

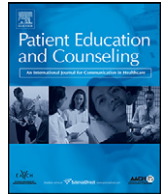
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## Review

## The reassuring value of diagnostic tests: A systematic review

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## ABSTRACT

**Objective:** This review is a narrative synthesis of the RCTs which studied the efficacy of using diagnostic tests to reassure patients.

**Methods:** We searched for RCTs that examined the level of reassurance after diagnostic testing in outpatients. We used PubMed, Psychinfo, Cochrane Central, Ongoing Trials Database and Scopus.

**Results:** We found 5 randomized controlled trials that included 1544 patients. The trials used different diagnostic tests (ECG, radiography of lumbar spine, MR brain scan, laboratory tests, MR of lumbar spine) for different complaints (e.g. chest pain, low back pain and headache). Four out of 5 RCTs did not find a significant reassuring value of the diagnostic tests. One study reported a reassuring effect at 3 months which had disappeared after one year.

**Conclusion:** Despite the sparse and heterogeneous studies, the results point in the direction of diagnostic tests making hardly any contribution to the level of reassurance. We recommend further studies on the use of diagnostic tests and other strategies to reassure the patient.

**Practice implications:** A clear explanation and watchful waiting can make additional diagnostic testing unnecessary. If diagnostic tests are used, it is important to provide adequate pre-test information about normal test results.

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## 1. Introduction

According to the Oxford Dictionary of English, reassurance is 'the action of removing someone's doubts or fears'. Providing reassurance is one of the most important tasks of GPs [1]. Patients often fear that something serious is wrong and expect to be reassured by their physician [2]. Physicians have several strategies for reassuring their patients: paying sincere attention by listening well, explaining medical terminology in comprehensible language and 'laying hands' during physical examination [3]. Another way of reassuring the patient is making use of diagnostic tests.

The use of diagnostic tests for reassurance of the patient is considerable in family practice. In a Dutch cohort study in primary care ( $n = 31,000$ ) the reasons for requesting diagnostic tests were recorded over a one year period. Of all requested diagnostic tests, reassurance of the patient was the fourth reason for ordering tests, in 11% of the requests it was the main reason for testing [4]. This percentage might be lower than in other countries, regarding the fact that Dutch family practitioners are not paid for ordering tests.

Despite the apparent confidence of physicians in the reassuring value of diagnostic tests, the effects remain doubtful. For example, in 40 replicated single case studies McDonald et al. [5] examined whether normal test results reduce patients' fears. Patients were referred for echocardiography, in 10 cases because of symptoms and in 30 cases because of a heart murmur. All but one had normal test results. The patients presenting with symptoms were all left with worries despite a normal test result. Of the patients with a heart murmur, 20 became anxious after the detection of the murmur; 11 had residual worries despite the normal test result. Thus, negative test results are not always effective in reassuring patients.

We performed a systematic review of randomized controlled trials assessing the reassuring value of diagnostic tests, both in primary care and outpatient secondary care settings. As there is no generally accepted instrument to measure the level of reassurance, we accepted different instruments for the measurement of reassurance. We included various diagnostic tests, therefore we did not expect that we would be able to perform a meta-analysis. Our goal was to give a narrative synthesis of the current evidence. The effect of diagnostic tests on the level of reassurance is our primary outcome. Furthermore, we assessed whether diagnostic testing influenced symptom and disability levels and patient satisfaction.

## 2. Methods

### 2.1. Selection criteria

In October 2009 we systematically searched for RCTs assessing the reassuring properties of diagnostic tests. Our inclusion criteria were: (1) type of study: RCT, (2) any diagnostic test, (3) subjects: outpatients, (4) control condition: patients not receiving results of a diagnostic test, and (5) outcome: level of reassurance.

