Patients' general satisfaction with telephone counseling by pharmacists and effects on satisfaction with information and beliefs about medicines: Results from a cluster randomized trial ☆

MARCEL JAN KOOY[A,*], ERICA C.G. VAN GEFFEN[A,1], EIBERT R. HEERDINK[A], LISET VAN DIJK[B], MARCEL L. BOUVY[A]

[a] Department of Pharmacoepidemiology & Clinical Pharmacology, Utrecht University, Utrecht, The Netherlands

[b] NIVEL (Netherlands Institute for Health Services Research), Utrecht, The Netherlands

ABSTRACT

Objective Assess effects of pharmacists' counseling by telephone on patients' satisfaction with counseling, satisfaction with information and beliefs about medicines for newly prescribed medicines.

Methods A cluster randomized trial in Dutch community pharmacies. Patients ≥18 years were included when starting with antidepressants, bisphosphonates, RAS-inhibitors or statins. The intervention comprised counseling by telephone to address barriers to adherent behavior. It was supported by an interview protocol. Controls received usual care. Outcomes were effects on beliefs about medication, satisfaction with information and counseling. Data was collected with a questionnaire.

Results Responses of 211 patients in nine pharmacies were analyzed. More intervention arm patients were satisfied with counseling (adj. OR 2.2 (95% CI 1.3, 3.6)). Patients with counseling were significantly more satisfied with information on 4 items, had less concerns and less frequently had a 'skeptical' attitude towards medication (adj. OR 0.5 (0.3–0.9)). Effects on most outcomes were more pronounced in men than in women.

Conclusions Telephone counseling by pharmacists improved satisfaction with counseling and satisfaction with information on some items. It had a small effect on beliefs about medicines.

Practice implications Pharmacists can use counseling by telephone, but more research is needed to find out which patients benefit most.

1. INTRODUCTION

Patients starting medication need information about their medicines to support appropriate and safe use [1], [2], [3], [4] and [5]. This includes practical instructions on usage but also information about possible side effects, the expected pharmacological action and what happens if a patient does not take the medication [2], [6] and [7]. This information should improve patients' understanding of the expected benefits and risks [3] and [8].

Physicians and pharmacists play an important role in providing counseling about benefits, risks and correct use of medication [9]. In counseling-sessions a healthcare provider can tailor information to the patients' needs [10], [11] and [5], assess whether a patient understands the information and also assess barriers that may negatively influence adherence to medication [12].

Counseling, including education and behavioral support, can improve medication adherence [13]. Adherence to long-term therapy is generally defined as the extent to which a person's behavior (e.g. taking medication) corresponds with agreed recommendations from a healthcare provider [14]. Adherence to medication for long-term treatment is low [14], [15], [16] and [17], which severely compromises the effect of the therapy. Dutch pharmacy guidelines recommend education and counseling at the pharmacy including exploration of lack of knowledge, information needs and experiences with the medication. The first period after the start of treatment is especially important since discontinuation of therapy is highest in the first weeks after the start of a new treatment [18].

In daily practice not all patients starting with medication receive optimal care from physician [19] or pharmacists [20]. Studies show that information needs of patients are not always met [6], [7], [21] and [22] and that barriers to adherent behavior are not always assessed [12], [23] and [24]. The quality of communication can be improved [25] and [26], also because part of the information is forgotten or remembered incorrectly [27].

Considering barriers that hamper implementation of counseling in pharmacies [28] and [29], a feasible alternative to face-to-face counseling may be counseling by telephone [30]. This has been proven to improve adherence measured after 4-week follow-up and to be effective in reducing mortality in non-adherent patients [31].

We designed the TelCIP trial, a cluster randomized controlled trial in patients starting with antidepressants, antihypertensives, lipid lowering drugs or bisphosphonates to study the effect of counseling by telephone on medication

adherence [32]. Cluster randomization was chosen as this was supposed to increase feasibility of implementation of the study protocol in pharmacies and to reduce the risk of contamination.

In the counseling calls the pharmacists assess and address possible barriers including lack of knowledge, concerns about medication and low necessity beliefs. Our hypothesis is that this type of counseling will improve knowledge, reduce concerns about medication and improve necessity beliefs. This may ultimately improve medication adherence. Although this effect of the intervention on adherence is important, it is as important to assess the impact on the pathway that ultimately leads to adherent behavior. This is because it is this pathway where the pharmacist addresses the needs of each individual patient and where the actual intervention takes place. Therefore the objective of the present study is to assess the effect of a telephone counseling intervention at the start of pharmacotherapy on patients' (1) general satisfaction with counseling, (2) satisfaction with information and (3) beliefs about medicines.

2. METHODS

This study is part of a cluster randomized controlled trial of which the trial protocol has been published before [32].

2.1. Setting and population

This study was conducted in community pharmacies in various parts of the Netherlands. Pharmacists could apply for participation by a website and after consenting the pharmacies (clusters) were randomly allocated by a researcher (MK) to either study arm A or study arm group B (Fig. 1) in a 1:1 ratio. All pharmacists had to provide the intervention; pharmacies in arm A for patients starting with antidepressants and bisphosphonates and in arm B for RAS-inhibitors and statins. Given the nature of the study design it was impossible for both pharmacists and researchers to be blinded to the group assignment.

