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Effects of an information booklet on patient anxiety and satisfaction with information in magnetic resonance imaging: A randomized, single-blind, placebo-controlled trial

A. Bolejko [a, *], P. Hagell [b]

[a] Department of Translational Medicine, Department of Medical Imaging and Physiology, Lund University, Skåne University Hospital, Carl Bertil Laurells gata 9, 205 02, Malmö, Sweden
[b] The PRO-CARE Group, Faculty of Health Sciences, Kristianstad University, Elmetorpsvägen 15, 291 88, Kristianstad, Sweden

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ABSTRACT

Introduction: Magnetic resonance imaging (MRI) is an important modality in diagnostics and treatment follow-up. However, MRI can be perceived as unpleasant even though the examination is non-invasive. Patients' knowledge of the MRI procedure is usually scarce, which may enhance patient anxiety at examination. We investigated the effects on anxiety and satisfaction with an information booklet on MRI compared to a placebo booklet delivered to adult patients prior to their first MRI examination.
Methods: This randomized, single-blind, placebo-controlled trial included 197 patients. The intervention group (n = 95) received a booklet about MRI prior to the examination, whereas the control group (n = 102) received a placebo booklet of the same size and layout but containing general information. The State Trait Anxiety Inventory with supplementary questions from the Quality from the Patient's Perspective questionnaire were used as patient-reported outcome measures.
Results: Anxiety did not differ between the groups, either prior to MRI or during the examination, but those who received the placebo booklet were at higher risk of experiencing high anxiety prior to the MRI examination (odds ratio 2.64; P = 0.029). The intervention group was more satisfied with the information received (P = 0.044), and a majority of participants in both groups (≥87%) considered it important to obtain information on the MRI procedure.
Conclusion: Written MRI information decreases the risk of high anxiety levels before MRI and improves patient satisfaction with the information. Further research is needed to investigate whether written information prior to MRI is beneficial not only from the perspective of the patient but may also be cost-effective.
Implications for practice: Written MRI information prior to the examination is recommended in radiography care.
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Introduction

Magnetic resonance imaging (MRI) is an important examination in diagnostics and treatment follow-up. Although non-invasive, MRI may be perceived as unpleasant and stressful.[1] Experiences of fear and loss of self-control have been described,[2,3] and 14% of patients experience severe anxiety during MRI.[4] Various measures to alleviate patient discomfort have been investigated,[5] including premedication,[6] relaxation,[7–9] hypnosis,[10] extensive oral information and counselling,[9,11] video demonstration of the procedure, phone contact, or visit prior to the examination.[12–14] Most of these interventions are time-consuming and complicated to provide in clinical practice. The aim of this randomized, single-blind, placebo-controlled trial was to investigate the effects of an information booklet on patient anxiety and satisfaction with information during MRI.

* Corresponding author.
E-mail addresses: anetta.bolejko@med.lu.se (A. Bolejko), peter.hagell@hkr.se (P. Hagell).

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Literature review

Lack of information can worsen anxiety during MRI.[15,16] Patients' knowledge of MRI is usually scarce, and the source of information is often relatives.[17] Thus, written information on MRI is needed and welcomed by patients,[1,18] and an informational booklet would be a simple means to ameliorate MRI distress. Written patient information should contain several types of information, including procedural (how the examination is carried out), behavioral (how the patient can cooperate), and sensory (what the patient may experience).[19] However, evidence of the potential effects of an information booklet prior to MRI is scarce. One non-randomized study used written information in combination with other measures[12] and found reduced anxiety levels during MRI. Another non-randomized study failed to demonstrate any differences in anxiety or satisfaction with the information between groups receiving standard care information or extended written information, though motion artefacts in the MRI images were fewer in the latter group.[20]

Methods

The study was conducted in accordance with the Declaration of Helsinki and was reviewed by the local ethics advisory committee (VEN A1104). All participants provided informed consent.

