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Towards an optimal composition of general practitioners and nurse practitioners in out-of-hours primary care teams: a quasi-experimental study

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Journal:	BMJ Open
Manuscript ID	bmjopen-2016-015509
Article Type:	Research
Date Submitted by the Author:	12-Dec-2016
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Primary Subject Heading :	General practice / Family practice
Secondary Subject Heading:	Emergency medicine, Health services research, Nursing
Keywords:	Nurse practitioner, PRIMARY CARE, acute care, out-of-hours care, substitution



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Abstract

Objectives– To compare teams with different numbers of general practitioners (GPs) and nurse practitioners (NPs) in primary out-of-hours care.

Design- Quasi-experimental study

Setting- An out-of-hours primary care organisation in the Netherlands.

Intervention – Team-2 (1 NP, 3 GPs) and Team-3 (2 NPs, 2 GPs) were compared with team-1 (4 GPs). Each team covered 35 weekend days.

Participant - All 9,503 patients who received a consultation during the study period.

Main outcome measure – Primary outcome was the total number of consultations per provider on weekend days between 10:00 and 18:00h. Secondary outcomes concerned numbers of patients outside NPs' scope of practice, patient safety, resource use, direct health-care costs and GPs' performance.

Results– The mean number of consultations per team per shift was lower in teams with NPs compared to teams with GPs only (team-1: 93.9, team-3: 87.1; P<0.001). The mean observed proportion of patients outside NPs' scope of practice per hour was 9.0% (SD 6.7), the highest value in any hour was 40%. The proportion of patients who did not receive a consultation within the targeted time period was higher in teams with NPs (team-2, 5.2%; team-3, 8.3%) compared to team-1 (3.5%) (P<0.01). Team-3 referred more patients to the emergency department compared to team-1, respectively 12.0% vs team-2: 14.7% (P=0.028). GPs treated more urgent patients (GPs team-1: 13.2%, GPs team-2: 16.3%, GPs team-3: 21.4%; P<0.01) and more patients with digestive complaints (GPs team-1: 11.1%, GPs team-2: 11.8%, GPs team-3: 16.7%; P<0.01).

Conclusions– Primary health-care teams up to a ratio of two GPs and two NPs provided enough capacity to provide care to all patients during weekend days. Areas of concern are the number of consultations, the number of patients who do not receive care within the targeted time period and referrals to the emergency department.

Trial registration- ClinicalTrials.gov ID NCT02407847

Keywords - Nurse practitioner, primary care, acute care, out-of-hours care, substitution, skill mix

Strengths and limitations of this study

- This is the first comparative evaluation of teams with NPs and GPs in out-of-hours care.
- The study has a large representative patient sample and a long follow-up period, although done in one centre only.
- Health outcomes were not measured.
- The use of a cost-minimization analysis does provide limited insight in the costs.
- No change patient in allocation gives an accurate representation of the daily practice and peak /es a.. hours.

"What this paper adds" box

What is already known on this subject

- Research showed that NPs as GPs' substitutes during daytime provide safe and good quality of care, while overall healthcare costs remain the same.
- Comparative evaluations on the composition of primary care with of GPs and NPs during out-of-hours are lacking.

What this study adds

• Given the identified maximum of 33% patients outside NPs' scope of practice per day, teams up to a ratio of 2 NPs and 2 GPs offer enough capacity to provide care to all patients during weekend days.

Areas of concern are that with an increased number of NPs in the team, the number of patients who
do not receive care within the defined time period (a potential patient safety issue) and higher
numbers of referrals to the emergency department by the team (given impacts on capacity and costs).

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Introduction

The quality of primary care during out-of-hours influences the functioning of the whole health-care system. Internationally, different organizational models are used to deliver urgent care during out-of-hours. Patients in the UK have access to services such as walk-in centres, urgent care centres, out-of-hours centres, telephone consultation and the emergency department, which often operate side by side (1). However, those services show various results on patient outcomes and efficiency (2-4). In the Netherlands out-of-hours care is organised in general practitioners cooperatives (GPC) (5). Although these large GP-based models show positive results (3), current and expected problems like aging, increased prevalence of chronic conditions and task shifts from hospitals to the community put a pressure on (out-of-hours) primary care (6, 7). Policymakers are challenged to find a model that ensures accessibility, quality and efficiency of out-of-hours care (1, 8).

As many complaints during out-of-hours do not necessarily require the knowledge and skills of a GP, there is an increasing interest in care delivering models that include nurse practitioners (NPs) into primary care teams (9-11). Systematic reviews of published research have shown that NPs in daytime primary care provide good quality and safe care to patients, but not necessarily more efficient care compared to GPs (12-14). Models in which care is provided by teams with only NPs are arising, but based on the capacity, resources or skill levels those services are not able to provide high-quality care to some patients. In the light of above, team-based care involving both GPs and NPs is an alternative model to deliver care during out-of-hours.

Current evidence does, not provide insight in the optimal ratio of GPs and NPs in out-of-hours teams. Results of NPs in daytime primary care cannot simply be translated to out-of-hours care. Organisations differ in size, the incidence of life threatening conditions is higher in out-of-hours setting, and care outside office hours has unpredictability's in its patient flow. The acute character of complaints limits the potential of scheduling forward and the main complaint after triage does not always correspond to the main complaint evaluated during consultation (15, 16). Second, while the overall patient care is determined by the sum of its parts, most studies compare care between healthcare providers instead of comparing teams (17). To the best of our knowledge, this is the first randomised comparative study to provide insight in the optimal composition of GPs and NPs in primary care teams during out-of-hours.

Aim

To compare teams with different ratios of GPs and NPs on the number of consultations, patient care and GPs' performance features and provide insight in the number of patients, which are outside NPs' scope of practice in out-of-hours primary care.

Methods

<u>Design</u>

Quasi-experimental study measuring the total number of patients and the distribution of patients outside NPs' scope of practice in out-of-hours primary care on weekend days between 10 a.m. and 6 p.m.. Moreover, two types of teams with NPs were compared with teams with GPs only:

- Team-1: care is provided by a team of four GPs (care-as-usual);
- Team-2: care is provided by a team of three GPs and one NP;
- Team-3: care is provided by a team of two GPs and two NPs.

Study setting

The study was conducted at a general practitioner cooperative (GPC) situated within a hospital next to the Emergency Department (ED) in the South East of the Netherlands. In this GPC, GPs work in shifts from 5 p.m. to 8 a.m. on weekdays and the entire weekend to take care of a population of approximately 304,000 people. All patients in need for acute care during out-of-hours contact the GPC by a single, regional telephone number were triage nurses allocate patients to an appropriate care pathway based on risk stratification. Patients who are eligible for a consultation at the GPC are scheduled in a common presentation list, depending on the urgency of the complaints (box 1). A maximum of five patients are scheduled every hour per health-care provider. GPs and NPs choose attending patients from this presentation list (18).

Box 1. NTS Urgency levels (19)

Urgency level	Description	Time period for consultation
U1	Life threatening: Immediate action required, the vital functions are threatened or delaying treatment will cause serious and irreparable damage to the patient's health.	Within 15 minutes
U2	Emergent: Vital functions are not (yet) in danger, but there is a fair change that the patient's condition will soon deteriorate or delaying treatment will cause serious and irreparable damage to the patient's health. Take action as soon as possible.	Within 1 hour
U3	Urgent: Do not postpone too long. Treat within a few hours because of medical- or humane reasons.	Within 3 hours
U4	Non-urgent: There is no pressure resulting from medical- or other grounds. Time and place of treatment should be discussed with the patient.	No time pressure
U5	Advice: A physical examination can wait until the next day.	No time pressure

Study population

General practitioners

All GPs who delivered patient care during the study period were included. This included both practice owners (n=162) and GPs who are employed by another GP. Their mean age was 47.5 years (SD 9.7) and 50.3% were male. GPs employed by another GP are often recently graduated GPs.

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Nurse practitioners

A sample of 10 NPs participated in the study. Their mean age was 45.2 years (SD 9.4) and one was male. On average, they were graduated as an NP for 1.8 years (SD 1.2) and worked at the GPC for 1.6 years (SD 1.1). All NPs had completed a two-years Master's programme 'Advanced Nursing Practice' (NLQF/EQF level 7). Their programme included an academic course on treating common complaints in primary care and an internship in general practice (20, 21). During office hours they took

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care for patients with minor ailments in general practices, elderly care or care for disabled people. To ensure their competency to work in out-of-hours care they received three half days of additional training in commonly presented complains during out-of-hours (eye disorders, musculoskeletal disorders (such as fractures, bruises and sprains) and wound care (e.g. suturing)). NPs in the Netherlands have the authority to independently indicate and perform reserved procedures (including prescribing) in their area of expertise, using the same practice guidelines as GPs (22, 23). The support staff at the GPC (1 receptionist and 1 medical assistant per shift) was equal for the different teams.

Patients

All patients who had a consultation at the GPC during the data collection were included in the study. Due to the explorative character of the study a statistical power calculation could not reliably be done. In order to get reasonably accurate estimates, a 35-week follow up period per team was chosen to get a sufficiently large sample. Based on the educational training of the NPs, the GPC excluded the following patients from NP care: those younger than one year or presenting psychiatric complaints, abdominal pain, chest pain, a neck ailment, headache, or dizziness during triage (see box 2). Based on the information of the triage nurse, NPs decided which patients from the common presentation list they would call in for consultation. Patients outside the predefined scope of the NP received consultation from a GP. In case the complaint of the patient during the triage was different from the complaint during consultation, NPs were allowed to decide autonomously whether they felt competent or not to complete the consultation themselves. If not, they could consult a GP about the patient or refer the patient to a GP at the GPC.

Allocation to study arms

The teams were rotated systematically between Saturday and Sunday. The rotation scheme was determined in advance. GPs were randomly assigned to the weekend days; they did not know whether they would work with an NP at the time of scheduling.

The scheduling of the patients was done by triage nurses at the call center who were in charge of scheduling patients for several GPCs. They were blind for the composition of GPs and NPs in the

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team, they only know the total number of team members. As a consequence, patients were not informed about the presence of NPs in the teams when they contacted the call center.

Measures and data collection

The primary outcome was the number of consultations per team and per health-care provider. This was indicated as the mean number of patients per team per weekend day and per health-care provider per hour.

In the secondary outcomes we focused on the percentage and distribution of patients outside NPs' scope of practice on weekend days between 10 a.m. and 6 p.m.. In addition, we measured the effect of different team compositions with NPs and GPs on: 1) patient care and 2) GPs' performance features.