[FIGURE 1]

Patients of 18 years or older were selected if they filled a first-time prescription for an antidepressant, a bisphosphonate, an antilipaemic or a Renin-Angiotensin-System (RAS) inhibitor. Patients were excluded if they were not responsible for their own medication or if they received medication in multi dose dispensing systems.

For technical reasons only pharmacies participating in the TelCIP trial using a specific pharmacy information system were asked to participate in this sub study. The nine pharmacies that participated in this sub study were located in various parts of the Netherlands, both rural and urban areas [32].

2.1.1. Intervention arms

In addition to usual care, patients in the intervention arm received the intervention consisting of telephone counseling by the pharmacist. An interview protocol was developed to support the pharmacists in counseling patients on the following topics: (1) actual medication intake, (2) practical and perceptual barriers related to medication use (including side effects) and (3) information needs and lack of knowledge about the medication, which has been published as additional file to the trial protocol [32]. When needed the pharmacist provided information, motivated the patient to keep using the medication, suggested strategies to adhere to the medication regimen and if necessary referred the patient to the physician. After the call, the pharmacists had to register the content of the call in an online form.

All participating pharmacists received an e-learning communication training based on the Health Belief Model (HBM) which is described in more detail in the study protocol [32]. The HBM suggests that adherence behavior is influenced by perceived severity (beliefs about how severe the condition is), perceived susceptibility (the extent to which the patient feels at risk of suffering from the condition) and the expected beneficial effects and perceived disadvantages of the advised behavior [33] and [34].

2.1.2. Usual care

Dutch pharmacy guidelines recommend counseling when a first prescription for a new medication is filled. This first fill provides for a maximum of 2 weeks. Guidelines recommend additional counseling at the first refill. This refill counseling should include exploration of patients' needs and experiences with medication. However as mentioned before, these guidelines are not always properly implemented in daily care [29].

2.1.3. Outcome measures

Outcomes were measured at patient level. Patients in both arms received one questionnaire 3 months after the first prescription. The inclusion period was not the same for all clusters but overall questionnaires were sent from August 2011 till December 2012. Questionnaires were sent 3 months after the first prescription and contained socio-demographic questions and questions on general satisfaction with counseling, satisfaction with information and beliefs about medicines (see below). Patients were asked about the reason for use of the medication in an open question and three authors (MK, RH, and MB) independently categorized the answers in the most plausible indication. Authors were blinded for group allocation and disagreements between authors were resolved by discussion.

2.1.3.1. General satisfaction with counseling

Patients were asked to rate their general satisfaction with pharmacy counseling in the preceding 3 months. Four questions from the Consumer Quality Index (CQI) were used aiming to assess different aspects of pharmaceutical care [35]. The following questions were used: (1) "Did the pharmacist or technician ask you about your experiences with the medication?", (2) "Did the pharmacist or technician ask you if

you suffered from any side effects?", (3) "Did the pharmacist or technician provide enough personal counseling?" and (4) "Did the pharmacist or technician ask you if you manage to take your medication as prescribed?" For each question, three answer options were offered: "yes", "no" or "I don't remember".

In addition, in the intervention arm patients' satisfaction with telephone counseling was assessed with four questions: "Do you appreciate this service?", "Do you think it has an added value?", "Would you like to be called next time you start with a medicine?" and "Do you prefer face-to-face counseling over telephone counseling?"

2.1.3.2. Satisfaction with information

The Satisfaction with Information about Medicines Scale (SIMS) was used to assess the satisfaction with the information provided on particular aspects of medicine use [3]. We used 9 of the 17 items of the original questionnaire (see appendix) because some items were not relevant for all four groups of medication and we aimed to study the effect of the intervention on particular aspects of information about medicines that were likely to be addressed during telephone counseling [20]. Patients were asked to rate the amount of the information received on the following response scale: "too much", "about right", "too little", "none received" and "none needed". Patients answering "about right" were labeled as satisfied.

2.1.3.3. Beliefs about medicines

High concerns about medication or low necessity beliefs negatively influence adherence to medication [8]. A method to assess the necessity beliefs and concerns patients have about medication is offered by the Necessity-Concerns Framework and can be valued with the Beliefs about Medicines Questionnaire – specific (BMQs) [36]. The BMQs measures both the perceived necessity and concerns about prescribed medication. Both scales consist of five items and each item is scored using a 5-point Likert scale (1 = strongly disagree to 5 = strongly agree); therefore the individual score per scale ranges from 5 to 25. A necessity-concerns differential is calculated by subtracting the concerns score from the necessity score. A positive differential implies that the necessity beliefs are stronger than the concerns while a negative differential means that the concerns are stronger than the necessity beliefs. Four attitudinal groups are generated, using the median of the two separate scales: accepting (necessity ≥ 15, concerns < 15), ambivalent (necessity ≥ 15, concerns ≥ 15), skeptical (necessity < 15, concerns ≥ 15) and indifferent (necessity < 15, concerns < 15) [37].

