

Randomised controlled trial of effect of leaflets to empower patients in consultations in primary care

Paul Little, Martina Dorward, Greg Warner, Michael Moore, Katharine Stephens, Jane Senior, Tony Kendrick

Abstract

Objective To assess the impact of leaflets encouraging patients to raise concerns and to discuss symptoms or other health related issues in the consultation.

Design Randomised controlled trial.

Setting Five UK general practices in three settings.

Participants 635 consecutive patients, aged 16-80 years, randomised to receive a general leaflet, a depression leaflet, both, or neither.

Main outcomes Mean item score on the medical interview satisfaction scale, consultation time, prescribing, referral, and investigation.

Results The general leaflet increased patient satisfaction and was more effective with shorter consultations (leaflet 0.64, 95% confidence interval 0.19 to 1.08; time 0.31, 0.0 to 0.06; interaction between both -0.045 , -0.08 to -0.009), with similar results for subscales related to the different aspects of communication. Thus for a 10 minute consultation the leaflet increased satisfaction by 7% (seven centile points) and for a five minute consultation by 14%. The leaflet overall caused a small non-significant increase in consultation time (0.36 minutes, -0.54 to 1.26). Although there was no change in prescribing or referral, a general leaflet increased the numbers of investigations (odds ratio 1.43, 1.00 to 2.05), which persisted when controlling for the major potential confounders of perceived medical need and patient preference (1.87, 1.10 to 3.19). Most of excess investigations were not thought strongly needed by the doctor or the patient. The depression leaflet had no significant effect on any outcome.

Conclusions Encouraging patients to raise issues and to discuss symptoms and other health related issues in the consultation improves their satisfaction and perceptions of communication, particularly in short consultations. Doctors do, however, need to elicit expectations to prevent needless investigations.

Introduction

Effective doctor-patient communication probably improves patient satisfaction and health outcomes.¹ Modifying doctors' behaviour and empowering patients (patient "activation") are two ways that patients can be encouraged to bring their concerns and agenda to the consultation. In patients with particular chronic

diseases this can be by intensive counselling and for most other conditions by leaflets.¹ Patient satisfaction and consultation time have generated mixed results when patients have been encouraged to write lists or to use patient activation leaflets before a consultation.²⁻¹⁰ Few of these studies, however, were from typical UK primary care settings, most were small (<200 patients), some were not randomised, and few reported changes in number of investigations or referrals. Patient activation might help bring difficult issues such as depression to the consultation, where detection rates are low, where training of doctors does not help, and where outcomes vary when doctors are informed about a patient with depression.¹¹⁻¹⁸

General practitioners have concerns about the effects of patient activation on time and patients' introspection and anxiety.^{1 3 4 7 8 19} Pressures may also be increased on the doctor to prescribe, refer, or investigate. We aimed to assess in the range of patients presenting in primary care whether patient activation leaflets improve patient satisfaction and health outcomes; whether they increase consultation time, and the number of prescriptions, referrals, and investigations and help doctors to detect depression.

Methods

Our study sample comprised 636 patients, aged 16-80 years, consulting at one of five general practices in the United Kingdom (two in deprived urban areas, two in market towns, and one in a city).

Patient satisfaction was measured on the medical interview satisfaction scale and its subscales. Scores reflect aspects of doctor-patient communication (relieving distress, intention to comply with management, communication, and rapport) and correlate strongly with a patient centred approach.²⁰

Recruitment occurred in the winter months during 2000-2. Patients were randomised to one of four groups, defined by two factors: factor 1, general leaflet and no leaflet; factor 2, depression leaflet and no leaflet. Patients in the first group received a general leaflet, asking them to list issues they wanted to raise and

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Primary Medical Care, Community Clinical Sciences Division, Southampton University, Aldermoor Health Centre, Southampton SO16 5ST
Paul Little
professor of primary care research
Martina Dorward
research nurse
Katharine Stephens
medical student
Jane Senior
medical student
Tony Kendrick
professor
Nightingale Surgery, Romsey SO51 7QN
Greg Warner
general practitioner

Three Swans Surgery, Salisbury SP1 1DX
Michael Moore
general practitioner

Correspondence to: P Little
psl3@soton.ac.uk

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Table 1 Characteristics of groups. Values are numbers (percentages) of patients unless specified otherwise

