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Reference:

Dilles Tinne, Vander Stichele Robert H., van Bortel Lucas M., Elseviers Monique M..- *The development and test of an intervention to improve ADR screening in nursing homes*

Journal of the American Medical Directors Association - ISSN 1525-8610 - 14:5(2013), p. 1-6

DOI: <http://dx.doi.org/doi:10.1016/j.jamda.2013.02.011>

Handle: <http://hdl.handle.net/10067/1090120151162165141>

The development and test of an intervention to improve ADR screening in nursing homes

Running title

ADR screening in nursing homes

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Keywords:

Safety Management/ methods (MeSH)
Nursing homes (MeSH)
Drug Therapy/ adverse effects (MeSH)
Drug Monitoring/ methods (MeSH)
Interdisciplinary Health Team (MeSH)

INTRODUCTION

Adverse drug reactions (ADRs) are appreciably harmful or unpleasant reactions, related to drug use, predicting hazard from future administration and warranting prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product.¹ Nursing home residents have a high risk of suffering from ADRs. An intake of more than 8 medications increases the risk of ADRs with a factor of 2,3.² In nursing homes, 23% to 50% of the residents take more than 9 different medications.^{2,3} By medication review, Ruths et al. identified 2445 potential drug related problems in 1036 nursing home residents, of which 26% were ADRs.⁴ To create the opportunity to alter the treatment and to minimize the burden of ADRs, ADRs have to be diagnosed.

In Flemish nursing homes, the nursing team is responsible for the daily care of the residents. Medical care is provided by general practitioners, who visit their residents regularly. More contact time with the residents gives nurses more opportunities than physicians to screen for the presence of ADRs. In practice, however, nurses are unsure about their role in drug monitoring. A quarter of the nursing home nurses believes the observation of ADRs is not a part of their job.⁵ Furthermore, different barriers have been reported: a lack of pharmacology knowledge, a lack of interdisciplinary communication with general practitioners and a lack of attention from nurses to report observations to physicians.⁵

The aim of this study was to develop an instrument, called Pharmanurse, to facilitate nurse-driven ADR screening as an input for interdisciplinary medication review in nursing homes and, afterwards, to test the effect of the Pharmanurse intervention on the detection rate of ADRs, the value of the detected ADRs for the treating physicians and the number of medication alterations based on the ADRs detected. Finally, the intervention was evaluated by the health care professionals involved in the study.

METHODOLOGY

The concept of Pharmanurse

Pharmanurse is a software program developed for the purposes of this study. It creates a list of potential ADRs, which may affect a resident. The list is based on the residents' own medication. So, for each resident a personal list of potential ADRs is created. For each ADR, the list shows the medications of the resident which may cause the ADR. The list enables nurses to perform focused screening for ADRs for each resident. When completing the screening list by indicating if symptoms are observed in a resident, a standardized report is created to communicate the results to physicians or pharmacists. In medication review, nurses' observations can support the evaluation of the pharmacotherapy. (table 1) Pharmanurse is specifically adapted to the use by nurses and to the use in nursing homes.

Development of Pharmanurse

During the last decade, for different research purposes, the authors collected information on the use of medication by residents of Belgian nursing homes. From 2005 till 2009, over 25.000 prescription lines of medication were entered into a software program to be classified at the active ingredient level with the 5th level International Anatomical Therapeutic Chemical Classification (ATC).⁶ Prescriptions were aggregated on 5th level ATC-code, summarizing the number of times the active ingredient had been prescribed. Active ingredients prescribed to more than 5 residents were included, creating a list of 378 5th level ATC-codes.

In Belgium, the two main sources of information on potential ADRs are the Belgian Centre for Pharmacotherapeutic Information (www.bcfi.be) and the Formulary for Prescribing in Nursing Homes (www.farmaka.be). BCFI has over 15 years of experience in providing information on potential ADRs, evaluated and selected on clinical relevance, taking into account frequency, severity and avoidability. Based on these sources, the 378 ATC-codes were linked to their associated potential ADRs. Potential ADRs were only selected in case the following criteria were fulfilled: (a) ADRs had to be observable by nurses without the help of other professionals (excluding for example ADRs only detectable by

laboratory results); (b) ADRs had to be relevant for the nursing home population (excluding for example ADRs only described in pregnant women or children); (c) ADRs had to be described in normal medication dosages (excluding for example ADRs in case of overdoses or special dosages in palliative care). In total, 135 different ADRs were included in the database.

