Randomised controlled trial to evaluate the effects of tele-monitoring weight in oncology and COPD patients.

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The primary objective of this study is to investigate if monitoring weight by tele-monitoring and its procedure in oncology and COPD patients results in less weight loss (or in weight gain), compared to the control group.The secondary objective of...

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

Summary

ID

NL-OMON35829

Source
ToetsingOnline

Brief title
View on weight

Condition

- Other condition

Synonym
Weight loss

Health condition

Gewichtsverlies

Research involving
Human

Sponsors and support

Primary sponsor: Medizorg BV
Source(s) of monetary or material Support: Abbott Nutrition,Medizorg BV;Nutricia Nederland BV en Abbott Nutrition,Nutricia

Intervention

Keyword: Compliance, Infections, Monitoring weight, Sip feed

Outcome measures

Primary outcome

Primary study parameter in this study (change from baseline):

- Weight [kg]

Secondary outcome

Secondary parameters in this study are:

- Sip feed intake [ml/day, % of prescribed]

- Number of complications

- Number of infections

- Number of unplanned hospitalization

Study description

Background summary

Many oncology and COPD patients are at risk of malnutrition. Malnutrition in oncology patients, results in an increased risk of infections and post-operative complications, an impaired response on chemotherapy an increased length of hospital stay. Underweight in COPD patients, which is accompanied by shortage of lean body mass and weakness of the respiratory muscles, is associated with a higher level of complaints more unplanned readmissions to the hospital. This results in higher health care costs.
In a wide variety of hospital and community patients, the use of oral nutritional supplements has been shown to significantly improve energy and nutrient intake, body weight and functional outcomes in comparison with routine

care. It is important that patients comply with the prescribed nutrition regimen to ensure that nutritional requirements are met. Studies have been shown that wastage of nutritional sip feeds may be considerable and that the amount of sip feeds prescribed did not ensure that minimum energy requirements are met.
Especially in patients in the community, it is very important to monitor them regularly, to prevent severe weight loss due to a low compliance. Because of lack of time and/or finance, a lot of patients at home do not visit the dietician on a regular basis. This can lead to a decrease in compliance and an increase of weight loss.
This study has been designed, to investigate if tele-monitoring weight (with a scale connected to a modem, which sends the weight to a server) results in a decrease of weight loss, a better compliance of sip feed intake and a lower incidence of infections and/or complications.

Study objective

The primary objective of this study is to investigate if monitoring weight by tele-monitoring and its procedure in oncology and COPD patients results in less weight loss (or in weight gain), compared to the control group.
The secondary objective of this study is to evaluate if monitoring weight by tele-monitoring and its procedure in oncology and COPD patients, results in a higher compliance of sip feed intake and a lower incidence of infections and/or complications, compared to the control group.

Study design

Randomised, controlled, open-label, multi centre study.

Intervention

During the study, subjects in the intervention group will be monitored by tele-monitoring and measure their weight twice a week (which is sent electronically to a server). If a patient loses weight, a message is sent to the dietician who will contact the patient to discuss sip feed use and, if needed, change sip feed prescription.

Study burden and risks

Burden of the patient:
Patients in the intervention group have to measure their weight twice a week.
Patients in the control group have to measure their weight once per 4 weeks and register their weight..
Every 3 to 4 weeks a questionnaire will be taken by a phone call.
Benefit for subjects in the intervention group could be that their body weight

is better monitored, which results in a better nutritional status.

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

- Male or female adult * 18 years of age
- Oncology or COPD patient
- Risk of malnutrition (assessed by a validated screening tool)
- Subject is prescribed sip feed at home for at least 3 months
- Written informed consent from subject

Exclusion criteria

- Life expectancy < 6 months
- Subject who is frequently seen by a dietician (> 2 times/month)
- Investigator*s uncertainty about the willingness or ability of the subject to comply with the protocol requirements
- Participation in any other study involving investigational or marketed products concomitantly or within two weeks prior to entry the study

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:	Completed
Start date (anticipated):	15-11-2011
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	21-10-2011
Application type:	Amendment

Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	16-12-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	06-03-2012
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	13-06-2012
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	16-08-2012
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24869
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL36151.072.11
OMON	NL-OMON24869