2.2. Data analysis

Patient characteristics between groups were compared using Student's *t*-test or χ^2-test (SPSS for Windows version 2.0). Conditional logistic regression was applied to study the effect on dichotomous outcomes (e.g. proportion of satisfied patients, attitudinal groups). Linear regression was used to study the effect on continuous outcomes (e.g. concerns and needs scale). Effect modification was assessed with gender, medication class, age and ethnicity as variables. Effect modification was

defined as a significant interaction ($p < 0.10$) between group allocation and the variable in question. Gender, age and medication class were studied as potential confounders. Because of the possibility of selection bias, we performed both an intention-to-treat (ITT) analysis and a per-protocol (PP) analysis. In the ITT-analysis we compared all patients in the intervention arm (the 'eligible' patients) whether they received counseling or not with patients who received usual care. In the PP analysis we included only the patients who actually received counseling. Linear and logistic analysis taking clustering within pharmacies into account (by using the vce cluster command) was performed using Stata 13.0.

2.3. Ethics and confidentiality

The Medical Ethics Review Committee (METC) of the University Medical Centre Utrecht concluded that the Dutch Medical Research Involving Human Subjects Act (WMO) was not applicable. The divisional Institutional Review Board approved the protocol. In order to protect the patients' privacy, all data were coded by the participating pharmacies. The trial was registered at the Dutch trial registry via www.trialregister.nl under the identifier NTR3237.

3. RESULTS

The overall response rate on the questionnaire was 22.9% (229 patients). 18 questionnaires were excluded because of incompleteness. Of the remaining 211 respondents, 117 belonged to the usual care arms and 94 to the intervention arm ('Eligible' patients) (see Fig. 1). Of the 'eligible' patients 60% (56) actually had received counseling and 38 did not. Registered reasons for not providing counseling in the intervention group were: patients refused the counseling (7), patients could not be reached (6) and no telephone number was available (4). For the remaining 21 patients no (clear) reason was registered.

Table 1 shows the baseline characteristics of the responders. The average age of patients who were randomized to the intervention was not significant different from the usual care arm. However, patients in the intervention arm who did not receive the intervention ($n = 38$), were younger compared to patients in the usual care arm ($p < 0.05$). Moreover, in the intervention arm the proportion of antidepressant users was higher compared to the usual care arm ($p < 0.05$).

[TABLE 1.]

3.1. General satisfaction with counseling

In the usual care arm 31% (33/108) of the patients answered positive on at least one of the questions compared to 47% (40/85) (ITT) and 63% (32/51) (PP) in the intervention arm (see Table 2). In the intervention arm relatively more patients indicated that the pharmacists asked about the experiences, side effects, whether the patient managed to take the medication as prescribed and provided enough personal counseling. Gender was a significant effect modifier and thus we studied the effect of the intervention in women and men separately. In this subgroup analysis the stronger

effects of the intervention were mostly attributable to low counseling rates among men in the usual care arm.

[TABLE 2.]

Of the patients in the intervention arm, 86% (42/49) said to appreciate this intervention, 74% (34/46) stated that telephone counseling had an added value and 63% (30/48) stated that they would like to be contacted by the pharmacist the next time they start with medication. However, 46% (22/48) preferred face-to-face counseling over telephone counseling. Of the men 88% (21/24) stated that telephone counseling had an added value compared to 59% (13/22) of the women (χ^2 test $p < 0.05$).

3.2. Satisfaction with information about medicines

In the intention-to-treat analysis there were no statistically significant differences between both arms in the satisfaction with information on medicines (see Table 3). However patients with counseling were more satisfied on four items: "How long it will take to act", "How you can tell if it is working", "How long you will need to be on your medicine" and "How to get a further supply". Also on three other items we found some effect but this was not statistically significant. After stratification for gender, men in the intervention arm were significantly more satisfied on 6 of 9 information items compared to usual care whereas women were less satisfied with information on four items compared to women with usual care. In the PP-analysis this number was 7 respectively 1.

[TABLE 3.]

3.3. Beliefs about medicines

In the overall study population there was no significant difference in necessity beliefs and concerns between the intervention arm and the usual care arm (see Table 4). In the usual care arm the necessity-concerns differential was −0.35 points which implies that the concerns were 0.35 points higher than the necessity beliefs. Theoretically the differential can range from −20 to +20. For the 'eligible patients' this difference was 0.60 and for patients with counseling 1.2 which implies that the necessity beliefs outweighed the concerns. The difference between the differential in the usual care arm and intervention arm was 1.0 (95% CI −1.1, 3.2) (ITT) and 1.7 (95% CI 0.08, 3.2) (PP). This significant effect in patients with counseling was due to a non-significant increase in necessity beliefs (0.5) and a significant decrease in concerns (1.3 with 95% CI −2.5 to −0.02). As only gender was an effect modifier, the effect was studied for both genders. Men in the intervention arm reported significantly lower concerns compared to men in the usual care arm. For women no differences between both arms were found.

[TABLE 4.]