Patient care included four measures in which the different teams were compared: patient safety, resource use following a consultation at the GPC and direct health-care costs. Patient safety was examined by two measures. The first included the number of (near) incidents. In the Netherlands, GPCs are required by law to report (near) incidents to an internal reporting of patient care incidents committee. Both patients and provides are able to report (near) incidents. Second, the number of patients who did not receive care within the targeted time period was calculated. At the call center triage nurses classify all patients into urgency levels. The Netherlands Triage Standard (NTS) defined within what time period a patient needs treatment (see box 1). Resource use included X-rays, drug prescriptions and referrals to the emergency department (ED). Other imaging tests or laboratory samples than X-rays could not be ordered by the providers. If such diagnostic tests were necessary patients were referred to the ED or to their own GP the next day. Next, direct health-care costs were calculated based on personnel costs (based on number of consultations per hour and salary) and combining volumes of resource use by unit prices that constitute costs.

The impact on GPs' performance features was measured by comparing GPs' patient characteristics and resource use. Characteristics of GPs' patients included patients' age, urgency level and ICPC code. In addition to these characteristics, the number of patients outside NPs' scope of practice treated by GPs in different teams was compared. Lastly, the percentage of consultations in which NPs ask consultation from a GP was measured. All data was extracted from the electronic medical patient records at the GPC and coded by the providers as part of their routines during the consultation. Data was collected from May 2014 to November 2015.

Box 2. Patients outside predefined scope of NP care

du	tient characteristics and complaints expressed ring triage defined as outside NPs' scope of actice	out	tient characteristics and diagnoses defined as tside NPs' scope of practice during data alysis
_	Patients younger than one year old	_	Age < 1 year
_	Patients suffering from psychiatric complaints	_	ICPC group P Psychological
_	Patients suffering abdominal pain	_	 ICPC group D Digestive (except ICPC codes: D04 (Rectal/anal pain), D05 (Perianal itching), D19 (Teeth/gum symptom/complaint), D20 (Mouth/tongue/lip symptom/complaint)
_	Patients suffering chest pain	-	 ICPC group K Cardiovascular (except ICPC codes: K06 (Prominent veins), K07 (Swollen ankles/oedema), K95 (Varicose veins of leg), K96 (Haemorrhoids)
-	Patients suffering neck ailment	_	ICPC code L01 Neck symptom/complain
_	Patients suffering headache or dizzines.	_	ICPC group N Neurological o (except ICPC code: N72 (Tetanus)

Statistical analysis

Baseline characteristics

Baseline characteristics were presented as proportions (%) and included potential confounders for the comparison: age (in four categories), urgency (in five categories), gender, and type of complaint (indicated as an International Classification Primary Care [ICPC] code). Differences between team-1 with team-2 and team-3 were tested using a Chi²-test.

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Primary outcome

First, the total number of patients per team was calculated. An independent sample t-test was used to test differences in number of consultations per shift between team-2 and team-3 with team-1. The mean number of consultations per professional per hour was calculated by dividing the total number of patients per team by the exact number of hours and the number of health-care providers per team. In addition, we calculated the number of consultations per hour for the GP and NP separately.

Secondary outcomes:

Percentage and distribution of patients outside NPs' scope of practice

First, researchers indicated those patients whose diagnosis fitted the complaints excluded from NP care (see box 2). Descriptive analysis (mean; SD) was used to indicate the percentage of patients outside NPs' scope of practice on weekend days.

In order to get insight in the distribution of those patients during the day, the total number of patients outside NPs' scope of practice per hour was divided by the number of patients that could be scheduled per hour (maximum of 5 patients per health-care provider per hour = 20 patients per team per hour).

Comparisons patient care between teams

Patient safety - Descriptive analysis was used for the number of (near) incidents. Differences between teams in number of patients receiving treatment within the targeted time period was tested with a logistic regression analysis for dichotomous outcomes. Estimates were adjusted for ICPC group, age and the proportion of patients with an U2 urgency level per day.

Resource use (i.e. X-rays, drug prescriptions and referrals to the ED) was evaluated by analyzing differences in volumes between teams. Logistic regression analysis for dichotomous outcomes that corrected for age, gender, urgency level and ICPC group was conducted to compare team-2 and 3 with team-1.

Direct health-care costs - The economic evaluation was designed as a cost-minimization analysis, considering direct health-care costs of the consultation only (24). Direct costs were

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Costs for personnel per consultation were calculated by dividing the tariff per hour by the mean number of patients per hour. For NPs the tariff per hour was set at €61,32 based on their salary from the GPC, including social security contributions (approximate 40%) and premium pay (50%). For GPs the tariff was set at €74,66 based on the payment agreements with health insurance companies. GPs in the Netherlands receive a tariff per patient for providing 24/7 care. Based on these tariffs the total tariff per hour per team was €298,64 for team-1, €285,30 for team-2 and €271,96 for team-3. For a better comparison between GPs' and NPs' tariff we also calculated a tariff based on the salary for GPs employed by another GP (specified in collective labour agreements). This tariff included social security contributions and premium pay similar to NPs and was set at €93,56 per hour. Inclusion of this tariff resulted in a total tariff per hour per team of €374,24 for team-1, €342,00 for team-2 and €309,76 for team-3.

Next, following the guidelines of the Dutch manual for costing, the cost for each referral to the ED was set at €261 and for an X-ray at €52,79 (25). As a result of the differences between the minimum and maximum price for medicine two separate costs were calculated per drug prescription. All costs were valid for the year 2015.

To provide insight in the cost differences between team-2 and -3 with team-1, a linear regression model was used that corrected for casemix (i.e. age, gender, urgency level, ICPC group). In the primary analysis the minimum price per medicine and the personnel costs valid for the GPC were used. Deterministic uncertainty was explored by: 1. one-way sensitivity on costs of drug prescriptions by including the maximum prize per medicine and 2. one-way sensitivity on personnel cost by including the tariff for GPs employed by another GP. Finally we applied a bootstrapping procedure (with 1000 replications) to manage the highly skewed costs across patients.

Comparison GPs' performance features between teams

Patient characteristics - To characterize patients seen by GPs in the different teams, descriptive statistics were used for patients' age, gender, urgency level and type of complaint (ICPC). Differences between GPs in team-2 and -3 with team-1 were tested using a Chi²-test for categorical data. Descriptive analysis was used for the number of patients that are outside NPs' scope of practice GPs treated in different teams.

Resource use - Resource use (i.e. X-rays, drug prescriptions and referrals to the ED) was evaluated by analyzing differences in volumes between GPs in different teams. Logistic regression analysis for dichotomous outcomes that corrected for age, gender, urgency level and ICPC group was conducted to compare GPs in team-2 and -3 with GPs in team-1.

Consultation NP with GP - NPs reported a code in patients' medical records when they consulted a GP for a patient. There were three codes in case they consulted a GP but completed the consultation themselves: 1. consultation GP by phone; 2. consultation GP outside surgery room and; 3. consultation GP in surgery room. A fourth code was reported when the patient was referred to a GP to complete the consultation.

Tests were two-tailed and outcomes were statistical significant with an alpha level P<0.05. The statistical analysis including the bootstrapping was carried out using SPSS software version 22 (SPSS Inc, Chicago, IL, USA). 4.01

Results

All presenting patients during the study period were included in the analyses (see figure 1). There were no significant differences in age, gender and ICPC groups between the teams (see table 1). In all teams the top four of ICPC codes covered more than two-thirds of all patients and included skin (21%), musculoskeletal (21%), respiratory (14%) and digestive complaints (11%). Team-2 treated in comparison to team-1 slightly more patients with urgency level U2 (14.3% vs. 13.2%) and less patients with urgency level U3 (47.5% vs. 51.8%) (P=0.01).

Figure 1. Flow diagram of the study

	Team-1 (control; 4 GPs)	Team-2 (3 GPs & 1 NP)	Team-3 (2 GPs & 2 NPs)	GPs Team-1	GPs Team-2	GPs Team-3
Age in categories (%)						***
0-1 year	4.1	3.5	4.6	4.1	3.9	7
2-17 years	22.6	24.3	25.8	22.6	22.4	22.4
18-64 years	57.5	56.2	54.3	57.5	56.7	54.2
65 years and older	15.8	16	15.3	15.8	16.9	16.5
Gender (% male)	46.7	46.9	47.9	46.7	46.2	46.6
Urgency (%)	0.	*			**	***
U1	0.1	0.1	0.1	0.1	0.1	0.1
U2	13.2	14.3	15.3	13.2	16.3	21.4
U3	51.8	47.5	50.5	51.8	46.9	47.8
U4	31.0	33.8	30.6	31	32.4	27.4
U5	3.9	4.3	3.4	3.9	4.3	3.3
Complaints top 10 (%)					**	***
Skin	22.0	21.8	19.3	22	18.7	13.6
Musculoskeletal	20.6	21.7	22.0	20.6	19	18.5
Respiratory	14.3	13.0	15.8	14.3	12.6	16
Digestive	11.1	9.6	11.0	11.1	11.8	16.7
General and unspecified	7.3	7.4	7.4	7.3	8.1	7.9
Eye	5.9	6.0	6.1	5.9	6.4	5.3
Urological	5.6	7.1	5.2	5.6	7.9	5.6
Ear	4.7	4.3	4.7	4.7	4.2	3.7
Neurological	2.9	2.8	2.6	2.9	3.6	3.9
Cardiovascular	1.9	1.9	1.8	1.9	2.5	2.7
Other	3.8	4.3	4.1	3.8	5.1	5.9

 Table 1. Baseline patient characteristics

Tested using a Chi²-test

* Significant difference with team-1 P<0.05

** Significant difference with GPs in team-1 P<0.01

*** Significant difference with GPs in team-1 P<0.001

Primary outcome: Total number of consultations

In total 9,503 patients had a consultation during the study period. Team-1 had contact with 3,287

patients, team-2 with 3,166 patients and team-3 with 3,048 patients. The mean number of

consultations per shift by the team was 93.9 (SD 9.0) in team-1 versus 90.5 (SD 7.2) in team-2 (not significant), and 87.1 (SD 6.2) in team-3 (P<0.001). The mean number of consultations per hour per health-care provider was 3.1 consultations in team-1, 3.0 consultations in team-2 (GP 3.2, NP 2.6) and 2.9 consultations in team-3 (GP 3.3, NP 2.5).

