The effect of hospital-initiated and patient-initiated intensive follow-up on medication adherence in patients with chronic pain: a randomized controlled clinical trial.

Published: 29-09-2014
Last updated: 21-04-2024

The primary objective is to evaluate the effect of hospital-initiated and patient-initiated intensive follow-up on medication adherence in patients with chronic neuropathic pain.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40973

Source
ToetsingOnline

Brief title
The effect of Intensive follow-up on medication use - PAINTHER2

Condition

- Other condition

Synonym
chronic pain

Health condition

chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic pain, follow up, medication use

Outcome measures

Primary outcome

Medication adherence after 11 weeks, assessed by a combination of selfreport

and the Morisky Medication Adherence Scale (MMAS-8).

Secondary outcome

The effect of intensive hospital follow up or patient-initiated follow-up on:

- Pain intensity (NRS)

- Health perception (SF-36)

- Patient satisfaction (1-10)

- Health care costs

Study description

Background summary

A lack of adherence is a common problem in patients with chronic non-malignant pain. Determinants of adherence in chronic pain populations include the physician-patient relationship, age, polypharmacy, mental disorders, knowledge of the prescription, and attitudes and concerns towards medication use.

No interventions were described that promote medication adherence. It is assumed that 'shared decision making', good information and clear agreements on follow-up facilitate medication adherence. In rheumatoid arthritis patients the

value of patient-initiated follow-up compared to fixed appointments at the hospital was investigated. In this study, patients themselves determined the follow-up frequency. This resulted in an improved satisfaction and lower health care costs. Compliance was not assessed. Long-term outcome of patient-initiated care was at least as good as hospital-initiated care. Patient initiated care resulted in lower healthcare costs.
Pharmacological pain therapy consists of initiation of a prescription, and follow-up afer a few weeks to evaluate the therapy. An intensive follow-up regimen at the beginning of the therapy result in the possibility to adress questions and side effects at an earlier stage. By earlier adjusting pain therapy when needed less time is lost. More frequent follow-up may further improve the doctor-patient relationship, which is an independant predictor for medication adherence on its' own.

Study objective

The primary objective is to evaluate the effect of hospital-initiated and patient-initiated intensive follow-up on medication adherence in patients with chronic neuropathic pain.

Study design

A randomized controlled clinical trial

Intervention

- control group: standard care, follow-up after 6 and 12 weeks.
- hospital-initiated follow-up: standard care, additional follow-up by phone after 2,4,8 and 10 weeks.
- patient-initiated care: standard care, additional follow-up at request within 48 hours.

Study burden and risks

There are no risks associated with this research. One disadvantage is the time investment for patients while completing three questionnaires at home.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosed with chronic neuropathic pain (> 3 months) confirmed by DN4 questionnaire
- 18 years or older
- Able to complete an electronic questionnaire in the Dutch language at home

Exclusion criteria

- patient does not have email access
- patient is treated by primary investigator

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	29-09-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL49682.100.14