A consultation leaflet to improve an older patient's involvement in general practice care: a randomized trial

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Abstract

Objective To evaluate the effects of a programme to enhance the involvement of older patients in their consultations in general practice.

Design Cluster randomized trial, in which data was collected from different cohorts.

Setting and participants Twenty-five general practices in the south-east part of the Netherlands and their patients aged 70 years and over.

Intervention Patients in the intervention group received a leaflet to help them prepare for the consultation. General practitioners (GPs) received an outreach visit to optimize older patients' involvement when visiting their GP. Patients in the control group received usual care.

Main outcome measures Questionnaires measuring involvement (COMRADE), enablement (Patient Enablement Index) and satisfaction with their care (EUROPEP).

Results Pre-intervention 315 patients and post-intervention 263 patients were included. Subjects were satisfied with their involvement and the GP's behaviour during the consultation. No differences in effect as a result of the leaflet on involvement, enablement or satisfaction were found between the intervention and the control group. Of 318 patients who received the leaflet and visited their GP in the intervention period, 47 patients used the leaflet. These users were more accustomed to prepare themselves for consultations. Users reported more psychological problems than non-users.

Conclusions No relevant effects of the implementation programme on involvement, enablement or satisfaction were found. Other strategies are needed to enhance involvement of older patients in their care. Alternatively, older patients may perceive themselves sufficiently involved.

Introduction

Involving patients actively in their care may have a positive influence on patients' health outcomes, their adherence to treatments, their functional independence¹⁻³ and their satisfaction with care.^{4,5} Involving patients in their care is obviously important to meet their health needs. The mutuality that originates from involvement is an achievement of both patients and doctors, and requires the active participation of patients in decisions regarding their care and situations.⁶ Although patient satisfaction with care is usually very high, it has been suggested that patients' involvement in their care needs to be improved. There are a wide range of methods for enhancing the involvement of patients,⁷ but only scant information is available on their implementation in everyday general practice, especially for older patients.

A recent review showed that interventions directed at patients can be successful in increasing patient participation.⁸ As far as written materials are concerned, a general leaflet that encouraged patients to raise concerns during their GP visit improved patients' satisfaction and perceived communication.⁹ Another study found an increase in consultation length and more question asking as a result of a leaflet designed to increase the level of patient participation in consultations.¹⁰ So there is some evidence on the positive influence of written patient directed interventions, but it is not clear whether they are suitable for older patients as well.¹¹ In one of the above-mentioned studies younger patients were more likely to benefit from the intervention than older patients. It was suggested that older patients have a more fixed pattern of consultations and a high level of satisfaction with care, so they may have less need to modify their behaviour in consultations.¹⁰

In an unpublished pilot study we evaluated four different written patient involvement tools. This pilot study showed that such tools are definitely useful for some older patients in some situations. The tools helped to explore patients' ideas, fears and expectations and stimulated older patients to address important issues that

they had not addressed before. But, general practitioners (GPs) and patients need support, encouragement and time to use such tools if they are to enhance their involvement.

We developed and tested a consultation leaflet implementation programme, in which GPs and older patients were stimulated to optimize older patients' involvement when visiting their GP. Beforehand we hypothesized that:

- Implementation of the consultation leaflet would improve patients' evaluations of their care.
- Patients with underreported health problems would benefit from the intervention because they would be more likely to discuss these.¹²

The aim of the study was to determine the effects of the programme and to test these hypotheses.

Methods

A cluster-randomized trial was performed in which the pre-/post-intervention data was collected from different cohorts (Fig. 1). This design was chosen because we could not predict when patients included in the baseline measurement were going to visit their GP again and we had a limited study time. The Ethical Committee of the University Medical Centre Nijmegen assessed the study and gave approval.

Randomization

We recruited 25 GPs in the south-east of the Netherlands. Recruitment of GPs occurred in May and June 2002 by mail. GPs were randomized. To ensure similar numbers of GPs in each group we used block-randomization (blocks of two). This random group allocation of GPs was performed after the baseline measurement among patients. To secure blinding of allocation, practices were numbered in the order of their arrival in our mail. All participating GPs in a particular practice were randomized to the same intervention. An independent person, who was blinded for the practices as these were numbered, performed the allocation.

