Effect on Health-Related Outcomes of Interventions to Alter the Interaction Between Patients and Practitioners: A Systematic Review of Trials

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ABSTRACT

PURPOSE We wanted to identify published randomized trials of interventions to alter the interaction between patients and practitioners, develop taxonomies of the interventions and outcomes, and assess the evidence that such interventions improve patients' health and well-being.

METHODS Undertaking a systematic review of randomized trials, we sought trials in primary and secondary care with health-related outcomes, which we found by searching MEDLINE, HealthSTAR, and PsycINFO bibliographic databases through 1999. We also completed one round of manual citation searching.

RESULTS Thirty-five trials were included. Most were set in primary care in North America. Trials were heterogeneous in populations, settings, interventions, and measures. Interventions frequently combined several poorly described elements. Explicit theoretical underpinning was rare, and only one study linked intervention through process to outcome measures. Health outcomes were rarely measured objectively (6 of 35), and only 4 trials with health outcomes met predefined quality criteria. Interventions frequently altered the process of interactions (significantly in 73%, 22 of 30 trials). Principal outcomes favored the intervention group in 74% of trials (26 of 35), reaching statistical significance in 14 (40%). Positive effects on health outcomes achieved statistical significance in 44% of trials (11 of 25); negative effects were uncommon (5 of 25, 20%). Simple approaches to increasing the participation of patients in the clinical encounter, such as providing practitioners with a note from patients about their concerns beforehand, showed promise, as did more complex programs providing specific information about disease and attention to emotion. Apparently similar interventions varied in effectiveness across studies.

CONCLUSIONS Successful interactions between patients and their practitioners lie at the heart of medicine, yet there are few rigorous trials of well-specified interventions to inform best practice. Trial evidence suggests that a range of approaches can achieve changes in this interaction, and some show promise in improving patients’ health. To advance knowledge further, we need to replicate promising studies using rigorous methods. These should include explicit theoretical frameworks designed to link effects on key communication and interaction characteristics through to effects on health outcomes.

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INTRODUCTION

It is now generally accepted that effective communication is as essential to high-quality medical practice as is clinical knowledge. A body of evidence suggests that participation of the patient in all stages of the
clinical encounter improves effectiveness and efficiency. Despite this evidence, practitioners often fail to listen or to elicit patients’ concerns or to negotiate treatment options.3,7 This failure may be in part because skills are not effectively taught,1 but there may remain skepticism about the importance of partnership with patients in the consultation.

Much of the available evidence comes from observational studies in which a range of processes has been assessed. Identification and discussion of patient concerns, the provision of appropriate information, and patient involvement in choice of treatment options are associated with resolution of emotional and physical symptoms, greater treatment compliance, improved satisfaction, and fewer repeated consultations, referrals, and investigations.8 Interpretation of these studies can be affected by bias and confounding, however. In particular, apparent associations between patient participation in the clinical encounter and better health outcomes could occur if sicker patients participate less.9

Rigorous randomized trial evidence is required to establish causality, and a number of relevant trials have been conducted. Some have been included in reviews with nonrandomized designs8,10 or have focused on physician-training programs,11 interventions directed at patients,12 or the context of the consultation.9 Although individual studies reporting significant effects on both emotional distress13 and disease control14 are quoted in teaching texts,1,2,15 no systematic reviews of their number, quality, or findings have yet been conducted.

We report the first comprehensive review of randomized controlled trials of interventions to alter patient-practitioner interaction, including health outcomes. It aims to inform future research design and indicate promising approaches for further evaluation and application in practice.

METHODS

Identification of Relevant Trials and Data Extraction

We developed the search strategy using Delphi consensus methods (SJG, MWMV, ALK, MS) (Figure 1). Each term was combined with the Cochrane trials search strategy16 in MEDLINE (1966–1999), HealthSTAR (1975–1999) and PsycINFO (1967–1999) databases.

We then hand-searched bibliographies of trials meeting the inclusion criteria. Titles and abstracts (where available) of identified reports were assessed. Full copies of reports resembling relevant trials were obtained. At least 2 authors independently checked them against inclusion criteria and extracted data onto standardized forms. Discrepancies were assessed by an independent researcher and resolved by discussion (SJG, MWMV, SG, JG, ALK, MS).

Inclusion Criteria

Studies set in primary or secondary medical or nursing care were included. Participants had to be allocated at random to an intervention aimed at altering the interaction between patients and practitioners within a consultation or office visit. The evaluation had to include assessment of a health outcome or satisfaction. Studies in any language were included.

