

Bibliographic reference	Hallert (2009) Ref ID: 347													
Study type	RCT (method of randomisation not reported)													
Study quality	Low quality													
Number of patients	Total = 65; Intervention = 33, Placebo = 32													
Patient characteristics	<p>Inclusion criteria: Diagnosis based on histology showing findings compatible with CD, age 45–64 years, a history of being on a GFD for at least 8 years and evidence of remission. <i>Note: Absence of serum IgA tissue transglutaminase (tTG) antibodies and asymptomatic DH controlled by diet alone were accepted as evidence of remission.</i></p> <p>Exclusion criteria: Concomitant serious disorder, positive serology for CD, any B vitamin supplementation within 3 months of inclusion, pharmacological doses of vitamin B-12, folic acid or pyridoxine (vitamin B-6) within 3 years of inclusion, ongoing therapy with drugs known to influence plasma total tHcy levels, resection of terminal part of the small intestine, hypersensitivity to B vitamins and assumed inability to comply with the study protocol.</p> <p>Baseline characteristics:</p> <table border="1"> <thead> <tr> <th></th> <th>Intervention (n=33)</th> <th>Placebo (n=32)</th> </tr> </thead> <tbody> <tr> <td>Male/Female</td> <td>14/19</td> <td>10/22</td> </tr> <tr> <td>Withdrawals</td> <td>5/33</td> <td>5/32</td> </tr> <tr> <td>Per-protocol analysis</td> <td>n=28</td> <td>n=29</td> </tr> </tbody> </table>			Intervention (n=33)	Placebo (n=32)	Male/Female	14/19	10/22	Withdrawals	5/33	5/32	Per-protocol analysis	n=28	n=29
	Intervention (n=33)	Placebo (n=32)												
Male/Female	14/19	10/22												
Withdrawals	5/33	5/32												
Per-protocol analysis	n=28	n=29												

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		Intervention (n=28)	Placebo (n=29)
	Baseline P-tHcy ($\mu\text{mol/L}$) [median and range]	11.7 (7.8 to 23.0)	11.4 (7.4 to 21.9)
		Intervention (n=11)	Placebo (n=12)
	Baseline PGWB index [median and range]	89 (76 to 98)	90 (43 to 99)
	Note: for PGWB index, data only available for analysis: Intervention (n=11); Placebo (n=12)		
Intervention	A daily dose of 0.8 mg folic acid, 0.5 mg cyanocobalamin (vitamin B-12) and 3 mg pyridoxine (vitamin B-6)		
Comparison	Placebo for 6 months		
Length of follow up	6 months (end of intervention)		
Location	The patients recruited into the study had been diagnosed with CD at four hospitals in Sweden in 1974–95 after showing a flat or nearly flat intestinal mucosa that improved on a GFD as stated in the medical records.		
Outcomes measures and effect size	<p>The outcome measures were psychological general well-being (PGWB) and the plasma total homocysteine (tHcy) level, marker of B vitamin status.</p> <p><u>P-tHcy ($\mu\text{mol/L}$) [median and range]:</u> Baseline: Intervention = 11.7 (7.8-23.0); placebo = 11.4 (7.4-21.9) At 6-month: Intervention = 7.9 (5.0-11.3); placebo = 11.1 (5.3-22.4), $p < 0.001$ <i>(also significant between baseline and 6-month for the intervention group only, $p < 0.001$)</i></p> <p><u>PGWB index [median and range]:</u> Baseline: Intervention = 89 (76-98); placebo = 90 (43-99) At 6-month: Intervention = 105 (87-115); placebo = 94 (40-121), $p > 0.05$ (ns) <i>(only significant between baseline and 6-month for the intervention group only, $p < 0.01$)</i></p> <p>The upper reference limit for plasma tHcy was set at $15.6 \mu\text{mol/L}$ using the 95th percentile of a local population sample (n = 65) representing age- and gender-matched general population controls.</p>		
Source of funding	None reported.		