Figure 1 Flow chart patients.

Participants

For the baseline measurement the participating GPs were asked to send a letter with a questionnaire to 25 patients aged 70 years or older who had consulted them recently. Study subjects

were patients aged 70 years or over, consulting one of the included general practices during the study period (June to November 2002). Patients were excluded if they were visually impaired or if their GP thought they were not suitable for participating.

Post-intervention GPs were asked to send questionnaires to the last 30 patients (aged 70 or over) who visited them. Because of difficulties with organization of patient appointments in some practices it was not always possible to gather the needed 30 patients per GP.

Sample size calculation

To detect a medium effect (effect size = 0.5)¹³ between intervention and control group we required 24 GPs and 10 patients per GP (power = 0.80, alpha = 0.05, intra-cluster correlation = 0.1¹⁴). A formula was used to calculate a sample size for cluster randomized studies.¹⁵ To account for non-response we asked GPs to invite 25 patients to participate for the baseline measurement. As pre-intervention response rates were low, post-intervention GPs were asked to send questionnaires to the last 30 patients (aged 70 or over) who visited them.

Intervention

All patients aged 70 or over in the intervention practices received a consultation leaflet by mail. The leaflet consisted of a short motivating text on patient involvement and a mixture of open and pre-structured questions to help patients prepare for the next consultation and prioritize which problems they wanted to discuss with their GP (Box 1). The leaflet was based on questions from the instruments used in the pilot study. These questions were selected as they helped to explore patients' ideas, fears and expectations and stimulated them to address important issues.

We concluded from our previous qualitative study that it is important to include GPs in the implementation of the patient involvement leaflet as well.¹⁶ Therefore GPs in the intervention group received a 30-min practice visit, in which they were motivated for involving patients and instructed in the use of the consultation leaflet. We used the SWOT (strengths, weaknesses, opportunities and threats) model to help the GP consider all aspects of involvement. In this visit we used and informed the GPs about

Box 1 Content of consultation leaflet

Two general open questions:

- 1 Which points do I want to raise with the doctor?
- 2 What thoughts or ideas do I have about these points, for example causes, possible treatments?

Five questions to be answered with yes or no:

- 3 What do I want the doctor to do?
 - 1 Investigate
 - 2 Explain causes/diseases
 - 3 Prescribe medication
 - 4 Give advice on what I can do myself
 - 5 Other (please say what it is)

Three questions to be answered on a five-point scale*:

- 4 In general, would you say your health is:
- 5 During the past 2 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities?
- 6 To what degree do you feel lonely?

*Derived from Dartmouth COOP Functional Assessment Charts/WONCA. Copyright © Trustees of Dartmouth/COOP project 1985.

the findings of previous qualitative studies performed among GPs and patients.¹⁶

GPs and their patients in the control group did not receive any intervention or information; their usual care was continued.

Outcome measures

The primary outcome measure was the use of the leaflet and perceived involvement in primary care, measured using a questionnaire. We used four questions from the COMRADE¹⁷ 'Satisfaction with communication'-scale, scored on a four-point scale (strongly agree to strongly disagree); six questions from the Patient Enablement Index (PEI),¹⁸ scored on a three-point scale (much better, better, same or less); and 10 questions from EUROPEP,¹⁹ scored on a five-point scale (poor to excellent). In addition, we measured patient reported use of the leaflet, consultation length, and demographic characteristics and whether they discussed one of eight underreported health problems (visual, hearing, urinary, sleeping, or memory problems, loneliness, depressive or other mental symptoms).

The questionnaires at baseline and post-intervention were similar, except for some process evaluation questions about the consultation leaflet after the intervention period.

