Influence of context effects on health outcomes: a systematic review

Zelda Di Blasi, Elaine Harkness, Edzard Ernst, Amanda Georgiou, Jos Kleijnen

Summary

Background Throughout history, doctor–patient relationships have been acknowledged as having an important therapeutic effect, irrespective of any prescribed drug or treatment. We did a systematic review to determine whether there was any empirical evidence to support this theory.

Methods A comprehensive search strategy was developed to include 11 medical, psychological, and sociological electronic databases. The quality of eligible trials was objectively assessed by two reviewers, and the type of non-treatment care given in each trial was categorised as cognitive or emotional. Cognitive care aims to influence patients’ expectations about the illness or the treatment, whereas emotional care refers to the style of the consultation (eg, warm, empathic), and aims to reduce negative feelings such as anxiety and fear.

Findings We identified 25 eligible randomised controlled trials. 19 examined the effects of influencing patients’ expectations about treatment, half of which found significant effects. None of the studies examined the effects of emotional care alone, but four trials assessed a combination of both cognitive and emotional care. Three of these studies showed that enhancing patients’ expectations through positive information about the treatment or the illness, while providing support or reassurance, significantly influenced health outcomes.

Interpretation There is much inconsistency regarding emotional and cognitive care, although one relatively consistent finding is that physicians who adopt a warm, friendly, and reassuring manner are more effective than those who keep consultations formal and do not offer reassurance.

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Introduction

As long as 400 BC, Hippocrates wrote of how “the patient, though conscious of his condition is perilous, may recover his health simply through his contentment with the goodness of the physician”. Balint added that what mattered was “not only the medicine . . . or the pills . . . but the way the doctor gave them to the patient—in fact the whole atmosphere in which the drug was given”. Although many have suggested that good doctor–patient relationships can have a therapeutic effect irrespective of any specific treatments provided by the practitioner, the extent to which this assumption is based on rigorous empirical evidence is not known. This lack of evidence is possibly a result of the focus of clinical research on the assessment of surgical and pharmacological interventions, and little emphasis on the effects of human care or “bedside manner” on health outcomes.

Nowadays, the influence of patients’ expectations and the power of suggestion tend to be controlled for rather than investigated, and when noted, these effects are discounted as “non-specific” or “placebo” effects. However, given the proportion of patients who get better after receiving placebos, such effects are potentially of great value, and investigation of their healing properties is a worthwhile undertaking. In 1994, a series of articles and a review in The Lancet highlighted various aspects of the placebo effect, outlining how non-specific or “context” factors such as the method of treatment delivery interact with specific therapies (figure 1).

A systematic review by Turner and colleagues on pain and the placebo effect concluded that “The quality of the interaction between physician and patient can be extremely influential in patient outcomes, and . . . patient and provider expectations may be more important than specific treatment”. Effects originating from health-care interactions include factors common to all medical, alternative, and psychological therapies—eg, attention, bedside manner, empathy, positive regard, compassion, hope, and enthusiasm. Although a great deal of research has assessed the effects of training in communication skills, these
In this study, we use the neutral and broader term of expectations and health-care interactions is real and powerful, and related to the patient–practitioner relationship, and placebo effects. In addition, we made requests from an internet discussion list (Evidence-Based-Health) and contacted experts in the field.

We included all randomised controlled trials in which at least one treatment was a contextual intervention related to the patient–practitioner relationship in a clinical population with a physical illness. We excluded studies examining contextual factors related to treatment characteristics (eg, size and shape of medication) and identified psychological interventions or those with a theoretical base such as psychotherapy, counselling, health education (including communication training), or interventions directed at drug addicts, psychiatric patients, or healthy volunteers.

Data were extracted by use of National Health Service Centre for Reviews and Dissemination Guidance and a standard data extraction sheet to assess the quality of clinical trials. Trials scoring 8–10 of 10 points were rated as very good, 7–8 as good, 5–6 as acceptable, and less than 5 as poor. To determine internal validity, the checklist also assessed the method of randomisation concealment, comparability of groups at baseline, masking, completeness of follow-ups, and intention-to-treat analysis.

Data were extracted and cross-checked by two assessors (ZDB and EH). Quality assessment was used for descriptive purposes and for underpinning recommendations for improving the quality of further research.

Our primary outcome measures were objective or subjective health status. Secondary outcome measures were health-service use, adherence to treatment, satisfaction with care, anxiety, treatment expectations, understanding of illness, and quality of patient–practitioner relationships.

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**Figure 2:** Healing and the biopsychosocial consultation

<table>
<thead>
<tr>
<th>Health-care professional</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical care</td>
<td>Physical reaction to treatment</td>
</tr>
<tr>
<td>Behavioural care</td>
<td>Medication, surgery</td>
</tr>
<tr>
<td>Cognitive care</td>
<td>Behavioural response</td>
</tr>
<tr>
<td>Emotional care</td>
<td>Adherence, lifestyle changes</td>
</tr>
<tr>
<td>Health outcome</td>
<td></td>
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</tbody>
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Emotional care: produce benefits such as helplessness, anxiety, and depression. Unhelpful emotions such as fear or anxiety by providing support, empathy, reassurance, and warmth. Emotional and cognitive care are expected to work in an interactive manner, and to enhance substantially the effectiveness of therapy or physical care.