Bibliographic reference	Hallert (2009) Ref ID: 347
Comments	No mention of allocation concealment and not reported the method of randomisation. Imprecise effect estimates due to small sample size with high number of withdrawals. Only conducted per-protocol analysis (no ITT). Study population only comprised of middle-aged adults living in Sweden. The design of the study was unable to clarify which B vitamins were connected with the study outcomes.
Authors' own conclusion: Adults with longstanding coeliac disease taking extra B vitamins for 6 months showed normalized tHcy and significant improvement in general well-being, suggesting that B vitamins should be considered in people advised to follow a gluten-free diet.	
Bibliographic reference	Hogberg (2004): Oats to children with newly diagnosed coeliac disease: a randomised double blind study Reference ID: 367 Hollen (2006a): Coeliac children on a gluten-free diet with or without oats display equal anti-avenin antibody titres Reference ID: 603 Hollen (2006b): Urinary nitric oxide during one year of gluten-free diet with or without oats in children with coeliac disease Reference ID: 559 <i>Note: multiple publications of the same study</i>
Study type	RCT
Study quality	Low quality
Number of patients	Total = 116 children; GFD with oats = 57, standard GFD = 59 Withdrawals and lost-to-follow up: GFD with oats = 15 withdrawn (6/15 withdrawn due to suspected intolerance to study diet), no lost to follow-up Standard GFD = 7 withdrawn (2/7 withdrawn due to suspected intolerance to study diet), 2 lost to follow-up Per-protocol analysis (GFD with oats = 42, standard GFD = 50)
Patient characteristics	Inclusion criteria: Children with 'newly diagnosed' symptomatic CD, willingness to participate, aged less than 18 years, small bowel biopsy showing enteropathy, and a good understanding of the Swedish language. Baseline characteristics:

Bibliographic reference	Hallert (2009) Ref ID: 347
	<ul style="list-style-type: none"> • Mean age = 6.5 years (SD 4.6; median 6.0; range 8 months–17.5 years). • Children less than 2-year old (PP) = 20/42 (GFD with oats); 12/50 (standard GFD) • The male/female distribution was equal in the two groups (1.0/1.4). • 7 children had diabetes mellitus (3 in the GFD-oats group; 6 had IgA deficiency only one of them in the GFD-oats group. The only patient with Down's syndrome had GFD without oats).
Intervention	<p>GFD with oats (aimed at a daily oat intake of 25–50g)</p> <ul style="list-style-type: none"> • The oats used were specially grown, milled, and packaged so as not to become contaminated with wheat, rye, or barley. The oat products were tested by an ELISA assay to ensure absence of gluten contamination.
Comparison	Standard GFD
Length of follow up	12-month study period (the parents of each study patient were requested to monitor the daily intake of study products for the first month of the diet and thereafter for one week immediately prior to visits to the clinic at 3, 6, 9, and 12 months, respectively).
Location	8 Swedish paediatric clinics in Norrköping, Linköping, Motala, Västervik, Västera's, Örebro, Stockholm (Sachska Hospital), and Göteborg, between April 1998 and September 2001.
Outcomes measures and effect size	<p>Blood samples were taken at 0, 3, 6, and 12 months. Sera were stored at 220°C pending analysis. IgA anti gliadin antibody (AGA), antiendomysium antibody (EMA), and anti-tissue transglutaminase (TGA) titres were measured. Total IgA titre was also measured. When a low IgA value was found, measurement of IgG EMA titre was also done. After approximately one (mean 1.1 years; range 0.9–1.5) year on the GFD with or without oats, a small bowel biopsy was done to assess healing of the mucosa.</p> <p>No ITT, only per-protocol analysis (GFD with oats = 42, standard GFD = 50)</p> <p>In the GFD-oats group, due to some children consumed very small amounts of oat products towards the end of the study year, the GFD-oats patients were further divided into two subgroups according to the amount of oats ingested at the end of the study year: children taking at least 8 g of oats daily (n=34) and children taking less than 8 g daily (n=8).</p> <p>Outcomes (at 12-month):</p>