Analysis

An intention to treat analysis at the patient level was performed using SPSS 11.0 and SAS (8.0) software. Mean scores per scale (PEI, COM-RADE, EUROPEP) and consultation time were calculated. Missing values were substituted for mean scores only if two-third of the scale-items were completed. We used a multi-level model to compare the estimated effect sizes of intervention and control group per outcome measure. The model included a correction for GP clustering. The multi-level analysis thus showed whether the estimated effect size differences (between intervention and control group) were statistically significant. The same analysis was performed on patients who reported using the intervention leaflet as intended. Differences in demographic characteristics and underreported health problems were calculated using a chi-square test.

Results

Recruitment and response rates

After randomization the sample consisted of 13 GPs in 11 intervention practices and 12 GPs in nine control practices. Pre-intervention 315 of 598 (52.6%) patients returned their questionnaire, post-intervention, 263 of 648 (41%) patients returned their questionnaire (Fig. 1). Patient characteristics pre- and post-intervention are presented in Tables 1 and 2. Post-intervention there were significantly more females in the intervention group [Pearson chi-square: 6.89 (d.f. 1); $P = 0.009$].

Effect of intervention

Concerning their involvement, the patients were satisfied with the information they were given, their opportunities to ask questions, to give their opinion and to take part in decisions. No differences between intervention and control group were detected. Concerning enablement, patients felt themselves the same or better enabled to deal with their health problem after

Table 1 Baseline characteristics of study population; n (%)

	Intervention group ($n = 171$)	Control group ($n = 144$)
Gender		
Male	63 (36.8)	68 (47.2)
Female	107 (62.6)	76 (52.8)
Age (mean $\pm$ SD)	75.6 $\pm$ 4.6	75.6 $\pm$ 4.7
< 80 year	131 (76.6)	110 (76.4)
≥ 80 year	39 (22.8)	34 (23.6)
Education		
Primary or lower secondary school	105 (61.4)	83 (57.6)
Upper secondary school	48 (28.1)	39 (27.1)
Further and higher education	17 (9.9)	15 (10.4)
Health		
Excellent	2 (1.2)	6 (4.2)
Very good	15 (8.8)	9 (6.3)
Good	63 (36.8)	50 (34.7)
Fair	84 (49.1)	71 (49.3)
Poor	5 (2.9)	6 (4.2)
Serious or chronic diseases		
Yes	99 (57.9)	66 (45.8)
No	67 (39.2)	72 (50.0)

the consultation. However, the intention to treat analysis showed significant negative results in these scores (Table 3). Intervention patients seemed to be less able to cope with their health problem after visiting their doctor compared to control patients. Finally, patients were very satisfied with the way their GP behaved during the consultation. No differences between intervention and control group were detected.

Use of leaflet

Of 318 patients who received the leaflet and visited their GP in the intervention period, 47 patients used the leaflet at home ($n = 39$) and/or during the consultation ($n = 26$) and/or they discussed the points they had written down ($n = 36$). Sub-analyses showed that the scores for these 47 patients did not differ significantly on the outcome measures from those of the control group or the intervention group non-users (Table 3). Intervention group leaflet users reported more psychological symptoms to their

Table 2 Post-intervention characteristics of study population [*n* (%)]

	Intervention group (<i>n</i> = 121)	Intervention group non-users (<i>n</i> = 74)	Intervention group users (<i>n</i> = 47)	Control group (<i>n</i> = 142)
Gender				
Male	46 (38.0)	32 (43.2)	14 (29.8)	77 (54.2)
Female	74 (61.2)	41 (55.4)	33 (70.2)	64 (45.1)
Age (mean $\pm$ SD)	76.2 $\pm$ 4.8	76.3 $\pm$ 4.9	75.9 $\pm$ 4.7	75.2 $\pm$ 4.8
< 80 year	95 (78.5)	57 (78.1)	38 (80.9)	109 (76.8)
$\geq$ 80 year	25 (20.7)	16 (21.6)	9 (19.1)	32 (22.5)
Education				
Primary or lower secondary school	68 (56.2)	44 (59.5)	24 (51.1)	85 (59.9)
Upper secondary school	39 (32.2)	22 (29.7)	17 (36.2)	44 (31.0)
Further and higher education	10 (8.3)	6 (8.1)	4 (8.5)	12 (8.5)
Health				
Excellent	3 (2.5)	2 (2.7)	1 (2.1)	0
Very good	10 (8.3)	7 (9.5)	3 (6.4)	10 (7.0)
Good	38 (31.4)	24 (32.4)	14 (29.8)	59 (41.5)
Fair	59 (48.8)	34 (45.9)	25 (53.2)	66 (46.5)
Poor	4 (3.3)	2 (2.7)	2 (4.3)	6 (4.2)
Serious or chronic diseases				
Yes	59 (48.8)	33 (44.6)	26 (55.3)	66 (46.5)
No	56 (46.3)	37 (50)	19 (40.4)	74 (52.1)