Sample

Study participants were recruited consecutively over 18 months at the Department of Diagnostic Imaging and Physiology, University Hospital in Malmö, Sweden. The department has four MRI modalities and performs approximately 5000 outpatient MRIs each year. The inclusion criteria were outpatients aged 18–70 years who were to undergo MRI using a non-open camera Siemens Symphony 1.5 T. Inpatients, patients who previously underwent MRI, those who were to undergo MRI under anesthesia, patients with cognitive impairment, and those who did not speak Swedish were excluded from the study. The study participants were randomized to either intervention or control using simple randomization (Fig. 1).[21]

The sample size was estimated a priori based on previous study results using the State Trait Anxiety Inventory (STAI). The STAI has been used in a variety of areas, including the assessment of anxiety at the time of MRI.[11,12,14,20,22] Based on these previous results, mean pre-scan anxiety scores in the intervention and control groups were estimated to be 37 and 41, respectively, and scores after MRI were estimated to be 32 and 37, respectively, with a common SD of 10. Based on these parameters, which gave effect sizes of 0.4 and 0.5, respectively, approximately 99 and 64 individuals were required in each group for 80% power at a two-tailed alpha level of 0.05.[23]

Intervention

The intervention consisted of an information booklet on MRI that was developed based on our previous study results.[18] The booklet contained an extensive explanation of how an MRI examination is conducted (procedure information), a detailed description of what might be expected by the patient in connection to the MRI procedure (behavior information), and examples of potential reactions and experiences in connection with MRI (sensory information).[18]

The placebo intervention consisted of an information booklet of the same size and layout as the intervention booklet, but only containing information about the department and no information about MRI.

In addition to the booklets, both groups received standard care from the same MRI staff. This consisted of an MRI safety check-up and short oral information (duration of the examination, the need to lie still, and that a loud noise would be heard when images are taken). Ear protection was utilized and patients were offered the ability to listen to music. Everyone received a buzzer to call on the staff if needed. Relatives were welcomed in the examination room but had no opportunity to communicate with the patient.

Instruments and other study data

Anxiety was assessed using the STAI, which consists of two parts: STAI FORM Y-2 T and STAI FORM Y-1 S.[24] STAI FORM Y-2 T ("trait anxiety") assesses the individual's general tendency to experience stressful situations as worrying, and STAI FORM Y-1 S ("state anxiety") assesses current anxiety levels.[24] STAI FORM Y-1 S is available in two different designs; one is worded in present tense and intends to assess the respondent's anxiety right now, and the other is worded in past tense and intends to assess recently perceived anxiety. These STAI forms are hereafter referred to as STAI-T (trait anxiety), and STAI-SB and STAI-SA (state anxiety before and immediately after MRI, respectively). STAI-SA assessed the anxiety experienced during the MRI procedure. The forms consisted of 20 items each with four ordered response categories scored 1–4, yielding total scores between 20 (less anxiety) and 80 (more anxiety). A total score $\geq$40 is considered to indicate a high level of anxiety.[12,20] In cases of $\leq$10% missing responses, scores were imputed by averaging scores across available responses.[24]

There is general support for the validity and reliability of scores on the STAI forms,[25] and the present study used the Swedish version.[26] Cronbach's coefficient alpha in the control and intervention groups was 0.94 and 0.92 for STAI-T, 0.93 and 0.94 for STAI-SB, and 0.94 and 0.93 for STAI-SA, respectively.

Satisfaction with the information about MRI was assessed by three single items. The first item concerned the agreement between the patient's expectations of MRI and the actual experience. The two other items were adapted from the Quality from the Patient's Perspective questionnaire for mammography[27] and concerned whether the information made them understand what was going to happen and how important the patient considered the information. All items had four ordered response categories scored 1–4, with 4 representing a higher degree of satisfaction.

In addition, whether sedatives were taken prior to MRI, relatives were present in the examination room, and the patient listened to music during MRI were recorded. Other data included age, gender, duration of the examination, scanned body part, whether the patient called or visited the MRI department before the examination, whether the patient aborted the examination, and medical history (classified as malignant or other disease) at referral.

Data collection

An invitation to participate and information about the study were included with the call letter for MRI. Those randomized to the intervention group received the MRI information booklet and the control group received the placebo booklet. Patients were asked to sign and return a written informed consent form together with the STAI-T.