There was no significant difference in distribution of patients over the four attitudinal beliefs groups (see Table 5). In the intervention arm the proportion of skeptical patients (11.0%) is smaller compared to the usual care arm (21.2%) but this is not statistically significant ($p = 0.06$, χ^2-test). But after correcting for age, gender and medication class, the likelihood of being 'skeptical' was significantly lower in the PP-arm compared to the usual care arm (OR 0.5 with 95% CI 0.3, 0.9).

[TABLE 5.]

4. DISCUSSION AND CONCLUSION

4.1. Discussion

Patients who received telephone counseling by pharmacists after the start of a new medication therapy were more satisfied with counseling in general compared to patients in the usual care arm. This satisfaction related to all contacts with the pharmacy staff in the first 3 months after the start. Three quarters of the patients who received telephone counseling believed that this kind of counseling has added value. However in the overall population this did not result in a significant increase in satisfaction with information. Nonetheless patients who received the intervention were more satisfied with some information. We did find a small effect of telephone counseling on medication beliefs: patients with telephone counseling had less concerns towards their medication and had a more positive necessity-concerns balance. These effects on medication beliefs are in line with an earlier finding that counseling by telephone can increase the necessity-concerns differential [38].

We found significant effect modification by gender and stratification showed that the intervention had almost no effect in women. On the other hand, in men the intervention had a significant effect on all three outcomes. First, compared to the usual care arm more men in the intervention arm said to have received counseling. Moreover, men in the intervention arm were more frequently satisfied with counseling and with information on medicines. Finally, men who received telephone counseling had less concerns about their medication which resulted in a more positive necessity-concerns balance. Although we corrected the effect sizes for age and medication class, the possibility exists that the differences between men and women are explained by an unmeasured variable. However, plausible explanations exist for the difference of effect in men and women. First of all it can be a practical one: men are likely to visit the pharmacy less frequently and ask someone else to pick up the medication. This might lead to a decreased exposure to usual care in men compared to women. Another explanation can be gender differences in communication style of both the healthcare provider and the patient. Communication style is important for optimal treatment [39] and male and female physicians in general use different styles [40] and [41]. In the Netherlands slightly more than half of pharmacists and almost all technicians are female. Especially technicians have an important role in counseling patients during the dispensing process. Gender differences also exist in the patients' needs for information and communication

[42] and [43]. These gender differences might also influence the level of care. The fact that several scores in the usual care group were lower in men compared to women corresponds with both explanations. In addition we asked the patients in the intervention arm about their opinion about this intervention and more men thought it had an added value compared to women. So it is plausible that this service is more suitable for men, however more research is needed to provide more information on this possible gender difference.

A limitation of our study is that the pharmacists failed to register the reasons for not providing counseling for one in four patients. A likely explanation for this 'failure' is that the selection for the intervention had to be run weekly and in some weeks this selection has not been made, for example due to vacation or illness of the responsible pharmacist. According to the protocol the call had to be made 7–21 days after the first prescription so, if a pharmacist was not able to call the patient within this time window, some patients were missed. The selection of patients for the questionnaire was run independently of the fact that patients were actually called. Therefore it is likely that patients were not selected for the intervention but were selected for the questionnaire. Since pharmacists did register patient related reasons for not calling we believe that the reasons for not registering were probably not patient related but of an organizational nature. To eliminate all risks of bias we decided to include these patients in the intention to treat analysis. Comparing the results of the ITT and the PP-analysis, the results were in line with the expectation that the effects of the intervention are stronger in the PP-analysis than in the ITT-analysis. Another limitation is the low overall response rate of 22.9%. Our sample size was based on an expected response rate of 30% and we did not take any effect modification into account which leaves our study possibly underpowered. Moreover, we were not able to present the results on adherence yet. These are expected to become available late 2015.

A major strength of this study is that it was implemented in routine care with four different medication classes. The fact that pharmacists were able to include more than half of the patients and perform the intervention in 'daily practice' suggests that it is feasible to implement this intervention in routine care. The quality of the intervention depends on the skills of the pharmacist. To assure treatment integrity we provided training to the pharmacists, an interview protocol and the pharmacists had to register the content of all the calls. The nine participating pharmacies were located both in rural and urban areas of the Netherlands which improves the external validity. Also positive is that the intervention focuses on patients starting treatment regardless if they return for a refill or not. This is relevant since a substantial part of the patients discontinue therapy in the first weeks after the start and will not return to the pharmacy for a refill [44]. This suggests that the intervention can be implemented in a broad range of settings for different types of medication classes.

4.2. Conclusions

Counseling by telephone by pharmacists at the start of therapy improves the general satisfaction with counseling. Most patients appreciate this type of counseling and it seems feasible to implement this intervention in daily clinical practice. In the overall

study population telephone counseling has no distinct effect on satisfaction with information and on beliefs about medicines. However, patients who received counseling were more satisfied with some information, had less concerns about medication and less frequently had a 'skeptical' attitude. The effects of the intervention were more pronounced in men.

4.3. Practice implications

The results of this study suggest that counseling by telephone at the start of therapy improves the satisfaction with counseling by pharmacists. In men telephone counseling also improves satisfaction with information and reduces the concerns about medication. The difference in effect between men and women suggests that additional counseling will not benefit all patients. Pharmacists should find strategies to direct this intervention to patients who are most likely to benefit. Attention should be paid how to reach more patients although the intervention is relatively easy to implement.