To increase the usability for nurses, the list of 135 ADRs was then reduced to 108 ADRs, distinguishable with nurse observations (for example esophageal ulcers and esophagitis were combined into one ADR) (Table 2). Difficult terminology was simplified to make sure that the meaning of the ADRs could be understood by all nurses.

The ADR database was validated by an expert team, including a clinical pharmacologist, a pharmacist, a general practitioner, a geriatrician and three nurses. The pharmacist checked all the potential ADRs in the database using the information of the BCFI and the Formulary for Prescribing in Nursing Homes.

The understandability of the ADRs was validated by three nurses. The nurses were asked to indicate on a list of the potential ADRs the words they did not understand or they were not sure of. After the adaptation of the indicated words by the first author, the nurses reevaluated the list. Finally, the clinical pharmacologist, the geriatrician and the general practitioner independently reviewed the list to validate the correctness of the adaptations. Reversible tooth discoloration was removed, because of the low impact on quality of life and the reversible character.

The test of the Pharmanurse

Research design

Pharmanurse was tested in an intervention study with pre-posttest design. The intervention consisted of interdisciplinary medication review, prepared by nurses' screening of ADRs using the lists of potential ADRs created by the Pharmanurse software. Outcome parameters were the ADRs detected by nurses, ADRs confirmed by general practitioners and medication changes. After the post test, participants were questioned about the use of Pharmanurse.

Intervention study

Participants

In September 2010, a convenience sample of ten Flemish nursing homes with a minimum of 80 beds were contacted. Eight nursing homes consented to participate. Residents needed to reside at least one month in the nursing home and to take four or more different drugs to be included. Residents were excluded in case the general practitioner opposed to the participation or in case of palliative care.

Data collection and intervention

Data on the nursing homes, the residents and their medication use were collected from administrative documents and medication charts in November 2010. Based on the medication use, a list of potential ADRs was created per resident, using the Pharmanurse software program. Nurses were consequently asked to use the lists to screen the residents on the presence of ADRs. ADRs had to be reported to the general practitioners using the Pharmanurse reports. Physicians were informed about the project by the researchers and invited by nurses for a medication review session during their next visit to the nursing home. The physician, together with the nurse had to perform the medication review. In medication review, physicians indicated on the reports for each ADR observation whether they confirmed the presence of the ADR and whether they chose to change medication because of the ADR.

Before the end of March 2011 and at least two weeks after medication review, data on the medication use of the residents were collected again.

Data analysis

PASW Statistics 18.0 was used for statistical analysis. Mainly descriptive statistical methods were used. Significance levels of differences in proportions were calculated using chi-square statistics. Significance levels of the differences in medication use between the pre- and posttest were calculated using paired samples t-tests. A p-value <0.05 was considered significant.

Evaluation of the Pharmeducation intervention

Participants

All physicians and nurses who contributed to the screening for ADR and the interdisciplinary medication review, were questioned about the feasibility and the perceived value of the intervention.

Measurement instrument

A quantitative questionnaire was developed for the evaluation. Nurses and physicians were asked to score on a ten point scale their level of satisfaction about different items: general satisfaction, relevance of the ADR triggers, number ADR triggers per resident, user-friendliness, the value of nurse screening for ADRs in preparation of medication review and the potential of the intervention to improve pharmacotherapeutic care. Furthermore, participants were asked to indicate whether the intervention was advisable and feasible monthly, quarterly, half-yearly, or less.

Ethical considerations

Permission of the ethics committee of the Antwerp University Hospital was received in October 2010. Participation was voluntary. The coordinating physician of the nursing home contacted the general practitioners to guarantee their privacy. General practitioners had the possibility to refuse their participation or to refuse the participation of their residents. All names of residents, care givers, general practitioners and institutions were coded.

RESULTS

The research population

The nursing homes had a total of 983 beds (range 90 to 164, median 120). Nursing homes had between 17 and 44 different visiting general practitioners. The intervention was completed for 418 residents. Residents were on average 85 years old and 74% were women. (table 3) Resident characteristics corresponded to the general Flemish nursing home population.³ Residents took up to 20 different chronic medications (mean = 8.1).