Quality assessment took into account established criteria predicting the likely presence of bias.17 Criteria included allocation concealment at randomization and outcome assessment, losses to follow-up, and adjustment for cluster design, if present.

Development of Taxonomies of Intervention Type and Measures

Interventions used in trials to alter patient-practitioner interaction are varied and difficult to classify. We developed a taxonomy based on our theoretical understanding of the ways in which collaboration between patient and practitioner can be enhanced and may lead to improved outcomes. This framework has been described as the new clinical method.15 It involves the patient and practitioner reaching a mutual understanding of each other’s explanatory models of illness and disease. It therefore takes into account the patient’s

Figure 1. Search terms.

Patient-centred care
Patient compliance
Patient education
Patient participation
Patient satisfaction
Physician-patient relations
Professional-patient relations
Recall
Referral and consultation
Verbal behaviour
Patient acceptance of healthcare
Consumer participation
Consumer satisfaction
Doctor-patient communication
Doctor-patient relations
Nurse-patient communication
Nurse-patient relations
Hospital-patient relations
Interpersonal relations
Interviews
Medical history taking
Patient advocacy
Patient care team
ideas, concerns, and expectations at all stages of the clinical interview, from gathering information through problem formulation to decisions about management. It is hypothesized that this method will lead to more precise framing of the problem and management that makes sense to the patient, which could enhance outcomes through several mechanisms. Specifically, a correct diagnosis will be matched to a more effective prescription. Involvement of the patient will lead to engagement in taking any agreed treatment. It will also mobilize a range of self-care activities tending to increase well-being and function through social, psychological, and perhaps even immunological mechanisms. Finally, the collaborative approach might reduce the mismatch between a patient's and the practitioner's representations of the problem and thereby increase efficiency through a reduction in unnecessary investigations, consultations, and unused medication.

Approaches to changing the interaction between patient and practitioner within this framework can be aimed directly at patients (for example by a preconsultation leaflet or interview), via the practitioner (for example through courses), or at both parties. Components of interventions that we consider central to the new clinical method include those aimed at (1) increasing the patient's contribution at all stages of the clinical interview (patient activation), and (2) increasing the practitioner's ability to elicit and integrate the patient's views with the biomedical view (communication skills training).

More specifically, interventions can aim to (1) increase the patient's understanding of the biomedical model (provision of information about disease or treatment; discussion of behavior change), and (2) increase the practitioner's understanding of psychosocial aspects of the illness (attention to patient's emotion).

Having specified these components, we refined them by reading the studies and developed brief descriptions of each study intervention and comparison approach. Three authors undertook this process independently prior to consensus discussion (ALK, SJG, MS, SG). This effort added 2 further intervention subtypes: one where the practitioner receives information by a note or questionnaire before the clinical encounter to alert him or her to a patient's concerns or functional status (practitioner activation by patient questionnaire), and one where the practitioner changed the style of consultation between a biomedical or patient-centered approach (changes style). The extent to which these components were associated with improved health outcomes was then explored in the analyses.

A wide range of process measures was used. We defined measures of communication as subjective (self-report) or objective (videotape, for example). Process measures most often assessed among patients included frequency of question asking, controlling behaviors, and overall involvement in the consultation, particularly the decision making. They also included patients' ratings of the extent to which the practitioner offered relevant, understandable information and explanation, and the extent to which patients felt understood and helped. Those processes measured among practitioners included the degree to which they elicited patient concerns, exhibited empathy, or considered psychosocial aspects of presenting complaints.

We classified health outcomes as objective measures of disease processes (for example, blood pressure and blood glucose concentrations), or subjective measures of illness experience by self-report (symptoms, anxiety, depression, functional status, well-being, and quality of life). We also included separately patient satisfaction with care and other health-related outcomes (health service costs, patient knowledge, and health-related behaviors including treatment adherence). The principal outcome for each study, when not specified by the author, was defined from sample size calculations, hypotheses, or aims.

Analysis
Descriptive analyses were undertaken of study settings, participants, quality, interventions, process, and outcome measures. Studies were too heterogeneous for meta-analysis. We grouped studies according to intervention type. Study process and outcome measures were reported as favoring intervention or comparison groups with accompanying probability (statistically significant at P < .05). We assessed the extent to which principal outcomes favored intervention or comparison groups across all studies. Then, for those with health outcomes, we assessed the effect of each prespecified category of intervention. The denominator for each comparison was the number of studies reporting the relevant outcome.