The staff at the MRI unit were informed of the study but were blinded regarding which group to which the patients were randomized. Prior to MRI, participants were asked to complete the STAI-SB and seal it in an envelope before being provided standard care. Immediately after the examination, the patients were asked to complete the STAI-SA as well as the satisfaction questions, which

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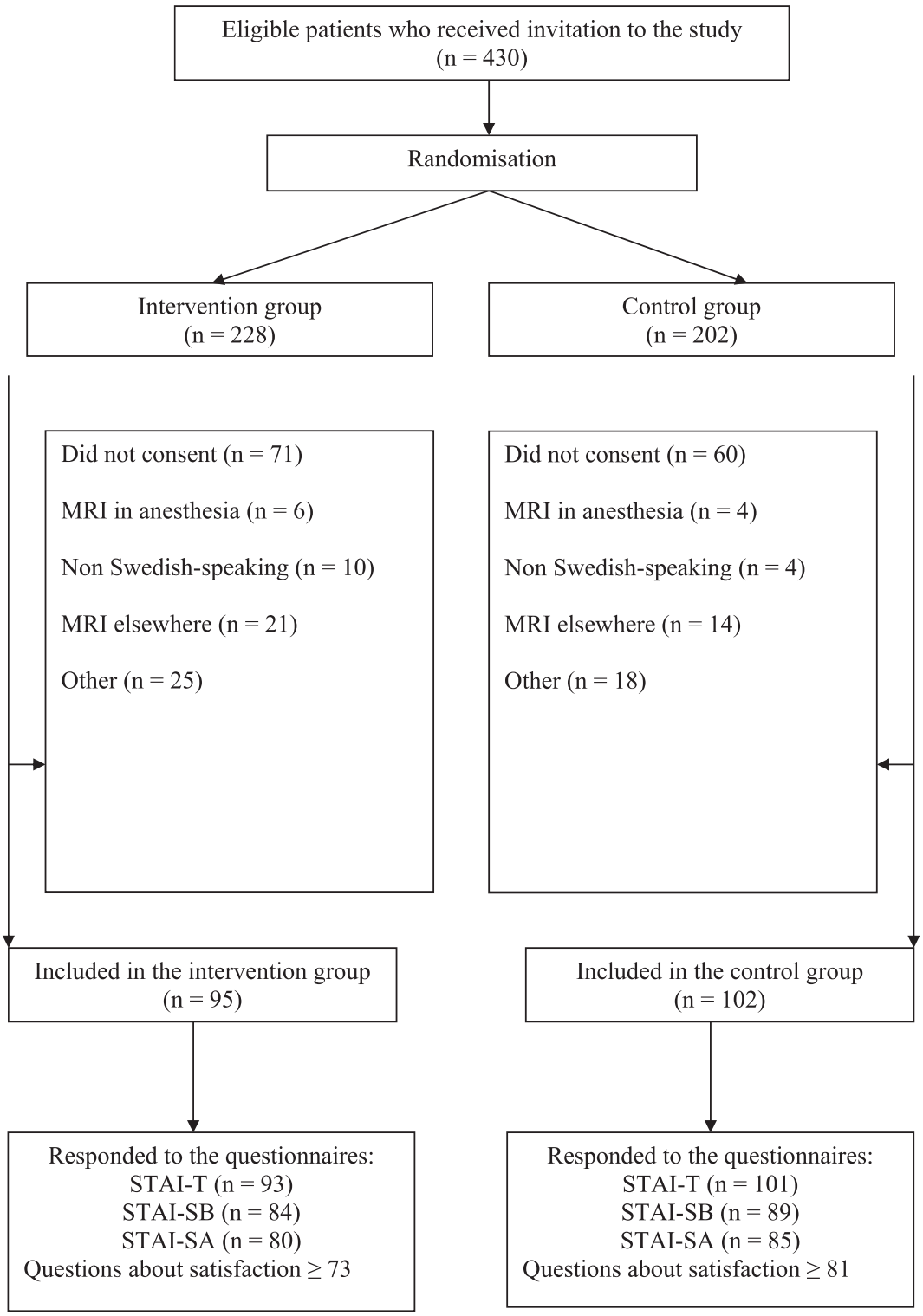

Figure 1. Flow chart of the study sample.MRI, magnetic resonance imaging; STAI, State Trait Anxiety Inventory; STAI-T, trait anxiety; STAI-SB, state anxiety before scanning; STAI-SA, state anxiety during scanning.

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were also returned in sealed envelopes. Patients who aborted the examination were also asked to answer the questionnaires.

