IMPROVE: Evaluation of a combined lifestyle intervention program to improve quality of life in long-term ICU-survivors

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Evaluation of the effects of a integrative lifestyle intervention program on health related quality of life after ICU-admission.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49292

Source
ToetsingOnline

Brief title
IMPROVE

Condition

- Other condition

Synonym
Recovery after critical illness

Health condition

Post-intensive care syndroom

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Intensive care, Lifestyle intervention, Recovery

Outcome measures

Primary outcome

Physical functioning (subscale score of the RAND-36) at the end of the 12 week

intervention period.

Secondary outcome

Hand grip strength test

Six-minute walking test

Ultrasound measurements of the quadriceps muscle

Morton mobility index

Dietary intake

Health-related quality of life (RAND-36, complete questionnaire)

Hospital Anxiety and Depression Scale (HADS)

Cognitive Failure Questionnaire (CFQ)

Happiness Index (HI)

All endpoints are assessed after the 12 week intervention period.

Study description

Background summary

Survival rates of patients with critical illness have increased due to improved facilities and treatment methods in the intensive care unit (ICU). However, surviving critical illness does not mean these patients are cured. In general, ICU-admission is associated with decreased physical and mental health, reflecting in an impaired long-term recovery and decreased quality of life (QoL). Long-term health problems can partly be contributed to prolonged muscle weakness and malnutrition. Mono-interventions focusing on improving physical performance or nutritional intake have limited effect on long term functioning and QoL. A lifestyle intervention encompassing physical therapy and optimisation of caloric and protein intake may improve wellbeing and QoL in these patients. Previous studies found that interventions focused on mobilization and physical rehabilitation are feasible within the ICU and outpatient programs. Additionally, promising results were found in personalized healthcare and lifestyle programs for other patient groups with long-term health problems, such as cancer survivors and patients with diabetes or mental health problems. Based on this, we hypothesize that a lifestyle intervention program may improve wellbeing and quality of life in long-term ICU-survivors.

Study objective

Evaluation of the effects of a integrative lifestyle intervention program on health related quality of life after ICU-admission.

Study design

Randomised controlled trial

Intervention

The intervention group will be part of a 12-week combined lifestyle intervention encompassing group physical therapy twice a week and improvement of dietary caloric and protein intake by means of nutritional advice and, if applicable, caloric and/or protein supplementation. The control group will be subject to follow up meetings with research staff to assess physical and mental health and quality of life.

Study burden and risks

All participants have two additional appointments where they participate in an interview and perform physical tests (bioimpedance measurements, ultrasound of the upper thigh muscles, hand grip strength test, Morton mobility index test, and the six-minute walking test with pulse oximetry). At baseline and week 12 of the program, all participants complete a combination of questionnaires on mental health and quality of life. The intervention group will additionally be subject to supervised group training sessions twice a week for the duration of the intervention (12 weeks). Further, two meetings with a professional about

their diet will be organised. If a patient has a deficit in caloric and/or protein intake, dietary supplements with daily intake instructions will be provided. The risks and disadvantages of this intervention are minimal. However, this study requires considerable time investment and physical and mental effort. The extent of this study is crucial to clarify the effect of a combined intervention program on recovery after critical illness. *

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Long stay post-ICU patients (length of stay >=48h) between 6 weeks and 6 months after hospital discharge
AND >18 years old
AND able to visit the hospital 2 times a week

AND a RAND-36 physical functioning subscale score < 67%

Exclusion criteria

- Allergy to components of ProSource®
- Inability to understand the Dutch language
- Actively participating in a professional physical rehabilitation program during the study period. Note: previous participation in a concluded rehabilitation program is NOT an exclusion criterion.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-10-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2020
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL74913.099.20
Other	Onderzoek wordt geregistreerd na goedkeuring RTPO