RESULTS
Search Strategy
More than 21,200 reports were identified, of which 148 were potentially relevant and fully assessed. Thirty-five trials met the inclusion criteria. The most common reasons for exclusion were nonrandomized design, no reported health outcomes, and the intervention not specifically targeting patient-practitioner interactions. Most were reported after 1995. Two similar but distinct trials were reported in one article. Data were incomplete for one trial despite correspondence with the author. Characteristics of included trials are summarized in Table 1.
Participants and Settings
Most trials were undertaken in primary care in North America. All were reported in English. More than 13,500 patients (median 200, interquartile range, 105-380) participated. Most trials involved patients who had a chronic problem (n = 15 trials), including cardiovascular disease, diabetes, epilepsy, depression, or cancer of breast or prostate, or they enrolled a sample of patients consulting in primary care (n = 11).
Trial Quality

Trial quality varied. Descriptions of allocation concealment at randomization and outcome assessment were frequently inadequate or missing (21 and 18 trials, respectively). Follow-up was short (median 4 weeks, interquartile range 0-26). Losses to follow-up were either not reported or exceeded 30% in more than a quarter of studies. Clustering was present in 15 of the included trials, in 10 some adjustment was made for this clustering in the analysis. Health-related principal outcomes were measured objectively in 6 studies and subjectively in 19 studies. Four measured symptom resolution, and 5 measured well-being or functional status. Two studies measured adherence to treatment. In 8 studies satisfaction was the principal outcome. Only 4 studies with health outcomes met our prespecified quality criteria.

Characteristics of interventions are summarized in Table 2. Eleven interventions were aimed at the patient directly, 16 were administered by the practitioner, and 8 used a combination of these approaches. Most interventions involved activation of the patient in the consultation, which included stimulating patients to take a more active role, for example, by considering questions to ask in advance of the consultation (n = 18), or writing down needs and expectations to be given to practitioners, thus activating them in turn (n = 5). Eleven studies evaluated training practitioners in communication skills. Skills included listening, eliciting patients’ views, and negotiating treatment plans.

In 12 studies information about disease or treatment and in 7 discussion of behavior change was a main feature of the intervention. In 14 studies there was explicit attention to emotion (for example reference to affect, trust or patients’ concerns), always in the context of more complex interventions. Classification of attention to emotional issues was the hardest on which to agree. In 4 studies practitioners simply altered their consultation style.

Interventions most commonly incorporated booklets, letters, or tapes either alone or in combination with training sessions, and they varied widely in intensity and complexity. Comparison groups were split fairly evenly between usual care and attention control.

Effects on the Process of the Consultation

Effects of the intervention on the process of the consultation were measured in most trials (30 of 35, 86%).

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| Outcome Assessment | Duration | Percent Lost to Follow-up |
|--------------------|----------|---------------------------|
| Adequate           | 8 weeks  | <30                       |
| Adequate           | 12 weeks | <30                       |
| Inadequate         | 12 weeks | Missing                   |
| Inadequate         | Immediate | >30                      |
| Inadequate         | 3 weeks  | >30                       |
| Inadequate         | 1 week   | <30                       |
| Adequate           | Immediate | <30                      |
| Inadequate         | 6 weeks  | <30                       |
| Inadequate         | Immediate | <30                      |
| Adequate           | Immediate | >30                      |
| Inadequate         | 1 month  | <30                       |
| Inadequate         | Immediate | <30                      |
| Inadequate         | 4 weeks  | Missing                   |
| Inadequate         | 2 weeks  | <30                       |
| Adequate           | 2 days   | <30                       |
| Inadequate         | 1 week   | >30                       |
| Adequate           | Immediate | Missing                   |
| Adequate           | 6 months | <30                       |
| Inadequate         | Immediate | Missing                   |
| Inadequate         | 1 year   | <30                       |
| Adequate           | 1 year   | >30                       |
| Adequate           | 18 months | <30                      |
| Adequate           | 4 weeks  | Missing                   |
| Adequate           | 4 months | <30                       |
| Inadequate         | 6 months | <30                       |
| Adequate           | 3 months | <30                       |
| Adequate           | Immediate |                      |
| Adequate           | 7 months |                      |
| Adequate           | 6 months |                      |
| Inadequate         | 12 months | <30                      |
| Inadequate         | Immediate | <30                      |
| Inadequate         | Immediate | <30                      |
| Adequate           | 2 weeks  | <30                       |
| Adequate           | 15 months | <30                      |