Data analysis

Data were analyzed using IBM SPSS Statistics 25 with a two-tailed significance level of $P < 0.05$. Demographic data, use of sedatives, the presence of relatives, whether the patients listened to music, STAI-T scores, and other baseline data were analyzed using chi-squared/Fisher's exact tests, Mann–Whitney U-tests, and independent t-tests as appropriate. Mann–Whitney U and Wilcoxon signed-rank tests were used for between and within group comparisons of the STAI-SB and STAI-SA scores, and Mann–Whitney U-test was used to compare satisfaction scores.

The proportion of patients with STAI-SB and STAI-SA total scores ≥40 was compared between the intervention and control groups using chi-squared tests. To examine whether the intervention booklet was associated with a lower risk of high anxiety immediately before and during MRI, a multivariate logistic regression was performed using dichotomized STAI-SB and STAI-SA total scores (<40 = 0; ≥40 = 1) as dependent variables. Group assignment, high trait anxiety (STAI-T ≥40), gender, telephone contact or visiting the MRI department, use of sedatives, presence of relatives, music during the examination, and medical history were entered as independent variables.

Results

The study sample consisted of 109 (55%) women and 88 (45%) men. Other demographic data are presented in Table 1. Five people in the intervention group, but none in the control group, visited the MRI unit prior to their scheduled examination. No other group differences were found regarding sample characteristics, including STAI-T scores.

Anxiety prior to and during MRI

We found no significant difference in anxiety between the intervention and control groups either prior to MRI or during the examination (Table 2). Both groups had significantly lower anxiety during MRI than immediately before the examination. Group comparisons were also conducted excluding the patients in the intervention group who visited the MRI unit prior to the examination. The analysis yielded median [q_1–q_3] STAI-SB (n = 79) and STAI-SA (n = 75) scores of 32 [25–39] and 27 [22–37], respectively, for the intervention group. Compared to the control group, these results gave P-values of 0.231 and 0.421 for STAI-SB and STAI-SA, respectively.

Table 2
State anxiety before and after MRI between and within groups.

	STAI-SB	STAI-SA	P-value[b]
Intervention group	n = 84	n = 80	
median [q_1–q_3]	32.8 [26.0–41.0]	27.5 [22.0–37.5]	0.002
Control group	n = 89	n = 85	
median [q_1–q_3]	35.0 [27.0–42.6]	30.0 [21.0–37.4]	<0.001
P-value[a]	0.437	0.694	

MRI, magnetic resonance imaging; STAI-SB, state anxiety before scanning; STAI-SA, state anxiety during scanning; q_1–q_3, 25th to 75th percentiles.
[a] Mann–Whitney U-test.
[b] Wilcoxon test.

Thirty-three respondents (39%) in the control group and 22 (25%) in the intervention group had a total STAI-SB score ≥40 (P = 0.124; chi-squared test). For STAI-SA, equal numbers of respondents in both groups (n = 17) had a total score ≥40 (P = 0.843; chi-squared test). Logistic regression demonstrated that high trait anxiety (total STAI-T score ≥40), having visited the MRI unit, presence of relatives, and receiving the placebo intervention rather than the MRI information booklet were associated with high levels of pre-scan anxiety (Table 3). High anxiety levels during scanning (STAI-SA scores ≥40) were associated with high trait anxiety and having called the MRI unit prior to the examination (Table 3).

Satisfaction with information

Participants in both groups found pre-scan information to be important (median [q_1–q_3], 4 [3–4] in both groups, P = 0.837; Mann–Whitney U-test). Both groups also considered their expectations of the examination to agree with their experiences (3 [2–4] and 3 [3–4] for the control and intervention groups, respectively, P = 0.253; Mann–Whitney U-test). However, the intervention group was more satisfied with the information they received (4

Table 1
Demographic data and other characteristics of the study groups.

