

# Portal implementation within anticoagulation care; amplification of selfmanagement.

Published: 31-01-2013

Last updated: 24-04-2024

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 well-being, health care use and actual use of the portal....

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Embolism and thrombosis
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON43686

### Source

ToetsingOnline

### Brief title

PORTALS

### Condition

- Embolism and thrombosis

### Synonym

bloodlump, thrombosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** anticoagulation therapy, implementation, portals, selfmanagement

## Outcome measures

### Primary outcome

Clinical effects:

1. blood clotting speed (INR) expressed as Time in Therapeutic Range (TTR)
2. number of thromboembolic events

### Secondary outcome

Secondary outcomes:

1. well being / quality of life
2. health care use
3. use of the portal

Tertiary outcomes

1. users' satisfaction
2. user profiles

## Study description

### Background summary

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 selfmanagement 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.

## **Study 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 well-being, health care use and actual use of the portal. Differences in user profiles and user satisfaction will be investigated as tertiary goals.

## **Study design**

This research will be performed using a parallel cohort study.

## **Intervention**

Participants who start with self-management will be randomly selected in a study group for face to face group training or in a study group for e-learning. 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 control group receive usual care.

## **Study burden and risks**

All patients will receive an online supported self-management program. Although not evidence based, this program is being used by other Thrombosis Services without report of adverse events. Included patients will be trained in self-management by e-learning or group sessions. E-learning for thrombosis patients are already used with satisfaction by several other Thrombosis Services. The group sessions are part of the current self-management program of Saltro Thrombosis Centre that has been provided since 2010 according to national guidelines and with objective quality label.

According to national quality standards, all patients act under daily supervision of specialists of the Thrombosis Centre to monitor deviations in clinical values. Additionally, they are controlled two times a year for self-testing and self-dosage skills and to validate the self-testing device. 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 as a reward. Furthermore, current care processes can be improved for patients by results of this study.

Patients who do not wish to start with self-management receive care as usual. They will be invited to participate in the control group for research purposes.

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. Professionals from the Saltro Thrombosis Service Centre can decide to withdraw a subject from the e-learning group or the study for urgent medical reasons.

## Contacts

### Public

Leids Universitair Medisch Centrum

Hippocratespad 21

Leiden 2333 RC

NL

### Scientific

Leids Universitair Medisch Centrum

Hippocratespad 21

Leiden 2333 RC

NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Under control for regular care by Saltro Thrombosis Service for at least the past 6 months

Longterm anticoagulant therapy

Stable clinical values for at least past 6 months

Internet acces (with exception of control group)

## Exclusion criteria

Less than six months regular support by Saltro Thrombosis Service  
Shortterm indication for anticoagulant therapy  
Instable clinical values during last 6 months  
No internet acces (with exception of control group)  
Inability to complete questionnaires  
Severe terminal illness, substance abuse or immobility

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL  
Recruitment status: Recruitment stopped

Start date (anticipated): 22-04-2013

Enrollment: 216

Type: Actual

## Ethics review

Approved WMO  
Date: 31-01-2013  
Application type: First submission  
Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO  
Date: 21-07-2015  
Application type: Amendment  
Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL42647.058.12

## Study results

Date completed:	02-01-2017
Actual enrolment:	247