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* References 13, 20, 26, 31, 41, 42, 45, 46, 49.
† References 14, 20-28, 39, 40, 42, 43, 45, 46, 52.
‡ References 13, 31, 35, 39, 40, 41, 43-45, 48.
§ References 13, 14, 21, 22, 24, 26, 30, 33, 42, 46, 51, 52.
|| References 13, 14, 21, 22, 24, 39-41, 43-45, 48-50.
¶ References 14, 20-26, 29, 32-34, 37, 39, 42, 45, 51.
# References 13, 27, 28, 30, 31, 35, 36, 40, 41, 43, 44, 46-50, 52.
## Table 2. Characteristics of the Interventions in Included Trials

| Author, Year | Intervention Group | Comparison Group |
|--------------|--------------------|------------------|
| **Interventions delivered directly to patients** | | |
| Greenfield et al, 1985<sup>22</sup> | Preconsultation interview, skills training and materials | Preconsultation interview about disease course, treatment, self-care, and adherence to treatment |
| | Patient activation with attention to emotion and provision of information about treatment decisions | |
| Greenfield et al, 1988<sup>14</sup> | Preconsultation interview, skills training and materials | Preconsultation interview about disease course and treatment |
| | Patient activation with attention to emotion and provision of information about treatment decisions | |
| Kaplan et al, 1989<sup>31</sup> | Preconsultation interview, skills training and materials | Preconsultation interview about disease course, treatment, and self-care |
| | Patient activation with attention to emotion and provision of information about treatment decisions | |
| Thompson et al, 1990a<sup>20</sup> | Preconsultation, list of possible health concerns, and leaflet encouraging question asking | Usual care and questionnaire on waiting room facilities |
| | Patient activation | |
| Thompson et al, 1990b<sup>20</sup> | Preconsultation, message from physician encouraging question asking, or checklist of information to be obtained during consultation | Usual care and questionnaire on waiting room facilities |
| | Patient activation | |
| Butow et al, 1994<sup>23</sup> | Preconsultation, leaflet encouraging question asking | Handout on cancer services available |
| | Patient activation | |
| Street et al, 1995<sup>24</sup> | Multimedia program providing information about disease and treatment and encouragement to ask questions, explain concerns, and offer opinion in consultation | Given same material in brochure form without treatment options. |
| | Patient activation with provision of information about disease and treatment and attention to emotion | |
| McCann & Weinman, 1996<sup>25</sup> | Preconsultation, leaflet encouraging questions, and ideas about causes, diagnosis, and treatment | Leaflet giving dietary advice |
| | Patient activation | |
| Davison & Degner, 1997<sup>26</sup> | Precin buck facilitatati provision of information, encouragii questions and participation in decisions | Social interview and unfacilitated information pack |
| | Patient activation and provision of information about disease | |
| Kravitz et al, 1997<sup>27</sup> | Preconsultation, patient completes request for services and is interviewed on expectations for care in consultation | Usual care |
| | Patient activation | |
| Fleissig et al, 1999<sup>28</sup> | Preconsultation help card, and encouragement to ask questions | Usual care |
| | Patient activation | |
| **Interventions delivered via practitioners** | | |
| Thomas, 1978<sup>29</sup> | During consultation, provision of positive information about diagnosis and treatment | Given positive information that there was no illness |
| | Changes style of information giving | |
| Schulman & Swain, 1980<sup>30</sup> | During consultation, practitioner provided information about hypertension and its management alone, or with contingency contracting | Usual care |
| | Provision of information about disease and discussion of behavior change | |
| Evans et al, 1987<sup>31</sup> | Lecture, booklet, discussion | Usual care |
| | Communication skills training | |
| Thomas, 1987<sup>32</sup> | During consultation, certainty about diagnosis, treatment and prognosis | Uncertainty about diagnosis |
| | Changes style of information giving | |
| Olsson et al, 1989<sup>33</sup> | During consultation, positive style, personal, with provision of information about disease (prognosis) | Less positive diagnosis, less personal, no information on prognosis |
| | Changes style of information giving and provides information about disease | |
| Savage, 1990<sup>34</sup> | During consultation, shared style, eliciting patients ideas about symptoms, diagnosis, and treatment | Directive style, giving clear information on diagnosis, treatment and prognosis |
| | Changes style of information giving | |
| Evans et al, 1992<sup>35</sup> | Lectures small groups and videotape feedback | Usual clerking |
| | Communication skills training | |
| Roter et al, 1995<sup>36</sup> | Course with simulated psychiatric patients and videos | Usual practice |
| | Communication skills training with attention to emotion and information about disease management | |

