Primary care

Impact of nurse practitioners on workload of general practitioners: randomised controlled trial
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Abstract

Objective To examine the impact on general practitioners' workload of adding nurse practitioners to the general practice team.

Design Randomised controlled trial with measurements before and after the introduction of nurse practitioners.

Setting 34 general practices in a southern region of the Netherlands.

Participants 48 general practitioners.

Intervention Five nurses were randomly allocated to general practitioners to undertake specific elements of care according to agreed guidelines. The control group received no nurse.

Main outcome measures Objective workload, derived from 28 day diaries, included the number of contacts per day for each of three conditions (chronic obstructive pulmonary disease or asthma, dementia, cancer), by type of consultation (in practice, telephone, home visit), and by time of day (surgery hours, out of hours). Subjective workload was measured by using a validated questionnaire. Outcomes were measured six months before and 18 months after the intervention.

Results The number of contacts during surgery hours increased in the intervention group compared with the control group (P < 0.06), particularly for patients with chronic obstructive pulmonary disease or asthma (P < 0.01). The number of consultations out of hours declined slightly in the intervention group compared with the control group, but this difference did not reach significance. No significant changes became apparent in subjective workload.

Conclusion Adding nurse practitioners to general practice teams did not reduce the workload of general practitioners, at least in the short term. This implies that nurse practitioners are used as supplements, rather than substitutes, for care given by general practitioners.

Introduction

Demand for general practitioners’ services has increased in many Western countries because of ageing populations, rising expectations of patients, and reforms that shift care from hospitals to the community. To accommodate this expansion in workload many countries have sought to shift care from general practitioners to other health professionals, notably nurses. The presumption is that aspects of care provided by general practitioners could be provided by nurses instead. Nurses can undertake much of the health promotion work of general practice and have a leading role in the routine management of chronic diseases such as asthma, diabetes, and coronary heart disease. Depending on the complexity of tasks, degree of autonomy, and level of training, care may be provided by nurse practitioners, practice nurses, or care assistants.

A review of available research has shown that nurses can achieve health outcomes that are as good as those of general practitioners and that they may have superior interpersonal skills. It is unclear, however, whether nurses reduce the workload of general practitioners. Nurses may supplement or extend general practitioner care rather than substitute for it.

We measured the impact of adding a nurse practitioner to the general practice team on general practitioners' workload. We anticipated that measures of objective workload, such as consultation rates, would decline if nurse practitioners were used as substitutes for doctors. No such reductions were expected if nurse practitioners were instead used to supplement or extend general practitioner care. In either case general practitioners might report improvements in subjective aspects of workload, such as job satisfaction and work stress.

Participants and methods

Design

We conducted a randomised controlled trial of the impact on general practitioners' workload of adding nurse practitioners to the practice team. In the Netherlands general practitioners are organised into “local groups” for the purposes of care out of hours and continuing medical education. Regional policy states that each local group should ideally have one full time nurse practitioner. The local association of general practitioners approached the 21 local groups (167 general practitioners) in a southern region of the Netherlands, and seven of these volunteered to participate (figure). We grouped local groups into matched pairs, using deprivation of the population and rural or urban location of the practices as the matching criteria. We assigned the odd local group to one pair, creating a matched threesome. Next, after baseline measurement, two independent researchers randomly assigned one local group from each pair and two local groups from the threesome to the intervention (four local groups, 30 general practitioners, 20 practices) by using sealed opaque envelopes. The other local groups were assigned to the control group (three local groups, 18 general practitioners, 14 practices).

Intervention

We recruited nurse practitioners from the community nursing service and had a mean of 12.1 (SD 3.1) years' postgraduate experience as community nurses. Three nurse practitioners worked full time (32-36 hours per week), and two shared one job (20 hours per week each). Each nurse served six to nine general practitioners. On average one full time nurse worked for seven
full time doctors. The nurse practitioners were expected to work cooperatively with the doctors according to agreed guidelines (box).

**Measures**

We measured objective and subjective workload of participating doctors six months before and 18 months after nurse practitioners were introduced. We also recorded demographic and practice characteristics for doctors (table 1).

We measured objective workload by diary. For 28 consecutive days, including evenings and weekends, general practitioners recorded the time they started and finished the working day and, for patients with chronic obstructive pulmonary disease or asthma, dementia, and cancer separately, the number of consultations in the practice, of telephone consultations, and of home visits. Although we did not assess the validity of the diary, the method is widely used and also proved to be valid in previous studies. We also recorded demographic and practice characteristics for doctors (table 1).

