Innovatie van zorg voor patienten met coeliakie: Een multidisciplinair ICT zelf management systeem.

No registrations found.

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

Summary

ID

NL-OMON24851

Source
NTR

Brief title
CoelKids

Health condition

Coeliakie is een frequent voorkomende ziekte van de dunne darm en andere organen en dient behandeld te worden met een glutenvrij dieet (GVD). Een GVD is moeilijk te volgen en kan de kwaliteit van leven (quality of life, QoL) beïnvloeden. Follow-up van kinderen met coeliakie bestaat uit jaarlijkse bezoeken aan de polikliniek ter beoordeling van groei, klachten en compliance van het dieet. Innovatie van zorg door middel van een ICT zelf management systeem (ZMS) zal daarom worden geëvalueerd.

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Dept. of Pediatrics
P.O. Box 9600
2300 RC leiden
the Netherlands
Source(s) of monetary or material Support: ZonMw en MLDS

Intervention

Outcome measures

Primary outcome

Primary outcome measure: disease control assessed by negative TG2 antibodies after 6 months of standard care or SMS. Secondary outcome: patient satisfaction and health related quality of life (QoL).

Secondary outcome

Secondary outcome measures include patient satisfaction assessed by specific questionnaires, including both practical, societal and emotional aspects as well as QoL at time of enrolment and after 6 months. QoL will be assessed using the childhood CD specific ICT-based instrument CDDUX. HUI3 will also be used.

Study description

Background summary

Coeliac disease (CD) is a frequent chronic disease affecting the small intestine and other organs. CD is caused by an inflammatory T-cell response to the storage proteins in wheat (gliadin), rye (secalin) and barley (hordein), which are collectively called gluten. It is estimated that 12.500 children in the Netherlands have CD: more that 2/3 of them are girls, since CD is significantly more frequent in females than in males. A rise in CD diagnoses is to be expected due to increasing awareness.

CD in children has a variable clinical presentation: from a clear malabsorption syndrome with chronic diarrhea and failure to thrive to less specific symptoms such as irritability and anemia. CD is characterized by histological abnormalities found in small bowel biopsy specimens. Screening for CD can be done by measuring CD specific antibodies against the enzyme tissue transglutaminase type 2 (anti-TG2), endomysium (EMA) and against deamidated gliadin peptides (DGP). CD has a strong genetic component; 98% of CD patients possess the human leucocyte antigen (HLA)-DQ2/DQ8 molecules. HLA genotyping is useful as a diagnostic tool, mainly to exclude CD.
The treatment of CD is a life-long gluten-free diet (GFD) which may considerably affect the patient’s overall quality of life. Moreover, the compliance to the diet is difficult to achieve, it is expensive, it may have negative nutritional consequences and no adherence may lead to complications as diarrhea, abdominal pain, osteoporosis, and cancer. After the diagnosis is confirmed, the child with CD and its parents should be referred to a dietician for information about the treatment.

The usual care in the Netherlands for children with CD consists of hospital visits and consultations with a paediatrician or paediatric gastroenterologist, according to the Dutch CBO-Guidelines. In the first year after diagnosis, visits take place every 3 months or more frequently if indicated, after that, annual visits are done.

These visits consist of:

1. Evaluation of health and complaints;

2. Evaluation of (compliance to) the GFD;

3. Evaluation of growth by measuring weight and length (growth chart);

4. Measurement of CD specific antibodies anti-TG2.
This way of health care is an expensive and time consuming procedure for all parties. Assessment of gluten intake and QoL is difficult during a 20 minutes consultation. In addition, the health care of many children with CD is not adequate and not compliant with the guidelines.

Much research has been done on improvement of patient satisfaction and self help in patients with chronic diseases, such as diabetes mellitus, asthma and chronic obstructive pulmonary disease. Both items can influence the level of illness and the consumption of care resulting from it. Web-based interventions have proven to be able to improve empowerment and self efficacy compared to standard care. Research performed in our hospital in patients with asthma showed that there is enhanced control of disease and improvement of lung function by care done by self management.

For these reasons a self management system (SMS) will be evaluated: an innovative, efficient, interactive and personalized form of health care for children with CD, independent of time and place.
The SMS care consists of filling in online questionnaires concerning:

1. Electronic Patient Record (EPR) to assess the symptoms relevant for CD on health status and CD related complaints;

2. Growth monitoring using at home measurements and a digital growth analyser;

3. Outcome of at home measurement of anti-TG2 using rapid, point of care tests;

4. Assessment of adherence to the GFD using an ICT based food questionnaire;

5. Assessment of health related QoL using the validated childhood CD-specific instrument CDDUX.

The usual care for children with CD is performed by paediatricians or paediatric gastroenterologists and by dieticians: the expertise of all groups is present in the project group of this proposal.

Study objective

That the percentage of patients with well controlled CD will be similar in the group of children using the traditional way of follow-up compared to the group of children using SMS.

Study design

1. Months 1-3: Recruitment of patients;

2. Months 3-12: Intervention;

3. Months 9-18: Assessment of anti-TG2 antibodies, CDDUX and patient satisfaction;

4. Months 18-24: Data analysis and writing of scientific report.

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. These visits consist of:

1. Evaluation of health and complaints;

2. Evaluation of (compliance to) the GFD;

3. Evaluation of growth by measuring weight and length (growth chart);

4. Measurement of CD specific antibodies anti-TG2.

The SMS group will be controlled by online questionnaires and at home test of growth and blood values using validated instruments.
The SMS care consists of filling in online questionnaires concerning:

1. Electronic Patient Record (EPR) to assess the symptoms relevant for CD on health status and CD related complaints;

2. Growth monitoring using at home measurements and a digital growth analyser;

3. Outcome of at home measurement of anti-TG2 using rapid, point of care tests;

4. Assessment of adherence to the GFD using an ICT based food questionnaire;

5. Assessment of health related QoL using the validated childhood CD-specific instrument CDDUX.

The results of the internet based consultation will be processed in a web-based way and evaluated by the paediatrician and/or paediatric gastroenterologist and by the dietician. The SMS will give the patient a report on the outcome of the evaluation: if all is well, the next SMS control will be planned; if there are abnormal results, contact with the paediatrician/paediatric gastroenterologist and/or dietician will be scheduled.

At the end of the questionnaire there will be the possibility of online contact between patient/parents and paediatrician/paediatric gastroenterologist. If needed parents can ask for a telephonic or in-patient appointment.

Both groups will be evaluated internet based, 6 months after the intervention. Again, anti-TG2 will be measured using point of care tests at home. QoL will be assessed by using the CDDUX. Patient satisfaction will also be measured.

Contacts

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Eligibility criteria

Inclusion criteria

Children with CD, currently attending our outpatient CD clinic and having been diagnosed with CD for at least 1 year, will be asked to participate in the study.

Exclusion criteria

No access to internet and/or difficulty in understanding questionnaires due to cognitive impairment or language problems.

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):	01-04-2012
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-10-2012
Application type:	First submission

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
NTR-new	NL3533
NTR-old	NTR3688
Other	METC LUMC : P11-099
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A