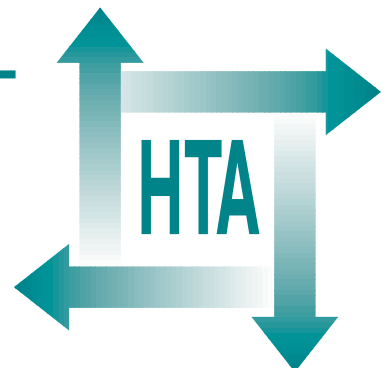# The role of expectancies in the placebo effect and their use in the delivery of health care: a systematic review

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HTA

Standing Group on Health Technology

Details of the membership of the HTA panels, the NCCHTA Advisory Group and the HTA
Commissioning Board are given at the end of this report.

The role of expectancies in the placebo effect and their use in the delivery of health care: a systematic review

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NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Methodology Panel and funded as project number 94/34/04.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

Contents

List of abbreviations

ACE	angiotensin-converting enzyme[*]
ASMP	Arthritis Self-Management Programme[*]
BP	blood pressure[*]
BPH	benign prostatic hyperplasia[*]
CB	cognitive-behavioural[*]
CBSM	cognitive-behavioural stress management[*]
GHP	General Health Perceptions (questionnaire)[*]
GP	general practitioner
HbA$_1$	glycosylated haemoglobin[*]
HMO	health maintenance organisation (USA)[*]
NSAID	non-steroidal anti-inflammatory drug[*]
RCT	randomised controlled trial

[*] Used only in tables and appendices

Executive summary

Objectives

- The original aim was to assess the nature and extent of the placebo effect and to consider how it may be harnessed within the NHS to improve the quality of care.
- The first step was to develop an approach to the review that would address specific questions about the placebo effect.

Methods

A broad definition of placebos was adopted, and a placebo component was assumed to be associated with all aspects of health care. A model of the placebo effect was derived from the background literature. This review focused on the expectancy mechanism. Expectancies were defined as treatment-related outcome expectations (beliefs that treatments will have positive or negative effects on health status) and patient-related self-efficacy expectations (beliefs that one can carry out the actions necessary for successful management of a disease or coping with the treatment).

On this theoretical basis, this review tested the hypothesis that changes in health status attributed to placebos are achieved by manipulations of these outcome and self-efficacy expectations. The review was confined to healthcare delivery in the clinical sector. A case was made for the exclusion of studies concerned with psychotherapy, complementary therapies and laboratory-based experiments.

A structured review of a subset of the literature on the placebo effect was conducted.

Initial searches of electronic data bases identified 47,600 references which were narrowed down to 689. These were screened and this reduced the total to 489 abstracts, of which 93 were primary research papers. Data were extracted from the primary research papers and tabulated. All studies were rated for methodological quality as either acceptable or poor.

A working definition of expectancy was developed together with criteria for identifying papers in which expectancy was the key feature; these reduced the number of primary research papers to 85. Expectancy was classified as process expectancy, positive outcome expectancy, negative outcome expectancy, interaction self-efficacy and management self-efficacy. Classification was based on information reported in the methods sections on the content of the intervention. Papers were classified into three clinical areas, in terms of the type of expectancy they addressed. A narrative review of the studies in each category was conducted. The analysis made explicit the placebo element of the three clinical areas by identifying which of the expectancies were either implicitly or explicitly changed in the course of the intervention or treatments.

Results

Preparation for medical procedures

The expectancies created were process expectancy and management self-efficacy and, to a lesser extent, positive outcome expectancy. The main health outcomes were reduced use of analgesics and a more comfortable subjective experience for the patient through less anxiety. Management self-efficacy created by skills training prior to the medical procedure, either alone or in combination with process expectancy, was more effective than process expectancy created alone.

Management of illness

The expectancies created were primarily management self-efficacy or interaction self-efficacy and both resulted in benefits for the patient. Benefits included an improvement in the patient's symptoms (e.g. improved mood, less anxiety, reduced pain, and less bothered by asthma) and an improvement in the patient's disease status (e.g. lowered blood pressure, immunological changes, and better metabolic control). A few studies also reported a reduction in the use of health services.

Medical treatment

This area involved the creation of positive (and occasionally negative) outcome expectancies. The majority of studies provided evidence of the power of positive outcome expectancy to enhance the effects of medical treatment. Most of the

improvements were patient self-reports of reduced anxiety, pain and distress. There was also some evidence for the effects of negative outcome expectancy where the frequency of the patient's self-report of symptoms increased.

Expectancies and the placebo effect

Given the evidence for the subjective and objective benefits of creating expectancy, the studies reviewed provide support for the hypothesis that expectancies are a mechanism by which placebos have their effects. However, because of the heterogeneity of outcomes assessed and the uneven distribution of the expectancies across the three clinical areas, it was not possible to use meta-analysis to combine effect sizes across studies. A more quantitative analysis of the results was not, therefore, possible. Few studies addressed economic issues in any of the three clinical areas. The review of the methodological quality indicated that the main weakness of studies concerned with placebo effects were small sample sizes and a lack of detail on design, randomisation and statistics.

Conclusion and recommendations

The existing evidence justifies the use of strategies to enhance expectancies, specifically to:

- enhance patients' accurate expectations about medical procedures and how to cope with them and their effects
- enhance patients' skills for self-management of their illness and their ability to communicate about their health problems with health-care providers
- enhance patients' beliefs in the benefits of effective medical treatments.

Enhancement of these expectancies would be achieved by training healthcare professionals to communicate positive outcome expectations effectively and training them in interaction styles that promote patient involvement in consultations. Equally, training of patients is also recommended to increase their ability to manage their disease and its treatment, and to participate more fully in consultations. Such training is often viewed as patient education; however, it involves training in specific skills that the patient can apply in combination with medical interventions and may therefore be more usefully viewed as an integral part of health care. Through provision and implementation of such training, beneficial so-called 'placebo' effects can be increased. A number of areas for further research are identified to help increase our understanding of the expectancy mechanism in the placebo effect.

Chapter 1

Background

The purpose of this review

The review was commissioned by the NHS National Coordinating Centre for Health Technology Assessment in September 1996. In the context of establishing evidence-based practice, the brief was to assess the nature and extent of placebo effects, and to consider how these could be harnessed within the NHS to improve the quality and cost-effectiveness of healthcare delivery.

For this purpose, a multidisciplinary team was assembled with expertise in nursing, health psychology, sociology, biomedical statistics, health economics, and health services research and systematic reviewing. The stages of work that were undertaken are documented in this review. It begins with an overview of the theoretical and conceptual literature on the placebo effect, from which a theoretical model of the placebo effect was developed in order to provide a structural framework for guiding the review.

Defining the placebo effect

There is considerable debate, variability and confusion in the literature concerning the usage and interpretation of the terms 'placebo' and 'placebo effect'.[1–6] A brief overview of the main issues is presented here.

In the narrowest sense, a placebo is a biomedically inert substance (e.g. the legendary sugar pill) given by a healthcare practitioner to please a patient. Despite being inefficacious substances, placebos can produce physical effects,[7–9] the nature of which vary with individuals, situations and medical conditions. Placebos can have diverse physical and psychological effects of a beneficial (placebo) or adverse (nocebo) nature.[10–12]

Since the advent of randomised controlled trials (RCTs), placebos have been used extensively in pharmacological research. Protected by informed consent, investigators administer placebos to a control group of patients so that the 'real' effects of an active preparation may be deduced by subtraction of the effects produced by a placebo in the same clinical situation. The use of placebos in clinical practice has, however, been subject to extensive debate because their potential therapeutic success hinges to some extent on deceiving the patient.[13–23] Whereas some commentators may argue for limited placebo use in certain well-defined clinical circumstances, others have serious concerns that even the most benevolent deception will destroy both the long-term trust which patients place in their clinicians and the general credibility of the medical profession. Significantly, these factors are thought to be important determinants of the placebo effect in its wider and more modern interpretation, in which patient autonomy and involvement is emphasised rather than professional paternalism and control.[24]

Probably the most widely quoted definitions of placebo and placebo effect are those of Shapiro.[25–29] Shapiro extends the definition of the placebo to "any therapy (or component of therapy) deliberately used for non specific psychological or psychophysiological effect ... and without specific activity for the condition being treated..." The placebo effect, accordingly, is defined as "the non specific psychological or psychophysiological effect produced by placebos". The focus on non-specific in these definitions suggests that the magnitude of the placebo effect can be deduced by excluding known specific effects of the therapy on the condition in question.[30]

Grünbaum advanced on Shapiro's definition by observing that a treatment is composed of two components: characteristic factors and incidental factors.[4,5] The characteristic factors are those that are known or believed to affect the disease as a result of the theoretical rationale for the therapy. The incidental factors are those that may affect disease but cannot be derived from the theoretical rationale for the therapy. Therapies can affect the target conditions for which they are intended and/or other aspects of patients' health. Given this framework, Grünbaum argued that the use of the terms 'specific' and 'non-specific' to distinguish between treatment and placebo effects is not helpful. A placebo may have a highly specific effect on the target disease (e.g. make a headache go away). The specificity metaphor is borrowed from medicine, where specific therapies are developed to address specific diseases and a general panacea is

looked upon with scepticism. However, as Shepherd observed,[31] the concept of specificity in biology and medicine has always been at issue, whether or not any given disease has a specific versus non-specific cause and cure.

The term 'incidental' is intended to signal that such effects are not expected on the basis of the underlying rationale behind the treatment. This point is similar to one made by Critelli and Neumann,[32] who observed that placebos may be theoretically but not therapeutically inert. In other words, placebos may have beneficial effects for no apparent reason. However, that should not be taken to imply that the theoretical basis for incidental effects is inevitably mysterious.

Many commentators have noted that the placebo effect is equated to non-specific because of ignorance about its component parts and, reflecting this, it has been referred to as 'Factor X'.[33] A distinction can be made between effects that are unspecified rather than non-specific.[34] The challenge of gaining a better understanding of the placebo effect remains; it awaits conceptual developments that isolate parameters and scientific enquiry that tests for their precise clinical significance. The end product of this process will be the transformation of the non-specific (placebo) effect into named specific therapeutic activities.[2,3,8,27,31,34–36] At that point, the term placebo effect could be dispensed with since there would no longer be any mysterious, atheoretical component to therapy. Thus there is an inherent paradox in investigating placebo effects – once they are understood they are no longer defined as placebo effects. One purpose of this review is to develop a framework for the study of non-specific effects, as a first step towards explicating the mechanisms by which they can enhance beneficial health outcomes.

It has been argued that eliciting the placebo effect does not require a placebo in the traditional sense of the term, and that placebos and the placebo effect should therefore be separately defined.[8,15,37,38] According to this interpretation, the placebo effect derives from the symbolic effect of treatment as determined by the total context in which health care is delivered; the causes of the placebo effect are located anywhere in the care delivery process except in the inert placebo itself. Consistent with this approach is the suggestion that placebo effects are generic in applicability,[37,39] which also permits the extension of the definition of a placebo beyond that of an inert medication to encapsulate all aspects of the treatment environment. Many things, including health practitioners themselves, have been described as placebos.[40] Indeed, a continuum of placebos has been suggested, ranging from tangible items such as scars, pills, injections, white coats and procedures, to intangible features of healthcare delivery like touch, gesture, ambience and support.[41,42]

Thus the issue of whether or not a placebo is necessary to produce a placebo effect reduces to one of semantics and depends on which definitions of placebo and placebo effect are adopted. If a placebo is narrowly defined as an inert substance, it is only one aspect of the total treatment context, and one of many possible means of eliciting a broadly defined placebo effect.

For the purpose of the present review, an inclusive definition of placebo has been adopted. The relationships between any aspects of the healthcare delivery encounter were open to investigation of their effects on health outcomes. This included the effects of placebo medications but extended beyond that to consider the significance of the features associated with the environment in which care is delivered and the practitioner–patient interaction. This approach acknowledges that an opportunity exists for a placebo effect to be activated in some form or other in virtually all encounters between healthcare practitioners and patients. It suggests that with a proper understanding of the placebo effect practitioners can, through their relationships with their patients, and in conjunction with appropriate medical technologies, use a multitude of non-deceptive means to promote positive placebo responses. The ethical dilemmas associated with prescribing placebo medications are thereby avoided.[43] The advantage of this approach is that the results of the review have potentially wide practical significance. A variety of ethically acceptable healthcare delivery improvements can be considered.

A conceptual framework for the placebo effect

This review was guided by a framework which relates three classes of factors: determinants, mechanisms, and outcomes. The initial model is shown in *Figure 1*. Determinants consist of four broad classes (patient characteristics, practitioner characteristics, patient–practitioner interactions, and treatment and the setting in which it occurs). It is proposed that these determinants produce placebo effects by acting on a number of mechanisms as shown (anxiety reduction, conditioning, social support and expectancy). The most
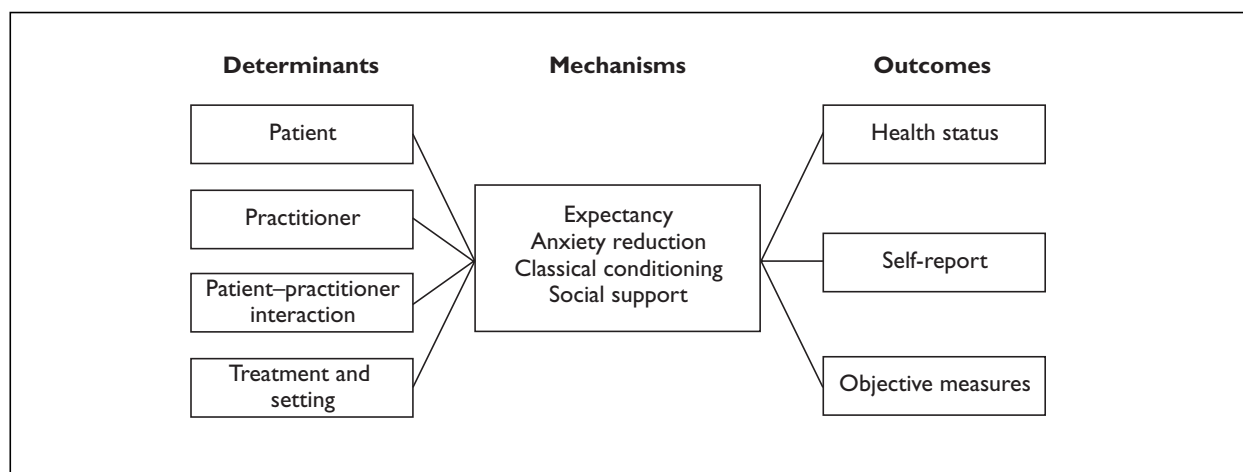
FIGURE 1 *An initial conceptual framework for the placebo effect*

inclusive of these mechanisms is expectancy and, hence, this mechanism has been adopted as the focus of this review. Three classes of health outcomes on which placebo effects can be assessed are indicated in *Figure 1:* health status, self-report and objective measures.

Expectancies

In planning our strategy, it soon became apparent that reviewing the literature on all aspects of this model of placebo effects was well beyond the scale of this project. Placebo effects have been demonstrated repeatedly in numerous studies across a range of treatments for a range of disorders. In order to increase the possibility of harnessing such effects, it is important to investigate the mechanisms by which they operate. This is more valuable than continuing with research which merely adds to the inventory of demonstrable placebo effects. Therefore it was decided to focus on the mechanisms of placebo effects and, within this category, to limit the review to one type of mechanism: expectancy.

Expectancy mechanisms were selected for this review because they are seen as subsuming several of the other mechanisms that have commonly been proposed.[7,36,44–50] For example, anxiety reduction as a placebo mechanism may be a consequence of positive expectancy. Classical conditioning has been proposed as a mechanism for placebo effects.[36,45,49–51] Repeated association of medical care with symptom relief results in a classically conditioned response of symptom relief after receiving care even when the therapy is non-active. Moreover, negative conditioned responses ('placebo sag') have also been observed among

patients with chronic conditions who have received a series of ineffective therapies in the past and are thereby conditioned to not respond to new ones offered.[36,52] However, there is some doubt as to whether humans can be classically conditioned.[53] Insofar as past experience sets up learned expectancies, these possible classical conditioning effects may be more usefully understood in terms of expectancy mechanisms. Expectancy, as a mechanism, is open to manipulation in an ethically permissible manner; hence, a better understanding of this mechanism of the placebo effect is of direct value to the NHS.

There is a very large and multidisciplinary literature on the role of social support of varying types to both individual patients or patient groups. Social support from family members and outside organisations, as well as from healthcare practitioners, can influence patients' attitudes and expectancies, and thereby their health status. Social support obtained outside the healthcare setting is beyond the scope of this review. Social support as one mechanism by which healthcare practitioners engender placebo effects is addressed, insofar as the role of patient–practitioner interactions are considered as determinants of expectancies. However, social support has not been assessed directly because it is seen as a relatively distinct placebo mechanism not subsumed by expectancy.

Because of the decision to focus on expectancy as a mechanism of the placebo effect, all studies have been excluded that investigate placebo effects without reference to expectancy. Therefore, mere demonstrations of placebo effects have been excluded, such as all randomised trials of new treatments and drugs that are intended to demonstrate the superiority of the new

therapy above and beyond placebo effects. In addition, the neurophysiological mechanisms by which expectancy mechanisms affect biological processes are controversial and beyond the scope of this review; for example, the role of endogenous opiates in placebo analgesia has been debated.[45,54–57]

The expectancy mechanism is central to the psychological literature on the placebo effect,[58–61] and has been commented on by many authors.[62–66] Expectancy is recognised as important by clinicians also. For example, treatments once thought to be efficacious by their proponents but found more recently not to be so, are seen as having produced positive outcomes by the positive expectations of both patients and clinicians.[67] Bandura[68–70] distinguished two types of expectancies.

- Outcome expectations are beliefs that certain actions will achieve particular outcomes.
- Self-efficacy expectations are beliefs that one can successfully execute the actions required to achieve valued outcomes.

Self-efficacy is derived from four sources: previous performance accomplishments, vicarious experiences (i.e. seeing others succeeding), verbal persuasion and the individual's psychological state. Self-efficacy has been demonstrated to affect behaviour in a range of health and non-health areas.[68–70] In the present context, expectancies may be seen as beliefs about the effects of treatment (outcome expectancies) and the beliefs held by patients about their abilities to carry out or cope with the disease and its treatment (self-efficacy). This application of Bandura's theories to the placebo literature is, as far as we know, a novel development and is expanded upon further in chapter 3.

Determinants

The placebo effect is a multi-determined phenomenon. A large number of placebogenic variables are advanced in the literature.[27,34,35,44,64,71–80] The various factors may be organised into four groups:

- patient characteristics
- practitioner characteristics
- patient–practitioner interaction
- treatment and treatment setting.

Patient characteristics
The patient's expectancy created in a particular treatment situation reflects her/his pre-existing beliefs and any influences on these exerted by the immediate healthcare delivery. Pre-existing beliefs have been formed over time and reflect the macro context within which care is delivered, the past healthcare experience of the patient and those of the patient's family, friends and acquaintances. They are also influenced by other characteristics of the patient, such as personality traits, anxiety, age, IQ, gender, race or socio-economic status, and their placebo responsiveness. However, empirical studies which have sought to explain observed placebo effects entirely on the basis of patient characteristics have generally failed. Even within an individual, the placebo response is not consistent.[77,81,82]

Practitioner factors
Practitioner factors linked with the formation of patient expectancies include practitioners' personal characteristics and their own beliefs regarding the treatment they are prescribing or performing.[28]

A practitioner who adopts a concerned, warm, supportive, caring and empathetic, attitude to her/his patients may inspire trust, confidence and rapport in the relationship.[83] Conversely, a distracted, unsympathetic and abrupt practitioner may create hostility, distrust and dismay in her/his patient. A confident practitioner, displaying strong beliefs in the diagnosis and treatment, can enhance positive expectancy in the patient, while a neutral or uncertain attitude could have little or even a negative effect on the patient.[37,84,85]

Patient–practitioner interaction

Many commentators emphasise the therapeutic potential of patient–practitioner interactions.[71,86–89] Patient expectations can be influenced through patient–practitioner interaction. A practitioner's communication skills will influence the nature and extent of the interaction that takes place but will also be a reflection of the patient's own ability to take part in the interaction. Both parties will further be influenced by their views on the importance of communication and the appropriate balance of power in the relationship, and by the time available for consultation.[90]

Treatment characteristics including setting

The nature of the treatment may have a placebo (or nocebo) effect on patients, influencing their faith or belief in the care they are receiving. Although

elaborate procedures, including surgery, can be effective placebos,[91–93] routine tasks like prescription writing can also have a placebo effect.[94] The traditional placebo medication falls into this category.[95] Furthermore, the way in which a medication is delivered may affect its perceived action. Injections have been perceived as more effective than pills, and capsules as more effective than pills.[96,97] Even the colour of pharmaceuticals can affect peoples' perceptions of their action and their effectiveness.[97–99]

Outcomes

The placebo effect is the change in a patient's condition attributable to the action of the placebo. It can be assessed in terms of a change in health status (e.g. less swelling), by self-reports of health (e.g. less pain, increased well-being), and by objective measures such as amount of analgesia required, and length of hospital stay. Only studies in which health outcomes were included in one or more of these categories were retained for analysis in this review.

Expectancy literature excluded from this review

Laboratory-based studies
There is a large psychological literature reporting laboratory-based experiments which provide evidence of the placebo effect.[100] In some cases instruction is used to deliberately manipulate subject expectancies. Frequently focused on pain, or the effects of alcohol, caffeine and nicotine, such studies can provide useful evidence through their use of the 2×2 balanced placebo design[45] or a more sophisticated eight-group design.[101] This literature has been excluded from the present review because crucial psychological variables in patients are likely not to be found in non-patient volunteers (e.g. distress), which casts doubt on the generalisability of these findings. Differences between healthy volunteers and patients may account for the fact that placebo pain relief studies show effect sizes in the laboratory almost double those found in clinical settings.[77] Experimental laboratory studies investigating the effect of instruction or expectancy manipulation on patients[102,103] have also been excluded because of similar concerns about generalisability from laboratory to clinical settings.

Psychotherapy
Measuring the effectiveness of psychotherapy over placebo treatment presents serious challenges to researchers in that area. It has been argued that the placebo effect works like psychotherapy through transference[65] and that, since psychotherapy affects patients' expectancies by providing support, compassion, reassurance, advice, and sharing knowledge, it is in fact analogous to a placebo. While some commentators argue that the specific and non-specific (or expectancy or placebo) effects of psychotherapy cannot be separated because of the problem of finding a credible placebo,[8,51,104–108] others argue that credible placebos are possible[32] and that a treatment effect can be discerned.[109,110] There is, however, significant debate about this conclusion and many investigations have found no evidence of a treatment effect from psychotherapy above the placebo effect.[111–115] As a result of such uncertainties, it was decided to exclude psychotherapy from consideration in this review.

Complementary medicine
There is a similar debate about the alternative or complementary medical sector; this is frequently discussed as an entity although, in reality, it includes a range of varied therapeutic modalities. Some commentators suggest that the therapeutic value of these alternative approaches may be largely, if not entirely, accounted for by the placebo effect rather than by specific physiological effects of the treatments themselves.[72,86,95,116–118] There is little empirical evidence to assist in the debate and what does exist is subject to methodological difficulties, not least the problem of finding appropriate placebo controls.[119–124]

In view of the diversity of the complementary sector and the methodological difficulties associated with identifying the placebo effect in it, this area was also excluded from the review.

Summary

The model of the placebo effect that guided this review identified determinants, mechanisms, and outcomes. Through conceptual analysis, the terms placebo and placebo effect were demystified and the outcome measures that would be employed were made explicit. The final version of the model used to structure the review is presented in *Figure 2*. The original four broad classes of determinants remain: patient characteristics, practitioner characteristics, patient–practitioner characteristics, and treatment and setting in which the effect occurs. Only the expectancy mechanism is included since the review was limited to this mechanism. The outcomes used to measure placebo effects are observed changes in physical and psychological health status, patient self-reports and health service

Determinants

- Patient
- Practitioner
- Patient–practitioner interaction
- Treatment and setting

Mechanisms

- Expectancy

Outcomes

- Changes in physical and psychological health status
- Patient self-reports
- Objective measure health service utilisation
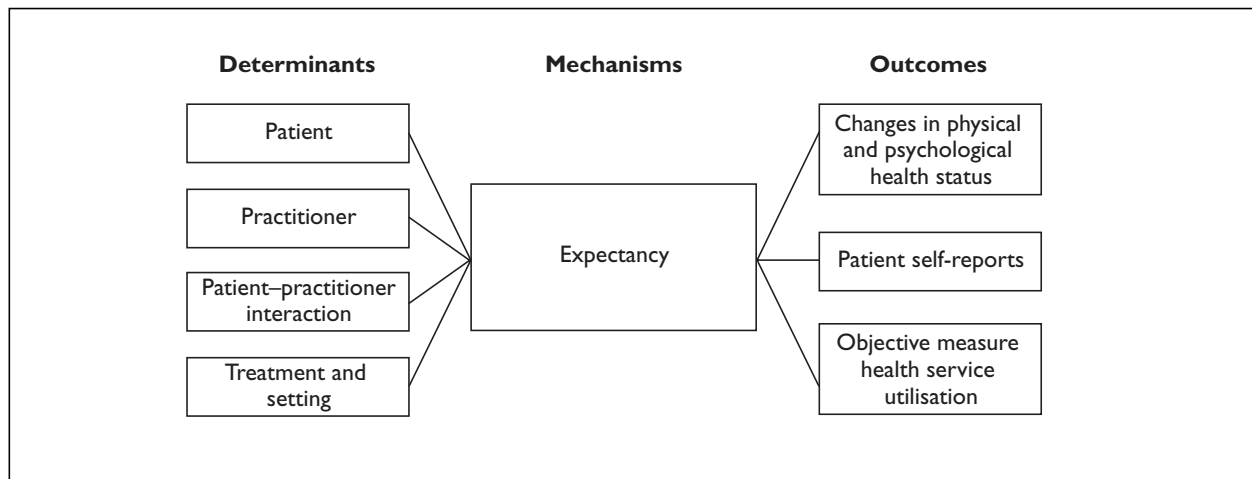
FIGURE 2 *A revised conceptual framework for the placebo effect*

utilisation measures. This revised model allowed us to proceed with a structured review of that portion of the vast literature on the placebo effect confined to the expectancy mechanism. Specifically, in this review we set out to test the hypothesis that changes in health status attributed to placebos are achieved by manipulations of outcome and self-efficacy expectations. Accordingly, a search strategy was developed to identify studies examining the determinants of expectancies and studies manipulating expectancies, subject to the exclusions noted above.

Chapter 2
Review methodology

The scope of the review

The search strategy was developed, in part, following the initial scoping electronic searches of the main databases which produced a daunting number of papers with 'placebo' and 'placebo effect' in their titles or abstracts. Searching for placebo as a keyword alone produced approximately 20,000 references. This led to the final decision that only literature on the placebo effect which was confined to the expectancy mechanism would be reviewed. The search stage thus sought to identify studies examining the determinants of expectancies and studies which manipulated expectancies, subject to the exclusions described in chapter 1.

Four main groups of determinants of the placebo effect were explored:

- patient characteristics
- practitioner factors
- patient–practitioner interaction
- treatment characteristics, including the setting features.

The search focused on primary research undertaken in clinical settings which reported final health outcomes of either a physical or psychological nature or health service utilisation outcome measures. Studies that reported only intermediate behavioural outcomes were excluded, partly because behavioural change could not be linked directly to health status change and partly because this further enabled us to concentrate the analysis in the face of tight resource constraints. This decision excluded a large body of literature which points to a link between expectancies and compliance, an area that deserves reviewing in its own right.

Study retrieval

Studies were retrieved from a number of sources and included books, chapters in books, letters and editorials, as well as journal articles. Although electronic sources were not searched before 1980, pre-1980 studies were included if identified by other means. Moreover, a comprehensive bibliography of placebo studies prior to 1980 is already available[125] (see *Table 1*).

Electronic databases

The major sources were the electronic databases chosen to afford optimal coverage of the literature, and spanning a broad range of disciplines from both European and American sources. The following literature sources were searched:

- PsycLIT, 1980–96
- CINAHL, 1982–96
- MEDLINE, 1980–96
- BIDS (Bath Information and Data Sources), Science 1981–96
- BIDS Social Science, 1981–96
- Sociofile, 1982–95.

Other sources

Other sources included a search of the Cochrane database of systematic reviews, the NHS Centre for Reviews and Dissemination database of reviews and the Cochrane Library. Handsearching included the reference lists of identified papers (exploding references).

Personal contacts

Personal contact was made with known experts in the field (appendix 1) and a workshop was held shortly after the inception of the project which was attended by six external advisors plus the review team (see appendix 2). Other contacts were made at two conferences: *The placebo response: biology and belief,* University of Westminster, November 1996; *Placebo and other non-specific effects,* Einsiedeln, Switzerland, October 1997. These conferences highlighted the relevant and current issues in placebo literature and widened our personal contacts. Unpublished literature and ongoing work (grey literature) which was relevant to the approach being taken was pursued through these contacts. However, no such studies were identified for inclusion in the review.

Search strategy

Stage 1

The terms used for the electronic searches are set out in appendix 3. The initial search identified the presence of the terms in key words and text of titles in papers located from each of the electronic databases used in the search. Counts used single and combined terms and produced 47,600 references!

TABLE 1 Summary results of the electronic search

Search term	Number of papers located	MEDLINE 1980–96	BIDS Science 1981–96	BIDS Social Science 1981–96	PsycLIT 1980–96	Sociofile 1982–96	CINAHL 1982–96	Abstracts identified for retrieval
Reference counts								
Expectanc[*]	17,176[a]	6129	2597	2604	4571	858	417	
Expectatio[*]	19,143[a]	8665	10,234	8194	15,016	4760	1708	
Belief	49,336[a]	8206	2751		17,273	8128	3118	
Title and abstract reviews								
Placebo and								
Expectanc[*]	431	127	64	81	143	1	15	123[a]
Expectatio[*]	253[a]	81	53	35	70	5	10	47[a]
Belief	214[a]	72	40	25	51	7	19	24[a]
Untreated	1050[a]	593	390	17	37	0	13	9[a]
Non-specific	361	270	0	0	77	3	6	21[a]
Incidental	16[a]	8	3	0	3	3	0	0
Nocebo	18	5	6	4	3	0	0	2
Patient–provider Interaction: (all variants)	7303	1284	973	805	1548	1676	612	405[a]
Expectancy and therapist Characteristics: encouragement, etc.	666[a]	102	94	178	199	18	75	17[c]
Environment, etc., of care	3	0[b]	0	0	3	0	0	0[c]
Information, etc.	2423[a]	395[b]	259	388	937	194	250	17[c]
Informed consent	37	14[b]	10	5	1	0	7	8[c]

[*] *Indicates 'wild card' searching for truncation of terms*
[a] *Some double counting*
[b] *MEDLINE 1990–96 only*
[c] *Papers identified at earlier stage excluded from count*

Stage 2

At the second stage the terms used to locate the references were restricted to the hypothesised determinants of expectancy. This reduced the number of references to manageable proportions. Terms were selected so that both high recall (sensitivity) and high precision (specificity) were achieved.

A total of 689 references were retrieved, of which approximately two-thirds were identified by the electronic search. Some of the references entered the count more than once because some database subject areas overlapped.

Stage 3

Titles and abstracts of all 689 references were then scrutinised by at least two members of the team to identify papers which warranted closer consideration. A copy of the abstract or a brief summary of each reference was transferred to an 'Initial Review'

form (see appendix 4). This initial scan reduced the number from 689 to 472 papers. These were then categorised into primary research papers (93) and background papers (379). Relevant primary research papers were defined as those which either examined the determinants of expectancies or manipulated expectancies and reported health outcomes. No restrictions were placed on the study design. Background papers were defined as those which included theoretical, methodological and review papers relating to the placebo effect.

Papers which satisfied these inclusion criteria were retained for review.

Data extraction and synthesis

Background papers

Each background paper retrieved during the second stage of the search process was reviewed

by at least one member of the team. The objective was to select those papers which would inform the writing of the background and discussion sections of this review. The papers could be reviews, commentaries, conceptual analyses or methodological analyses.

Primary research papers

Data extracted from each primary research paper was entered on a specially designed *proforma*. It included:

- author, title and source of the paper
- full details of the study's design, methodology, analysis, results
- type of expectancy manipulated
- any comments about quality and implications for healthcare delivery.

At the same time a note was made of any further references to be followed-up (see appendix 5).

In order to ensure inter-rater reliability, the *proforma* was initially tested by all six members of the team, each of whom read the same three papers. In the light of the results, the method used to extract the data was improved by developing a set of guidelines to accompany the *proforma*. Each paper was analysed by two people and an agreed extraction summary table was produced.

Methodological quality

At the same time as the data extraction from the primary research papers was being undertaken, a quality checklist was completed. The checklist (see appendix 6) covered:

- research method
- randomisation
- blinding of participants/assessors
- follow-up attrition
- comparability of groups at baseline
- representativeness of sample to target population
- sample size/statistical power
- appropriate statistical methods of analysis
- reliability and validity measures
- any other comments.