We used analysis of covariance (ANCOVA) for normally distributed data to assess the significance of differences between the intervention and control group. For objective workload the mean number of contacts at follow up was the dependent variable, with the baseline value as covariate. For subjective workload we used the mean score at follow up as the dependent variable, with the

**Power calculation**

Charlton et al showed a 50% reduction in the number of patients’ contacts with general practitioners after the introduction of a nurse run asthma clinic, operating 10 hours per week, in a practice of four doctors serving 8049 patients. A power calculation ($\alpha = 0.05$, power 80%), based on a fall in the number of contacts with general practitioners during surgery hours of 50% of the eligible patients, showed that a total of 21 general practitioners were needed in our study. Given an expected response rate of 70% we needed to recruit at least 30 general practitioners.

**Analysis**

The unit of analysis was the general practitioner because the intervention was targeted at individual doctors. Although randomisation of nurse practitioners was by local group, we had no reason to suppose that the behaviour of doctors within groups would be more alike than the behaviour of doctors in different groups.

For each doctor in each observation period we calculated the total number of contacts with patients per week in surgery hours and out of hours. We also calculated the number of contacts per week for each of three groups of patients (with chronic obstructive pulmonary disease or asthma, with dementia, and with cancer); by type of consultation (in practice, by telephone, and by home visit); by time of day (surgery hours, out of hours); the number of hours worked per day; and the number of evenings, nights, and weekends on call. We standardised each measure to account for differences between general practitioners in actual hours worked during the day or on call over the study period.

We transformed questionnaire items measuring subjective workload to ensure that a higher score represented a higher perceived workload. We then also computed the average score on each subscale for each doctor.

We used analysis of covariance (ANCOVA) for normally distributed data to assess the significance of differences between the intervention and control group. For objective workload the mean number of contacts at follow up was the dependent variable, with the baseline value as covariate. For subjective workload we used the mean score at follow up as the dependent variable, with the
baseline score as covariate. We used the Mann-Whitney U test where the outcome measures were not normally distributed, with the difference between follow up and baseline measures as the dependent variable.

Results

Study population

Table 1 summarises the characteristics of participating general practitioners (n = 48). The intervention and control groups were comparable with regard to general practitioners’ demographic and practice characteristics at baseline. Participating general practitioners resembled non-participants in the region with regard to sex and type of practice. The study group as a whole resembled general practitioners nationally in terms of age, sex, and characteristics of the practice.10

Thirty six of the 48 doctors completed baseline and follow up diaries, of whom 35 (73%) were included in the analysis (figure). One doctor was excluded because he worked too few hours in the follow up period (under 40 hours) for workload estimates to be reliable. Thirty two (67%) of the 48 doctors completed baseline and follow up questionnaires.

Objective workload

We found no significant differences at baseline between doctors who completed diaries at follow up (n = 35) and those who did not (n = 12) in their mean number of contacts during surgery hours (z = −0.90, P = 0.367) or out of hours (z = −1.50, P = 0.135).

The number of contacts during surgery hours increased by 4.5 per week over the study period in the intervention group but not changed in the control group (table 2). The increase was, however, not significant (z = −1.90, P = 0.057). The excess of contacts in the intervention group was due to an increase in the number of contacts with patients who had chronic obstructive pulmonary disease or asthma (z = −2.73, P = 0.006).

The number of contacts out of hours decreased by 1.5 in the intervention group and increased by 2.1 in the control group (table 2). The decline in the intervention group was non-significant (z = −1.24, P = 0.217).

At baseline and follow up 80% of the patients with chronic obstructive pulmonary disease or asthma attended the practice (baseline measurement 69.68 of 214.18 contacts; and follow up measurement 213.87 of 267.63 contacts), whereas 60% of patients with dementia and cancer received home visits (dementia baseline measurement 46.13 of 80.07 contacts, follow up measurement 62.8 of 106.68; cancer baseline measurement 77.76 of 117.51 contacts, follow up measurement 71.25 of 130.15 contacts). As the intervention group had more contacts for chronic obstructive pulmonary disease or asthma, they additionally experienced a greater increase in the number of practice based consultations than the control group (z = −3.0, P = 0.003; table 3).