Secondary outcomes

The percentage and distribution of patients outside NPs' scope of practice

Overall, the number of patients outside NPs' scope of practice expressed as proportion of the total number of patients per day was 19.1% (SD 50.4). The range was 6% to 33% patients per day that were outside NPs' scope of practice (see figure 2). There was no difference between Saturdays (18%) and Sundays (20%) or between team-1 (19.9%), team-2 (18.0%) and team-3 (19.4%).

Figure 2. Patients outside NPs' scope of practice per day on weekend days (*expressed as proportion of the total number of patients per day*)

The absolute number of patients outside NPs' scope of practice was a minimum of 0 and a maximum of 8 per hour. Expressed as proportion of the total number of patients that can be scheduled (= 20 per hour), the maximum proportion of patients outside NPs' scope of practice per hour was 40% (mean 9.0%, SD 6.7) (see figure 3).

Figure 3. Patients outside NPs' scope of practice per hour on weekend days (*expressed as proportion of the total number consultations that can be scheduled per hour*)

Comparisons patient care between teams

During the study no any (near) incidents were reported. The proportion of patients who did not receive a consultation within the targeted time period according to the NTS was 3.5% in team-1, 5.2% in team-2 and 8.3% in team-3. After adjusting for confounders, the proportion of patients who did not receive a consultation within the targeted time period was significantly higher in team-2 (P=0.001) and team-3 (P<0.001) compared to team-1 (see table 2).

Across the overall sample adjusted volumes of resource use did not change significantly for X-rays between team-1, team-2 and team-3. Compared to team-1, after correction for casemix, team-2 more often prescribed drugs (respectively: 41.3% vs. 44.2%, P=0.033). In contrast, team-3 did not prescribe more drugs (39.5%; not significant). The number of patients referred to the ED was 12% in team-1, 13.2% in team-2 and 14.7% in team-3. After adjusting for casemix the difference between team-3 and team-1 was significant (P=0.028) (see table 2).

Table 2. Comparison teams in resource use and patient safety

	Team-2 (3	GPs & 1	NP) vs		Team-3 (2	GPs & 2 I	NPs) vs	
	Team-1 (c	ontrol; 4	GPs)		Team-1 (control; 4 GPs)			
		95%	6 CI for ex	xp b		95%	6 CI for e	xp b
	B (SE)	Lower	Exp b	Upper	B (SE)	Lower	Exp b	Upper
X-ray ¹	-0.09	0.67	0.91	1.24	-0.17	0.62	0.84	1.15
	(0.16)				(0.16)			
Drug	0.13	1.01	1.14	1.28	-0.07	0.83	0.93	1.05
prescription ¹	(0.06)*		~		(0.06)			
Referral ED ¹	0.10	0.92	1.11	1.33	0.20	1.02	1.22	1.45
	(0.09)				(0.09)*			
Consultation not	0.30	1.02	1.35	1.77	0.67	1.51	1.95	2.52
within targeted	(0.14)**				(0.13)***			
time period ²								

¹ Tested within a logistic regression model adjusted for age, gender, urgency level and ICPC group ² Tested within a logistic regression model adjusted for age, ICPC group and proportion of patients with urgency level U2 per day

* *P<*0.05

** *P*< 0.01

*** *P<*0.001

Costs for personnel per consultation were $\in 23,85$ in team-1, $\in 23,65$ in team-2 and $\in 23,41$ in team-3. The inclusion of costs of other resources (X-rays, medication, referrals to the ED) led to total mean cost per consultation in the primary analysis at $\in 59,22$ (SD 86,63) in team-1, $\in 62,23$ (SD 90,49) in team-2 and $\in 65,68$ (SD 94,11) in team-3. After adjustment for age, gender, urgency and ICPC group the costs per consultation in team-3 were significant higher compared to team-1 (P=0.04). In the sensitivity analysis, which used the tariff of a GP employed by another GP, the costs for personnel per consultation were $\in 29,89$ for team-1, $\in 28,36$ for team-2 and $\in 26,66$ for team-3. There were no significant differences between teams in the sensitivity analyses, which used the tariff for a GP

employed by another GP, and in sensitivity analysis, which used the maximum price for medication

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	Team-1 (co vs	ontrol; 4 GPs)	Team-1 (control; 4 GPs) vs		
	Team-2 (3	GPs & 1 NP)	Team-3 (2	GPs & 2 NPs)	
	Corrected mean difference	95% CI	Corrected mean difference	95% CI	
Primary analysis (personnel cost valid GPC, X-ray, minimum price drug prescriptions, referral ED)	€-3,01	€-7,33 to €1,48	€-4,55*	€-8,94 to €-0,09	
Sensitivity analysis 1 (personnel cost valid GPC, X-ray, maximum price drug prescriptions, referral ED)	€-3,07	€-7,65 to €1,09	€-4,45	€-8,83 to €0,05	
Sensitivity analysis 2 (personnel cost tariff GP employed by another GP, X-ray, minimum price drug prescriptions, referral ED)	€-1,68	€-6,00 to €2,81	€-1,76	€-6,15 to €2,70	

Table 3. Comparison of teams regarding direct healthcare costs

Tested within a linear regression model with bootstrapping (1000 replications) adjusted for age, gender, urgency, ICPC group

* *P<0*.05

(see table 3).

Comparison GPs' performance features between teams

Compared to GPs in team-1, GPs in team-3 treated patients with different age categories (P<0.001); especially more patients <1 year old (see table 1). Moreover, there were significant differences in urgency level between GPs in team-2 (P=0.001) and team-3 (P<0.001) compared to team-1; GPs increasingly treated more patients at urgency level U2 and fewer patients at U3. Lastly, there were significant differences in type of complaints between patients treated by GPs in team-1 compared to GPs in team-2 (P<0.01) and team-3 (P<0.001). Major differences include more digestive complaints and less skin problems. Moreover, GPs treated a greater proportion of patients outside NPs' scope of practice with increasing number of NPs in the team. In team-1 19.9% (SD 5.1) of GPs' patients were outside the scope of NP practice, in team-2 22.5% (SD 6.4) and 30.8% (SD 9.1) in team-3. Based on

the number of consultations per shift the absolute number of patients outside NPs' scope of practice treated per GP per shift is on average 4.7 patients in team-1, 5.3 in team-2 and 7.6 in team-3.

Across the overall sample adjusted volumes of resource use did not change significantly for X-rays between GPs in team-1, team-2 and team-3. Compared to GPs in team-1, GPs in team-2 more often prescribed drugs (respectively: 41.3% vs. 45.4%, P=0.002). There was no difference between GPs in team-1 with GPs in team-3 (40.8%). In addition, GPs in team-3 more often referred patients to the ED (18.5%) compared to GPs in team-1 (12.0%) (P=0.003) (see table 4).

Lastly, in team-2, NPs completed 93.4% of their consultations autonomously without consultation from a GP. In team-3 they completed 97.5% of the consultations without consultation. Across the overall sample consultations from an NP with a GP were in 1.9% of the cases within the surgery room; in 1.3% outside the surgery room and 0.6% by phone. There were no cases reported in which the patient was referred to the GP in order for the GP to complete the consultation.

Table 4. Comparison GPs in resource use	

	GPs Tear	GPs Team-2 (3 GPs & 1 NP) vs				GPs Team-3 (2 GPs & 2 NPs) vs			
	GPs Tea	m-1 (conti	rol; 4 GP	s)	GPs Team-1 (control; 4 GPs)				
		95% CI for exp b				95%	6 CI for e	хр <i>b</i>	
	B (SE)	Lower	Exp b	Upper	B (SE)	Lower	Exp b	Upper	
X-ray	-0.26	0.54	0.77	1.11	-0.12	0.77	0.89	1.02	
	(0.18)				(0.07)				
Drug	0.21	1.08	1.23	1.40	0.02	0.97	1.02	1.07	
prescription	(0.07)*				(0.03)				
Referral ED	0.14	0.95	1.16	1.40	0.10 (0.03)*	1.03	1.11	1.18	
	(0.10)								

Tested within a logistic regression model adjusted for age, gender, urgency level and ICPC group * *P*<0.01

Discussion

Statement of principal findings

As a consequence of NPs treating fewer patients per hour than GPs, the total number of consultations per team per shift decreased with approximately 3.7% when the ratio NP-GP in teams increased with one extra NP (team-1: 93.9, team-2: 90.5 team-3 87.1). Of the total of number patients who can be scheduled per hour, the mean observed proportion of patients outside NPs' scope of practice was

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9.0%, the highest value in any hour was 40%. This implies that teams up to a ratio of two GPs and two NPs provide enough capacity to treat all patients, even at peak hours.

Teams with more NPs were associated with an increased number of patients who did not receive care within the targeted time period. Although there were no adverse events reported in any of the teams, this might have a negative impact on patient safety. Moreover, there were more ED referrals by the teams with more NPs. This increase lead to higher health-care cost, although this did not sustain in the sensitivity analysis.

As a consequence of increasing the number of NPs per team, GPs treated a larger proportion of patients outside NPs' scope of practice. These included patients younger than 1 year old, patients with urgent complaints and patients with digestive problems. After adjustment for case-mix, GPs working in teams with more NPs referred more patients to the ED. In the overall sample, NPs asked in 3,8% of the cases advice from a GP. This means each GP is asked for advice once in per 2 shifts.

Strengths and weaknesses of the study

As far as we are aware, this is the first study to provide an rigorous comparison between teams providing out-of-hours care and the impact on patients and GPs. Strengths include the comparative evaluation design, the large patient sample and the long follow-up period.

Limitations of the current study concern the single-centre character of the study and limitations in the available data, such as the relatively large number of missing ICPC codes. The missing ICPC codes were caused by few GPs who repeatedly not reported ICPC codes (more than 50% of the missing codes were caused by 7% of the GPs), indicating that bias is on the level of GP and not diagnosis.

A potential limitation includes the method of identifying patients outside NPs' scope of practice based on the diagnosis after consultation. After all, the initial exclusion is based on complaint during triage, which can differ from the actual complaint presented during consultation (15, 16). However, because there were no reports of consultations the NP started but had to be completed by a GP, it appeared to be uncommon that patients who seemed within NPs' scope of practice after triage turned out not to be during the consultation.

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Lastly, the economic evaluation was limited by a focus on costs relevant from the GPCs' viewpoint, so we cannot draw conclusions on efficiency from a societal viewpoint.

Comparison with other studies

Although evidence is limited, in line with current study, previous studies suggest that NPs are able to provide 67-93% of all primary care services (26). This is however the first comparative study to show how teams with NPs and GPs may response to peak loads in patients who do not fit the scope of NPs' practice. Since ICPC codes in current study are comparable to other out-of-hours services is Western countries, results are well generalizable to other models of primary care delivery during out-of-hours (27). Generalizability of findings has to be considered with respect to NPs' education, legislation and scope of practice between and within countries and health-care systems (28, 29).