*continued*
| Author, Year          | Intervention Group                                                                 | Comparison Group                                                                 |
|----------------------|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Smith et al, 1995    | Communication skills training with discussion of behavior change and skills in disease management | Usual care                                                                       |
| Meland et al, 1997   | Training using video and cognitive self-help materials for patients                  | Usual care and leaflets                                                          |
| Kinmonth et al, 1998 | Communication skills training in listening, eliciting patient's agenda, and supporting behavior change | Usual care and provision of information on disease                                 |
| Pill et al, 1998     | Practice based training in eliciting patient concerns and discussing behavior change | Usual care                                                                       |
| Smith et al, 1998    | Course of seminars, video and booklets on communication, and disease management skills | Usual care                                                                       |
| Peters et al, 1999   | Information leaflets and invitation to consult practice nurse who was trained to present information on disease, risk, and treatment and encourage women to ask questions | Disease information leaflet                                                      |
| Thom et al, 1999     | Workshop                                                                          | Usual care                                                                       |
| Brown Betz et al, 1999 | Communication skills training program with attention to emotion                    | Usual practice                                                                   |
| Lewis et al, 1991    | Separate communication skills training sessions, videos and materials for patients and practitioners | Course on bicycle safety (patient) assessment of febrile child (practitioner)    |
| Katon et al, 1995    | Videos and materials on cognitive-behavioral management of depression and encouraging question asking, Practitioner course on treatment of depression and case-based feedback | Usual care                                                                       |
| Rubenstein et al, 1995 | Patients completed functional status questionnaire preconsultation, practitioners taught questionnaire interpretation | Usual care                                                                       |
| Joos et al, 1996     | Preconsultation, patient completes request for service form, practitioners taught communication skills | Usual care                                                                       |
| Hornberger et al, 1997 | Preconsultation, patient completes request for services form including emotional needs | Usual care                                                                       |
| Wagner et al, 1997   | Preconsultation; patients completed functional status questionnaire in consultation, practitioners taught interpretation | Usual care                                                                       |
| Maly et al, 1999     | Preconsultation; patient recorded two questions which were attached to the medical record, given medical notes and glossary | Information sheet and patient suggestion list                                     |
| Reuben et al, 1999   | Specialist advice to practitioners via telephone; provision of information about disease and its treatment. Preconsultation booklet and telephone call to patient | Usual care and nonstudy incentives                                                |
Table 3. Effects of Interventions on Patient Outcomes

| Author, Year | Interventions delivered directly to patients | Objective Health Outcomes (Disease Processes)* | Subjective Health Outcomes (Illness Experience) | Other Outcomes | Satisfaction |
|--------------|---------------------------------------------|-----------------------------------------------|-----------------------------------------------|----------------|-------------|
| Greenfield et al, 1985 | | Pain: + | Knowledge: – – | – | |
| Greenfield et al, 1988 | HbA1c: ++ | Functional status: ++ | Cost: + | |
| Kaplan et al, 1989 | Blood pressure: ++ | Functional status: ++ | Cost: + | |
| Thompson et al, 1990a | Anxiety: ++ | Cost: + | 0** | |
| Thompson et al, 1990b | Anxiety: + | Knowledge: checklist + | Message + | |
| Butow et al, 1994 | Quality of life: 0= | Knowledge: – | |
| Street et al, 1995 | Well-being: 0† | Knowledge: + | |
| McCann & Weinman, 1996 | Anxiety: + | Depression: + | |
| Davison & Degner, 1997 | Blood pressure: + | Quality of life: + | |
| Kravitz et al, 1997 | Symptom resolution: – | Symptom resolution: ++ | Cost: not analyzed + | + | |
| Fleissig et al, 1999 | Symptom resolution: – | Symptom resolution: – | Cost: O† | + | |
| Thomas, 1978 | Blood pressure: + | Quality of life: + | Health behavior: exercise + | – | |
| Schulman & Swain, 1980 | Cholesterol: + | Well-being: + | Smoking 0† | |
| Evans et al, 1987 | Thiolcyanate: + | Functional status: + | Cost: + | |
| Thomas, 1987 | HbA1c: + | Quality of life: + | Health behavior: diet 0† | + | |
| Olsson et al, 1989 | Cholesterol: – | Well-being: + | Exercise/smoking - Knowledge: – | |
| Savage, 1990 | Triglyceride – | – | |
| Evans et al, 1992 | Body mass index: – | Blood pressure: – | |
| Roter et al, 1995 | Depressioin: ++ | Cost: – | |
| Smith et al, 1995 | Blood pressure: – | Quality of life: + | |
| Meland et al, 1997 | Cholesterol: – | Well-being: + | |
| Kinmonth et al, 1998 | Thiocyanate: + | Functional status: + | |
| Pill et al, 1998 | HbA1c: – | Quality of life: + | Health behavior: 0† | – | |
| Smith et al, 1998 | Blood pressure: – | Functional status: – – | Cost: 0† | |
| Peters et al, 1999 | Depression: + | Functional status: + | |
| Thom et al, 1999 | Perceptions of health: – | Functional status: + | |
| Brown Betz et al, 1999 | Health behavior: 0† | Cost: 0† | |