All quality checklists were reviewed by the statistician so that an assessment could be made of each paper. The criteria used to judge the quality included matters of methodology and validity, resulting in a subjective quality ranking on a two-point scale – acceptable and poor. A poor study was one in which no clear inferences could be drawn either because of poor study

design, inappropriate statistical analysis or because insufficient detail was given. Many of the studies rated as poor were such that any apparent intervention effects were clearly confounded by other factors. For instance, in an uncontrolled observational study apparent intervention effects are confounded by the natural course of the health problem under investigation. Another example is where different intervention groups are clearly not comparable in terms of baseline factors. In addition, many of the studies that were rated as poor contained insufficient methodological detail, thereby making it difficult to judge the validity of the findings.

Originally a more detailed rating scale had been tried. However, this was eventually simplified to the two-point scale (acceptable/poor) because the key aspect was to identify methodologically weak papers (i.e. those rated as poor). Attempting to, in effect, award merit points to papers that were not poor was of relatively minor importance given that no formal quantitative analysis was to be undertaken. Also, given the high degree of heterogeneity between studies (in terms of discipline, publication date, style, etc.), it would be very difficult to maintain consistency of a complicated classification across studies. Indeed, given this heterogeneity, it can be argued that an essentially univariate classification scale beyond a simple dichotomy would be a distortion and that a tree structure would be more appropriate. It is doubtful whether such additional complexity would have been of significant benefit in the present study over and above the simple dichotomy adopted.

Summary table and final overview

The data extracted from each paper were transferred to a summary table. This included information on first author, title and source, study population, sample size, study design and quality assessment, key features of the intervention, outcomes measured and results.

The 93 research papers described studies conducted in a range of different countries, settings and clinical areas, using different research designs and manipulating a number of different expectancies. Thus no quantitative meta-analysis could be conducted.

Time limitations on the search strategy

Although references were found using several different search routes, resource constraints limited the extent to which personal contacts,

handsearching of journals and seeking grey literature such as conference proceedings could be utilised. However, existing major reviews of

relevant issues were identified and, in the later stages of the search, the rate at which new papers were discovered declined substantially.

Chapter 3

Results

Strategy

To test the hypothesis that changes in health status can be achieved by manipulating outcome expectancies and self-efficacy expectations required a definition of expectancy. Criteria for systematically identifying papers in which expectancy was a key feature of the study were also developed.

Definition of expectancy

Bandura's[68–70] concept of outcome expectancy has been interpreted as treatment-related expectancy and his concept of self-efficacy expectations as patient-related self-efficacy and developed for the purposes of this analysis.

Treatment-related expectancy

Treatment-related expectancy was developed into three separate categories, namely process expectancy, positive-outcome expectancy and negative-outcome expectancy as follows.

- Process expectancy refers to expectations about medical interventions created for patients either with no knowledge of an unfamiliar medical procedure, or with inaccurate expectations about the actual processes involved.
- Positive-outcome expectancy refers to the expectancies created by practitioners when they convey their own faith and enthusiasm in a treatment, thus going further than simply providing accurate information about what experiences the patient can expect.
- Negative-outcome expectancy refers to those expectancies created when the practitioner conveys uncertainty or even lack of faith in a procedure or when the practitioner informs the patient of the negative consequences of treatment, such as possible side-effects.

Patient-related self-efficacy expectations

Patient-related self-efficacy expectations are based on observations that self-efficacy affects behaviour in a range of health and non-health areas. Building-up a patient's confidence and self-worth all contribute to self-efficacy and are part of good practitioner skills. Changing self-efficacy is, therefore, considered to be one of the most important components of any behavioural healthcare intervention.[126] Based on these

assumptions, patient-related self-efficacy was developed into two separate categories, namely interaction self-efficacy and management self-efficacy. It is promoted whenever an intervention is designed to provide the patient with confidence that she/he can cope or behave in such a way that she/he can manage the disease or its treatment and is defined as follows.

- Interaction self-efficacy is promoted when interventions are designed to increase the patient's involvement in decision-making regarding their care and is achieved by empowering or activating the patient thus enabling more effective participation in the medical consultation.
- Management self-efficacy is promoted by teaching the patient specific skills for coping with or managing the effects of treatment or the disease itself in order to augment the patient's self-efficacy beliefs in these particular skills, thus increasing the likelihood of the patient putting these skills into practice.

Criteria developed to establish expectancy as a key feature of the investigation

The criteria developed to establish whether expectancy was a key feature of the investigation were the presence in the methods section of one or all of the following.

- An explicit statement/description of the content of any practitioner information given to patients which formed a key feature of the intervention and included an expectancy which met the definition developed for the purpose of the analysis.
- An explicit statement/description of the information given to the patient, either orally, during audio- or videotaped messages or during group teaching sessions, which formed a key feature of the intervention and included an expectancy which met the definition developed for the purpose of the analysis.
- An explicit statement/description of the skills provided in the training given to the patient which formed a key feature of the intervention and included an expectancy which met the definition developed for the purpose of analysis.

Final selection of papers and the organisation of the analysis

A total of 93 papers reached the final stage of the literature search, each of which was read by two members of the research team in order to:

(a) classify the type of expectancy present
(b) establish that expectancy was a key feature of the investigation.

Eight papers did not meet the stringent requirements developed for the inclusion of studies in the analysis and these were removed. The final 85 papers were categorised according to the clinical focus of the study so that the effects of expectancy could be considered in terms of their usefulness for the NHS. The groupings were as follows:

- studies in which the effects of preparation for medical procedures were investigated (25 papers)
- studies in which the management of short-term/acute or chronic illness was investigated (40 papers)
- studies concerned with the effects of expectancy on medical treatment (20 papers).

Within each clinical area, the aspects of each study relevant to expectancy are summarised in the tables below. In addition, an overall summary table is provided in which the effects of expectancy on health outcome examined in at least four studies are shown.

Summaries of the 85 papers included in the review are presented in appendix 7.

Expectancies created in the preparation of patients for medical procedures

This group includes 25 studies in which process expectancy was either created alone, or in combination with other types of expectancy.

Process expectancy and management self-efficacy

There were 15 papers *(Table 2)* in which both process expectancy and management self-efficacy expectation were created as a key feature of the intervention.[127–141] Of these, 11 studies were conducted in the USA, one in the UK,[134] one in Canada[129] and one in Australia.[138] Fourteen studies were of clinically controlled trials of which 13 used randomisation; one, by Langer and colleagues,[128] did not and one, by Weis and colleagues,[135] was an observational study.

It is customary for hospitals to provide general information to patients who are about to undergo medical procedures such as surgery. In the studies featured in this section of the review, this general information was usually provided in the control condition. The information which formed the key feature of process expectancy was a description of any specific medical procedures that patients were to undergo and any accompanying sensations they would experience as a consequence. The procedures included cardiac catheterisation, cholecystectomy, coronary artery bypass graft, gastrointestinal surgery, inguinal herniorrhaphy, hysterectomy, orthopaedic surgery and radiotherapy. Management self-efficacy expectation was created by training programmes in which patients were either taught how to cope with stress or given specific training in how to perform exercises which aid recovery.

Four studies[129,132,135,139] combined both information and training, creating both process expectancy and management self-efficacy expectation, and compared the effects against a control group who received normal hospital procedures. A further study[141] provided a combined programme and compared the results with a control group to investigate its effect on the negative impact of radiotherapy. All five studies reported significantly better positive health outcomes in patients who received the combined information and training. The reported health improvements were a reduction in anxiety,[135,139] less pain,[139] better recovery/adjustment[139] and less use of analgesics.[129,132,135,139] However, the scientific quality of two studies[132,135] was poor thus reducing the size of the combined effect *(Table 3)*.

In a further five studies,[127,130,136,138,140] the effects of specific as opposed to general procedural information were separated from a combined information and training programme. The results were mixed. Three studies[127,130,140] reported better outcomes. Two studies[127,130] showed that the combined programme reduced the length of hospital stay,[127,130] and patients required fewer analgesics[127] and recovered faster[130] when the results were compared with procedural information only. In a third study[140] both specific procedural information and a combination of information and training were found to reduce anxiety and improve recovery by day 7. Patient expectancy was measured in this study, which showed that information alone and in combination with training increased patients' beliefs in their control over recovery. Zeimer[136] reported a relationship between coping and pain but no relationship between coping and accurate process expectancy. Postlethwaite and colleagues[138] reported no effect but the scientific

TABLE 2 *Preparation for medical procedures: effects on health outcomes of process expectancy and management self-efficacy*

Study (location)	Expectancy	Clinical area	Health outcomes	Type and quality of study
Fortin & Kirouac, 1976[129] (Canada)	**Process expectancy** created by providing a description of experiences of surgery that patients can expect; **management self-efficacy** created by teaching patients how to do postoperative exercises.	General surgery	On days 2, 10 and 33, level of physical functioning was higher in education group than in control group ($p < 0.05$) and they had less i.m. meperidine ($p < 0.025$); no differences in use of oral analgesics, length of hospital stay and days of work lost.	Two-group RCT using usual hospital care as a control; rated poor.
Johnson, *et al.,* 1988[141] (USA)	**Process expectancy** created by information about procedure, setting and effects the patient is likely to experience; **management self-efficacy** created by giving patient tips on how to manage side-effects.	Patient with stage A, B or C prostate cancer undergoing radiotherapy for the first time	Treatment group experienced less disruption to normal activities than control group except 3 months after completion of therapy ($p < 0.025$); mood effects related to age and side-effects, not information and training.	Two-group RCT, control no specific information; rated acceptable.
Voshall, 1980[132] (USA)	**Process expectancy** created by providing procedural and sensation experiences of surgery; **management self-efficacy** created by teaching patients how to relax and do leg exercises in order to cope with pain and discomfort.	Elective cholecystectomy	No differences in ranking of pain and distress between groups; fewer analgesics given to treatment group overall than to control group ($p < 0.025$) accounted for differences on postoperative days 3, 4 and 5; no effects on days in hospital.	Two-group RCT, control normal hospital procedures; rated poor.
Weis, *et al.,* 1983[135] (USA)	**Process expectancy** created by providing a description of surgical procedures; **management self-efficacy** created by teaching patients how to manage pain and promote postoperative recovery through exercise.	Major general, gynaecological, and orthopaedic surgery	Anxiety ratings fell for treatment and control groups ($p < 0.05$) but greater fall in treatment group ($p < 0.01$); fewer ($p < 0.05$) analgesics required by treatment group than control group.	Two-group observational study using routine visit by the anaesthetist as a control; rated poor.
Wells, *et al.,* 1986[139] (USA)	**Process expectancy** created by standard information about hospital procedures for surgery; **management self-efficacy** created by teaching patients how to cope with stress, deal with pain and adjust to postsurgical condition.	General surgery	Treatment group reported lower pain intensity after surgery ($p < 0.01$) than control group; treatment group experienced less anxiety pre- ($p < 0.002$) and post-operatively ($p < 0.001$) than control group; trend for treatment group to use fewer analgesics than control group ($p = 0.08$); nurses rated treatment group adjustment to hospitalisation more positively ($p < 0.05$) than control group.	Two-group RCT, control a standard inoculation; rated acceptable.
Anderson, 1987[140] (USA)	**Process expectancy** created by information about routine hospital procedures for surgery; **management self-efficacy** created by training patients how to do postoperative exercises.	Coronary artery bypass graft patients	Both information and information and training group rated by nurses as having better physical recovery ($p < 0.04$) by day 7 than control group; both treatment groups less anxious than control group preoperatively ($p < 0.02$), reported less negative effect ($p < 0.01$) and rated by nurses as having made a better psychological recovery ($p < 0.05$) than control group; both treatment groups increased belief in their control over recovery ($p < 0.05$) but there was no difference in effect between type of preparation.	Three-group RCT, control usual hospital procedural information; rated acceptable.
Egbert, *et al.,* 1964[127] (USA)	**Process expectancy** created by providing accurate information about the surgical procedure; **management self-efficacy** created by teaching patients post-operative pain management, relaxation and how to move about in bed.	Intra-abdominal surgery	Patients in intervention group were more comfortable, in a better physical and emotional condition, used less pain relief in the first 5 days postoperatively ($p < 0.01$) and were sent home 2.2 days earlier ($p < 0.01$) than patients in control group.	Two-group RCT using information only as a control; rated acceptable.
Johnson, *et al.,* 1978[130] (USA)	**Process expectancy** created by providing a description of hospital procedures and information about what patients will experience; **management self-efficacy** created by giving instructions about postoperative exercise.	Cholecystectomy and inguinal herniorrhaphy surgery	Groups of cholecystectomy patients receiving information and exercise reduced postoperative hospitalisation ($p < 0.001$) and improved postoperative recovery ($p < 0.001$), sensory information combined with exercise instruction most effective (no figures given); repeating sensory information (process only) postoperatively reduced use of analgesics ($p < 0.05$), telling patients the order in which procedures will take place (process only) reduced feelings of helplessness ($p < 0.01$); only trends found for patients undergoing herniorrhaphy surgery.	Five-group RCT with repeated measures using two information groups and three information and exercise training groups; rated acceptable.
Postlethwaite, *et al.,* 1986[138] (Australia)	**Process expectancy** created by providing a description of post-operative pain experiences; **management self-efficacy** created by teaching patients how to cope with stress using relaxation and cognitive restructuring.	Coronary artery graft surgery	No effects for pain rating but trend for coping group to report more pain; no differences in presence of anxiety and depression but trend for coping group to report more of both; analgesic intake did not vary.	Three-group RCT, using no treatment as a control; rated poor.
Wilson, 1981[133] (USA)	**Process expectancy** created by providing information about surgical procedures, sensations and asking for medications; **management self-efficacy** created by teaching patients how to manage stress by relaxation.	Elective cholecystectomy and hysterectomy	Patients who had relaxation training made better recovery ($p < 0.05$) and had increased epinephrine outputs ($p < 0.03$); patients in all treatment groups discharged on average 1.01 days sooner ($p < 0.01$) than control group.	Four-group RCT, using normal hospital care as control; rated acceptable.

TABLE 2 contd Preparation for medical procedures: effects on health outcomes of process expectancy and management self-efficacy

Study (location)	Expectancy	Clinical area	Health outcomes	Type and quality of study
Ziemer, 1983[136] (USA)	**Process expectancy** created by providing a description of surgery and sensations experienced; **management self-efficacy** created by informing patients how to cope physically and psychologically postoperatively.	Gynaecological and gastrointestinal surgery	Linear relationship between physiological coping and pain intensity ($p < 0.03$) and distress ($p < 0.05$); linear relationship between psychological coping and pain intensity ($p < 0.04$) and distress ($p < 0.003$); accurate process expectancy does not affect outcomes by improving coping.	Three-group randomised trial, all treatment groups; rated acceptable.
Kendall, *et al.*, 1979[131] (USA)	**Process expectancy** created by procedural information; **management self-efficacy** created by training in cognitive-restructuring.	Cardiac catheterisation	Group given cognitive training maintained lower anxiety during procedure, based on self-report ($p < 0.01$), and rated as being more adjusted than education group by physician and technician ($p < 0.005$).	Four-group RCT, included attention placebo and control group who received normal hospital inform-ation; rated acceptable.
Langer, *et al.*, 1975[128] (USA)	**Process expectancy** created by providing a standard description of surgery; **management self-efficacy** created by teaching patients to cope with stress by cognitive structuring.	Variety of surgical procedures with favourable prognosis	No effect on BP and pulse; coping group reported greater relief from anxiety preoperatively ($p < 0.05$), dealing with stress ($p < 0.01$), and made lowest request for pain relievers and sedatives ($p < 0.04$); information alone did not affect outcomes.	2 x 2 RCT using normal hospital information as control; rated acceptable.
Ridgeway & Mathews, 1982[134] (UK)	**Process expectancy** created by providing a description (information group) of surgical procedures and sensations; **management self-efficacy** (CB group) created by teaching patients how to cope with stress using cognitive restructuring.	Elective hysterectomy (no malignancy and no vaginal hysterectomy)	CB group had fewer days of pain postoperatively ($p = 0.03$) and used less analgesics ($p < 0.05$); controls reported more pain ($p < 0.05$) after discharge. CB group reported fewest symptoms compared with both information and control groups ($p = 0.06$); CB and information groups showed trend towards reduced anxiety ($p = 0.06$); highest rating of information manual by information group ($p < 0.01$).	Three-group RCT, control general information about ward; rated acceptable.
Scott & Clum, 1984[137] (USA)	**Process expectancy** created by providing a description of surgery and experiences postoperatively; **management self-efficacy** created by training patients how to cope with stress and discomfort postoperatively using relaxation methods.	Cholecystectomy, abdominal and vaginal hysterectomy	Sensitisers in coping group reported less pain than sensitisers in information ($p < 0.05$) and information plus coping groups ($p < 0.05$); sensitisers in coping group less anxious ($p < 0.01$) than those in information plus coping group; personality was important in effects created by expectancies.	2 x 4 group RCT, control no special information or training; rated acceptable.

quality of the study was poor and therefore may not have adequately tested for the effects *(Table 3)*.

In the remaining five studies,[128,131,133,134,137] all of which were of an acceptable quality, the effects of information were successfully separated from those of training by treating the training programme as a separate treatment condition. Four studies[128,131,134,137] showed that management self-efficacy expectations produce better positive health outcomes when created alone than in combination with process expectancy. The effects reported were fewer requests for analgesics,[128,134] less anxiety,[128,131,134,137] less pain,[134,137] and better recovery/adjustment[128,131] *(Table 3)*. In the fifth study,[133] it was found that while only patients in the training group had a reduced hospital stay, all treated patients, compared with a control, were discharged earlier.

All five studies thus show the powerful effect of training as opposed to information on the benefits of preparing patients for surgery. However, Scott and Clum[137] found that training may only augment management self-efficacy in people with a sensitising coping style (i.e. people who are alert to threatening cues) but that people who cope using avoidance may be better left alone. However, Scott and Clum used only relaxation training so their comments may not generalise to training which uses other techniques for reducing stress such as cognitive restructuring. Any further research should include coping styles as an independent variable.

Process expectancy alone or in combination with other expectancies

There were five papers in which the creation of process expectancy only was identified,[142–146] one in which process and positive outcome expectancy were created together[147] and one in which process expectancy was combined with interaction self-efficacy[148] *(Table 4)*. Five of the studies were conducted in the USA and two in the UK.[143,147] All seven studies were clinically controlled trials, five of which were randomised (Rainey[148] was not and, in Andrew,[142] the design was not clear). Process expectancy was created by information which described specific procedures and post-operative sensations for major and minor surgery (including hernia surgery, elective laparoscopy), upper gastrointestinal endoscopy and radiotherapy.

TABLE 3 *Preparation for medical procedures: significant effects reported in at least four studies in which process expectancy and management self-efficacy were created*

Study	Fewer analgesics	Reduced hospital stay	Less pain	Less anxiety	Better recovery/ adjustment	Rating
Fortin & Kirouac, 1976[129]	$p < 0.025$ (i.m. meperidine)	No effect				Acceptable
Johnson, *et al.*, 1988[141]						Acceptable
Voshall, 1980[132]	$p < 0.025$ (days 3, 4, 5)	No effect	No effect			Poor
Weis, *et al.*, 1983[135]	$p < 0.05$			$p < 0.003$ s*		Poor
Wells, *et al.*, 1986[139]	$p = 0.08$		$p < 0.01$	$p < 0.002$ (pre- and postoperatively)	$p < 0.05$	Acceptable
Anderson, 1987[140]				$p < 0.02$ (preoperatively)	$p < 0.04$ (by day 7)	Acceptable
Egbert, *et al.*, 1964[127]	$p < 0.01$ (5 days postoperatively)	$p < 0.01$ (0.2 days)	✔	✔		Acceptable
Johnson, et al., 1978[130]	$p < 0.05$ (only process)	$p < 0.001$			$p < 0.001$	Acceptable
Postlethwaite, *et al.*, 1986[138]	No effect		No effect	No effect		Poor
Wilson, 1981[133]		$p < 0.01$ (1.01 days) (all treatment groups)			$p < 0.05$ (management self-efficacy only)	Acceptable
Ziemer, 1983[136]			No effect (process)	No effect (process)		Acceptable
Kendall, *et al.*, 1979[131]				$p < 0.01$	$p < 0.005$	Acceptable
Langer, *et al.*, 1975[128]	$p < 0.04$			$p < 0.05$ (preoperatively)	$p < 0.001$	Acceptable
Ridgeway & Mathews, 1982[134]	$p < 0.05$		$p = 0.03$ fewer days of pain	$p = 0.06$ (trend) both process and management self-efficacy		Acceptable
Scott & Clum, 1984[137]			$p < 0.05$ s*	$p < 0.01$ s*		Acceptable

✔ *Reported an overall statistical effect but no specific probability included*

s* *Sensitisers*

Process expectancy alone

In the five studies[142–146] in which process expectancy alone was created, the most frequently reported effect was a reduction in anxiety. However, in two studies[144,145] coping style was manipulated and found to have an important bearing on the outcomes, with sensitisers being the main beneficiaries. Other effects included a reduction in the use of analgesics[146] and, in patients whose coping style was neutral, a reduced hospital stay. Two studies were rated as being of poor quality,[142,143] in one of which fewer subjects who were rated as avoiders used analgesics[142] *(Table 5)*.

Process expectancy combined with interaction self-efficacy

A study in which process expectancy was combined with interaction self-efficacy[147] showed that by the end of therapy patients also reported less anxiety *(Table 5)*. However, it was rated poor in quality.

Process expectancy combined with positive outcome expectancy

Finally, in the study in which process expectancy was combined with positive outcome expectancy,[148] a reduction in anxiety was reported in patients who received the intervention together with a reduction in hospital stay and a shorter period of pyrexia *(Table 5)*. There was no increase in mobilisation despite the fact that this aspect was being targeted.

Economic assessments in all process expectancy studies

Despite the resource implications of preparatory interventions, the study by Wells and colleagues[139] *(Table 3)* is the only one in the above sample to explicitly consider financial ramifications by calculating that stress inoculation results in a net saving of \$650 per patient (at 1986 prices). The majority of studies use medication intake or length of hospital stay as outcome measures but omit to convert these into economic issues.

TABLE 4 *Preparation for medical procedures: effect on health outcomes of creating process expectancy alone or with other expectancies and pre-existing expectancies*

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Process expectancy alone				
Andrew, 1970[142] (USA)	Process expectancy created by providing a description of pre- and postsurgical procedures.	Hernia surgery, minor surgery and other non-surgical treatment	Prepared patients fewer days in hospital ($p < 0.05$), fewer medications ($p < 0.05$); prepared avoiders fewer medications ($p < 0.05$); neutral patients fewer days ($p < 0.05$), fewer medications ($p < 0.05$); no significant findings for sensitisers.	Two-group clinical controlled study, control no preparation prior to surgery; quality rating poor.
Leigh, *et al.,* 1977[143] (UK)	Process expectancy created by description of pre- and postoperative experiences.	Immediate surgery	Postoperative outcome anxiety reduced in patients visited by anaesthetist assistant ($p < 0.01$) and in those who received booklet ($p < 0.02$), although less than former group; even less reduction in control group.	Three-group observational study, no specific information as control; quality rating poor.
Reading, 1982[146] (USA)	Process expectancy created by providing information about surgery and how the patient would feel.	Elective laparoscopy	Information group used less analgesics than placebo or control groups ($p < 0.05$); no difference between groups in expectations of pain; also, less anxious patients with less pain reported more rapid recovery, indicating influence of anxiety on outcomes.	Three-group RCT with a factor for anxiety, one group a placebo attention and control no intervention; quality rating acceptable.
Shipley, *et al.,* 1978[144] (USA)	Process expectancy created by description of endoscopy procedure and sensations.	New patients awaiting upper-gastrointestinal endoscopy	E3 group (three viewings of tape) had lower increase in heart rate than E1 (one viewing) ($p < 0.01$) and E0 groups ($p < 0.05$) during procedure; physician–nurse ratings of anxiety in E3 ($p < 0.025$) or E1 ($p < 0.05$) groups less than controls; patient self-reports of anxiety greater when not prepared than when prepared once ($p < 0.05$) or three times ($p < 0.05$); post-endoscopy E1 and E3 sensitisers reported less anxiety ($p < 0.025$).	Three-group RCT with two factors for personality, control no viewing of tape; quality rating acceptable.
Shipley, *et al.,* 1979[145] (USA)	Process expectancy created by description of endoscopy procedure and sensations.	Patients with previous experience awaiting a further upper-gastrointestinal endoscopy	First 5 minutes: higher heart rate in E0 group than E3 ($p < 0.025$); E3 repression, greater in heart rate than E0 ($p < 0.05$); no increase overall effects on anxiety as rated by patients; physician–nurse ratings of anxiety showed E3 less anxious than E0 and E1 groups during procedure ($p < 0.025$), and E3 sensitiser less anxious than E0 after ($p < 0.05$); no comparisons between repressors significant.	Three-group RCT with two factors for personality, control group no viewing of tape; quality rating acceptable.
Process expectancy plus interaction self-efficacy				
Rainey, 1985[147] (USA)	Process expectancy created by describing radiotherapy, treatment setting, procedures and what patient will experience; interaction self-efficacy by encouraging information seeking.	Cancer patients undergoing radiotherapy for the first time	After intervention but before therapy, treatment group better knowledge group ($p < 0.001$); at end of therapy, treatment group less anxiety ($p < 0.05$) and lower mood disturbance ($p < 0.005$).	Two-group controlled trial, no randomisation, control current departmental procedures; quality rating poor.
Process expectancy plus positive outcome expectancy				
Evans & Richardson, 1988[148] (UK)	Process expectancy created by describing surgery and sensations; positive outcome expectancy by information about treatment success, both created during anaesthetic.	Total abdominal hysterectomy	Treatment group made better than expected recovery ($p < 0.002$), reported reduced gastrointestinal problems ($p < 0.03$), and had a shorter period of pyrexia ($p < 0.005$); treatment group spent less time in hospital ($p < 0.005$).	Two-group RCT, control group listened to blank tape; quality rating acceptable.
Pre-existing outcome expectancies and management self-efficacy				
Barry-Flood, *et al.,* 1993[150] (UK)	Positive outcome expectancy created by patient's belief that surgery would lead to cure.	Prostate surgery	Patients reported better recovery after surgery when cure expected ($p = 0.036$); improvement persisted for a year postoperatively.	Longitudinal observational study; quality rating acceptable.

TABLE 4 contd Preparation for medical procedures: effect on health outcomes of creating process expectancy alone or with other expectancies and pre-existing expectancies

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Pre-existing outcome expectancies and management self-efficacy contd				
Oetker-Black, *et al.,* 1992[149] (USA)	Positive outcome expectancy created by patient's belief that activity would improve recovery after surgery; management self-efficacy by belief in ability to perform postoperative exercises.	Cholecystectomy	Higher management self-efficacy produces better performance on deep breathing and walking ($p < 0.05$); higher positive outcome expectancy produced more requests for pain medication ($p < 0.05$).	Observational study; quality rating poor.
Perry, *et al.,* 1994[151] (USA)	Negative outcome expectancy created by patient's expectation of pain; management self-efficacy by belief in ability to be in control.	Simple abdominal hysterectomy	Higher pain expectation produces more reported pain ($p < 0.045$) but less sensory pain ($p < 0.05$). Those with more self-control needed more medication ($p < 0.02$) and made more requests for drugs ($p < 0.016$).	Observational study: quality rating acceptable.

TABLE 5 Preparation for medical procedures: significant effects reported in studies creating process expectancy alone or in combination with other expectancies

Study	Fewer analgesics	Less anxiety	Rating
Andrew, 1970[142]	$p < 0.05$ (avoiders)		Poor
Leigh, *et al.,* 1977[143]		$p < 0.01$ anaesthetic assistant; $p < 0.02$ booklet	Poor
Reading, 1982[146]	$p < 0.05$	No effect	Acceptable
Shipley, *et al.,* 1978[144]		$p < 0.025$ (3 times); $p < 0.05$ (once); $p < 0.025$ sensitisers post-endoscopy	Acceptable
Shipley, *et al.,* 1979[145]		$p < 0.025$ (3 times) sensitisers	Acceptable
Rainey, 1985[147]		$p < 0.05$ end of therapy	Poor
Evans & Richardson, 1988[148]			Acceptable
Barry-Flood, *et al.,* 1993[150]			Acceptable
Oetker-Black, *et al.,* 1992[149]	$p < 0.05$ (positive outcome expectancy)		Poor
Perry, *et al.,* 1994[151]	$p < 0.016$ (management self-efficacy)		Acceptable

Studies of pre-existing outcome expectancies and management self-efficacy

Three studies investigated the effects of patients' pre-existing positive and negative outcome expectancy and management self-efficacy on post-operative behaviour[149–151] *(Table 4)*. All three were observational studies; two were conducted in the USA and one in the UK. Two were acceptable in quality and one[149] was rated poor.

One study[149] investigated the relationship between patients' self-assessment of their performance of post-operative exercises (management self-efficacy), their belief in the effectiveness of their behaviour (positive outcome expectancy) and their postoperative behaviour. The results of the study showed that management self-efficacy improved performance on postoperative exercises but higher positive outcome expectancy was associated with an increased request for medications *(Table 5)*. In a second study,[151] an association was reported between management self-efficacy and increased level of requests for analgesics, and between a negative outcome expectancy created by a belief that an increase in pain will be experienced and the amount of pain experienced *(Table 5)*. The third study[150] found that patients with a positive outcome expectancy, created by a belief that they will be cured, reported a better recovery from surgery *(Table 5)*.

Economic assessments

The studies in this group did not involve interventions that manipulated patients' expectancies but rather measured baseline expectancy levels and investigated the direct relationship between these and health outcomes. No cost data were provided.

Summary and methodological quality

All studies reviewed above reported positive health outcomes when patient expectancy is created during preparation for medical procedures as follows.

- In 13 studies the effects of creating **process expectancy** alone were reported, of which only five (38%) reported a reduction in anxiety, two (15%) a reduction in hospital stay and one the use of fewer analgesics and better recovery.
- In 11 studies the effects of creating **process expectancy and management self-efficacy** in combination was reported, of which eight (73%) reported a reduction in the use of analgesics, seven (64%) a reduction in anxiety, six (55%) a better recovery, four (36%) less pain and three (27%) a reduction in hospital stay.
- Five studies reported the effects of creating **management self-efficacy** alone, of which four (80%) reported less anxiety, two (40%) fewer use of analgesics and less pain, and one a reduction in hospital stay.

These results thus suggest that management self-efficacy, when created alone, is most likely to reduce patient anxiety. Its effect appears to be moderated when combined with process expectancy, possibly because process expectancy appears to be the least effective of the three programmes. Overall, however, the studies suggest that a combined programme will produce the greatest number of positive health outcomes. The benefit of preparation for patients is an enhancement of the quality of their hospital experience (less anxiety, better recovery and less pain), with the caveat that personality may counteract the effect. For the NHS there are potential cost savings (less use of analgesics and reductions in the length of hospital stay).

In terms of methodological quality, studies were rated as poor in quality for the following reasons. Weis and colleagues[135] did not randomise subjects to treatment groups, the groups were not comparable in terms of the medical procedures to be undergone and the different groups were processed at different times of the year. Thus, there was serious confounding. Voshall[132] and Andrew[142] supplied insufficient methodological detail; for example, no information on whether groups were comparable at baseline was given. The study by Leigh and colleagues[143] was small (32 subjects in three groups) and did not randomise subjects to groups. Rainey[147] did not randomise subjects to groups which were heterogeneous. Oetker-Baker and colleagues[149] performed multiple testing of

hypotheses and while some statistically significant correlations were found, they were small in magnitude, leading to rather weak results.

Expectancies created by interventions for managing illness

All 40 studies reviewed in this section addressed the management of illness. Many of them examined patient-centred management of chronic illness, and a number were concerned with patients seeking care from their general practitioner (GP) for a variety of conditions. A small minority dealt with care for acute conditions. The studies were categorised according to the type of expectancy examined.

The largest category was concerned with studies of management self-efficacy, either alone or in combination with other types of expectancy. There were 16 studies that addressed management self-efficacy;[126,152–166] 14 studies were conducted in the USA, one in Canada[165] and one in Israel.[157]

Five studies addressed management self-efficacy in combination with positive outcome expectancies[167–171] and two in combination with process expectancy.[172,173] Four of these studies were conducted in the USA, two in the UK[170,172] and one in Australia.[173]

It should be noted that management self-efficacy necessarily incorporates positive outcome expectancies, in the sense that trainers will convey the belief that undertaking good self-management will have beneficial effects on health. Only where explicit mention was made of enhancing positive outcome expectancy has this been separated from management self-efficacy for review purposes. The defining feature of management self-efficacy is that it is achieved through acquiring confidence in specific behavioural skills, such as relaxation, food choices, and exercising. However, only four studies actually measured changes in self-efficacy or sense of control;[126,157,161] for the remainder, it has been assumed that the interventions affected patients' beliefs about their ability to manage or cope with their health problems.

In 15 studies the effects of aspects of patient–provider interactions on health outcomes were examined.[84,174–187] These studies typically related aspects of the interactions coded from audiotape to a variety of subjective and objective outcomes. Eight were conducted in the USA, three in Canada and one each in the UK, Mexico, Poland and Sweden.