Reviews of previous study indicate that patient safety is not negatively influenced by NP's based on the quality of care provided by NPs (12). As far as we know, this is the first study to measure patient safety in terms of the number of patients who were not treated within a targeted time period based on urgency level. It may be questioned whether patients who were indicated as being urgent by the call center were actually urgent when they presented themselves at the GPC. A recent study in the Netherlands showed that more than half of the patients who were indicated as being urgent (U2) by the triage nurse, the GP at the GPC indicated the patient as non-urgent (U3 or less) (30). There should however be no reason why patients in teams with more NPs would not get their treatment in time, since only a maximum of 40% of the patients that can be scheduled per hour are outside NPs' scope of practice. Delay in care for the patients who are outside NPs' scope of practice seems more likely when teams do not collaborate effectively. As a consequence, GPs do not focus on the patients that cannot be treated by NPs (31). For NPs it means they should treat the full range of patients that fit their scope of practice. However, working in mixed teams is an innovation and GPs express different views on team-collaboration (32, 33). Critical factors for successful implementation of the NP role like involvement of all GPs in the implementation process, acceptance of the NP role and the understanding of intentions for role implementations are especially difficult in large scale organizations like GPCs (31, 32).

The introduction of NPs showed, in accordance to reviews of previous studies, not necessarily to be more efficient (12, 14). Fewer consultations among NPs can be the result of higher use of protocols, better provision of information or less experience compared to GPs, and might have further influenced patients delay (34-36). Since evidence shows that diagnostic accuracy and use of resources of NPs are comparable to those of physicians, we did not expect an increase in ED referrals when the ratio NP-GP increased (34, 37, 38). We cannot determine whether this increase is an overuse by one team or an underuse by the other, because there is no capacity to examine how outcomes would differ if care was provided by another team. Moreover, it remains difficult to drawn firm conclusions on healthcare costs due to mixed results on the primary and sensitivity analyses (13, 39). Consistent with previous studies, care delivered by teams with NPs seemed not necessarily associated with lower health-care costs compared to teams with GPs only in current study.

In accordance with the literature, the current study shows a slight increase in the complexity of GPs' caseload (33, 40). More qualitative insight is needed how this is experienced by GPs. It might be considered an advantage to practice more to the full scope of their training (41). Supervision of NPs barely had an effect on GPs workload and the need for supervision even further decreased during the study as NPs gained more experienced. Te4

Implications for policymakers and future research

Following the NHS report 'general practice forward view' (9, 42), the current study provides an evidence base for expanding the primary health-care workforce by the deployment of nurses. In 99% of the hours during weekend days the proportion of patients outside NPs' scope of practice was less than 25% of all who could be scheduled. This indicates that teams with both NPs and GPs are well suitable to provide all care during out-of-hours. The assumption is obviously that NPs provide good guality of care to those patients who are within their scope of practice. Reviews of previous studies showed that quality of care delivered by NPs is comparable to those of GPs (14, 42).

Our results show that incorporating NPs along with GPs in out-of-hours primary care teams is a feasible option for decreasing GPs' workload in terms of number of shifts or increase service capacity. However, it is uncertain whether it is a cost-effective solution. Therefore, the optimal ratio of GPs and NPs should not be defined by the impact on efficiency of care itself, but by a long-term vision

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regarding (expected) demands for care, workforce needs and professional roles. More research is needed on the impact of NPs in out-of-hours care on patient safety in a larger sample of GPCs, including a more in depth understanding of team-collaboration during out-of-hours.

Conclusion

A model in which out-of-hours primary care is provided by teams with a ratio up to two GPs and two NPs offers enough capacity to provide care to all patients during out-of-hours. Teams with two GPs and two NPs were associated with a decrease in number of patients per shift and a small increase in referrals to the ED by the team. Patient safety needs extra attention in both teams as the number of patients who do not receive care within the targeted time period increased. There was a minimal difference in GPs' performance features.

Competing interests:

All authors have completed the ICMJE uniform disclosure form at <u>www.icmje.org/coi_disclosure.pdf</u> and declare: "no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work."

Contributorship statement:

ML, RB and MB conceived and designed the study. ML supervised the study and is the guarantor. MB and ML were involved in the data analysis. MB, RB, MW, ML interpreted the results. MB wrote the first draft of the manuscript. RB, MW and ML revised the manuscript with important intellectual contributions. All authors read and approved the final manuscript. The research was independent of any involvement from the sponsors of the study.

Ethical considerations

The medical ethics committee of the university medical centre waived approval (CMO-nr 2014-1409). Confidentiality was assured through exercising professional ethical codes of conduct, whereby all patients were assured that data cannot lead to any identification.

Funding statement

This study was funded by the Ministry of Health, Welfare and Sport. Researchers were independent from funders. Funders had no role in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

Access to data

Authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Transparency declaration

The first author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data sharing statement

Patient level data and technical appendix are available at <u>http://dx.doi.org/10.17026/dans-z2p-b85a</u> after approval of the authors. Consent was not obtained but the presented data are anonymised and there is no risk of identification.

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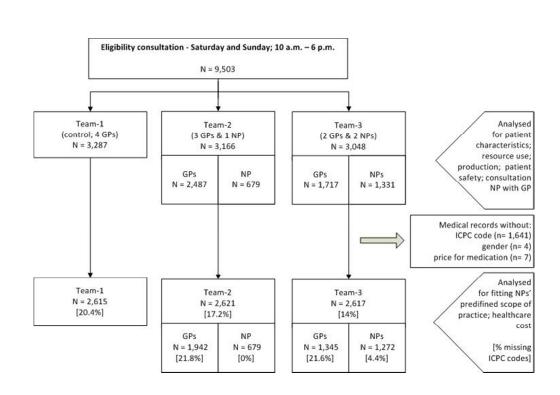
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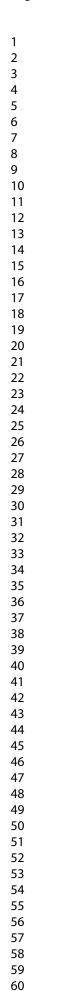
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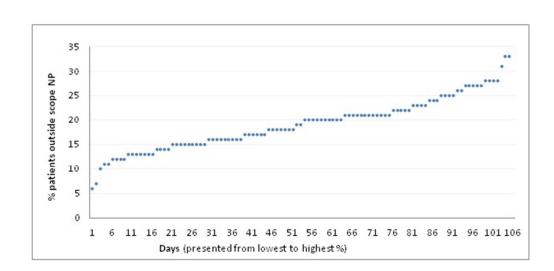
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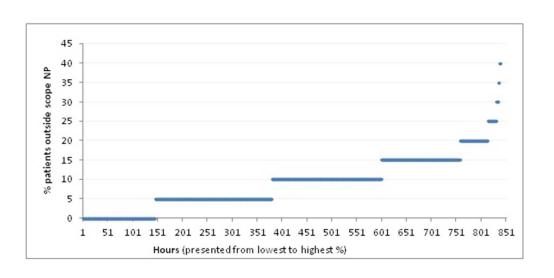
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Towards an optimal composition of general practitioners and nurse practitioners in out-of-hours primary care teams: a quasi-experimental study

Journal:	BMJ Open
Manuscript ID	bmjopen-2016-015509.R1
Article Type:	Research
Date Submitted by the Author:	14-Mar-2017
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Primary Subject Heading :	General practice / Family practice
Secondary Subject Heading:	Emergency medicine, Health services research, Nursing
Keywords:	Nurse practitioner, PRIMARY CARE, acute care, out-of-hours care, substitution



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Abstract

Objectives– To gain insights into the ability of general practitioners (GPs) and nurse practitioners (NPs) to meet patient demands in out-of-hours primary care by comparing the outcomes of teams with different ratios of practitioners.

Design- Quasi-experimental study

Setting- A GP cooperative (GPC) in the Netherlands.

Intervention– Team-2 (1 NP, 3 GPs) and Team-3 (2 NPs, 2 GPs) were compared with Team-1 (4 GPs). Each team covered 35 weekend days.

Participants– All 9,503 patients who were scheduled for a consultation at the GPC through a nurse triage system.

Outcome measures– The primary outcome was the total number of consultations per provider for weekend cover between 10 am and 6 pm. Secondary outcomes concerned the numbers of patients outside the NPs' scope of practice, patient safety, resource use, direct healthcare costs and GPs' performance.

Results– The mean number of consultations per shift was lower in teams with NPs (Team-1: 93.9, Team-3: 87.1; P<0.001). The mean proportion of patients outside NPs' scope of practice per hour was 9.0% (SD 6.7), and the highest value in any hour was 40%. The proportion of patients who did not receive treatment within the targeted time period was higher in teams with NPs (Team-2, 5.2%; Team-3, 8.3%) compared to GPs only (Team-1 3.5%) (P<0.01). Team-3 referred more patients to the emergency department (14.7%) compared to Team-1 (12.0%; P=0.028). In teams with NPs, GPs more often treated urgent patients (Team-1: 13.2%, Team-2: 16.3%, Team-3: 21.4%; P<0.01) and patients with digestive complaints (Team-1: 11.1%, Team-2: 11.8%, Team-3: 16.7%; P<0.01).

Conclusions– Primary healthcare teams with a ratio of up to two GPs and two NPs provided sufficient capacity to provide care to all patients during weekend cover. Areas of concern are the number of consultations, delay in patient care and referrals to the emergency department.

Trial registration- ClinicalTrials.gov ID NCT02407847

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Keywords - Nurse practitioner, primary care, acute care, out-of-hours care, substitution, skill mix

Strengths and limitations of this study

- This is the first comparative evaluation of teams with nurse practitioners and general practitioners during out-of-hours practice.
- The study has a large representative patient sample and a long follow-up period, although undertaken in only one centre. Health outcomes were not measured.
- The use of a cost-minimization analysis provides limited insight into the costs.
- No change patient in allocation gives an accurate representation of daily practice and peak hours.

Introduction

The quality of out-of-hours primary care influences the functioning of the whole healthcare system. Internationally, different organizational models are used to deliver urgent care during out-of-hours practice. Patients in the United Kingdom have access to services such as walk-in centres, urgent care centres, out-of-hours centres, telephone consultations and emergency departments (EDs), which often operate side by side (1). However, these services show varying results in terms of patient outcomes and efficiency (2-4). In the Netherlands, out-of-hours care is organized in general practitioner cooperatives (GPCs) (5). Although these large GP-based models show positive results (3), current and expected problems, such as population aging, the increased prevalence of chronic conditions and the shifting of tasks from hospitals to the community, put pressure on (out-of-hours) primary care (6, 7). The challenge for policymakers is to find a model that ensures accessibility, quality and efficiency in out-of-hours care (1, 8).

