E-Healthcare for Celiac Disease—A Multicenter Randomized Controlled Trial

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Objective To evaluate the (cost-)effectiveness of online consultations in follow-up of patients with celiac disease (CD).

Study design Multicenter randomized, controlled trial involving 304 patients aged ≤25 years with CD for ≥1 year, randomized to an online (n = 156) or outpatient consultation (n = 148). An online consultation included questionnaires for symptom and growth measurement. Antitransglutaminase-type-2 antibodies were determined using a point-of-care (POC) test. Controls had a traditional consultation with antitransglutaminase-type-2 antibodies testing in laboratories. Both groups completed questionnaires concerning CD-specific health-related quality of life (HRQOL), gluten-free diet adherence, and patient satisfaction. Six months later, participants repeated HRQOL and patient satisfaction questionnaires and the POC test. The primary outcome was anti-transglutaminase-type-2 antibodies after 6 months, and the secondary outcomes were health problems, dietary adherence, HRQOL, patient satisfaction, and costs.

Results The performance of the POC test was inferior to laboratory testing (2/156 positive POC tests vs 13/148 positive laboratory tests; $P = .003$). Health problems were detected significantly more frequently using online consultation. The detection of growth problems and dietary transgressions was similar. HRQOL (from 1 [good] to 5 [poor]) improved after online consultation (from 3.25 to 3.16 [$P = .013$] vs controls from 3.10 to 3.23; $P = .810$). Patient satisfaction (from 1 [low] to 10 [high]) was 7.6 (online) vs 8.0 (controls; $P = .001$); 58% wished to continue online consultations. Mean costs per participant during the studied period were €202 less for the online group ($P < .001$).

Conclusions The primary outcome could not be tested because the POC test was unreliable. Nevertheless, our results indicate that online consultations for children and young adults with CD are cost saving, increase CD-specific HRQOL, and are satisfactory for the majority. *(J Pediatr 2017;■■:■■-■■).*

Trial Registration Trialregister.nl: NTR3688.

See editorial, p •••

Celiac disease (CD) is an immune-mediated systemic disorder occurring in genetically susceptible individuals and it is elicited by gluten ingestion.[1] CD may be considered a public health problem, with a prevalence ranging from 1% to 3%, which corresponds with about 5 million affected people in the European community.[1-3] Treatment with a gluten-free diet (GFD) restores the small bowel alterations and improves clinical complaints in the majority of the patients.[1,4] In The Netherlands, children with CD diagnosed >1 year ago are usually followed up annually.[5] Traditional medical care for patients with CD consists of regular physician visits to evaluate their health, weight, height (in children), GFD adherence, and CD-specific serum antibodies.[5,6] Although important, these measures

CD	Celiac disease
ELISA	Enzyme-linked immunosorbent assay
GFD	Gluten-free diet
HRQOL	Health-related quality of life
POC	Point-of-care (test)
TG2A	Antitransglutaminase-type-2 antibodies

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Funded by the Dutch "Maag Lever Darm Stichting" (WO-1198), ZonMW (171201006), and STICOON (Dutch Foundation for Research in Celiac Disease). The point-of-care tests were provided free of charge by the manufacturers. The authors declare no conflicts of interest.

