to a significant reduction in patient anxiety levels. While there was a slight decrease in the post intervention STAI scores for the video link group compared to the telephone group, this was not statistically significant. Qualitative data (which will be reported upon within a separate paper) also supports the benefits of both interventions (video link and telephone conversation) as higher levels of satisfaction with no negative comments observed from the intervention groups in comparison to the control group. It is therefore clear that detailed visual and or verbal information leads to a greater reduction in patient anxiety prior and during MRI scan. This is supported by previous literature demonstrating the usefulness of patients watching a DVD to help reduce pre procedural anxiety prior to MRI scanning<sup>17</sup> and other medical procedures.<sup>14,15,16,22</sup>

The aim of this study was to use two different interventions that better inform patient prior to their scan to reduce anxiety, and to also increase their satisfaction and a feeling of control over their procedure. Previous work has shown that extended written information better informs patient and consequently reduces anxiety<sup>1,13</sup>, our results corroborate this fact. From the population within this current study, 51.4% were anxious before the scan, with the reported cause predominantly being either worry about the results and findings, the enclosed space, or a combination of both. Additional information in whatever form is expected to have a positive impact on patients as anxiety often stems from not knowing what to expect<sup>13</sup>, which indirectly suggests that first time attending patients, with no experience of a MRI, are likely to be more anxious. There is however controversy within the literature as Tornqvist and colleagues<sup>2</sup> reported that anxious or claustrophobic patients will always be fearful prior to their scan regardless of whether it is first time attendance or not (the experience doesn't get any easier). However, another study found that anxiety were lower in patient who knew what

to expect from previous experiences.<sup>23</sup> This discrepancy highlights the complex nature of anxiety and the diverse patient population with varying informational needs attending a typical MRI department. Note the difference between the various studies may also be due to the inclusion of different patient cohorts, with Tornqvist and colleagues<sup>2</sup> including only those patients with known anxiety and claustrophobic tendencies. Their results would suggest it is important to make note of these nervous patients on the radiology information system in order to recognise these patients early if they attend again, as based on our results these patients may benefit the most from greater information about the procedure beforehand.

The pre intervention STAI scores were significantly lower in those patients who selected 'not anxious' compared to the ones who selected one of the other available answers for question five on the post scan survey, demonstrating consistency between the STAI scores and the answers to this question. This helps to reinforce the validity of the post scan survey. Although this may seem to be an obvious correlation (lower pre intervention STAI scores = not anxious on the post scan survey), there were a few patients within the study that had low pre and post intervention STAI scores who then became very nervous when entering the scanner or during the scan, which was later reflected in the post scan survey. Question five on the post scan survey only related to the anxiety they felt prior to the scan and not as they entered the environment or during the procedure. These patients who reported low anxiety pre scan but later commented about the negative feelings experienced during the scan were perhaps oblivious to how they may react. This phenomenon is often seen in clinical practice where the calmest of patients have a sudden unexpected reaction but there is limited published work surrounding this issue. The environment in the scanner can however have an impact on patients<sup>2,24,25,26</sup> and therefore re-enforces the potential for patients entering the MRI environment to suddenly have an unexpected anxiety reaction. It can be very difficult to identify and target this cohort of patients prior to their MRI scan as they are likely unaware of their fears, however, by better informing all of our patients by using a simple video clip, better information or a telephone line to call with any questions gives patients the opportunity to thoroughly understand the procedure in hand and to gain a level of control.

This current study did not find a correlation between anxiety levels and motion artefacts on the resultant images however the sample used for this analysis was reduced as cardiac patients were excluded due the difficulty in detecting patient induced motion artefact in an already moving structure. There are other studies that also did not find correlation between STAI scores and motion artefacts<sup>27,28</sup>; this questions the direct relationship assumed by many studies between anxiety and motion artefacts. Tornqvist and colleagues<sup>2</sup> on the other hand found a significant difference between anxiety and motion artefact but did not find a difference between any other outcome measures such as STAI scores and satisfaction. The intervention within their study was extended written information and therefore it questions whether motion artefact is in fact correlated to the patient's understanding prior to scan instead of anxiety. If patients understand the consequences of movement on resultant images, they might keep extremely still during the scan. Although this phenomenon was not apparent within our study when additional information was provided to patient, this could be due to a small sample size or the subjectivity associated with visual image quality assessment. In addition, it was only motion artefacts assessed by observers for both brain and spine scans, it would be interesting to explore motion further such as assessing swallowing reflexes for neck scans or peristalsis on pelvis scans in order to understand the effect of anxiety on more than just motion artefacts.

