

Table 4: Benefits and harms of kilned and unkilned oats (adults)

Bibliographic reference	<p>Kemppainen (2008): Unkilned and large amounts of oats in the coeliac disease diet: A randomized, controlled study Reference ID: 437</p> <p>Kemppainen (2009): Effect of unkilned and large amounts of oats on nutritional state of celiac patients in remission Reference ID: 2595</p> <p>Kemppainen (2010): Nutrient intakes during diets including unkilned and large amounts of oats in coeliac disease Reference ID: 276</p> <p><i>Note: multiple publications of the same study.</i></p>
Study type	Crossover RCT (only results from first phase before crossover were reported)
Study quality	Low quality
Number of patients	Total = 31; kilned oats = 16, unkilned oats = 15
Patient characteristics	<p><u>Inclusion criteria:</u> Adult patients with coeliac disease 'in remission' who were previously using moderate amounts of regular kilned oats as part of their gluten-free diet.</p> <p>Kilned oats group = 16, Gender (men/women) = 6/10 Unkilned oats group = 15, Gender (men/women) = 7/8</p> <p>Overall:</p>

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	<ul style="list-style-type: none"> • The mean age of the patients (both groups) = 47 (range 16–64) years. • The diagnosis of coeliac disease had been made 8.6 (range 7–29) years earlier. • The patients had followed a gluten-free diet for 8.3 (1–29) years and consumed oats for 5 (0–9) years. • At baseline, 10 patients had partial villous atrophy and 9 had mild mucosal inflammation. Other biopsies were interpreted as normal. In the beginning of the study, all patients had normal (negative) values of EMA antibodies.
Intervention	<p>The goal of the daily intake of oats was 100g.</p> <p>Half of the daily oat portion was given as oat flour and half-baked in oat bread during the 12 months. The daily portion of 100g of oat flour consisted of a minimum of 120 g of oat bread and 50g of oat flour for cooking and baking according to gluten-free oat recipes</p>
Comparison	<p>As above but with unkilned oats.</p> <p>Samples of the oat flours and bread were taken randomly from each process to be tested for purity.</p>
Length of follow up	<p>6-month treatment period (the 12-month follow-up data was not fully reported).</p>
Location	<p>Summer–autumn of 1998 in Kuopio University Hospital area, Finland.</p>
Outcomes measures and effect size	<ul style="list-style-type: none"> • The consumption increased during the first 6 months from 24 g to 93–96 g daily in both groups ($p = 0.01$). • The groups using either kilned or unkilned oats did not differ from each other during the follow-up in consumption of oats [Oats in gram, mean (SD): Baseline: Kilned group = 24 (24), Unkilned group = 24 (18); at 6-month: Kilned group = 93 (28), Unkilned = 96 (38); $p = 0.74$]. • There was no significant change in the histological status of the small intestinal architecture and no abnormal values of EMA occurred during the follow-up (actual measurements not reported). • At 12 months only 5 patients had partial villous atrophy and 4 had mild inflammation (denominator not reported).

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	<ul style="list-style-type: none"> At 12-month follow-up no statistically significant changes were found in symptoms, as assessed by verbal rating (actual measurements not reported). The group using kilned or unkilned oats did not differ from each other regarding changes in symptoms, including abdominal pain, flatulence and diarrhoea, or welfare during the first 6 months (Mann–Whitney U-test, $p > 0.05$) (categorical data see below Table 1). 			
	Table 1:			
	Baseline		At 6-month	
Symptoms	Kilned oats group (n=16)	Unkilned oats group (n=15)	Kilned oats group (n=16)	Unkilned oats group (n=15)
Abdominal pain				
1. <i>Not at all</i>	14	9	11	11
2. <i>To some extent</i>	2	6	5	4
3. <i>Moderate</i>	0	0	0	0
4. <i>Extreme</i>	0	0	0	0
Flatulence				
1. <i>Not at all</i>	6	6	7	6
2. <i>To some extent</i>	9	7	6	6
3. <i>Moderate</i>	1	2	3	2
4. <i>Extreme</i>	0	0	0	0
Abdominal distention				
1. <i>Not at all</i>	13	9	10	11