	Intervention group (n = 95)	Control group (n = 102)	P-value
Gender, male/female	43 (45)/52 (55)	45 (44)/57 (56)	0.872[a]
Age (years), mean (SD)	48.7 (12.9)	49.4 (13.0)	0.686[b]
Duration of MRI (minutes), mean (SD)	34.0 (13.1)	34.3 (16.7)	0.857[b]
Aborted MRI	2 (2.1)	4 (3.9)	0.684[c]
Telephone call prior to MRI	13 (13.7)	7 (6.9)	0.113[a]
Visit prior to MRI	5 (5.3)	0 (0)	0.025[c]
Sedatives prior MRI	5 (5.3)	8 (7.8)	0.476[a]
Relatives present in the MRI room	10 (10.5)	13 (12.7)	0.609[a]
Music during MRI	58 (62.1)	63 (61.8)	0.939[a]
Referral diagnosis, malignancy/other	28 (29.5)/67 (70.5)	29 (28.4)/73 (71.6)	0.872[a]
Trait anxiety (STAI-T) median [q_1–q_3]	33 [28–43]	33 [27–44]	0.850[d]
Investigated body par			0.154[c]
Head	38 (40.0)	31 (30.4)	
Thorax/abdomen	25 (26.3)	24 (23.5)	
Spine	16 (16.8)	24 (23.5)	
Upper extremity	4 (4.2)	1 (1.0)	
Lower extremity	12 (12.6)	22 (21.6)	

Data are given as n (%) unless otherwise noted.
[a] Chi-squared test.
[b] T-test.
[c] Fisher's exact test.
[d] Mann–Whitney U-test MRI, magnetic resonance imaging; SD, standard deviation; q_1–q_3, 25th to 75th percentiles.

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Table 3
Multivariate logistic model[a] of predictors of high anxiety levels (≥40) prior to and during MRI examination.

Anxiety[b]	Significant predictors[c]	B (SE)	P-value	Odds ratio (95% CI)
STAI-SB	High trait anxiety (STAI-T)	2.36 (0.44)	<0.001	10.64 (4.45, 25.40)
	Visit prior to MRI	3.44 (1.28)	0.007	31.06 (2.55, 378.88)
	Relatives present in the MRI room	1.46 (0.59)	0.013	4.31 (1.36, 13.69)
	Placebo intervention	0.97 (0.45)	0.029	2.64 (1.10, 6.33)
STAI-SA	High trait anxiety (STAI-T)	1.26 (0.42)	0.003	3.54 (1.55, 8.05)
	Telephone call prior to MRI	1.27 (0.42)	0.023	3.57 (1.19, 10.70)

STAI-SB: Hosmer–Lemeshow goodness-of-fit test, P = 0.601; Nagelkerke's pseudo R-square, 0.399; STAI-SA: Hosmer–Lemeshow goodness-of-fit test, P = 0.371; Nagelkerke's pseudo R-square, 0.149.
B, regression coefficient; SE, standard error; CI, confidence interval; MRI, magnetic resonance imaging; STAI-SB, state anxiety before scanning; STAI-SA, state anxiety during scanning.
[a] Forward stepwise (likelihood-ratio) multivariate logistic regression.
[b] Dichotomized total score according to the cut-off value (<40 = 0; ≥40 = 1).
[c] Independent variables entered into the model: gender (man = 0, woman = 1), visit prior to MRI (no = 0, yes = 1), telephone call prior to MRI (no = 0, yes = 1), sedatives prior to MRI (no = 0, yes = 1), relatives present in the MRI room (no = 0, yes = 1), music during MRI (no = 0, yes = 1), referral diagnosis (malignancy = 1, other disease = 0), high trait anxiety (STAI-T total score <40 = 0, STAI-T total score ≥40 = 1), group affiliation (intervention group = 0, control group = 1). Independent variables that are not presented in the table were not significantly associated with high anxiety levels.

[4–4]) than the control group (4 [3–4], P = 0.044; Mann–Whitney U-test).

Discussion

In this randomized, single-blind, placebo-controlled trial, we investigated the effects of an information booklet about MRI on anxiety and satisfaction among adult outpatients undergoing their first MRI examination. We found no differences in anxiety between the intervention and control groups before or during MRI, but patients who received the placebo booklet had a significantly higher risk of experiencing severe anxiety immediately prior to MRI. The results also revealed that the information is considered important, and that those who received MRI-specific written information before their examination were more satisfied than those who received general information.