The data from our study used both ITT and per protocol analysis because six patients did not receive the intervention they were randomised to. These patients however were still included within the sample since they did receive <u>an</u> intervention. Three patients did not watch the video due to password/ link problems, and therefore they only received the routine appointment information. These three patients highlight potential issues with the video if it was to be implemented into routine clinical practice, however in clinical practice the password protection would not exist, which may resolve this issue. In addition, if implemented in practice, there would likely be an option for patients to watch the video in the waiting room, and referring doctors could also use the video to inform patients.

Following the results of this study we recommend that a video demonstration be implemented into routine practice, and that the routine appointment letter be modified to include recommendations from the patients, for example, information regarding receiving results, severity of noise and clearer instructions on the removal of various metallic objects and undressing. These recommendations come from additional in-depth information collected from the study patients using the open-ended post scan survey questions in addition to interviews with a small sample of patients, and is reported in a separate linked paper.

#### **Limitations**

The generalisability of results needs to be explored further. This study was undertaken on one type of scanner. Also the exclusion of various patients from the sample is a limitation; involving other groups of patients such as in-patient and patients having other areas scanned, would greatly enhance genralisability. In addition, the routine appointment letter was specific to the institution where the study was conducted and therefore other hospitals may differ in what information they disclose in their appointment letter to patients. Lastly, the referral indication for each patient was not documented. This would be interesting to explore further as the main reason for pre scan anxiety was indicated as findings/results. It may be reasonable to assume that a referral indication such as cancer would exacerbate anxiety levels in patients.

#### **Conclusion**

This study clearly demonstrated the effectiveness of two different interventions in reducing patient anxiety prior to MRI scanning. The use of a video link to visually demonstrate to patients what to expect from their MRI scanning experience, or a telephone conversation with a radiographer to verbally explain what to expect, whilst answering any questions, both reduced anxiety levels in comparison to those patient who received the routine appointment letter and information. The video link is easy to implement and can be administrated to all patients prior to their MRI scans with no additional time and financial implications associated with it. It could therefore have the potential to be implemented routinely. A telephone conversation with a radiographer on the other hand is not as easy to implement due to time implications, however a telephone number could be provided at the end of the appointment letter which would allow patients to ask or speak to a professional from the MRI scanning department if required. It may be beneficial to make both interventions available to patients in conjunction with each other, whereby the extra information from the video may reduce the need of patients to speak to a radiographer, but the option would still be available.

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APPENDIX 1





#### Office use only

#### Date of scan:

<u>Area scanned:</u> Head Spine Heart Other

.....

Intervention (please tick):

No intervention □ Telephone Conversation □ Video Demo. □

### Patient Satisfaction Survey

# Please complete the following Patient Satisfaction Survey based on your recent MRI scan experience

\*Note: the word preperation in the below survey refers to the infromation/intervention you received prior to scan which may have been an information sheet only, DVD or telephone conversation.

#### 1. Were you anxious prior to your MRI scan?

Less than	□ As expected	More than	Considerably
expected		expected	more

#### 2. Did the preparation for the MRI scan alleviate your worries?

Less than	□ As expected	More than	Considerably
expected		expected	more

## **3.** Did you feel the information you received prior to your MRI appointment informed you of what to expect?

<ul> <li>Less than desirable</li> </ul>	□ As expected	Better than expected	Consistently better	

#### 4. The overall MRI experience was......

Less than	□ As expected	Better than	Consistently
desirable		expected	better

#### 5. What made you anxious prior to your MRI appointment?

I wasn't anxious	Enclosed space	MRI findings/results	Others (please specify below)
Other		• • • • • • • • • • • • • • • • • • • •	•••••

6. What did you think about the preparation and information you received prior to your scan?

#### 8. What did you like most about the preparation you received prior to the scan?

9. What additional information or preparation would you have liked to receive prior to the scan?

**10.** Please comment or give ideas of how to improve a patients experience in MRI?

Thank you very much for taking the time to complete this survey. Your feedback is valued and very much appreciated!