Characteristic	General leaflet	No general leaflet	Depression	No depression
Mean (SD) consultation time	10.64 (1.85)	10.67 (1.94)	10.57 (1.81)	10.74 (1.97)
Male	135 (43)	134 (42)	136 (43)	133 (42)
New problem	133 (43)	145 (47)	134 (43)	144 (47)
Longstanding problem	138 (45)	129 (42)	133 (43)	134 (44)
Doctor asked patient to attend the practice	73 (24)	78 (25)	81 (26)	70 (23)
Wanting investigation	72 (23)	79 (25)	74 (24)	77 (25)
Wanting referral	51 (16)	64 (21)	57 (18)	60 (19)
Investigation medically needed	86 (29)	80 (26)	86 (25)	90 (30)
Referral medically needed	48 (19)	57 (24)	64 (21)	68 (23)
Married	174 (73)	166 (68)	175 (72)	165 (69)
Having sickness certificate	19 (8)	18 (8)	20 (8)	17 (7)
Having disability benefit	11 (5)	9 (4)	10 (4)	10 (5)
In paid work	132 (55)	127 (52)	138 (56)	121 (50)
Seeing usual doctor	220 (71)	224 (72)	223 (72)	221 (71)

Denominators vary owing to missing values.

explaining that the doctor wanted them to be able to talk, discuss, and ask questions about any problems they were concerned about. Patients in the second group received a leaflet on depression, listing symptoms of depression (without labelling them as such) and asking whether they had had any of these and, if so, that the doctor would like to discuss them. Patients in the third group received both leaflets, and patients in the fourth group received no leaflets (control group).

Patients completed a questionnaire before the consultation, recording what they wanted in terms of examination, prescription, investigation, or referral. After the consultation they completed a questionnaire for age, marital status, number of children, employment status, medical problems, general health (World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians scale), the measure yourself medical outcome profile score (a patient generated measure for resolution of symptoms), satisfaction, and “enablement”—the extent to which patients feel helped to manage their illness. Doctors recorded the duration of the consultation (time between patient being called and patient leaving consultation), whether they thought the patient was depressed, whether they prescribed, investigated, or referred, how much they thought these interventions were medically needed, and the pressure they felt from patients to undertake these. Data were analysed on an intention to treat basis.

Results

The groups were comparable at baseline (table 1). Non-responders to the postconsultation questionnaire were equally distributed between groups (general leaflet 75/317 (24%), depression leaflet 72/317 (23%)), similar to those who completed the study.

Satisfaction and perceived communication

We found no significant interactions between the two leaflets for any outcome and thus present the main effects (table 2). No significant changes were found in any of the outcomes for either of the leaflets, except for satisfaction: 0.17 represents a 6% (six centile point) increase in satisfaction. Both consultation time and the general leaflet were significantly associated with improved satisfaction, and the leaflet was significantly more effective when consultations were short, even after clustering by doctor was allowed for (leaflet 0.64, 95% confidence interval 0.19 to 1.08; time 0.31, 0.0 to 0.06; interaction between both -0.045 , -0.08 to -0.009). This meant that for consultations lasting five, eight, and 10 minutes, satisfaction increased by 14%, 10%, and 7%, respectively. The effect of the leaflet on subscales for satisfaction was similar when the interaction with time was allowed for: comfort from communication 1.02 (0.36 to 1.68), relief of distress 0.74 (0.0 to 1.49), intention to comply with management 0.65 (0.06 to 1.23), and rapport 0.81 (0.16 to 1.45).

Effect of leaflet on doctors’ behaviour

The general leaflet increased the number of investigations (odds ratio 1.43, 1.00 to 2.05 after control for clustering for doctor). Perceptions of the medical need for investigation and of patients’ expectations strongly predicted investigation.²¹ After controlling for these potential confounders we found that the effect of leaflets on investigations was unlikely to be due to either chance or confounding (odds ratio 1.87, 1.10 to 3.19). Most of the increase in number of investigations (90 v 71—that is, 19 extra) was among patients in whom investigations were thought not to be needed or slightly needed (14 extra: leaflet 41 (46%), no leaflet 27 (38%)). In the study population there were 60 consultations where the doctor thought the pressure from patients was moderate or strong, but of these patients only 20 (33%) actually reported a moderate or strong preference for investigation.