Some reviewers argue that the therapeutic influence of expectations and health-care interactions is real and powerful, whereas others feel that this effect is simply the result of methodological bias. Such debates are understandable given the conceptual and operational difficulties associated with the term “placebo effect”. In this study, we use the neutral and broader term “context effects” to refer to placebo effects deriving from patient–practitioner relationships. Since the assessment of therapeutic efficacy is best done by summarising evidence from randomised controlled trials, we did a systematic review of all such trials of the effects of patient–practitioner relationships on patients’ health outcomes.

### Methods

We designed comprehensive search strategies for a large number of medical, psychological, and sociological electronic databases (MEDLINE, Cochrane Controlled Trials Register, Cinhil, PsycLIT, Amed, Sociofile, Social Science Citation Index, Science Citation Index, EMBASE, SIGLE, and Dissertation Abstracts). These strategies are available from the authors. For MEDLINE alone, 183 search terms were used. These terms were related to the characteristics of practitioners, the patient–practitioner relationship, and placebo effects. In addition, we made requests from an internet discussion list (Evidence-Based-Health) and contacted experts in the field.

We included all randomised controlled trials in which at least one treatment was a contextual intervention related to the patient–practitioner relationship in a clinical population with a physical illness. We excluded studies examining contextual factors related to treatment characteristics (eg, size and shape of medication) and identified psychological interventions or those with a theoretical base such as psychotherapy, counselling, health education (including communication training), or interventions directed at drug addicts, psychiatric patients, or healthy volunteers.

Data were extracted by use of National Health Service Centre for Reviews and Dissemination Guidance and a standard data extraction sheet to assess the quality of clinical trials. Trials scoring 8–10 of 10 points were rated as very good, 7–8 as good, 5–6–9 as acceptable, and less than 5 as poor. To determine internal validity, the checklist also assessed the method of randomisation concealment, comparability of groups at baseline, masking, completeness of follow-ups, and intention-to-treat analysis.

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Our primary outcome measures were objective or subjective health status. Secondary outcome measures were health-service use, adherence to treatment, satisfaction with care, anxiety, treatment expectations, understanding of illness, and quality of patient–practitioner relationships.
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similar pain to those who expected the test to simply detect changes in their tracing. Amigo found systolic blood pressure to be higher in hypertensive patients who were told to expect a higher reading in a second assessment than patients who were informed that such a reading would be lower or that there would be no change.29 The effect decreased with decreasing contrast between the two messages (figure 3). A similar but less pronounced gradient occurred for diastolic blood pressure. In randomly assigning patients with mild hypertension to receive three types of feedback about their blood pressure, Linden found no difference for systolic blood pressure, but similar effects to those of Amigo for diastolic blood pressure.27

Cognitive care and treatment

We identified 19 studies (three of which were published in a single paper) that examined the impact of randomly assigning patients to different levels of treatment expectancy.17,18,21–25,26,37 Details of these studies were difficult to summarise because of heterogeneity. Data extraction tables will be available in the forthcoming report of the Centre for Reviews and Dissemination (www.york.ac.uk/inst/crd).

Ten of these studies found that practitioners who attempted to influence patients' beliefs about the effects of therapy had a significant impact on patients' health outcomes.17,18,21–25,26,37 In three of these studies, health was only partly influenced: in one, effects did not last until follow-up,31 and in the others, effects were limited to certain outcome measures.21,22,37 Of the ten studies that identified a significant effect after manipulation of treatment expectations, only two were rated as good;29,37 the rest were average or poor. However, in the nine trials that found no significant difference, three were rated as very good (ref 24 and studies B and C of ref 25) and two as good (ref 21 and study A of ref 25).25

Suggestion seemed to be more effective when treatment expectations were positively, rather than negatively, enhanced. In five trials, patients were given negative expectations about treatment, in the form of information about the likely side-effects of medication (study B of ref 25).21,22,25,37,38 Three of these studies found no significant difference in the number of reported adverse effects (study B of ref 25).21,22

Cognitive and emotional care

None of the studies included in this review examined the effects of emotional care alone. Four trials examined the influence combining cognitive care—ie, giving patients a clear diagnosis, a positive prognosis, or raising treatment expectations, with emotional care—ie, being warm and friendly,24,25,33 or firm and reassuring (described by some of the authors as “positive consultations”). These consultations were found to be significantly more effective than neutral consultations in decreasing pain33 and increasing the speed of recovery.17,18

In 1978, Gryll and Katahn13 allocated dental patients to three types of information about the effectiveness of a painkiller. Those who were told that they would receive a “new, fast acting drug, very effective in reducing tension, anxiety and pain”, reported significantly less pain and anxiety than patients whose expectations about the drug had not been raised. The effect size was particularly strong when the message was delivered by a warm and friendly practitioner. Similarly, a Swedish team14 found that patients with tonsillitis recovered faster and were more satisfied when treated by a friendly practitioner who gave a positive prognosis, encouraged questions, and spent an extra 4 min with them.

