Prediction model for multidisciplinary treatment

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22712

Source
NTR

Brief title
PREDICT

Health condition

Patients with persistent pain following the “movement with pain” program in Excellent Care Clinics Velsen Noord.

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam, Faculteit der Gedrags- en Bewegingswetenschappen Excellent Care Clinics
Source(s) of monetary or material Support: No

Intervention

Outcome measures

Primary outcome

Level of recovery measured with Global Perceived Effect Questionnaire and Disability measured with Pain disability index

Secondary outcome

Pain intensity
Depressive symptoms
Anxiety symptoms
Fear of movement
Illness beliefs
Quality of life
Self-efficacy
Inflammatory biomarkers
Mechanical sensitivity
Physical activity
Pain grade
Work status/functionality
Resilience
Treatment expectancy

Study description

Background summary

Chronic low back pain is the leading cause of disability worldwide. There is a large variety of treatment possibilities and up to 80% of the patients feels that the given treatment is inadequate. Multidisciplinary treatment using the bio-psychosocial model of pain, supervised by a medical specialist and adheres to the patients' needs is recommended for chronic pain patients. This research project aims to follow a cohort of 110 individuals with chronic pain following the Beweging Met Pijn Program at Excellent Care Clinics – Velsen-Noord. In line with the biopsychosocial model of pain, we will assess the pain characteristics, inflammatory response, lifestyle factors, and psychological factors of this cohort before, during, and after the multi-disciplinary treatment program. Our two main research questions are: How do patients following the "movement with pain" program recover? Which factors can predict recovery after following the "movement with pain" program?

Study objective

We expect the "movement with pain" program will result in a reduction in disability, improved perceived recovery, improvement of psychological wellbeing and increase in physical condition. Moreover, we expect that a combination of the amount of disability, psychological wellbeing, inflammatory biomarkers and mechanical sensitivity will predict treatment outcome at 6 and 12 months follow up.

Study design

Baseline, mid-treatment (8 weeks), end of treatment (16 weeks), follow-up (6 months after the end of treatment) and long-term follow-up (12 months after the end of treatment)

Intervention

Multi-disciplinary treatment program called: “Bewegen met pijn” (BMP), (movement with pain) offered by Excellent Care Clinics Velsen Noord. BMP is ~16-week program including 36 visits to the clinic that are 1 to 3.5 hours each in duration. Each program is individualized and tailored to suit the needs of the patient. The program includes graded physical exercise, psychological treatment, pain education, dietary advice, and modalities such as cryotherapy and whole-body electrostimulation are available.

Contacts

Public
Vrije Universiteit Amsterdam
Meghan Koop

+31 6 18768151
Scientific
Vrije Universiteit Amsterdam
Meghan Koop

+31 6 18768151

Eligibility criteria

Inclusion criteria

Consecutive patients will be included in Excellent Care Clinics Velsen Noord in The Netherlands. Potential patients will be eligible for participation if they are: 1) at least 18 years of age, 2) have persistent pain (more than 3 months) and 3) have sufficient knowledge of the Dutch language to complete the questionnaire and 4) participate in the movement with pain program in Excellent Care Clinics Velsen Noord. All patients will be asked to sign an informed consent prior to inclusion.

Exclusion criteria

Patients with contra-indications for exercise therapy, recent spinal surgery (less than 6 months ago), cytokine modularity medication (e.g. infliximab) inflammatory diseases such as

Rheumatoid arthritis or central neurological conditions are excluded.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	110
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-05-2020
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	NL8574
Other	METC Zuyderland-Zuyd : METCZ20190020

Study results