Detection of depression

Overall, 80 patients (16%) had possible major depression (score of ≥ 8 on the hospital anxiety and

Table 2 Effect of leaflets on outcomes. Values are means (95% confidence intervals) for control arms and mean differences (95% confidence intervals) for intervention arms unless stated otherwise

Variable	General leaflet			Depression leaflet		
	No leaflet	Leaflet	P value	No leaflet	Leaflet	P value
Satisfaction*	5.25 (5.14 to 5.36)	0.17 (0.01 to 0.32)	0.04	5.34 (5.23 to 5.46)	-0.03 (-0.15 to 0.08)	0.56
Time (min)	10.51 (10.05 to 10.97)	0.36 (-0.54 to 1.26)	0.42	10.52 (10.06 to 10.98)	0.34 (-0.27 to 0.95)	0.27
Depression score†	4.04 (3.59 to 4.49)	0.02 (-0.62 to 0.67)	0.94	4.23 (3.78 to 4.68)	-0.37 (-0.98 to 0.24)	0.23
Anxiety score†	6.33 (5.77 to 6.89)	-0.13 (-0.74 to 0.48)	0.67	6.35 (5.81 to 6.90)	-0.17 (-0.87 to 0.53)	0.62
Overall score	10.37 (9.46 to 11.28)	-0.10 (-1.12 to 0.91)	0.35	10.58 (9.67 to 11.49)	-0.54 (-1.71 to 0.62)	0.35
State trait anxiety inventory	11.00 (10.50 to 11.50)	-0.23 (-0.73 to 0.27)	0.35	10.77 (10.28 to 11.25)	0.25 (-0.42 to 0.91)	0.45
Enablement	3.74 (3.24 to 4.24)	0.29 (-0.29 to 0.88)	0.31	3.86 (3.36 to 4.37)	0.04 (-0.66 to 0.75)	0.91
Resolution of symptoms at one month‡	3.58 (3.39 to 3.77)	-0.04 (-0.31 to 0.24)	0.78	3.63 (3.43 to 3.82)	-0.14 (-0.39 to 0.12)	0.28

*Medical interview satisfaction scale.

†Hospital anxiety and depression scale.

‡Measure yourself medical outcome profile.

depression scale). Of these patients the doctors judged 45 to be depressed and 35 not depressed. Neither leaflet significantly increased the detection of depression (table 3).

Discussion

Encouraging patients to raise concerns and to discuss symptoms or other health related issues in the consultation improves their satisfaction and perceived communication, particularly when consultation time is limited. Doctors may, however, request more investigations than are needed.

Limitations of study

One limitation of our study was that consultation time had an impact on recruitment; if doctors kept to time it was difficult for us to recruit patients because we had less time to complete the initial study protocols (see bmj.com). The impact of this selection bias was probably to underestimate the effect of the leaflets on outcome.

The prevalence of undetected depression (16%) was slightly less than in previous studies, and we had fewer patients than the power calculation required.^{22 23}

Although some patients may not have had sufficient time to read the leaflets before consultation, we found that the greatest effect of leaflets was with short consultations, which meant less time available before the consultation. To avoid contamination, we needed to distribute individual leaflets, but in practice there are other more pragmatic approaches, such as videos or posters in the waiting room and practice booklets and newsletters.

Training doctors about depression has been shown to be of little benefit.¹⁵ Our study suggests that encour-

Table 3 Odds of detecting depression according to leaflet type. Values are numbers (percentages) of doctors detecting depression in patients with possible major depression

Leaflet	Depression correctly detected (n=45)	Depression not detected (n=35)	Odds ratio* (95% CI)	P value†
General	21 (47)	15 (43)	1.04 (0.43 to 2.52)	0.93
Depression	19 (42)	16 (46)	0.97 (0.40 to 2.38)	0.95

Score of ≥ 8 on hospital anxiety and depression scale indicated possible major depression.

*Adjusted mutually for each leaflet.

†Wald test.

aging patients to discuss symptoms of depression during consultation is also unlikely to be beneficial.

Requested investigations

Controlling for the major potential confounders of patients' expectation and perceived medical need suggests that the increase in number of requested investigations with leaflets is not likely to be due to chance or confounding. It is also plausible that by raising more concerns and discussing symptoms in the consultation, doctors may respond with more investigations. Most of the increase in requested investigations was in categories where the doctor did not think there was a strong medical need. This highlights the importance of the need for doctors to discuss patients' expectations for investigation, particularly if a patient activation approach is used.