continued
usually by patient (n = 21) or practitioner self-report (n = 11). Objective measures were used in 15 studies (patient, 10; practitioner, 12).

Processes significantly favored the intervention groups in most studies (22 of 30, 73%). In 6 studies at least 1 process deteriorated20,34,44,45,49,52 (2 significantly34,49), although in 4 of these studies other process measures significantly favored the intervention.20,44,45,49. (The effects of the interventions on the effects of consultations are displayed as supplemental data in Table 2a, which is available online only at: http://www.annfammed.org/cgi/content/full/2/6/595/DC1).

Effects on Patient Outcomes
Table 3 summarizes the effects of the interventions on outcomes and the direction of results in relation to the main intervention categories.

Overall Pattern of Results Across All Studies
In 18 of 35 studies at least 1 health-related outcome significantly favored the intervention group. Multiple measures of outcome were used, however, and in 8 studies at least 1 outcome significantly favored the control group. Objective measures of health favored the intervention in 5 of 6 (83%) studies and the comparison group in 2 of these studies. Subjective measures of health favored the intervention in 21 of 25 (84%) and the comparison group in 4 of 25 (16%).

Health-related behaviors favored the intervention group in 4 of 8 (50%) studies and the control group in 2 of 8 (25%). Knowledge favored the intervention group in 4 of 8 (50%) and the control group in 4 of 8 (50%). Duration of consultations was shorter in 4 of 12 (33%) intervention groups14,20,22,51 and 6 of 12 (50%) controls.13,25,34,42,49,50 Other costs were rarely measured.13,14,37,40,43 Satisfaction with care was higher in the intervention group in 17 of 27 (63%) studies and in the comparison group in 7 of 27 (26%).

Interventions were evaluated with multiple measures of process and outcome, but interrelationships were rarely hypothesized or tested. In only 1 study was there any trial analysis of the effect of the intervention through process on outcome.22 Other studies analyzed the effects of the intervention on process and outcome separately.

Principal Outcomes Across All Studies
Principal outcomes favored the intervention groups in 26 of 35 (74%) trials, significantly in 14. Among 25 studies with a principal health outcome, 20 favored the intervention group (80%), 11 significantly (44%). Among 6 studies measuring disease processes objectively, only 2 reported statistically significant benefits (33%). Neither of 2 studies with behavior change

| Author, Year | Objective Health Outcomes (Disease Processes)* | Subjective Health Outcomes (Illness Experience) | Other Outcomes | Satisfaction |
|--------------|-----------------------------------------------|-----------------------------------------------|----------------|--------------|
| Lewis et al, 199145 | Anxiety: + | Knowledge: ++ | + + |
| Katon et al, 199546 | Depression: + |
| Rubenstein et al, 199547 | Functional status: missing |
| Joos et al, 199648 | Functional status: + + |
| Hornberger et al, 199749 | Depression: + |
| Wagner et al, 199750 | Anxiety: ++ |
| Maly et al, 199951 | Functional status: + + |
| Reuben et al, 199952 | Mortality: + |

HbA1c = glycosylated hemoglobin; ++ = result significantly favors intervention group; + = result favors intervention group; – = result favors control group; – – = result significantly favors control group; 0∞ = outcome identical in both groups; cost = health services cost.

Note: Principal outcome for each study in boldface; not analyzed = results not reported in original paper; missing = no data presented in the paper.

* Physiology, survival, mortality.
† No significant difference reported with no further data presented.

** References 13, 14, 21-25, 34, 35, 40, 41, 45, 47-49.
(medication adherence) as the principal outcome favored the intervention group. Among 8 studies with satisfaction as the principal outcome, 6 favored the intervention group (75%), 3 significantly (37%).