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APPENDIX A. APPENDIX

Satisfaction with Information about Medicines Scale

Please rate the information you have received about each of the following aspects of your medicines.	Included
1. What your medicine is called.	
2. What your medicine is for.	
3. What it does.	
4. How it works.	
5. How long it will take to act.	Yes
6. How you can tell if it is working.	Yes
7. How long you will need to be on your medicine.	Yes
8. How to use your medicine.	
9. How to get a further supply.	Yes
8. Whether the medicine has any unwanted effects (side effects).	Yes
9. What are the risks of you getting side effects.	Yes
10. What you should do if you experience unwanted side effects.	Yes
11. Whether you can drink alcohol whilst taking this medicine.	

12. Whether the medicine interferes with other medicines.	Yes
13. Whether the medication will make you feel drowsy.	
14. Whether the medication will affect your sex life.	
15. What you should do if you forget to take a dose.	Yes

Items 1–9: action and usage scale. Items 10–17: potential problems of medication subscale.

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☆ The trial was registered at www.trialregister.nl under the identifier NTR3237

FIGURES AND TABLES

Fig. 1. Participant flowchart. *[1]: for two patients the pharmacy could not be identified.

Kooy,M.J.,Geffen,E.C.G.van,Heerdink,E.R.,Dijk,L. van,Bouvy,M.L. Patients' general satisfaction with telephone counseling by pharmacists and effects on satisfaction with information and beliefs about medicines:results from a cluster randomized trial.Patient Education and Counseling:2015

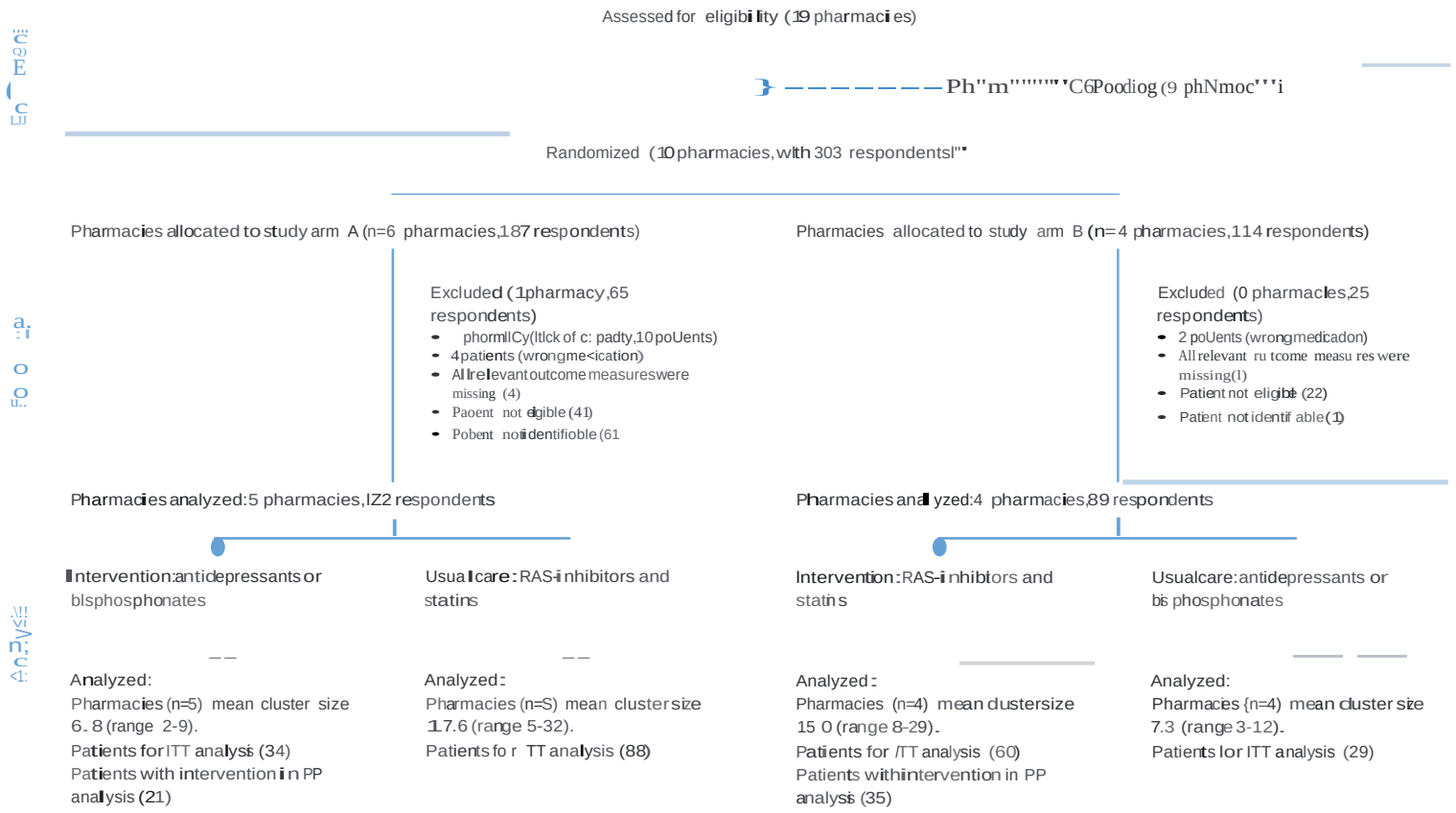

Table 1
Socio-demographic and medication characteristics of responding patients.