Bibliographic reference	Hallert (2009) Ref ID: 347
	<ul style="list-style-type: none"> • Enteropathy: GFD-oats (all) = 0/42, GFD-oats ≥8g = 0/34, standard GFD = 2/50, RR (N/A), p>0.05 • Mean IEL count (per 100 enterocytes) (SD): GFD-oats (all) = 16 (4.5), GFD-oats ≥8g = 16 (4.0), standard GFD = 16 (5.0); P_(all vs. std) = 0.84, P_(≥8g vs. std) = 0.94 • IgA EMA positive: GFD-oats (all) = 14/42, GFD-oats ≥8g = 12/34, standard GFD = 12/50 [RR_(oat-all vs. std) = 1.39 (95%CI: 0.72 to 2.67); RR_(oats≥8g vs. std) = 1.47 (95%CI: 0.75 to 2.88)] • IgA EMA titres 1:10-1:20: GFD-oats ≥8g = 5/34, standard GFD = 8/50, RR = 0.92 (95%CI: 0.33 to 2.57) • IgA EMA titres 1:40-1:80: GFD-oats ≥8g = 7/34, standard GFD = 4/50, RR = 2.57 (95%CI: 0.82 to 8.12) • TGA positive: GFD-oats (all) = 7/42, GFD-oats ≥8g = 7/34, standard GFD = 5/50 [RR_(oat-all vs. std) = 1.67 (95%CI: 0.57 to 4.87); RR_(oats≥8g vs. std) = 2.06 (95%CI: 0.71 to 5.95)] • Median TGA titres (range): GFD-oats ≥8g = 7.0 (5.1-11.0), standard GFD = 12.0 (5.7-15.0), p=0.04 <p>Other serological outcomes (at 12-month):</p> <p><i>Optical density values (in relation to a high antibody level reference serum):</i></p> <p><u>Median IgA anti-avenin antibodies (range):</u> GFD-oats [n=38] = 0.24 (0.06 to 1.89), standard GFD [n=43] = 0.18 (0.01 to 1.05); p = 0.13</p> <p><u>Median IgG anti-avenin antibodies (range):</u> GFD-oats [n=38] = 0.93 (0.38 to 1.55), standard GFD [n=45] = 1.08 (0.51 to 1.62); p = 0.26</p> <p><i>Nitric oxide (NO) metabolites in morning urine as indicator of ongoing inflammation in the small intestine (the cut-off value = 1406 µM):</i></p> <p><u>Number of children above the cut-off value at 12-month:</u> GFD-oats = 9/34, standard GFD = 8/41; RR = 1.36 (95%CI: 0.59 to 3.13)</p>
Source of funding	The Cerealia Foundation R&D, the Health Research Council in the South-East of Sweden, Swedish Nutrition Foundation, the

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	Swedish Medical Society, Semper AB, the Va ^o rdal Foundation, the Odd Fellow Foundation, and Pharmacia Diagnostics, Sweden.
Comments	<ul style="list-style-type: none"> • Methods of randomisation not reported, blinding achieved by mixing oats were with otherwise gluten free products, such as mixes for formula, porridge and bread, baked ready-made bread, and cookies. • High number of withdrawals from the GFD with oats group due to intolerance to the diet, hence, bias towards underestimating the effect estimates. • No ITT analysis, different PP analyses were conducted. • Only 12-month follow-up, lack of data on long-term consequences.
Author's conclusion: This is in accordance with the findings of studies in adult coeliacs and indicates that oats, added to the otherwise GFD, can be accepted and tolerated by the majority of children with CD.	

Bibliographic reference	Janatuinen (1995): A comparison of diets with and without oats in adults with coeliac disease Reference ID: 1122 Janatuinen (2000): Lack of cellular and humoral immunological responses to oats in adults with coeliac disease Reference ID: 957 Janatuinen (2002): No harm from five year ingestion of oats in coeliac disease Reference ID: 375 Kemppainen (2007): No observed local immunological response at cell level after five years of oats in adult coeliac disease Reference ID: 548 <i>Note: multiple publications from the same study</i>
Study type	RCT
Study quality	Low quality
Number of patients	In remission: Total = 52; oat-group = 26, control-group = 26 Newly diagnosed: Total = 40; oat-group = 19, control-group = 21

