Jenna Tugwell

CoRIPS Research Grant 113

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Title: A pilot single-centre single-blinded randomised controlled trial comparing the use of video demonstration or telephone interview verses routine intervention to alleviate patients' anxiety prior to MRI

Principle Aim: The aim of this study is to determine whether a video demonstration or telephone interview with a radiographer compared to routine preparation (information leaflet) can be successfully utilised to alleviate patient's anxiety prior to MRI examinations.

Objectives:

1. To assess the effectiveness of two patient based interventions aimed at reducing motion artefacts on routine MRI.

2. To explore patient satisfaction post MRI to determine which intervention better prepared them for the scan.

3. To assess the relationship between the levels of pre procedural anxity and the reason for scan.

Diagnostic imaging plays a vital role in the patient's journey through illness and disease. Patient's undergoing magnetic resonance imaging (MRI) often experience fear and anxiety prior and during scanning which often causes them to opt out of the examination or causes early termination of scan. Various studies including Tornqvist et al, (2006) Eshed et al, (2007) reported that up to 37% of patients examined by MRI experience moderate to high levels of anxiety. These scans require the patients to be extremely still for a long period of time whilst acquiring the images. From clinical experience, patient who are nervous tend to move more during the scan plus various literature suggest that respiratory rate, peristalsis and fluid flow also tend to increase with anxiety, all potentially having detrimental effects on image quality. (Grey et al, 2000) (Tornqvist et al, 2006). There have been several research papers suggesting and comparing different interventions to improve patient

experience during the scanning process, however, the majority of these interventions are either time consuming, difficult to implement into practice or very costly.

MRI is the gold standard investigation for numerous pathologies. Failed examinations lead to wasted appointment windows, which increases waiting times for other patients and leads to wasted resources. Several studies have looked at how to reduce patient based anxiety problems in MRI examinations. For example the use of open MRI scanners has been compared to closed scanner use finding a reduction in anxiety and improved compliance (Bangard et al, 2007) (Michel et al, 2002) (Spouse and Gedroyc, 2000), however image quality is often reduced in open MRI scanners, the duration of the scan increases (Loew et al, 2000) and these types of scanners may not available in the majority of hospitals. Other studies have looked at quieter machines (McNulty and Mc Nulty, 2009), psychological support (Caruso et al, 2006) and cognitive strategies to reduce anxiety (Argue, 1995) (Lukins et al, 1997). Up to 33% of the interventions previously reported are aimed at paediatrics with several of these focusing on the use of mock MRI scans to prepare patients (Rosenberg et al, 1997) (Carter et al, 2010) (Hallowell et al, 2008). Prone positioning (McCauley et al, 1992) (Eshed et al, 2007), additional information (Tornqvist et al, 2006) and relaxation and hypnosis (Grey et al, 2000) (Lang et al, 2010) have also been used to deal with MRI pre-procedural anxiety. While all the above have been trailed, they do not address the individual anxieties of patients. (Selim, 2001). As Mathers et al (2009) state, patients have diverse informational needs; this reflects the importance of finding an intervention that is flexible and caters for different individual requirements.

Video demonstrations and phone interviews have been selected for this study as they allow an individualised, directed approach for each patient whilst being cost-effective. In a previous study Chesson et al (2002) report that over 50% of patients did not know the type of investigation they were going to have when attending the radiology department. This lack of information about the procedure in hand decreases the patients perceived level of control and increases their fear and uncertainty (Bolejko et al, 2008). As mentioned above, additional written information has been a common method explored to better inform patients and to reduce anxiety prior to MRI but there has been mixed views regarding this intervention (Tornqvist et al, 2006)(Selim, 2001). Quirk et al (1989) suggested that interacting with staff was considered the most vital method of reducing stress prior to being scanned, this is supported by Youffefzahed et al (1997) who suggested that verbal information was paramount to achieve optimal patient compliance. Krupat et al (2000) demonstrated that from a surgical perspective, patient satisfaction and experience were closely related to the amount and form of verbal information received prior to procedures.

Video demonstration also has been reported to be an effective method to improve the level of patient satisfaction prior to various medical procedures and to help reduced anxiety (Jamshidi et al, 2013) (Papa et al, 2008) (Schofield et al, 2008). For example Sorlie et al (2007) used a DVD for patients prior to coronary surgery and their findings were very positive. An example of where a similar intervention is already being implemented with very little evidence base for effectiveness is in a local

paediatric ward who have recently purchased “Ditto Lite”, a tablet that plays various cartoon scenarios of different radiology procedures. Anecdotally these wards report the use of this intervention to be extremely useful in better informing children prior to various procedures.

