Effects of telephone counseling intervention by pharmacist on medication adherence for patients starting treatment: A cluster randomized controlled trial.

No registrations found.

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

Summary

ID

NL-OMON24491

Source
Nationaal Trial Register

Brief title
TelCIP

Health condition

compliance, adherence, persistence, statins, bisphosphonates, antidepressants, RAS-inhibitors, BMQ, beliefs, SIMS

Sponsors and support

Primary sponsor: Utrecht Institute for Pharmaceutical Sciences
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

The primary outcomes measured are taking-compliance measured over 365 days and the occurrence of complete discontinuation. Taking-compliance will be based on refill data and will be expressed as Proportion of days covered over a period of 365 days (12 months PDC). Differences in median proportion of days covered will be tested using the non-parametric Mann Whitney U test and the percentage of adherent patients between groups will be analyzed with χ2-test. Complete discontinuation will be defined as exceeding the permissible gap of 90 days within the one year observation period. Cox-proportional hazards will be used to compare discontinuation between intervention and control patients.

Secondary outcome

The occurence of early discontinuation after 3 and 6 months. Score on the Beliefs about Medicines Questionnaire (BMQ) and Satisfaction with Information about Medicines Scale (SIMS) after 3 months.

Study description

Background summary

N/A

Study objective

Prescription of medication is the most common intervention in health care. Adherence to medication is often low. Non-adherence to long-term therapies severely compromises the effectiveness of treatment and thereby is a critical issue from both the perspective of quality of life of individual patients and from a public health perspective. Interventions aimed at improving adherence could increase both the effectiveness of medication and prevent the occurrence of adverse health outcomes. Counselling by telephone is a promising intervention to deliver patient-tailored care. In this study the effects of a counselling call at the start of the therapy will be investigated.

Study design

Compliance and persistence will be assessed 12 months after the start of the therapie. Beliefs (BMQ) and satisfaction (SIMS) will be assessed 3 months after the start.

Intervention

A trained pharmacist or pharmacy technician calls patients by between 1 and 3 weeks after the start of therapy. The main purpose of this call is to evaluate the first two weeks, to explore factors that can negatively influence therapy, like drug related problems, beliefs or attitudes.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age over 18 years;

2. In posession of telephone;

3. Responsible for medication taking;

4. Receiving a first prescription in 12 months for a statin (C10), RAS-inhibitor (C09), Bisphosphonate (M05B) or antidepressant (N06A).

Exclusion criteria

1. Life expectancy of less than 6 months;

2. Receiving medication weekly (e.g. automated dispensing);

3. Not speaking the language of the pharmacist;

4. Not having a telephone.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2011
Enrollment:	4400
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-01-2012
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	NL3089
NTR-old	NTR3237
Other	Institutional Review Board (IRB) : UP1019
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A