Bibliographic reference	<p>Janatuinen (1995): A comparison of diets with and without oats in adults with coeliac disease Reference ID: 1122</p> <p>Janatuinen (2000): Lack of cellular and humoral immunological responses to oats in adults with coeliac disease Reference ID: 957</p> <p>Janatuinen (2002): No harm from five year ingestion of oats in coeliac disease Reference ID: 375</p> <p>Kemppainen (2007): No observed local immunological response at cell level after five years of oats in adult coeliac disease Reference ID: 548</p> <p>Note: multiple publications from the same study</p>
	<p><u>Withdrawals (total = 11):</u> <i>In remission group:</i> Oat-group = 3 (worsening of itching x 2, abdominal symptoms x 1) Control-group = 3 (worsening of itching x 1, withdrew without reason x 2) <i>Newly diagnosed group:</i> Oat-group = 3 (abdominal symptoms x 1, withdrew without reason x 2) Control-group = 2 (worsening of itching x 1, withdrew without reason x 1)</p> <p>At 5-year follow-up (merged in remission group and newly diagnosed group): Total = 63; oat-group = 35, control-group = 28</p>
Patient characteristics	<p><i>Inclusion criteria (in remission group):</i></p> <ul style="list-style-type: none"> • 18 years of age or older and have normal or almost normal duodenal villous architecture while eating a gluten-free diet for at least 12 months (the original diagnosis of coeliac disease was based on the presence of subtotal or total villous atrophy of the duodenal mucosa before the introduction of the gluten-free diet). <p><i>Inclusion criteria (newly diagnosed group):</i></p> <ul style="list-style-type: none"> • All new adult patients with subtotal or total villous atrophy diagnosed (biopsy confirmed) at the Kuopio University Hospital between 1 December 1988 and 1 December 1990, were included in the study.

<p>Bibliographic reference</p>	<p>Janatuinen (1995): A comparison of diets with and without oats in adults with coeliac disease Reference ID: 1122</p> <p>Janatuinen (2000): Lack of cellular and humoral immunological responses to oats in adults with coeliac disease Reference ID: 957</p> <p>Janatuinen (2002): No harm from five year ingestion of oats in coeliac disease Reference ID: 375</p> <p>Kemppainen (2007): No observed local immunological response at cell level after five years of oats in adult coeliac disease Reference ID: 548</p> <p>Note: multiple publications from the same study</p>
	<p><i>Exclusion criteria (for both in remission and newly diagnosed groups):</i></p> <ul style="list-style-type: none"> • Previous or current corticosteroid therapy; a history of complications of coeliac disease; any neurologic, cardiovascular, pulmonary, metabolic, hematologic, or endocrine disorder that could hinder participation; a history of drug or alcohol abuse; mental impairment; lack of cooperation; and refusal to take part. • Patients were also excluded if their diagnosis was not definite (e.g. if there was any other reason for villous atrophy such as cancer, previous irradiation, collagenous disease, or inflammatory bowel disease. • Patients who already consumed oats. <p>Baseline characteristics:</p> <p><i>In remission group</i></p> <p>Gender (men/women): oat-group = 9/17 ; control-group = 8/18 Mean age (years) (SD): oat-group = 48 (12) ; control-group = 42 (10) Baseline mean (SD) symptom score (flatulence, abdominal pain and distention, general well-being): oat-group = 15.6 (13.7) ; control-group = 24.9 (23.1) Baseline mean (SD) villous atrophy grade (histopathological grade): oat-group = 0.57 (0.43) ; control-group = 0.54 (0.39)</p> <p><i>Newly diagnosed group</i></p> <p>Gender (men/women): oat-group = 7/12 ; control-group = 5/16 Mean age (years) (SD): oat-group = 42 (14) ; control-group = 48 (11) Baseline mean (SD) symptom score (flatulence, abdominal pain and distention, general well-being): oat-group = 35.3 (20.2) ;</p>

