He-move-philia, a combined lifestyle intervention program for patients with hemophilia and other congenital coagulation disorders

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON51600

Source
ToetsingOnline

Brief title
He-move-philia, lifestyle intervention for hemophilia

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Blood and lymphatic system disorders congenital

Synonym
bleeding diathesis, hemophilia

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: congenital bleeding disorders, hemophilia, lifestyle intervention, prevention

Outcome measures

Primary outcome

body weight

Secondary outcome

Abdominal circumference (cm)

Number of spontaneous bleeds

Number of induced bleeds

Units coagulation factor concentrate used/year (IU)

Blood-pressurre (mm Hg)

Cholesterol spectrum including: total cholesterol, triglycerides,

HDL-cholesterol, LDL-cholesterol (mmol/l), all in non-fasting state

Glucose (mmol/l) in non-fasting state

Haemophilia activities of daily life (HAL): total score

Shortened Fat List: total score

Study description

Background summary

The prevalence of overweight and obesity is increasing in patients with hemophilia and other bleeding disorders. In these patients physical activity is often difficult due to arthropathy as a result of intra-articular bleeding in

the past, with decreased joint movement and pain and the fear of new bleeds. This enhances weight gain, increases pressure on joints, leading to more bleeds and more arthropathy. In the long term overweight and obesity increases risk of cardiovascular diseases, with the concomitant need for anticoagulant therapy, which further enhances the bleeding risk in these patients

Study objective

The aim of this exploratory study is to compare the effect of a lifestyle intervention program consisting of combined individual coaching and group sessions (CLI) with a lifestyle intervention program with individual coaching only (II).The program is especially designed for patients with a bleeding disorder

Study design

an exploratory randomised controlled unblinded intervention study

Intervention

15 patients will receive a combined lifestyle intervention program with individual sessions and group sessions lasting for 2 years, the other 15 patients will receive individual sessions only and will be given the same information as given in the group sessions, but on paper.

Study burden and risks

The main burden is in the group visits (16 times in2 years) the risk of bleeding is very small:
- people with severe bleeding disorders use prophylactic coagulation factor treatment
- people are supervised in their activities by the physiotherapist of the hemophilia treatment center
- for physical activities personalized small goals are set by the patients together with the specialized physiotherapist.

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 hemophilia A, B, FVII deficiency, fibrinogen deficiency, von Willebrand Disease or other bleeding disorder preferably requiring coagulation products for prophylaxis or on demand in case of bleeding
- >= 18 years of age
- BMI >= 30 kg/m2
- Motivated to change their lifestyle

Exclusion criteria

- Health care insurance with ONVZ as this health insurance has no contract with Profitt Lifestylecoaching.
- A contraindication or inability for physical activity as judged by the treating hemophilia physician
- Participation in another research trial
- Unable to understand the written information

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	26-09-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-12-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL82228.091.22