

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24869

Source

Nationaal Trial Register

Brief title

View on Weight

Health condition

Oncology

COPD

Malnutrition

Weight

Infections

Complications

Sponsors and support

Primary sponsor: Medizorg BV

Nutricia Netherlands

Abbott Nutrition

Medizorg

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Abbott Nutrition

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Source(s) of monetary or material Support: initiator = sponsors

Intervention

Outcome measures

Primary outcome

Weight [kg].

Secondary outcome

1. Sip feed intake [ml/day, % of prescribed];
2. Number of infections [-];
3. Number of complications [-];
4. Unplanned hospitalisations [-].

Study description

Background summary

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Many oncology and COPD patients are at risk of malnutrition. Malnutrition results in an increased risk of infections and post-operative complications, an impaired response on chemotherapy an increased length of hospital stay, shortage of lean body mass and weakness of the respiratory muscles, is associated with a higher level of complaints and more unplanned readmissions to the hospital.

It is important that patients comply with the prescribed nutrition regimen to ensure that nutritional 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 results in a decrease of weight loss, a better compliance of sip feed intake and a lower incidence of infections and/or complications in oncology and COPD patients.

Study objective

The 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.

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

Weight:

Intervention: Recorded twice a week throughout whole study period.

Control: Recorded at baseline and every 3 weeks.

Infections, complications, unplanned hospitalisations:

Recorded every 3 weeks in both study groups.

Sip feed intake:

Recorded every 3 weeks in both study groups.

Intervention

During the study, subjects in the intervention group will be monitored by tele-monitoring and measure their weight twice a week. If a patient has lost weight, the dietician will contact the patient.

The control group will receive care as usual.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female adult ≥ 18 years of age;
2. Oncology or COPD patient;
3. Risk of malnutrition (assessed by the screening tools MUST or SNAQ);
4. Subject is prescribed sip feed at home for at least 3 months;
5. Written informed consent from subject.

Exclusion criteria

1. Life expectancy < 6 months;
2. Subject who is frequently seen by a dietician (≥ 3 times/month);
3. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;
4. 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)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-07-2011
Enrollment:	168
Type:	Anticipated

Ethics review

Positive opinion	
Date:	13-07-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35829

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2853
NTR-old	NTR2995
CCMO	NL36151.072.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35829

Study results

Summary results

N/A