Subjective workload

Table 4 summarises the mean scores for each of the four aspects of subjective workload. We found no significant differences in questionnaire responses at baseline between doctors who completed the follow up (n = 32) and those who did not (n = 16).

The change in subjective workload measures from baseline to follow up did not differ significantly between intervention and control groups.

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### Table 1 Characteristics of the study population at baseline, 1998

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of local groups</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>No of practices</td>
<td>20</td>
<td>14</td>
</tr>
<tr>
<td>No of general practitioners</td>
<td>30</td>
<td>18</td>
</tr>
<tr>
<td>No of male doctors</td>
<td>24</td>
<td>15</td>
</tr>
<tr>
<td>Mean age (SD)</td>
<td>44.8 (7.9)</td>
<td>45.3 (8.0)</td>
</tr>
<tr>
<td>Mean hours worked per week (SD)</td>
<td>33.9 (8.1)</td>
<td>33.6 (8.9)</td>
</tr>
<tr>
<td>Mean No of years since graduation (SD)</td>
<td>15.5 (7.9)</td>
<td>14.9 (8.8)</td>
</tr>
<tr>
<td>Mean No of years in current practice (SD)</td>
<td>12.8 (8.8)</td>
<td>13.1 (8.3)</td>
</tr>
<tr>
<td>Mean hours support from practice assistants per full time general practitioner (SD)</td>
<td>33.9 (6.2)</td>
<td>35.4 (10.1)</td>
</tr>
<tr>
<td>Mean No of patients per full time general practitioner (SD)</td>
<td>2595.2 (411.7)</td>
<td>2608.3 (584.0)</td>
</tr>
<tr>
<td>Mean No of patients with insurance through national health service per full time general practitioner (SD)</td>
<td>1703.0 (537.1)</td>
<td>1879.0 (513.6)</td>
</tr>
<tr>
<td>No of nurse practitioners</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>

*In the Netherlands most general practices employ one or more practice assistants who take responsibility for administrative and laboratory tasks.5

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### Nurse practitioners: a job description

**Target population**

- Patients with chronic obstructive pulmonary disease, asthma, dementia, or cancer.

**Tasks performed according to agreed guidelines (developed for this study)**

- Performing diagnostic tests (measurement of lung function, cognitive tests, interviewing patients and their family)
- Assessing the patient’s health and home situation
- Educating patients and if appropriate the family to explain the disease, prognosis, rationale of treatment, etc
- Performing (preventive) social visits to patients to support the patient and if appropriate the family
- Coordinating the care of patients and making contact with community health services, specialised nurses, or other healthcare professionals

**Procedure**

- A patient was referred by a general practitioner to the nurse practitioner
- After the first contact with a patient the nurse practitioner makes decisions on the management of the patient according to the agreed guidelines. Four possible courses of action can be taken: the nurse takes care of the patient; the nurse and general practitioner share the care of the patient; the patient is referred back to the general practitioner; or the patient does not need care
- The nurse practitioner had access to the (electronic) medical records of the patient and reported the contacts with the patients in the medical records. If necessary, the nurse discussed the patient and course of action with the general practitioner

**Training**

- Registered nurse with the highest training level (BSc degree) who had worked at least two years as a community nurse
- The nurses followed a special training programme for two weeks before they were introduced to the general practice

**Definition of a nurse practitioner**

- Nurses with additional knowledge, skills, and attitudes who take responsibility for the assessment and treatment of patients in primary care. They work with, rather than for, a general practitioner. They work as co-practitioners and can be seen as collaborative members of the general practice team
Discussion

The introduction of nurse practitioners to assist general practitioners in the management of patients with chronic obstructive pulmonary disease or asthma, dementia, and cancer did not reduce the workload of the general practitioners. This is particularly likely to occur when the care of patients with chronic diseases is first delegated to nurse practitioners and may diminish with time once the backlog of pre-existing problems is dealt with. Doctors and nurses may also require considerable time to develop the mutual understanding and trust needed to facilitate delegation of tasks.

Longer term studies will be needed to establish whether workload is reduced beyond 18 months.

Possible benefit of introducing nurse practitioners

The increase in surgery contacts was partially offset by a small (non-significant) reduction in the number of contacts during evenings and weekends. It is possible that nurse practitioners improved the quality of care for patients during surgery hours, thus preventing calls out of hours. Further research is needed to evaluate this potential benefit.