Bibliographic reference	<p>Janatuinen (1995): A comparison of diets with and without oats in adults with coeliac disease Reference ID: 1122</p> <p>Janatuinen (2000): Lack of cellular and humoral immunological responses to oats in adults with coeliac disease Reference ID: 957</p> <p>Janatuinen (2002): No harm from five year ingestion of oats in coeliac disease Reference ID: 375</p> <p>Kemppainen (2007): No observed local immunological response at cell level after five years of oats in adult coeliac disease Reference ID: 548</p> <p>Note: multiple publications from the same study</p>
	<p>control-group = 26.6 (21.4) Baseline mean (SD) villous atrophy grade (histopathological grade): oat-group = 1.85 (0.68) ; control-group = 1.89 (0.65)</p> <p>At 5-year follow-up (merged in remission group and newly diagnosed group): Gender (male/female): oats-group = 13/22; control-group = 10/18 Mean age (SD): oats-group = 53 (12) years; control-group = 52 (10) years. Mean (SD) duration of the gluten free diet: oats-group = 10 (7) years; control-group = 10 (6) years Mean (range) intake of oats: oats-group = 34 (10–70)g/day. Compliance with strict-GFD: oats-group = 25/35 (71.4%); control-group = 22/28 (78.6%)</p>
Intervention	<p>The oat group received products supplemented with oats (2 types of gluten-free wheat-starch flour mixed with an equal amount of oats, muesli containing 60 percent oats, and rolled-oat breakfast cereal). The goal for the daily intake of oats was 50g to 70g.</p> <p><u>Mean oat intake per day (SD):</u> At 6-month: In remission group = 49.9g (14.7g); Newly diagnosed group = 43.6g (11.3g) At 12-month: Newly diagnosed group = 46.6g (13.3g) 21 (81%) of the patients in remission and 14 (74%) of the patients with newly diagnosed disease were consuming more than 30 g of oats per day by the end of the study.</p>
Comparison	Control group received gluten-free cereal products (a mixture of low-protein flours containing 0.74 mg of gluten per gram of

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	foodstuff).
Length of follow up	6-month for the in remission group; 12-month for the newly diagnosed group; 5-year follow-up for a subgroup of patients
Location	The Kuopio University Hospital, Finland, between 1 Dec 1988 and 31 Dec 1990
Outcomes measures and effect size	<p>Villous atrophy was graded as 1 = partial; 2 = subtotal; or 3 = total. A grade of 0 indicates the absence of villous atrophy.</p> <p>Villous atrophy (mean histopathological grade) <i>Mean change from baseline (SD):</i> <u>In remission group (at 6-month)</u> Oat-group = 0.01 (0.36) ; control-group = -0.06 (0.31); p=0.53 Mean change differences between groups = 0.07 (95%CI: -0.12 to 0.26) <u>Newly diagnosed group (at 12-month)</u> Oat-group = -1.07 (0.58) ; control-group = -1.20 (0.42); p=0.74 Mean change differences between group = 0.13 (95%CI: -0.23 to 0.43)</p> <p>Symptom score (flatulence, abdominal pain and distention, general well-being) (average of the 4 variables, each variable measured on a 100-mm scale, ranging from 0 = no symptoms at all; to 100 = extremely severe symptoms) <i>Mean change from baseline (SD):</i> <u>In remission group (at 6-month)</u></p>

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	<p>Oat-group = 6.7 (17.5) ; control-group = 2.1 (10.8); p=0.45 Mean change differences between groups = 4.6 (95%CI: -3.5 to 12.8) <u>Newly diagnosed group (at 12-month)</u> Oat-group = -8.2 (26.6) ; control-group = -8.4 (22.7); p=0.78 Mean change differences between groups = 0.2 (95%CI: -15.6 to 16.0)</p> <p>Anti-gliadin IgA (EU/ml) <u>In remission group (at 6-month)</u> Median (range) change from baseline: Oat-group = 0.0 (-0.47 to 0.41); control-group = 0.0 (0.0 to 0.39); p=0.33 <u>Newly diagnosed group (at 12-month)</u> Median (range) change from baseline: Oat-group = -0.73 (-0.99 to 0.00); control-group = -0.57 (-9.38 to 0.00); p=0.69</p> <p>Anti-gliadin IgG (EU/ml) <u>In remission group (at 6-month)</u> Median (range) change from baseline: Oat-group = 0.0 (-1.21 to 2.02); control-group = 0.0 (-2.63 to 0.86); p=0.12 <u>Newly diagnosed group (at 12-month)</u></p>

