Self-medication of common cold symptoms with Katimun®: a non interventional feasibility study in community pharmacies

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BACKGROUND & OBJECTIVES

The aim of this pilot study was to evaluate methodological issues of non interventional studies in community pharmacies. Self-medication of common cold symptoms with Katimun® was used as a model because of the mild and self-limiting character of this illness.[1] Moreover, common cold is often self-diagnosed and self-treated with pharmacy-only medicines including herbal remedies or homoeopathics. Therefore, this study also focused on experienced common cold symptoms and the usage patterns of the homoeopathic drug Katimun®.

Table 1. Baseline characteristics of the participants

Participants (total)	64 (100%)
Sex (females)	49 (77%)
Age (range)	44 (18–78) years
BMI (range)	25 (17–38) kg/m²
First time use	49 (77%)
Employment status	
Employed	50 (78%)
Unemployed	13 (20%)
Missing	1 (2%)
Frequency of common cold (last six months)	
No symptoms	22 (34%)
Once	22 (34%)
Twice	11 (17%)
Three times and more	9 (14%)
Duration of symptoms before Katimun® intake	
One day	23 (36%)
Two or three days	28 (44%)
Four days or more	13 (20%)
Patients with additional cold medication	25 (40%)

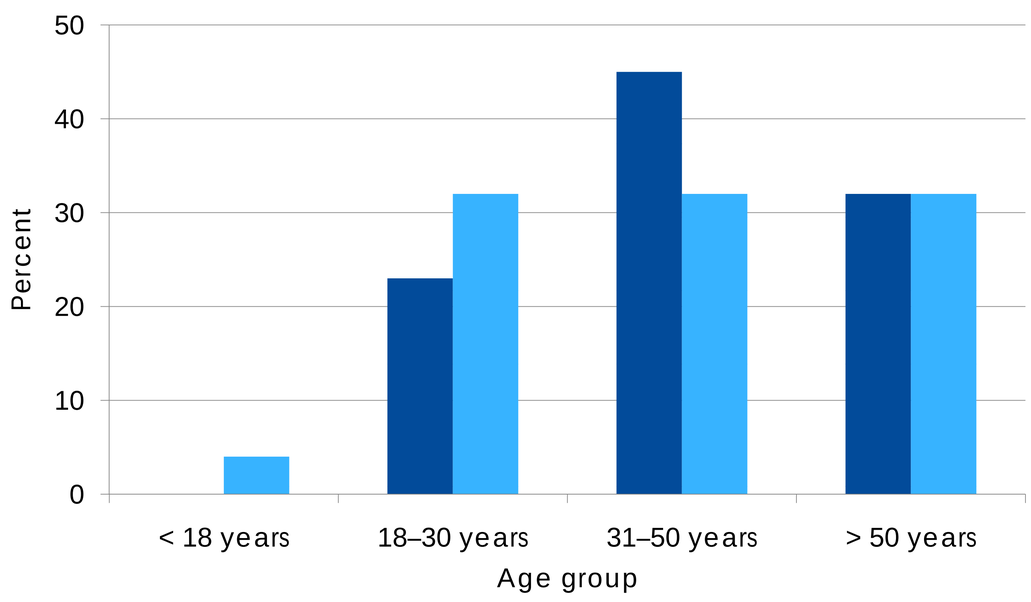

Figure 1. Age distribution (relative frequency), comparison of participants (dark blue, n = 64) and non-participants (light blue, n = 28)

METHODS

A trained network of community pharmacies (n = 14) recruited participants from customers, after they had purchased Katimun® for common cold symptoms. Participants were asked to complete a self-administered questionnaire before and after the medication. In order to estimate whether participants differ from non-participants, pharmacy staff kept a record of some characteristics (age, gender, etc.) in a logbook.[2] All data were collected in an anonymous way. Within the study recommendations of the Federal Institute for Drugs and Medical Devices were adopted.[3] Except the intake of antibiotics no inclusion or exclusion criteria were defined. The statistical analysis was descriptive due to the design as an open study under "real life" conditions. Data processing and calculations were performed using the software program SPSS Statistics 17.