Methodology

The study will be undertaken in a large district hospital (Ysbyty Gwynedd) utilising a Philips Achevia 1.5T scanner. This pilot study allows us to test whether the components of the main study can all work together. It also allows focus on the processes of the main study, for example recruitment, randomisation, treatment, and follow-up assessments. Nevertheless, the data from this study may still contribute to the final analysis. The study will use both quantitative and qualitative data to answer the above aims. The qualitative data used merely to enhance the finding of the quantitative data.

Inclusion criteria

1. Awaiting an MRI scan,
2. MRI scan is a ‘head first examinations’ that uses the head, spine or cardiac coil *
3. Capacity to understand and consent to the study
4. Ages 18+
5. First MRI examination

*From local experience and reading the literature, the examinations with the highest incidence of patient anxiety and premature termination are head. Spine was also fairly high. Cardiac patient have not been explored in the literature however it is one of the longest lasting scans in MRI (Eshed et al, 2007) (Grey et al, 2000)

Exclusion criteria

1. Inpatients (these patients are not allocated appointment slots early enough, they are built-in around the availability on the day so not enough notice to consent and be randomised),
2. Outpatients that haven’t had 5 days notice of scan i.e. last minute booking such as urgent cancer referrals,
3. Non-English/ Welsh speaking individuals

4. Out of hours scanning

5. Taking Benzodiazepines

6. Parkinson's' disease

7. Needs contrast (gadolinium)

Recruitment of patients

Attached to all eligible patients' MRI appointment letters will be an invitation letter to take part in the research; this will be incorporated into the patient information sheet (PIS). Also a consent form and one State Trait Anxiety Inventory (STAI) questionnaire will be attached to the appointment letter. This will be followed up by a telephone call to inquire about willingness to participate. If they are willing to participate, they will be asked to fill in one of the STAI questionnaires immediately and will be informed within 24 hours of the intervention they will be receiving.

Randomisation

After consent and baseline assessment, participants will be individually randomised. Randomisation to the study will be achieved by secure web access to the remote randomisation centre, NWORTH CTU, at Bangor University. This system will be set up, maintained and monitored independently of the trial statistician or other trial staff. The randomisation will be performed by dynamic allocation (1) to protect against subversion while ensuring that the trial maintains good balance to the allocation ratio of 2:1 both within the stratification variable and across the trial. Participants will be stratified by the scanning type. For validation purposes, additional information will be taken including the participant's trial number, initials, and date of birth, and details of the person requesting the randomisation (Russell et al, 2011)

Interventions

There will be two interventions within this study which will be compared to routine preparation (control group). The first intervention sees the patient receiving a video demonstration, and the second intervention sees the patient having an informal but semi-structured telephone conversation with a radiographer who explains the produce and answers any questions prior the procedure.

Control group

Control-group patients received the standard routine hospital appointment letter where a standard A4 MRI information leaflet is attached.

Intervention group 1

Intervention one consists of a video made specifically for the study which can be viewed at home using a password protected link to a website or when the patient arrives in the department on a tablet. The video uses actors to illustrate the most important events occurring during the MRI procedure. The video intends to visually show patients what the MRI machine looks like, how it works, the noise it makes and what is required of them during the scan.

Intervention group 2

The second intervention is a telephone conversation prior to the MRI scan. This is seen as an informal but semi-structured information session over the telephone where the radiographer can provide the patient with relevant information, answer questions and reassure them about any worries they may have prior to the procedure. The researcher will have an informal sheet to guide the conversation however the conversation will follow the patient's informational needs.

Sample size

Study power calculation has been completed with the advice of a senior statistician in order to justify recruitment numbers. The power calculations are based on assumptions derived from published randomised clinical trials and from clinical practice. We have calculated the size of this sample to ensure it is sufficiently powered to allow us to control for a range of variables. In addition we have made allowances for possible sample attrition and non-response across the life of the study. Our assumption was that anxiety levels between patients receiving an intervention as oppose to routine preparation, their anxiety level would reduce by 25%. Hence, based on an average reduction of the anxiety level of 25% with a standard deviation of 0.5 and an attrition rate of 25%, a total sample size of 90 would have 80% power to detect a 25% reduction in patient's anxiety level.