As many complaints during out-of-hours care do not necessarily require the knowledge and skills of a GP, there is increasing interest in care delivery models that include nurse practitioners (NPs) in primary care teams (9-11). Systematic reviews of published research have shown that NPs in daytime primary care provide good-quality and safe care to patients, but not necessarily more efficient care compared to GPs (12-14). There are models in which care is provided by teams with only NPs, but such services are not able to provide high-quality care to some patients due to a lack of capacity, resources or skill levels. In light of the above, team-based care involving both GPs and NPs is an alternative model for delivering out-of-hours care.

Current evidence does not provide insights into the optimal ratio of GPs and NPs in out-of-hours teams. The results for NPs in daytime primary care cannot simply be translated to out-of-hours care. Organizations differ in size, the incidence of life-threatening conditions is higher in out-of-hours settings and care outside office hours is unpredictable in terms of patient flow. The acute nature of complaints limits the potential for forward scheduling and the main complaint after triage does not always correspond to the main complaint evaluated during consultation (15, 16). Second, while overall patient care is determined by the sum of its parts, most studies compare care between healthcare providers rather than comparing teams (17). To the best of our knowledge, this is the first randomized comparative study to provide insights into the optimal composition of GPs and NPs in primary care teams during out-of-hours provision.

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Aim

The aim of the study was compare teams with different ratios of GPs and NPs in terms of the number of consultations, patient care and GPs' performance and provide insights into the number of patients outside the NPs' scope of practice in out-of-hours primary care.

Methods

<u>Design</u>

A quasi-experimental study was conducted to measure the total number of patients and the distribution of patients outside NPs' scope of practice in out-of-hours primary care over the weekend (Saturday and Sunday) between the hours of 10 am and 6 pm. Two types of teams with NPs were compared with a team comprising only GPs, as follows:

- Team-1: care provided by a team of four GPs (care as usual);
- Team-2: care provided by a team of three GPs and one NP;
- Team-3: care provided by a team of two GPs and two NPs.

Study setting

The study was conducted at a GPC situated within a hospital next to the ED in the south-east of the Netherlands. In this GPC, GPs work in shifts from 5 pm to 8 am on weekdays and over the entire weekend, taking care of a population of approximately 304,000 people. All patients in need of acute care outside regular office hours contact the GPC using a single, regional telephone number. Triage nurses then allocate patients to an appropriate care pathway based on risk stratification. Patients who are eligible for a consultation at the GPC are scheduled on a common presentation list, depending on the urgency of the complaints based on the Netherlands Triage Standard (NTS; see Table 1). A maximum of five patients are scheduled every hour per healthcare provider. GPs and NPs select attending patients from this presentation list (18).

Table 1. Netherlands	Triage Standard (NTS) urgency le	vels (19)
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Urgency level	Description	Time period for consultation
U1	Life threatening: Immediate action required, the vital functions are threatened or delaying treatment will cause serious and irreparable damage to the patient's health.	Within 15 minutes
U2	Emergent: Vital functions are not (yet) in danger, but there is a fair change that the patient's condition will soon deteriorate or delaying treatment will cause serious and irreparable damage to the patient's health. Take action as soon as possible.	Within 1 hour
U3	Urgent: Do not postpone too long. Treat within a few hours because of medical- or humane reasons.	Within 3 hours
U4	Non-urgent: There is no pressure resulting from medical- or other grounds. Time and place of treatment should be discussed with the patient.	No time pressure
U5	Advice: A physical examination can wait until the next day.	No time pressure

Study population

General practitioners

All GPs who delivered patient care during the study period were included. This included both practice owners (n=162) and GPs employed by another GP. Their mean age was 47.5 years (SD 9.7) and 50.3% were male. Those employed by another GP have often recently graduated.

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Nurse practitioners

A sample of 10 NPs participated in the study. Their mean age was 45.2 years (SD 9.4) and one was male. On average, they had been qualified as an NP for 1.8 years (SD 1.2) and had worked at the GPC for 1.6 years (SD 1.1). All NPs had completed a two-year Master's programme on 'Advanced Nursing Practice' (NLQF/EQF level 7). This programme included an academic course on treating common complaints in primary care and an internship in general practice (20, 21). During office hours,

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they took care of patients with minor ailments in general practices and undertook elderly care or care for disabled people. To ensure their competency to work in out-of-hours care, they received three half days of additional training concerning complaints commonly presented during out-of-hours care: eye disorders; musculoskeletal disorders, such as fractures, bruises and sprains; wound care (e.g. suturing). NPs in the Netherlands have the authority independently to indicate and perform reserved procedures (including prescribing) in their area of expertise, using the same practice guidelines as GPs (22, 23). The numbers of support staff at the GPC (1 receptionist and 1 medical assistant per shift) were equal for the different teams.

Patients

All patients who had a consultation at the GPC during the period of data collection were included in the study. Due to the exploratory nature of the study, no calculation of statistical power could reliably be made. To attain reasonably accurate estimates, a 35-week follow-up period per team was selected to obtain a sufficiently large sample. NPs decided which patients from the common presentation list would be called in for consultation; other patients received a consultation with a GP. In the case that the patient's complaint during triage was different from that during the consultation, NPs were allowed to decide autonomously whether they felt competent or not to complete the consultation themselves. If not, they could consult a GP about the patient or refer the patient to a GP at the GPC.

Allocation to study arms

The teams were rotated systematically between Saturday and Sunday. The rotation scheme was determined in advance. GPs were randomly assigned to the days over the weekends and they did not know whether they would work with an NP at the time of scheduling.

The scheduling of the patients was done by triage nurses at a call centre, which is in charge of scheduling patients for several GPCs. They were blind to the composition of GPs and NPs in the team, only knowing the total number of team members. As a consequence, patients were not informed of the presence of NPs in the teams when they contacted the call centre.

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Measures and data collection

The primary outcome was the number of consultations per team and per healthcare provider. This was measured as the mean number of patients per team per day and per healthcare provider per hour. In terms of secondary outcomes, we first focused on the number of patients outside NPs' scope of practice. In the Netherlands, NPs are allowed to enter independently into a treatment relationship in their area of expertise and take independent decisions about the interventions to be executed (23). In addition to this national authority, the GPC has formulated a scope of practice for NPs based on their professional training. All the patients meeting the following criteria were defined by the GPC as being outside NPs' scope of practice: patients younger than one year old, or suffering psychiatric complaints, abdominal pain, chest pain, a neck ailment, headache, or dizziness (see Table 2). All other patients were within NPs' scope of practice (18). We looked at all patients presenting at the GPC on Saturdays and Sundays between 10 am and 6 pm and measured the percentage and distribution of those patients who were outside NPs' scope of practice.

Next, we measured the effect of different team compositions comprising NPs and GPs on: 1) patient care and 2) aspects of GPs' performance. Patient care included four measures, based on which the different teams were compared: patient safety, resource use following a consultation at the GPC and direct healthcare costs. Patient safety was examined using two measures, the first of which included the number of (near) incidents. In the Netherlands, GPCs are required by law to report (near) incidents to an internal committee for the reporting of patient care incidents. Both patients and providers are able to report (near) incidents. Second, the number of patients who did not receive care within the targeted time period was calculated. At the call centre, triage nurses classify all patients into urgency levels. The NTS defines the time period in which a patient needs treatment (see Table 1). Resource use included X-rays, drug prescriptions and referrals to the ED. Imaging tests or laboratory samples other than X-rays could not be ordered by the providers. If such diagnostic tests were necessary, patients were referred to the ED or to their own GP the next day. Next, direct healthcare costs were calculated based on personnel costs (based on the number of consultations per hour and salary) and combining volumes of resource use by unit prices that constitute costs.

The impact on aspects of GPs' performance was measured by comparing GPs' patient characteristics and resource use. The characteristics of GPs' patients included age, urgency level and the

International Classification of Primary Care (ICPC) code. In addition to these characteristics, the number of patients outside NPs' scope of practice treated by GPs in different teams was compared. Finally, the percentage of consultations in which NPs asked for consultation with a GP was measured. All data were extracted from the electronic medical patient records at the GPC and coded by the providers as part of their routines during the consultations. Data were collected from May 2014 to November 2015.

Table 2. Patients outside the predefined scope of NP care

Patient characteristics and complaints expressed	Patient characteristics and diagnoses defined as					
during triage defined by the GPC as being outside	outside NPs' scope of practice during data					
NPs' scope of practice	analysis					
 Patients younger than one year old Patients suffering from psychiatric complaints 	 Age < 1 year ICPC group P Psychological 					
 Patients suffering abdominal pain 	 ICPC group D Digestive (except ICPC codes: D04 (Rectal/anal pain), D05 (Perianal itching), D19 (Teeth/gum symptom/complaint), D20 (Mouth/tongue/lip symptom/complaint) 					
 Patients suffering chest pain 	 ICPC group K Cardiovascular (except ICPC codes: K06 (Prominent veins), K07 (Swollen ankles/oedema), K95 (Varicose veins of leg), K96 (Haemorrhoids) 					
 Patients suffering neck ailment 	 ICPC code L01 Neck symptom/complain 					
 Patients suffering headache or dizziness. 	 ICPC group N Neurological (except ICPC code: N72 (Tetanus) 					

Statistical analysis

Baseline characteristics

Baseline characteristics were presented as proportions (%) and included potential confounders for the comparison: age (in four categories), urgency (in five categories), gender and type of complaint

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(indicated as an ICPC code). Differences between Team-1 and Teams-2 and Team-3 were tested using a Chi² test.

Primary outcome

First, the total number of patients per team was calculated. An independent sample t-test was used to test differences in the number of consultations per shift between Team-2 and Team-3 and Team-1. The mean number of consultations per professional per hour was calculated by dividing the total number of patients per team by the exact number of hours and the number of healthcare providers per team. In addition, we calculated the number of consultations per hour for the GPs and NPs separately.

Secondary outcomes:

Percentage and distribution of patients outside NPs' scope of practice

First, we took the ICPC codes from all patients presenting themselves at the GPC over weekends and identified those patients whose diagnosis fitted the complaints excluded from NP care (see Table 2). Descriptive analysis (mean; SD) was used to indicate the percentage of patients outside NPs' scope of practice .