Finally, three studies[188–190] addressed positive outcome expectancy only, either by assessing patients' pre-existing levels of positive outcome expectancy, or by examining the effects of manipulating the doctor's positive outcome expectancy.[188] Two studies were conducted in the UK and one in the USA.[189]

Management self-efficacy

Without exception, the 16 studies in this group *(Table 6)*,[126,152–166] all demonstrated the beneficial effects of enhancing management self-efficacy for health outcomes, both subjective and objective, across a range of conditions including arthritis, chronic pain, post-traumatic headache, myocardial infarction, seasickness, Parkinson's disease, and hypertension. These studies all involved training patients in specific behaviours and or skills to manage their health problems. The studies included RCTs, pre/post assessment with no control group, and one matched-pairs design. Four studies were rated poor in quality.[154,155,156,162] Nevertheless the consistency of the findings overall is a powerful demonstration of the effectiveness of these self-management interventions for improving health outcomes.

Significant beneficial effects were obtained on subjective and objective health outcomes. The most frequently reported benefits were fewer symptoms such as loss of weight,[162] improved mood,[155] prevented depression,[152] reduced pain,[126] better control of asthma symptoms[153] and less seasickness.[157] A number of studies also reported an improvement in disease status in terms of lowered blood pressure,[159] immunological changes,[152] and physicians' ratings of health status.[153] Finally, in four studies[126,154,158,165] a reduction in the use of health services was reported *(Table 7)*.

Management self-efficacy and positive outcome expectancy or process expectancy

In five studies[167–171] the interventions created both management self-efficacy and explicitly created positive outcome expectancies *(Table 8)*. In two of these studies[170,171] there was no attempt to separate systematically the effects of these types of expectancy. However, the remaining three studies[167–169] distinguished between the effects of creating management self-efficacy and creating positive outcome expectancies. These studies indicated that positive outcome expectancy alone is not as beneficial for health outcomes as when it is combined with learning specific skills and, hence, increasing management self-efficacy.

Clinical conditions included insomnia, hypertension and mild depressive illness. No single benefit emerged from this group of studies, indicating the heterogeneity of effects (see *Table 9*) but significant effects were reported for both subjective and objective outcomes. The subjective outcomes included self-reported sleep-onset latency[167] and reduced distress from symptoms.[168] Objective outcomes included reduced office visits,[168] reductions in blood pressure,[169,171] and reductions in depressive symptom ratings.[170]

Two further studies in this group[172,173] were concerned with the management of the acute phase of myocardial infarction *(Table 8)*. Interestingly, the healthcare problem addressed is comparable to preparation for medical procedures and, accordingly, the expectancy involved is process expectancy. In these studies, interventions were evaluated that involved creating both accurate expectancies about the experience of hospitalisation for myocardial infarction and management self-efficacy. Both[172,173] showed the interventions to have beneficial effects (one over 5 days and one over 12 months) on self-reported reduction in anxiety levels *(Table 9)*. One of the studies[173] showed beneficial effects on lifestyle sustained at 12 months (smoking, alcohol, and workload); however, it was rated poor in quality and thus the results need to be treated with caution.

Economic assessments

In seven of the above studies health service cost implications were calculated to some degree,[126,154,156,161,163,168,170] and in a further five, utilisation without assessing the associated cost implications was considered.[153,158,160,165,173] In two studies[154,163] financial outcomes were considered exclusively and in the study by Robinson and colleagues[158] only utilisation was considered. However, none of the studies included either the private or productivity-related costs and benefits or undertook a careful, detailed appraisal utilising rigorous economic techniques in accordance with BMJ guidelines.[191–194]

Of the studies calculating health service cost implications, Caudill and colleagues,[154] Hellman and colleagues,[168] Lorig and colleagues,[126] and Simmons and colleagues[163] recorded net savings associated with the interventions. Medina[156] argued (without detailed supporting evidence) that the cost of post-traumatic headache treatment is good value given the chronic nature of the illness, the cost of other pain management programmes and the large proportion of participants returned to the workforce. Scott and Freeman[170] claimed, although

TABLE 6 Managing illness: effect on health outcomes of creating management self-efficacy alone or with other types of expectancy

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Antoni, *et al.*, 1991[152] (USA)	Management self-efficacy created by training in CB stress management and progressive muscle relaxation.	Homosexual men unaware of HIV status until end of intervention	Seropositive men in intervention group showed pre/post increases in some immune markers ($p < 0.01$), and no increases in pre/post depression ($p < 0.03$) compared with controls.	Two-group RCT, control men assessed only; quality rating acceptable.
Caudill, *et al.*, 1991[154] (USA)	Management self-efficacy created by behavioural medicine intervention.	Chronic pain patients in a health maintenance organisation	In pre/post comparisons, intervention resulted in reduction in clinic visits ($p < 0.001$) from average of 1.07 per month before intervention to average of 0.68/0.58 per month 1–2 years after intervention.	Before/after observational study; quality rating poor.
Eden & Yaakov, 1995[157] (Israel)	Management self-efficacy created by vicarious experience for managing sea-sickness.	Sea-sickness	Experimental group had less sea-sickness and better performance ($p < 0.01$); trend for experimental effects to be stronger in those with lower initial self-efficacy.	Two-group RCT, control only given general information on sea-sickness; quality rating acceptable.
Fawzy, *et al.*, 1993[166] (USA)	Management self-efficacy created by training in stress management and cognitive restructuring with education in the clinical problem.	Patients with stage I and II malignant melanoma receiving some form of active treatment	Fewer deaths ($p = 0.03$) and trend for lower rate of recurrence ($p = 0.09$) in intervention group; increase in coping scores in first 6 months related to survival ($p = 0.03$) and trend apparent for lower rates of recurrence ($p = 0.06$).	Two-group RCT; control no intervention; quality rating acceptable.
Klerman, *et al.*, 1987[155] (USA)	Management self-efficacy created by learning coping skills during interpersonal counselling.	Stress and distress in primary care (health maintenance organisation) patients	Patients receiving counselling had fewer symptoms post-treatment, especially improved mood, than control group ($p < 0.01$).	Two-group matched pairs study; quality rating poor.
Lorig, *et al.*, 1993[126] (USA)	Management self-efficacy created by a taught programme of exercises, relaxation (behaviours) and problem-solving.	Chronic arthritis	At 4 months reduction in pain and depression ($p < 0.05$), increase in taught behaviours ($p < 0.01$), and trend towards reduced frequency of physician visits compared with controls; apart from depression, improvements sustained over 4 years despite 9% rise in disability; self-efficacy improved as time passed.	Two-group longitudinal observational study; controls were patients whose medical care was provided by their personal physicians; quality rating acceptable.
Medina, 1992[156] (USA)	Management self-efficacy created in an individualised outpatient programme which included symptom management.	Disabling, chronic, post-traumatic headache	All patients showed improvement.	Observational study; quality rating poor.
Mercer, 1996[160] (USA)	Management self-efficacy created by participation in the PROPATH programme, developed by Healthtrac Inc., which provides education, assessment and reports.	Parkinson's disease	Pre/post improvement in perceptions of general health and well-being after 1 year ($p = 0.04$), declined for controls; physician ratings of patient health changes did not differ significantly between groups.	Two-group RCT, control usual care; quality rating acceptable.
Montgomery, *et al.*, 1994[161] (USA)	Management self-efficacy created by participation in the PROPATH programme (Healthtrac Inc.) which provides education, assessment and reports.	Parkinson's disease	After 6 months intervention group had lower rate of progression of disease ($p = 0.03$), more self-reporting of Parkinson's exercise programme ($p = 0.006$) and reduced numbers of side-effects ($p = 0.0.4$), a trend of fewer visits to doctor per 6 months ($p < 0.06$), and increased self-efficacy ($p < 0.05$) relative to control group.	Two-group RCT, control enrolled patients who received programme after the trial was completed; quality rating acceptable.
Morisky, *et al.*, 1983[162] (USA)	Management self-efficacy created by three-phase education programme.	Hypertension	Education programme resulted in improvements on subjective and objective outcomes, including all-causes 5-year mortality rate ($p < 0.05$) and obesity ($p < 0.04$) relative to control conditions.	RCT using a factorial design, control no treatment; quality rating acceptable.
Parker, *et al.*, 1988[164] (USA)	Management self-efficacy created by CB treatment compared with attention-placebo and control groups.	Rheumatoid arthritis	Patients receiving CB treatment significantly improved coping over 12-months follow-up ($p < 0.0017$ at 6 months, $p = 0.0001$ at 12 months) relative to controls, no effect on disease status or other measures.	Three-group RCT, one group attention-placebo, control routine care and no follow-up; quality rating acceptable.

TABLE 6 contd *Managing illness: effect on health outcomes of creating management self-efficacy alone or with other types of expectancy*

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Philips, 1987[165] (Canada)	Management self-efficacy created by CB treatment.	Chronic pain	Apart from behavioural measure of pain, reduction on all subjective measures of pain, depression, life impact and feeling in control ($p < 0.05$), increase in self-efficacy ($p = 0.002$), fall in perceived size of problem ($p = 0.001$) and reduction in medication use (85%).	Two-group RCT, waiting list control; quality rating acceptable.
Robinson, *et al.*, 1989[158] (USA)	Management self-efficacy created by training parents in how to cope with childhood fever.	Children attending 'out-of-hours' paediatric clinic	At 8 months children whose parents had received training had fewer acute clinic visits than controls ($p < 0.001$) and fewer irrespective of the season of year ($p < 0.001$).	RCT, control no viewing of videotape; quality rating acceptable.
Simmons, et al., 1988[163] (USA)	Management self-efficacy created by training programmes which included physical and occupational therapy, cognitive restructuring, behaviour modification, relaxation, biofeedback aquatics and nutritional education.	Chronic pain out-patients; mean duration 3 years	Training led to significant cost savings ($p < 0.01$). Average reduction in medical costs of $8469 (59%) and surgical costs of $7688 (58%).	Before/after observational study; quality rating poor.
Stuart, *et al.*, 1987[159] (USA)	Management self-efficacy created by a behavioural intervention.	Hypertension	Significant reductions in mean clinic and home systolic BP ($p < 0.0001$), mean clinic diastolic ($p < 0.0001$), mean home diastolic ($p < 0.0005$), cholesterol ($p = 0.009$), triglycerides ($p = 0.015$), deviations from ideal weight ($p < 0.0001$) and body fat percentages ($p < 0.001$).	Observational study; quality rating poor.
Wilson, *et al.*, 1993[153] (USA)	Management self-efficacy created either by group or individual self-management education, positive outcome expectancy created by information condition.	Asthma	Compared with information only and usual care patients, more patients in education groups were less bothered by symptoms ($p = 0.03$); all treatment groups had improved asthma status at 5 months ($p = 0.03$) and 1 year ($p = 0.04$), and fewer symptomatic days ($p = 0.025$) compared with controls.	Four-group RCT, control usual care and no formal asthma education; quality rating acceptable.

TABLE 7 *Managing illness: significant effects reported in at least four studies creating management self-efficacy expectations*

Study	Fewer symptoms	Improvement in disease status	Less use of services	Rating
Antoni, *et al.*, 1991[152]	$p < 0.03$ (did not increase depression)	$p < 0.01$ (immunological changes)		Acceptable
Caudill, *et al.*, 1991[154]			$p < 0.001$	Poor
Eden & Yaakov, 1995[157]	$p < 0.01$ (sensitisers)			Acceptable
Fawzy, *et al.*, 1993[166]				Acceptable
Klerman, *et al.*, 1987[155]	$p < 0.01$			Poor
Lorig, *et al.*, 1993[126]	$p < 0.01$ (pain)		$p < 0.05$	Acceptable
Medina, 1992[156]				Poor
Mercer, 1996[160]				Acceptable
Montomery, *et al.*, 1994[161]		✔		Acceptable
Morisky, *et al.*, 1983[162]	$p < 0.04$ (obesity)			Acceptable
Parker, *et al.*, 1988[164]				Acceptable
Philips, 1987[165]			85%	Acceptable
Robinson, *et al.*, 1989[158]			$p < 0.001$	Acceptable
Simmons, *et al.*, 1988[163]				Poor
Stuart, *et al.*, 1987[159]		BP		Acceptable
Wilson, *et al.*, 1993[153]	$p < 0.03$ (asthma)	✔ $p < 0.03$ at 5 months		Acceptable
✔ *Reported an overall statistical effect but no specific probability included*				

TABLE 8 *Managing illness: effect on health outcomes of management self-efficacy either with positive outcome expectancy or process expectancy*

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Carr-Kaffashan & Woolfolk, 1979[167] (USA)	Positive outcome expectancy created by clinical psychologist's belief in success of treatment; management self-efficacy by training in coping with symptoms.	Moderate and severe insomnia	Training-only group improved ($p < 0.001$) more during first 3 weeks (counter-demand period) than placebo group, but no difference after introduction of positive expectancy of therapy.	2 x 2 RCT, control attention placebo treatment; quality rating acceptable.
Goebel, *et al.,* 1993[169] (USA)	Positive outcome expectancy created by practitioner's belief in success of treatment; management self-efficacy by training in bio-feedback, relaxation and taking BP.	Borderline to moderate hypertension	All training groups reduced BP ($p < 0.001$) more than control group, despite creation of positive outcome expectancy in all groups.	Five-group repeated measures RCT, control transactional analysis, reading only and no skills training; quality rating acceptable
Hellman, *et al.,* 1990[168] (USA)	Positive outcome expectancy created by information that programme would be beneficial; management self-efficacy by training in relaxation, awareness and cognitive restructuring.	Volunteers with 'psychosomatic' dysfunction; high health users	Both treatment groups reported greater reduction in physical symptoms ($p < 0.01$), decline in psychological distress ($p < 0.05$) and average of 2.8 fewer visits per person to Harvard Community Health Plan ($p < 0.001$) than control group.	Three-group RCT, control received an intervention but did not practise techniques that they were told about; quality rating acceptable.
Powers & Wooldridge, 1982[171] (USA)	Positive outcome expectancy created by telling patients of treatment's success and importance of following doctor's instructions; management self-efficacy by training in taking BP.	Essential hypertension	No significant effects reported.	Two-group factorial randomised experiment, no control; quality rating acceptable.
Scott & Freeman, 1992[170] (UK)	Positive outcome expectancy created by telling patient to expect an improvement; manage-ment self-efficacy by training in cognitive restructuring.	Mild to moderate depressive illness	After 16 weeks all specialist treatment groups improved significantly ($p < 0.001$); patients evaluated social work counselling more positively than psychiatrist treatment and GP care ($p < 0.05$); cost of specialist treatments calculated and claimed not to be commensurate with their clinical superiority over routine GP care.	Four-group RCT, control routine GP care, including drugs and referral as required; quality rating acceptable.
Oldenburg, *et al.,* 1985[173] (Australia)	Process expectancy created by information about illness and risk factors; management self-efficacy by training in relaxation and behavioural strategies for changing risk factors.	First myocardial infarction	At 12 months both treatment groups reported improvement in psychological functioning ($p < 0.05$); counselling group better at maintaining healthy life style ($p < 0.05$). No differences in use of health services or physical symptoms.	Three-group RCT, control no treatment; quality rating poor.
Thompson, 1989[172] (UK)	Process expectancy created by information about experience of illness and hospitalisation; management self-efficacy created by training in coping with primary and secondary risk factors and problem solving.	First myocardial infarction	Treatment group experienced lower levels of anxiety ($p < 0.005$) and depression ($p = 0.01$) compared with controls over 5 days.	Two-group RCT, control received routine hospital care; quality rating acceptable.

TABLE 9 *Managing illness: significant effects reported in at least three studies creating management self-efficacy with positive outcome or process expectancy*

Study	Improved psychological status	Rating
Carr-Kaffashan & Woolfolk, 1979[167]		Acceptable
Hellman, *et al.,* 1990[168]	$p < 0.05$ (less distress)	Acceptable
Powers & Wooldridge, 1982[171]		Acceptable
Scott & Freeman, 1992[170]		Acceptable
Goebel, *et al.,* 1993[169]		Acceptable
Oldenburg, *et al.,* 1985[173]	$p < 0.05$ at 12 months	Poor
Thompson, 1989[172]	$p < 0.05$ (anxiety) (over 5 days); $p < 0.01$ (depression) (over 5 days)	Acceptable

with little hard supporting evidence, that the extra costs (largely of time afforded to patients) of specialist care for depressed patients, compared with general practice care, are not commensurate with the marginal health benefits, although it was suggested that GP costs were underestimated in the analysis.[170] Simmons and colleagues[163] presented evidence of significant cost reductions associated with initiating earlier, rather than later, treatment of chronic pain conditions.

Of the studies looking at utilisation implications, Oldenburg and colleagues[173] found no utilisation effects of a cardiac intervention, although in investigations in other clinical areas fewer office visits are recorded after interventions than before them,[153,158] or less medication,[165] or both.[161] The latter finding, however, is challenged in a different study of the same intervention.[160]

Interaction self-efficacy
Patients' contribution
In four studies[175,177,179,181] (see *Table 10),* the patients' contribution to the consultation was considered. Each study evaluated interventions to change provider–patient interactions in consultations for chronic illness (e.g. ulcers, diabetes). All demonstrated some beneficial effects of brief interventions to activate or empower patients to ask more questions during a consultation. Improvements in both self-reported health status and objective measures were obtained in all four studies.[175,177,179,181] Objective measures showed an improvement in disease state which included blood glucose control[175,181] and improved functional ability[175,177,179,181] *(Table 11).*

Providers' contribution
In 11 studies, elements of the providers' contribution to the consultation were considered (see *Table 10).* There were seven studies which demonstrated that doctor–patient agreement in the doctor–patient consultation was associated with health benefits.[182–187] In four studies it was shown that such agreement may come about through giving the patient more opportunity to speak or ask questions;[182,184–186] this agreement may be associated with interaction self-efficacy and positive outcome expectancy. In another study[178] the beneficial effects of agreement, in the form of confirmation of a problem by the doctor and reassurance that treatment is available, was demonstrated for mild psychiatric problems without the patients even receiving the treatment. Two further studies found that more exposition from the doctor may also lead to better outcomes,[84,174] perhaps because patients feel increased interaction self-efficacy by the degree to which the doctor is responding to their problem.

In one study it was reported that doctors' awareness of patients' problems was associated with patients' perceptions of recovery;[176] this suggests the importance for subjective health outcomes of patients having the opportunity to communicate their concerns. In the final study in this group, it was reported that doctors showed that when patients were not given the opportunity to have a full exchange because a nurse was controlling them, the outcomes were poorer.[180]

Summary
These 15 studies of patient–provider consultation, most of which addressed chronic illness, suggest that there are health benefits either from interactions in which the patient is trained to ask questions or as a consequence of the provider giving the patient more opportunity to present his or her problem, confirming the problem and giving reassurance that the problem can be treated. The most frequently reported effects were an improvement in the patient's symptoms,[174,178,180,183–186] and an improvement in the patient's disease state[180,185] *(Table 11).* The patient–provider interaction is a primary source of expectancy but further studies are needed to investigate whether, in fact, the creation of appropriate expectancies through asking questions and receiving explanations is the mechanism that results in better health outcomes. Also, eight of the 11 studies covering provider contribution were rated poor in quality; hence, the findings can only be seen as tentative.

Interaction self-efficacy: economic assessments
Of the 15 studies[174–187] reviewed above, three studies[175,177,179] which investigated the effects of an increase in patient questions reported improved health outcomes but no increase in consultation time. Given the heavy personal and economic burden of chronic disease, and the potential benefits associated with increasing patient involvement in care suggested by these studies, there is a need for a full economic analysis of this issue. As these studies were all conducted in the USA there is also a need for it to be conducted in the UK context. None of the other 11 studies considered the effects of health outcomes on health utilisation. No cost data were provided.

Positive outcome expectancy
Two studies[189,190] examined patients' levels of positive outcome expectations for treatment *(Table 12).* One study was concerned with headache[189] and found no link between pre-treatment expectancy and headache improvement. The other study[190] showed that belief in treatment

TABLE 10 *Managing illness: effect on health outcomes of creating interaction self-efficacy*

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Patient contribution				
Greenfield, *et al.,* 1985[177] (USA)	Interaction self-efficacy created by encouraging patient involvment in decision making.	Peptic ulcer	Patients in intervention group reported fewer limitations imposed by peptic ulcer on functional ability ($p < 0.05$) and role limitations ($p < 0.05$).	Two-group RCT, control usual education on ulcer disease management; quality rating acceptable.
Greenfield, *et al.,* 1988[175] (USA)	Interaction self-efficacy created by empowering patients to seek information and negotiate treatment during the consultation.	Diabetes	Patients in intervention group reported fewer functional daily living limitations ($p < 0.01$) than controls and their mean HbA_1 decreased ($p < 0.01$) and differed ($p < 0.01$) from that in the control group.	Two-group RCT, control standard educational materials provided in sessions of equivalent length; quality rating acceptable.
Kaplan, *et al.,* 1989[179] (USA)	Interaction self-efficacy created by teaching patients how to ask questions and negotiate medical decisions.	Hypertension and post-mastectomy breast cancer	Intervention group reported reduced functional limitations ($p < 0.05$); fewer days lost from work, fewer health problems and functional limitations associated with more patient involvement in consultation at baseline ($p < 0.05$).	Two RCTs, control usual education about disease management; quality rating acceptable.
Rost, *et al.,* 1991[181] (USA)	Interaction self-efficacy created by training in information-seeking and being involved in decision making.	Adult insulin-dependent diabetes with poor metabolic control	Treatment group reported fewer physical functional limitations ($p < 0.02$) and improved metabolic control ($p < 0.02$) 4 months after discharge.	Two-group RCT, control not reported in paper; quality rating acceptable.
Provider contribution				
Bass, *et al.,* 1986[183] (Canada)	Interaction self-efficacy created by encouraging patients to be involved in decision making.	New episode of range of symptoms in primary care	Symptom resolution best predicted by agreement between doctor and patient ($p < 0.001$); presenting problem best predictor of outcome if doctor recorded no psychosocial care required ($p < 0.05$).	Observational study; quality rating poor.
Finkler & Correa, 1996[84] (Mexico)	Interaction self-efficacy created by doctor responding to patient's problems and encouraging questions during consultation.	Internal medicine patients	Patient perception of recovery correlated with doctor's accurate description of problem ($p < 0.01$), gave a diagnosis ($p < 0.005$), patient asked questions ($p < 0.05$) and patient agreed with doctor's diagnosis ($p < 0.05$).	Observational study; quality rating poor.
Heszen-Klemens & Lapinska, 1984[182] (Poland)	Interaction self-efficacy created by giving patient more opportunity to speak and ask questions.	New out-patients with gingivitis catarrhalis, pulmonary tuberculosis and coronary heart disease	Patient-initiated health activity related to degree of patient involvement in consultation ($p < 0.05$) and treatment outcome ($p < 0.05$). Important component of involvement is information exchange ($p < 0.05$).	Observational study; quality rating poor.
Kellner & Sheffield, 1971[178] (UK)	Interaction self-efficacy created by psychiatrist confirming patients' problems and providing reassurance that treatment available.	Anxiety, depression and psychological symptoms continuously for over 6 months	Patients with anxiety and depression reported difference in level of distress ($p < 0.01$) and patients with psycho-physiological problems reported difference in psychosocial symptoms ($p < 0.05$) between beginning and end of first waiting period; no significant differences in self-rating in other waiting periods.	Two-group observational study, no control; quality rating poor.
Olsson & Tibblin, 1989[174] (Sweden)	Interaction self-efficacy created by doctor spending time talking to patients and responding to their problems.	Acute tonsillitis	Greater improvement in throat symptoms in treatment group ($p < 0.005$) than in control group.	Two-group RCT, control received routine examination, less information and pre-printed prescription; quality rating acceptable.
Orth, *et al.,* 1987[185] (USA)	Interaction self-efficacy created by patients being encouraged to ask questions and given an opportunity to voice concerns.	Essential hypertension (community care)	Greater expression correlated with reduction in systolic and diastolic BP taken at home ($p < 0.05$) compared with clinic; better explanations by GP correlated with lower diastolic BP at home ($p < 0.05$).	Observational study; quality rating poor.

TABLE 10 contd Managing illness: effect on health outcomes of creating interaction self-efficacy

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Provider contribution contd				
Putnam, *et al.,* 1985[186] (USA)	Interaction self-efficacy created by encouraging patients to discuss their problems during consultation.	Women first-time attenders at a medicine walk-in hospital clinic	More symptom improvement over 1 week in patients who gave more details of medical history ($p < 0.05$), although this disappeared after controlling for initial symptom status (tendency for patients with more disabling symptoms to give more details; almost all patients symptom-free at week 1).	Observational study; quality rating poor.
Starfield, *et al.,* 1981[187] (USA)	Interaction self-efficacy created by an agreement between doctor and patient about nature and severity of problem.	Follow-up appoint-ments in primary care (including ear infections, fatigue, rashes, hypertension, diabetes, pain)	More improvement recorded by doctor when both patient and doctor had recognised the problem ($p = 0.02$), regardless of severity.	Observational study; quality rating poor.
Stewart, *et al.,* 1979[176] (Canada)	Interaction self-efficacy created by doctor's awareness of patients' problems.	Chronically ill patients, including hypertension, arthritis, diabetes, stroke, congestive heart failure, peptic and venous ulcers)	Patient perception of recovery showed positive association with doctor's awareness ($p < 0.02$).	Observational study; quality rating acceptable.
Street, *et al.,* 1993[180] (USA)	Interaction self-efficacy created by encouraging patients to be involved in decision making.	Non-insulin-dependent diabetes mellitis	Poorer metabolic control when nurse controlling and directive ($p < 0.01$); nurses' patient-centred responses related to degree to which patients experienced negative feelings ($p < 0.05$) and exhibited decision-making behaviour ($p < 0.001$).	Observational study; quality rating poor.
Headache Study Group of the University of Western Ontario, 1986[184] (Canada)	Interaction self-efficacy created during consultation by giving patients more opportunity to discuss problems.	New complaint of headache	Resolution of headache associated with full discussion of problem with doctor ($p < 0.01$) and organic final diagnosis ($p < 0.01$) and no visual symptoms ($p < 0.01$); patient per-ception of full discussion highly correlated to physician liking patient ($p = 0.001$).	Observational study; quality rating acceptable.

efficacy was associated with improvements in walking distance in patients with chronic bronchitis.

Both studies were rated poor in terms of quality. However, they do highlight the need for more research that measures patients' expectations of treatment prior to receiving care, in order to deter-mine the extent to which these expectations can be changed by the experience of the intervention and the extent to which these prior beliefs interact with the intervention to affect outcomes.

Economic assessments
No cost data were provided.

Methodological quality
Of the 15 studies above that were rated as being of poor quality, 14 were either rather weak observational studies, had a high drop-out rate, or contained insufficient methodological detail. The other study rated as poor was that by Bass and colleagues,[183] which relied heavily on retrospective reporting.

Expectancies created in medical treatment

In all, 22 studies make up the group concerned with medical treatment in which practitioners either created positive or negative outcome expectancies, negative outcome expectancies alone or in which patients' expectancies were considered in terms of effect on treatment outcomes.

Studies comparing the effects of positive and negative outcome expectancy
Patient response to drug therapy
In a group of nine studies,[188,195–201] the effects of creating a positive versus a negative outcome expectancy on patient response to drug therapy were investigated *(Table 13)*. Five of the studies were conducted in the USA, two in the UK[188,198] and one in Norway.[201] All were clinical trials in which the doctor's attitude was manipulated. All, with the exception of the study by Rabkin and colleagues,[200] used randomisation.

TABLE 11 *Managing illness: significant effects reported in studies creating interaction self-efficacy*

Study	Fewer symptoms	Improved functional ability	Improved disease status	Rating
Patient contribution				
Greenfield, *et al.,* 1985[177]		$p < 0.05$		Acceptable
Greenfield, *et al.,* 1988[175]		$p < 0.01$	$p < 0.01$ (HbA$_1$)	Acceptable
Kaplan, et al., 1989[179]		$p < 0.05$		Acceptable
Rost, *et al.,* 1991[181]		$p < 0.02$	✔ (metabolic control)	Acceptable
Provider contribution				
Bass, *et al.,* 1986[183]	$p < 0.001$			Poor
Finkler & Correa, 1996[84]				Poor
Heszen-Klemens & Lapinska, 1984[182]				Poor
Kellner & Sheffield, 1971[178]	$p < 0.05$			Poor
Olsson & Tibblin, 1989[174]	$p < 0.005$			Acceptable
Orth, *et al.,* 1987[185]			$p < 0.05$ (BP)	Poor
Putnam, *et al.,* 1985[186]	$p < 0.05$			Poor
Starfield, *et al.,* 1981[187]				Poor
Stewart, *et al.,* 1979[176]				Acceptable
Street, *et al.,* 1993[180]			$p < 0.01$ (metabolic control)	Poor
Headache Study Group, University of Western Ontario, 1986[184]	$p < 0.001$			Acceptable
✔ *Reported an overall statistical effect but no specific probability included*				

TABLE 12 *Managing illness: effect on health outcomes of positive outcome expectancy created by patients' beliefs*

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Barrios & Karoly, 1983[189] (USA)	Positive outcome expectancy created by patients' belief in treatment effectiveness.	Migraine headache	No correlation between patient expectancies and improvement in headache.	Observational study; quality rating poor.
Morgan, *et al.,* 1983[190] (UK)	Positive outcome expectancy created by patients' beliefs about their illness and its treatment.	Chronic bronchitis	Exercise tolerance (distance the patient walked in 12 minutes) correlated best with belief in treatment and perceived value of exercise ($p < 0.05$).	Observational study; quality rating poor.

In four studies,[195–198] positive outcome expectancy was created by the doctors' warm, optimistic and enthusiastic attitude, and negative outcome expectancy by a neutral attitude. A neutral attitude describes the approach adopted in clinical trials when doctors convey doubt about the efficacy of treatment and therefore create uncertainty as part of obtaining informed consent. The effects reported in the results were patient responses to the active (medication being tested) as opposed to the inactive drug (placebo). One of the studies controlled for the effects of patients' positive and negative attitudes.[198] All the studies reported improved symptom relief from the medication being tested *(Table 14)*. All but one of the studies[196] were of poor quality.

The classic study by Thomas[188] demonstrated that patients with ambiguous symptoms were more likely to have recovered (in the GP's judgement) after 2 weeks when given a (placebo) prescription and positive outcome expectations by the GP, than those given placebo without the positive outcome expectancy. This study demonstrates the ability of the doctor to create positive outcome expectancies but needs to be independently replicated.