The effects of written patient information on elevated patient anxiety associated with MRI have been investigated previously.[12,20] One study found significantly decreased anxiety during MRI among patients who received an information booklet compared to those who did not.[12] However, the written information was supplemented by counselling, which makes it uncertain as to what extent the outcomes can be attributed to the written information *per se*. Another study failed to demonstrate any reduction in MRI-associated anxiety from provision of an information booklet alone.[20] This may have been due to providing written MRI information to both study groups and only supplemental information to the experimental group. However, our study demonstrated that those who received the placebo booklet had a higher risk of experiencing high anxiety before the MRI than those who received MRI-specific information. This association was independent and beyond that of high baseline anxiety levels, pre-scan visits, and the presence of relatives during MRI. Furthermore, factors such as cause of referral, use of sedatives, and gender, which all have been found to be associated with MRI anxiety in previous studies,[6,14,20] did not contribute to high anxiety levels once the written information was taken into account. These findings are strengthened by the randomized placebo-controlled design, which differs from previous quasi-experimental studies of the effects of written information on MRI-associated anxiety.[12,20] To the best of our knowledge, our study is the only randomized controlled trial on the effects of written information alone during MRI and demonstrates that such an intervention can reduce MRI-associated anxiety.

Perceived anxiety prior to and during the examination was significantly different for both groups. This may be due to a feeling of relief after the examination. Although STAI-SA intended to assess anxiety during the examination, it cannot be ruled out that responses may have been influenced by perceptions at the time when the inventory was answered. Furthermore, oral information and care may also have had an anxiety-reducing effect.[2,3,28] For example, support from staff has a significant impact on patients' experiences with MRI, and the staff/patient interaction may facilitate self-control and coping during the examination.[2]

The intervention group was more satisfied with the information than the control group, which is contradictory to previous results in MRI.[20] This could be explained by our study providing a booklet that was developed from interactions with people who had undergone MRI,[18] which probably enhances the relevance and comprehension of the information.

A strength of our study was the use of a placebo booklet. Nevertheless, there is also a risk to using placebo considering that the attention provided by the placebo booklet may have affected the patients' experiences with MRI even though it did not include any information about the examination. However, these effects have been argued to be negligible in patient education interventions applied over a short period of time.[29] Indeed, the Nordic Cochrane Centre concluded that, in general, there is no evidence that placebo interventions have a clinical effect, with the exception of a possible influence on experiences of pain and nausea.[30] In addition, the placebo booklet was used because we wanted to study effects of the written MRI information beyond any general effects of receiving any kind of written information. An alternative would have been to conduct a study in which patients were randomized to any of three study arms: written MRI information and standard care (our intervention group), written non-MRI specific information and standard care (our placebo group), or standard care only. However, we considered placebo to be more appropriate than a standard care only group, as the latter would raise the question as to whether any effects were due to the specific MRI information or to the mere fact that participants received the extra attention associated with providing any written pre-scan information.[31] Thus, to control for the potential "general information effect", we used the placebo booklet approach.

As with any intervention study, it is relevant to consider whether the observed outcome is clinically relevant. In this study, the independent effect of not receiving the written MRI information on high pre-scan anxiety levels was associated with an OR of 2.64, suggesting that the effect can be considered clinically meaningful.[32] However, other variables were associated with greater effect sizes (e.g., pre-scan visits and high trait anxiety), but the effect of not receiving written MRI information is seen after

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controlling for other co-variates, which favors a clinically meaningful outcome.

One aspect that should always be considered in relation to any intervention is its cost-effectiveness (i.e., whether the additional cost associated with printing and distributing an MRI information booklet is compensated by its effects). To the best of our knowledge, no such evidence is available regarding written information prior to MRI. However, it appears reasonable to consider the relatively small costs acceptable in view of the results presented here, particularly as previous studies have suggested that this type of intervention may also reduce motion artefacts.[20,33] Nevertheless, future studies should consider cost-effectiveness in addition to motion artefacts and MRI-associated anxiety and well-being.[34]

Conclusion

This randomized, placebo-controlled, single-blind trial examined the effects of written information given to adults undergoing their first MRI. The results showed that such information reduces the risk of experiencing high anxiety prior to the procedure. In addition, patients find it important to receive information before the examination, and satisfaction is increased with the MRI-specific information compared to general information.

Author contribution

Both authors have contributed to the study, were involved in writing the paper, and approved the submitted version of the manuscript.

Conflicts of interest statement

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.radi.2020.07.011.

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