GP compared with non-users of the leaflet ($P = 0.034$). No other differences in discussion of underreported health problems were found (Table 4). The demographic characteristics of the leaflet users were not significantly different to those of the non-users, although there were more females among the users. The prevalence of chronic diseases was similar. However, users were more accustomed to prepare themselves for the consultation than non-users. Roughly one-third of non-users (25 of 74) and almost two-third of users (28 of 47) said they prepared themselves for consultations [Pearson chi square: 11.5 (d.f. 2); $P = 0.003$].

Discussion

Our study showed no relevant effect of the implementation programme on involvement, enablement or satisfaction of older patients in their general practice care. Patients, who were not used to preparing themselves, did not change this habit. The intervention may have had a negative effect on those who received the leaflet, but did not use it. Patients were not stimulated to discuss more health problems, apart from

mental health problems. Finally, we could not identify a subgroup of patients in which the programme was effective.

Another intervention trial to empower older patients during a group programme with cue cards and a preparation booklet for consultations also did not show any significant differences.⁵ Although, the sub-group analysis among programme attenders in that study did show more active behaviour among intervention patients.

There may be several reasons for these disappointing results. One reason may be the heterogeneity of the group of older patients, who varied in the conditions they had, in their attribution of clinically important changes to aging, in educational background and in the patient role they adopted. Patients may need personally tailored interventions to become more involved instead of a fixed programme.

Another reason may be the consulting style adopted by older patients. Most had illnesses which resulted in frequent GP consultations. Together with their high satisfaction with care, older patients may need longer-term personal support to modify their consulting behaviour.

Table 3 Mean scores per independent variable per group, estimated effect size differences and *P*-value of multi-level analysis

	Range mean score	Intervention group (<i>n</i> = 121)		Intervention group who used leaflet correctly (<i>n</i> = 47)		Control group (<i>n</i> = 142)		Estimated effect size difference* (95% CI) ^{†‡}	<i>P</i> -value	Estimated effect size difference [†] (95% CI) [‡]	<i>P</i> -value
		Pre	Post	Pre	Post	Pre	Post				
PEI	0-2	0.72	0.56	0.56	0.69	0.62	0.69	-0.232 (-0.444 to -0.021)	0.032	-0.226 (-0.475 to 0.022)	0.075
COMRADE	1-4	1.82	1.83	1.83	1.80	1.89	1.80	0.090 (-0.096 to 0.277)	0.344	0.091 (-0.129 to 0.311)	0.42
EUROPEP	1-5	4.19	4.32	4.20	4.37	4.18	4.37	-0.056 (-0.302 to 0.192)	0.660	-0.171 (-0.472 to 0.131)	0.267
Consultation length (min)		13.0	12.2	13.0	12.2	12.5	12.2	-0.545 (-2.513 to 1.423)	0.588	0.411 (-2.043 to 2.866)	0.74

*Difference in estimated effect between control and intervention group, corrected for clustering.

†Difference in estimated effect between control and intervention group who used leaflet correctly, corrected for clustering.