https://doi.org10.1016/j.jpeds.2017.10.027

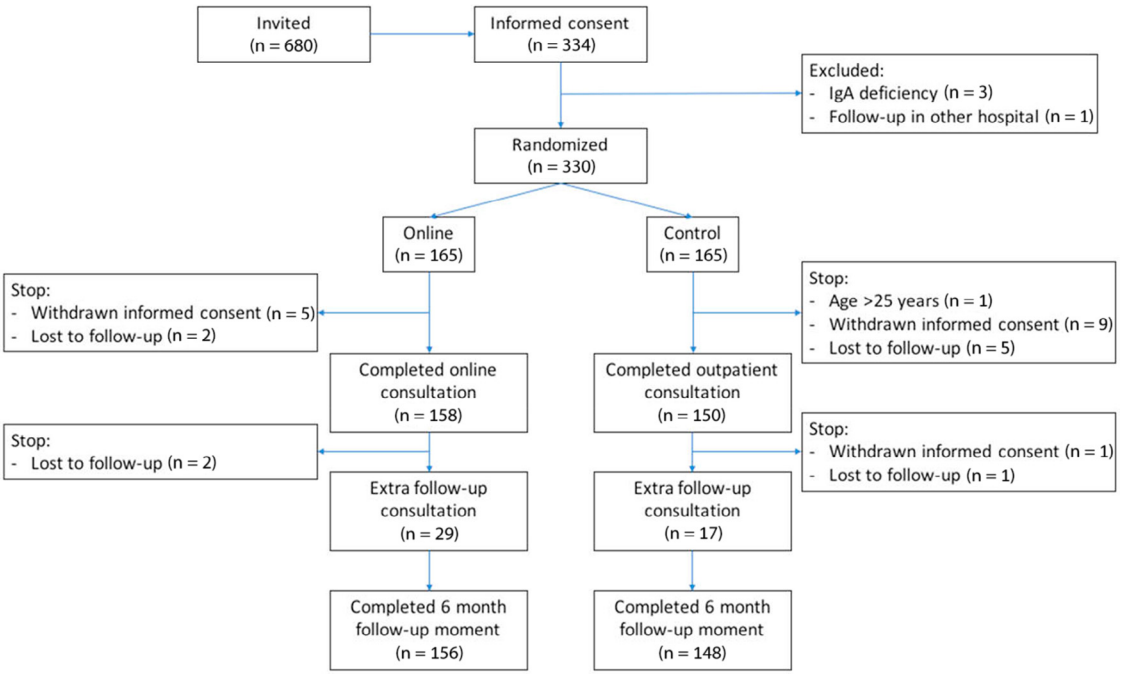

Figure 1. Recruitment, randomization, and follow-up of children and young adults with CD. Four patients did not meet the inclusion criteria and were excluded before randomization. After randomization, 1 participant was excluded for exceeding the age limit (age 25.7 years). During the project, the number of participants decreased to 304 (online n = 156; control n = 148) because 15 participants withdrew their informed consent and another 10 participants were lost to follow-up.

can be time consuming. Moreover, many patients do not visit their physician for regular CD follow-up.[7] Time constraints during outpatient follow-up also restrict comprehensive assessments of a patient's health-related quality of life (HRQOL) and dietary adherence. Previous studies in adults with other chronic diseases suggest that online consultations can encourage patients to improve healthcare participation and enable them to deal with symptoms, treatment, physical and psychosocial consequences, and lifestyle changes through successful disease self-management.[8,9] We developed an online consultation as a substitute for an outpatient consultation in the follow-up of CD in children and young adults (CoelKids). We hypothesized that disease control and participant satisfaction would be similar in patients using an online consultation or traditional outpatient follow-up.

Materials

For this multicenter, randomized, clinical trial (Trialregister.nl: NTR3688), children and young adults ≤25 years with diagnosed CD for ≥1 year were recruited between May 2012 and July 2014 from 3 academic and 4 nonacademic hospitals in the Netherlands. Exclusion criteria were IgA deficiency, no Internet access, and insufficient comprehension of Dutch language. All authors had access to the study data and had reviewed and approved the final manuscript.

Intervention

After obtaining written informed consent, participants were randomized to the online or control group, stratified by age at inclusion and sex (**Figure 1**, **Table I**). The patients (or parents) in the online group were asked to complete a symptom questionnaire (ie, abdominal pain, appetite, lassitude, and defecation) and instructed to measure height and weight, which were subsequently plotted on their growth charts.[11,12] For determination of the CD-specific IgA antitransglutaminase-type-2 antibodies (TG2A), the online group was provided (free of charge) with the validated and commercially available point-of-care (POC) test (Biocard Celiac Test, AniBiotech, Vantaa,

Table I. Characteristics of the 304 participants with CD randomized to the online or control group

Characteristic	Online group (n = 156)	Control group (n = 148)
Female, n (%)	107 (68.6)	97 (65.5)
Age (y), mean (min-max)	11.0 (2.6-24.1)	11.4 (2.1-24.5)
Age at CD diagnosis (y), mean (min-max)	4.3 (0.9-17.9)	4.9 (1.0-23.4)
Disease duration (y), mean (min-max)	6.9 (1.0-20.3)	6.7 (1.0-22.9)
GFD score,* n (%)		
0-1	12 (7.7)	19 (12.8)
2	2 (1.3)	1 (0.7)
3-4	142 (91.0)	128 (86.5)

*Scores of 0-1 = GFD not followed; 2 = GFD followed but with errors; 3-4 = strict GFD followed.[10]

FLA 5.5.0 DTD ■ YMPD9535_proof ■ December 21, 2017