The use of the Pharmanurse software

The 418 screening lists for residents contained 14702 potential ADRs. The average number of potential ADRs per resident was 35 (range 6 – 61). With the support of the screening lists, nurses observed 1527 ADRs in 81% of the residents. During the medication review process, physicians confirmed 821 ADRs in 60% of the residents. This corresponds to a confirmation rate of 53.8% of the nurse observations. Based on nurses' ADR observations, 214 medication changes were planned by the general practitioners.. Alterations of the therapy were planned for 13.2% of the confirmed ADRs in 21% of the residents. Most changes were planned in case of confusion, sedation, gastro-intestinal complaints, drowsiness, constipation and nausea.

Per resident the median number of ADRs observed was 3 (range 0-22). The median number of ADRs confirmed was 2 (range 0-17). The median number of ADRs leading towards the planning medication changes was 0 (range 0-8). (table 4)

The effect of the intervention

Changes in medication use between pre- and posttest

Medication use of the residents before and after the intervention was compared. Medication was changed in 275 out of 409 residents (67%). At least one extra medication was prescribed in 50% of the residents. At least one prescription was annulled in 48% of the residents. On medication level, 380 new prescriptions were added and 362 prescriptions were annulled. Medication changes did not

result in a decrease of medication use in residents. The types of medication used were not influenced by the intervention, except for psycholeptics, which were used by 65.3% of the residents before the intervention and 68,5 % of the residents after the intervention. (table 5)

Evaluation of the Pharmanurse intervention

The CRA and a visiting general practitioner were both present in 2.5% of the medication review sessions. A pharmacist supported the review in 1.4%. The medication review took less than 10 minutes in 88% of the residents.

Table 6 shows the results of the evaluation of the Pharmanurse intervention by the health care professionals who performed the screening for ADRs or the medication reviews. In general, the Pharmanurse intervention was evaluated positively by nurses and physicians. General practitioners were very satisfied with the improvement in nurses' screening for ADRs. User-friendliness and the communication with the general practitioners received the lowest scores. In total, 65% scored 7 or more in 10 when rating the perceived improvement in pharmacotherapeutic care.

DISCUSSION

Pharmanurse

Supporting drug monitoring in nursing homes with the Pharmanurse intervention had several advantages. The software created resident specific ADR-lists which allowed targeted observations of ADRs, even in the absence of advanced pharmacological knowledge and without having to look up information on the different medications. The adaptation of the software to nurses' terminology and nurses' role in nursing homes, combined with standardized communication reports strengthened nurses position to contribute to drug monitoring and to report their observations. General practitioners received structured reports of the ADR-observations, linked to the residents' medications potentially causing the ADR. General practitioners used the information in the evaluation of the pharmacotherapy..

The effect of the Pharmanurse intervention

Nurses observed a median of 3 ADRs per resident. About half of these ADRs were confirmed by a physician during the medication review session. Based on the ADR-observations, medication changes were planned in 20% of the residents. These results show that the prevalence of ADRs in nursing homes is high and nurses are able to contribute to the detection and reporting of ADRs, when supported by the Pharmanurse software, as a source of information for medication review.

When the results are compared with earlier findings in literature, the detection rate of ADRs in our study seems to be higher. By the use of a standard symptoms assessment form, nurse-led medication reviews in elderly hospitalized patients identified a mean of 1.2 drug related problems not detected by usual care.⁷ The combination of a standard observation form, computerized drug-drug interaction screening, creatinine clearance calculation and medication review by a nurse and a clinical pharmacologist, resulted in the detection of a mean of 2 drug related problems and 0.6 ADRs per patient in an internal medicine clinic.⁸ Differences in the drug related problems studied and differences in settings, interventions and study methodology, however, make indisputable comparisons with the Pharmanurse intervention impossible.

The effect of the intervention on the quality of the pharmacotherapy is not clear. The effect highly depends on the decisions made during the medication review procedure. General practitioners were supported in medication review by indicating which medications of the residents had the potential to cause the ADR, yet, no advises to improve the pharmacotherapy were given. Physicians were not supported in the decision to alter the dosage or the medication, to withdraw the product or to prescribe additional treatment. Furthermore, more rigorous intervention research with a randomized controlled design and intensive analysis of the quality of the prescriptions is required to obtain evidence on the effect on the quality of the pharmacotherapy.