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	2. <i>To some extent</i>	2	5	4	3	
	3. <i>Moderate</i>	1	1	2	1	
	4. <i>Extreme</i>	0	0	0	0	
	Diarrhoea					
	1. <i>Not at all</i>	16	12	12	13	
	2. <i>To some extent</i>	0	3	3	2	
	3. <i>Moderate</i>	0	0	1	0	
	4. <i>Extreme</i>	0	0	0	0	
	Note: No significant difference between the groups during the first 6 months (Mann-Whitney U-test).					
	Nine of 31 patients reported abdominal distention. All of them had coeliac disease in remission					
		Kilned oats group		Unkilned oats group		p-value*
		Baseline	6-month	Baseline	6-month	
	BMI (kg/m ²) (mean, SD)					
	<i>Men</i>	24 (3)	24 (3)	25 (4)	24 (3)	0.95
	<i>Women</i>	25 (3)	25 (3)	23 (3)	23 (3)	0.15
	Erythrocyte folate (mean, SD)	490 (159)	582 (185)	430 (87)	496 (102)	0.18
	Serum vitamin B-12 (mean, SD)	447 (182)	279 (109)	424 (64)	287 (93)	0.68
	Serum calcium (mean, SD)	2.35 (0.11)	2.30 (0.14)	2.40 (0.09)	2.30 (0.10)	0.63
	Note: Normal values for the general population: Erythrocyte folate: 315-850nmol/L; Serum vitamin B-12: 140-540pmol/L; Serum calcium: 2.2-2.65mmol/L					

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	<p>Note: *Difference between groups at 6-month.</p> <p>Intake of nutrients at 6-month:</p> <p><u>Folic acid in µg, mean (SD):</u> Baseline: Kilned group = 231 (69), Unkilned group = 214 (99); at 6-month: Kilned group = 235 (79), Unkilned = 226 (64); p = 0.89</p> <p><u>Calcium in mg, mean (SD):</u> Baseline: Kilned group = 1272 (513), Unkilned group = 1241 (576); at 6-month: Kilned group = 1313 (473), Unkilned = 1213 (692); p = 0.55</p> <p><u>Iron in mg, mean (SD):</u> Baseline: Kilned group = 12 (3), Unkilned group = 14 (6); at 6-month: Kilned group = 13 (3), Unkilned = 14 (5); p = 0.80</p>
Source of funding	Finnish Cultural Foundation, Antti and Jenny Wihuri Foundation and EVO funding.
Comments	<ul style="list-style-type: none"> • Methods of randomisation not reported, allocation concealment unclear, blinding unclear. • Potential reporting bias on some outcomes where there was a lack of details. • Only data from the first phase (before crossover) was used, as there was no analysis of crossover effects.
<p>Author's conclusion: Unkilned or kilned oats, even in large amounts produced no harm to the nutritional status of celiac patients during over a 1-year period.</p>	

Bibliographic reference	Gatti (2014) Oats in the diet of children with celiac disease: preliminary results of a double-blind, randomized placebo-controlled multicentre Italian study
Study type	RCT; cross-over trial- only first phase presented here
Study quality	
Number of patients	N=171; Group A = 75, Group B = 96
Patient characteristics	<p><u>Inclusion criteria:</u></p> <ul style="list-style-type: none"> • Children aged between 4 - 14 years • Biopsy-proven diagnosis of CD • On a GFD at least 2 years <p>Exclusion criteria: Patients who:</p> <ul style="list-style-type: none"> • Have another chronic condition i.e. T1D or inflammatory bowel disease • Did not adhere to a GFD • Were on a GFD for less than 2 years
Intervention	<p>Participants were randomised to follow one of 2 diets:</p> <p>A-B treatment</p> <ul style="list-style-type: none"> • 6 months of diet A, 3 months of standard GFD, 6 months of diet B <p>B-A treatment</p> <ul style="list-style-type: none"> • 6 months of diet B, 3 months of standard GFD, 6 months of diet A <p>A and B diets consisted of gluten-free products (i.e. pasta, biscuits, cakes, crisps) with either purified oats, or placebo</p>
Comparison	<ul style="list-style-type: none"> • Clinical data and intestinal permeability tests were measured throughout the study period
Length of follow up	Clinical data measured at 0, 3, 6, 9, 12, and 15 months - This paper looks at preliminary first 6 month results
Location	Italy
Outcomes measures and effect size	306 children were enrolled in the study (mean age 9.62 years) 55/154 and 42/152 patients from group A-B and B-A respectively dropped out within first 6 months (not significant, p=0.14)

Bibliographic reference	Gatti (2014) Oats in the diet of children with celiac disease: preliminary results of a double-blind, randomized placebo-controlled multicentre Italian study
	<p>GSRs score</p> <ul style="list-style-type: none"> • Group A baseline = 3 (0 - 5.25) • Group B baseline = 2 (0-4.5) • Group A 6 months = 1 (0 - 4.5) • Group B 6 months 0 (0-2) <p>In both groups, a significant reduction in GSRs was seen. There was no difference between groups in GSRs score</p>
Source of funding	Sponsored by Heinz Italia S.p.A
Comments	<ul style="list-style-type: none"> • Methods of randomisation not reported, allocation concealment unclear, blinding unclear. • Potential reporting bias on some outcomes where there was a lack of details. • Only data from the first phase (before crossover) was used, as there was no analysis of crossover effects.
<p>Author's conclusion: Oats varieties used for producing the gluten-uncontaminated products used in this study are safe when administered for a 6 month period of time in children with Coeliac disease.</p>	