Discussion

In reviewing context effects, we identified 25 trials that fulfilled our inclusion criteria. About half of these studies found positive effects on patients’ health status after manipulation of patient–practitioner relationships. Conflicting findings are likely to have been influenced by the level of heterogeneity in the type of intervention, clinical sample, health outcomes, the methodological quality, and timing of the studies.

A combination of emotional and cognitive care (positive consultation) was found to produce the most consistent effect. Practitioners who attempted to form a warm and friendly relationship with their patients, and reassured them that they would soon be better, were found to be more effective than practitioners who kept their consultations impersonal, formal, or uncertain.14,17,31 One exception was a study by Berk and colleagues13 in which there was no difference between the positive and negative consultation groups in the effects of acupuncture or placebo. There was also no variation in the ratings of perceived health-professional competence, enthusiasm, empathy, and friendliness between the two groups. This finding suggests that patients might interpret a formal consultation with little interaction as serious and professional.

Ten of the 19 studies that examined the effects of cognitive care by influencing patients’ expectations about treatment were found to affect health outcomes, but these trials had lower methodological quality than those finding no effect after manipulations of treatment...
expectations. Since these trials were older, poor quality was likely to have resulted from lack of reporting (eg, randomisation, drop-out rate), when such information was not always reported.

At the time, informed consent was not essential, and this might also have influenced the effects of the study, since participants who are unaware of a trial may react differently to patients who agree to be studied and know they have a 50% chance of receiving a placebo.22,30 Because context interventions commonly consisted of a single verbal statement (eg, “this is a very effective drug that will reduce your pain immediately after taking it”), it is possible that some might not have been strong enough to influence expectations, especially those of patients with chronic illnesses. This group might feel that the treatment is generally effective but might not believe that it will work for them, owing to previous experiences.39 Because of the lack of data on the practitioners who delivered each intervention, it is difficult to establish the extent to which their beliefs about treatment or difficulty in assuming a “warm” and then “cold” interactive style contributed to the results.

Giving different diagnoses to patients presenting with similar symptoms had little or no effect, perhaps because the diagnoses given were for relatively mild conditions. For more serious illnesses, effects are possibly stronger, but ethical and practical reasons would obviously prevent researchers from doing such studies.

None of the studies examined the effects of emotional care. However, one trial, which failed to meet our inclusion criteria because of the lack of a health status outcome measure, found that patients who frequently attended emergency departments and who were assigned compassionate care had fewer repeated visits and increased satisfaction than patients receiving standard care.40

In this review, we chose to focus on doctor–patient relationships because the area of context effects is very large. Some work on other context factors is available elsewhere.39,41,42 Since there are a number of related systematic reviews assessing the effectiveness of communication training,10 preparing patients for stressful medical procedures,43 and changing patients’ expectations,39 these studies were excluded from our review.

Although extensive search strategies were done, this being a conceptually and operationally complex area, we might have missed some eligible randomised controlled trials. Research examining the effects of patient–practitioner interactions on health outcomes has often been based on healthy volunteers or psychiatric patients. A larger analysis that included these studies might have found different effects. However, these populations are likely to process context interventions differently, making the findings less generalisable to other patient groups.

Our findings suggest that studies could be too disparate to allow for any serious conclusions to be drawn, somewhat like comparing apples with oranges. Several aspects need to be considered. At one level, specific doctor–patient interactions are likely to be determined by individual factors, which vary substantially due to the unique nature of relationships. At another level, the effect of these interactions is likely to be modified by the specific disease and other interventions. Moreover, for most of the main conditions studied in this review (eg, hypertension), “specific” or established medical interventions might not have been more effective. We feel that both aspects need further careful study, but on the basis of the current evidence, we speculate that there is an independent effect of doctor–patient interactions as well.

Vast amounts of energy and resources have been spent to advance diagnostic tools, and pharmacological and surgical treatment. The lack of attention to the more humane aspects of care, alongside increased specialisation and shortened consultation time, could have affected the patient–practitioner relationship and our understanding of its effects. To increase the effectiveness and quality of health services, it is important to study further the interactions between conventional or complementary medicine and context effects occurring during consultations. Our understanding of the therapeutic effectiveness of context effects in doctor–patient interactions could be advanced through an integration of rigorous qualitative and quantitative research, alongside assessments of changes in understanding (eg, treatment expectations, therapeutic alliance), and affect (eg, anxiety).

**Contributors**

Z Di Blasi developed the protocol; collected, analysed, and interpreted the data; and wrote the paper. E Harkness collaborated in data collection and analysis. E Ernst commented on the study process, the final written document, and supervised part of the data collection and analysis. A Georgiou helped in the conception and design of the study and commented on drafts. J Kleijnen coordinated and supported the study design, data analysis and interpretation, and commented on all revisions of the paper.

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**References**