User - evaluation of Pharmanurse

Despite the lack of evidence at this moment, the Pharmanurse intervention was given a score of 7 in 10 for the potential to improve pharmacotherapy and 83% of the physicians were satisfied about

nurses' screening for ADRs. We, therefore, believe the Pharmanurse software should be further refined and the hypothesis of the improvement of pharmacotherapeutic care in nursing homes by re-enforcing nurses' contribution to drug monitoring should be further investigated.

Conclusions

Pharmanurse enabled nurses of nursing homes for older people to detect and report relevant ADRs.

In interdisciplinary medication review, the information of nurses' observations resulted in medication changes, yet, the effect on the quality of prescribing should be further investigated.

The authors state there are no conflicts of interest. Pharmanurse is a software program developed in the PhD research project of the first author and is not a sponsored product or a commercial product and no contracts for commercial exploitation are signed at the time of submission.

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Potential ADRs in the resident	Nurse observations of potential ADRs			Interdisciplinary medication review			
	Present?	Frequency*	Additional notes (drug? Adherence? Changes?)	Medication that can cause the ADR in the resident	ADR confirmed?	Medication changed?	Additional notes
Nausea and vomiting	No - Yes	1- 2- 3- 4		Citalopram Sandoz tabl 56 x20 mg	No – Yes	No – Yes	
				Lanoxin tabl 60 x 0.125mg	No – Yes	No – Yes	
				Omeprazol Sandoz caps ec 98 x 20 mg	No – Yes	No – Yes	
Dry mouth	No - Yes	1- 2- 3- 4		Citalopram Sandoz tabl 56 x20 mg	No - Yes	No – Yes	
Irritation of the gastric mucosa	No - Yes	1- 2- 3- 4		Cardioaspirine tab ec 60 x 100 mg	No – Yes	No – Yes	
Gastro-intestinal bleeding	No - Yes	1- 2- 3- 4		Citalopram Sandoz tabl 56 x20 mg	No - Yes	No – Yes	
				Cardioaspirine tab ec 60 x 100 mg	No – Yes	No – Yes	
Liver problems	No - Yes	1- 2- 3- 4		Citalopram Sandoz tabl 56 x20 mg	No – Yes	No – Yes	
Diarrhea	No - Yes	1- 2- 3- 4		Citalopram Sandoz tabl 56 x20 mg	No – Yes	No – Yes	
				Fero-gradumet tabl retard 60 x 525mg	No – Yes	No – Yes	
				Omeprazol Sandoz caps ec 98 x 20 mg	No – Yes	No – Yes	
Constipation	No - Yes	1- 2- 3- 4		Cacit vitd3 1000/880 30 x 1000/880	No - Yes	No - Yes	
				Fero-gradumet tabl retard 60 x 525mg	No - Yes	No - Yes	
Flatulence	No - Yes	1- 2- 3- 4		Cacit vitd3 1000/880 30 x 1000/880	No - Yes	No - Yes	
Anorexia	No - Yes	1- 2- 3- 4		Lanoxin tabl 60 x 0.125mg	No - Yes	No - Yes	
Weight gain	No - Yes	1- 2- 3- 4		Citalopram Sandoz tabl 56 x20 mg	No - Yes	No - Yes	
				Seroquel tabl 60 x 200 mg	No - Yes	No - Yes	

Table 1: Example of an screening list for ADRs of Pharnurse (* Frequency: 1= daily, 2= weekly, 3= monthly, 4= less frequent)