Characteristic	Usual care arm n•117	Intervention arm		
		'Eiigible' patients (IIT) n-94	'Patients with counseli ng' (PP) *n*•56	No counseling (n•38)
Age, mean [SD), years	622± 11.9	59.9± 13.5	62.8 ±12.1	55.7±14.4
Female gender,% (n)	62 (530%)	52 (55.3%)	30 (53.6%)	22 (57.9%)
Western ethnicity,% (n)	109 (93.2%)	84 (89.4%)	109 (93.2%)	35 (92.1%)
Respondents per medication class				
RAS-inhibitor	52 (44.4%)	30 (31.9%)	18 (32.1%)	12 (31.6%)
Antilipaemic	36 (30.8%)	30 (31.9%)	17 (30.4%)	13 (34.2%)
Bisphosphonate	16 (13.7%)	10 (10.6%)	8 (14.3%)	2 (5.3%)
Antidepressant	13 (11. 1%)	24 (25.5%)	13 (23.2%)	11 (28.9%)
Indication according to patient				
RAS-inhibitors primary prevention	36 (69.2%)	23 (76.7%)	15 (83.3%)	8 (66.7%)
Antilipaemic: primary prevention	25 (69.4%)	24 (800%)	13 (76.5%)	11 (84.6%)
Bisphosphonate: osteoporosis treatment	9 (562%)	6 (60. 0%)	4 (50.0%)	2 (100%)
Antidepressant: depression	8 (61.5%)	15 (62.5%)	8 (61.5%)	7 (63.6%)

Data are presented as mean ± SD, *n* (%).
Bold: $p<0.05$ compared to usual care anm.

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Table 2
Effect of inteivention on patients' general satisfaction with counseling/pharmaceutical care in the first three months.

Question asl<ed:"Did a pharmacist or pharmacy-ernployee…	Proportion ofrespondents with positive answer %(n/N)			Adjusted effect size• OR (95% Cl)	
	Usual care arm	'Eiigible' patients (!TT)	Patients with counseling (PP)	'Eiigible' patients (ITT)	Patients with counseling (PP)
Overall					
… ask you about your experiences with *the* medication?	15.6 (17/109)	32.2 (29/90)	**48.1** (26/54)	2.54 (1.21, 5.31)	5.47 (2.25, 13.3)
… ask you if you suffered from any side effects?	**10.1** (11/109)	29.2 (26/89)	43.4 (23/53)	3.62 (1.90, 6.89)	7.41 (373, 147)
… provide enough personaf counseling?	17.6 (19/108)	27.6 (24/87)	40.4 (21/52)	**1.76** (1.13, 2.74)	**3.09** (1.77, 5.39)
… ask you if you manage to take your medication as prescribed?	19.4 (21/108)	34.1 (30/88)	45.3 (24/53)	2.33 (1.38, 3.94)	3.76 (1.76, 8.01)
Patient responded positive on at least one item	30.6 (33/108)	**47.1** (40/85)	62.7 (32/51)	2.16 (1.32, 3.56)	**4.21** (1.81, 9.83)
Women					
… ask you about your experiences with *the* medication?	25.4 (15/59)	28.0 (14/50)	50.0 (13/26)	1.19 (0.50, 2.84)	2.87 (1.14, 7.20)
… ask you if you suffered from any side effects?	16.9 (10/59)	26.5 (13/49)	46.2 (12/26)	1.69 (0.97, 2.94)	**3.60** (1.79, 7.25)
… provide enough personaf counseling?	18.6 (11/59)	18.8 (9/48)	50.0 (13/26)	1.02 (0.44, 238)	2.13 (0.87, 5.19)
… ask you if you manage to take your medication as prescribed?	**27.1** (16/59)	30.6 (14/49)	50.0 (13/26)	1.34 (0.71, 255)	2.17 (0.70, 6.70)
Men					
… ask you about your experiences with *the* medication?	4.0 (2/50)	37.5 (15/40)	46.4 (13/28)	14.6 (3.48, 61.7)	28.5 (6.21, 130)
… ask you if you suffered from any side effects?	2.0 (1/50)	32.5 (13/40)	40.7 (11/27)	**25.1** (431, 146.6)	**47.6** (7.99, 283)
… provide enough personaf counseling?	16.3 (8/49)	38.5 (15/39)	30.8 (8/26)	3.06 (1.18, 7.94)	5.22 (1.69, 16.1)
… ask you if you manage to take your medication as prescribed?	10.2 (5/49)	38.5 (15/39)	40.7 (11/27)	**5.41** (1.78, 16.4)	8.74 (2.57, 297)

Bold: $p<0.05$ compared to usual care arm.