TABLE 13 *Medical treatment: effect on health outcomes of positive versus negative outcome expectancy and negative outcome expectancy alone*

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Positive versus negative outcome expectancy: patient response to drug therapy				
Fisher, *et al.*, 1964[197] (USA)	Positive outcome expectancy created by doctor's belief that treatment would work; negative outcome expectancy by doctor's neutral attitude about treatment.	Psychoneurotic outpatients with symptoms of anxiety	Drop-out rate from trial less for patients given active drug by positive doctors than those in other groups ($p < 0.05$).	Three-group (each with two conditions) RCT, control an inactive drug (placebo); quality rating poor.
Thomas, 1987[188] (UK)	Positive outcome expectancy created by GPs giving patient a firm diagnosis with the belief that they will recover soon; negative outcome expectancy by GPs giving patient no firm assurances about diagnosis and uncertainty about treatment effect.	Symptomatic but undiagnosed illness	Group in which positive outcome expectancy was created made better recovery within 2 weeks than those in whom negative outcome expectancy created ($p = 0.001$).	2 x 2 group RCT, control no prescription for treatment (inactive placebo); quality rating acceptable.
Uhlenhuth, *et al.*, 1959[195] (USA)	Positive outcome expectancy created by doctor's belief that treatment would work; negative outcome expectancy by doctor's neutral attitude about treatment.	Psychoneurotic outpatients with symptoms of anxiety	Better symptom relief from meprobamate than placebo ($p < 0.01$) and from phenobarbital than placebo ($p < 0.03$); doctor who was optimistic seen as more dependable ($p < 0.02$) and helpful ($p < 0.01$).	Three-group (each with two conditions) crossover trial, control an inactive drug (placebo); quality rating poor.
Uhlenhuth, *et al.*, 1966[196] (USA)	Positive outcome expectancy created by doctor's confident, encouraging, optimistic, enthusiastic attitude; negative outcome expectancy by doctor's detached, uncertain attitude.	Psychoneurotic outpatients drawn from three clinics (A, B, & C)	Clinic A: more effective relief from active drug with doctor's positive attitude; a little less relief when doctor's attitude was negative. Clinics B and C: more relief from active drug with negative doctor's attitude; about same relief from active and inactive drugs when doctor's attitude positive.	Three-group (with 2 x 2 conditions) RCT, control an inactive drug (placebo); quality rating acceptable.
Wheatley, 1967[198] (UK)	Positive outcome expectancy created by GP's optimistic attitude to treatment outcome; negative outcome expectancy by GP's neutral attitude to treatment outcome. Patients' positive outcome expectancy created by their optimistic attitude to treatment; patients' negative outcome expectancy by their negative attitude to treatment.	General practice patients with anxiety and neurotic depression	Best symptom relief from anxiety when doctor ($p < 0.05$) and patient (not quite $p < 0.05$) were optimistic regardless of drug.	Observational study; quality rating poor.
Positive versus negative outcome expectancy: patient response to inactive drug (placebo)				
Freund, *et al.*, 1971[199] (USA)	Positive outcome expectancy created by doctor telling patients that drug was effective; negative outcome expectancy by doctor telling patients that effects of drug were not yet known.	Obese black female outpatients	Greater weight loss at 1 week when doctor positive ($p < 0.025$) which was twice as much as in other groups at 4 weeks but not significant; active drug resulted in more weight loss than placebo at week 1 ($p < 0.001$) and week 4 ($p < 0.05$); tested for personality but no effect.	Four-group RCT, control was an inactive drug (placebo); quality rating acceptable.
Rabkin, *et al.*, 1990[200] (USA)	Positive outcome expectancy created by doctor telling patients that outcome of treatment (inactive drug) was good and that they did not need to continue with treatment.	10-day placebo responders with mild, chronic, mood-reactive depression (10% of all patients receiving single blind placebos)	Significant improvement between baseline and 10-day re-evaluation for all patients ($p < 0.000$); 40% of patients in intervention group maintained improvement for 12 weeks.	Two-group RCT, control patients continuing with inactive drug (placebo); quality rating acceptable.
Skovlund, 1991[201] (Norway)	Positive outcome expectancy created by telling patients that they would receive active treatment (trial 2); negative outcome expectancy by telling patients that they may receive a drug that is ineffective (trial 1).	Postpartum pain in maternity ward	Greater reduction in pain intensity in trial 2 than trial 1 at 1 hour ($p < 0.079$) but effects only short term, as at 4 hours effects did not reach significance ($p < 0.084$).	Insufficient information provided; quality rating poor.

continued

TABLE 13 contd *Medical treatment: effect on health outcomes of positive versus negative outcome expectancy and negative outcome expectancy alone*

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Positive versus negative outcome expectancy: patient response to dental treatment				
Gryll & Katahn, 1978[82] (USA)	Positive outcome expectancy created by dentist's belief in success of treatment (oversell condition); negative outcome expectancy by dentist's belief that treatment was not very effective (undersell condition).	Oral surgery	Positive outcome expectancy led to least pain ($p < 0.05$ or better), greater reduction in fear of injection ($p < 0.01$); positive and negative outcome expectancy led to fall in anxiety ($p < 0.05$); self-report of pain experience related to message (expectancy factor) ($p < 0.001$) and attitude (warmth) of dentist ($p < 0.05$) and attitude (warmth) of dental assistant ($p < 0.01$); no effect of status.	Four-group ($2 \times 2 \times 2 \times 4$) RCT, control inactive drug; quality rating acceptable.
Hashish, *et al.*, 1988[202] (UK)	Positive outcome expectancy created by dentist's belief in success of treatment; negative outcome expectancy by dentist conveying information that patient can expect some discomfort but that it will not be excessive.	Dental surgery	Greater reduction in pain intensity for inactive treatment 1 (intensity set to zero) rather than control ($p < 0.05$); reduction in swelling for those in treatment and inactive treatment 1 groups ($p < 0.05$, $p < 0.05$ and $p < 0.01$) compared with control group; reduction in anxiety in inactive treatment 2 group (low intensity and no movement of applicator) ($p < 0.05$).	Five-group RCT, control no treatment; quality rating acceptable.
Ho, *et al.*, 1988[203] (UK)	Positive outcome expectancy created by dentist's belief in the success of treatment; negative outcome expectancy by dentist conveying some doubt about effectiveness of treatment.	Removal of impacted third molar under general anaesthetic	Greater reduction in pain intensity ($p = 0.08$) and swelling ($p < 0.05$) in all intervention groups (active and inactive treatment).	Five-group RCT, control no treatment; quality rating acceptable.
Negative outcome expectancy only				
Daniels & Sallie, 1981[204] (Australia)	Negative outcome expectancy created by doctor telling patient that headache might occur after lumbar puncture.	Lumbar puncture in patients, some of whom had schizophrenia	Negative outcome expectancy led to more reported headaches than in control group ($p < 0.05$).	Two-group RCT, no information given on control group; quality rating acceptable.
Lamb, *et al.*, 1994[206] (USA)	Negative outcome expectancy created by nurse telling the patient that side-effects could be expected from drugs.	General medicine outpatients receiving a new prescription	No significant differences between treatment and control groups in numbers of patients reporting side-effects and number of side-effects reported.	Two-group RCT, control normal discharge instructions; quality rating poor.
Myers, *et al.*, 1987[205] (Canada)	Negative outcome expectancy created by doctor telling patient that there may be minor side-effects from drugs.	Unstable angina pectoris	When told to expect side-effects (negative outcome expectancy) more patients reported minor gastrointestinal symptoms ($p < 0.02$), and reported them earlier ($p < 0.02$), than patients not told about adverse outcomes (no negative outcome expectancy).	Four-group, two-factor (for expectancy) RCT, control inactive drugs (placebo); quality rating acceptable.

Patient response to placebo

In three studies,[199–201] the effect of creating positive and negative outcome expectancies on patient response to an inactive drug (placebo) was reported *(Table 13)*. Two studies were conducted in the USA and one in Norway.[201] Two were of an acceptable quality and one not.[201] All the studies found that patients given an inactive drug by an enthusiastic doctor reported an improvement in their condition *(Table 14)*. The improvements included patient self-reports of reduction in post-partum pain,[201] feeling less depressed[200] and an objective measure of weight loss in patients being treated for obesity.[199] Rabkin and colleagues' study[200] went further, showing that, in some patients, positive outcome expectancies can

be sustained over a period of up to 3 months without medication.

Patient response to dental treatment

A second group of three studies[82,202,203] investigated the effect of positive and negative outcome expectancy on patient response to dental treatment *(Table 13)*. Two studies were conducted in the UK and one in the USA.[82] All three studies were RCTs and all were of an acceptable quality. In all three studies patients reported benefits when dentists conveyed a positive message about the treatment. The positive outcome expectancy that was created was effective for both the active and inactive (placebo) treatment groups and, importantly, did not appear to interact with the

TABLE 14 *Medical treatment: significant effect in at least four studies in relief from or increase in symptoms with positive and negative outcome expectancies*

Study	Symptom change	Rating
Positive versus negative outcome expectancy: patient response to drug therapy		
Fisher, *et al.,* 1964[197]	$p < 0.05$ (lower drop-out rate)	Poor
Thomas, 1987[188]	$p < 0.001$ (non-specific symptoms)	Acceptable
Uhlenhuth, *et al.,* 1959[195]	Drug A, $p < 0.01$; drug B, $p < 0.03$ (anxiety)	Poor
Uhlenhuth, *et al.,* 1966[196] (Clinic A)	✔ (anxiety)	Acceptable
Wheatley, 1967[198]	$p < 0.025$ (anxiety)	Poor
Positive versus negative outcome expectancy: patient response to inactive drug (placebo)		
Freund, *et al.,* 1971[199]	$p < 0.025$ (weight reduction)	Acceptable
Rabkin, *et al.,* 1990[200]	40% (maintained improvement with medication)	Acceptable
Skovlund, 1991[201]	$p < 0.079$ (postoperative pain)	Poor
Positive versus negative outcome expectancy: patient response to dental treatment		
Gryll & Katahn, 1978[82]	$p < 0.05$ (pain); $p < 0.05$ (fear and anxiety)	Acceptable
Hashish, *et al.,* 1988[202]	$p < 0.05$ (pain); $p < 0.05$ (swelling)	Acceptable
Ho, *et al.,* 1988[203]	$p = 0.08$ (pain); $p < 0.05$ (swelling)	Acceptable
Negative outcome expectancy only		
Daniels & Sallie, 1981[204]	$p < 0.05$ (headache)	Acceptable
Lamb, *et al.,* 1994[206]		Poor
Myers, *et al.,* 1987[205]	$p < 0.02$ (more minor gastrointestinal symptoms)	Acceptable
✔ *Reported an overall statistical effect but no specific probability included*		

patient's anxiety or coping style.[203] In terms of the mechanism involved, the information given by a dentist seems to be more effective in creating positive outcome expectancy than the dentist's personal style.[82] The improvements were patient self-reports of reduced pain and improved health status in the form of reduced swelling, both unpleasant consequences of dental treatment *(Table 14)*. The evidence is robust and shows the powerful effect of the dentists' positive approach on post-treatment experience after dental surgery.

Studies creating negative outcome expectancies
Three studies[204–206] were concerned with negative outcome expectancy *(Table 13)*. The studies were investigations of the effects of negative outcome expectancy created by practitioners telling patients to expect symptoms following their treatment. The studies were conducted in the USA,[206] Australia[204] and Canada.[205]

In two studies, the increased frequency of symptom-reporting was described – one self-reported

headaches,[204] the other minor gastrointestinal irritation[205] *(Table 14)*. Both studies were rated as acceptable and both were RCTs. In the third, a poorly rated RCT, in which some of the control group patients may also have been told to expect side-effects,[206] no effect was reported.

Evidence that negative outcome expectancy increases the frequency with which patients report symptoms illustrates the influence that practitioners can have over whether or not patients report symptoms.

Outcome expectancies which appear to be created by factors other than the practitioner
There were five studies[196,207–210] in which the health outcomes reported could not be solely attributed to the positive or negative outcome expectancies created by the practitioner *(Table 15)*. Three studies were conducted in the USA, one in the UK[209] and one in France.[210] Four were RCTs of an acceptable quality,[196,207,209,210] and one was a small crossover study of poor quality.[208]

TABLE 15 Medical treatment: effect on health outcomes of treatment outcome expectancy created by factors other than the practitioner and positive and/or negative outcome expectancy created by patient beliefs

Study	Expectancy	Clinical area	Health outcomes	Type and quality of study
Outcome expectancies apparently created by factors other than the practitioner				
Affleck, *et al.,* 1966[208] (USA)	Positive outcome expectancy (strong expectancy) created by psychiatrist telling patients that treatment was effective; negative outcome expectancy (weak expectancy) by psychiatrist conveying uncertainty about effectiveness of treatment.	Psychiatric outpatients with anxiety	Doctor's rating of anxiety showed reduction with the active drug irrespective of expectancy ($p < 0.01$); patients reported an improvement in anxiety in positive expectancy condition with active drug ($p < 0.01$).	Four-group crossover clinical controlled trial, control inactive drug (placebo); quality rating poor.
Bergmann, *et al.,* 1994[210] (France)	Positive outcome expectancy created by doctor telling patient that drug was effective; negative outcome expectancy by doctor telling patient that drug may not be effective.	Cancer patients with mild to moderate pain but who did not need narcotic analgesics	Pain better controlled by active and inactive drug when negative outcome created ($p = 0.012$) (simulated trial condition); effectiveness of active drug in controlling pain better than inactive in therapeutic condition ($p = 0.08$).	Two-group RCT, control given no information about trial; quality rating acceptable.
Branthwaite & Cooper, 1981[209] (UK)	Positive outcome expectancy created by conveying information that a branded drug was effective and by volunteers' belief in a branded drug.	Volunteers taking painkiller for headache	Branded drug gave greater relief than unbranded drug at 30 minutes and 1 hour ($p < 0.01$); more headaches reported and more analgesic use in branded group ($p = 0.05$); active drugs gave greater relief than inactive drugs (placebo) ($p = 0.01$); regular users of branded drug obtained more relief generally and more relief from branded than unbranded drug ($p = 0.05$).	2 x 2 RCT, control inactive drug (placebo); quality rating acceptable.
Kantor, *et al.,* 1966[207] (USA)	Positive outcome expectancy created by doctor telling patients that they are being given active drug; negative outcome expectancy by telling patients that they may be given inactive drug.	Surgical, fracture, orthopaedic and gynaecological patients with moderate or severe postoperative or fracture pain	Analgesic potency of inactive drug (placebo) as a second dose functionally dependent on preceding medication ($p < 0.05$–0.01.)	Five-group RCT, control inactive drug (placebo); quality rating acceptable.
Uhlenhuth, *et al.,* 1966[196] (USA)	Positive outcome expectancy created by doctor's confident, encouraging, optimistic, enthusiastic attitude; negative outcome expectancy by doctor's detached, uncertain attitude.	Psychoneurotic outpatients drawn from three clinics (A, B & C)	Clinic A: more effective relief from active drug with doctor's positive attitude and a little less relief when doctor's attitude negative. Clinics B and C: more relief from active drug with doctor's negative attitude but about same relief from active and inactive drug when doctor's attitude positive.	Three-group (with 2 x 2 conditions) RCT, control inactive drug (placebo); quality rating acceptable.
Treatment expectancies created by patient belief				
Kincheloe, *et al.,* 1991[211] (USA)	Negative outcome expectation created by patients' belief that pain and discomfort would be experienced; positive outcome expectancy created by dentist telling patients that injection would prevent pain.	Dental treatment under local anaesthetic	More pain and discomfort experienced in patients with higher negative outcome expectation ($p < 0.05$).	2 x 2 RCT, control inactive drug (placebo); quality rating acceptable.
MacDonald, *et al.,* 1980[212] (UK)	Positive outcome expectancy created by patients' belief in effectiveness of new drug; negative outcome expectancy by patients' belief in its failure.	Endoscopically confirmed duodenal ulcer	Relief of symptoms more common in patients who expected cure than in those who did not ($p = 0.036$); healing associated with relief of symptoms ($p < 0.01$).	Two-group RCT, control inactive drug (placebo); quality rating poor.

In two of the studies,[196,207] patients reported an improvement in their symptoms following medication even though doctors conveyed a message that the drug may or may not be effective. In the first study,[196] only patients given an active drug reported improvements (reduction in their anxiety), while in the second study,[207] better improvements (reduction in postoperative pain) were reported when an inactive drug was preceded by an active drug. In a third study,[208] although patients reported an improvement in their symptom (anxiety) when they received the active drug and when doctors created a positive outcome expectancy, the significant effect only occurred in the second week of treatment. In all three studies the effects appear to link either to the potency of the drug or its action and, therefore, would seem to be the result of an outcome expectancy created

by the treatment itself. The effect is powerful *(Table 16)* and suggests that patients are more likely to report a positive outcome if the drug has an effect the first time that it is administered. The hypothesis clearly needs further research under more rigorous conditions.

The two remaining studies[209,210] considered other factors that can affect patients' responses to drugs. One study illustrates the positive outcome expectancy created by a branded drug (use of aspirin for a headache), although the best effect was reported by regular users which may have enhanced the effects.[209] The other study reported the effects of testing new drugs under two clinical condition.[210] One of these simulated a clinical trial when patients were given only a non-committal message (negative outcome expectancy), while the other simulated the therapeutic setting when doctors created a positive outcome expectancy. The intention was to test whether the clinical environment in which RCTs are conducted influences results. The findings showed that the active drug (better control of pain) was more effective in the simulated therapeutic condition. It demonstrates that the creation of a positive outcome expectancy enhances patients' perception of a drug.

Studies in which a patient's beliefs created treatment expectancies
Two studies reported the effects of a patient's positive and negative beliefs on health outcomes *(Table 15)*. One study[211] considered the pain of an injection during dental surgery and the other[212] the medication used in the treatment of peptic ulcer. Both were RCTs, with one of acceptable quality[211] and one of poor quality.[212] Both studies

showed the influence of patient belief in a treatment on the self-report of symptom relief from the medications administered *(Table 16)*, in one case[212] apparently despite the recognised ineffectiveness of the medication, although the study was poor in quality. Both studies illustrate the influence that patients' positive or negative approach may have on their self-reports of their medical treatment.

Summary
The majority of studies provide evidence for the power of positive outcome expectancy to enhance the effects of medical treatment and, in one study,[212] apparently despite the ineffectiveness of the medication. Most of the improvements were in patient self-reports of reduced anxiety, pain, and distress. Sometimes these improvements may parallel improvements in health status, as MacDonald and colleagues[212] showed when relief from peptic ulcer pain was significantly associated with healing of the ulcer.

There is also evidence that negative outcome expectancy affects health outcomes but that the benefits may be double-edged. On the one hand, they alert patients to hazardous side-effects and so could be harnessed in health care to enable them to be recognised early. On the other hand, if patients become preoccupied with their symptoms this may adversely affect their quality of life and possibly increase the call they make on health services. Gains for the patient are, therefore, the early prevention of side-effects which, if left untreated, could become hazardous secondary complications. Gains for the NHS are the avoidance of unnecessary additional services.

TABLE 16 *Medical treatment: significant relief in symptoms reported in at least four studies as a result of expectancies other than those created by practitioners*

Study	Symptom change	Rating
Outcome expectancies apparently created by factors other than the practitioner		
Affleck, *et al.,* 1996[208]	$p < 0.01$ (anxiety)	Poor
Bergmann, *et al.,* 1994[210]	$p < 0.012$ (cancer pain)	Acceptable
Branthwaite & Cooper, 1981[209]	$p < 0.01$ (headache)	Acceptable
Kantor, *et al.,* 1966[207]	$p < 0.05–0.01$ (pain)	Acceptable
Uhlenhuth, *et al.,* 1966[196] (Clinics B and C)	(anxiety)	Acceptable
Treatment expectancies created by patient belief		
Kincheloe, *et al.,* 1991[211]	$p < 0.05$ (more pain and discomfort	Acceptable
MacDonald, *et al.,* 1980[212]	$p < 0.036$ (peptic ulcer pain)	Poor

Economic assessments

The studies covered above are too diverse in clinical area, setting and health outcome for generalisation to be useful. A wide variety of resource implications are involved but have generally been ignored by investigators.

Methodological quality

A number of the studies reviewed above were rated as being of poor quality. Those reported by Skovlund,[201] Affleck and colleagues,[208] MacDonald and colleagues,[212] Wheatley,[198] and Fisher and colleagues[197] contained insufficient detail. Lamb and colleagues,[206] in a two-group randomised trial of whether warning patients about side-effects might cause side-effects, acknowledge that the control group may or may not have been told about side-effects, thus undermining the results. The classic study by Uhlenhuth[195] is a crossover trial in which not all crossover orderings were used and which is thin on methodological detail.

Chapter 4

Discussion

Guided by a conceptual framework for the factors responsible for the placebo effect, the hypothesis that placebo effects are brought about by the expectancy mechanism was examined in this review. The search procedure identified 85 studies that included evidence relevant to the expectancy mechanism. These studies were organised by clinical area (preparation for medical procedures, management of illness and medical treatments). Within each clinical area, they were organised in terms of the type of expectancy addressed. For the purpose of this review, Bandura's[68–70] concepts of outcome expectancy and self-efficacy were extended to form a more detailed typology of expectancy. Specifically, three types of expectancy associated with treatment were proposed: positive and negative outcome expectancies and process expectancy; and two types of expectancy associated with the patient's actions: management self-efficacy and interaction self-efficacy.

A narrative review of the studies in each category was conducted. A more quantitative approach was not possible because of the heterogeneity of the outcomes studied. Importantly, the types of expectancy were unevenly distributed across the three clinical areas. Preparation for medical procedures involved process expectancy and management self-efficacy and, to a lesser extent, positive outcome expectancy. Interventions for managing illness involved primarily management self-efficacy or interaction self-efficacy. Medical treatments typically involved the creation of positive (and occasionally negative) outcomes expectancies. The analysis therefore has made explicit the placebo element of these three categories of clinical care by identifying the expectancies that are changed either implicitly or explicitly in the course of these interventions or treatments.

It is important to note that the three clinical areas used to categorise the results emerged from a content analysis of the studies identified by the search procedures, which were guided by the emphasis on expectancy. Hence, this review should not be evaluated as a systematic review of each of these clinical areas; we do not claim to have identified all studies in these areas. Moreover, the review did not include any unpublished studies which may have introduced a bias in favour of demonstrating expectancy effects.

In all three clinical areas, it was not possible to use meta-analysis to combine effect sizes across studies because of the heterogeneity of outcomes assessed. Results for outcomes assessed in at least four studies were tabulated, to give a clear summary of the findings. However, where several studies did use the same outcomes (e.g. reduced hospital stay, requests for analgesia) they did not provide sufficient detail to permit the calculation of effect sizes, and/or the studies were of poor quality.

Enhancing process expectancy and management self-efficacy in preparation for medical treatment

The review indicated that increasing management self-efficacy through skills training prior to medical procedures, either alone, or in combination with process expectancy, led to improved outcomes, most notably reduced use of analgesics and a more comfortable subjective experience because of less anxiety. (Two studies went against this,[149,151] demonstrating an increased use of analgesics associated with higher pre-existing levels of management self-efficacy. One interpretation of these findings is that patients higher in management self-efficacy were more assertive about their analgesia requirements.) It is difficult to separate information from training in these interventions. For example, training in relaxation techniques to manage pain after surgery necessarily means informing patients about postoperative pain. However, results from those studies that attempted to separate these two components, or which used information alone when comparing the results of a combined package, indicated that information alone was not a very effective component. Such a finding is consistent with the large amount of literature in health psychology which shows that information alone does not change beliefs, attitudes or behaviour. It is information combined with strategies to respond appropriately to that information that produces desired outcomes. However, no intervention was identified that examined the incremental cost-effectiveness of adding training to an information intervention in preparation for medical treatment.

The review identified a few studies in which individual differences in the way in which people cope with an impending unpleasant procedure were considered. No clear picture emerged other than evidence that some people avoid thinking about the procedure while others become very attentive (referred to as sensitisers). Previous research has shown that becoming over-attentive is not an effective preparation for surgery.[213] Training in cognitive restructuring is designed to help people think positively rather than spend time thinking about the unpleasant consequences and may explain why management self-efficacy improved health outcomes more than process expectancy. More research in which the patients' beliefs and responses to interventions which prepare them for medical procedures are considered is now needed to extend our understanding in this important area.

The findings reviewed in the section on preparation for medical procedures are consistent with earlier reviews regarding instructions in hospital stay. A meta-analysis of studies reporting length of stay outcomes found that psycho-educational interventions reduced hospital stays, on average, by 1.25 days,[214] although recent managed-care initiatives may by now have reduced clinical discretion in this regard. The apparent lack of cost-effectiveness evidence in this area probably reflects the fact that none of the studies was conducted in the last decade, and 12 were conducted more than 15 years ago. The resource implications of interventions hinge on the details of the preparatory programmes themselves. These can be delivered at the individual or group level, using written, verbal, audiotape or audio-visual mediums, by staff of varying levels of seniority. Recent reviews in this area suggest overall small to moderate beneficial effect sizes but considerable variability across types of preparatory intervention, outcome measure and clinical area.[215,216] Accordingly, preparatory interventions of some form or other are now standard practice in many settings and the question of the cost-effectiveness of alternative programmes needs to be assessed. The practice of using usual-care instead of a no-treatment control group as the comparison against which an intervention was evaluated may have underestimated the effectiveness of the intervention. Patient personality characteristics can also significantly affect responses to preparatory interventions of different types[217] and should be considered in economic analyses of resource use in this area. Most available studies concentrate on the immediate recovery period after the medical procedure in question, whereas the longer-term productivity implications need to be assessed before any judgements about economic validity can be made.

Enhancing management and interaction self-efficacy in the management of illness

The clinical conditions covered in these studies were, in the main, chronic illnesses in which the patient plays an active role in the treatment. In some studies, where the focus was on the nature of the patient–provider interaction, the health condition may have been acute or chronic. However, a common feature of all these studies was the emphasis on the patient as an active participant in health care, either as the person responsible for day-to-day self-management of their condition (e.g. in diabetes) or as the person attempting to communicate to a doctor the nature of the health problem (e.g. in GP consultations).

This group of studies included a large group of evaluations of interventions to enhance the self-management of chronic illness. Although the quality of the research varied, the findings consistently demonstrated beneficial effects on subjective and objective outcomes of these interventions. However, more research is needed that examines the processes by which the interventions are effective, particularly the role of self-efficacy. Such studies need to look at long-term follow-up because the benefits may be observed several years later, as in the prevention of diabetes complications.

The lack of rigorous cost-effectiveness information, and the breadth of clinical areas where health education and support programmes have potential clinical benefits, points to the need for good quality economic appraisals of these types of interventions so that evidence-based healthcare delivery decisions can be made.

Most of the studies investigating the impact of chronic disease management programmes reviewed were conducted in the USA in the last decade, possibly reflecting increasing cost-consciousness associated with the spread of managed care. Although they span 12 clinical conditions, and involve different types of interventions, there is consistency in the positive nature of most of the findings across a range of physical, psychological, behavioural and utilisation outcomes. This result is confirmed by existing review papers on cardiac disease,[218–220] diabetes,[221] pain[222,223] and asthma.[224,225] Although there is a

substantial body of evidence confirming the potential health gains from health education and support programmes in general, there is a need for rigorous appraisals of the cost-effectiveness of interventions in different settings in the context of the NHS.

The provision of education and support programmes has important resource implications and, indeed, cost saving objectives underlie many such programmes, especially those initiated by American health maintenance organisations. In addition to the resources used in delivering the intervention, the opportunity costs of which must be counted, the programmes frequently target clinical conditions that involve high healthcare system costs and incur heavy private costs on patients and their families, and social costs in terms of reduced productivity. Any health benefits reaped from the intervention which result in reductions in health system, personal or social costs must be weighed against the resource costs of the intervention.

The other large group of studies consisted of those looking at the effects of enhancing interaction self-efficacy, either explicitly in studies of interventions to increase patient empowerment or implicitly in observational studies which demonstrated that if patients were given the opportunity to present their problems and/or had their views on their health condition endorsed by the provider, then this led to better health outcomes. These studies open up elements of the placebo effect attributed to the patient–provider relationship by examining how types of utterances are associated with health outcomes. They indicate that increased patient involvement in the interaction is associated with better health outcomes, both subjectively and objectively, but the costs of increased patient involvement have not been fully explored. Do such interactions need to take longer, or could the typical interaction be modified to allow greater patient participation at the expense of some other aspects of the interaction which are not associated with better health outcomes? Alternatively, if such consultations do take longer, is the expense offset by later savings achieved either as a result of better health outcomes or as a result of fewer doctor visits?

The finding that doctor–patient agreement improves health outcomes was not directly analysed from an economics perspective by the individual investigators. It suggests, however, that a delivery environment that fosters a strong patient–practitioner relationship is generally therapeutic. Concern has been expressed in the USA about the repercussions for doctor–patient interactions in managed care. In particular, commentators point to new cost-conserving incentive structures that reduce the time practitioners can personally spend with their patients to develop the type of relationship that will foster positive expectancies and maximise health gains.[71,72,86,179,226–228] The trade-offs involved in reforms of the healthcare delivery system need to be carefully evaluated so that socially optimal arrangements can be identified. This issue is as significant for the NHS as it is for the American health maintenance organisations.

Enhancing positive outcome expectancies of medical treatment

The studies in this group probably come closest to examining the placebo effect in its traditional sense. Typically, these studies examined the effect of the healthcare provider explicitly or implicitly telling the patient that the treatment would have beneficial effects. These manipulations of positive outcome expectancies successfully boosted patients' perceptions of their response to the treatment in the majority of studies but there was no evidence for objective improvements in disease status. Nocebo effects were not as consistently observed when patients were given negative outcome expectancies. Moreover, it may be that for certain types of patients, such as those who are depressed, the creation of positive outcome expectations is more difficult. Patients' pre-existing expectancies, from past experience with the treatment or with medical interventions more generally and other factors, may also affect the ease with which positive expectancies can be created. Future research is needed to measure pre-existing expectancies and to determine how these and other patient characteristics interact with manipulations of positive or negative outcome expectancy.

Chapter 5
Conclusions

This review demonstrates how the placebo effect can be analysed into components that are amenable to research. The hypothesis that expectancies are a mechanism for placebo effects received support across a range of clinical areas in a variety of studies. These findings suggest a number of recommendations and implications, including the need for research into the psychological and physiological pathways by which expectancies are translated into health outcomes.

Recommendations

Increased management self-efficacy for patients undergoing medical procedures

The research justifies the use, prior to medical procedures, of presurgical preparation and other interventions that train patients in skills to cope with procedures and manage their consequences. These interventions are particularly effective when they provide skills training. However, how such interventions interact with patient characteristics is not fully understood, and further research is required in this area.

Increased management self-efficacy for patients with chronic illness

Patients who have undergone interventions that train them in self-management skills show improvements in both subjective and objective health outcomes. Thus the use of self-management interventions is justified in terms of effects on health outcomes; however, further research is required into the cost-effectiveness of such interventions, particularly in the NHS context.

Increased patient interaction self-efficacy

It is seen from both observational and interventions studies that patients who participate more in the medical encounter have better subjective and objective outcomes. Thus the evidence justifies the training of patients and practitioners in techniques that facilitate patient participation in consultations. However, the cost-effectiveness of such measures remains to be examined. Furthermore, it is necessary to provide a facilitating delivery system and an incentive structure that encourages patient involvement.

Increased use of communications to increase positive outcome expectancy when administering medical treatment

The findings justify the creation of positive outcome expectancies in conjunction with administering medical treatment, where the practitioner is confident that the treatment is indeed effective. Positive expectancies are created when the practitioner communicates to the patient her/his enthusiasm for the treatment.

Further research

A number of areas for further research are highlighted in the review and a number of improvements to research design are suggested. Four broad areas for further research are identified.

- Remarkably few studies assessed patients' pre-existing expectancies. Such assessment should be conducted pre- and post-interventions that are postulated to have their effects through expectancy mechanisms so that this can be tested directly.
- No study included a rigorous economic analysis that examined the cost-effectiveness of the interventions presumed to change expectancies. Future research should routinely incorporate the economic dimension.
- Studies are needed that examine the interaction between patient characteristics such as coping style, personality traits, pre-existing expectancies, and manipulations to enhance management self-efficacy.
- Studies are needed that examine the interaction between the effects of personality and mental health status on patients' responsiveness to strategies which enhance positive outcome expectations.

Implications

These recommendations should not raise ethical concerns because they do not require healthcare providers to engage in any form of deception, which has been commonly associated with placebo effects. Outcome expectancy can be enhanced by the provision of accurate information about the

success of treatment and self-efficacy expectations can be enhanced by skills training. The main implication of our findings is for training of both healthcare providers and patients. Training of healthcare professionals may need to be extended to include skills in creating the relevant expectancies in their interactions with patients. Training needs for patients include programmes covering preparation for and coping with the effects of medical procedures, training in the self-management of illness, and training to facilitate patients' interaction self-efficacy. These programmes have hitherto been considered narrowly as patient education. However, the research suggests that these programmes are most beneficial when they teach specific skills rather than impart knowledge; hence they are more properly viewed as training. Through provision and implementation of such training programmes, beneficial so-called 'placebo' effects can be obtained.

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Acknowledgements

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Appendix 1

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Appendix 2

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Appendix 3

Terms used in searching electronic databases

Synonyms and standard truncations of all terms were used to ensure complete coverage. Separate searches were conducted using the following single search terms or combinations of search terms.

First stage: preliminary scoping search

Placebo
Placebo effect
Expectanc*
Expectat*
Belief
Non specific
Incidental
Nocebo
Placebo **and** Expectanc*
   Expectat*
   Belief
Placebo **and** Untreated (to identify three-group study designs)

Second stage: determinants of expectancy

First term	plus one of	plus one of
Provider	Patient	Relationship
Physician	Client	Interaction
Doctor		Communication
Nurse		
Practitioner		
Therapist		

Iatroplacebogen*
Expectanc* **and** encouragement, optimism, empathy, trust, confidence, hope
   (therapist characteristics)[a]
   context, milieu, setting, environment (of care)[a]
   information, education, instructiona
Informed consent[a]

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[a] MEDLINE not searched before 1990

[*] Indicates 'wild card' ending of words in search terms

Appendix 4

Initial paper review

REMINDER Studies should:

      1. Identify determinants (or sources) of expectancies, or focus on the expectancy mechanism

AND   2. Result in a health outcome.

RECOMMENDATION

☐ Exclude

☐ Include – Background
             Review/Commentary/Conceptual/Methodology

☐ Include – Clinical (original research)

Statistical analysis	Yes	No
Qualitative analysis	Yes	No
Economic evaluation	Yes	No
Implications for health service delivery		

Appendix 5

Proforma

ID reference number: **Reviewer:**

Bibliographic details
◊ Title
◊ Author
◊ Source

      Year   Volume (and part)
      Pages

Details of study
◊ Specific health area
◊ Study population
◊ Country
◊ Describe key features of intervention and setting

Expectancy
◊ Source of expectancy   Doctor
                                     Therapist
                                     Other (please specify)
◊ Nature of expectancy that was manipulated – characteristic of:
        therapist
        setting
        therapist–patient relationship
        education/instruction
        environment of care
        other (please specify)
◊ Verbal or non-verbal?
◊ Positive or negative?
◊ Is expectancy manipulation explicit (by authors)
                        or implicit?

Study design
◊ Type of study (RCT, observational etc.)
◊ Sampling method, groups and group sizes
◊ Inclusion/exclusion criteria
◊ Randomisation and how groups were allocated
◊ *A priori* estimate of sample size
◊ Power of study

Assessments
◊ Follow-up times
◊ What was measured: at baseline   after intervention
◊ Blinding?

Analysis and results

◊ Drop-out numbers/rates   Followed-up?

◊ Intention-to-treat analysis?

◊ Were treatment and control groups comparable?