Doctors' subjective workload

Although we expected that nursing support would reduce the stress of a demanding job,20 general practitioners reported no subjective benefits in terms of workload. This might be because general practitioners were already satisfied with three of the four aspects of work we investigated. Dissatisfaction with the fourth

Table 2 Objective workload of general practitioners, expressed as the mean number of contacts with patients per week (95% confidence intervals) per group of patients during surgery hours (standardised by median number of days worked) and out of hours (standardised by mean number of shifts) before and after the introduction of the nurse practitioner

<table>
<thead>
<tr>
<th>Patient contacts</th>
<th>Before</th>
<th>After</th>
<th>Δ*</th>
<th>Before</th>
<th>After</th>
<th>Δ*</th>
<th>P value†‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery hours</td>
<td>12.9 (9.0 to 16.8)</td>
<td>17.4 (12.4 to 22.4)</td>
<td>+4.5 (0.6 to 8.3)</td>
<td>10.3 (7.8 to 13.0)</td>
<td>10.4 (7.9 to 13.0)</td>
<td>+0.1 (-1.9 to 2.2)</td>
<td>0.967†</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease or asthma</td>
<td>6.6 (4.1 to 9.2)</td>
<td>9.5 (6.0 to 12.9)</td>
<td>+2.8 (0.3 to 5.3)</td>
<td>5.4 (3.6 to 7.3)</td>
<td>5.2 (3.2 to 7.3)</td>
<td>-0.2 (-1.4 to 1.1)</td>
<td>0.006‡</td>
</tr>
<tr>
<td>Dementia</td>
<td>2.5 (1.4 to 3.5)</td>
<td>3.4 (2.0 to 4.9)</td>
<td>+0.9 (-0.2 to 2.1)</td>
<td>2.1 (1.4 to 2.7)</td>
<td>2.6 (1.2 to 4.0)</td>
<td>+0.5 (-0.8 to 1.9)</td>
<td>0.548‡</td>
</tr>
<tr>
<td>Cancer</td>
<td>3.8 (2.5 to 5.1)</td>
<td>4.5 (3.3 to 5.7)</td>
<td>+0.7 (-0.7 to 2.2)</td>
<td>2.8 (1.9 to 3.7)</td>
<td>2.6 (1.4 to 3.8)</td>
<td>-0.2 (-1.4 to 1.0)</td>
<td>0.099‡</td>
</tr>
<tr>
<td>Out of hours</td>
<td>4.8 (2.1 to 7.5)</td>
<td>3.3 (1.9 to 4.7)</td>
<td>-1.5 (-3.9 to 0.9)</td>
<td>3.7 (0.8 to 6.6)</td>
<td>5.8 (0.5 to 11.0)</td>
<td>+2.1 (-1.3 to 5.5)</td>
<td>0.217</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease or asthma</td>
<td>2.8 (1.2 to 4.4)</td>
<td>1.3 (0.5 to 2.0)</td>
<td>-1.5 (-3.0 to -0.03)</td>
<td>1.6 (-0.09 to 3.3)</td>
<td>2.3 (-0.09 to 4.6)</td>
<td>+0.7 (-0.9 to 2.2)</td>
<td>0.094†</td>
</tr>
<tr>
<td>Dementia</td>
<td>0.7 (-0.04 to 1.5)</td>
<td>0.3 (0.06 to 0.5)</td>
<td>-0.5 (-1.3 to 0.3)</td>
<td>0.5 (0.11 to 0.9)</td>
<td>0.9 (0.05 to 1.7)</td>
<td>+0.4 (-0.4 to 1.1)</td>
<td>0.172</td>
</tr>
<tr>
<td>Cancer</td>
<td>1.2 (0.2 to 2.1)</td>
<td>1.8 (0.7 to 2.8)</td>
<td>+0.5 (-0.5 to 1.5)</td>
<td>1.6 (0.3 to 2.8)</td>
<td>2.6 (0.4 to 4.9)</td>
<td>+1.1 (-0.5 to 2.6)</td>
<td>0.673†</td>
</tr>
</tbody>
</table>

* Change over time in intervention and control groups (effect size).
† Mann-Whitney U test.
‡ Analysis of covariance.