Effect of Different Categories of Intervention on Health Outcomes
Interventions delivered directly to patients showed a positive effect on any health outcome in 6 of 8 (75%) studies, reaching significance in 4 (50%) and no negative effects. Interventions delivered via practitioners showed a positive effect in 9 of 11 (82%) studies, reaching significance in 5 (45%) and negative effects in 5 of 11 (45%), reaching significance in 2. Interventions targeting both practitioners and patients showed a positive effect in 6 of 7 (86%) studies where measured, significantly so in 4 (57%) and no negative effects.

Patient activation was associated with improved health outcomes in 15 of 17 trials in which they were measured, significantly so in 9. Three studies reported health outcomes favoring the control group, significantly in 2. Both simple approaches, such as preconsultation requests for services, and more complex interventions, including preconsultation interviews, skills training, and materials for patients, significantly improved health outcomes. Not all studies favored the intervention group, and some interventions had negative effects. Two complex interventions involving patient activation, evaluated in the United States, reported particularly large benefits, not achieved in pragmatic trials among the same patient group in this country.

Isolation of potentially active ingredients of patient activation was not easy. For example, in the study of a complex intervention cited above, patients with diabetes were coached in question asking and negotiating change to a more personal, positive style of consultation. Two of 4 interventions involving patient activation, evaluated in the United States, reported particularly large benefits, not achieved in pragmatic trials among the same patient group in this country.

Effect on Health Outcomes in High-Quality Studies
Only 4 studies met all predefined quality criteria. Interventions ranged from a complex multidisciplinary intervention to improve geriatric care to a change to a more personal, positive style of consultation by the family doctor, and from encouragement of women to ask questions at cervical screening with the office nurse to preconsultation recording by patients of their 2 main questions for the practitioner. In 3 of the studies subjective health outcomes were significantly better in the intervention group.

DISCUSSION
Trial Quality
This review of trials of interventions to alter the interaction between patient and practitioner and their effects on health-related outcomes is the most comprehensive yet undertaken. It shows clear weaknesses in the field. Only 35 trials up to the end of 1999 were identified by clear criteria. Studies tended to be small...
and short, with major design limitations. Only 4 studies with health outcomes met our prespecified quality criteria, which were selected for their ability to predict the likely presence of bias.\textsuperscript{17} It could be argued that these criteria could be wider still, for example, populations were often poorly characterized, and measures of process and outcome were unvalidated. Other reviews have analyzed these shortcomings in detail.\textsuperscript{12} Here we focus on the limitations in description and evaluation of the interventions, which were often multifaceted, poorly described, and not clearly linked to measures of their likely effects. The mechanisms by which components of the intervention were hypothesized to affect processes within the consultation to influence outcomes (the underlying causal models) were rarely made explicit, and only once tested.\textsuperscript{13} Such testing is essential for the field to advance. For example, this review showed the difficulty of isolating the effects of interventions to promote question asking. Kidd et al\textsuperscript{14} have recently drawn on a theoretical framework from psychology to overcome cognitive and affective barriers to question asking. Brief interventions to promote question asking are based on the studies by Roter,\textsuperscript{55} Greenfield et al,\textsuperscript{22} and Thompson.\textsuperscript{20} In a randomized design, interventions were offered to patients attending a hospital diabetic clinic. Audiotapes were used for objective assessment of question asking. Those in the intervention groups showed an increase in self-efficacy of question asking after the consultation, and less anxious patients asked more questions. No significant differences were found between intervention, attention-control, and pure control groups in the number of questions asked, however. All groups asked more questions than in previous studies, suggesting a possible ceiling effect. This example shows forcibly the need for stronger research before implementing apparently simple, feasible, but possibly ineffective, interventions in practice.

**Taxonomy of Process and Outcome**

The taxonomy clarifies the wide range of measures of process and outcome used. Measures may be self-report or objective, both are clinically important and both have predictive validity.\textsuperscript{10,56-59} We differentiated health outcomes into self-reports of the illness experience and objective assessment of the disease process. Practitioners have traditionally placed more emphasis on disease processes, but patients are naturally concerned also with current well-being. Showing that positive effects on illness experiences, such as well-being, can coincide with negative effects on disease processes, such as dyslipidemia,\textsuperscript{49} emphasize further the need to measure both. Disease processes, however, were rarely measured.

Satisfaction, while an important health-related outcome, was excluded from our analyses of health outcomes because measures frequently overlap with the patients' subjective assessment of the consultation process.\textsuperscript{60,61}

**Impact on Process and Outcomes**

The weight of evidence reviewed supports the hypothesis that the way practitioners and patients interact in the clinical encounter can be measured and altered. This finding is supported by other reviews.\textsuperscript{15} The effect on health-related outcomes is more equivocal. If weight is given to the direction of findings, principal outcomes favored the interventions in almost three quarters of the studies, however, results reached statistical significance in less than one half of the studies. Among the 4 trials meeting our quality criteria, only 2 interventions were associated with significant improvements in the principal outcome. Only 2 of 6 studies with disease processes as the principal outcome significantly favored the intervention group, and 1 of 6 significantly favored the control group. Analysis by intervention type provides some promising directions, although study numbers become small.