Outcome measures

State-Trait Anxiety Inventory (STAI)

The STAI questionnaire will be utilised for this study to assess patient's pre procedural anxiety. Patients will complete the questionnaire at home before they receive any intervention in order to

measure their state and trait anxiety. They will be required to complete the same questionnaire again in the MRI waiting room to determine whether the intervention has been successful in eliminating or reducing their anxieties. The questionnaire has 40 short statements (20 positive and 20 negative) which assess both their current state of anxiety and general state of anxiety (Enders et al 2011). It's about quantifying their current anxiety levels by indicating their agreement or disagreement with the 40 statements on a four-point scale (see appendix 3).This questionnaire is a self reported psychometric test that has been used in several previous MRI studies including (Caruso et al, 2006)(Grey et al, 2000) (Tornqvist et al, 2006) and proven to be a valid tool for screening those patients who may be unable to tolerate the examinations prior to attendance (Selim, 2001)

Image Quality

Image quality will be assessed subjectively by a radiologist and a superintendent MRI radiographer, who will be blinded to the patient's intervention group. They will assess image quality on the basis of motion artefacts. The images will be graded as follows:-

1. No motion artefacts 2. Mild artefacts 3. Moderate artefacts 4. Significant motion artefacts

Patient Satisfaction

In order to compliment the STAI questionnaires, participants will be asked to fill in a satisfaction questionnaire with four participants from both intervention groups and the control group approached for a one to one interview after their MRI examination. Due to the large sample size, interviewing all participants would be unfeasible due to time implications. The 12 patients' to be interviewed will be selected using a convenience sample.

Questionnaire

The majority of participants will fill in a satisfaction questionnaire before they leave the department. Questions have been designed to address specific aspects of the MRI experience and to extract patients' views and preferences for the delivery of the MRI service especially the preparation phase. The questionnaire has been design with the interview agenda in mind and will have questions that derive both quantitative and qualitative data. It is short and easy to follow with five closed questions and five open ended question. The first four questions uses a 4-point Likert scale type questions with the fifth question exploring reasons behind participants anxiety, if any. The open ended question seeks ideas from participant on how to improve the MRI experience, what they liked and disliked about the

preparation/ intervention and how these impacted on their experience. This questionnaire will be piloted by 4 patients and 2 radiographers to ensure clarity and readability of the questions.

Interview

A convenience sample of participants will have a one to one interview with the researcher in a quiet office next to the scanner room. The aim of the interview is to capture the patient's experience and to assess the effectiveness of the interventions. The interview will be semi-structured with open questions directed by and interview agenda. A portable digital recorder will be use along with a sophisticated dictation/transcribing kit. Participants who are selected for interviews will sign an additional consent form to ensure they have understand what is required of them and how the data will be analysed and disseminated. Once the interviews are transcribed, the recordings will be erased from the digital device and also participants will be given the opportunity to view the written data from the interview to ensure the researcher has captured their experience accurately. In addition, the research supervisor (who is impartial and blinded to the intervention received by the patient) will examine the transcripts to ensure there are no issues such as vague descriptions, assumptions made by researcher or under/over emphasised points and so on.

Statistical analysis

The data from the two STAI questionnaires and image quality assessment will be entered onto SPSS-PC for Windows with the STAI anxiety levels pre and post intervention analysed using ANCOVA and image quality analysed using ANOVA. Intra class coefficient (ICC) will be used to compare image quality scores between the two observers.

Data analysis with regards to the interviews and the open ended question on the questionnaire will be carried out using a thematic approach in order to identify patterns. This will be done by reading and re-reading the transcripts and using a process of coding, categorising, and identification of themes (Lichtman, 2013). The transcripts will be read several times and the content will be systematically sorted and divided into concepts that derive from the predetermined themes; new themes that arise will be categorised separately.

9. Further data collection

Other than the data from the above outcome measures, further data will be extracted from the radiology information system (RADIS) post. This will include:

- Area of examination,
- Clinical indication,
- Duration of scan,
- Problems on the safety questionnaire

Dissemination

The findings from this research project will be put forward for publication in Radiography journal and will be submitted to be presented in UKRC and hopefully other conferences such as ECR and BIR (as a novice I would be open to any more suggestions from the panel, thank you)

1. Argue KR. *The effect of psychological intervention upon anxiety associated with magnetic resonance imaging.* 1995. San Diago: California School of Professional Psychology

2. Bangard C, Paszek J, Berg F et al. *MR imaging of claustrophobic patients in an open 1.0T scanner: motion artefacts and patient acceptability compared with closed bore magnets*. European Journal of Radiology. 2007; 64(1): 152-157

3. Bolejko A, Sarvik C, Hagell P, Brinck A. *Meeting patient information needs before magnetic resonance imaging: development and evaluation of an information booklet*. Journal of Radiology Nursing. 2008; 27(3): 96-102

4. Carter AG, Greer MLC, Gray SE, Ware RS. *Mock MRI: reducing the need for anaesthesia in children*. Paediatric Radiology. 2010; 40(8): 1368-74

5. Caruso A, Bongiorno L, Vallini I, Russo P, Tomao F, Grandinetti ML. *Breast cancer and distress resulting from magnetic resonance imaging (MRI): the impact of a psychological intervention of emotional and informative support.* Journal of Experimental and Clinical Caner Research. 2006; 25(4): 499-504

