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

Gepubliceerd: 13-07-2011 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24869

Bron
Nationaal Trial Register

Verkorte titel
View on Weight

Aandoening

Oncology
COPD
Malnutrition
Weight
Infections
Complications

Ondersteuning

Primaire sponsor: Medizorg BV
Nutricia Netherlands
Abbott Nutrition
Medizorg

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Nutricia Netherlands

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Abbott Nutrition

Wegalaan 9

2132 JD Hoofddorp
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Overige ondersteuning: initiator = sponsors

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Weight [kg].

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2011
Aantal proefpersonen:	168
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-07-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35829
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A