Patient reported complaints as an inducement for interventions in medication reviews: the PROMISE randomised controlled trial

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Background Healthcare professionals mainly focus on potentially serious symptoms and tend to ignore common ones. However also less threatening symptoms may have a substantial impact on the quality of patients' live. As a suitable instrument was lacking, a questionnaire ?Patient Reported Outcome Measure, Inquiry into Side Effects? (PROMISE) was developed to collect information on patient reported symptoms.

Purpose To determine whether PROMISE was useful to assist patients in preparing themselves for a clinical medication review (CMR) and to facilitate pharmacists in reducing drug related symptoms.

Method A randomized clinical trial in 15 community pharmacies in the Netherlands was conducted between January and June 2016. Patients with written informed consent were randomised into an intervention group (IG) and a control group (CG). Outcomes were measured with PROMISE as well at study start as at follow up after three months. IG patients received a CMR at study start, CG patients had usual care until follow up. Patients could report all symptoms experienced during the last four weeks for 22 predefined symptoms in PROMISE and indicate whether they assumed these symptoms to be associated with their drugs in use as patient reported drug-associated symptoms (PRDAS). Number of PRDAS in IG and CG patients at follow up were compared with a negative-binomial log linear regression model, adjusted for age, sex and number of drugs in chronic use.

Findings Complete data of 78 IG and 67 CG patients were available. At study start IG patients reported on average 5.8 symptoms, 5.1 as PRDAS, CG patients 6.0 symptoms and 4.8 PRDAS. 56 (72 %) IG patients and 51 (76 %) CG patients reported at least one PRDAS at follow up, with an odds ratio of 0.85 (95 % CI 0.38-1.88) for persisting PRDAS between the groups. Most frequently persisting PRDAS in the IG were ?muscle pain? (52%, 17 of 33 patients with persisting symptoms), ?dry mouth, thirst ( 63 %, 20 of 32), and ?weakness, tiredness? (59 % , 17 of 29) and in the CG: ?weakness, tiredness? (56 %, 15 of 27), ?bruises, bleedings? (65 %,17 of 26), ?skin complaints (50 %,12 of 24), and flatulence (38 % of 24 patients).

Conclusion PROMISE aided patients to report various common symptoms and discuss PRDAS with their pharmacists. However, no difference was seen for the number of PRDAS at follow up compared to usual care. Further research is needed on how to enable pharmacists to deal with PRDAS.