

Lifestyle coaching in myeloproliferative illnesses

No registrations found.

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

Summary

ID

NL-OMON21768

Source

NTR

Brief title

TBA

Health condition

polycythaemia vera (PV), essential trombocytose (ET) en Primary myelofibrosis (PMF)

Sponsors and support

Primary sponsor: University Medical Centre Groningen, Martini Hospital Groningen

Source(s) of monetary or material Support: Martini Hospital

Intervention

Outcome measures

Primary outcome

fatigue (Multidimensional Fatigue Inventory), achieving personal goal(s) measured with a subscale of the EORTC QLQ-30

Secondary outcome

Study description

Background summary

myeloproliferative illnesses are also called myeloproliferative neoplasms (MPN). Patients often report fatigue and weight loss and suffer from splenomegaly. Because of its multi-dimensional approach, lifestyle coaching seems an applicable intervention to improve fatigue and quality of life in MPN patients. This intervention has not been studied previously in these patients.

The aim of this study is to determine the effect of lifestyle coaching on fatigue and quality of life in MPN patients. In this study, part of the MPN patient treated in the Martini Hospital will receive this intervention.

The study will be a randomised trial with a waiting list control group; half of the participants start immediately, and half of the participants start after six months.

The study population will comprise 46 MPN patients aged 18 years or older, who received the diagnosis MPN at least 12 months ago.

The interventions will be lifestyle coaching built on the model of positive health, in which the patient sets his/her own goals with respect to six dimensions. This trajectory consists of two phases: An active phase of three months with active support and treatment of a lifestyle coach. The lifestyle coach will provide personalised support to facilitate patient's behavioural changes that lead to improved lifestyle. The patient will be guided to set his own 'SMART' goals and consecutive actions. Secondly there will be a passive phase of 9 months, during which the patient can call the lifestyle coach for help without a pre-set programme initiated by the coach. During the whole trajectory, the coach uses techniques of 'motivational interviewing'.

Main study parameters/endpoints:

- Fatigue (MFI) measured after 3 and 12 months
- Achieving personal goals

Study objective

Lifestyle coaching will lead to reduced fatigue and improved quality of life

Study design

Both primary and secondary outcomes will be measured by validated questionnaires at 3 and 12 months follow-up. Follow up will be completed in all participants 2 years after starting the study, which will be in April 2022. In September 2022 data will be analysed and results presented.

Intervention

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

- ☐ Treated at the outpatient clinic in the Martini Hospital, diagnosed at least one year before informed consent.
- ☐ Aged 18 years or above

Exclusion criteria

- ☐ Insufficient capability to read or speak Dutch.
- ☐ Psychological or cognitive problems that make it impossible to provide informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	46
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	28-01-2021
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	NL9242
CCMO	NL75048.042.20

Study results