◊ What statistical techniques were used?

         Quantitative – give brief summary

         Qualitative

◊ Expectancy effect statistically significant?

◊ Statistically significant interaction between expectancy and other effects?

◊ Was there any economic analysis?

         Costs of intervention

         Cost-effectiveness results

Commentary

◊ Authors' conclusions

◊ Reviewers' conclusions (including internal validity, role of chance, confounding variables, bias)

◊ Grade of study: Poor   Reasonable   Good

Implications

◊ Implications of study for use of expectancy in healthcare delivery

◊ Generalisability of findings

References from bibliography to be chased:

Other comments:

_____

_____

_____

_____

_____

Appendix 6

Assessing study quality checklist

ID reference number: **First author:**   **Reviewer:**

Study design *(we will categorise this later; please be as specific as possible):*

_____

_____

Sampling method: _____

Randomisation: _____

Blinding of participants: Yes   No   Not clear

       assessors: Yes   No   Not clear

Follow-up – attrition rate: _____

Comparability of groups at baseline: Yes   No   Not clear

Were the groups treated identically   Yes   No   Not clear
other than for the named interventions?
(confounding factors)

Representativeness of sample to   Yes   No   Not clear
target population:

Sample size/statistical power: _____

Appropriate statistical methods of analysis?   Yes   No   Not clear

Reliable and valid measures?   Yes   No   Not clear

Any other comments: _____

_____

_____

_____

_____

_____

Appendix 7

Data extracted from studies

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Affleck, *et al.*, 1966[208] (USA)	Anxiety patients, without complicating factors; age range 18–37 years (median 27 years). Outpatient psychiatric facility. Size: n = 14 (8 women). Design: crossover. Quality assessment: poor (insufficient detail).	5 psychiatric residents treated patients over 4 weeks according to four conditions: A. strong expectancy and drug B. strong expectancy and placebo C. weak expectancy and drug D. weak expectancy and placebo. Residents were not aware that drugs A and C were same and B and D were placebo, but were informed of potency of each and how this inform-ation should be communicated to the patient. Four orders of admin-istration used so each condition preceded and followed a different condition equally often.	Physician rating of nine anxiety indicators 1 week before trial started, on day first preparation prescribed and at 4 weekly visits thereafter. Patients' ratings of anxiety on daily basis during week pre-trial and the 4-week trial period.	Physician ratings: drug preparations both reduced anxiety significantly irrespective of expectancy ($p = 0.02$). No significant change in rated anxiety with either placebo condition. Patients' ratings: reported anxiety dropped significantly only in drug/strong expectancy condition A ($p < 0.01$). No significant changes in other conditions.
Anderson, 1987[140] (USA)	Coronary artery bypass graft patients who suffered only coronary artery disease and had not had surgery within last 5 years; men, age range 31–75 years (mean age 59.1 years). Size: n = 60, randomly assigned to three groups: A. control, n = 20 B. information, n = 20 C. information plus teaching coping skills, n = 20. Design: RCT. Quality assessment: acceptable.	A. Control: Usual hospital preparation (i.e. nurse visit with two pamphlets) and 30-minute neutral interview by investigator to control for time spent with other groups. B. Information preparation: Hospital preparation and detailed information about procedure and what patients were likely to feel. Video *Living proof* (18 minutes) and audiotape (6 minutes). C. Information plus coping preparation: Usual hospital preparation and information preparation (as in B), plus sound/slide show outlining postoperative regimen, including physical exercises for post-operative period. Practice of exercises.	Preoperative measures: • Spielberger Trait Anxiety Inventory – evening before and 7 days after surgery • Preoperative opinion survey to assess fears of surgery on evening before surgery • Patient survey questionnaire on admission and evening before surgery assessed amount of information gained from intervention and patient's perceived control over recovery • Nurse's rating of anxiety and coping. Postoperative measures: • Postoperative Affect Scale (negative emotions over 7 postoperative days • Recovery Inventory (physical state on day 7) • Staff Observation Scale (nurses' perceptions of physical and psychological recovery) • Preoperative preparation form (assessed credibility of preparation on day 7 postoperatively) • Postoperative hypertension.	• Groups comparable at baseline. • Preoperatively (1 day after preparation) both experimental groups were significantly less anxious and fearful than control groups, $p < 0.02$. • Both experimental preparations increased patients' beliefs in control over recovery. • Postoperatively both experimental groups reported less emotional distress ($p < 0.005$), were judged by nurses as making better psychological recoveries ($p < 0.005$) and physical recoveries ($p < 0.04$), and had a 32.5% lower incidence of postoperative hypertension ($p < 0.02$). • No significant differences between two experimental groups on any outcomes.
Andrew, 1970[142] (California, USA)	Men from Veterans Administration hospital. Most in for hernia surgery (n = 40), other procedures (n = 19); age range 24–75 years, mean 54 years. Size: n = 59: A. 1–4 prepared avoiders; 2–13 prepared neutrals; 3–5 prepared sensitisers. B. 1–6 unprepared avoiders; 2–6 unprepared neutrals; 3–6 unprepared sensitisers. Design: experimental, controlled. Quality assessment: poor (insufficient detail).	Group A listened to informative 8-minute tape, 6 days before surgery, Group B listened to tape on average 2.8 days after surgery. Coping style assessed for all subjects who were then categorised as avoiders, neutrals or sensitisers. It was hypothesised that sensitisers would benefit most and avoiders least from information. Knowledge levels tested before and after hearing tape.	• Learning from tape • Days from surgery to discharge • Medications from surgery to discharge.	Compared with unprepared, prepared neutral patients had fewer hospital days and fewer medications ($p < 0.05$). Prepared avoiders had fewer medications ($p < 0.05$) but no difference on hospital days compared with unprepared avoiders. No significant difference in hospital days or medication between prepared and unprepared sensitisers. Learning unrelated to recovery.

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Antoni, *et al.*, 1991[152] (Miami, Florida, USA)	Homosexual men, age range 18–40 years, unaware of serostatus, recruited by newspaper advertisements. Size: n = 47, randomly assigned to: 1. Cognitive-behavioural stress management (CBSM) 2. Assessment only control. Exclusions: • known HIV or herpes diagnosis • alcohol or recreational drug users • anaerobic steroids/ antihistamines being taken • in psychotherapy or stress management. Design: pre/post, randomised. Quality assessment: acceptable.	CBSM group met twice weekly for 10 weeks in groups of 4–6 patients with clinical psychologist: • trained in cognitive restructuring, assertiveness, behaviour change • given information about psychology and physiology of stress • educated about HIV-1 transmission and risk behaviours • relaxation training and self-monitoring of daily practice. HIV-1 status then identified.	At recruitment: • physical examination • evaluation of aerobic fitness • anxiety and mood. 72 hours before notification of HIV-1 status and 1 week after: • blood sample for immunological measures and determination of HIV-1 status • psychometric data, including anxiety and mood.	Four groups identified: 1A – seronegative and CBSM (n = 14); 1B – seronegative and control (n = 16); 2A – seropositive and CBSM (n = 10); 2B – seropositive and control (n = 7). No difference between groups in a range of socio-economic and other possible confounding variables. No significant increase in depression pre/post notification for group 2A (CBSM) while 2B (controls) experienced significant increase in depression (*p* < 0.01). No significant difference in anxiety observed between groups. Group 2A also showed significant increases in some of a range of immune markers while controls did not.
Barrios & Karoly, 1983[189] (San Francisco, California, USA)	Recruited from general population by advertising in city and university newspapers. Women only, with diagnosis of migraine for at least 2 years. Included if: headache frequency of 1–2 per week; gradual onset; family history; responsive to ergotamine tartrate. Mean age 36 years, mean length of suffering 17 years. Size: n = 39 (three dropped out). Design: before and after. Quality assessment: poor (insufficient detail, weak sampling method).	Patients self-monitored headache activity for 4 weeks. Participants given description of five types of intervention: (a) relaxation training (b) temperature biofeedback (c) social skills training (d) pharmacological (e) psychological. Patients divided into treatment groups A, B, C; treated for 4 weeks (8 sessions).	At baseline and at end of treatment patients rated each of five treatments on three aspects of expectancy: • plausibility • effectiveness • willingness to undergo therapy. Self-monitored headaches for 4 weeks prior, 4 weeks during and 4 weeks following treatment.	Three aspects of expectancy measurement significantly correlated (*p* < 0.001). Three experimental measures perceived as at least as plausible as two comparison treatments. Patients did not alter expectancy treatment over time. All experimental groups experienced headache improvement but no one treatment superior to others. No relationship between pre-treatment expectancy and headache improvement. Neither pre- nor post-ratings were correlated with improvements in headaches.
Barry-Flood, *et al.*, 1993[150] (UK)	Prostatectomy patients in 1988 in two Regional Health Authorities. Size: All benign prostatic hyperplasia (BPH) patients of 16 and 9 urological surgeons in NW Thames and Oxford-shire, respectively, were approached. 400 patients participated, 348 completed (drop-outs accounted for). Design: longitudinal, observational. Quality assessment: acceptable.	Study investigated if patients' presurgery positive expectations about improvement influenced: (i) their postoperative reports of symptoms (ii) their overall health after treatment. It also investigated whether these trends persisted during year following treatment.	Baseline: Preoperation questionnaire completed by 398 patients recorded: • health problems and general health history (Nottingham Health Profile) • BPH specific symptoms • socio-economic background • perceptions and expectations of surgery and outcomes. After surgery: Information collected from patients at 3, 6, 12 months relating to their: • BPH specific symptoms • perceptions of improvement comparing current health with preoperative status. Overall health status.	Predictor variable was expectation, prior to surgery, of BPH symptom improvement after surgery; 98% expected improvement, 33% expected to be a lot better, 20% expected to be 'somewhat' or 'a little' better. There was, at best, a little evidence to suggest that having positive expectations presurgery led patients to report fewer symptoms postsurgery (*p* < 0.05). Postoperative symptoms significantly affected by health status and preoperative symptoms but not by socio-demographic variables. No significant time effects of expectations on symptoms found. There was strong support for positive presurgery expectations increasing likelihood that patients report feeling better after surgery compared with before, even after controlling for symptom changes (*p* < 0.001). This effect persisted through post-operative year. There was no support for the hypothesis that positive expectations result in better overall health reports after surgery, except for Nottingham Health Profile mobility index at 3 months, which was also the only significant time effect found.

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Bass, *et al.,* 1986[183] (Ontario, Canada)	Adult patients in 13 family practices in three selected months in 1981 with new episode of abdominal symptoms, back or neck pain, chest pain, fatigue, headache, eye symptoms or rectal bleeding; age range 18–70 years. Size: n = 232 enrolled; 193 successfully followed. Design: observational. Quality assessment: poor (accuracy in doubt because of retrospective reporting).	Chart review by independent doctors and standardised telephone interview 1 month and 3 months after attending for care.	Measured technical and psychosocial aspects of care from records. Telephone interviews with patients at 1 and 3 months follow-up for: • report on outcome, i.e. symptom resolution • compliance • patient–doctor communication details • life problems.	50% had symptoms resolved at 1 month, 38% of remainder had symptoms resolved at 3 months. The most powerful predictor of symptom resolution at 1 month was complete agreement between patient and physician about nature of problem (adjusted relative odds = 5.58, *p* < 0.01), then underlying symptoms, then stress and psychological factors. Late resolution associated with nature of symptoms, patient not asking to discuss health problems with doctor and psychosocial factors. Technical aspects of care (e.g. history-taking, physical examinations, therapy, medication, investigation, follow-up) not important predictors of symptom resolution at 1 or 3 months. Likelihood of symptom resolution fell with length of time symptoms experienced.
Bergmann, *et al.,* 1994[210] (France)	Consecutive admissions of cancer patients with mild to moderate pain (no need for narcotic analgesics) over a 4-month period. Size: n = 49. Patients randomly assigned to two groups: A. given information about the trial (n = 24, 6 refused to participate) B. no information given about trial (n = 25). Design: RCT with crossover. Quality assessment: acceptable.	Aim was to determine whether informed consent in therapeutic trial modifies analgesic effect of naproxen and placebo. Informed consent group received information about trial; control group did not. All patients received single dose of naproxen and placebo (consecutive days) according to crossover, double-blind design. Order in which placebo and naproxen administered randomised.	Visual analogue pain scales used: (a) before intake of naproxen and placebo (b) 30, 60, 120, 180 minutes after.	No significant differences in characteristics of two groups at baseline. Findings: • naproxen more effective as analgesic in both groups (*p* = 0.01) • naproxen and placebo analgesic effect better in informed consent group than in control group (*p* = 0.012) • difference between naproxen and placebo higher in uninformed group, but not statistically significant (*p* = 0.08) • order of administering naproxen and placebo not significant.
Branthwaite & Cooper, 1981[209] (UK)	Women volunteers in urban England who took painkillers for headaches at least once a month. Study looked at treatment of headaches with branded or unbranded analgesics or placebo. Size: n = 869; 34 excluded due to allergies, asthma, gastric problems, pregnancy, other medication. Random assignment to four groups: i. ii. A. 209 102 107 B. 206 107 99 C. 215 110 105 D. 205 109 96 A. unbranded analgesics; B. branded analgesics; C. unbranded placebo; D. branded placebo. Groups further subdivided according to whether patient regularly used test brand (i) or not (ii). Design: RCT, 2 x 2 study. Quality assessment: acceptable.	Women given analgesics (aspirin) or placebo in identical canisters to take when they had a headache over next 2 weeks.	Participants asked to complete questionnaire themselves, including number of tablets taken and severity of headache. Pain relief indicated on 6-point scale, 30 minutes and 1 hour after having taken tablets.	More headaches reported and more analgesic use in branded group (*p* = 0.05). Branded tablets gave greater relief than unbranded at 30 minutes and 1 hour (*p* = 0.01). Branding effects more noticeable in women with placebo (*p* = 0.01). Branding effects more noticeable after 1 hour than 30 minutes and less than effects of active medication. Active analgesics gave greater relief than placebo (*p* = 0.01). Regular users of branded analgesic obtained more relief generally and more relief from branded than unbranded drugs (*p* = 0.05).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Carr-Kaffashan & Woolfolk, 1979[167] (New Jersey, USA)	Sleep-onset insomnia sufferers recruited through newspaper advertisement to take part in drug-free treatment programme. Inclusion criteria: • insomnia for 6 months or longer (mean = 11.5 years) • age, 18 years or over (mean 40 years, range 18–76 years) • average sleep-onset latency 30 minutes or more • willing to suspend sedative use. Size: 73 responded, 43 returned pre-treatment questionnaire; 18 women, 2 men completed study. Two groups: • moderate/severe insomnia (mean sleep-onset latency 30–75 minutes/ > 90 minutes) • treatment/placebo. Design: RCT, 2 x 2. Quality assessment: acceptable.	Comparison of relaxation with credible placebo designed to elicit expectation for improvement comparable to relaxation training. Individual treatment by four experienced clinical therapists, specially trained for study. Each patient given four weekly 1-hour sessions. Active treatment: relaxation and meditation at bedtime Attention placebo treatment (quasi desensitisation): inert insomnia bedtime procedure. Sessions 1–3: patients advised to expect no improvement until after week 4 (counter demand instructions). Session 4: Patients advised to expect marked improvement in sleeping patterns (positive demand instructions).	Pre-treatment questionnaire: sleep history, anxiety, sleep log. Post-treatment questionnaires: (a) 4 x 1 week – latency of sleep onset, duration of sleep, number of nocturnal awakenings, daytime naps (b) 6-month follow-up (13 subjects) – 7-day sleep log.	No significant pre-treatment differences between groups. No interaction effects involving therapists ($p > 0.20$). Moderate and severe subjects differ significantly on sleep onset latency ($p < 0.001$), difficulty in falling asleep ($p < 0.004$), quality of sleep ($p < 0.04$). Active treatment subjects improved significantly in counter demand and positive demand periods ($p < 0.001$). Placebo subjects only improved after adding positive demand instructions ($p < 0.007$). No differences observed between severe and moderate groups in response to counter demand and positive demand instructions. Significant differences in sleep onset latency between active and placebo subjects in counter demand period ($p < 0.02$) but not in positive demand period ($p > 0.3$). Anxiety fell for all subjects ($p < 0.001$). At follow-up: placebo subjects did not retain treatment gains as effectively as active group.
Caudill M, *et al.*, 1991[154] (Nashua, New Hampshire, USA)	Chronic pain patients from an HMO; January 1987–December 1990. Mean age 40.5 years. Variety of pain sites; included patients with chronic pain > 6 months unless receiving treatment outside organisation through workmen's compensation scheme; average duration of chronic pain 6.5 years). Size: n = 109; two patients dropped out when hospitalised for unrelated illness. Design: Before and after, uncontrolled observational study. Quality assessment: poor.	Medical examination followed by group therapy provided by internist and psychologist. 11 independent and sequential groups each meeting for 10 sessions of 90 minutes. Aim: multidisciplinary approach to treat four components of pain experience – somatic, affective, behavioural, cognitive. Sessions 1–5 covered patho-physiology of pain, medical and behavioural management, relaxation, life style, nutrition, yoga and self-management strategies. Sessions 6–10 taught cognitive restructuring.	Objective outcome measures chosen, rather than subjective reports, namely: (i) return to work (ii) clinic and emergency room use (a) pre-intervention (i.e. 12 months before and 2.5 months during intervention programme) (b) post-intervention (groups I–XI (n = 109) followed for 12 months; groups I–IV (n = 50) followed for 24 months). Visits per month were calculated.	No statistically significant group differences at baseline. Treatment resulted in statistically significant reduction in clinic visits ($p < 0.001$) from average of 1.07 per month before intervention to average of 0.68/0.58 visits per month 1/2 years after intervention. Patients with largest numbers of pre-intervention clinic visits exhibited largest reductions in visits after intervention. Economic analysis: • 511 fewer visits for 109 patients at $45 (average cost) per visit = $23,000 saving in year 1 • cost of intervention including staff time and overheads = $1000 per group • net saving to HMO was minimum of $12,000 in year 1 of intervention rising to $23,000 for year 2 (calculations ignored potential medication and diagnostic test savings).
Daniels & Sallie, 1981[204] (Kiribati, Australia)	Schizophrenic patients and 13 controls, inpatients from medical and surgical wards given lumbar puncture. Patients had no expectations of effects of lumbar puncture. Size: n = 28; both groups randomly assigned to: A. information group, n = 15 B. no information group, n = 13. Additional untreated control group, C, medical and surgical inpatients, n = 14, not receiving lumbar puncture. Design: RCT. Quality assessment: acceptable.	Group A told they might experience a headache. Group B given no information.	Patients assessed for headaches 4 hours and 24 hours after lumbar puncture.	7/15 lumbar puncture patients told they would have headache reported having one. 1/13 no information group reported that they had headache. This difference is significant ($p < 0.05$). No difference seen between schizo-phrenic patients and controls receiving lumbar puncture; four in each group reported headaches. Control group: one patient reported headache in 24 hour period (similar frequency to no information group).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Eden & Yaakov, 1995[157] (Israel)	25 naval cadets, age range 18–20 years, none of whom had been to sea before. Size: n = 25; random assignment to intervention or control group. Design: RCT, correlational analysis. Quality assessment: acceptable.	Intervention group instructed by personal interview and group video presentations that they had ability to overcome sea-sickness and perform well at sea. Control group given by same means general information on sea-sickness.	Baseline: • general self-efficacy. After intervention, before going to sea: • specific self-efficacy, i.e. how well cadet expected to perform at sea despite sea-sickness. After sea voyage: • cadets rated level of sea-sickness on 29 symptoms • performance of cadet rated by blinded observer on three scales.	• Sea-sickness and performance correlated (–0.72). • Larger differences between specific self-efficacy groups (after intervention) than in general self-efficacy groups (before intervention). • Experimental group had less sea-sickness than controls and better performance ($p < 0.01$).
Egbert, *et al.*, 1964[127] (Boston, USA)	Elective intra-abdominal operations. Size: n = 97; A. special care group, n = 46 B. control group, n = 51. Design: RCT. Quality assessment: acceptable.	Anaesthetist saw all patients on day before surgery to describe anaesthetic and recovery procedure. Special care group also given information about postsurgical pain and its management through relaxation and medication. Special care group received regular postsurgery care visits from anaesthetist.	Postoperative narcotics for pain Length of stay Postoperative physical and emotional state, subjective assessed by independent observer.	No significant difference between groups in gender and age. Special care patients used less pain relief in 5 days after operation than controls ($p < 0.01$). Independent observer recorded special care patients as more comfortable and in better physical and emotional condition than controls. Special care patients sent home by surgeons, on average, 2.2 days earlier than controls ($p < 0.01$).
Evans & Richardson, 1988[148] (London, UK)	Patients admitted to teaching hospital over 12-week period for total abdominal hysterectomy. Size: n = 39 (46 patients of whom four declined, two did not complete and one was excluded); controls, n = 20; treatment group, n = 19. Design: RCT. Quality assessment: acceptable.	Treatment consisted of audiotape played during the operation which included following information: • normal postoperative procedures with advice on how best to cope (9 minutes), e.g. mobilisation. • third person comments about success of operation (1 minute). Tape played continuously until wound closure. Control group listened to blank tape.	Baseline, on admission: • mood • Spielberger (State–Trait anxiety) • distress (visual analogue scale). Postoperative: • mobility, assessing amount of help required when first got up • vomiting. 5 days after surgery: • mood and anxiety • pain intensity and distress • difficulty with micturition, flatulence and defecation • severity of nausea. Over 5 days postoperatively: • pyrexia • analgesic usage. At discharge: nurses' assessment of patient recovery (worse, same, better than expected); patient's guess at tape content.	Main effects: No significant differences between groups at baseline. Suggestion group significantly better than expected recovery ($p < 0.002$), mean postoperative stay 1–3 days shorter than control group ($p < 0.002$). Suggestion group also experienced shorter period of pyrexia ($p < 0.005$) and reported reduced gastrointestinal problems ($p < 0.03$). No significant differences between groups on nausea and vomiting, analgesia, mobilisation, distress from pain, mood and anxiety. No patients were able to recall intraoperative events and sounds. All but one patient in suggestion group guessed correctly that they had been played an instruction tape while those in control group guessed no better than chance would predict.
Fawzy, *et al.*, 1993[166] (California, USA)	Patients with Stage I (no metastasis) or Stage II (local node metastasis) malignant melanoma, aged ≥ 18 years and English-speaking. Excluded if undergoing immuno-therapy, chemotherapy, radiation therapy or receiving medication that affected immunofunction. Size: n = 80, randomly assigned to: intervention group, n = 40 (34 available for recurrence/survival analysis); control group, n = 40 (34 available for recurrence/survival analysis). Design RCT. Quality assessment: acceptable.	Relates baseline mood, coping and immune factors to 5–6 year recurrence and survival. Intervention compared 6 weekly 1 hour and one half-hour structured sessions (7–10 patients) covering education about the disease, stress management, coping skills and support from staff. Control group received no intervention.	Time from surgery to recurrence, death.	No differences in gender, Breslow depth (size of tumour) or sites between groups. Intervention group (mean age 46 years) significantly older than controls (mean age 40 years). Fewer deaths in intervention group ($p = 0.03$) and trend for fewer recurrences ($p = 0.001$). Breslow depth significantly related to recurrence ($p = 0.001$) and survival ($p = 0.001$). Adjusting for Breslow depth, treatment was still significant ($p = 0.04$ for recurrence, $p = 0.006$ for survival). Increases in coping scores in first 6 months significantly related to survival ($p = 0.03$) and trend apparent for recurrence ($p = 0.06$).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Finkler & Correa, 1996[84] (Mexico)	First time internal medicine outpatients; abdominal, back, chest and head pain, predominantly immigrant married women in mid-30s with primary education and, on average, 5 children; age range 18–65 years. Size: n = 267 recruited, 205 completed; 17 physicians. Design: observational uncontrolled; correlational and qualitative analysis. Quality assessment: poor.	Patients interviewed and taped while waiting to see doctor (open-ended). Medical consultation (and follow-ups if appropriate) audio-taped, after which doctor told investigator diagnosis. Guided interview (also taped) at home post-consultation on symptom relief and problem management and length of time symptoms experienced. All interviews transcribed verbatim.	Recovery rate (full/partial/none) Physician's diagnosis, and tests and treatments prescribed Variables related to doctor–patient communication: • doctor's explanation of nature of illness • doctor offers diagnosis • patient agreement with diagnosis • doctor meets patient's expectations of treatment • doctor gives instruction concerning medication • doctor gives reassurance • doctor addresses patient in formal or familiar way • time patient spent with doctor • patient participation in consultation.	**Quantitative analysis** 17% fully recovered, 58% partly recovered and 25% no recovery. No relationships between patient's perception of recovery and physician's diagnosis, number of diagnoses, laboratory analyses, prescription for medication. Significant predictors of recovery: average length of time symptoms experienced ($p < 0.01$), doctor explaining nature of illness ($p = 0.006$), doctor giving diagnosis ($p = 0.002$), patient agreeing with diagnosis ($p = 0.018$), patient participating in consultation ($p = 0.04$) (not significant: doctor giving reassurance or instruction of medication, use of familiar means of addressing patient, time spent with doctor and doctor meeting patient's expectations). Separate analysis for patients reporting full and partial recovery show communication variables to be significant predictor for former and time experiencing symptoms to be significant predictor for latter. Full recovery associated with self-limiting symptomatology for which authors argue doctor–patient relationship can influence perceived outcome. Partial recovery (majority of cases) is in chronic conditions where doctor can do little. However, length of time before seeking treatment highly significant for this group: treatment within 1 month compared with 12 months raises chances of partial recovery threshold. Patients treated during first month are 59 times more likely to report partial recovery than those seeking treatment after 1 year. Sociodemographic variables hindering recovery: having children under 5 years; immigrant status ($p < 0.05$). **Qualitative analysis** Patients attributing full (partial) recovery to medication 51% (28%); relationship with physician 17% (21%); laboratory or other diagnostic test 11% (9%); don't know 17% (36%) (relationship with physician reflects advice, reassurance, confidence given verbally, non-verbally and through physical examination).
Fisher, *et al.*, 1964[197] (USA)	Neurotic out-patients who dropped out of a placebo-controlled trial; no information on age or gender. Size: n = 66 drop-outs (study total, n = 238). Design: 2 x 2 factorial balanced placebo. Quality assessment: poor (insufficient detail).	50% patients given meprobamate, 50% placebo. Within these groups, half given therapeutic expectancy, half given experimental expectancy. Therapeutic expectancy was positive about drug's effectiveness and mentioned drowsiness side-effects as evidence of that effectiveness. Experimental expectancy stressed that drug was experimental, did not mention side-effects, and created impression of uncertainty.	Percentage of patients who dropped out of treatment after 6 weeks.	Drop-out rate: 16% for group given meprobamate and therapeutic expectancy; 32% for other three groups. Difference significant ($p < 0.05$).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Fortin & Kirouac, 1976[129] (Montreal, Canada)	Inpatients awaiting general surgery, men and women, age range 20–59 years. Size: n = 69 recruited, 59 completed; patients paired by age and type of surgery and randomly assigned to: A: n = 37, received education intervention; B: n = 32, usual care controls. Design: RCT with matched pairs where possible. Quality assessment: acceptable.	Group A given preoperative patient education (Programme d'Enseignement Preoperatoire Dispense à des Patients de Chirurgie Elective) by nurses, 15–20 days before admission to hospital; included details of hospital, surgery, postoperative symptoms and exercises and self-care suggestions. Group B (Controls) treated identically apart from education programme.	No baseline measurements except assessment of socio-demographic factors. Physical functional capacity: • inpatient ambulatory activity assessed physical function • activities of daily living on 10th and 33rd postoperative day • time taken to return to work/ usual activity. Others: • analgesics taken • comfort • satisfaction • length of stay in hospital • re-admission • death in first 33 days. Assessors were blinded.	Groups comparable at baseline. Postoperatively – level of physical functioning higher in experimental group than control group at each testing time ($p < 0.05$). Experimental group reported more comfort throughout ($p < 0.05$). Experimental group used less i.m. analgesics in first 72 hours ($p < 0.025$). Non-significant trend for earlier resumption of work/usual activities for experimental group (averaging 2 days). No significant differences between satisfaction or length of stay in hospital between groups. One experimental re-admission for unrelated event. No deaths.
Freund, *et al.*, 1971[199] (Virginia, USA)	Obese black women patients and 8 white physicians. Patients screened and included if clearly field-dependent or field-independent. Size: n = 64, equally divided between field-dependent (32) and field-independent (32); also equally divided between physicians (eight patients, four of each type). In each group of four patients, random assignment to: • known drug and dextroamphetamine • investigational drug and dextroamphetamine • known drug and placebo • investigational drug and placebo. Design: 2 x 2 x 2 x 8 factorial design. Quality assessment: acceptable.	To test effect on drug (dextro-amphetamine)/placebo response of patient's personality (field-dependent/independent) and treatment atmosphere (known drug/investigational drug). Field-dependent people more highly influenced by immediate social and interpersonal environment than field-independent individuals. Known drug condition assumed to raise doctor and patient expectancies compared with investigational drug condition. Doctors told aim was to compare dextroamphetamine and new drug (rubrate) but, in fact, dextroamphet-amine and placebo used. Patients saw doctors weekly for 5 weeks. Interviews taped and patient attitudes to doctors studied.	Weight loss after 1 week and 4 weeks.	Drug resulted in more weight loss than placebo ($p < 0.001$ at 1 week, $p < 0.05$ at 4 weeks). Physician variable was significant ($p < 0.025$) at 1 week but not at 4 weeks. Field (in)dependency had no effect on weight loss. Known drug treatment condition associated with greater weight loss at 1 week ($p < 0.025$). At 4 weeks more than twice the weight loss occurred under known drug conditions than under investigational drug conditions but difference not significant. Large number of interactions investigated, many highlighting physician differences.
				continued

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Goebel, *et al.,* 1993[169] (Illinois, USA)	Outpatient volunteers at Veterans Administration hospital, borderline to moderate hypertension, without comorbidities, age range 21–65 years. Size: 175 volunteers; 117 met inclusion criteria. 10–20 patients yearly treated over 12 years. Assigned to five groups in order of entry: A. relaxation only, n = 24 B. relaxation and electromyogram biofeedback, n = 23 C. BP biofeedback only, n = 20 D. relaxation and BP biofeedback, n = 26 E. transactional analysis control group, reading only, believable placebo, no skills training, n = 24. Design: complex repeated measures RCT. Quality assessment: acceptable.	Phase 1: baseline – creation of positive expectancies • weeks 1–5, BP and medication (if required) stabilisation • weeks 6–26, positive expect-ancies deliberately raised about possibilities for self-regulation of BP of all participants, through video or behavioural treatment and individual counselling. Self-measurement of BP taught, and physiology, risks, etc. explained • weeks 24–26, randomisation to five groups, plausible rationales for each treatment method offered, individual goals set. Phase 2: 12 weeks learning • patients instructed and encouraged to practice their allocated techniques regularly at home. Patients instructed twice weekly for 6 weeks, then once weekly for 6 weeks. Positive encouragement continued throughout. Phase 3: follow-up • once weekly for 6 weeks, then once monthly for 6 months. Study design aims to: (i) see if behavioural treatments have effects over and above placebo (positive expectancy) effects, by introducing behavioural treatments in second phase, after impact of fostering positive expectancies has been fully exposed in Phase 1 (ii) isolate specific learning effect from placebo effects of behavioural treatment in Phase 2 through use of control group (iii) identify different effectiveness of different behavioural treatments through additive stepped care design.	Regular BP measurements throughout study by participants and staff (close correlations between participant and professional readings taken as verification of accuracy).	Baseline comparison of groups: no significant differences, except with respect to duration of hypertension. Phase 1: significant and parallel reductions in BP in all groups. Phase 2: although more modest, parallel but significant reductions in BP in four treatment groups continued (p range, 0.0001–0.01). Control group BP remained close to stabilised Phase 1 level. No significant difference between treatment modalities. Conclusions: Phase 2 isolated specific learning effects of behavioural treatments. Control groups showed no extra effects beyond stabilised baseline despite equal time, attention, warm relations, belief in treatment. Control Phase 1 (liberal positive expectancy/placebo factors) potentiated specific effects during regular clinical work.
Greenfield, *et al.,* 1985[177] (Los Angeles, California, USA)	Chronic care population, peptic ulcer patients in Veterans Administration hospital. Age range, 43–67 years, mean 55 years; 91% men, 47% employed. Size: n = 51, 44 completed): A. n = 22 (intervention); B. n = 22 (controls). Design: RCT. Quality assessment: acceptable.	Group A: algorithm used to help patients read their medical records. Patients coached to ask questions and negotiate medical decisions when meeting doctor. Group B: usual education concern-ing ulcer disease management. Equivalent amounts of time spent with patients in each group (20 minutes). Intervention carried out just prior to second scheduled appointments by trained research assistants.	Baseline audio-recording of consultation and questionnaire to patients (mailed back) covering health status, preference for active involvement and knowledge of ulcer disease. Intervention delivered immediately before second consultation. Second consultation recorded and (with physicians blind to patient's group) consultation-specific questionnaire completed by patient, including ulcer disease knowledge. 6–8 weeks after intervention, second questionnaire measuring physical and role limitation, pain, preference for involvement in medical care and satisfaction mailed to patients. Teams of trained and blinded coders classified verbal utterances of doctor and patients according to control, communication and affect categories.	Groups comparable at baseline and representative of all clinic patients. Strong agreement between coders ($\geq$ 85%). No difference in length of consultations after interventions (both groups averaged 16 minutes) but way time spent differed significantly between groups. In experimental group, patients more involved in consultation: 30% increase in intensity of conversation compared with controls ($p < 0.05$) and more assertive ($p < 0.05$) although they did not ask significantly more questions. Patients in experimental group reported less physical limitations ($p < 0.05$) and there was a non-significant trend to less pain after intervention. For experimental group patients' health outcome improve-ments correlated with involvement by patient in consultation. No significant difference in satisfaction with care but preference for involve-ment increased with experimental group compared with controls ($p < 0.01$) and ulcer knowledge levels of controls rose compared with experimental group ($p < 0.01$). Knowledge, however, did not correlate with functional ability.

