Effectiveness of a tailored intervention to improve medication adherence

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29062

Source
NTR

Brief title
BOMM (In Dutch: Begeleiding Op Maat bij Medicatie; in English: tailored adherence support)

Health condition

Medication adherence; cardiovascular disease; diabetes.
In Dutch: therapietrouw; cardiovasculaire aandoeningen; diabetes

Sponsors and support

Primary sponsor: IQ healthcare (Radboudumc), Philips Research, DOH care group
Source(s) of monetary or material Support: Philips

Intervention

Outcome measures

Primary outcome

The difference in percentage of patients with an initial high risk of non adherence) with a percentage of days covered (PDC) by medication dispensed in community pharmacies of at least 80% between the intervention and control group, at follow-up at 8 months

Secondary outcome

1) the difference in percentage of patients with a score of at least 13 on the Probabilistic Medication Adherence Scale (ProMAS) at follow-up between the intervention and control group;

2) the difference in the ProMAS score at follow-up between intervention and control group as a continuous measure;

3) the positive predictive values of the ProMAS score and the ACE profile measured at baseline in relation to medication adherence at 8 months follow-up;

4) PDC in subgroup of patients with a follow-up period of at least one year after the initial drug dispense.

Study description

Background summary

Adherence to chronic medication is problematic in clinical practice and leads to poor disease control with a burden on patients' quality of life and health care systems. Research shows that about 50% of patients with a chronic condition are not adherent, with estimates ranging from 17 to 80% adherence. Especially drugs for asymptomatic chronic conditions are found to have low adherence rates. In several studies, non adherence was shown to be highest in the first year after start with chronic medication. Consequently, interventions to warrant good compliance are most efficient at drug initiation.

The multifaceted nature of the adherence problem illustrates that improving adherence is complex and needs interventions tailored to the individual patient. Possible interventions can be distinguished to focus more on perceptual barriers (intentional non-adherence) or on practical barriers (non-intentional non-adherence), with different options for interventions and different involvement of primary health care providers. As at start of therapy the future drug use by prescribing or dispensing patterns is not known, a predictive tool is needed to assign a patient to one of the main intervention lines. Furthermore to implement interventions in primary health care in an effective and efficient way so that they become part of usual care, a good cooperation between pharmacists and technicians on the one hand and General Practitioners (GPs) and practice nurses and assistants on the other hand is needed.

Philips Research and the University of technology in Eindhoven developed the Probabilistic Medication Adherence Scale (ProMAS), which is an 18-item questionnaire to assess actual non-adherence behaviour. In parallel, Philips Research developed the Adherence Control Engine (ACE), a questionnaire with 23 questions that assess the underlying causes of non-adherence. The result of ACE provides insight into perceptual and practical barriers that may

hamper a patient's adherence. Such an insight can support care professionals in selecting the appropriate intervention set. Consequently, in patients starting chronic medication and at high risk for non-adherence as assessed by PROMAS a subsequent ACE outcome could be used to assign them to an intervention strategy to overcome perceptual or practical barriers. Taken together, this study aims to assess the effectiveness of combined use of ProMAS and ACE in starters with cardiovascular or oral blood glucose lowering medication in improvement of medication adherence. Moreover, since an explicit tailored adherence intervention is not yet implemented in the primary care group context, a second main objective is to develop the implementation strategy such that it can run in a manner acceptable to all stakeholders in the health care collaborative (being pharmacists, general practitioners and patients).

Study objective

Patients receiving the intervention (testing for risk for non-adherence and offering a tailored intervention based on the patient's ACE profile when at high risk for non-adherence) will be more adherent compared to patients who will not receive the intervention

Study design

baseline measurement and 8-months follow-up

Intervention

In the pharmacy, the pharmacist will intervene at the moment of the second dispense when an intervention is appropriate. In the intervention pharmacies for patients with a risk for non-adherence, the Adherence Control Engine (ACE) questionnaire will be used as a systematic decision support tool to tailor interventions based on the patient's ACE profile that identifies potential perceptual (intentional non-adherence) and practical (unintentional non-adherence) barriers. Depending on the nature of the barriers, an intervention strategy is chosen.
All interventions start with a discussion of the ACE results in a manner that makes use of the patient-centered techniques. When perceptual barriers (e.g. concerns, motivational issues, fear of side effects) appear to exist for the specific patient, the pharmacist discusses the relevant issues in the ACE profile using the patient-centered communication techniques and aims to take away or diminish the perceptual barriers. In addition to the conversation, self-assessment of clinical measures will be proposed, since these have been shown to increase medication adherence. When agreed by the patient, these will be initiated in the pharmacy. When practical barriers appear to be the most important barriers for the specific patient, the pharmacist offers one of several practical solutions, e.g. pill organizer, use of a Baxter system, reminders, seek the help of the patient's social network, simplification of dosage scheme. The pharmacist monitors the result of the intervention.

Contacts

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Eligibility criteria

Inclusion criteria

All patients listed in participating pharmacies are included that start with cardiovascular or oral blood glucose lowering medication (no prior dispensing of the same substance during the prior 12 months) during study period. Medication is on a prescription of a GP who is a member of primary care cooperation De Ondernemende Huisarts (DOH) or The Innovative General Practitioner. Furthermore, patients need to give informed consent and also their pharmacist needs to give informed consent that the pharmacy dispense data of his/her patients will be used for this research

Exclusion criteria

Participants that are not considered eligible for participation by the pharmacist due to an inability to provide informed consent will not be invited for participation in the study. Also, when the pharmacist considers participation a too high burden for the specific patient under consideration or doubts the appropriateness of the patient for any other reason, the patient is not invited for the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	6250
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-05-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5055
NTR-old	NTR5186
Other	CMO regio Arnhem-Nijmegen : 2015-1604

Study results

Summary results
none yet