

Innovation in health care for patients with Coeliac Disease: a multidisciplinary ICT self management system.

Published: 18-01-2012

Last updated: 29-04-2024

Evaluation of a multidisciplinary ICT SMS for children with CD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malabsorption conditions
Study type	Interventional

Summary

ID

NL-OMON39749

Source

ToetsingOnline

Brief title

Self management system coeliac disease

Condition

- Malabsorption conditions

Synonym

coeliac disease, sprue

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW doelmatigheid, Maag Lever Darm Stichting

Intervention

Keyword: celiac_disease, disease_controle, patient_satisfaction, self_management_system

Outcome measures

Primary outcome

Primary outcome measure: disease control assessed by negative TG2 antibodies after 6 months of standard care or SMS.

Secondary outcome

Secondary outcome: patient satisfaction and health related quality of life (QoL).

Economic evaluation: A cost minimization analysis will be performed from a societal perspective. Costs of both groups will be compared by assessing costs of in-hospital versus at home tests and cost and time spent by patients, parents and physicians. Furthermore, costs of implementation will be assessed.

Study description

Background summary

Coeliac disease (CD) is a frequent chronic disease of the small bowel and other organs, which is treated by a gluten free diet (GFD). A GFD is not easy to follow and it can affect quality of life (QoL). The usual care in the Netherlands for children with CD consists of annual hospital visits for analysis of growth, complaints and compliance to the GFD. Innovation of care by using an ICT self management system (SMS) will be evaluated. SMS can lead to efficient and interactive care for CD patients, independent of time and place. We expect a reduction of health care costs and time spent by the children, parents and medical specialists. Furthermore, SMS can lead to more empowerment and increased QoL, which in its turn, can enhance compliance to the diet and diminish complications. The proposed project is innovative, since, to our knowledge, there is no similar project anywhere else in the world.

Study objective

Evaluation of a multidisciplinary ICT SMS for children with CD.

Study design

Randomized controlled trial

Intervention

Randomization into usual care or the SMS. Usual care consists of in-hospital consultations with a paediatrician or paediatric gastroenterologist and measurement of growth and blood values. The SMS group will be controlled by online questionnaires and at home test of growth and blood values using validated instruments.

Study burden and risks

Instead of hearing history, doing a physical exam with measurement of length and height and drawing of blood at the outpatient clinic, the subjects will fill in webbased questionnaires at home on complaints, diet and quality of life. Furthermore, they will measure their height and length at home and will perform a point of care blood test with a droplet of blood. The burden is estimated not be higher than the standard care. The subjects in the intervention group are at risk of failure of the home bloodtesting. In that case, they will have to go to the hospital. Studies on self management for adults and adolescents have been performed, not on children under age. Like adults, children can benefit from implementation of a self management system.

Contacts

Public

Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Scientific

Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

Children and young adults with coeliac disease (CD).

Children attending the outpatient CD clinic of the Leiden University Medical Center LUMC (www.coeliakiepoli.nl) or the pediatric outpatient clinics of Academic Medical Center, Amsterdam; VU Medical Center, Amsterdam; Medical Center Alkmaar, Alkmaar; Rijnland Hospital, Leiderdorp; Rijnstate Hospital, Arnhem; Juliana Childrens' Hospital, The Hague. Young adults ($> \leq 25$ years) attending the outpatient clinic for gastroenterology of the LUMC.

Having been diagnosed with CD for at least 1 year.

Exclusion criteria

No access to internet.

Difficulty in understanding questionnaires due to cognitive impairment or language problems.

Failure of obtaining informed consent.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2012
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO	
Date:	18-01-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	01-05-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	11-11-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	05-06-2014

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

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	NL36534.058.11