Benefits From and Barriers to Portable Detection of Gluten, Based on a Randomized Pilot Trial of Patients With Celiac Disease

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Research links diminished quality of life (QOL) to the challenges of a strict gluten-free diet (GFD), the only treatment for celiac disease (CD).[1–4] This pilot study assessed the acceptability and feasibility of a portable gluten sensor device (Nima) to promote GFD adherence and QOL.

A prior validation study found that Nima reliably indicates "gluten found" in gluten-free foods having ≥20 ppm added gluten (92.6% of samples tested).[5] With 5–19 ppm of gluten added (considered gluten-free by the US Food and Drug Administration[6]), specificity varies: "gluten found" 34.6% of the time with 5 ppm added, 56.4% of the time with 10 ppm.[5,7]

Methods

This study was conducted at the Celiac Disease Center of Columbia University in New York City (IRB#AAAR6004; authors had data access and approved the manuscript). Eligibility was assessed by telephone and required biopsy-confirmed diagnosis, treatment at Center, no current Nima, and owning an iPhone 5+.

Enrollment occurred from February to April 2018. The target goal was 15 adults (≥18 years) and 15 teenagers. Recruitment was via flyers and emails to tristate affiliates. Five each of adults and teenagers were enrolled and randomized to receive 24, 12, or 6 single-use testing capsules per month. Researchers demonstrated the use of the device but offered no recommendations for what, where, or when to test. Manufacturer's handouts described how to pair the device with the app, how to run a test, and what can and cannot be accurately tested.

Outcomes, collected at baseline and 3-month follow-up, included validated measures of CD-specific QOL, GFD adherence, depression, and anxiety. Closed-format items included 17 benefits, 9 barriers, 4 plans for continued use, and overall recommendation. We also asked about satisfaction with capsule supply and administered a quiz regarding the device's capability of accurately testing specific foods.

Results

Two-thirds (67%) of participants were female. All but 1 self-identified as white, non-Hispanic. Mean age of adults was 38.6 years (standard deviation, 16.5), and of teenagers 15.5 years (standard deviation, 1.6). All but 2 adults were college graduates.

At follow-up, adults reported improved overall and limitations CD-specific QOL and depression scores (Table 1). Teenagers exhibited no changes. Six participants, all randomized to the lower use groups, desired more capsules. Adults and teenagers displayed a similar understanding of the device's testing limitations (mean, 4.5 of 6 foods correct).

More than 90% of both adults and teenagers agreed that Nima was easy to understand, helped them follow a GFD, gave peace-of-mind, and was useful. About 90% of adults and teenagers agreed that the capsules were hard to close. Although only 47% of adults agreed that testing was time-consuming, 86% of teenagers found it to be so (chi-square test, 3.3; $df = 1$; $P = .07$). More teenagers than adults agreed that using Nima made them anxious (43% vs 0.0%; chi-square test, 5.7; $df = 1$; $P = .02$). Most participants would recommend the device to others with CD and planned to continue using it.

Eighty-seven percent of adults reported having the Nima indicate "gluten found" in foods they thought to be gluten-free, 77% of those reported always trusting that finding, and 69% never ate the food after such a result. Corresponding percentages for teenagers were 64%, 100%, and 89%.

Abbreviations used in this paper: **CD, celiac disease; GFD, gluten-free diet; QOL, quality of life.**

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Table 1. Quality of Life, Adherence, Depression, Anxiety, and Gastrointestinal Symptoms Before and After Nima Intervention Q8

	Preintervention, Mean (SD)	Postintervention, Mean (SD)	Paired *t* test[a]	
			t test	*P* value
Adults				
Overall quality of life (CD-QOL)[b]	45.7 (22.6)	54.5 (22.6)	-3.4	.005
Dysphoria subscale[b]	66.7 (25.7)	72.1 (25.8)	-1.7	.12
Limitations subscale[b]	37.2 (24.8)	48.8 (26.1)	-3.7	.002
Health concerns subscale[b]	45.7 (27.8)	53.3 (23.7)	-1.7	.12
Inadequate treatment subscale[b]	42.5 (32.7)	47.5 (36.7)	-1.1	.29
Gluten-free diet adherence (CDAT)[c]	11.1 (1.5)	10.8 (2.1)	0.6	.58
Depression (CESD)[d]	15.3 (9.2)	11.3 (9.5)	2.4	.03
Anxiety state (STAI Adults)[e]	63.1 (13.6)	61.4 (11.4)	0.4	.70
Anxiety trait (STAI Adults)[e]	57.4 (12.4)	57.5 (10.7)	-0.0	.97
Teenagers				
Overall quality of life (CD-QOL)[b]	72.7 (23.4)	70.5 (21.5)	0.5	.63
Social subscale[b]	72.2 (22.8)	68.9 (19.7)	0.9	.41
Uncertainty subscale[b]	75.6 (25.0)	71.4 (31.0)	0.8	.45
Isolation subscale[b]	74.6 (30.2)	73.7 (24.9)	0.1	.89
Limitations subscale[b]	68.5 (26.2)	69.0 (20.0)	-0.1	.92
Gluten-free diet adherence (CDAT)[c]	12.3 (4.0)	10.7 (2.3)	1.7	.11
Depression (CES-DC)[d]	10.4 (10.3)	10.5 (8.3)	-0.0	.96
Anxiety state (STAI Children)[e]	48.0 (3.0)	48.1 (3.1)	-0.3	.78
Anxiety trait (STAI Children)[e]	31.4 (8.9)	33.6 (8.8)	-1.2	.25