### 2.2. Search methods

We searched in PubMed, Psycinfo, Cochrane Central, Ongoing trials database and Scopus, which includes the Embase database. For Pubmed, our search consisted of three parts, combined with the Boolean operator AND: the text word 'reassur\*', the string 'Diagnostic Techniques and Procedures' or 'Laboratory Techniques and Procedures' (MeSH terms) and an established search string for controlled trials (5). Repeating this search with other words ('consola\*', 'relie\*', 'comfor\*', and 'alleviat\*') instead of reassur\* did not reveal additional publications. We adapted the searches for the other databases as required. There was no language restriction.

### 2.3. Data collection

Three investigators (DD, PL, and HvR) independently included publications from the list of retrieved publications by reading title and abstract. When title and abstract did not reveal sufficient information for inclusion, the investigators read the whole publication. After inclusion we checked the references for additional publications. Subsequently, three investigators (DD, HvR, and IvD) extracted and registered the data on standard forms. Disagreements about in- or exclusion or data extraction were resolved by consulting a fourth investigator (FvdL). Inter-investigator agreement on in- and exclusion was calculated as kappa; we considered kappa 0.6–0.8 as good, and kappa 0.8–1.0 as excellent agreement [6]. Our primary outcome measure is the level of reassurance. Secondary outcome measures are symptom levels, disability levels and patient satisfaction.

### 2.4. Data analysis

Outcomes are described per study. We assessed whether there was a difference in the level of reassurance between the test group and the control group. For the evaluation of the risk of bias we (HvR, PL, and IvD) assessed the randomization procedure, allocation concealment, the drop-out rate and blinding of the outcome assessor. Two reviewers assessed each trial independently. Patient and physician blinding was not a part of the assessment, because in this type of studies blinding is practically impossible.

## 3. Results

The searches yielded 4602 different publications to be judged for in- and exclusion. We included 6 journal articles that described 4 different randomized controlled trials [7–12]. The kappa for in- and exclusion was 0.80 (CI 0.77–0.83). One additional study resulted from checking references [13]. In sum, we present the results of 5 RCTs of in total 7 articles on the reassuring effect of diagnostic tests (Fig. 1). In Table 1 study details are provided. The trials were published between 1981 and 2009.

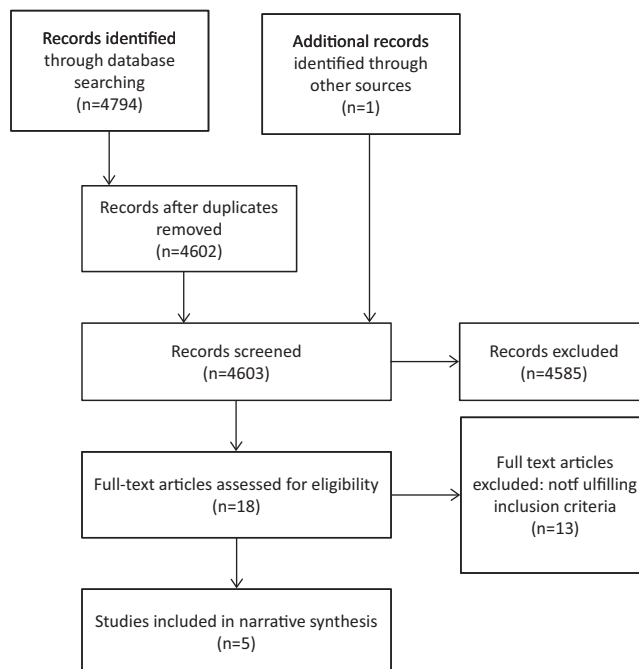


Fig. 1. Flowchart of study inclusion.