Table 3 Objective workload of general practitioners, expressed as the mean number of contacts with patients per week (95% confidence interval) per type of consultation during surgery hours (standardised by median number of days worked) and out of hours (standardised by mean number of shifts) before and after the introduction of the nurse practitioner

<table>
<thead>
<tr>
<th>Patient contacts</th>
<th>Before</th>
<th>After</th>
<th>Δ*</th>
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<th>After</th>
<th>Δ*</th>
<th>P value†‡</th>
</tr>
</thead>
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<tr>
<td>Surgery hours</td>
<td>12.9 (9.0 to 16.8)</td>
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<td>+4.5 (0.6 to 8.3)</td>
<td>10.3 (7.6 to 13.0)</td>
<td>10.4 (7.0 to 13.0)</td>
<td>+0.1 (-1.9 to 2.2)</td>
<td>0.967†</td>
</tr>
<tr>
<td>Practice</td>
<td>6.4 (4.0 to 8.8)</td>
<td>9.5 (6.4 to 12.7)</td>
<td>+3.1 (0.9 to 5.4)</td>
<td>5.7 (3.8 to 7.6)</td>
<td>5.6 (3.2 to 8.0)</td>
<td>-0.09 (-1.6 to 1.4)</td>
<td>0.003†</td>
</tr>
<tr>
<td>Telephone</td>
<td>1.6 (0.7 to 2.4)</td>
<td>2.2 (1.3 to 3.3)</td>
<td>+0.7 (-0.4 to 1.7)</td>
<td>0.8 (0.4 to 1.3)</td>
<td>1.2 (0.6 to 1.8)</td>
<td>+0.3 (-0.1 to 0.6)</td>
<td>0.677</td>
</tr>
<tr>
<td>Home visits</td>
<td>5.0 (3.3 to 6.8)</td>
<td>5.6 (3.6 to 7.6)</td>
<td>+0.6 (-1.0 to 2.4)</td>
<td>3.7 (2.6 to 4.8)</td>
<td>3.6 (2.0 to 5.3)</td>
<td>-0.09 (-1.2 to 1.0)</td>
<td>0.321</td>
</tr>
<tr>
<td>Out of hours</td>
<td>4.8 (2.1 to 7.5)</td>
<td>3.3 (1.9 to 4.7)</td>
<td>-1.5 (-3.9 to 0.9)</td>
<td>3.7 (0.8 to 6.6)</td>
<td>5.8 (0.6 to 11.0)</td>
<td>+2.1 (-1.3 to 5.5)</td>
<td>0.217</td>
</tr>
<tr>
<td>Practice</td>
<td>1.7 (0.5 to 3.0)</td>
<td>1.0 (0.4 to 1.6)</td>
<td>-0.8 (-1.9 to 0.4)</td>
<td>1.0 (-0.4 to 2.3)</td>
<td>2.0 (-0.2 to 4.2)</td>
<td>+1.0 (-0.7 to 2.8)</td>
<td>0.105†</td>
</tr>
<tr>
<td>Telephone</td>
<td>0.9 (-0.1 to 2.0)</td>
<td>0.3 (-0.03 to 0.6)</td>
<td>-0.6 (-1.7 to 0.5)</td>
<td>0.6 (-0.01 to 1.2)</td>
<td>0.5 (-0.1 to 1.1)</td>
<td>-0.1 (-0.5 to 0.2)</td>
<td>0.771</td>
</tr>
<tr>
<td>Home visits</td>
<td>2.1 (1.1 to 3.2)</td>
<td>2.0 (1.0 to 3.1)</td>
<td>-0.1 (-1.3 to 1.0)</td>
<td>2.1 (0.8 to 3.5)</td>
<td>3.3 (0.5 to 6.1)</td>
<td>+1.2 (-1.0 to 3.4)</td>
<td>0.338†</td>
</tr>
</tbody>
</table>

* Change over time in intervention and control group (effect size).
† Mann-Whitney U test.
‡ Analysis of covariance.