CD-QOL, Coeliac Disease Quality of Life Survey; CDAT, Celiac Dietary Adherence Test; CESD, Center for Epidemiologic Studies Depressions Scale; SD, standard deviation; STAI, State-Trait Anxiety Inventory.

[a]*df* = 14 for adults; *df* = 13 for teenagers (1 teenager missing all follow-up data).

[b]Higher scores more desirable, possible range 0 to 100; 20 items for adults, 18 items for teenagers; a difference of approximately 10 points higher on the CD-QOL scale or subscale implies potential clinical relevance. Dorn SD, Hernandez L, Minayas MT, et al. The development and validation of a new coeliac disease quality of life survey (CD-QOL). Aliment Pharmac Ther 2009;31:666–675; Jordan NE, Li Y, Magrini D, et al. Development and validation of a celiac disease quality of life instrument for North American children. J Pediatr Gastroenterol Nutr 2013;57:477–486.

[c]Lower scores more desirable, possible range 7 to 35, scores >13 suggest inadequate adherence; 7 items. Leffler DA, Dennis M, Edwards JB, et al. A simple validated gluten-free diet adherence survey for adults with celiac disease. Clin Gastroenterol Hepatol 2009;7:530–536.

[d]Lower scores more desirable, possible range 0 to 60, scores >15 suggest depression; 20 items each for adults and teenagers. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Meas 1977;1:385–401; Radloff LS. The use of the Center for Epidemiologic Studies Depression Scale in adolescents and young adults. J Youth Adolesc 1991;20:149–166.

[e]Higher scores more desirable, possible range 20 to 80; 40 items each for adults and teenagers. Spielberger CD, Gorsuch RL, Lushene R, et al. Manual for the State-Trait Anxiety Inventory. Palo Alto, CA: Consulting Psychologists Press, 1983; Spielberger CD. Manual for the State-Trait Anxiety Inventory for Children. Menlo Park, CA: Mind Garden, 1973.

Discussion

This pilot highlights benefits of and barriers to using a newly marketed gluten sensor device by individuals with CD. Nima's convenient size/portability were appreciated. Physical difficulty with the capsules was a major drawback, especially for teenagers, who found the struggle embarrassing around friends and generally created a lack of enthusiasm. The manufacturer now offers a wrench to facilitate closing. Nearly half of participants failed to recall the device's testing limitations; Nima cannot correctly detect gluten in fermented foods, such as soy sauce and barley malt. This knowledge deficit is concerning, and would likely be even greater among the general population.

Open-ended responses added nuance. In line with Nima's intended use as "an extra layer of information,"[8] participants used the device to double check foods believed to be gluten-free. Some reported inconsistent results on repeat testing of the same meal. Some believed the device to be too sensitive for their personal needs. Users should be aware of Nima's limitations, particularly for foods with gluten levels close to the 20 ppm cutoff.

This pilot had a small and demographically homogeneous sample and no control group. Having provided the device, we could not evaluate cost effects ($229 for the device; $5 per single-use capsule, as of February 21, 2019). Nevertheless, our data suggest potential beneficial effects of using the Nima on QOL and depression, at least for adults with CD.

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Conflicts of interest
These authors disclose the following: Peter H. R. Green serves on the Advisory board of ImmusanT, Cellimmune, and ImmunogenX; and is an unpaid member of Nima's Scientific Advisory Board. Benjamin Lebwohl serves as a consultant for Takeda; serves on the Advisory Board of Innovate Biopharmaceuticals; and is an unpaid member of Nima's Scientific Advisory Board. The remaining authors disclose no conflicts.

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