Patient Centered Care through eHealth Solutions

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We hypothesize that implementation of eHealth with higher levels of personal assistance will result in increased use and thereby higher impact in terms of increased clinical benefits and increased well-being. We expect that these effects are...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21897

Bron
Nationaal Trial Register

Verkorte titel
eVita COPD

Aandoening

COPD

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Stichting Zorg Binnen Bereik

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

the primary objective of this study is to investigate clinical effects of different implementation methods of online supported self-management for COPD patients in primary care.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The number of patients in need of COPD management is increasing. Self-management may help to provide accessible health care but costs are high due to ineffective health care processes. Evidence based improvements of efficiency and quality in health care processes and in clinical outcomes have been reported for online automated monitoring systems (patient portals). However, sustainable realization in daily practice stays behind. Insights in optimal implementation methods in large real-life primary care populations are needed for successful integration in practice.

Objective: the main aim is to investigate clinical effects of different implementation methods of online supported self-management for COPD patients in primary care. Secondary objectives include effects on well-being, health care use and actual use of the portal. Differences in users' satisfaction will be investigated as tertiary goals. Patient characteristics will be investigated as determinants for actual use of the portal.

Study design: parallel cohort design. The clinical effects will be measured according to interrupted time series (ITS) design.

Study population: COPD patients according to GOLD criteria (post-bronchodilator FEV1/FVC<0.7) of 3 primary care cooperation's will be included (group A-B-C). In group A and B an online self-management program (patient portal) is integrated in the care process of professionals (fixed use). In group C the self-management program is not integrated in the care process (free use). To be able to measure significant differences in health status (>0.4 point according to the CCQ) at 80% power and á = 0.05, 112 patients must be included per setting. Based on an estimated 20% drop-out during the study, 140 (112/0.80) patients are necessary to achieve sufficient statistical power. Because patients in group A and B are randomized in subgroups with different levels of personal assistance for implementation of the portal, 224 patients (112*2) are needed per setting Therefore, a total of 700 (280+280+140) COPD patients will be included in this study.

Intervention: participants who wish to start with self-management will be supported with an online platform in group A and B, called eVita COPD patient platform. This platform enables

patients to manage their own health and disease. The COPD platform is integrated in a patient platform (eVita platform) for chronic diseases (diabetes, heart failure and COPD) that is developed by health care professionals, ICT professionals and (COPD) patients. Patients in group A and B will be randomly divided in 2 subgroups after inclusion. Patients in subgroup A1 and B1 will be individually supported to use the online patient portal by an account manager in face-to-face (A1) or telephone contacts (B1). Subgroups A2 and B2 will not receive additional support from an account manager. For COPD patients in group C a more simple portal will be provided by Saltro Diagnostic Centre, with basic information of COPD and individualized test results.

Main study parameters/endpoints: the primary objective of this study is to investigate clinical effects of different implementation methods of online supported self-management for COPD patients in primary care. The secondary objectives are to investigate the effects of different implementation methods on well-being, health care use and actual use of the online patient portal.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: the General Practitioners in the three primary care cooperations in this study provide COPD care since many decades. The care programs are grounded on evidence based national guidelines and have received objective quality labels. Professionals of the primary care cooperations are in control of the safety of all patients on daily base: deviations in CCQ, medication or other determinants are automatically and daily sent to the professionals to guarantee safety of all patients. Comparable self-management programs are broadly accepted and being used by other professionals without report of adverse events, despite lack of evidence based support.

For research goals, patients are asked to fill in questionnaires every three months during a period of 15 months. The questionnaires will be provided online and take between 10-20 minutes to complete. After replying the first and last set of questionnaires, participants will receive gift cards (€30 in total) as a reward. This study is important as current care processes can be improved in favor of patients by its results.

Patients who do not wish to start with self-management continue to receive regular care. Participants are free to withdraw from the study any moment without specification of reasons. This will not affect continuity of care. Furthermore, professionals within the cooperations can decide to withdraw subjects from the study for urgent medical reasons.

Doel van het onderzoek

We hypothesize that implementation of eHealth with higher levels of personal assistance will result in increased use and thereby higher impact in terms of increased clinical benefits and increased well-being. We expect that these effects are influenced by demographic, (psycho)social characteristics and characteristics of the health care cooperation of the GP is member of. With respect to the latter we expect that higher levels of integration of the online portal in the care process will result in higher usage of the portal.

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- primary care COPD-patients with chronic respiratory symptoms and post-bronchodilator FEV1/FVC<0.7, in accordance with the international GOLD-classification 30 and the Dutch GPs COPD Guidelines .

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- patients who are unable to fill in questionnaires

- patients that have no access to internet

- patients with terminal illness

- severe immobile patients

- patients with severe substance abuse

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2013
Aantal proefpersonen:	700
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-07-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3936
NTR-old	NTR4098
Ander register	METC LUMC : P13.098
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A