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Greenfield, *et al.,* 1988[175] (Los Angeles, California, USA)	Women patients (mean age 49.5 years) attending two university hospitals outpatient departments for management of diabetes. 37 physicians involved, blinded to patient groupings. Size: 98 eligible patients, 73 agreed to participate and randomly assigned to experimental and control groups. Experimental: n = 39 (33 completed, 18 at one clinic, 15 at the other); Control: n = 34 (26 completed, 14 at one clinic, 12 at the other). Design: RCT Quality assessment: acceptable.	Experimental group: diabetic algorithm used in conjunction with medical records to teach patients how to focus on treatment issues so that they could improve their information-seeking skills and negotiate treatment with doctor (20 minutes). Control group: standard educational materials provided in sessions of equivalent length.	Baseline: First clinic visit: • HbA_1 level measured • physician–patient interaction by analysing audiotape of consultation • functional limitations (i.e. disease severity using simple count of conditions present) • health-related quality-of-life measures, patient satisfaction and knowledge of diabetes collected by questionnaire that was mailed back • change in treatment regimen extracted from records. Random assignment to groups; intervention delivered immediately preceding second scheduled doctor's appointment; consultation recorded. Intervention repeated before third doctor encounter – also recorded. 2 weeks later (fourth consultation), baseline measures repeated (consultations were typically 12 weeks apart). Teams of trained and blinded coders classified verbal utterances of doctor and patients according to control, communication and affect categories.	Strong agreement between coders ($\geq 85\%$). No differences between drop-outs and completers on functional status, age or gender. No differences between experimental and control groups on demographic disease characteristics. Mean HbA_1 in experimental group decreased significantly ($p < 0.01$) and differed significantly from that in control group ($p < 0.01$), which did not fall at all. All but seven experimental patients experienced HbA_1 reductions. Experimental groups had reductions in treatment regimes compared with controls ($p < 0.01$). They also reported less days off work (controls showed increase) ($p < 0.01$), significantly fewer function limitations ($p < 0.01$) and assessed their health more favourably than controls ($p < 0.001$). Experimental patients twice as effective as controls in eliciting information from physician after intervention ($p < 0.05$), although there were no pre-intervention differences and some patients (possibly those preferring passive role) did not respond by participating more. Experimental intervention, functional limitations at baseline, HbA_1 at follow-up and number of diabetic complications explained 66% of the variance in follow-up functional limitations. No differences in satisfaction or knowledge between groups at baseline or endpoint assessment.
Gryll & Katahn, 1978[82] (Texas, USA)	Oral surgery clinic dental patients needing local anaesthetic for mandibular block injection before extraction; mean age 33 years, 53% men. Size: n = 160; ten per group formed by manipulation of four factors. Design: 2 x 2 x 2 x 4 factorial. Quality assessment: acceptable.	A green placebo capsule and a message about its effect was administered to three in every four patients prior to injection. Four factors varied in consultation: (i) status of individual telling patient effect of pill (dentist or dental technician) (ii) attitude of dentist to patient (warm, much verbal interaction; neutral, minimal verbal interaction) (iii) attitude of dental technician to patient (warm or neutral) (iv) message as to anticipatory effect of pill (oversell: pill very effective at reducing tension, anxiety and pain; undersell: pill may reduce tension, anxiety and pain; saliva: pill will reduce saliva; no pill).	• Pain of injection: 5-point scale • Fear of injection rating, pre- and post-placebo • Level of anxiety rating, pre- and post-placebo.	Pain of injection related to dentist's attitude ($p < 0.05$), dental technician's attitude ($p < 0.01$), the message ($p < 0.0001$). Status of practitioner approached significance. Many complex interactions between variables explored. Anxiety fell significantly after placebo for patients in oversell and undersell groups compared to no placebo ($p < 0.05$). Anxiety and fear rose significantly after placebo for patients in saliva and no pill groups ($p < 0.01$). Fear fell significantly after placebo for patients in oversell group ($p < 0.01$). Different dentists or technicians had no significant effects on pain, fear and anxiety.
Hashish, *et al.,* 1988[202] London, UK	Patients admitted to hospital, not day cases, for surgery to remove bilateral impacted third molars, age range 16–70 years. Size: n = 125, randomly allocated to groups, using random numbers: A. received ultrasound, intensity 0.1 w/cm^{-2} with circular movement of applicator, n = 25 B. as A except intensity set to zero, n = 25 C. as B but no movement of applicator, n = 25 D. patients massaged with applicator disconnected, n = 25 E. no form of ultrasound, n = 25. Group sizes maintained by replacing drop-outs and exclusions. Design: RCT. Quality assessment: acceptable.	4–6 hours after surgery, treatment groups received 5 minutes of presented ultrasound treatment over jaw. Groups A, B, C, D told that treatment had been found to reduce pain and swelling. Coupling cream used. All patients received normal antibiotic and analgesic cover but no anti-inflammatory drugs.	Baseline: measured on day prior to surgery: • anxiety • serum C-reactive protein • serum cortisol • swelling • mouth opening (trismus). Follow-up: On first postoperative day, measured all again plus pain, distress and coping ratings.	Swelling and postoperative increase in serum C-reactive protein significantly less than controls in ultrasound group A ($p < 0.05$), mock ultrasound group B ($p < 0.05$), stationary mock ultrasound group C ($p < 0.01$). Small but significant decrease in trismus for groups A and B compared with untreated control (p value not given). Trend (not significant) to decrease in trismus for groups C and D. No significant effect for plasma cortisol. Only one effect for pain, distress and coping ratings with decrease in pain intensity for B and in anxiety for C compared with E ($p < 0.05$). No association between reductions in anxiety scores and relief of pain and swelling.

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Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Hellman, *et al.,* 1990[168] Boston, USA	80 volunteers with 'psychosomatic' dysfunction, high health service users in Harvard Community Health Plan; age range 20–73 years (mean 37 years). Variety of symptoms including headache, gastro-enteritis, palpitation, malaise, sleep disorders. Size: 116 subjects referred by primary physicians, 80 recruited and randomly assigned to three groups, using random numbers: A. n = 28 B. n = 27 C. n = 25. 9 non-attenders dropped; 63 completed 6-month follow-up. Study design: RCT. Quality assessment: acceptable.	Two groups (A and B) received different 'behavioural medicine' interventions covering information on stress management, relaxation, awareness and cognitive restructuring. Actively tried to address relationships between thoughts, behaviours and symptoms. A. Ways to wellness intervention. B. Mind–body group. C. Control group (who received information only intervention but did not practise techniques they were told about). A and B met weekly for $1^1/2$ hours for 6 weeks; C met weekly for 2 weeks.	Office visits 6 months before and 6 months after intervention for chart reviews. Distress from physical symptoms, using Medical Symptom Checklist at baseline and 6 months after intervention. Psychological distress using Bipolar Profile of Mood States at baseline and 6 months after intervention.	Behaviour medicine groups experienced significantly greater reduction in office visits ($p < 0.001$) and discomfort from physical ($p < 0.01$) and psychological ($p < 0.05$) symptoms than information only group. When financial benefits of office visits saved compared with costs of providing behavioural medicine interventions, estimated net savings of $3900 in 6 months after intervention for patients involved.
Heszen-Klemens & Lapinska, 1984[182] (Warsaw, Poland)	All new patients in categories below attending six specialist outpatient clinics. Size: 62 patients, 11 doctors: n = 22 (minor illness, gingivitis catarhalis) n = 20 (moderately severe curable illness, pulmonary tuberculosis) n = 20 (serious, dangerous illness, coronary heart disease). Design: observational. Quality assessment: poor (apart from intervention, groups not treated identically).	Complete first and second verbal interactions between patient and physician audiorecorded and analysed according to nine categories of utterances. Patients interviewed to determine their health behaviours 7–10 days after each consultation. Physician evaluated treatment results at second visit on basis of: A. subjective patient complaint reports B. objective test results giving a medical data index.	• Patient recall • Health behaviour • Treatment results.	Relationships found between process of doctor–patient interaction and patient recall and health behaviour 7–10 days later and treatment results at next consultation. Recall increased with more doctor utterances and fell with larger amounts of advice ($p < 0.05$). Similar relationships for compliance ($p < 0.05$). Patient initiated health activity directly related to degree of patient involvement in consultation ($p < 0.05$). Treatment outcome significantly related to patient initiated health activity ($p < 0.05$) but not to compliance. Doctor–patient interaction significantly related to both treatment outcome measures but particularly to patients' subjective reports. Greater improvement in patients' health evaluated on basis of subjective measure if doctor asked more questions and if there was greater emotional exchange between doctor and patient ($p < 0.05$). An important factor influencing objectively assessed treatment outcome is information exchange ($p < 0.05$).
Ho, *et al.,* 1988[203] (London, UK)	Patients undergoing removal of impacted third molar under general anaesthetic; age range 15–44 years. Size: n = 79 (24 men, 55 women) randomised to five groups: A. active ultrasound (0.1 w/cm^2), n = 16 B. placebo ultrasound (zero intensity), n = 16 C. stationary zero intensity ultrasound, n = 15 D. self manage, n = 16 E. control, no treatment, n = 16. Design: RCT. Quality assessment: acceptable.	After emerging from general anaesthetic, patients received: groups A & B: 5-minute simultaneous massage of both sides of face by dentist group C: 5-minutes stationary application to both sides of face by dentist group D: instructions on massaging cheeks with disconnected applicator. Groups A, B, C, D: patients told treatment prescribed had been found to reduce pain and swelling. Coupling cream applied to applicators.	On day before and 24 hours after surgery: • trait and state anxiety • stress arousal • pain intensity • pain distress • pain coping • plasma cortisol (higher with passive/ dependent coping) • facial swelling.	No significant differences between groups at baseline. Women had higher pain and anxiety levels ($p < 0.05$). Ultrasound groups A, B, C had less swelling than control group (A: $p < 0.01$; B, C: $p < 0.05$). Pain and swelling closely correlated. Treatment had no effect on emotional state or coping. Cortisol levels lower in massage groups ($p < 0.05$).

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Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Johnson, *et al.*, 1978[130] (Michigan, USA)	Cholecystectomy or inguinal herniorrhaphy surgery patients without other recent health problems; age range 21–69 years. Size: 58 cholecystectomy patients (11 men), mean age 46 years; 57 herniorrhaphy patients (2 women), mean age 45 years. Random assignment stratified by age and physician to five groups: A. n = 12; non-specific pre-admission information and sensory information B. n = 9; specific pre-admission information and sensory information C. n = 8; non-specific pre-admission information and sensory information on two occasions. D. n = 11; specific pre-admission information and sensory information on two occasions. E. n = 11; sensory information and exercise instruction after admission. Original study had two further conditions: F. n = 12; sensory information and exercise instruction G. n = 12; no intervention, control. Design: complex repeated measures, RCT. Quality assessment: acceptable.	Different degrees of detail in information given to different groups preoperatively. Sensory information (delivered by audiotape) in replication study differed from that of original study only in that it included procedural (temporal) details. Restated information was delivered on first postoperative day.	Preoperatively: • mood checklist • pain (self-reported). Postoperatively: • mood, pain and ambulation on first, second and third postoperative days • analgesic use • length of hospital stay • post-hospitalisation recovery.	**Cholecystectomy** Preoperative information reduced postoperative hospitalisation ($p < 0.001$) and post-hospital recovery ($p < 0.001$). Sensory information, when combined with exercise instruction most effective. Repeating information reduced analgesic use ($p < 0.05$). Temporal orienting information reduced postoperative feelings of helplessness ($p < 0.01$). No significant effects on pain. **Herniorrhaphy** No significant results, only trends for effects observed, notably with respect to moods, ambulation and pain, analgesics, hospitalisation and post-hospital recovery.
Johnson, *et al.*, 1988[141] (New York, USA)	84 men, with no history of radiation therapy, with stage A, B, or C prostate cancer. Mean age: 67.8 years, 64% retired. Size: n = 97; 84 completed, 11 dropped for metastatic disease or language and cognitive deficits, two withdrew. Random assignment to: A. information group B. usual care, attention control group. Design: RCT. Quality assessment: acceptable.	Intervention group given four taped messages, 4–7 minutes in length, covering procedural, temporal, setting, sensory information. Self-care tips for managing side-effects were included. Controls had interviews of similar length to taped messages with research assistant on neutral topics. Two messages delivered before first treatment and further two during treatment period.	Coping measured by: • Sickness Impact Profile, showing functional status • Profile of Mood States during first, third and last week of treatment and 1 and 3 months after treatment ended (self-reported). Disruption score calculated covering sleeping, eating, mobility, social interaction, recreation (disruptions in work, body care, intellectual functioning were infrequent and not included in disruption index).	Information group experienced significantly less disruption in normal activities than controls at all points except last 3 months after completion of treatment ($p < 0.025$). Although information group on average had less mood disturbance, there was no significant difference between groups because of high variance and low overall levels in this variable. Mood disturbance was significantly related to side-effects ($p < 0.025$) and was lower for older men ($p < 0.05$).
Kantor, *et al.*, 1966[207] (USA)	Surgical patients reporting postoperative pain. Size: n = 244 on day 1; n = 77 on day 2. Design: RCT, double unknowns design. Quality assessment: acceptable.	Day 1: randomly assigned to placebo or one of four analgesics Day 2: switched to placebo.	Pain intensity and relief assessed 5 times at hourly intervals after receiving medication.	Data suggests that effectiveness of placebo depends on effectiveness of drug on day 1. Placebo on day 2 provided more pain relief when preceded by active drug on day 1.
Kaplan, *et al.*, 1989[179] (USA) This paper covers four similar studies, two of which are separately recorded above (Greenfield, *et al.*, 1985[177] – ulcers; Greenfield, *et al.*, 1988 – diabetes). The other two studies are reported here.	• Hypertension patients sampled from free clinic • Postmastectomy breast cancer patients scheduled for adjuvent chemotherapy. Size: hypertension, n = 105, randomly assigned to intervention and control groups; breast cancer, n = 43, enrolled in experimental group until quota reached; subsequent patients assigned to control group. Design: two studies reported – hypertension RCT; breast cancer: non-equivalent controlled trial. Quality assessment: acceptable.	Group A: algorithm used to help patients read their medical records. Patients coached to ask questions and negotiate medical decisions when meeting doctor. Group B: usual education concerning disease management. Equivalent amounts of time spent with patients in both group (20 minutes). Intervention carried out just prior to second scheduled appointments by trained research assistants.	Baseline recording of consultation and questionnaire to patients (mailed back) covering health status, preference for active involvement and knowledge of disease. Intervention delivered immediately before second consultation. Consultation recorded (physicians blind to patient's group) and consultation-specific questionnaire completed by patients, including disease knowledge. 6–8 weeks after intervention, second mailed questionnaire covering self-reported functional status, health, days lost from work. BP measures of hypertensive patients, chemotherapy experiences of breast cancer patients (from diaries). Teams of trained and blinded coders classified verbal utterances of doctor and patients according to control, communication and affect categories.	Similar results from all four studies resulted in them being combined for analysis, n = 252. Treatment had significant effect in reducing functional limitations in all four groups ($p < 0.05$). Fewer days lost from work, fewer health problems and functional limitations associated with more patient involvement in consultation at baseline ($p < 0.05$). Intervention resulted in significantly more patients controlling behaviour during office visit ($p < 0.05$) and greater eliciting of information from physicians.

continued

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Kellner & Sheffield, 1971[178] (Liverpool, UK)	Outpatients suffering anxiety and depression or psychophysiological symptoms continuously for more than 6 months, but without other psychiatric illness; age range 19–50 years, median 31 years; duration of symptoms, 6 months–12 years, median 3 years. Size: n = 24 (four failed to attend retests), 12 men, 8 women; 15 completed; A. anxiety and depression patients, n = 10 (8 completed) B. psychophysiological symptoms, n = 10 (neurotic hypochondriac patients) (7 completed). Design: longitudinal, observational. Quality assessment: poor (insufficient detail; high attrition rate in very small study).	Each patient seen by psychiatrist in clinic and told they would need to wait 6–8 weeks for treatment. After initial wait: Group A: Three sessions of abreactions (intravenous drip to encourage free talking about problems, which were recorded). Then further 6–8 week wait, followed by three psycho-therapy sessions based around tape recordings. Then third 6–8 week wait, followed by regular treatment. Group B: Physical examination, X-rays, blood work as necessary to exclude physical illness. These discussed with patient and genesis of somatic symptoms in absence of physical pathology was explained. Then another 6–8 week wait for further treatment.	Symptom rating test administered by psychologist every 2 weeks throughout study. This was semi-structured interview based on checklist of neurotic symptoms that measure neurotic distress.	Group A: significant reduction in distress between beginning and end of first waiting period ($p < 0.01$). No significant differences found between self-ratings in other two waiting periods. Group B: significant difference found between self-ratings at beginning and end of first waiting period ($p < 0.05$). No significant differences between self-ratings during second waiting period.
Kendall, *et al.*, 1979[131] (Palo Alto, California, USA)	44 adult men in Veterans Administration hospital undergoing cardiac catheterisation, age range 39–77 years (mean 56.5 years); 42 white, 1 black, 1 hispanic; 32% experiencing first cardiac catheterisation; 41% current smokers. Size: 44 patients randomly assigned to four equal groups: A. CB intervention B. patient education intervention C. attention placebo control D. current hospital conditions control. Design: RCT. Quality assessment: acceptable.	A. Individual training in coping. B. Individual education about the heart and the impeding catheterization. C. Individual discussions focused on neutral issues. Day before admission, patients completed questionnaire and State–Trait Anxiety Inventory. Intervention delivered and anxiety measured again. Patient adjustment during catheterisation assessed by professionals involved, blinded to patient group. After catheterisation, patient completed questionnaire and anxiety assessed.	Anxiety, self-rated, before intervention, after intervention, after catheterisation. Professional assessment of anxiety during procedure.	Professional assessments during procedure correlated with self-report ($p < 0.005$). Professional assessments resulted in significant main effect for intervention groups compared with control groups ($p = 0.08$). No difference between mean group anxiety levels at baseline. Post-intervention groups A, B, C had significantly lower anxiety than group D ($p < 0.05$). In group A, CB intervention maintained lower anxiety during catheterisation ($p < 0.01$), while groups B and C did not.
Kincheloe, *et al.*, 1991[211] (Florida, USA)	Men and women aged 18–74 years attending a university College of Dentistry for dental treatment. Size: n = 77: A. 37 (21 women , 16 men, mean age 35 years) received topical anaesthetic B. 40 (21 women, 19 men, mean age 37.2 years) received placebo topical anaesthetic. A and B subdivided: A1, B1 received instructions; A2, B2 received no instructions. All groups further subdivided by patients' basic expectancies, i.e. high or low pain from dental injection. Design: RCT; 2 x 2 x 2 (8-group design). Quality assessment: acceptable.	Double-blind study: (i) patients asked about expectancy of pain from injection (ii) patients in instruction group told that topical anaesthetic would numb them and make injection less painful (iii) topical anaesthetic or placebo placed on gum for 3 minutes (iv) vitolometer applied to area affected by topical anaesthetic and patient asked when felt first sensation (v) injection given (vi) patients asked to rate injection.	• Patient's baseline expectations of pain from injection. • Level of sensory detection immediately after topical application. • After injection: rating of pain and how it compared with expectations.	Few significant results. No evidence that topical anaesthetic had any effect compared with placebo. No evidence that informing patient of effects of topical anaesthetic made any difference. Only significant finding was that patients with high pain expectations fulfil their expectations and perceive a dental injection as being more painful than patients with low pain expectation ($p < 0.05$).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Klerman, *et al.*, 1987[155] (Boston, Massachusette, USA)	People newly enrolled on Harvard Community Health Plan from seven health centres. Primary care patients with common conditions of psychological distress using a disproportional share of healthcare resources, referred for brief psychosocial intervention (interpersonal counselling) by nurse-practitioner. Size: group A (interpersonal counselling) n = 127 (64 completed); B (matched to group A on gender) n = 64. Design: 2-group design, matched pairs on gender. Quality assessment: poor (high attrition rate).	All mailed questionnaire, including the GHP questionnaire (negative symptoms). Score of ≥ 6 was taken as indicator of psychosocial morbidity. Individuals were telephoned and asked to take part in study. Early recruits assigned to treatment condition and later ones to control group. Group A: interpersonal counselling, 6 x 30-minute sessions by nurse-practitioner based on specially prepared manual. Intervention focused on life events, stresses and interpersonal relationships. Group B: untreated.	Baseline: • GHP questionnaire • utilisation of health services • intervention patients only – interviews to exclude serious psychiatric problems; medical status assessed to exclude serious medical problems. After intervention: • Group A – GHP questionnaire at end of interpersonal counselling; Group B sent GHP questionnaire 3 months after baseline (equivalent timing) • utilisation of health services for 12 months post-intervention.	No difference between total sample and completers. Groups comparable at baseline and consisted of mainly young adults. Many intervention subjects found at baseline to have psychiatric problems e.g. depression, phobias. GHP questionnaire scores fell more for intervention group ($p < 0.01$) and main benefit was in mood (especially depression) improvement. Trend (not significant) for less health care utilisation in Group A in 12 months after intervention.
Lamb, *et al.*, 1994[206] (Wisconsin, USA)	All patients receiving new prescriptions for ACE-inhibitors or NSAIDs (provided they had a telephone and no history of peptic ulcer) at an outpatient clinic; 77% were women; mean age 53 years. Size: n = 203 (57% receiving NSAIDs) randomly assigned to four teams of physicians and assistants. A and B, n = 104, intervention teams; C and D, n = 99, control teams. Design: RCT. Quality assessment: poor (insufficient detail).	Patients in intervention teams received verbal instruction and written handout about the name, purpose and dosage of prescribed medication together with details of the most common side-effects, neutrally worded. Instruction was delivered by team nurse, and was unknown to doctor. Control patients received normal discharge instructions which may or may not have included descriptions of side-effects.	Standard telephone questionnaire by blinded interviewer 14 and 21 days after prescription issued to measure number of patients reporting side-effects from targeted list.	Study groups similar on age, sex, financial status, medication prescription. No difference in incidence of targeted side-effects: A:B 38% C:D 37% ($p = 0.87$). Patients in intervention groups A and B reported 102 symptoms compared with 99 in control groups C and D ($p = 0.99$). Strong correlation between non-compliance and reported side-effects ($p = 0.001$). Compliance was 25% (75%) for patients with (without) side-effects.
Langer, *et al.*, 1975[128] (Connecticut, USA)	Adult patients undergoing variety of elective surgical procedures for which prognosis favourable. Size: n = 60, assigned to four groups on stratified random basis to equate groups on type and seriousness of operation, gender, age and religion: A. coping strategy only B. information only C. coping and information D. neither coping nor information. 15 per group for preoperative measures. One drop-out postoperatively. Design: RCT, 2 x 2 factorial design. Quality assessment: acceptable.	Two strategies for stress control evaluated. Four types of pre-operative interview carried out by investigator: A. emphasis on cognitive coping control over aversive events; patients trained in cognitive coping strategies e.g. calming self, talk and selective attention B. realistic information and reassurance about surgery procedures and postoperative feelings C. A and B combined D. neutral interview about hospital procedures to control for attention effects and avoiding giving information or coping advice.	• Before interview: nurses' ratings of patients' anxiety and dealing with stress, BP and pulse measures • 15 minutes after interview: nurses repeated same anxiety and stress, BP and pulse measures • Postoperatively: amount of pain medication and sedatives, BP and pulse measures.	Coping intervention produced improved nurses' ratings post interview on anxiety ($p < 0.05$) and dealing with stress ($p < 0.01$). Information only reduced both ratings. Groups A, B and C requested less pain relief than D ($p < 0.05$), and fewer sedatives ($p < 0.03$). Significant main effect for coping strategy. Non-significant trend to increased length of stay A (shortest)–C–B–D (longest). Information alone did not affect postoperative outcomes. No effects on BP and pulse.
Leigh, *et al.*, 1977[143] (UK)	Men and women aged 20–60 years undergoing a variety of minor or intermediate operations for non-malignant disease in a district general hospital. All had undergone previous anaesthesia without ill effects. Size: n = 32. To prevent intergroup contact consecutive patients were recruited in the order: C. n = 8, controls/no intervention A. n = 12, visit from anaesthetist B. n = 12, issued with booklet *About your anaesthetic*. Design: 3-group controlled trial with no randomisation. Quality assessment: poor (subjects not randomised to groups).	Booklet described procedures, anaesthesia and its safety and what to expect postoperatively. Visit from anaesthetist covered the same material as booklet plus a discussion of individual patients' concerns. Maximum length of visit 10 minutes, no physical examination. Two assessments on day of operation, well before premedication: (i) before intervention. (ii) 3 hours after intervention (or 3 hours after first assessment for controls).	Anxiety level using Eysenck personality inventory and Speilberger self-evaluation questionnaire – part 1 trait anxiety (pre-intervention only); part 2 state anxiety.	No basic personality differences between groups. No anxiety differences between groups pre-intervention. Pre-intervention anxiety levels were consistently high. All patients showed decrease in anxiety between assessments. On average, reduction was A > B > C. Non-significant reduction in anxiety in C. Falls in anxiety for A and B were significant ($p < 0.01$, $p < 0.02$, respectively).

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Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Lorig, *et al.*, 1993[126] (California, USA)	Chronic arthritis volunteers recruited by media advertisements 1984–85. Size: 1. n = 343 (1984); n = 219 (1985) 2. n = 284 of original 343 patients 3. n = 224 (79% of 284) + 177 (81% of 219). Design: longitudinal, observational. Quality assessment: acceptable.	Arthritis self-management programme (ASMP) comprised six weekly 2-hour sessions in groups of 10–15 covering physiology of the disease, exercises, relaxation, medication, problem solving. 1. Outcomes compared with controls at 4 months; controls then treated. 2. Reinforcement programme after 1 year; assessed at 20 months after start of programme (for early participants only). 3. All participants traced at 4 years to assess long-term effects, and compared with 'comparison group' and natural data concerning arthritis.	Validated instruments, self-administered questionnaire, covering: • pain • disability • self-efficacy • depression • health service utilisation (physician visits) validated by chart reviews. This paper records outcomes at 4 months and 4 years, having noted no significant benefits observed with education reinforcement programme after 1 year.	At 4 months ASMP patients recorded significant increases in taught behaviours ($p < 0.01$), significant reduction in pain ($p < 0.05$) and trend towards reduced frequency of physician visits compared with controls. At 4-year follow-up, ASMP and comparison groups were similar at baseline for osteoarthritis but some differences observed between groups for rheumatoid arthritis. ASMP patients on average showed 15–20% less pain and 40% fewer physician visits despite 9% rise in physical disability compared with baseline. The depression improvement at 4 months was not sustained at 4 years. Self-efficacy improved as time passed. Comparison groups did not show similar improvements: pain and physician visits remained same or increased slightly (National Health Interview Survey). Financial extrapolations suggested 4-year savings on physician visits (6% discount rate), net of cost of ASMP programme, were $648 and $189, respectively (nationally this would sum to $13.5 and $19.5 per patient).
MacDonald, *et al.*, 1980[212] (Dundee and London, UK)	Patients aged over 18 with endo-scopically confirmed duodenal ulcers. One doctor at each centre treated all patients at that centre. Size: 58 patients completed trial, mean age 42.5 years: A. n = 29, given new anti-peptic drug B. n = 29, given placebo. Design: RCT. Quality assessment: poor (insufficient detail).	Aimed to determine factors contributing to response of duodenal ulcers to placebo treatment, specifically the role of: • demographic characteristics • duration of illness and effect of treatment • expectation of success or failure of new drug • presence of psychiatric problems • suggestibility. Patients given placebo or drug (identical in appearance) and antacid tablets for relief.	Baseline: • endoscopy • questionnaire: – demographic data – duration of illness – time lost from work – previous treatment and efficacy – expectations of result from new treatment • General Health questionnaire to detect psychiatric problem • body sway test to assess primary suggestibility resulting from authoritative verbal instruction that patient is swaying. Patients kept diary of symptoms. Follow-up: endoscopy 3 weeks and 6 weeks after start of medication or placebo.	No significant difference between drug and placebo with respect to: • healing (measured by endoscopy), which occurred in 37 patients, 17 of whom received placebo • relief of symptoms, which occurred in 35 patients, 16 of whom received placebo. Healing significantly associated with relief of symptoms but no other variable ($p < 0.01$). Symptom relief more common in males, higher social class, those expecting complete cure and those without evidence of psychiatric problems ($p < 0.01$). Expectancy had no significant effect on healing. 18 of 25 patients expecting to be cured reported symptomatic relief. None of three patients not expecting to benefit had relief from symptoms ($p = 0.036$). The remaining 26 patients (four did not answer) who were uncertain about outcome or had not expected cure showed no significant association between expectation and outcome. Suggestibility not significant.

