Feasibility and potential effectiveness of the primary care functioning scale in daily general practice

No registrations found.

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

Summary

ID

NL-OMON22135

Source
Nationaal Trial Register

Brief title
ICFPC

Health condition

patients with DM2, COPD and chronic cardiovascular diseases and the presence of at least one other chronic condition

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

perceived health and functioning measured by the primary care functioning scale (PCFS)

Secondary outcome

Experience and actions derived from the results of the PCFS will be explored during a 15-minutes interview with the patient by telephone.
Self-efficacy is evaluated by the General Self-Efficacy Scale. Expectations about the course and prognosis of the chronic disease will be assessed by the Illness Perception Questionnaire (IPQ-R). Course and outcome of performance indicators in DM2, COPD and heart failure care. For DM2 we will use the available assessments of HbA1c, blood pressure, cholesterol levels (LDL), renal functioning (eGFR) and body mass index (BMI). For COPD we will use
The available measurements of smoking behavior, and FEV1 and FVC measured by spirometry. In patients with heart failure we are interested in blood pressure, cholesterol levels (LDL), renal functioning (eGFR), and body mass index (BMI). These disease specific outcome measures, coming from routine control consultations, will be extracted from the electronic medical health record. Medical consumption is assessed a short questionnaire after 3 months. Patient satisfaction with the use of the PCFS and patient satisfaction with the feedback of the results of the PCFS will be rated on a 5-point Likert-type scale (extremes labelled as ‘not at all’ and ‘very much’).Baseline characteristics, such as age, gender, marital status, social economic status (employment and level of education), source of income, and working hours are already incorporated in the PCFS questionnaire.

Study description

Background summary

Background: Recent reports have put emphasis on the huge challenge to maintain the delivery of high quality primary care in an ageing society. In the older population, a growing number of individuals will suffer from multi-morbidity, polypharmacy, and frailty. Both from a patient and doctor’s perspective, the disease-oriented approach seems too limited and primary care may need a more person-centered approach, incorporating the consequences of multimorbidity. This would necessitate to focus more on aspects of health-related behavior and functioning. Recently, we have developed a generic tool on functioning for people with multiple and chronic conditions in primary care; the Primary Care Functioning Scale (PCFS). The PCFS is a self-administered questionnaire about the different aspects of functioning, such as body functions, activities and participation, environment, and personal factors. The PCFS questionnaire is a valid and reliable instrument for use in primary care to measure the different aspects of functioning in patients with chronic conditions and is promising and acceptable to professionals and patients.

Aim: The aim of the proposed study is to determine the feasibility of the PCFS instrument in daily primary care practice in patients with chronic conditions (when used both as a self-administered tool and as an aid in face-to-face contacts with practice nurses) and potential effectiveness on functioning in daily life in a cluster randomized controlled trial.

Study objective

In this pilot cluster randomized control trial, primary care practices will be randomized either into the professional-guided PCFS group (in which patients will be seen by the practice nurse during their regular scheduled consultation follow up of their chronic healthcare plan and a discussion of the results of the PCFS will be incorporated in this consultation) or into the self-guided PCFS group (in which patients will decide themselves whether to incorporate a discussion of the results of the PCFS in their regular scheduled consultation follow up of their chronic healthcare plan). We hypothesize that patients in de professional guided group will score better on perceived health and functioning, quality of life, self-efficacy and report less medical consumption compared to patients in the self-guided group.

Study design

Primary and secondary outcome measures will be measured at base line and after 3 months (questionnaires PCFS, General Self-Efficacy scale and IPQ-R). After 3 months we will also have a short qualittative interview by telephone (15 minutes) in which experiences and actions derived from the results of the PCFS will be explored. Disease specific outcome measures will be extracted from medical records after 3 months. Medical consumptions is assesed after 3 months. At least, patient satisfaction with the feedback of the results of the PCFS will be measured after 3 months

Intervention

Patients will be seen by the practice nurse during their regular scheduled consultation follow up of their chronic healthcare plan and a discussion of the results of the primary care functioning scale questionnaire will be incorporated in the consultation

Contacts

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Eligibility criteria

Inclusion criteria

Patients in primary care age 65 years or older with the inlcusion of two or more chronic medical conditions

Exclusion criteria

Patients who are terminal ill, receive palliative care, have severe psychiatric disorders (e.g. severe depression, psychosis) and patient who are not able to speak, read or write in Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-07-2020

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	NL8809
Other	METC Radboudumc : 2020-6747

Study results