PORTALS.

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Implementation of online patient portals with higher levels of personal assistance will result in increased use and increase impact of the portals on clinical benefits and well-being.

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

Samenvatting

ID

NL-OMON28251

Bron
Nationaal Trial Register

Verkorte titel
PORTALS

Aandoening

Thrombosis

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center
department Public Health and Primary Care (PHPC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical effects expressed in blood clotting speed (Time in Therapeutic Range; TTR).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The number of patients in need of thrombosis 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 thrombosis 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 study.

Study population: In this study two different implementation methods will be compared, each conducted in a separate research group of patients who are willing to start with self-management. Additionally, a third research group will be included, existing of non-self-management participants who wish to continue regular care. For significant differences in TTR (Time in Therapeutic Range) (>3.5%) at power 80% and $\alpha = 0.05$, 142 patients must be included per group. Taking into account 20% drop out,5 178 (142/0.80) patients are needed per study group. Hence, three research groups of 178 patients each will be included from the Saltro Thrombosis Service. All eligible patients currently receive regular Anticoagulation Care.

Intervention: participants who wish to start with self-management will be randomly selected in a study group for e-learning (group 1) or for face to face group training (group 2) or. Both groups will be trained in general knowledge on thrombosis, self testing, self dosage of medications (optional) and registration in and use of the online patient portal. Patients in the non-self-management group (group 3) receive regular care.

Main study parameters/endpoints: the main endpoint is clinical effects expressed in blood clotting speed (Time in Therapeutic Range; TTR); TTR is based on daily measurements. Second main endpoint is the number of thromboembolic events and bleedings, which is also based on daily reports.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Saltro Thrombosis Service provides Anticoagulation Care since 2000 and currently includes over 10,000 patients. Nowadays Saltro provides two types of care programs: regular care and self-management without online support. Both programs are grounded on evidence based national guidelines (FNT)12 and have received objective quality labels. Professionals of the Saltro Thrombosis Service Centre are in control of the safety of all patients on daily base: deviations in TTR, medication or other determinants are automatically and daily sent to the professionals to guarantee safety of all patients. Additionally, self-management patients are controlled two times a year for self-testing and self-dosage skills and for validation of the self-testing device. Comparable self-management programs are broadly accepted and being used by other Thrombosis Services without report of adverse events, despite lack of evidence based support.

In this study, the current self-management program will be extended with online support and - in study group 1- with e-learning. The e-learning implementation method will be compared with face-to-face group training (study group 2). E-learnings for thrombosis patients are being used with satisfaction by other Thrombosis Services. The group sessions are already of the current self-management program of Saltro Thrombosis Centre, as has been described above. Patients who wish to start with self-management but who do not want to participate in the study will be included in the group training sessions as well. Patients who do not wish to start with self-management continue to receive regular care and will be invited to participate in study group 3 for research purposes.

For research goals, patients are asked to fill in questionnaires every six months during a period of 1,5 years. 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 (€25,- and €50,-) as a reward. This study is important as current care processes can be improved in favor of patients by its results.

Participants are free to withdraw from the study any moment without specification of reasons. This will not affect continuity of care. Furthermore, specialists of the Saltro Thrombosis Service can decide to withdraw subjects from the e-learning group or the study for urgent medical reasons.

Doel van het onderzoek

Implementation of online patient portals with higher levels of personal assistance will result in increased use and increase impact of the portals on clinical benefits and well-being.

Onderzoeksopzet

For research goals, patients are asked to fill in questionnaires every six months during a period of 1,5 years.

Onderzoeksproduct en/of interventie

Participants who wish to start with self-management will be randomly selected in a study group for e-learning (group 1) or for face to face group training (group 2). Both groups will be trained in general knowledge on thrombosis, self testing, self dosage of medications (optional) and registration in and use of the online patient portal. Patients in the non-self-management group (group 3) receive regular care.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. At least 6 months usual care from the
Thrombosis Service;

2. In need of long-term Anticoagulant Therapy (>6 months);

3. Internet access.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients who already use self-management for thrombosis;

2. Instable patients according to judgment of physicians of the Thrombosis Service;

3. Patients who are unable to complete questionnaires;

4. Patients with terminal illness;

5. Patients with severe substance abuse;

6. No internet access.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2013
Aantal proefpersonen:	534

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-04-2013
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	NL3781
NTR-old	NTR3947
Ander register	ABR : 42467
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A