Table 4 Subjective workload expressed as a mean score (95% confidence interval) on a five point scale, before and after the introduction of nurse practitioners. A higher score represents higher job stress

<table>
<thead>
<tr>
<th>Scored variable</th>
<th>Before</th>
<th>After</th>
<th>Δ*</th>
<th>Before</th>
<th>After</th>
<th>Δ*</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available time</td>
<td>2.7 (2.3 to 3.0)</td>
<td>2.8 (2.5 to 3.2)</td>
<td>+0.1 (-0.5 to 0.7)</td>
<td>2.9 (2.6 to 3.2)</td>
<td>2.8 (2.4 to 3.2)</td>
<td>-0.1 (-1.0 to 0.8)</td>
<td>0.285</td>
</tr>
<tr>
<td>Job satisfaction</td>
<td>2.2 (1.8 to 2.5)</td>
<td>2.2 (1.9 to 2.4)</td>
<td>-0.0 (-0.4 to 0.4)</td>
<td>2.3 (1.9 to 2.8)</td>
<td>2.4 (2.1 to 2.7)</td>
<td>+0.1 (-0.3 to 0.5)</td>
<td>0.415</td>
</tr>
<tr>
<td>Inappropriate demands</td>
<td>3.4 (3.1 to 3.7)</td>
<td>3.5 (3.1 to 3.8)</td>
<td>+0.1 (-0.4 to 0.7)</td>
<td>3.4 (3.1 to 3.7)</td>
<td>3.5 (3.1 to 3.8)</td>
<td>+0.1 (-0.3 to 0.5)</td>
<td>0.608</td>
</tr>
<tr>
<td>Cost benefit</td>
<td>2.9 (2.5 to 3.3)</td>
<td>3.0 (2.7 to 3.3)</td>
<td>+0.1 (-0.4 to 0.6)</td>
<td>2.8 (2.3 to 3.2)</td>
<td>2.8 (2.5 to 3.2)</td>
<td>-0.1 (-0.8 to 0.6)</td>
<td>0.479</td>
</tr>
</tbody>
</table>

* Analysis of covariance.
aspect—inappropriate demands from patients—was not readily susceptible to change as the general practitioner is the first point of contact for all patients and nurse practitioners assisted in the care of only three groups of patients. Interventions with general practitioners in the intervention group indicated, however, that doctors believed that nurses had lightened their burden of care for patients in the targeted groups.

Limitations of the study
We investigated the effect of adding nurse practitioners to the practice team on both objective and subjective aspects of general practitioners’ workload in a controlled trial. The study was performed in only one region of the Netherlands, which may limit the generalisability of the findings. Several general practitioners were lost to follow up, which threatens the internal validity of the trial. Although not reaching significance, measures of objective workload were slightly higher among the general practitioners who withdrew. The dropout rate was higher in the intervention group and may reflect uncertainty at that time about whether government policy would continue to support the employment of nurse practitioners. Although we have no reason to believe that these limitations appreciably biased the findings, the work would benefit from being replicated elsewhere.

Conflicting evidence
Although it is widely believed that adding nurses to the general practice team can reduce doctors’ workload, the existing evidence is conflicting. Some have noted that nurses reduce general practitioners’ workload,3 11–20 Others have found no effect.25 26 Differences in the effect might be explained by differences in nurses’ degree of autonomy, level of training, and the conditions that they are asked to manage. Another explanation might be variation in the ratio of nurses to doctors.

Our findings are consistent with the view that nurses are often used as supplements, not substitutes, for general practitioner care. Gains for the efficiency of services can be achieved only if general practitioners give up providing the types of care they have delegated to nurses and instead invest their time in activities that only doctors can perform.27 Further research is therefore needed into what factors facilitate delegation of tasks from nurses to doctors (for example, type of services, nurses’ education, and training, etc) and how doctors invest their time savings.

We thank all general practitioners who participated in the study. We also thank Reiner Akkermans, statistician at the University Medical Centre Nijmegen, for his statistical advice.

Contributors: MGHL set up the study design and performed the data collection and data analysis. JCCB supervised the project and gave methodological advices. RPMG supervised the statistical analysis and the interpretation of the data. BS was involved in the structuring of the paper. RPTMG was responsible for the whole trial and participated in the discussion of the different stages of the project. All authors discussed the objectives of the paper. MGHL drafted the paper, which was edited by RPTMG, JCCB, BS, and RPMG. MGHL is guarantor for the study.

Funding: Local Association of General Practitioners (DHV Midden Brabant), Local Community Nursing Authorities (Thebe thuishoorn), and two local insurance companies (CZ Actief in Gesondheid, VZG Midden Brabant).

Competing interests: None declared.

Primary care

(Accepted 20 February 2004)
doi 10.1136/bmj.38041.493519.EE

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