

Lifestyle coaching in myeloproliferative illnesses

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

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

Samenvatting

ID

NL-OMON21768

Bron

NTR

Verkorte titel

TBA

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Centre Groningen, Martini Hospital Groningen

Overige ondersteuning: Martini Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 a 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

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

lifestyle coaching

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek
Onderzoeksmodel: Cross-over

Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	46
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	28-01-2021
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	NL9242
CCMO	NL75048.042.20

Resultaten