• Effectsize adjusted for age, gender, medication class.Odds ratio(OR) with 95% confidence interval for the difference in outcome values between the intervention arm and usual care arm.The likelihood of experiencing counseling is bigger (OR > 1) or smaller (OR < I) for parlidpants in the intervention arm compared with participantsin the usual care arm.

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Table 3
Effect of intervention on patients'satisfaction with information about medicines.

"Piease rare the information you have received about each of the following aspects of your medicines."	Proportion patients answering 'about right' % (n/N)			Adjusted effect size OR (95% Cl)"	
	Usual care arm	'Eiigible' patients (fiT)	Patients with counseling (PP)	"Eiigible" patients (ITT)	Patients with coun seling (PP)
Overall					
How long it will take to act.	41.5 (44/106)	51.6 (47/91)	55.6 (30/54)	1.33 (0.88, 1.99)	**1.64 (1.03, 2.61)**
How you can teil if it is working.	36.9 (38/103)	41.9 (36/86)	46.0 (23/50)	1.24 (0.87, 1.78)	**1.58 (1.09, 2.29)**
How long you wiJl need tobeon your medicine.	30.5 (32/105)	40.0 (34/85)	48.0 (24/50)	1.34 (0.71, 2.53)	**2.17 (1.06, 4.46)**
How to get a further supply.	42.9 (45/105)	53.5 (46/86)	58.0 (29/50)	1.59 (0.93, 2.70)	**2.06 (1.26, 3.38)**
Whether the medicine has any unwanted effects (side effects)	31.8 (34/107)	38.6 (34/88)	44.2 (23/52)	1.12 (0.76, 1.65)	1.57 (0.97, 2.54)
What are the risks of you getting side effects	46.2 (48/104)	44.8 (39/87)	49.0 (25/51)	.87 (0.51, 1.48)	1.08 (0.59, 2.00)
What you should do if you experience unwanted side effects	42.9 (45/105)	*432* (38/88)	46.2 (24/52)	0.88 (0.48, 1.62)	1.07 (0.60, 1.92)
Whether the medicine interferes withother medicines.	27.4 (29/106)	34.5 (30/87)	41.2 (21/51)	1.20 (072, 2.00)	1.82 (0.94, 3.52)
What you should do if you forget to take a dose.	29.5 (31/10S)	34.1 (30/88)	44.2 (23/52)	1.15 (0.65, 2.04)	1.76 (0.90, 3.44)
Women					
How long it will take to act.	49.1 (28/57)	46.0 (23/50)	53.6 (15/28)	0.78 (0.40, 1.52)	0.97 (0.44, 2.15)
How you can teil if it is working.	46.4 (26/56)	34.8 (16/46)	40.0 (10/25)	0.64 (0.34, 1.21)	0.77 (0.33, 1.76)
How long you wiJl need to be on your medicine.	42.1 (24/57)	37.8 (17/45)	48.0 (12/25)	.76 (0.40, 1.41)	1.15 (0.53, 2.47)
How to get a further supply.	47.4 (27/57)	50.0 (23/46)	56.0 (14/25)	1.04 (0.43, 2.53)	1.44 (0.52, 4.01)
Whether the medicine has any unwanted effects (side effects)	39.7 (23/58)	27.7 (13/47)	30.8 (8/26)	**0.42 (0.20, 0.85)**	.57 (0.27, *121*)
What are the risks of you getting side effects	58.6 (34/58)	43.5 (20/46)	48.0 (12/25)	0.48 (0.27, 0.85)	.55 (.26. 1.16)
What you should do if you experience unwanted side effects	56.1 (32/57)	**362(17/47)**	38.5 (10/26)	**0.38 (0.23, 0.63)**	**0.39 (0.22, 0.69)**
Whether the medicine interferes withother medicines.	36.2 (21/58)	25.5 (12/47)	30.8 (8/26)	**0.49 (0.33, 0.73)**	.65 (32, I.35)
What you should do if you forget to take a dose.	36.2 (21/58)	19.1 (9/47)	26.9 (7/26)	**0.32 (0.17, 0.62)**	0.47 (0.20, 1.09)
Men					
How long it will take to act.	32.7 (16/49)	58.5 (24/41)	57.7 (15/26)	**2.86 (1.04, 7.90)**	3.30 (0.83, 13.I)
How you can teil if it is working.	25.5 (12/47)	50.0 (20/40)	52.0 (13/25)	**3.02 (1.42, 6.45)**	**4.44 (123, 16.1)**
How long you wiJl need tobeon your medicine.	**16.7 (8/48)**	42.5 (17/40)	48.0 (12/25)	3.34 (0.86, 13.02)	**7.46 (1.14, 48.9)**
How to get a further supply.	37.5 (18/48)	57.5 (23/40)	60.0 (I5/25)	**2.55 (1.15, 5.66)**	**2.85 (1.12, 7.27)**
Whether the medicine has any unwanted effects (side effects)	22.4 (II/49)	512 (21/41)	57.7 (15/26)	**3.52 (1.82, 6.82)**	**6.96 (4.17, 11.6)**
What are the risks of you getting side effects	30.4 (14/46)	46.3 (19/41)	50.0 (13/26)	1.79 (0.80. 4.01)	2.36 (0.86, 6.48)
What you should do if you experience unwanted side effects	27.1 (13/48)	*512* (21/41)	53.8 (I4/26)	2.79 (0.74, 10.5)	**4.73 (1.05, 21.3)**
Whether the medicine interferes withother medicines.	16.7 (8/48)	45.0 (18/40)	16.7 (8/48)	**4.01 (1.41, 11.4)**	**7.92 (1.80, 34.9)**
What you should do if you forget to take a dose.	21.3 (I0/47)	512 (21 /41)	21.3 (10/47)	**396 (1.64, 9.58)**	**791 (2.80, 22.31)**

Bold: $p < 0.05$ compared to usual care arm.