To gain an insight into the distribution of patients over a day, the total number of patients outside NPs' scope of practice per hour was divided by the number of patients who could be scheduled per hour (maximum of 5 patients per healthcare provider per hour = 20 patients per team per hour).

Comparison of patient care between teams

Patient safety was evaluated through descriptive analysis, used to determine the number of (near) incidents. Differences between teams in terms of the number of patients receiving treatment within the targeted time period were tested using logistic regression analysis for dichotomous outcomes. Estimates were adjusted for ICPC group, age and the proportion of patients with a U2 urgency level per day.

Resource use (i.e. X-rays, drug prescriptions and referrals to the ED) was evaluated by analysing differences in volumes between teams. Logistic regression analysis for dichotomous outcomes, corrected for age, gender, urgency level and ICPC group was conducted to compare Team-2 and 3 with Team-1.

Direct healthcare costs were examined through an economic evaluation designed as a costminimization analysis, considering only the direct healthcare costs of the consultation (24). Direct costs were calculated for each consultation separately including costs for personnel, X-rays, drug prescriptions and referral to the ED.

Costs for personnel per consultation were calculated by dividing the tariff per hour by the mean number of patients per hour. The tariff per hour for NPs was set at €61.32 based on their salary from the GPC, including social security contributions (approximate 40%) and premium pay (50%). The tariff for GPs was set at €74.66 based on the payment agreements with health insurance companies. GPs in the Netherlands receive a tariff per patient for providing 24/7 care. Based on these tariffs, the total tariffs per hour per team were €298.64 for Team-1, €285.30 for Team-2 and €271.96 for Team-3. To provide a better comparison between GPs' and NPs' tariffs, we also calculated a tariff based on the salary for GPs employed by another GP (specified in collective labour agreements). This tariff included social security contributions and premium pay, similar to NPs, and was set at €93.56 per hour. The inclusion of this tariff resulted in total tariffs per hour per team of €374.24 for Team-1, €342.00 for Team-2 and €309.76 for Team-3.

Next, following the guidelines of the Dutch manual for costing, the cost of each referral to the ED was set at €261 and for an X-ray at €52.79 (25). As a result of the differences between the minimum and maximum prices for medicine, two separate costs were calculated per drug prescription. All costs were valid for the year 2015.

To provide insights into the cost differences between Team-2 and -3 and Team-1, a linear regression model was used, corrected for case mix (i.e. age, gender, urgency level, ICPC group). In the primary analysis, the minimum price per medicine and the personnel costs valid for the GPC were used. Deterministic uncertainty was explored through: (i) one-way sensitivity analysis for the costs of drug prescriptions, including the maximum prize per medicine: (ii) one-way sensitivity analysis of personnel

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costs, including the tariff for GPs employed by another GP. Finally, we applied a bootstrapping procedure (with 1000 replications) to manage the highly skewed costs across patients.

Comparison of aspects of GPs' performance between teams

To obtain the *patient characteristics* for those seen by GPs in the different teams, descriptive statistics were used for patients' age, gender, urgency level and type of complaint (ICPC). Differences between GPs in Teams-2 and -3 and Team-1 were tested using the Chi² test for categorical data. Descriptive analysis was used for the number of patients outside NPs' scope of practice treated by GPs in different teams.

Resource use (i.e. X-rays, drug prescriptions and referrals to the ED) was evaluated by analysing differences in volumes between GPs in different teams. Logistic regression analysis for dichotomous outcomes, corrected for age, gender, urgency level and ICPC group, was conducted to compare resource use by GPs in Teams-2 and -3 and that of GPs in Team-1.

Consultations between NPs and GPs were examined using the codes reported by NPs in patients' medical records when they consulted a GP concerning a patient. There were three codes in the case that NPs consulted a GP but completed the patient consultation themselves: (i) consultation with a GP by telephone; (ii) consultation with a GP outside the surgery room; (iii) consultation with a GP in the surgery room. A fourth code was reported when the patient was referred to a GP to complete the patient consultation. Descriptive analysis was used to indicate the percentage of patients for whom NPs requested consultation with a GP.

The outcomes of two-tailed tests were considered statistically significant at an alpha level P<0.05. The statistical analyses, including bootstrapping, were carried out using SPSS software version 22 (SPSS Inc, Chicago, IL, USA).

Deviation from the original study protocol

The study protocol (ClinicalTrials.gov ID NCT02407847) described an extra study arm comprising a team with one GP and three NPs. Ethical approval for this study was obtained based on the arms in the study being part of GPCs' normal routines (CMO-no. 2014-1409). This meant that the teams

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followed on from each other in consecutive phases and each phase was followed by an evaluation. The final decision to continue with the last phase, incorporating the team with more NPs, was in the hands of the GPC management. Because the GPC decided not to continue, data on the team with one GP and three NPs as described in the protocol could not be compared to data from the other teams and are therefore not part of this paper.

Results

All patients presenting during the study period were included in the analyses (see figure 1). There were no significant differences in terms of age, gender or ICPC group between the teams (see Table 3). In all teams, the top four of ICPC codes covered more than two-thirds of all patients and included skin (21%), musculoskeletal (21%), respiratory (14%) and digestive (11%) complaints. In comparison to Team-1, Team-2 treated slightly more patients with an urgency level of U2 (14.3% vs. 13.2%) and fewer patients with an urgency level of U3 (47.5% vs. 51.8%) (P=0.01).

	Team-1 (control; 4 GPs)	Team-2 (3 GPs & 1 NP)	Team-3 (2 GPs & 2 NPs)	GPs Team-1	GPs Team-2	GPs Team-3
Age in categories (%)			1			***
0-1 year	4.1	3.5	4.6	4.1	3.9	7
2-17 years	22.6	24.3	25.8	22.6	22.4	22.4
18-64 years	57.5	56.2	54.3	57.5	56.7	54.2
65 years and older	15.8	16	15.3	15.8	16.9	16.5
Gender (% male)	46.7	46.9	47.9	46.7	46.2	46.6
Urgency (%)		*			**	***
U1	0.1	0.1	0.1	0.1	0.1	0.1
U2	13.2	14.3	15.3	13.2	16.3	21.4
U3	51.8	47.5	50.5	51.8	46.9	47.8
U4	31.0	33.8	30.6	31	32.4	27.4
U5	3.9	4.3	3.4	3.9	4.3	3.3
Complaints top 10 (%)					**	***

Table 3. Baseline patient characteristics

Skin	22.0	21.8	19.3	22	18.7	13.6
Musculoskeletal	20.6	21.7	22.0	20.6	19	18.5
Respiratory	14.3	13.0	15.8	14.3	12.6	16
Digestive	11.1	9.6	11.0	11.1	11.8	16.7
General and unspecified	7.3	7.4	7.4	7.3	8.1	7.9
Eye	5.9	6.0	6.1	5.9	6.4	5.3
Urological	5.6	7.1	5.2	5.6	7.9	5.6
Ear	4.7	4.3	4.7	4.7	4.2	3.7
Neurological	2.9	2.8	2.6	2.9	3.6	3.9
Cardiovascular	1.9	1.9	1.8	1.9	2.5	2.7
Other	3.8	4.3	4.1	3.8	5.1	5.9

Tested using a Chi²-test

* Significant difference with Team-1 P<0.05

** Significant difference with GPs in Team-1 P<0.01

*** Significant difference with GPs in Team-1 P<0.001

Primary outcome: Total number of consultations

In total, 9,503 patients had a consultation during the study period. Team-1 had contact with 3,287 patients, Team-2 with 3,166 patients and Team-3 with 3,048 patients. The mean number of consultations per shift by the teams was 93.9 (SD 9.0) in Team-1, versus 90.5 (SD 7.2) in Team-2 (not significant) and 87.1 (SD 6.2) in Team-3 (P<0.001). The mean number of consultations per hour per healthcare provider was 3.1 consultations in Team-1, 3.0 consultations in Team-2 (GP 3.2, NP 2.6) and 2.9 consultations in Team-3 (GP 3.3, NP 2.5).

Secondary outcomes

Percentage and distribution of patients outside NPs' scope of practice

Overall, the number of patients outside NPs' scope of practice, expressed as proportion of the total number of patients per day, was 19.1% (SD 50.4). The range of patients per day outside NPs' scope of practice was 6% to 33% (see Figure 2). There was no difference between Saturdays (18%) and Sundays (20%), or between Team-1 (19.9%), Team-2 (18.0%) and Team-3 (19.4%).

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The absolute number of patients outside NPs' scope of practice was a minimum of 0 and a maximum of 8 per hour. Expressed as proportion of the total number of patients who could be scheduled (= 20 per hour), the maximum proportion of patients outside NPs' scope of practice per hour was 40% (mean 9.0%, SD 6.7) (see Figure 3).

Comparison of patient care between teams

No (near) incidents were reported during the study. The proportion of patients who did not receive a consultation within the targeted time period according to the NTS was 3.5% in Team-1, 5.2% in Team-2 and 8.3% in Team-3. After adjusting for confounders, the proportion of patients who did not receive a consultation within the targeted time period was significantly higher in Team-2 (P=0.001) and Team-3 (P<0.001) compared to Team-1 (see Table 4).

Across the overall sample adjusted volumes of resource use did not change significantly for X-rays between Team-1, Team-2 and Team-3. Compared to Team-1, after correction for casemix, Team-2 more often prescribed drugs (respectively: 41.3% vs. 44.2%, P=0.033). In contrast, Team-3 did not prescribe more drugs (39.5%; not significant). The number of patients referred to the ED was 12% in Team-1, 13.2% in Team-2 and 14.7% in Team-3. After adjusting for casemix the difference between Team-3 and Team-1 was significant (P=0.028) (see Table 4).