**Table 1**  
Characteristics of RCT's which measure the reassuring value of diagnostic tests.

Source	Type of complaint	Inclusion criteria	Diagnostic test group	Control group	Setting	Patients intervention/control (n=)	Measure for reassurance	Baseline level of reassurance or worry	Follow up level of reassurance or worry	Direction of effects
Sox et al. [13]	Chest pain	Chief symptom is chest pain, with low risk of having ischemic pain	ECG and laboratory tests	Care as usual	Outpatient clinic	74/72	5-Point scale: worry that the pain was due to serious disease	67% of patients in the test group and 70% of patients in the control group worried	20% of patients in both groups worried (2 months); 16% of patients receiving tests and 22% in the control group worried (4 months)	No significant difference between groups at 2 and 4 months ( $p > 0.02$ )
Miller et al. [7]	Low back pain	Pain for at least 6 weeks, or at randomization and >6 weeks in past 6 months	Radiography of lumbar spine	Care as usual	Primary care practices	195/199	5-Point scale: reassurance that there is no serious condition causing the pain	44% of patients in the test group and 47% of patients in the control group felt reassured	58% of patients in the test group were reassured, 48% of patients in the control group were reassured	No significant difference between groups at 9 months ( $p = 0.37$ )
Howard et al. [10]	Headache	Headache at least 15 days a month for >6 months	MRI brain scan	Care as usual	Outpatient clinic	71/71	VAS: level of worry about health + 5-point scale: something seriously wrong causing the pain (0–100 maximal worry)	Mean score on VAS in test group 60 (SD 32) and in control group 69 (SD 25); no information available about scores on 5-point scale	Mean score on VAS 43 in both groups at one year; on 5-point scale: patients in test group less worried about serious cause at 3 months (no exact data), no difference at 1 year	Significant difference at 3 months, patients in test group have less fear for something serious ( $p = 0.004$ ); no significant difference at one year in 5-point scale, nor in VAS scores
Ash et al. [11]	Low back pain and/or radiculopathy	Low back pain and/or radiculopathy for <3 weeks; age 18–65 years	MRI of lumbar spine	MRI of lumbar spine, patient and physician blinded to results until 6 months after scan	Primary care and secondary care (with outpatients)	115/131	Fear avoidance questionnaire <sup>24</sup> : 4 items on beliefs about physical activity (0–24 maximal avoidance)	Mean score in test group 17.0 (SD 5.8) and in control group 17.4 (SD 5.5)	Mean score in test group 13.8 (SD 6.4) and in control group 13.4 (SD 6.3) at 6 weeks; mean score in test group 13.3 (SD 7.0) and in control group 13.9 (SD 6.5) at one year	No significant differences between groups at 6 weeks ( $p = 0.70$ ), nor at 1 year ( $p = 0.59$ )
van Bokhoven et al. [12]	Fatigue, abdominal complaints, musculoskeletal complaints, weight change, or pruritus	Complaint remained unexplained after history taking and physical examination; blood test might add to the diagnosis; age 18 years or older	Laboratory blood tests	Watchful waiting (with or without quality improvement education)	Primary care practices	229/269	10-point scale: level of anxiety (0–10) maximal anxiety	No baseline measures were taken	Mean score in test group 3.1 (SD 2.5), mean score in control group 3.0 (SD 2.8)	No significant difference between groups after the consultation

**Table 2**  
Quality assessment of RCT's on the reassuring value of diagnostic tests.

Study	Adequate randomization	Adequate allocation concealment	Adequate drop out handling: description of drop outs and dropout rate (<15%)	Blinding during outcome assessment
Sox et al. (1981)	No: procedure not mentioned	No: not mentioned	No: insufficient description and drop out 16%	Not mentioned
Miller et al. (2002)	Yes: computer generated scheme	Yes: sealed opaque envelope	No: clear description, but total dropout rate 77% (at reassurance level measurement)	No: outcome assessor was not blinded for the intervention
Howard et al. (2005)	Yes: computer generated scheme	Yes: sealed envelope	No: clear description, but dropout rate 36%	Yes: outcome assessor was blind to intervention
Ash et al. (2008)	Yes: stratified block design	Yes: concealed envelope	No: insufficient description and dropout rate at 3 months 28%	Not mentioned
van Bokhoven et al. (2009)	Yes: computer generated list	Not applicable, practices were randomized as a whole	Yes: clear description and total dropout rate 3%	No: outcome assessor was not blinded for the intervention