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Medina, 1992[156] (Chicago, USA)	Male and female patients, aged 26–69 years, with disabling chronic post-traumatic headache on daily basis over ≥ 3 months (mean headache duration 1.5 years), attending a neurocentre. Size: 20 patients in two groups: A. Pure post-traumatic headache group, n = 7 (5 men and 2 women) B. Post-traumatic headache-plus group, n = 13 (7 men and 6 women). Design: uncontrolled case study. Quality assessment: poor (uncontrolled observational study).	Evaluation and explanation of multidisciplinary approach. Individual treatment plan devised with neurologist and involving partners. • Pharmacological treatment: prescription of prophylactic medication, with gradual withdrawal of narcotics. • Therapy: education on condition and management of symptoms, biofeedback training and stress management. • Physical therapy: exercises, transcutaneous nerve stimulation and neuromuscular re-education for patients with spinal injury. Patients attended 1–2 times per week for 1–3 months depending on severity. Each visit included progress assessment by neurologist. Regular follow-up sessions arranged after end of treatment for average of 1–5 years.	Baseline: history, neurological examination, job activity assessment. Measures during treatment: • frequency, duration and severity of headache • record of usual activities for personal enjoyment • other pain and its severity • sleep pattern • side-effects of medications • return to work.	• All patients: headache scores improved, four markedly, four moderately, two slightly. • Improvement occurred within 7–150 days (average 48.7 days). • 17 from 20 patients returned to work (85%) within 21–224 days (average 111 days). Author claims programme resulted in financial and human savings. Cost of programme (mean duration 9 weeks): A. $3849; B. $7030. Author argues that headache disability following head injury involves 1.4 million Americans at annual cost of $2 billion. This programme is cheaper than inpatient care and than comparable outpatient care management programmes that cost, on average, $8160 for 3 weeks. It also breaks chronic nature of problem that has been shown by other studies to become permanent when not effectively treated.
Mercer, 1996[160] (Boston, Massachusetts, USA)	English-speaking Parkinson's disease patients (Hoehn and Yahr stages I-IV) in Harvard Community Health Plan, staff model HMO, June 1992–June 1993. Size: n = 50, randomly to: A. n = 27, usual care plus PROPATH (25 completed) B. n = 23, usual care (21 completed). Design: RCT. Quality assessment: acceptable.	PROPATH is a health management programme produced by Healthtrac Inc. to be used in conjunction with usual medical care for patients with Parkinson's disease. It consists of an introductory video cassette, a series of educational pamphlets, and periodic reports sent to patients and physicians based on patient completing a questionnaire. PROPATH seeks to provide individual in-depth coping advice for Parkinson's disease patients. This study seeks to assess independently the effects of PROPATH on patients' perceived general health and well-being, satisfaction with medical care and utilisation of healthcare resources. Physician impressions are also assessed.	Patient questionnaire at 0, 3, 6, 12 months measured: • general health, disability days, fatigue • psychological well-being • satisfaction with care. Physician questionnaire with patients in PROPATH group completed assessment of programme at 12 months. Utilisation measured by medical record review at 12 months covering documented physician visits, telephone calls and hospitalisations over study period.	No significant differences between groups at baseline. General health and well-being improved for PROPATH group and declined for controls (p = 0.04) (but no significant differences between groups for subscales of disability days, fatigue, psychological distress or of patient satisfaction). Physicians did not perceive PROPATH to be beneficial. No significant utilisation differences between groups. Physician ratings of patient health changes did not differ significantly between groups.
Montgomery, et al., 1994[161] (USA)	Parkinson's disease patients receiving Parlodel®, Eldepryl® or both. Patients could call toll-free to join free PROPATH programme (Healthtrac Inc.). 6-month trial. Size: patients from 400 consecutive enrolment cards randomly allocated to two groups (290 completed); A. n = 140, intervention group B. n = 150, control group, received questionnaire only Design: RCT. Quality assessment: acceptable.	Intervention delivered by mail. PROPATH programme designed to slow rate of disability progression using educational strategy that sought to improve personal self-efficacy and optimism, and support and encourage exercise. 1-page disease questionnaires completed by patient or caregiver at 0, 2, 4, 6 months and returned by mail. Their analysis yielded computer-generated progress reports and individualised exercise, diet, side-effect control recommendations which were sent to patients and physicians. Patients also received educational material.	At each assessment: • Unified Parkinson's disease rating covered 'on' and 'off' Activities of Daily Living, side-effects and global patient assessment • exercise • rate of disease symptom progression • direct and indirect costs (hospital days, days confined to home/unable to work, medication use and doctor visits) • self-efficacy • care-giver stress. At 6 months, quality-of-life assessment.	No difference between groups at baseline except controls slightly older. Over 6-month period, 12 of 13 variables showed differences favouring intervention group, compared with controls. Intervention group had: • increased exercise (p = 0.01) • less 'off' time (p = 0.002) • 10% reduction in Parkinson's summary score (p = 0.001) • reduced side-effects (p = 0.02) • flat progression scores (p = 0.01) (those for controls rose) • reductions in levodopa requirements (p = 0.001) (controls rose) • fewer doctor visits (p = 0.09). For quality-of-life measures intervention group showed: • improved self-efficacy (p = 0.05) • reduced caregiver stress (non-significant trend). Cost reductions (doctors visits, hospital and sick days) estimated at $570–$820 per patient over 6 months. Programme costs, $100 per patient per year yields benefit:cost ratio of 12:1.

continued

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Morgan, *et al.,* 1983[190] (Edinburgh, UK)	Chronic bronchitis patients attending respiratory outpatient clinics; mean age 60.5 years. Size: n = 50, 38 men, 12 women; 46 completed. Design: correlational. Quality assessment: poor (uncontrolled observational study).	No intervention.	Outcome: exercise tolerance measured by walking distance in 12 minutes (assessed twice and better distance used). Predictors: • anxiety, depression, hostility, by adjective checklist • General Health Questionnaire for general psychiatric disturbance • attitudes and beliefs about self, illness and treatment on sematic differential • perceived exertion in 12-minute walking test • ventilatory capacity; forced expired volume, forced vital capacity.	Independent factors contributing to walking distance identified by multiple regression were (in order of magnitude) subjective perception of exertion, belief in efficacy of treatment, seriousness of bronchitis, seeing self as delicate, believing treatment successful, forced vital capacity, and believing smoking is awful (all *p* < 0.05).
Morisky, *et al.,* 1983[162] (USA)	Poor, urban, hypertensive patients attending two clinics at Johns Hopkins Hospital, January–March 1975; median age 54 years. Size: n = 400; 91% black, 70% female, 290 completed. Accumulated sampling procedure allocated 50% to experimental phase 1 (E1) and 50% to control group (C1); in phase 2, 50% E1 remained experimental (E2), remainder became controls (C2); similarly for phase 3 (E3, C3). Result was eight different educational treatment combinations each of which was assigned 50 patients. Design: RCT, 2 x 2 x 2 factorial structure. Quality assessment: acceptable.	Three-phased education programme sequentially introduced over 18-month period, designed to address needs identified by hypertensive patients through diagnostic baseline survey. Phase 1: exit interview; 5–10 minutes individual counselling after seeing doctor to reinforce instruction. Phase 2: instruction of patient with family member to engender family support. Phase 3: three group sessions to help management and strengthen self-confidence about ability to manage BP.	Data extracted from medical records at entry, 18 months and 54–60 months later relating to: (1) BP (2) weight (3) appointment-keeping (4) mortality (5) presence of cardiovascular-related risk factors. Patient reports of medication compliance. Socio-economic, demographic, medical history and other background information collected at baseline.	Comparative analysis of characteristics of assigned and treated patients in each group revealed no significant differences. Drop-outs followed: (1) 65% increase in BP control over 5 years for patients in any intervention group (significant), compared with 22% increase for patients in usual care (C1, C2, C3) (not significant). Significant difference in proportion with BP control between Phase 2 and 3 participants and usual care. BP control not related to frequency of provider–patient interaction but to involvement of family members. (2) Reduction in obesity in most groups assigned any intervention. Slight increase in average weight for usual care group. Difference significant (*p* < 0.04). (3) Appointment keeping and compliance for all intervention groups better than controls, particularly in groups receiving phases 2 and 3. (4) Mortality lower, survival higher for intervention groups. All causes 5-yearly mortality rate 57.3% lower in treatment group than usual care (*p* < 0.05). Hypertension-related 5-yearly mortality rate 53% lower in treatment groups than usual care (*p* < 0.01). Outcomes correlated. Phase 2 and 3 participants have better weight control, appointment keeping, compliance and BP control.
Myers, *et al.,* 1987[205] (Ontario, Canada)	Patients (age and sex not reported) treated at three university affiliated hospitals with diagnosis of unstable angina pectoris. Size: 555 patients at 3 centres (A, n = 313; B, n = 86; C, n = 156) randomly assigned to four treatment groups: • aspirin (325 mg q.i.d.) • sulfinpyrazone (200 mg q.i.d.) • both drugs • matching placebo tablets (matched to drugs). Design: RCT, *post hoc*. Quality assessment: acceptable.	All patients given tablets in double-blind conditions. Patients at centres A and B told on informed consent form that side-effects not anticipated beyond occasional gastrointestinal irritation and, rarely, skin rash. Patients at centre C told that sulfinpyrazone and aspirin are generally well tolerated and have been used for many years to treat other conditions and there is no evidence that they will cause any harm, beyond a tendency to bleed, but serious haemorrhage is extremely unlikely. Differences in consent forms were not planned but reflected different hospital review processes.	At each visit (3-monthly), brief medical history, physical examination and ECG performed. Study physician saw patients on alternate visits (i.e. every 6 months) or on other occasions if new symptoms or medical problems occurred. Side-effects noted by nurse (3-monthly) without ascertaining clinical importance and adverse reactions evaluated by study physicians. In cases of minor symptoms (e.g. nausea, headache), patients encouraged to continue but many declined to do so. Patients followed-up for up to 2 years.	Inclusion by two of three centres, of statement outlining possible gastro-intestinal side-effects led to 6-fold increase (*p* < 0.01) in number of subjects reporting minor gastrointestinal symptoms and withdrawing from study. Symptoms not associated with clinical or laboratory abnormalities and could not be confirmed by study nurse and physician. Minor side-effects reported earlier by subjects at centres A and B than those at centre C (*p* < 0.02). Of 200 patients reporting minor gastrointestinal side-effects, only 56% were receiving aspirin. Major gastrointestinal complications similar at all three centres (peptic ulcer; bleeding). No patient discontinued therapy because of subjective, non-gastrointestinal side-effects.

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Oetker-Black, *et al.*, 1992[149] (USA, mid-West)	Female patients aged 22–78 years (mean 46 years) scheduled for cholecystectomy under general anaesthesia, and able preoperatively to walk for at least 10 minutes. Size: 70 patients in study period met criteria, 68 agreed to participate. Design: observational, correlational. Quality assessment: poor (weak observational study).	Study sought to relate preoperative self-efficacy to postoperative behaviour. Two types of self-efficacy (ex-Bandura, 1977[68]): (a) outcome expectation, i.e. believe that behaviour will generate certain outcomes (b) efficacy expectation, i.e. belief that can undertake task.	Preoperative Self Efficacy Scale, measuring efficacy expectations and outcome expectations concerning deep breathing, mobility, pain management. Postoperative self-reports: • recall of expected events • requests for pain medications. Deep-breathing capacity and walking measured pre- and postoperatively.	Higher preoperative efficacy expectations correlated with better postoperative performance on deep breathing, walking and recall of events ($p < 0.05$). Correlations accounted for only 4–7% of variance indicating that efficacy expectations and outcome expectations had minimal effects on enactment of postoperative behaviour. Higher preoperative outcome expectations related to more requests for pain medication ($p < 0.05$). Significant relationship between scores on two self-efficacy subscales ($r = 0.52$, $p < 0.01$). Those with high efficacy and outcome expectations walked longer than those with low scores on one or both scales ($p \leq 0.05$).
Oldenburg, *et al.*, 1985[173] (Sydney, Australia)	All patients under age 70 years admitted to Sydney University Hospital over 12-month period with confirmed diagnosis of first myocardial infarction. Mean age 56 years, range 29–69 years. Size: n = 46 (41 men, 5 women) allocated to groups according to month of admission; A. n = 16, education, relaxation and counselling B. n = 16, education and relaxation only C. n = 14, no-treatment controls Five patients died by 3-month follow-up, three from B, two from A. Design: RCT. Quality assessment: poor (weak observational study; minimal statistical analysis, high drop-out rate).	Interventions administered on transfer to medical ward, some 3–5 days after admission to coronary care unit. **Standardised individual counselling** Discussion of fears and anxieties, progress with relaxation and education tapes, and behavioural strategies for changing coronary risk factors post discharge. Given in 4–6, 45-minute sessions, first session within 48 hours of admission. **Standardised education** Three pre-recorded tapes to patient and families covering nature of heart attack, primary and secondary risk factors, impact of myocardial infarction on sexual functioning and strategies for modifying risk factors. Given on days subsequent to relaxation tape. **Relaxation training** A pre-recorded tape of progressive muscular relaxation using breathing, cognitive and tension awareness exercises. Given within 48 hours of admission.	Measures: • Heart Attack Inventory Scale: (1) type A behaviour (2) marital dissatisfaction (3) suppressed hostility (4) work overload (5) anxiety (Speilberger scale) (6) General Health Questionnaire (7) attitudes to illness • Frequency of cardiac symptoms • Cardiovascular medications • Doctor, hospital visits • Cigarette, alcohol consumption • Exercise. Measurement: • Day 10 (prior to discharge). • 6 and 12 months (after discharge).	No significant differences between groups at baseline. Participal components analysis yield three main factors: psychological dysfunction, unhealthy lifestyle, dependence on health care. At 12 months, significant improvement ($p < 0.05$) in both counselling and education groups in psychological functioning (anxiety, Type A behaviour, General Health Questionnaire, approach to illness, physical activity). Although all three groups showed lifestyle improvements (smoking, work overload, alcohol) at 3 and 6 months, but only counselling group maintained improvement at 12 months ($p < 0.05$). No statistical differences between three groups on dependence on health care (physical symptoms and use of health services) at 12 months. By 12 months, return to work level was 80% for A, 78% for B, 56% for C.
Olsson & Tibblin, 1989[174] (Sandviken, Sweden)	Patients at Knuten Health Centre, aged 16 years or older (mean age 30.8 years), suspected by counselling nurse of having acute streptococcal tonsillitis but testing negative for mononucleosis. Size: 35 men, 65 women, identified and randomly assigned to two groups: A. experimental B. control – before being seen by same doctor. Design: RCT. Quality assessment: acceptable.	Experimental group: met by doctor in corridor, given full ENT examination in darkened room, and full information about condition, its treatment and prognosis. Handwritten prescription for penicillin and promise that doctor would call in 2 days to check progress also given. Average consultation length, 10 minutes. Control group also met by doctor in corridor but received routine examination and less information and preprinted prescription. Average consultation length, 6 minutes.	At treatment patient asked about severity of throat symptoms and confidence in pharmacological treatment. Throat cultures taken and sent to laboratory, and 2 days after treatment, subjects were telephoned by interviewer, who was blind to patient's group, to administer structured questionnaire covering course of illness, effect of treatment on symptoms and satisfaction with consultation.	Cultures showed 58% had streptococcal tonsillitis. In other cases illness assumed to be viral in cause. Baseline analysis showed experimental and control groups to be comparable on age, gender, incidence. Analysis of outcome measures showed: • throat symptoms in experimental group improved significantly more than in control group, especially among women ($p < 0.005$) and among those with streptococcion throat culture • experimental group felt significantly more positive about treatment they had received than controls ($p < 0.005$) • experimental group were significantly more satisfied with information they received, especially men, than controls ($p < 0.001$)

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Orth, *et al.*, 1987[185] (Houston, Texas, USA)	Patients with essential hypertension; study conducted in four community health centres in low income areas and in the home. 1. Patients: mean age 60 years, 81.7% female; 79% black, 7% Mexican-American, 14% white. 2. Providers: physicians (2 black males, 4 white males, 3 Hispanic males, 1 Asian female) and physician's assistant (1 black male). Size: 217 patients, 170 completed. Two patients excluded as no history segment and 45 dropped because of BP equipment failure. 11 providers (9 physicians, 2 physician's assistants). Design: observational, correlational. Quality assessment: poor (weak observational study, high attrition rate).	Aim was to correlate two verbal components of doctor–patient interaction with BP control: (i) patient exposition of their history and symptoms (ii) provider explanation of illness and treatment (as distinct from instruction) to help patient's understanding, thus allowing them to make more constructive decisions about daily health behaviour, which should, in turn, promote BP control. Method: audiotaped record made of conversation between patients and providers during routine visits lasting on average 8 minutes. Content analysis of conversations using verbal response mode coding of frequency of utterances involving: (i) patient exposition resulting in a frequency-based patient exposition index that showed the quality of patient self-expression. (ii) provider explanation resulting in a percentage-based provider explanation index that showed the quality of provider informativeness.	Baseline: patient's seated BP before (by nurse) and during interview (by provider). Follow-up: by research assistant 2 weeks later: BP measurement and medication adherence (pill counts).	Patient exposition was significantly correlated with reductions in systolic and diastolic BP from clinic to home interview ($p < 0.05$) but not with BP levels at clinic or home interview. Patient exposition increased with age ($p < 0.05$), and was greater in women ($p < 0.05$) and white ($p < 0.01$) patients. It also varied significantly between 11 providers ($p < 0.001$). Provider explanation: significantly correlated with lower diastolic BP at home ($p < 0.05$); provider explanation differed significantly between doctors ($p < 0.001$). Medication adherence: no significant associations but sample reduced to 108 owing to various practical difficulties.
Parker, *et al.*, 1988[164] (Missouri, USA)	Patients (mean age of 60 years) with a diagnosis of rheumatoid arthritis admitted to Veterans Adminstration hospital for medical care. Mean disease duration 11.4 years, mean education 10.8 years. Size: n = 83 (80 men, 3 women) randomly assigned to three groups; A. n = 29, CB pain management B. n = 26, attention-placebo C. n = 28 (1 left area), controls. Design: RCT. Quality assessment: acceptable.	CB group received: • 1-week inpatient programme covering information about rheumatoid arthritis and medical management, gate control theory of pain, acute vs. chronic pain, plus training in specific coping strategies, family dynamics and communication • support group programme with routine clinic visits focusing on application of CB principles to everyday life (mean 6.6 sessions per patient over 12 months). Attention-placebo group: • 1-week inpatient programme covering information on rheumatoid arthritis and its management, pain theory and acute vs. chronic pain. No recommendations for behaviour or attitude change • support group sessions using didactic format but following same schedule as CB group (mean 6.2 sessions/patient over 12 months). Control group: • routine care and no follow-up beyond regular clinic visits.	No differences perceived in credibility of CB and attention-placebo programmes: • pain (visual analogue scale and McGill Pain Questionnaire) • Coping Strategies Questionnaire and Ways of Coping Questionnaire • impact of arthritis on dexterity, physical and social activity • depression (Beck Inventory) • rheumatoid arthritis symptoms and disease status • difficulties, pressures and problems in everyday life (Hassles Scale) • treatment adherence. Baseline measures taken on first day of inpatient stay for CB and attention-placebo groups and at outpatient clinic for control group. Repeated assessments in clinic at 6 and 12 months.	Groups similar at baseline. No significant treatment effects at 6 or 12 months. CB group showed significantly greater use of coping strategies and significantly more confidence in their ability to manage pain (Coping Strategy Questionnaire $p < 0.0017$ at 6 months and $p = 0.0001$ at 12 months). High adherence CB patients reported less pain ($p = 0.001$) and less helplessness ($p = 0.05$).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Perry, *et al.*, 1994[151] (Missouri, USA)	Women patients (age range 35–57 years) undergoing simple hysterectomy for reasons other than cancer at university hospital. Size: n = 99 patients. Design: correlational. Quality assessment: acceptable.	Standardised general anaesthesia, surgery and patient-requested and -delivered analgesia therapy postoperatively.	Baseline psychological questionnaire measured preoperatively: • anxiety • expectations regarding pain • need to be 'in control'. Postoperative measures: • McGill Pain Questionnaire (day 1) • patient-controlled anaesthesia (daily) • visual analogue scales for pain and anxiety (daily) • Likert scale measurements of overall pain and discomfort • recovery measures: time to oral intake and time to hospital discharge.	Multiple testing but only selected results relating to expectancy reported here. Preoperative: 45% expected bad/very bad pain; 90% expected moderate/severe pain; 10% expected mild/no pain. Expecting more pain predicted postoperative overall pain levels ($p = 0.005$) but resulted in lower pain rating index. Pain expectations had no effects on recovery indices or analgesic use.
Philips, 1987[165] (Vancouver, Canada)	Chronic pain (diverse) patients, mean age 39 years (range 18–61 years); mean pain duration 8.6 years (range 2–30 years). Size: n = 40, randomly allocated to A. n = 25, treatment group (22 available at 4 months, 19 at 12 months); B. n = 15, waiting list control. Types of pain: Back: A, n = 9; B, n = 4 Head: A, n = 9; B, n = 7 Other: A, n = 7; B, n = 4. Design: RCT. Quality assessment: acceptable.	9-week outpatient programme for groups of 5–7 patients, meeting 1^1/2 hours per week. Taught management strategies, relaxation, exercises, CB strategies, and medication reduction by multidisciplinary team. Evaluations: A. Baseline, after 9-week intervention, 8 weeks after end of treatment and at 1 year B. Before wait and between 2 and 6 months later.	• Beck Depression Inventory • Life impact checklist • McGill Pain Questionnaire • Pain behaviour checklist • Diary • Patient evaluation of effect of treatment on problem and feeling of control • Therapist's evaluation of effect of treatment on pain (not at 12 months).	Immediate effects of treatment: (a) reductions on all measures except behavioural ($p < 0.05$) (b) no significant changes over period on any measure (c) large increase in self-efficacy rating ($p = 0.002$) and fall in perceived size of problem suggesting attitude shift ($p = 0.0001$). Other changes for Group A: • therapist rated significant improvements • large reduction in medication use (85% drop on average). Persistence of treatment effects: these were sustained at 2-month follow-up but more pronounced at 12 months. Main effects on pain levels and impact of pain. Some slight increases in medication use and reductions in exercises reported at 12-month compared with 2-month follow-up.
Postlethwaite, *et al.*, 1986[138] (Victoria, Australia)	Coronary artery graft surgery patients, mean age 52 years. Size: 27 men admitted to public hospital for elective coronary artery graft surgery, 0.7 heart attacks, 31 months angina. Randomly assigned to one of three groups: A. stress inoculation group B. attention-education group C. no-treatment control group. Design: RCT. Quality assessment: poor (small study with weak results owing to lack of power).	Group A. Stress inoculation for pain control, i.e. • explanation of the pain • skills training phase for coping skills • rehearsal phase to test new skills. Group B. Attention-education. Group C. Discussions related to patient's previous experience of pain and factors contributing to pain. Groups A and B had two 90-minute sessions individually with first author of this paper. Group C (control group) patients were told that experimenter was collecting data on postsurgical pain, anxiety and depression. Patients not seen again after initial assessment session.	Preoperatively (all patients): • State–Trait Anxiety Inventory • Depression Adjective Checklist. Postoperatively (all patients) daily for 14 days: • 24-hour average pain • physical therapy pain rating scale • daily analgesic intake • Depression Adjective Checklist • state–anxiety from State–Trait Anxiety Inventory.	• Preoperatively groups did not differ on measures of depression, trait anxiety, or state anxiety. • Postoperatively no differences between groups in two pain rating measures, analgesic intake, measures of state anxiety and depression ($p > 0.05$).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Powers & Wooldridge, 1982[171] (Chicago, Illinois, USA)	Adult male and female patients aged under 75 years attending hospital clinics for management of essential hypertension. 72% black, 70% women, 34% unemployed, 46% no education beyond age of 15 years. Size: heterogeneous sample of 160 from inner city health facility (n = 62), community health facility (n = 20), private hospital clinic (n = 34), university hospital clinic (n = 27), private physician's office (n = 17). Random assignment (blocked by gender, race, time since diagnosis) to 16 different treatment combinations. Design: randomised, 2 x 2 x 2 x 2 factorial experiment. Quality assessment: acceptable.	Factorial design to test relative effectiveness of four variations in nurse's teaching approach: (a) directness of nurse's interaction style – either informed patient without considering patient's viewpoint or involved patient (b) degree of emphasis on self-responsibility and active health-care participation by patient, i.e. high or low degree of patient choice in decision making (c) degree of emphasis on negative consequences of uncontrolled hypertension, 'silent killer' versus emphasis on controllability (d) numbers of meetings with project nurse – high personal responsibility subjects were scheduled for two extra meetings with nurse and taught to monitor own BP. Other patients also randomised to this section. Time 1: Patients received instructions from tape recording, discussion with nurse, booklet. Goals identified. Content same for all patients but way information presented was manipulated. Time 2 (2 weeks later) and Time E (exit) (3 months later), education, medication, BP and progress to goals checked by nurse.	Time 2 and Time E compared with Time 1 for: • measures of patient knowledge of aetiology and symptoms, prescribed medications and BP levels collected by blinded research assistant • assessment by nurse of whether patients had attained goals regarding medication, health (diet, exercise, smoking, drinking) and social issues (relationships, finance, employment) • reduction of mean arterial BP.	Content analysis of nurse–patient interactions used to validate manipulation although effect of nurses on patients self-responsibility limited. Many interactions tested. Knowledge related significantly to number of meetings and emphasis on patient responsibility. Overall, patients in programme reduced BP but no statistically significant main variable or interaction effect of education approach found.
Putnam, et al., 1985[186] (North Carolina, USA)	Women first-time attenders at a walk-in hospital clinic (except for seriously ill). Of 364 approached over 6-month period, 27% refused, 8.5% too sick, 2% illiterate, 16.8% not first-timers. 14 physicians blind to purpose of study, all white, three women. Size: n = 143, 102 completed. Attrition rate reflected logistical problems. Design: correlational. Quality assessment: poor (insufficient detail, high drop-out rate).	Before and after consultation patient completed questionnaire. This included identifying any chronic illness and patient's health beliefs i.e. perceived severity of illness, control over illness and confidence in doctors. Consultation audiotaped. Telephone follow-up by research assistant 1 week and 4 weeks after clinic visit. Interviews transcribed verbatim and coded according to verbal response model which classified utterances. Three independent coders used and 70% agreement required. Interviews divided into medical history, physical examination and conclusion. Study focuses on patient exposition (frequency measure) and physician explanation (percentage measure).	1. Satisfaction 2. Compliance 3. Symptom status	Physician explanation positively and significantly correlated with satisfaction (*p* < 0.001). Physician explanation and patient exposition not correlated with compliance. Patient exposition significantly correlated with change in symptom status over 1 week (*p* < 0.05) (i.e. patients getting more explanation showed more improvement), although this correlation disappeared after controlling for initial symptom status.
(Rabkin, et al. 1990[200] (New York, USA)	Potential participants in RCT of antidepressant medication at university-affiliated outpatient research clinic over 5 years. Responders to 10 days of placebo treatment identified. Size: n = 58 (i.e. 10% of all patients receiving single blind placebo); 50 patients completed, 82% of whom had chronic depression, randomly assigned to: A. continue placebo, n = 27 B. discontinue placebo, n = 23. Design: experimental, observational. Quality assessment: acceptable.	10-day single blind placebo trial followed by re-evaluation by psychiatrist. Those patients improving with placebo randomly assigned to continue placebo medication for 6 weeks or have it discontinued (latter explained to patient as positive result of improvement). All patients told of placebo medication at end of 6 weeks.	Baseline data: Socio-demographic data and illness history. Hamilton Depression Scale and global improvement measured at baseline, 10 days, 2, 4 and 6 weeks. Telephone follow-up at 12 weeks.	Improvement between baseline and 10-day re-evaluation significant for all 50 patients included in study (*p* < 0.0000). After randomisation, half in each group relapsed within 6 weeks. Of 13 patients in group A maintaining improvement at week 6, 10 remained well at week 12. Of 11 patients in group B maintaining improvement at week 6, all remained well at week 12. Only variable distinguishing relapsers from those maintaining improvement was marital status (*p* = 0.0005).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Rainey, 1985[147] (Los Angeles, California, USA)	First time radiation therapy cancer patients. No restrictions on disease site or stage. Men and women equally represented, average age 50.8 years. Size: n = 60, assigned by treatment order (controls first) to: A. high information condition; 12-minute slide-tape programme designed to inform/reassure about process of radiation therapy B. usual care, controls received regular booklet on radiation therapy. Design: 2-group, controlled. Quality assessment: poor (patients not randomised to groups which were heterogeneous).	Assesses: (i) impact of audio-visual patient education module on cancer patient's treatment-related knowledge and affective status during radiation therapy (ii) whether difference in individual coping styles influences patients' responses to intervention (iii) radiation therapy 5 days per week for 4–6 weeks.	Coping styles measured before therapy on two scales: (1) Avoidant-Viglant Sentence Completion Test (2) modified Repression Sensitisation scale. Outcome variables: (1) patient knowledge of radiation therapy (2) patients' emotional state during therapy; State–Trait Anxiety and Mood Disturbance.	No significant differences between groups at baseline. Coping style results unrelated. After intervention but before treatment, significant differences between groups on knowledge but not on affective status. At end of treatment period, information group significantly less anxiety ($p < 0.05$) and mood disturbance ($p < 0.005$) than controls. No significant differences in knowledge because low information group had closed the gap (learnt from experience). Coping style did not significantly affect anxiety or mood.
Reading, 1982[146] (Los Angeles, California, USA)	Women in hospital for elective laparoscopy. Size: n = 59, randomly assigned to three groups A. n = 21, preparation B. n = 18, reassurance (placebo) C. n = 20, no intervention (control). Design: RCT. Quality assessment: acceptable.	On day before surgery patients interviewed for about 15 minutes: Group A given information about surgery in reassuring supportive way. Group B (placebo) given reassurance about general things but no specific information about surgery. This group received equivalent attention to information group. Group C given no intervention. Group A and B patients seen by research team for approximately 15 minutes before surgery. Staff in ward not aware of nature of study.	**Presurgery** Groups A and B asked about attitudes and completed Spielberger State–Trait Anxiety Inventory **Postsurgery** Interviewed by blinded assessor, 8–12 hours after surgery: • rated attitudes to surgery process • pain measured on visual analogue scale and card sort • State–Trait readministered • analgesic requirements recorded. **3-weeks postsurgery** Questionnaire covering subsequent pain, analgesic requirements and time to return to full health and work.	Groups comparable at baseline: presurgery anxiety measured pre-intervention in Group A was higher than in Group B whose anxiety ratings were measured post-intervention. Patients in placebo and control groups used significantly more analgesics than preparation group ($p < 0.05$). Pain ratings postsurgery no different between groups. Non-significant trend toward less time off work for prepared group.
Ridgeway & Matthews, 1982[134] (London, UK)	Hysterectomy patients of three surgeons using same ward at St George's Hospital, July 1980–June 1981. Excluded if: malignancy, two ovaries removed, vaginal hysterectomy, non-English speaking. Age range 27–61 years, mean 42 years. Size: 60 patients randomly assigned to one of three types of psychological preparation for surgery A. information about surgical procedure including sensations and postsurgical events (n = 20) B. introduction to cognitive coping technique by encouraging positive approach to worries (n = 20) C. general information about ward (control for non-specific effect of attention and reassurance) (n = 20). Ten further women declined to participate. Different surgeons' patients evenly spread between groups. Design: RCT. Quality assessment: acceptable.	Each group given booklet of similar appearance but instructions contained in it varied. Study aimed to separate effects of information from effect of behavioural coping strategies. Information reduces surprise and alarm generated by routine procedures and sensations, i.e. provides reassurance. Cognitive coping strategies teach a general strategy which can be applied to any worries.	(1) Penultimate day before surgery: • socio-demographic data. • illness history • personality and mood • coping questionnaire • expectations about surgery • instruction manuals distributed to those requesting them. (2) Day before operation: • nurse checks if patient read manual and information retained • anxiety rating • mood. (3) Postoperative day 3: • physical symptoms (nausea, vomiting, sleep) • three pain scales • mood • diary distributed to keep daily. (4) Postoperative 3 weeks: • mood • symptoms (from diary) – nausea, fatigue, pain, irritability, depression • resumption of activities (from diary) • reactions to instruction manuals. (5) Nursing records of hospital stay: • symptoms (nausea, wound, pain, temperature) • medications • days of hospital stay.	No significant differences between groups preoperatively. Second preoperative visit: • information group (A) knew most about hysterectomy surgery ($p < 0.01$) • cognitive coping (B) and information (A) groups showed trend towards reduced anxiety ($p = 0.06$). Day 3 postoperative: • no difference between groups or symptoms reported by patients, except sleeping where controls (C) more disturbed than other groups ($p = 0.04$) • nurse records showed decliners reported more pain and took more analgesics ($p = 0.05$); cognitive copers (B) took fewest analgesics ($p = 0.05$) • no length of stay or antibiotic consumption differences between groups. Post-discharge: • significant differences in symptom score: cognitive coping (B) least, then information group (A), then attention controls (C) ($p = 0.06$) • no significant differences between groups in resuming activity ($p = 0.16$) • mood – no significant differences between groups • rating of manual highest by information group ($p < 0.01$).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Robinson, *et al.*, 1989[158] (California, USA)	Over 8 months, families with child < 13 years with fever attending out-of-hours paediatric clinic (Kaiser Permanente HMO) recruited. Size: n = 497. Experimental (E), n = 247 (even record numbers); controls (C), n = 250 (odd record numbers). Random assignment to six subgroups each containing families from both groups A = 60E + 30C; B = 0E + 30C C = 40E + 40C; D = 30E + 30C E = 47E + 45C; F = 73E + 72C. Design: RCT. Quality assessment: acceptable.	Produced videotape *Fever in children: fears and facts*. Experimental group shown videotape while waiting to see physician. Both groups given written leaflet on childhood fever.	Baseline: recorded data on education, occupation, number of children, ethnicity. Outcomes: (i) fever knowledge score (i.e. number of wrong answers in a 10-item test) (ii) clinic utilisation, by chart reviews, over 1 year. All study families were followed for 2 months, 73.4% for 5 months and 40% for 8 months. Fever knowledge tested before intervention (in clinic) – subgroups A, B; immediately after intervention (in clinic) – subgroup B; 2 weeks, 3 months, 6 months after intervention (by telephone) subgroups C, D and E, respectively. Subgroup F was not tested.	No significant differences in characteristics of experimental and control groups at baseline. No significant difference in fever knowledge of experimental and control groups before intervention. After intervention, fever knowledge of both groups improved but that of experimental group had improved significantly more immediately after consultation, and at 2 weeks and 3 months later ($p < 0.001$). The significant difference in knowledge between the groups had faded by 6 months. However, at 6 months both groups scored significantly better than pre-intervention ($p < 0.005$), reflecting effect of pamphlet. Experimental group had significantly fewer fever-related visits after intervention. At 8 months experimental families had 25.3% fewer acute clinic visits than controls ($p < 0.001$) and 23.5% fewer after controlling for season of year ($p < 0.001$). No significant difference in non-acute clinic visits between groups.
Rost, *et al.*, 1991[181] (Missouri, USA)	Adult insulin-dependent and non-insulin-dependent diabetes patients with poor metabolic control attending 31/2 day in-hospital evaluation and treatment programme, Washington University. Size: n = 61, 52 completed. Experimental group, n = 30; control group, n = 31. Design: RCT (randomisation by weeks of treatment). Quality assessment: acceptable.	Experimental group patients given an additional two-part intervention: (i) 45-minute individual session with nurse on day before discharge to discuss (a) information-seeking and (b) decision-making skills (ii) 1-hour instructional package to be completed at home before next outpatient appointment to develop question-asking skills.	• Baseline – socio-demographic data, medical history • Audiotape analysis of consultations, at admission, discharge and 4 months after discharge • Psychosocial and physical functioning including Activities of Daily Living, assessed at baseline and 4 months after discharge • Metabolic control (HbA_1 assay, assessed at baseline and 4 months after discharge • Patients' recall of instruction assessed before discharge • Patient satisfaction • Physician satisfaction with encounter.	Experimental group patients asked significantly more questions at discharge, especially about disease process and test results ($p < 0.001$). Trend for experimental group to demonstrate more decision-making behaviour in discharge interviews than control group ($p = 0.08$). Experimental group had significantly longer discharge interviews than control group ($p < 0.05$). Intervention had no significant effect on patient's recall of discharge information. Patient and physician satisfaction not related to experimental condition. Metabolic control and functional status 4 months after discharge significantly improved for experimental group ($p < 0.02$) but not significantly improved for control group. Experimental group reported significantly better physical functioning than control group ($p = 0.02$). Intervention had no effect on psychological functioning.