‡Calculated as $\pm(1.96 \times SE)$.**Table 4** Percentage of older patients that discussed one of eight known underreported health problems

	Intervention group (<i>n</i> = 121) (%)		Intervention group non-users (<i>n</i> = 74) (%)		Intervention group users (<i>n</i> = 47) (%)		Chi-square (Pearson) users vs. non-users (<i>P</i> values)		Chi square (Pearson) Control vs. intervention (<i>P</i> values)	
	Intervention group (<i>n</i> = 121) (%)	Intervention group non-users (<i>n</i> = 74) (%)	Intervention group non-users (<i>n</i> = 74) (%)	Intervention group non-users (<i>n</i> = 74) (%)	Intervention group users (<i>n</i> = 47) (%)	Intervention group users (<i>n</i> = 47) (%)	users vs. non-users (<i>P</i> values)	users vs. non-users (<i>P</i> values)	Control group (<i>n</i> = 142) (%)	Control vs. intervention (<i>P</i> values)
Visual problems	13/98 (13.3)	8/60 (13.3)	8/60 (13.3)	5/38 (13.2)	5/38 (13.2)	5/38 (13.2)	0.980	0.227	22/113 (19.5)	0.227
Hearing problems	13/96 (13.5)	11/59 (18.6)	11/59 (18.6)	2/37 (5.4)	2/37 (5.4)	2/37 (5.4)	0.065	0.427	19/108 (17.6)	0.427
Urinary problems	20/99 (20.2)	13/61 (21.3)	13/61 (21.3)	7/38 (18.4)	7/38 (18.4)	7/38 (18.4)	0.728	0.999	21/104 (20.2)	0.999
Sleeping problems	19/96 (19.8)	12/60 (20.0)	12/60 (20.0)	7/36 (19.4)	7/36 (19.4)	7/36 (19.4)	0.947	0.899	21/110 (19.1)	0.899
Memory problems	10/91 (11.0)	6/55 (10.9)	6/55 (10.9)	4/36 (11.1)	4/36 (11.1)	4/36 (11.1)	0.976	0.345	7/99 (7.1)	0.345
Loneliness	14/93 (15.1)	7/56 (12.5)	7/56 (12.5)	7/37 (18.9)	7/37 (18.9)	7/37 (18.9)	0.397	0.178	9/102 (8.8)	0.178
Depressive symptoms	14/93 (15.1)	6/57 (10.5)	6/57 (10.5)	8/36 (22.2)	8/36 (22.2)	8/36 (22.2)	0.124	0.749	14/104 (13.5)	0.749
Other mental symptoms	15/88 (17.0)	5/51 (9.8)	5/51 (9.8)	10/37 (27.0)	10/37 (27.0)	10/37 (27.0)	0.034	0.089	9/102 (8.8)	0.089

For example, two intervention studies among older adults that evaluated a pre-consultation interview on the number of raised problems during consultations showed a trend towards more raised problems²⁰ and question-asking.²¹

Another reason could be that older patients already perceive themselves to be sufficiently involved. A qualitative study has suggested that older patients have some worries about becoming more involved, but also positive expectations of enhanced involvement.²²

Finally, the fact that we did not find any relevant differences might be related to some limitations of our study. First of all, the post-intervention response was low. There is no clear reason for this, except for the fact that this measurement took place in December, a month of celebration. Secondly, there were many missing values, suggesting that the questionnaire might have been too difficult for our study subjects. Thirdly, ideally we would have chosen a design in which pre- and post-intervention patients were the same. However, as mentioned this was not possible for practical reasons. We think however, that this design is second best, as it rules out the time effect and there were no major differences between the different groups, except for the overrepresentation of male patients in the post-intervention control group. Finally, a questionnaire may not be the appropriate measure for involvement.

Our study and previous studies suggest that it is difficult to improve an older patients' involvement in their care. It seems that written materials alone, whether or not offered by an involvement-focused GP, are not effective and that older patients may need to be assisted in using them. Face-to-face communication may be more appropriate, either during the consultation, or shortly before the consultation. These kinds of consultation preparations have been tried before, for example in cancer research,²³ when they seemed effective.

It was not clear which group of older patients might benefit from an intervention to enhance their involvement. Maybe general interventions to improve involvement are too vague, or too abstract for older patients, and therefore focus-

ing on more concrete, disease specific interventions might be more successful to improve older patients' involvement. The above-mentioned interventions in cancer research to improve patient participation are good examples of disease specific interventions.^{24,25} Further research should focus on subgroups of older patients, in combination with face-to-face interventions that stimulate involvement.

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