	Team-2 (3	GPs & 1	NP) vs		Team-3 (2 C	GPs & 2 M	NPs) vs	
	Team-1 (c	ontrol; 4	GPs)		Team-1 (control; 4 GPs)			
		95%	6 CI for e	xp b		95%	6 CI for e	xp <i>b</i>
	B (SE)	Lower	Exp b	Upper	B (SE)	Lower	Exp b	Upper
X-ray ¹	-0.09	0.67	0.91	1.24	-0.17	0.62	0.84	1.15
	(0.16)				(0.16)			
Drug	0.13	1.01	1.14	1.28	-0.07	0.83	0.93	1.05
prescription ¹	(0.06)*				(0.06)			
Referral ED ¹	0.10	0.92	1.11	1.33	0.20	1.02	1.22	1.45
	(0.09)				(0.09)*			
Consultation not	0.30	1.02	1.35	1.77	0.67	1.51	1.95	2.52
within targeted	(0.14)**				(0.13)***			
time period ²								

¹Tested within a logistic regression model adjusted for age, gender, urgency level and ICPC group

² Tested within a logistic regression model adjusted for age, ICPC group and proportion of patients with urgency level U2 per day

* P<0.05

** *P*< 0.01

*** P<0.001

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The costs for personnel per consultation were €23.85 in Team-1, €23.65 in Team-2 and €23.41 in Team-3. The inclusion of costs of other resources (X-rays, medication, referrals to the ED) led to total mean costs per consultation in the primary analysis of €59.22 (SD 86.63) in Team-1, €62.23 (SD 90.49) in Team-2 and €65.68 (SD 94.11) in Team-3. After adjusting for age, gender, urgency and ICPC group, the costs per consultation in Team-3 were significantly higher compared to those in Team-1 (P=0.04). In the sensitivity analysis, which used the tariff of a GP employed by another GP, the costs for personnel per consultation were €29.89 for Team-1, €28.36 for Team-2 and €26.66 for Team-3. There were no significant differences between teams in the sensitivity analyses using the tariff for a GP employed by another GP or in the sensitivity analyses using the maximum price for medications (see Table 5).

	Team-1 (co	ontrol; 4 GPs)	Team-1 (control; 4 GPs)		
	vs		vs		
	Team-2 (3	GPs & 1 NP)	Team-3 (2 GPs & 2 NPs		
	Corrected mean difference	95% CI	Corrected mean difference	95% CI	
Primary analysis	€-3,01	€-7,33 to	€-4,55*	€-8,94 to	
(personnel cost valid GPC, X-ray, minimum price drug prescriptions, referral ED)		€1,48		€-0,09	
Sensitivity analysis 1	€-3,07	€-7,65 to	€-4,45	€-8,83 to	
(personnel cost valid GPC, X-ray, maximum price drug prescriptions, referral ED)		€1,09		€0,05	
Sensitivity analysis 2	€-1,68	€-6,00 to	€-1,76	€-6,15 to	
(personnel cost tariff GP employed by another GP, X-ray, minimum price drug prescriptions, referral ED)		€2,81		€2,70	

Table 5. Comparison of teams regarding direct healthcare costs

Tested within a linear regression model with bootstrapping (1000 replications) adjusted for age, gender, urgency, ICPC group

* P<0.05

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Comparison of aspects of GPs' performance between teams

Compared to GPs in Team-1, GPs in Team-3 treated patients with different age categories (P<0.001), especially more patients <1 year old (see Table 3). Moreover, there were significant differences in urgency level between GPs in Team-2 (P=0.001) and Team-3 (P<0.001) compared to Team-1; specifically, GPs treated more patients at urgency level U2 and fewer patients at U3. Finally, there were significant differences in the types of complaints for patients treated by GPs in Team-1 compared to GPs in Team-2 (P<0.01) and Team-3 (P<0.001). Major differences included more digestive complaints and fewer skin problems. Moreover, GPs treated a greater proportion of patients outside NPs' scope of practice with increasing numbers of NPs in the team. In Team-1 19.9% (SD 5.1) of GPs' patients were outside the scope of NP practice, in Team-2 22.5% (SD 6.4) and in Team-3 30.8% (SD 9.1). Based on the number of consultations per shift, the absolute number of patients outside NPs' scope of practice treated per GP per shift was on average 4.7 patients in Team-1, 5.3 in Team-2 and 7.6 in Team-3.

Across the overall sample, adjusted volumes of resource use did not change significantly for X-rays between GPs in Team-1, Team-2 or Team-3. Compared to GPs in Team-1, GPs in Team-2 more often prescribed drugs (respectively: 41.3% vs. 45.4%, P=0.002). There was no difference between GPs in Team-1 and those in Team-3 (40.8%). In addition, GPs in Team-3 more often referred patients to the ED (18.5%) compared to GPs in Team-1 (12.0%) (P=0.003) (see Table 6).

Finally, in Team-2, NPs completed 93.4% of their consultations autonomously, without consulting a GP. In Team-3, they completed 97.5% of the consultations without recourse to a GP. Across the overall sample, consultations among NPs and GPs were within the surgery room in 1.9% of cases, outside the surgery room in 1.3% of cases and on the telephone in 0.6% of cases. There were no cases reported in which the patient was referred to the GP in order for the GP to complete the patient consultation.

	. ,			GPs Team-3 (2 GPs & 2 NPs) vs GPs Team-1 (control; 4 GPs)				
	95% CI for exp <i>b</i>				95% CI for exp <i>b</i>			
	B (SE)	Lower	Exp b	Upper	B (SE)	Lower	Exp b	Upper
X-ray	-0.26	0.54	0.77	1.11	-0.12	0.77	0.89	1.02

Table 6. Comparisor	n between GPs	s in terms o	f resource use
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	(0.18)				(0.07)			
Drug	0.21	1.08	1.23	1.40	0.02	0.97	1.02	1.07
prescription	(0.07)*				(0.03)			
Referral ED	0.14	0.95	1.16	1.40	0.10 (0.03)*	1.03	1.11	1.18
	(0.10)							

Tested within a logistic regression model adjusted for age, gender, urgency level and ICPC group * *P*<0.01

Discussion

Statement of principal findings

As a consequence of NPs treating fewer patients per hour than GPs, the total number of consultations per team per shift decreased by approximately 3.7% when the NP-GP ratio increased by one NP (Team-1: 93.9, Team-2: 90.5, Team-3: 87.1). Of the total number of patients who can be scheduled per hour, the mean observed proportion of patients outside NPs' scope of practice was 9.0% and the highest value in any hour was 40%. This increase lead to higher healthcare costs, although this was not sustained in the sensitivity analysis.

Teams with more NPs were associated with an increased number of patients who did not receive care within the targeted time period. Although there were no adverse events reported in any of the teams, this might have a negative impact on patient safety. Moreover, there were more ED referrals by the teams with more NPs. This increase lead to higher healthcare cost, although this did not sustain in the sensitivity analysis.

As a consequence of increasing the number of NPs per team, GPs treated a larger proportion of patients outside NPs' scope of practice. These included patients those younger than one year old, patients with urgent complaints and patients with digestive problems. After adjusting for the case mix, GPs working in teams with more NPs referred more patients to the ED. In the overall sample, NPs asked advice from a GP in 3.8% of cases. This means each GP was asked for advice once in every two shifts.

Strengths and weaknesses of the study

As far as we are aware, this is the first study to provide a rigorous comparison between teams providing out-of-hours care and to examine the impact on patients and GPs. The strengths of the

study include the comparative evaluation design and large patient sample. The study duration of a year and a half ensured all seasons (with presumably different patient complaints) were included. The limitations of the study are that it was conducted in a single centre only and limitations in the data available, in particularly the relatively large number of missing ICPC codes. The missing ICPC codes were caused by a few GPs who repeatedly did not report ICPC codes (more than 50% of the missing codes were caused by 7% of the GPs), indicating that bias is at the level of the GP and not diagnosis. A potential limitation includes the method of identifying patients outside NPs' scope of practice based on the diagnosis after consultation. The initial exclusion was based on the complaint presented during triage, which can differ from the actual complaint presented during consultation (15, 16). However, because there were no reports of consultations initiated by an NP but completed by a GP, it appeared to be uncommon for patients who seemed to be within NPs' scope of practice after triage to turn out not to be during the consultation.

Finally, the economic evaluation was limited to a focus on costs considered relevant from the GPCs' viewpoint, so we cannot draw conclusions on efficiency from a societal viewpoint.

Comparison with other studies

Although evidence is limited, in line with this study, previous studies have suggested that NPs are able to provide 67–93% of all primary care services (26). However, this is the first comparative study to show how teams comprising NPs and GPs may respond to peak loads among patients who do not fit the scope of NPs' practice. As the ICPC codes used in this study are comparable to those of other out-of-hours services in Western countries, the results are readily generalizable to other models of out-of-hours primary care delivery (27). The generalizability of findings has to be considered with respect to NPs' education, legislation and scope of practice between and within countries and healthcare systems (28, 29).

Reviews of previous studies indicate that patient safety is not negatively influenced by the inclusion of NPs in teams based on the quality of care provided by NPs (12). As far as we know, this is the first study to measure patient safety in terms of the number of patients who were not treated within a targeted time period based on urgency level. However, this measure only indicates one aspect of increased patient risk and therefore has its limitations. To draw firm conclusions on patient safety, we

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need more insight into patients' health outcomes after a longer follow-up period. Moreover, it may be queried whether patients who were indicated as being urgent by the call centre were actually urgent cases when they presented themselves at the GPC. A recent study in the Netherlands showed that more than half of the patients who were indicated as being urgent (U2) by the triage nurse were found by the GP at the GPC to be non-urgent (U3 or lower) (30). However, there should be no reason why patients in teams with more NPs would not get treatment in time as only a maximum of 40% of the patients who can be scheduled per hour are outside NPs' scope of practice. Delay in care for patients who are outside NPs' scope of practice seems more likely when teams do not collaborate effectively, for example when GPs do not focus on the patients who cannot be treated by NPs (31). NPs should treat the full range of patients that fit their scope of practice. However, working in mixed teams is an innovation and GPs express different views concerning team collaboration (32, 33). Critical factors for successful implementation of the NP role, such as the involvement of all GPs in the implementation process, acceptance of the NP role and understanding of the intentions of role implementations, are especially difficult in large-scale organizations like GPCs (31, 32).

In line with reviews of previous studies, the introduction of NPs does not necessarily result in greater efficiency (12, 14). Fewer consultations among NPs can be the result of greater use of protocols, better provision of information or less experience compared to GPs and might have further influenced delays in patient treatment (34-36). As the evidence shows that the diagnostic accuracy and use of resources of NPs are comparable to those of physicians, we did not expect an increase in ED referrals when the NP–GP ratio increased (34, 37, 38). We cannot determine whether this increase relates to overuse by one team or underuse by the other because there is no capacity to examine how outcomes would differ if care were provided by another team. Moreover, it remains difficult to draw firm conclusions on healthcare costs due to mixed results from the primary and sensitivity analyses (13, 39). Consistent with previous studies, care delivered by teams with NPs does not necessarily seem to be associated with lower healthcare costs compared to that delivered by the GP-only team in this study.

