Effectiveness of an interdisciplinary rehabilitation treatment for patients with post-COVID syndrome who perceive high levels of disabilities - Single Case Experimental Design Study

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Ethical review	Approved WMO
Status	Completed
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53306

Source
ToetsingOnline

Brief title
Effect of an interdisciplinary rehabilitation treatment for post-COVID

Condition

- Viral infectious disorders

Synonym
long lasting corona complaints, post-covid

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: interdisciplinary, Post-COVID syndroom, rehabilitation, Replicated and Randomized-Single Case Experimental Design

Outcome measures

Primary outcome

Primary outcome of the study will be participation in society (USER-P) and

health-related quality of life (EQ5D-5L).

Secondary outcome

Secondary outcomes will be daily diary items and validated questionnaires aimed

at physical, mental and cognitive complaints, healthcare- and social costs and

feasibility of the treatment.

Study description

Background summary

In the Netherlands, more than 8 million people have been infected with COVID-19. Most patients with COVID-19 recover fully. However, approximately 10-20% still experience symptoms after recovery from their initial illness. Post-COVID syndrome is defined as signs and symptoms that develop during or after an infection consistent with COVID*19, continue for more than 12 weeks and are not explained by an alternative diagnosis. Symptoms of PCS include fatigue, shortness of breath, anosmia, muscle aches, headache, chest pain, palpitations, cognitive dysfunction, anxiety or depression symptoms and sleep problems. For patients with post-COVID syndrome who have high levels of disability in daily activities, an interdisciplinary rehabilitation treatment in secondary care seems indicated. However, the effect of this treatment on participation in society and quality of life is still unknown.

Study objective

The primary objective is to test the effectiveness of a 12-week personalized interdisciplinary rehabilitation treatment in secondary care to evaluate changes in the recovery of participation levels and quality of life in patients with post-COVID syndrome. The secondary objectives are to test changes in physical, mental and cognitive functioning and to assess the healthcare- and social costs (i.e., loss of working hours and incomes) as well as to test the feasibility of the interdisciplinary rehabilitation treatment.

The hypothesis is that a personalized interdisciplinary rehabilitation treatment for patients with PCS will improve their participation levels and QoL, and will decrease physical, mental and cognitive complaints.

Study design

A Replicated and Randomized-Single Case Experimental Design (R-SCED) and a feasibility study. The study will take place at the rehabilitation department of Adelante location MUMC+.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There are no risks involved in this study, but the time investment might be experienced as a burden. The following time-consuming activities are being asked of all participants: filling in the validated questionnaires (45-60 minutes) at 3 time points, filling in the daily dairies (up to 5 minutes), depending on the randomization 54-60 times, and the individual semi-structured interview (30 minutes). Benefits of participation in this study: It is hypothesized that participants will benefit from treatment program offered. The main benefit of participation in the study is that of contributing to scientific knowledge and the quality of the interdisciplinary rehabilitation program.

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

To be eligible for participation in this study, patients must meet all the following criteria:
- COVID-19 symptoms persisting for more than 12 weeks after initial infection
- Experiencing high levels of disability in daily activities and/or participation due to PCS (rehabilitation physician based).
- Indicated for an interdisciplinary rehabilitation treatment in secondary care (as decided by a rehabilitation physician).
- Good command of written and spoken Dutch
- Having access to the Internet
- >= 18 years.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Illiteracy / no good knowledge of Dutch
- No access to a smartphone, tablet or computer (or insufficient digital skills)
- Experiencing high levels of disability in daily activities and/or participation before their COVID-19 infection

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-09-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL83848.068.23
Other	Registratienummer volgt