Table 2: adverse drug reactions included in the database			
Gastro-intestinal system	Nervous system (1)	Cardiovascular system	Dermatological system
gastro-intestinal complaints	depression	tachycardia	photosensitivity
bowel cramps	agitation (agitation + nervositas)	bradycardia (bradycardia + negative dromotropy + negative inotropy)	hair loss
diarrhea	excessive cheerfulness (excitation + euphoriant)	palpitations	skin eruptions
constipation (constipation + intestinal obstruction)	fear, anxiety	arrhythmia	itching
flatulence	aggression	hypertension	skin problems (allergic skin reactions + Leyll disease + Steven Johnson syndrome + skin problems)
anorexia	hallucinations	hypotension	Urogenital system
taste disorders	psychoses	bleeding	renal problems (decrease of renal function + renal insufficiency + nephropathy)
increase in body weight	anticholinergic side effects	trombosis	micturition disorders
decrease in body weight	extrapyramidal side effects	chest pain	urinary incontinence
nausea and vomiting	serotonin syndrome	heart problems	urinary retention
dry mouth	neuroleptic malignant syndrome	Blood and electrolytes	polyuria
thirst	cognitive disorders	deshydration	kidney stones
gingival hyperplasia	confusion	oedema (oedema + water and salt retention)	painfull breasts
hemorrhoids and fissures	balance and coordination problems	lactic acidosis	gynecomastia
irritation of the rectal mucosa	convusions	hyperglycemia	Erectile dysfunction
irritation of the gastric mucosa	drowsiness (drowsiness + vertigo)	hypoglycemia	Impotence
gastrointestinal bleeding	dyskinesia and dystonia	Respiratory system	priapism
esophageal complaints (esophagitis + esophageal ulcers)	tremor	respiratory depression	testicular atrophy
inflammation of the oral mucosa (stomatitis + candidose)	neuritis	tachypnoe	gynecological problems
abdominal pain	tingling skin sensation	asthma attack	Pharmacological ADRs
liver problems (hepatitis + other liver problems)	weakness	coughing	dependency
pancreatitis	tiredness	breathing difficulties	tolerance
Endocrine system	sleep disturbances	Musculoskeletal system	allergy and hypersensitivity
insuline resistance	somnolence	gout	anaphylactic shock
cushing' s syndrome	sedation	joint problems	Other ADRs
adrenocortical insufficiency	stupor	bone pain	lipodystrophia
thyroid dysfunction (thyroid dysfunction + hypothyreosis)	falling	osteonecrosis of the jaw	hyperthermia
	head aches	muscle pain	eye problems
		muscle weakness	hearing problems
			hoarseness

Table 2: potential ADRs included in the database of the DRP trigger tool
ADRs are divided in categories comparable to the 1th level ATC classifications

Table 3: Description of the research population

DESCRIPTION OF THE NURSING HOME RESIDENTS (n=418)	
General resident characteristics	
Age in years (mean, range)	84.9 (54-101)
Women (%)	76.6
Hospitalizations and mortality during the four month study period	
Hospitalized (%)	9.8
Mortality (%)	0
Physical activities of daily living	
Residents completely dependent for	
Washing (%)	60.7
Dressing(%)	57.1
incontinence for urine and/ or faeces (%)	49.1
Going to the toilet (%)	32.9
Mobility (%)	23.0
Eating or drinking (%)	20.1
Mental status	
Residents almost daily disoriented	
In time (%)	50.3
In place (%)	46.5

N=418 residents	Number of different ADR s within the category	Potential ADRs		ADRs observed by nurses		ADRs confirmed by physicians		ADRs resulting in medication changes	
		% of residents* (n)	Median (range) per resident	% of residents** (n)	Range	% of residents** (n)	Range	% of residents** (n)	Range
Gastro-intestinal	22	99.7 (417)	7 (0-13)	46.2 (193)	0-7	28.8 (120)	0-6	7.9 (33)	0-5
water- , blood- and electrolytes	6	91.4 (382)	2 (0-5)	16.2 (62)	0-2	8.4 (32)	0-2	2.1 (8)	0-1
Cardiovascular	10	98.3 (411)	4 (0-7)	14.1 (58)	0-3	9.0 (37)	0-3	3.2 (13)	0-1
Dermatological	5	85.4 (357)	2 (0-4)	17.1 (61)	0-3	7.0 (25)	0-3	2.0 (7)	0-2
Pharmacological	4	82.3 (344)	2 (0-4)	15.1 (52)	0-3	12.2 (42)	0-3	1.7 (6)	0-1
Urogenital	13	94.3 (394)	3 (0-7)	12.7 (53)	0-2	6.1 (24)	0-2	1.3 (5)	0-1
Hormonal	4	52.9 (221)	1 (0-4)	2.3 (5)	0-1	1.4 (3)	0-1	0.1 (2)	0-1
Musculoskeletal	6	54.3 (227)	1 (0-5)	18.5 (42)	0-4	10.1 (23)	0-3	2.2 (5)	0-3
Neurological	28	99.3 (415)	12 (0-22)	63.1 (262)	0-12	39.8 (165)	0-9	10.6 (44)	0-6
Respiratory	5	81.8 (342)	1 (0-4)	6.4 (22)	0-3	2.6 (9)	0-1	1.2 (4)	0-1
Other	5	43.5 (182)	0 (0-3)	12.1 (22)	0-2	3.8 (7)	0-2	0.1 (1)	0-1
Total	108	100.0 (418)	35 (6-61)	80.9 (338)	3 0-22	59.8 (250)	2 0-17	21.3 (89)	0 0-8