6. Chesson R, Mckenzie G, Mathers S. *What do patients know about Ultrasound, CT and MRI?* Clinical Radiology. 2002; 57: 477-482

7. Enders J, Zimmermann E, Rief M, Martus P, Klingebiel R, Asbach P, Klessen, Diederichs G, Bengner T, Teichgraber U, Hamm B, Dewey M. *Reduction of claustrophobia during magnetic resonance imaging: methiods and desing of the "CLAUSTRO" randomised controlled trial.* BMC Medical Imaging. 2011; 11(4): 1-15

8. Eshed I, Althoff C, Hamm B, Hermann KG. *Claustrophobia and premature termination of magnetic resonance imaging examinations.* Journal of Magnetic Resonance Imaging. 2007; 26:401-404

9. Grey S, Price G, Mathews A. *Reduction of anxiety during MR imaging: a controlled trial.* Magnetic Resonance Imaging. 2000; 18: 351-355

10. Hallowell LM, Stewart SE, De Amorim ESCT, Ditchfield MR. *Reviewing the process of preparing children for MRI Paediatric Radiology*. 2008; 38(3): 271-9

11. Jamshidi N, Abbaszadeh A, Kalyani MN, Sharif F. *Effectiveness of video information on coronary angiography patients' outcome*. Collegian. 2013; 20:153-159

12. Krupat E, Francey M, Cleary PD. *Information and its impact on satisfaction among surgical patients*. Soc Sci Med. 2000; 51:1817-1825

13. Lichtman M. 2013*. Qualitative Research in Education. A User's Guide Third Edition*. SAGE publications

14. Loew R, Kreitner KF, Runkel M, Zoellner J, Thelen M. *MR arthrography of the shoulder: comparison of low-field (0,2 T) vs high-field (1.5 T) imaging*. European Radiology. 2000;10(6):989-96.

15. Lukins R, Davan IG, Drummond PD. *A cognitive behavioural approach to preventing anxiety during magnetic resonance imaging*. Journal of Behavioural Therapy Exp Psychiatry. 1997; 28(2): 97-104

16. Mathers S, Chesson R, McKenzie G. *The information needs of people attending for computed tomography (CT): what are they and how can they be met?* Patient Education and Counselling. 2009; 77:272-278

17. McNulty JP, McNulty S. *Acoustic noise in magnetic resonance imaging. An ongoing issue*. Radiography 2009;15(4): 320-6

18. Michel SCA, Rake A, Gotzmann L et al. *Pelvimetry and patient acceptability compared between open 0.5T and closed 1.5T MR systems*. European Radiology. 2002; 12(12): 2898-905

19. Papa L, Seaberg D, Rees E, Ferguson K, Stair R, Goldfeder B, Meurer D. *Does a waiting room video about what to expect during an emergency department visit improve patient satisfaction*. CJEM. 2008; 10(4): 347-354

20. Quirk M, Letendre A, Ciottone R, Lingley J. *Anxiety in patients undergoing MR imaging. Radiology*. 1989; 170(2): 463-6

21. Rosenberg DR, Sweeney JA, Gillien JS et al. *Magnetic resonance imaging of children without sedation, preparation with simulation.* Journal of the American Academy of Child and Adolescent Psychiatry. 1997; 36(6): 853-9

22. Schofield P, Jefford M, Carey M, Thomson K, Evans M, Baravelli C, Aranda S. *Preparing patients for threatening medical treatments: effects of a chemotherapy educational DVD on anxiety, unmet needs, and self-efficacy.* Support Care Cancer. 2008; 16(1): 37-45

23. Selim MA. *Effect of pre-instruction on anxiety levels of patients undergoing magnetic resonance imaging examination.* Eastern Mediterranean Health Journal. 2001; 7(3): 519-525

24. Sorlie T, Busund R, Sexton J, Sexton H, Sorlie D. *Video information combined with individualized information sessions: effect upon emotional well-being following coronary artery bypass surgery – a randomised trial.* Patient Education and Counselling. 2007; 65:180-188

25. Spouse E, Gedroyc W. *MRI of the claustrophobic patient: interventionally configured magnets.* British Journal of Radiology. 2000; 73: 146-53

26. Tornqvist E, Mansson A, Larsson EM, Hallstrom I. *Impact of extended written information on patient anxiety and image motion artefacts during magnetic resonance imaging*. Acta Radiologica. 2006; 5: 474-480

27. Youssefzadeh S, Eibenberger K, Helbich T, Dorffner R, Dantendorfer K, Breitenseher M. *Reduction of adverse events in MRI of the breast by personal patient care.* Clinical Radiology. 1997; 52: 862-864