The included trials measured the reassuring effect of five different diagnostic tests, or combinations of tests: ECG and laboratory blood tests for chest pain, radiography of the lumbar spine for low back pain, MR brain scan for headache, laboratory blood tests for 5 specified unexplained complaints and one trial studied the reassuring effects of MR for low back pain. Most trials compared the reassuring effects of a diagnostic test with a control group without diagnostic tests [7,10,12,13]. In the study by Ash et al. [11] all patients were provided with a diagnostic test, both patients in the intervention group and in the control group received an MR scan. However, the patients and physicians in the control group did not receive the results of the MR scan until six months after the scan. The total number of patients that have been studied in the included trials is 1544. Two trials have been performed in the United States of America [11,13], two trials in the United Kingdom [7,10] and one trial in the Netherlands [12]. Three trials use a similar definition of reassurance: taking away the concern that something serious is wrong [7,10,13]. Ash et al. and van Bokhoven et al. defined reassurance by the absence of anxiety. They asked for the current anxiety level [12] and the anxiety level concerning the current and future physical situation [11].

Quality assessment details are provided in Table 2. Four out of five studies had adequate randomization and allocation concealment procedures. In the study by Sox et al. the procedures are not mentioned. All studies, except for the study by van Bokhoven et al., have high dropout rates: between 16 and 77%. Blinding during outcome assessment was described in only one trial, the trial by Howard et al.

### 3.1. Reassurance levels

None of the trials found a significant difference in reassurance levels between intervention and control group at the end of the follow up. One trial, the study by Howard et al., did find a significantly higher reassurance level in the intervention group at 3 months ( $p = 0.004$ ), but not at 12 months. Trials which measured the level of reassurance (or worry) both at baseline and at follow up, all show that with the passing time the level of worry decreases [7,10,11,13]

### 3.2. Symptom levels

Symptom levels have been measured in four trials [7,10,11,13]. Two trials did not find a significant difference in symptom levels between the intervention and control group [11,13]. One study shows that 3 months after randomization the percentage of patients that still experienced back pain was higher in the radiography group than in the control group, 74% versus 65% ( $p = 0.04$ ). At nine months there was no significant

difference between intervention and control group [7]. In another trial the subgroup of patients with high scores on anxiety and depression at baseline had significantly less headaches after receiving an MR scan, than the patients who had not received an MR scan at one year follow up. Patients without anxiety and depression at baseline did not show a difference in symptom levels between intervention and control condition [7,10,11,13].

### 3.3. Disability levels

In three trials the disability levels have been measured [7,11,13]. The study by Ash et al. measured self-rated disability due to back pain, no significant differences between the groups were found. Another trial found a significant difference in disability levels at three months follow-up; patients that were assigned to diagnostic testing, reported higher disability scores compared to the control group [7]. However, there was no significant difference at the end of follow up, at 9 months. The only study which found lower disability levels in the intervention group is the study by Sox et al. Disability was measured by asking whether the activity level was unchanged or less than at the index visit. At 3 weeks follow up 46% of the control group reported disability, whereas in the intervention group 20% of the patients reported disability ( $p < 0.01$ ). At four months follow up the difference had disappeared.

### 3.4. Patient satisfaction

Patient satisfaction was measured in three trials [7,12,13]. One did not find any difference between the groups [12]. In the trial by Miller et al. at nine months follow up the patients who received a radiography were more satisfied with care than the controls ( $p < 0.01$ ). Sox et al. found a short term difference: at 3 weeks follow up 57% of the patients in the intervention group were satisfied with care versus 31% in the control group ( $p < 0.0001$ ). At 4 months there was no difference between the groups.

## 4. Discussion and conclusion

Although the use of diagnostic tests to reassure patients is common [4], we identified only five randomized controlled trials which could be included in our systematic review. None of these trials found a significant difference in reassurance levels between intervention and control group at the end of the follow up. We did find an increase in reassurance over time, but this was irrespective of whether participants had the diagnostic test (intervention group) or not (control group).