Table 4: The table shows the potential ADRs on the screening lists, the ADRs observed by nurses, the confirmation of the observations by physicians and consequent medication changes in different categories of ADRs. In the second column, the number of ADRs assigned to that category is noted (see also table 1).

* denominator = total number of residents (= 418).

** denominator = number of potential ADRs in that category.

MEDICATION CHANGES IN RESIDENTS BETWEEN PRETEST AND POSTTEST ON ATC LEVEL (n=409)				
ATC Level		PRE %*	POST %*	DIFFERENCE % (CI 95%)
A	Alimentary tract and metabolism	84.1	82.6	1.4 (-0.7 to 3.7)
A02	Drugs for acid related disorders	44.7	43.8	0.9 (-1.0 to 2.6)
A06	Laxatives	49.9	47.9	2.0 (-1.1 to 5.1)
A10	Drugs used in diabetes	19.1	18.8	0.3 (-1.1 to 1.4)
B	Blood and blood forming organs	66.0	67.5	-1.4 (-3.6 to 0.7)
B01	Antihemorrhagics	61.4	62.6	-1.2 (-3.0 to 1.0)
C	Cardiovascular system	82.9	81.9	1.0 (-0.9 to 2.4)
C01	Cardiac therapy	23.0	23.2	-0.2 (-1.8 to 1.4)
C03	Diuretics	41.6	41.1	0.5 (-2.0 to 2.9)
C07	Beta blocking agents	33.7	31.5	2.2 (-0.1 to 3.8)
C09	Agents acting on the renin-angiotensin system	36.2	36.7	-0.5 (-1.1 to 1.2)
M	Musculo-skeletal system	22.2	20.3	1.9 (-0.2 to 4.1)
N	Nervous system	88.8	89.7	-0.9 (-2.3 to 0.9)
N02	Analgesics	35.9	36.2	-0.3 (-3.0 to 2.5)
N05	Psycholeptics	65.3	68.5	-3.2 (-5.9 to -0.4)*
N06	Psychoanaleptics	53.1	53.1	0 (-2.1 to 2.1)
R	Respiratory system	25.9	25.2	0.7 (-1.6 to 3.1)

Table 5

* % of residents with a prescription of a medication of the corresponding ATC level

How do you evaluate the Pharmanurse intervention on a 10-point scale? 1= not satisfied at all 10= very satisfied				
	Nurses (n=44)		General practitioners (n=72)	
	Mean (range)	%≥7	Mean (range)	%≥7
Pharmanurse intervention in general	6.7 (3-8)	60	6.5 (3-10)	60
Relevance of the ADR triggers	6.7 (4-9)	67	6.7 (3-9)	63
Number of ADR triggers	6.9 (5-10)	65	7.1 (4-10)	64
User-friendliness	6.5 (3-10)	63	6.0 (1-10)	56
Improvement of communication about medications within the nursing team	6,9 (4-9)	65		
Improvement of communication with the general practitioner	6.7 (5-9)	56		
Improvement of nurses' screening for ADRs	7.2 (4-10)	74	7.8 (3-10)	83
Improvement of pharmacotherapeutic care	7.0 (3-10)	65	7.0 (2-10)	65
How often is the Pharmanurse intervention advisable/ feasible?				
	Nurses (n=44)		Physicians (n=72)	
	Advisable (%)	Feasible (%)	Advisable (%)	Feasible (%)
Monthly	34.9	18.6	8.6	7.0
Quarterly	39.5	44.2	27.1	22.5
Half-Yearly	16.3	27.9	47.1	54.9
Less / not	9.3	9.3	17.2	15.5

Table 6 Evaluation of the Pharmanurse intervention