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What is already known on this topic

Evidence is mixed about whether empowering patients with leaflets or lists may improve outcomes of consultations, and there are concerns about consultation time

The effect on health service costs of empowering patients is unclear

Training doctors to detect depression or informing them of a patient with depression does not improve outcome

What this study adds

Empowering patients by using leaflets is not likely to improve the detection of depression

Leaflets increase patients' satisfaction and their perception of communication, particularly for short consultations

Leaflets do not greatly increase consultation time but may increase the number of investigations

If patients are encouraged to raise concerns and discuss symptoms in consultations, doctors need to elicit expectations to prevent needless investigations

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Importance of patient pressure and perceived pressure and perceived medical need for investigations, referral, and prescribing in primary care: nested observational study

Paul Little, Martina Dorward, Greg Warner, Katharine Stephens, Jane Senior, Michael Moore

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Primary Medical Care, Community Clinical Sciences Division, Southampton University, Aldermoor Health Centre, Southampton SO16 5ST
 Paul Little
professor of primary care research
 Martine Dorward
research nurse
 Katharine Stephens
medical student
 Jane Senior
medical student
 Nightingale Surgery, Romsey SO51 7QN
 Greg Warner
general practitioner
 Three Swans Surgery, Salisbury SP1 1DX
 Michael Moore
general practitioner
 Correspondence to: P Little
 psl3@soton.ac.uk

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Abstract

Objective To assess how pressures from patients on doctors in the consultation contribute to referral and investigation.

Design Observational study nested within a randomised controlled trial.

Setting Five general practices in three settings in the United Kingdom.

Participants 847 consecutive patients, aged 16-80 years.

Main outcomes measures Patient preferences and doctors' perception of patient pressure and medical need.

Results Perceived medical need was the strongest independent predictor of all behaviours and confounded all other predictors. The doctors thought, however, there was no or only a slight indication for medical need among a significant minority of those who were examined (89/580, 15%), received a prescription (74/394, 19%), or were referred (27/125, 22%) and almost half of those investigated (99/216, 46%). After controlling for patient preference, medical need, and clustering by doctor, doctors' perceptions of patient pressure were strongly associated with prescribing (adjusted odds ratio 2.87, 95% confidence interval 1.16 to 7.08) and even more strongly associated with examination (4.38, 1.24 to 15.5), referral (10.72, 2.08 to 55.3), and investigation (3.18, 1.31 to 7.70). In all cases, doctors' perception of patient pressure was a stronger predictor than patients' preferences. Controlling for randomisation group, mean consultation time, or patient variables did not alter estimates or inferences.


Conclusions Doctors' behaviour in the consultation is most strongly associated with perceived medical need of the patient, which strongly confounds other predictors. However, a significant minority of examining, prescribing, and referral, and almost half of investigations, are still thought by the doctor to be slightly needed or not needed at all, and perceived


patient pressure is a strong independent predictor of all doctor behaviours. To limit unnecessary resource use and iatrogenesis, when management decisions are not thought to be medically needed, doctors need to directly ask patients about their expectations.

Introduction

General practitioners act as the gateway to most prescribing, investigation, and referral. This has enormous implications for the use of resources in secondary care, "medicalisation," and iatrogenesis, particularly if management is unwittingly inappropriate or ineffective.¹⁻⁶ Investigating and referring also take time—the main resource in primary care and a major determinant of quality of care.⁷

Doctors' incorrect perceptions of patients' expectations predict prescribing, and, as doctors tend not to elicit patients' expectations or unvoiced agendas, this results in unnecessary prescriptions and poor compliance.⁸⁻¹² Most quantitative studies have not, however, controlled for perceived medical need: it may be that when this is controlled for there is little impact on doctors' behaviour from perceived patient pressure. Patients' personal characteristics influence referral and investigation, and a questionnaire survey of doctors showed a variety of non-medical factors that influence decisions to investigate.^{3 13} Yet little work has been done to quantify doctors' perceptions of pressures from patients in consultations which lead to physical examination, further investigation, and referral. Given the importance of appropriate referrals and investigations it cannot simply be extrapolated that all doctor behaviours are the same. We therefore assessed the relative

 Effect of consultation time and interventions on generalisability are on *bmj.com*

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