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Scott & Freeman, 1992[170] (Edinburgh, UK)	63 GPs in 14 primary care practices, March 1987–March 1989. Patients aged 18–65 years about to start treatment for mild–moderate depressive illness randomly allocated (sealed envelopes) to: A. routine GP care, including drugs and referral as required B. amitriptyline as prescribed by psychiatrist C. CB therapy with clinical psychologist D. counselling and case work with social worker. Size: 194 patients referred; 143 met inclusion criteria (i.e. dysphoric mood and ≥ four biological features of depression as stipulated in *Diagnostic statistical manual of mental disorders,* 3rd ed.). Excluded if delusions, schizo-plurenia, suicide risk, alcohol/drug abuse. 121 agreed to take part. Drop-outs (15) were accounted for in analysis. Design: RCT. Quality assessment: acceptable.	Group B patients told about nature of depressive illness and that improvement can be expected using antidepressant drugs. Group C patients taught self-monitoring coping and behaviour strategies. Group D patients supported by encouragement and listening, exercise of authority and arranging social support.	Compared clinical efficacy, patient satisfaction and cost of usual GP care with three groups receiving specialist treatment. Patients interviewed by independent trained raters on day treatment started and at 4 and 16 weeks to measure severity of depression (Hamilton rating scale) and recovery rate (recovery defined as Hamilton score < 7). Baseline – clinical, demographic and social class information collected. Therapists recorded number, length of appointments. GP management details recorded from patient notes.	Groups compared at baseline and were similar on most clinical and demographic details except: (i) group C had smaller proportion of patients with history of depressive illness (ii) twice as many men in group B than in groups C or D. After 4 weeks: • group B (medication group) – significantly better results than GP care with respect to Hamilton score and recovery rate • group D – significantly better recovery rate than GP care. After 16 weeks: • only group D superior to GP care, although these patients at outset had average lower depression. Sub-group analysis of 22 melancholic patients: at 4 and 16 weeks specialist care groups (16 patients) had substantially less depression than eight treated by GP. Also, those getting specialist treatment had significantly greater recovery rates. Intervention costs of drugs and therapist time calculated. All specialist treatments involved at least twice as many appointments and from four (group B) to 14 (group D) times more face-to-face contact than GP care.
Scott & Clum, 1984[137] (Virginia, USA)	Surgical patients: 41 cholecystectomy, 19 abdominal hysterectomy, 4 vaginal hysterectomy; age range 19–70 years, mean age 43 years. Size: 72 recruited, 64 completed (55 female; 9 male). Random assignment to four groups: A. relaxation training (breathing) B. procedural and sensory information C. relaxation training and information D. control, no special information or relaxation given. Design: RCT. Quality assessment: acceptable.	Aim to test whether patient's coping styles (avoiders–sensitisers) affected postoperative impact of pre-operative information and/or relaxation training.	Pre-intervention: • McGill Pain Questionnaire • state–trait anxiety inventory • coping process measure to determine sensitisers and avoiders via taped and coded interview. Days 1 and 4 postoperatively: • McGill Pain Questionnaire • state–trait anxiety inventory. On discharge, records checked for analgesic use.	No significant treatment effects, but study did match treatments to needs of individual patients. Sensitisers benefited most from relaxation therapy alone, particularly in regard to self-reported pain ($p < 0.05$). Avoiders did not benefit from any of the treatments in a consistent fashion. Avoiders may do better when left alone.

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Shipley, *et al.,* 1978[144] (Missouri, USA)	Hospitalised patients receiving upper-gastrointestinal endoscopy; 50 men, 10 women, aged 22–80 years (mean 53 years). Size: n = 60, randomly assigned to: A. one viewing of endoscopy preparation tape (E1), n = 20 B. three viewings of endoscopy preparation tape (E3), n = 20 C. controls: no viewing of endoscopy preparation tape (E0), n = 20. Design: RCT. Quality assessment: poor.	Before endoscopy patients either not shown or shown 18-minute preparation tape one or three times. Controls not seeing endoscopy preparation tape were shown 26-minute unrelated video. Anxiety over endoscopy procedure related to: • patient's coping style • number of viewings of preparation tape. Videotape supplemented normal care whereby patients received information about the process from physician, nurse and experimenter.	Patient's coping style measured on unidimensional continuum – repression (non-anxious), sensitisation (overtly anxious). Anxiety measured by: • physiological measures (heart rate) during procedures • behavioural measures (nurse–physician rating before, during and after endoscopy) • patient self-report (Spielberger State–Trait Anxiety Inventory before and after procedure and post-endoscopy interview schedule at end). Also recorded amount of tranquilliser required.	25 repressors and 25 sensitisers identified (patients with median scores eliminated). Physician–nurse ratings showed E3 group less anxious than E0 ($p < 0.025$) and E1 less anxious than E0 ($p < 0.05$). Less diazepam required by E3 than by E0 or E1 patients ($p < 0.05$). No differences between groups in baseline heart rate, but E3 had significantly smaller increases in first 5 minutes of procedure than E1 ($p < 0.01$) or E0 ($p < 0.05$). No significant differences in second 5 minutes. No differences between groups in state–trait inventory before procedure but state anxiety ordered E0, E1, E3 after, with significant differences between groups ($p < 0.05$). Post-endoscopy interview revealed E3 found subsequent viewings of tape less upsetting ($p < 0.005$). Analysis for sensitisers and repressors produced scattered significant results. Generally sensitisers' anxiety inversely related to number of tape viewings. Repressors showed an inverted U-shaped function with one viewing producing most diazepam usage and highest heart rate. Fear reduced by no viewings or more viewings.
Shipley, *et al.,* 1979[145] (Missouri, USA)	33 male and 3 female hospitalised volunteers scheduled for upper-gastrointestinal endoscopy; age range 22–80 years, mean 54 years. All had had previous upper endoscopies (range 1–14 occasions). Size: three groups (no details of randomisation of group sizes): A. preparatory endoscopic videotape shown once B. preparatory endoscopic videotape shown three times C. unrelated tape shown. Design: randomised (presumed), controlled. Quality assessment: acceptable.	This paper differs from Shipley, 1978[144] only in subject population covered.	Patient's coping style measured on a unidimensional continuum – repression (non-anxious), sensitisation (overtly anxious). Anxiety measured by: • physiological measures (heart rate) during procedures • behavioural measures (nurse–physician rating before, during and after endoscopy) • patient self-report (Spielberger State–Trait Anxiety Inventory before and after procedure and post-endoscopy interview schedule at end). Also recorded amount of tranquillisers required.	E3 group: insertion of endoscope faster than for E1 and E0 subjects ($p < 0.05$). No other dependent variables approached significance for whole sample. Analysis of sensitisers, n = 17, and repressors, n = 16 (3 patients with median scores excluded), showed some differences between groups. Nurses rated sensitisers anxiety levels as inversely related to number of video viewings. Scattered significance for other variables. On some measures of anxiety repressors viewing preparatory tape had higher scores than unprepared repressors.
Simmons, *et al.,* 1988[163] (Texas, USA)	Patients completing 2-week intensive outpatient programme for chronic pain (70% low back pain, 65% male, 47% white, 42% hispanic, 10% black). Mean pain duration 3 years (range 6 months–16.5 years). Size: n = 136 deemed suitable for programme but 74 denied cover by insurance carrier. Two declined, 60 participated. Design: before and after, observational, uncontrolled. Quality assessment: poor (weak observational study).	Multidisciplinary programme; physical and occupational therapy, clinical psychologist, cognitive restructuring, biofeedback, relaxation, nutrition, aquatic. Directors: neurologist and ortho-paedist. Individual and group sessions and family involvement. 6 monthly sessions after discharge.	Functional evaluations at 3 months and 6 months (not reported). Healthcare costs (from insurance carriers) for participant in 12 months prior to treatment and 12 months after treatment.	On basis of data supplied by insurance companies for 14 patients only, medical costs in 12 months after chronic pain clinic programme were, on average, 59% ($8469) lower than in 12 months before intervention. Adjusting for surgical costs (two patients) cost reductions were 58% ($7688) lower. Cost differences would have been larger with earlier entry to programme ($p < 0.01$).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Skovlund, 1991[201] (Norway)	Treatment for postpartum pain in maternity wards. Size: two trials compared: 1. paracetamol vs. placebo 2. paracetamol vs. naproxen. Paracetamol groups, 40 and 39 patients, respectively. Design: comparison of two studies (presumed RCTs). Quality assessment: poor (insufficient detail).	Compares effects of paracetamol on postpartum pain in two trials, one in which paracetamol was compared with placebo, and the other in which paracetamol was compared with naproxen.	Intensity of postpartum uterine cramping pain on visual analogue scale. Pain intensity measured at time of taking treatment and at 2 and 4 hours after treatment.	Paracetamol gave greater pain relief in trial 2 than in trial 1.
Starfield, *et al.*, 1981[187] (Maryland, USA)	Patients in prepaid HMO scheduled for follow-up appointments in primary care clinic; 18% were children, case-mix diverse – ear infections, fatigue, rashes, hypertension, diabetes, pain. Size: n = 94; 41 others dropped because follow-up information not complete. Design: observational. Quality assessment: poor (weak observational study).	Practitioners and patients interviewed (structured form) after initial visit to discuss nature and severity of problems and expectations for improvement. Immediately before follow-up visit, patients asked about degree of improvement. After consultation doctors recorded improvement.	Patients and practitioner rated improvements related to initial agreement about problem between patient and practitioner.	• 49% of problems were listed by both patients and practitioners (77% in cases of children). • 52% agreement on problems needing follow-up. • 20% disagreement between doctor and patients about degree of improvement. • Significantly more improvement recorded by practitioner when both patient and practitioner had listed problem ($p = 0.02$), regardless of severity of problem. • Improvement as reported by patients was same irrespective of whether it was mentioned only by patient or by both patient and practitioner.
Stewart, *et al.*, 1979[176] (Ontario, Canada)	299 chronically ill patients and five doctors in group practice (conditions included: hypertension, arthritis, diabetes, heart, stroke, ulcer, skin, back, respiratory, obesity). Patients followed for 3 months; 56% aged 45–65 years; 60% women; 66% no high school education. Size: n = 462 eligible; some refused, missed, ineligible, incapacitated; n = 299 completed. Design: observational. Quality assessment: acceptable.	Study examined: (i) factors affecting quality of doctor–patient relationship (measured by doctor's awareness of patient's problems) (ii) if doctor–patient relationship affects outcomes for patients.	Baseline: interview of patients covered demographic characteristics, complaints, worry, discomfort, social problems, functional limitations. Doctor questionnaire at end of 3-month study period concerning patients problems, discomfort, social problems. Information from doctors and patients compared to assess proportion of each patient's problems known to doctor. Patient interviewed again at end of study to assess: (i) recovery over 3 months: • general progress: better/same/worse • discomfort, worry, social problems, functional limitations (ii) satisfaction with: personal qualities of doctor, help given by doctor.	Doctor's awareness of complaints, worries, discomforts, functional limitations 'moderately high', but knowledge of social problems 'far less high'. Doctor's knowledge predicted by: • small number of patient problems ($p < 0.001$) • patient rather than doctor initiating appointment ($p < 0.001$ for four of five indicators, for fifth $p = 0.07$) • high number of recent visits (predicted knowledge of social problems only). Doctor's awareness not related to either satisfaction measure. Only patients' perception of recovery showed positive association with doctor's awareness ($p < 0.02$). Patient's age and education did not affect doctor's awareness.
Street, *et al.*, 1993[180] (Texas, USA)	Non-insulin-dependent diabetes mellitus patients with poor control ($HbA_1 < 8.0\%$). Size: 72 patients over 14-month period agreed to participate. Eight failed to complete education or attend nurse review. 12 failed to do 3-month blood work. One died, four incomplete data. 47 patients included (22 men, 25 women); three nurse educators reviewed 13, 16, 18 patients, respectively. Design: correlational, uncontrolled. Quality assessment: poor (uncontrolled observational study with high drop-out rate).	Patients attended 3$\frac{1}{2}$ days of diabetes education (films, lectures, discussions, consultations about risks, diet, exercise, therapies, etc.). Patient had follow-up consultation with nurse 1 month later to review progress. Study aimed to see if communication styles of nurses are related to patients' subsequent metabolic control.	1. At baseline, measured HbA_1 and collected background information about patient and condition 2. One month after education programme, nurse and patient communication characteristics recorded from consultation and transcribed verbatim: • frequencies of controlling, informative, patient-centred utterances of nurses counted • frequencies of utterances of patients that were information-seeking, related to decision taking and with negative affect were counted 3. HbA_1 assessment at 3 months.	In general, patients had better metabolic control after education intervention and follow-up consultation than before ($p < 0.01$). Influences of nurses' communication styles: • Patients experience poorer metabolic control after interacting with nurses who are more controlling and directive ($p < 0.01$), if they are women ($p < 0.02$), if they had less good control at outset ($p < 0.03$) • 31.1% of variance in follow-up HbA_1 explained by nurses controlling behaviour (15.1%), patient's gender (6.8%), patient's baseline HbA_1 (9.2%). Results of multiple testing of interactions between communication variables not reported here (scattered significant results). No significant relationship between sound metabolic control and information seeking, possibly because education programme had provided required information.

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Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Stuart, *et al.*, 1987[159] (Boston Massachusetts, USA)	1982–84 outpatient multiple risk reduction treatment program for essential hypertension at Beth Israel Hospital. Age range 20–77 years, mean 50 years; hypertension duration 2–40 years, median 7 years. Mainly professional, white middle-class. Inclusion criteria: essential hypertension diagnosed by primary care physician, whether on medication or not. Size: 162 patients started; 27 lost to follow-up; 37 excluded – missing data and confounding medical problems; 98 analysed, 42 men, 56 women; 71 taking antihypertensive medication. 17 consecutive programmes each comprising 11 x 2 hour group sessions over 6 months (average group size 10 patients). Design: before and after, uncontrolled. Quality assessment: poor (uncontrolled observational study with high drop-out rate).	Multidisciplinary team: cardiovascular clinical nurse specialist, physician, physical therapist, dietician, psychologist. At each session all patients reviewed individually. Group lectures given at sessions 1–4 on pathophysiology of hypertension and cardiovascular risk, self-monitoring of BP and relaxation, nutrition and exercise. Session 5: individual goals set (multidimensional). Sessions 6–11: progress reviews, medication adjustment, stress management. Programme sequence designed to help patients learn to help themselves, i.e: (i) recommend change (ii) scientific basis for recommendation (iii) steps and support to accomplish change; aim to move from fear of illness to search for wellness model.	At start and completion (6 months later) measured: • BP – at home, at clinic and 24 ambulatory • fasting serum cholesterol • high-density lipoprotein and triglyceride • height, weight • urine sodium • % body fat • exercise stress test • relaxation • psychological symptoms (Hopkins symptom checklist).	Comparing means of each outcome variable before and after intervention, significant reductions were observed in: • mean clinic systolic BP, 147–138 ($p < 0.0001$) • mean clinic diastolic BP, 95–85 ($p < 0.0001$) • mean home systolic BP, 133–129 ($p < 0.0001$) • mean home diastolic BP, 83–80 ($p < 0.0005$) • daytime ambulatory 24-hour systolic BP ($p = 0.008$) • anti-hypertensive medication use (72% of sample) • cholesterol ($p = 0.009$) • triglyceride ($p = 0.015$) • deviations from ideal body weight ($p < 0.0001$) • body fat percentage ($p < 0.0001$) • exercise heart rate ($p = 0.016$) • exercise systolic and diastolic BP ($p = 0.013$ and 0.003, respectively) • rate pressure product ($p = 0.004$). All psychological dimensions measured improved. No change in high-density lipoprotein, cholesterol, urine sodium levels. Separate analysis of medicated and non-medicated patients broadly similar to above. Changes in weight and anxiety explain 12% of variance in changes in clinic systolic BP. Relaxation also important for non-medicated patients.
Headache Study Group, University of Western Ontario, 1986[184] (Ontario, Canada)	21 family physicians recruited patients aged ≥ 14 years presenting with new complaint of headache. 68% women. Numbers decreased with increased age. Size: 272 patients admitted, 265 interviewed at 6 weeks. Headaches of organic origin: n = 56 (21%); non-organic muscle contraction headache: n = 45 (definite), n = 80 (possible); migraine: n = 13 (classic), n = 59 (possible). 235 completed 12 month follow-up. Design: correlational. Quality assessment: acceptable.	Investigated effect of various factors on resolution of different types of headache after 12 months. Independent variables included features of doctor–patient relationship, psychosocial variables, treatment delivered.	At enrolment: • patient questionnaire on headache history, including family • physician assessment of headache type, cause and description of treatment. At 6 weeks: • home interview of patient recording progress, time off work, further headaches, health behaviour and family circumstances • also asked about quality of discussion with doctor about headache. Patient questionnaires by mail or telephone at 6 and 12 months after enrolment concerning headache experience and time off work. Physician records checked at 6 months and 12 months concerning consultation and treatment for headache.	Uncertainties about headache types had no effect on results. Severity of pain gradient observed for non-organic causes: muscle-contraction headache (least) to migraine (worst). No difference in (self-reported) family, relationship or employment problems between headache types, although physicians more often attributed non-organic than organic headaches to depression ($p = 0.019$) and anxiety ($p < 0.001$). Doctors reported liking patients in all groups equally. 69% of patients reported they had fully discussed their problem with doctor (no differences between groups). At 12 months, no significant difference between resolution rates between organic and non-organic categories. Three variables independently associated with resolution: patients' assessment at 6 weeks that s/he had full discussion of problem with doctor, an organic diagnosis and no reported visual symptoms ($p < 0.01$). Not significant: age, sex, medication, referral investigation, psychosocial factors. 38 patients had poor outcomes: (≥ 1 day or more lost from work in preceding month) associated with severe pain, nausea and vomiting, and doctor initially not liking patient ($p < 0.05$). Patients perception of full discussion highly correlated to physician liking of patient ($p = 0.001$).

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Thomas, 1987[188] (UK)	Patients in general practice in England with symptoms but no abnormal physical signs and in whom no definite diagnosis was made. Size: n = 200; randomly selected for one of four types of consultation (with same doctor): A1. positive manner with treatment, n = 50 A2. positive manner without treatment, n = 50 B1. non-positive manner with treatment, n = 50 B2. non-positive manner without treatment, n = 50. Design: 2 x 2 RCT. Quality assessment: acceptable.	Positive consultation gave patient firm diagnosis and expectation of early recovery. If treatment not given it was explained that none was needed. Non-positive consultations gave no firm assurances. If treatment was given, patient told by doctor that s/he wasn't sure if it would help. Treatment was a prescription of placebo. No treatment was no prescription.	After consultation: • doctor graded contact with patient and degree of communication on 4-point scale • patient asked about satisfaction with consultation. 2 weeks after consultation patients contacted by mail and asked if they were better, how quickly they had recovered after consultation and if more treatment had been required.	Positive consultation generated higher patient satisfaction than negative ones (*p* = 0.001). 64% of patients receiving positive consultation got better within 2 weeks compared with only 39% of those who received a negative consultation (*p* = 0.001). Of those patients failing to get better there was no significant difference in rates of return to doctor between those who received positive and those who received negative consultations. No significant difference in numbers getting better between treated and untreated groups. Doctor's subjective assessment of consultation highly correlated to patient satisfaction but not to recovery rates. Patients not seeing doctor of their choice less likely to get better than those seeing doctor of their choice (*p* = 0.10).
Thompson, 1989[172] (Liverpool, UK)	Study of 60 first-time myocardial infarction in-patients (men aged 65 years or younger, with English as mother tongue) and their spouses. Size: n = 60; random assignment, in cells of ten to treatment group (n = 30) and control group (n = 30). Design: RCT. Quality assessment: acceptable.	Treatment group received systematic programme of nursing support in addition to routine care. A coronary care nurse provided support, education and counselling by verbal and written means, and tailored to individual needs. Intervention aimed to: (i) reduce uncertainty and fear about treatment (ii) inform about physical implications of myocardial infarction (iii) provide psychological support (iv) involve the couple. Control group received routine care only.	Hospital anxiety and depression scale administered by blinded assessor to patient and spouse 24 hours and 5 days after admission.	No significant differences between treatment and control groups with respect to age or social class. No significant differences between mean hospital anxiety and depression scores of groups at 24 hours. 5 days after myocardial infarction mean anxiety scores significantly lower for patients and spouses in treatment group compared with controls (*p* ≤ 0.01). Mean depression scores significantly lower for patients in treatment group (*p* = 0.01) but not for their spouses.
Uhlenhuth, *et al.*, 1959[195] (USA)	Male and female psychoneurotic patients (age not reported) with anxiety symptoms, without complicating factors, referred to a psychiatric outpatient clinic; 6-week study. Size: n = 65 (52 completed) assigned to A. n = 26 B. n = 26. Each group treated by different doctor with contrasting personal attributes and practice styles. Design: incomplete crossover design. Quality assessment: poor (insufficient detail; not all crossover orderings used).	Each patient saw psychiatrist four times for 10–20 minutes at biweekly intervals, i.e. at the beginning of treatment, between medications and at the end. (i) Medication: Meprobamate, 400 mg q.i.d., phenobarbital, 16 mg q.i.d., and placebo, q.i.d. Given for 2 weeks, with each patient receiving all three treatments. Each medication came first for one-third of each group. (ii) Physician characteristics: Physician A (younger) neutral manner, non-committal about treatments Physician B (older) fatherly manner, conveyed hopeful attitude.	Progress report forms completed at each consultation covered: (i) patient's overall judgement of condition (ii) doctor's overall judgement of condition (iii) checklist of 45 symptoms. At end of 6 weeks, doctor and patient ranked the three capsule colours for effectiveness.	No significant difference between groups A and B at baseline. Double-blinding worked successfully; psychiatrists' guesses about which medication patients had taken were no better than chance. Overall, patients responded favourably to treatment regimen with 81% improving over 6-week period. Responses to different agents were even. No significant differences in effectiveness among three agents. Dr B's patients, however, responded more favourably to active drug than placebo.

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Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Uhlenhuth, et al., 1966[196] (UK)	Prostatectomy patients in 1988, in two Regional Health Authorities. Size: all BPH patients of 16 and 9 urological surgeons in NW Thames and Oxfordshire areas, respectively, were approached; 400 agreed to participate in study; 348 completed (drop-outs accounted for). Design: longitudinal, observational. Quality assessment: acceptable.	Study investigated whether patients' presurgery positive expectations about improvement influenced: (i) their postoperative reports of symptoms (ii) their overall health after treatment. It furthermore investigated whether these trends persisted during year following treatment.	Baseline: preoperative questionnaire completed by 398 patients recorded: • health problems and general health history (Nottingham Health Profile) • BPH specific symptoms • socio-economic background • perceptions and expectations of surgery and outcomes. After surgery: information collected from patients at 3, 6 and 12 months concerning their: • BPH specific symptoms • perceptions of improvement comparing current health to preoperative status • overall health status.	Predictor variable was expectation, prior to surgery, of BPH symptom improvement after surgery; 98% expected improvement, 33% expected to be a lot better, 20% expected to be 'somewhat' or 'a little' better. (i) There was at best little evidence to suggest that having positive expectations presurgery led patients to report fewer symptoms after surgery ($p < 0.05$). Postoperative symptoms significantly affected by health status and preoperative symptoms but not by socio-demographic variables. No significant time effects of expectations on symptoms found. (ii) There was strong support for positive presurgery expectations increasing likelihood that patients report feeling better after surgery compared with before, even after controlling for symptom changes ($p < 0.001$). This effect persisted through the postoperative year. (iii) There was no support for the hypothesis that positive expectations result in better overall health reports after surgery, except for Nottingham Health Profile mobility index at 3 months, which was also the only significant time effect found.
Voshall, 1980[132] (Kansas, USA)	Patients admitted to hospital to undergo elective cholecystectomies (gender and ages of patients not reported). Size: n = 30, randomly assigned to A. experimental group, n = 15 B. control group, n = 15. Design: RCT. Quality assessment: poor (insufficient detail).	Both groups given information about anatomy and physiology of gallbladder, surgical incision, deep breathing, coughing, turning and leg exercise. Experimental group additionally told that postoperative discomfort is natural and taught how to decrease incisional discomfort through relaxation of abdominal muscles and to control 'gas pain' with leg exercises and ambulation.	• Postoperative ranking of pain and distress for 2 days. • Number of analgesics received for first 5 days after surgery. • Number of days hospitalisation and date of discharge.	No significant difference between groups in ranking of pain and distress levels in first 48 hours. Experimental group took significantly fewer analgesics across the treatment period than control group ($p = 0.025$). Experimental group discharged on average after 6.6 days compared with 7.6 days for control group.
Weis, et al., 1983[135] (New York, USA)	Patients aged 20–65 years, scheduled for major general, gynaecological and orthopaedic surgery. Excluded if experienced major operation previously, malignancy, mental illness, neurological disease or due for intensive care. Size: A. n = 56, intervention group B. n = 73, normal care control group. Design: Controlled trial not randomised, to ensure both groups treated with same staff teams, albeit at different times of year. Quality assessment: poor (patients not randomised into groups which differed at baseline; possible time-of-year confounder.	Group A (study group) shown 7 1/2-minute slide and tape presentation preoperatively explaining general pre- and post-operative procedures plus how to prevent pain when coughing. Group B (control group) had routine visit by anaesthetist on moving about and ways to keep one's mind occupied and not excessively focused on pain.	Both groups asked for level of anxiety preoperatively on a visual analogue scale before (T1) and after (T2) presentation or visit by anaesthetist. At T2, study group were also asked to give opinion on how presentation helped them cope. Analgesics taken in 24 hours after surgery recorded for both groups.	Less analgesics required in study group than in control group ($p < 0.05$). Anxiety ratings fell from T1 to T2 in both groups ($p < 0.05$), although percentage change was bigger in study group than control group ($p < 0.01$). Patients viewing slide presentation rated it favourably.

continued

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Wells, *et al.*, 1986[139] (Indiana, USA)	General surgery patients (various procedures) aged 14–62 years, both men and women where prognosis favourable. Size: n = 24, random assignment to two groups: A. stress inoculation, n = 12 B. controls, n = 12. Design: RCT. Quality assessment: acceptable.	Group A: stress inoculation – 1 hour, 1 week before surgery by clinical psychologists; learnt skills to cope with anxiety and discomfort and encouraged to practice them. Group B (control group): no intervention.	Assessments carried out at all times by blinded experimenter. Presurgery: • State–Trait Anxiety Inventory, biographical and health questionnaire for all patients, before intervention and 1 day presurgery. Postsurgery: • adjustment measures • pain on visual analogue scale on day 1 after surgery • pain ratings on days 2 and 3 • anxiety scale on day 3 (hospital anxiety scale) • analgesic use. On discharge: • Self and nurses' ratings of patient's adjustment.	Patients in stress inoculation training had less anxiety than control group presurgery ($p < 0.0003$) and postsurgery ($p < 0.0001$) (hospital anxiety scale). Nurses' ratings of recovery significantly more positive for treatment group ($p < 0.05$). Patients in treatment group: reported less pain than control group ($p < 0.01$); used marginally fewer analgesics ($p = 0.08$); were discharged from hospital on average 3.5 days earlier. Hospital bill savings for treatment patients estimated at $750 each. Therapist contact cost a maximum of $100/hour. Benefit:cost ratio = 7.5:1 (without counting other benefits).

Wheatley, 1967[198] (UK)	Private practice patients being treated for anxiety and depression over 2 months. Size: anxiety, 70 GPs, 134 patients; depression, 97 GPs, 170 patients. Design: observational, correlational. Quality assessment: poor (insufficient detail).	Two separate trials: Anxiety: compares chlordiazepoxide and amylobarbitone. Depression: compares imipramine and phenobarbitone. (No placebos). Doctors recorded both their own and patients' attitudes to outcome of treatment as pessimistic, indifferent or optimistic (hence nine possible combinations).	Initial severity assessed before treatment. At end of treatment percentage improvement assessed.	Both trials displayed similar patterns of *a priori* attitudes (expectations) with a bias toward optimism:
				
				        % Optimistic
				      GPs patients
				Anxiety 52 44
				Depression 54 44
				For each drug, doctor and patient optimism associated with better outcomes but doctor optimism twice as effective as patient optimism. Differences between results of optimistic, indifferent and pessimistic doctors significant in all cases ($p = 0.05$). Some but not all differences between outcomes for optimistic, indifferent and pessimistic patients were significant. Doctor and patient attitudes had closer relationship to outcomes in anxiety trial than in depression trial.

Wilson, 1981[133] (Michigan, USA)	33 (7 men) cholycystectomy and 37 total hysterectomy elective surgery patients in community hospital; mean age 42 years; 25 participating surgeons over 4-month period. Size: 93 eligible patients, 85% agreed to participate. n = 70, randomly assigned to one of four groups, stratified by type of operation: A. n = 18 B. n = 17 C. n = 17 D. n = 18. Design: RCT. Quality assessment: acceptable.	Group A: usual care preoperative visits by doctors and nurse. Group B: usual care plus tape of information about experiences and symptoms during and after surgery. Group C: usual care plus tape teaching muscle relaxation. Group D: treatment as for groups B plus C.	Preoperative: fear, mood, denial, aggressiveness, social support, coping ability. Postoperative: • length of hospital stay • medication for pain • self-reports of in-hospital recovery (mood, physical condition, pain, ambulation) • urinary output of epinephrine and norepinephrine per 24 hours (indicator of emotional stress).	No significant differences between groups at baseline. **Simple effects** Fear: high fear patients had poorer recovery ($p < 0.05$) and excreted more epinephrine ($p < 0.03$); denial: high denial patients had shorter hospital stays ($p < 0.01$); aggressiveness: more aggressiveness associated with poorer recovery ($p < 0.01$) and more pain medication ($p < 0.01$). Patients in all three treatment groups discharged on average 1.01 days sooner than control group ($p < 0.01$). Information group B did not differ from control group on recovery measures. Relaxation group C had better recovery ($p < 0.05$) and increased epinephrine ($p < 0.03$). **Interactions** Denial: none; fear: low fear patients in relaxation group were discharged sooner ($p < 0.005$); aggressiveness: more aggressive patients in information condition had less pain, negative mood and physical symptoms ($p < 0.05$). Less aggressive patients in information condition had increased pain, negative mood, more pain medication and higher epinephrine levels.

continued

Study	Study characteristics	Intervention: key features	Outcomes measured	Results
Wilson, *et al.,* 1993[153] (California, USA)	Adult patients with moderate to severe asthma enrolled in Kaiser Permanente HMO. Patients at five centres, aged 18–50 years, without confounding disease, and receiving daily asthma medication for more than 1 year eligible. Size: n = 323 (256 eligible patients declined offer to participate or did not complete). Random assignment to four groups, with blocking on a 'severity' index: A. small group education B. individual teaching C. information (work book) control D. usual care control, no formal asthma education. Design: RCT. Quality assessment: acceptable.	Individuals and group asthma education and self-management programmes over 3–4 months evaluated to determine CB and clinical effects, and impact on health service utilisation. Interventions focused on allergies (dust, smoke, pets) and behavioural change.	Medical records reviewed 1 year before and 2 years after enrolment for visits and prescriptions. Questionnaires to patients at enrolment and at 5 and 12 months after intervention covered: • asthma knowledge • symptoms diary • metered dose inhaler technique • bother from asthma in last month. Physician examinations at baseline, 5 months and 12 months recorded: • spirometry – peak flow measurement • wheezing • judgement about overall asthma status.	Groups A and B: lower 'bother' ratings at 1 year than groups C and D ($p = 0.03$). Groups A, B and C: fewer symptomatic days than group D ($p = 0.025$). Groups A, B and C: asthma status judged by physician to have improved more at 5 and 12 months than group D ($p = 0.03$, $p = 0.04$). No significant difference in spirometry. Trend towards fewer routine office visits followed group education ($p = 0.025$). No significant changes in medication. Groups A and B significantly greater improvement in environmental control and in metered dose inhaler technique than C < D ($p < 0.05$).
Ziemer, 1983[136] (Pennsylvania, USA)	Patients undergoing abdominal surgery invited to participate; seven men, 104 women, mean age 36 years (range 18–65 years); 71 Caucasian, 31 black, 1 Asian. 81 underwent gynaecological surgery, 30 gastrointestinal surgery. Size: random assignment to three groups: A. n = 40: procedural information, 5^1/$_2$ minute tape B. n = 34: procedural and sensation information, 9^1/$_2$ minute tape C. n = 37: as B plus physical and psycho-logical strategies, 22 minute tape. Design: RCT. Quality assessment: acceptable.	Audiotape on evening before surgery corresponding to their information condition. Blinded research assistant visited patient after surgery with questionnaire on coping, distress and symptoms. Chart review after discharge for demographic and medical information.	• Physical coping strategies • Psychological coping strategies • Physical symptoms • Pain intensity • Distress • Utilisation of sedatives, analgesics and length of hospital stay	No significant differences between information groups with respect to coping. Furthermore, coping not significantly related to symptoms and significantly related to pain and distress in unanticipated direction (i.e. more coping associated with more pain and more distress). No differences between groups on any utilisation measure.

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This report was identified as a priority by the Methodology Panel.

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