In accordance with the literature, this study shows a slight increase in the complexity of GPs' caseload (33, 40). More qualitative insight is needed into how this is experienced by GPs. It might be considered an advantage for GPs to practice more to the full scope of their training (41). Supervision of NPs

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barely had an effect on GPs' workloads and the need for supervision decreased even further during the study as NPs gained more experience.

Implications for policymakers and future research

Following the UK's National Health Service (NHS) report 'General Practice Forward View' (9, 42), this study provides an evidence base for expanding the primary healthcare workforce through the deployment of nurses. In 99% of hours over the weekend, the proportion of patients outside NPs' scope of practice was less than 25% of all those who could be scheduled. This indicates that teams with both NPs and GPs are well suited to providing all care during out-of-hours practice. The assumption is clearly that NPs provide good-quality care to those patients who are within their scope of practice. Reviews of previous studies show that the quality of care delivered by NPs is comparable to that of GPs (14, 42).

Our results show that incorporating NPs with GPs in out-of-hours primary care teams is a feasible option for reducing GPs' workloads in terms of the number of shifts and increasing service capacity. However, it is still uncertain whether this is a cost-effective solution. Therefore, the optimal ratio of GPs and NPs should not be defined by the impact on efficiency of care itself, but by a long-term vision regarding (expected) demands for care, workforce needs and professional roles. More research is needed on the impact of NPs in out-of-hours care on patient safety in a larger sample of GPCs, developing a more in-depth understanding of team collaboration during out-of-hours provision.

Conclusion

A model in which out-of-hours primary care is provided by teams with a ratio of up to two GPs and two NPs offers sufficient capacity to provide care for all patients during out-of-hours practice. Teams with two GPs and two NPs were associated with a decrease in the number of patients per shift and a small increase in referrals to the ED by the team. Patient safety needs extra attention, as the number of patients who did not receive care within the targeted time period in both teams increased. There was a minimal difference in aspects of GPs' performance.

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Competing interests:

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: "no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work."

Contributorship statement:

ML, RB and MB conceived and designed the study. ML supervised the study and is the guarantor. MB and ML were involved in the data analysis. MB, RB, MW, ML interpreted the results. MB wrote the first draft of the manuscript. RB, MW and ML revised the manuscript with important intellectual contributions. All authors read and approved the final manuscript. The research was independent of any involvement from the sponsors of the study.

Ethical considerations

The medical ethics committee of the university medical centre waived approval (CMO-nr 2014-1409). Confidentiality was assured through exercising professional ethical codes of conduct, whereby all patients were assured that data cannot lead to any identification.

Funding statement

This study was funded by the Ministry of Health, Welfare and Sport. Researchers were independent from funders. Funders had no role in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

Access to data

Authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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Transparency declaration

The first author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data sharing statement

Patient level data and technical appendix are available at http://dx.doi.org/10.17026/dans-z2p-b85a after approval of the authors. Consent was not obtained but the presented data are anonymised and there is no risk of identification.

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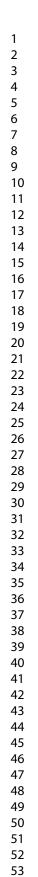
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Figure 1. Flow diagram of the study

Figure 2. Patients outside NPs' scope of practice per day over weekends (*expressed as the proportion of the total number of patients per day*)

Figure 3. Patients outside NPs' scope of practice per hour over weekends (*expressed as the proportion of the total number consultations that can be scheduled per hour*)

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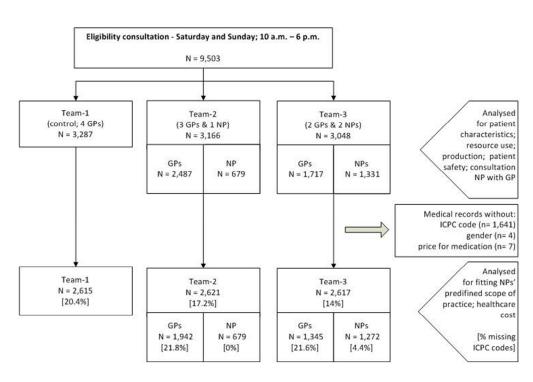
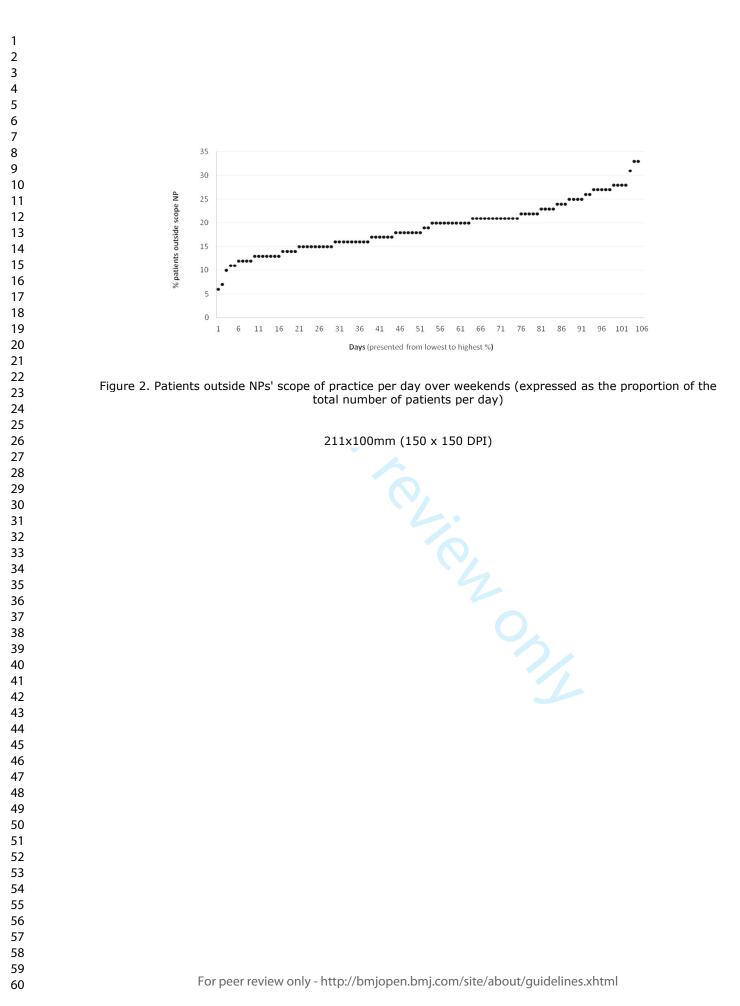
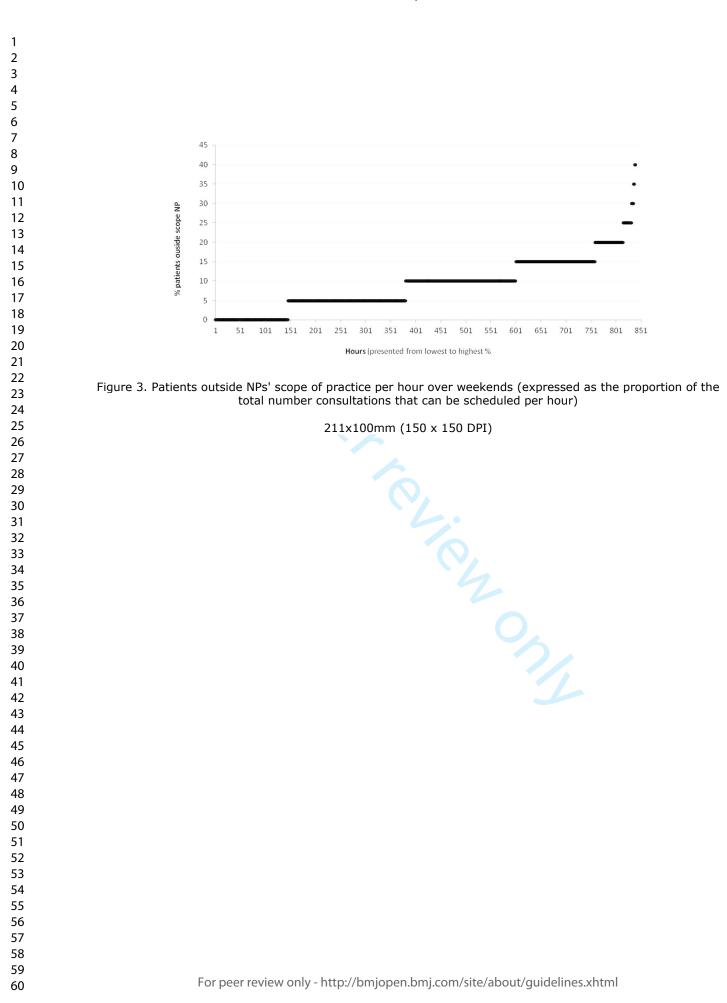


Figure 1. Flow diagram of the study

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Section/Topic	ltem No	Checklist item	Reported on page N
Title and abstract			
	1a	Identification as a randomised trial in the title	1 (quasi
			experiment
			study)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and	2a	Scientific background and explanation of rationale	6
objectives	2b	Specific objectives or hypotheses	7
Mathada			
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
Trial design	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applica
Participants	30 4a	Eligibility criteria for participants	8
Farticipants	4a 4b	Settings and locations where the data were collected	7
Interventions	40 5	The interventions for each group with sufficient details to allow replication, including how and when they were	10
Interventions	5	actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applica
Sample size	7a	How sample size was determined	Not applica
·	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applica
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	9
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	9
concealment		describing any steps taken to conceal the sequence until interventions were assigned	
mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	9
CONSORT 2010 checklist			P

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7 Statistical m 8	יר
10Results11Participant 112diagram is s13recommend14Recruitmen15Recruitmen161717Baseline da18Numbers ar192021Outcomes a22estimation232424Ancillary an	site t
 25 26 27 Harms 28 Discussion 29 Limitations 30 Generalisat 31 Generalisat 32 Interpretation 33 Other infor 34 Registration 36 Protocol 37 Funding 	Di Di Tr
38 39 40 41 42 <i>CONSORT 201</i> 43 44 45 46 47	

1

		interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9
		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	15
diagram is strongly		were analysed for the primary outcome	
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	15
Outcomes and	17a	by original assigned groups For each primary and secondary outcome, results for each group, and the estimated effect size and its	18, 19, 20
estimation	17a	precision (such as 95% confidence interval)	10, 19, 20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	18, 19, 20
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22
Other information			
Registration	23	Registration number and name of trial registry	3
	24	Where the full trial protocol can be accessed, if available	3
Protocol		Sources of funding and other support (such as supply of drugs), role of funders	25

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 crences relevant to this chec.

 *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist

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