Bibliographic reference	<p>Janatuinen (1995): A comparison of diets with and without oats in adults with coeliac disease Reference ID: 1122</p> <p>Janatuinen (2000): Lack of cellular and humoral immunological responses to oats in adults with coeliac disease Reference ID: 957</p> <p>Janatuinen (2002): No harm from five year ingestion of oats in coeliac disease Reference ID: 375</p> <p>Kemppainen (2007): No observed local immunological response at cell level after five years of oats in adult coeliac disease Reference ID: 548</p> <p><i>Note: multiple publications from the same study</i></p>
	<p>Median (range) change from baseline: Oat-group = -7.09 (-29.85 to 0.00); control-group = -2.99 (-55.2 to 0.53); p=0.99</p> <p>Anti-reticulin IgA (EU/ml)</p> <p><u>In remission group (at 6-month)</u> Median (range) change from baseline: Oat-group = 0.0 (-50.0 to 0.00); control-group = 0.0 (-50.0 to 0.00); p=1.00</p> <p><u>Newly diagnosed group (at 12-month)</u> Median (range) change from baseline: Oat-group = -200.0 (-2000.0 to 0.00); control-group = -175.0 (-4000.0 to 5.00); p=0.79</p> <p>Intraepithelial lymphocytes (IEL) count/100 epithelial cells</p> <p><u>In remission group (at 6-month)</u> Mean (SD) change from baseline: Oat-group = -0.6 (21.8); control-group = 2.0 (11.7); p=0.94 Mean change differences between group = -2.6 (95%CI: -12.3 to 7.2)</p> <p><u>Newly diagnosed group (at 12-month)</u> Mean (SD) change from baseline:</p>

<p>Bibliographic reference</p>	<p>Janatuinen (1995): A comparison of diets with and without oats in adults with coeliac disease Reference ID: 1122</p> <p>Janatuinen (2000): Lack of cellular and humoral immunological responses to oats in adults with coeliac disease Reference ID: 957</p> <p>Janatuinen (2002): No harm from five year ingestion of oats in coeliac disease Reference ID: 375</p> <p>Kemppainen (2007): No observed local immunological response at cell level after five years of oats in adult coeliac disease Reference ID: 548</p> <p>Note: multiple publications from the same study</p>
	<p>Oat-group = -23.8 (23.3); control-group = -21.7 (14.5); p=0.84 Mean change differences between group = -2.1 (95%CI: -14.4 to 10.2)</p> <p><u>At 5-year follow-up (merged in remission group and newly diagnosed group):</u> Total = 63; oat-group = 35, control-group = 28</p> <p>Villous atrophy (mean histopathological grade) <u>Mean change from 6-12month (SD):</u> Oat-group = -0.55 (0.54) ; control-group = -0.52 (0.45); p=0.54 Mean change differences between groups = 0.03 (95%CI: -0.29 to 0.23)</p> <p>Local cellular immunological responses at 5-year follow-up (Data only available for oat-group = 22, control-group = 20) Median CD3+: Oat-group = 47; control-group = 47; p=0.51 Median αβ+: Oat-group = 20; control-group = 30; p=0.23 Median γδ+: Oat-group = 14; control-group = 16; p=0.90</p>
<p>Source of funding</p>	<p>Supported by grants from the Yrjö Janhsson Foundation and the Finnish Gastroenterological Association. The oat products were supplied by Raisio Factories, Melia, Raisio, Finland.</p>

<p>Bibliographic reference</p>	<p>Janatuinen (1995): A comparison of diets with and without oats in adults with coeliac disease Reference ID: 1122 Janatuinen (2000): Lack of cellular and humoral immunological responses to oats in adults with coeliac disease Reference ID: 957 Janatuinen (2002): No harm from five year ingestion of oats in coeliac disease Reference ID: 375 Kempainen (2007): No observed local immunological response at cell level after five years of oats in adult coeliac disease Reference ID: 548 <i>Note: multiple publications from the same study</i></p>
<p>Comments</p>	<ul style="list-style-type: none"> • Randomisation according to gender, with allocation concealment and assessors blinded. • ITT analysis was conducted. • Small sample size.
<p>Author's conclusion: Moderate amounts of oats can be included in a gluten-free diet for most adult patients with coeliac disease without adverse effects.</p>	