## 4.1. Strengths and limitations

### 4.1.1. Strengths

Our extensive and thorough search in all relevant databases without language restriction and the selection of studies by two independent researchers make it unlikely that we missed relevant studies. Moreover, we had excellent interrater agreement ( $\kappa$  0.80) for in- and exclusion. Finally, two independent researchers extracted the data and assessed the quality of included studies with a validated checklist. In scientific literature the concept 'reassurance' has not yet been clearly articulated, therefore we used the definition of the Oxford dictionary of English. Our conceptualization of 'reassurance' as 'the action of removing someone's doubts or fears' was similar to the definitions which were used in the included RCT's.

### 4.1.2. Limitations

The small number of trials and the relatively low methodological quality of the included trials do not permit us to draw firm conclusions about the reassuring value of diagnostic tests. We found a high heterogeneity of instruments used to measure reassurance levels. Moreover, most trials used non-validated questionnaires. Due to the diversity among the measurement instruments, the diversity among medical conditions in the trials and the consequent diversity in diagnostic tests, we cannot make any statement about the reassuring properties of a specific diagnostic test. For the same reasons we could not perform a meta-analysis.

## 4.2. Considerations for clinical practice

There is a widely shared belief in clinical practice that patients will be reassured after additional testing. Physicians might heavily rely on the supposed reassuring effect of a normal test result, whereas patients might not share the implications of this. In this review we could not confirm this supposed reassuring effect of diagnostic testing. On the contrary, the application of diagnostic testing could also increase worrying as it might unintentionally confirm the patient's conviction that the symptoms are serious [14,15]. For example, in a qualitative study by Donovan and Blake [16] the investigators concluded that the typical methods of providing reassurance – allaying fears and anxieties by emphasizing the minor seriousness or early stage of a disease – are not necessarily interpreted as reassuring by patients. For patients who previously did not worry about their health ordering a diagnostic test can be a cause of anxiety itself [5]. However, we did not find an increase of worrying after diagnostic testing in our systematic review.

The diagnostic tests in the trials in this review have been targeted to the medical conditions to be studied and not to associated individual fears and worries. Concerning the quality and amount of information given by the physician before ordering the test, Petrie et al. found out that patients who received good pre-test information were significantly more likely to be reassured after the test than patients who did not receive this information [17]. It is not difficult to imagine that a good doctor–patient relationship increases the sense of reassurance of the patient: the patient finds a good listener, a person who gives a clear explanation and who is committed to caring over time [18]. van Bokhoven et al. [12] found that reassurance and patient satisfaction had a stronger association with the quality of the doctor–patient relationship in general, than with ordering of diagnostic tests. The reassuring value of diagnostic testing depends on how well the diagnostic test matches with disclosed worries and fears of the patient, on the information provided by the physician about the consequences of a positive or negative test result, and on the quality of the doctor–

patient relationship. Therefore, no firm conclusions about a reassuring value of diagnostic testing can be made when the individual fears, the pre-test information and the doctor–patient relation are not taken into account. Future research about the reassuring value of diagnostic testing should deal with these factors.

## 4.3. Conclusion

There is a lack of sound methodological studies about the reassuring value of diagnostic tests. More trials are needed to judge the efficacy of specific diagnostic tests in providing reassurance. It would be wise to use validated questionnaires for the measurement of reassurance. There is very limited evidence for the assumption that diagnostic tests intrinsically reassure patients.

## 4.4. Practice implications

In clinical practice we advise an early exploration of the patient's fears. By making them explicit, they can be discussed and an explanation about the symptom can be given. Watchful waiting can sometimes make diagnostic testing unnecessary. If diagnostic tests are used, it is important to provide adequate pre-test information about normal test results. Diagnostic tests are easily available and might seem to be a good instrument to reassure patients, but this review shows that the reassuring effect of diagnostic tests is limited.

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## Conflict of interest

None of the authors had any potential conflicts of interest including any financial, personal or other relationships with other people or organizations within three years of beginning the submitted work that could inappropriately influence, or be perceived to influence, their work.

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