RESULTS

Sixty-four participants were recruited in the pilot study, with each pharmacy recruiting an average of four customers (range 0–22). The response rate was 27%. Socio-demographic data are presented in Table 1. The mean age was 44 years (±16). Altogether, 28 records of non-participants were kept in six pharmacies. In these records the majority of subjects were females (71%) too. The logbook showed the most common reasons for non-participation of customers: a lack of interest (7), insufficient time (6) and pharmacy staff did not ask for participation (6). The age distribution of non-participants in comparison with participants is shown in Fig. 1. Common cold symptoms patients expected to treat with Katimun® are shown in Fig 2. On average patients took Katimun® for 6 days (± 3.5) and 5 to 6 times a day (34%).

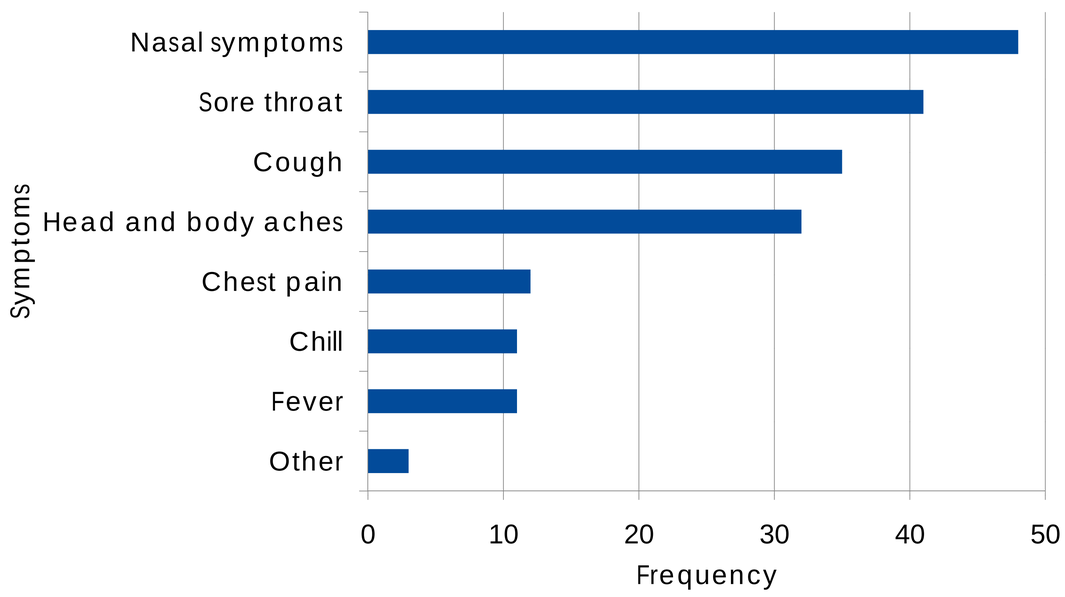

Figure 2. Patients' expectation of treated symptoms (absolute frequency)

DISCUSSION

The results of our pilot study show that the adoption of a logbook in a pharmacy based research project is feasible. Thus, data of non-participants are made available. However, the small number of cases in this study and the lack of control of logbook records allow no generally admitted statements. To validate and improve this method further research is necessary. The high proportion of females in our study correlates with other studies.[4,5] Although numerous returned questionnaires were carefully completed, the comparatively low response rate indicates that many customers may have not noticed the importance of participation.[5]

CONCLUSION

Pharmacy-based non interventional studies of OTC drugs are feasible and useful. They provide further information on usage patterns and appropriateness of use. Special attention should be paid on benefits and weaknesses of such "real world studies" including the careful interpretation of study results. Moreover, the use of a logbook contributes to a better understanding of sample representativeness and reliability of study results.

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