Bibliographic reference	Peraaho (2004): Effect of an Oats-Containing Gluten-free Diet on Symptoms and Quality of Life in Coeliac Disease. A Randomized Study Reference ID: 733
Study type	RCT (randomization was carried out using random-number tables)
Study quality	Low quality
Number of patients	Total = 39; GFD with oats = 23, GFD without oats = 16 Withdrawals: GFD with oats = 3, GFD without oats = 0 (reasons for withdrawal: due to gastrointestinal pain and abdominal distension)
Patient characteristics	Inclusion criteria: Adult patients with biopsy-proven coeliac disease and all had been on a gluten-free diet without oats, definite, though not necessarily complete, mucosal recovery was evident in all. Baseline characteristics: Gender (male/female): GFD with oats = 17/6, GFD without oats = 12/4 Median age (range): GFD with oats = 48 (25-69), GFD without oats = 46 (22-65) Time on GFD (median months, range): GFD with oats = 34 (13-81), GFD without oats = 27 (12-48) The average daily fibre consumption was similar at the time of enrolment, and neither group showed significant alterations in average daily fibre consumption; the average daily consumption of oats in the GFD with oats group was 30g.
Intervention	50g of oats-containing gluten-free products daily
Comparison	To continue their current diet without oats
Length of follow up	12-month
Location	Department of Medicine of Tampere University Hospital, Finland.
Outcomes measures and effect size	<u>Median daily oats consumption in grams (range):</u> At baseline: GFD with oats = 0, GFD without oats = 0 At 12-month: GFD with oats = 28 (0-70), GFD without oats = 0

Bibliographic reference							
Peraaho (2004): Effect of an Oats-Containing Gluten-free Diet on Symptoms and Quality of Life in Coeliac Disease. A Randomized Study Reference ID: 733							
<p><u>Mean Psychological General Well-being questionnaire (PGWB) score (SD):</u> Baseline: GFD with oats = 103.8 (11.4), GFD without oats = 105.4 (17.2) At 12-month: GFD with oats = 98.8 (20.0), GFD without oats = 101.3 (16.1); p>0.05</p> <p>Gastrointestinal symptom rating scale (GSRS):</p>							
	GFD with oats (mean, SD)		GFD without oats (mean, SD)		p-values (ANOVA)		
Symptom	Baseline	12-month	Baseline	12-month	Group	Period	Interaction
Total score	1.86 (0.55)	2.00 (0.50)	2.08 (0.77)	1.94 (0.70)	0.917	0.876	0.094
Diarrhoea	1.59 (0.51)	2.03 (0.74)	1.90 (0.88)	1.69 (0.91)	0.645	0.540	0.010
Indigestion	2.27 (0.66)	2.06 (0.59)	2.81 (1.17)	2.13 (1.14)	0.597	0.002	0.0651
Constipation	1.79 (1.03)	2.24 (0.70)	1.88 (1.22)	2.23 (1.23)	0.785	0.010	0.297
Abdominal pain	1.85 (0.73)	1.56 (0.39)	1.85 (0.57)	1.83 (0.58)	0.307	0.267	0.297
Reflux	1.75 (1.07)	2.07 (0.92)	1.63 (1.00)	1.81 (0.87)	0.432	0.051	0.781
<p>Mucosal and laboratory findings (at 12-month):</p>							
	GFD with oats (n=18)		GFD without oats (n=13)		p-value		
CD3+IELs*	44.6 (22.7)		26.7 (21.0)		0.039		
αβ+cells	29.8 (18.8)		19.9 (20.3)		0.141		
γδ+cells	11.3 (6.1)		5.3 (6.2)		0.050		
Mean haemoglobin g/L	130		134		>0.05		
Mean erythrocyte folate nmol/L	540		489		>0.05		
Mean serum iron μmol/L	16.4		17.7		>0.05		
*IELs = Intraepithelial lymphocytes/millimetre of epithelium							

Bibliographic reference	Peraaho (2004): Effect of an Oats-Containing Gluten-free Diet on Symptoms and Quality of Life in Coeliac Disease. A Randomized Study Reference ID: 733
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Comments	Randomised using random-number tables, with allocation concealment, blinding (especially assessor) not reported, small sample size, lack of baseline data (e.g. inclusion/exclusion criteria), unclear ITT was carried out.
	Author's conclusion: The oats-containing gluten-free diet caused more intestinal symptoms than the traditional diet. Mucosal integrity was not disturbed, but more inflammation was evident in the oats group. Oats provide an alternative in the gluten-free diet, but coeliac patients should be aware of the possible increase in intestinal symptoms.