**Analysis by Intervention Type**

Interventions could affect health outcomes whether aimed at patient, practitioner, or both. Almost one half of those interventions delivered via practitioners alone were associated with at least one worse outcome than the comparison group, whereas none was when delivered directly to patients. This finding is compatible with a greater positive effect of interventions directed to patients, and perhaps with the difficulties of consistently altering practitioner behavior.\textsuperscript{40}

Interventions including components directed at activation of patients, activation of practitioners by preconsultation note or questionnaire from patient, and provision of information and attention to emotion, all showed promise. Significantly positive outcomes favoring the intervention group were found in more than one half of these studies. Patient activation was the approach most frequently evaluated, and there were some discordant findings.\textsuperscript{23,24,40} Two complex interventions involving patient activation among groups with chronic disease, evaluated in the United States,\textsuperscript{14,21} reported particularly large benefits, not achieved in pragmatic trials in the United Kingdom.\textsuperscript{39,40} This work merits replication.

Complexity was not necessary for success. Patients who simply provided practitioners with written information about their needs, emotional concerns, and functional status in advance of the consultation were significantly less anxious, or showed improvement in
functional status afterward. Such written information may work as a substitute for the failure of doctors to elicit patients’ ideas, concerns, and expectations, a failure that is well documented. 7 Review findings also emphasize the centrality of appropriate provision of information to effective consulting 19 and the need to further develop and evaluate affective elements. We found insufficient evidence to support a particular style of consultation in general practice or to resolve the question of whether interventions to increase patient participation prolong consultations. Further work is needed.

Review Limitations
The review has a number of strengths: we had clear inclusion criteria, a comprehensive search strategy for published trials, assessment of trial quality, attention to a priori classification of intervention types, and careful accounting of process and outcome measures. Presentation of direction, as well as statistical significance of findings, allows consideration of the overall pattern of results. The review also has limitations. The search strategy was restricted to 3 databases and to the end of 1999. Relevant studies may not have been indexed with our search terms or may be unpublished. A recent review with a broader search strategy, however, did not include any trials that met our inclusion criteria but were omitted from our review. 9 Moreover, a related review including the year 2000 identified only 3 further trials with health-related outcomes. These trials did not challenge our findings. 12 In addition, unpublished studies are more likely to have negative findings, 62 which would only strengthen our conclusion that the evidence base is weak.

After initial unsuccessful attempts at correspondence, data were extracted and interpreted without reference to original authors, which may have led to some underestimation of trial quality and miscoding of intervention categories. 63 Interventions were multifaceted and consequently were classified into more than one category. Conclusions about effectiveness of individual components of interventions are therefore limited, and none can be drawn concerning the relative effects by patient age, sex, disease and ethnic group. The heterogeneity of populations, interventions, and measures precluded overall meta-analysis, although the possibility of further synthesis among subgroups of interventions, for example, to encourage question asking by patients, or improve practitioners’ communication skills, should be considered.

Implications and Conclusions
Successful interactions between patients and their practitioners lie at the heart of medicine, yet there are few rigorous trials of well-specified interventions to inform best practice. Trial evidence suggests that a range of approaches can achieve changes in this interaction and some show promise in improving patients’ health. In terms of practice there are strong justifications unrelated to evidence-based medicine for adopting a collaborative approach to the medical encounter, such as, for example, patient preferences and moral imperatives. 15 This review demonstrates the potential for the way patients and practitioners behave in consultations to have measurable effects, both positive and negative, on their future health. In terms of research, it demands collection of better evidence to inform practice. Improvements are needed across the board, from characterization of study populations to study designs. Outcome measures themselves should include both objective measures of disease process and self-report of illness experience where appropriate. Interventions should be more carefully developed and specified. Rigorous explanatory trials of such interventions are still needed before pragmatic studies of cost-effectiveness. To advance knowledge further, we need to replicate promising studies using rigorous methods. These studies should include explicit theoretical frameworks for interventions, designed to link effects on key characteristics of the interaction through to effects on health outcomes. Only in this way will the field advance beyond a series of tantalizing but disconnected and unconfirmed results.

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