• Effect size is the odds ratio (OR) with 95% confidence interval for the difference in outcome values between the intervention arm and usual care arm and is adjusted for gender, medication class and age.Usual care arm is reference category.OR:likelihood of being satisfied with information ('about right') is smaller (OR < 1)or bigger (OR > I) for partleipants in the intervention arm compared to partielpants in the usual care arm.

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Table 4
Effects of intervention on beliefs about medication.

Measures Beliefs about medicines	Average score•			Adjusted effect size (95% *Cl f*	
	Usual care arm	'Eiigible' patients (ITT)	Patients with counseling (PP)	'Eiigible' patients (ITf)	Patients with counseling (PP)
Overall					
BMQspecific necessity (5–25)b	13.1 (3.6)	13.4 (3.9)	13.6 (3.7)	0.55 (–1.15, 2.25)	0.52 (–1.48, 2.52)
BMQspecific concerns (5–25)b	13.5 (36)	12.8 (4.0)	12.4 (3.4)	-0.57 (–124, 0.10)	**–126 (–250, –0.02)**
BMQdifferential (–20 to +20)<	–0.35 (4.5)	0.60 (4.4)	12 (3.9)	1.02 (–1.14, 3.18)	**1.65 (0.08, 3.23)**
Women					
BMQspecific necessity (5–25)b	12.8 (3.7)	13.0 (4.0)	13.6 (0.36)	0.41 (–1.73, –2.54)	0.76 (–2.72, 4.24)
BMQspecific concerns (5–25)b	12.6 (3.6)	12.9 (4.4)	12.6 (3.5)	0.48 (–1.11, 2.06)	–0.08 (–1.84, 2.01)
BMQdifferential (-20 to +20) <	0.1 (4.5)	0.1 (4.5)	1.0 (4.3)	0.02 (-2.85, 2.289)	0.91 (–2.05, 3.87)
Men					
BMQspecific necessity (5–25)b	13.4 (3.5)	14.0 (3.8)	13.6 (3.5)	0.53 (–159, 2.64)	0.07 (–1.87, 2.01)
BMQspecific concerns (5–25)b	14.6 (3.3)	12.8 (3.4)	12.2 (3.3)	**–1.84 (–3.39, –0.30)**	**–258 (–424, –0.92)**
BMQdifferential (–20 to +20)<	-0.9 (4.5)	1.2 (4.2)	1.4 (3.6)	2.09 (–0.19, 4.36)	2.41 (-0.36, 5.18)

Bold: *P* <0.05 compared to usual care arm.
• Descriptive data are means (SDPer parient a score on both the necessity scale and concerns scale are assessed (with a range from 5 to 25).
b Higher scores indicate stronger necessity beliefs or more concerns.
< *Scores* >0 means that necessity beliefs are stronger than concerns beliefs. Score <0 means the opposite.
d Effect size is the regression coefficient with 95% confidence interval for the difference in outcome values between the intervention arm1and usual care arm. Effect size is adjusted for medicadon class, gender and age.

Table 5
Effects of intervention on beliefs about medication, expressed as attitudinal groups.

Attitudinal group	Proportion of patients (n)		Adjusted effect size (Cl 95%}'	
	Usual care arm	Eligible' patiellts (ITI)	'Eiigible' patiellts (ITf)	Patients with counseli ng (PP)
Skeptical (necessity < 15, concerns 15)	21.2% (22)	11.0% (9)	0.61 (0.30, 1.25)	**0.54 (0.33, 0.89)**
Ambivalent (necessiry 15, concerns 15)	21.2% (22)	26.8% (22)	3.14 (0.82, 12.6)	2.31 (0.44, 120)
Indifferent (necessity < 15, concerns < 15)	41.3% (43)	45.1% (37)	0.84 (059, 1.18)	0.96 (0.45, 2.06)
Accepting (necessiry15, concerns < 15)	16.3% (17)	17.1% (14)	1.53 (0.61. 3.83)	1.59 (059, 433)

Bold: p <0.05 compared to usual care arm.
• Effect size is the odds ratio (OR) with 95% confidence interval for the difference in outcome values between d1e intervention arm and usual care arm and is adjusted for gender, medication class and age. Usual care arm is referencecategory.OR: likelihood of being for example 'skeptical' is smaller (OR < 1) or bigger (OR > 1) for participantsin the intervention arm in comparison with participants in the usual care arm.