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Extrinsic wheat fibre consumption enhances faecal bulk and stool frequency; a randomized controlled trial†

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The beneficial effect of wheat fibres on faecal bulk and stool pattern has mainly been observed with *intact* wheat fibres. This study investigates the effect of *extrinsic* wheat fibre (VITACEL® wheat fibre), which can be easily incorporated in many food products, on faecal bulk, stool pattern, gastrointestinal complaints, satiety and food liking. In a double-blind randomized crossover trial, healthy male volunteers received meal boxes for 10 days, containing various food products enriched with extrinsic wheat fibre (~20 grams of additional fibre per day) or control food products containing conventional levels of fibre with similar taste, appearance and caloric values. Meal boxes were integrated in the normal dietary pattern. Stool frequency, stool consistency, gastrointestinal complaints, satiety and product liking were assessed daily, and the last 5 days of each intervention, participants collected all their faeces to analyse faecal bulk. We found that consumption of extrinsic wheat fibre-enriched products significantly enhanced faecal bulk; faecal wet and dry weight showed a 1.41 ± 0.1 and 1.55 ± 0.1 times increase compared to control, respectively ($p < 0.01$). Extrinsic wheat fibre intervention furthermore increased stool frequency (1.3 ± 0.1 defecations per day compared to 1.1 ± 0.1 defecations per day during control diet, $p < 0.05$), but did not affect stool consistency, satiety, gastrointestinal complaints or product liking. So, increased consumption of extrinsic wheat fibre enhances faecal bulk and stool frequency. As this extrinsic wheat fibre can be easily incorporated in many food products without affecting appearance or taste, it might facilitate the increase of overall fibre intake and subsequently improve (intestinal) health.

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Introduction

Dietary Fibres have been linked to improved bowel function for decades. But not all dietary fibres or fibre components have similar health effects.¹ A commonly consumed type of fibre is wheat fibre. Wheat is a type of grass plant, which serves as an important staple food. Most of the fibre is located in the outer layers of the wheat grain (pericarp and seed coat) also referred to as wheat bran. In several human studies, a beneficial effect of wheat bran on faecal bulk has been demonstrated.^{2,3} De Vries *et al.* recently published a systemic review of human intervention trials which showed that intact wheat fibres have a beneficial effect on bowel function, including increased total faecal weight, faecal dry weight and stool frequency.² This review reported no adverse effects of wheat fibre interventions. The underlying

mechanism of the capability of wheat fibre to increase faecal bulk is assumed to be that insoluble components of wheat fibre are minimally degraded by colonic bacteria, and thus remain to trap water, thereby increasing faecal bulk.⁴

Even though intake of dietary fibre is associated with various health effects, including prevention of (colorectal) cancer, cardiovascular disease, obesity and improved gastrointestinal functioning,⁵ in general the intake of dietary fibre is below the national guidelines (25–40 grams per day) in the US and Europe.^{6,7} In the US, average fibre intake is assumed to be even below 20 grams per day.⁷ To increase the amount of fibre in our daily menu, fibres can be added to food products, thereby enhancing human health.

In most previously performed studies on the effect of wheat fibre on faecal bulk, intact (non-extracted) fibre was used. Intact wheat fibres are derived from any part of the plant, including the kernel, hull or stalk. In general, intact wheat fibres are minimally processed, although some degree of processing may be required to obtain the fibre-rich portion of the kernel (*e.g.* milling of bran) or to improve food functionality or safety (*e.g.* pearling, grinding, or bleaching). In contrast, wheat fibres can be extracted, isolated, or made by chemical or enzy-

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matic means. A major advantage of extracted wheat fibres could be that they can be easily incorporated in food products without affecting appearance or taste, thereby facilitating fibre-enrichment in a low-threshold manner. However, effects of extracted (or extrinsic) wheat fibres on faecal bulk have been studied much less extensively. A previous study of Vuksan *et al.* suggests that extraction of wheat fibre does not necessarily affect its faecal bulk enhancing capacities,³ but this can so far not be guaranteed.

In this study, we investigated the effect of an extrinsic wheat fibre, called VITACEL® wheat fibre, on faecal bulk, stool pattern, gastrointestinal complaints, satiety and food liking. It is a mixed plant cell wall fibre and approved by FDA as dietary fibre. The extrinsic wheat fibre was incorporated into various products (*e.g.* meatballs, pizza, bread, sandwiches, cookies, instant soup, pancakes), thereby spreading the consumption of such fibres evenly throughout the day. The fibre-enriched food products provided during the study totally added up to 18–22 gram per day, in order to increase the habitual diet towards a recommended fibre intake of 30–40 grams per day (Dutch dietary guidelines).

Materials & methods

Trial design

A double-blind crossover randomized controlled trial was conducted, in which participants received daily meal boxes with an extrinsic wheat fibre-enriched or control diet for 10 days with a wash-out period of 4 days between the two interventions. In the last 5 days of each intervention, participants collected all faeces to analyse faecal bulk (faecal wet weight and faecal dry weight; primary outcome). After collection, faecal samples were frozen at -20°C and stored until further analyses. To check compliance with the intervention, participants kept a diary indicating if and when they consumed the provided products. They were furthermore asked to daily report stool frequency and complete a questionnaire on stool consistency (*via* Bristol Stool Chart⁸), gut-related complaints (*e.g.* cramps, bloating and flatulence; rated on scale 0–10: no complaints (0), very mild (2), mild (4), moderate (6), severe (8), or extremely severe (10)⁹), satiety (defined as ‘feeling of fullness’¹⁰) and product liking (scale 0–10) (secondary outcomes). A simple food diary had to be completed on a daily basis to get a general impression of the rest of the diet. Adverse events (AE) during the study were reported and discussed with the research physician. The trial was carried out in accordance with the declaration of Helsinki and was approved by the medical ethical committee of Wageningen University, the Netherlands. Signed informed consent was obtained from all subjects before initiation of the study. This trial was registered at ClinicalTrials.gov as NCT03313440.

Participants

Sample size calculation was based on the assumption that the addition of 1 gram of wheat fibre per day would increase faecal

output by ~ 2.7 grams per day.¹¹ Paired testing, with $\alpha = 0.05$, $\beta = 0.20$, $\mu = 54$ grams per day (expected relevant increase in faecal wet weight) and $\sigma = 70$ grams per day resulted in a sample size of 16 participants to find a significant increase in faecal wet weight between the control and extrinsic wheat fibre-enriched diet. Only male participants were recruited due to practical reasons for faecal collection. Healthy males, age 18–70 years old and BMI 20–30 kg m^{-2} , were screened for their habitual fibre intake by performing a food frequency questionnaire.¹² Participants with an habitual fibre intake of <23 grams per day were included in the trial. Men with digestive tract disorders (*e.g.* (partial) gastric resection, (hemi)colectomy, Crohn’s disease, ulcerative colitis, irritable bowel disease, Coeliac disease), known food allergies (*e.g.* lactose, gluten, nuts, egg, *etc.*), use of pro- or prebiotics, use of medication that could interfere with study outcomes (including laxatives, diuretics, antidepressants, codeine or antibiotics), alcohol intake ≥ 40 g day^{-1} , drug abuse, vegetarians and current smokers were excluded from the study.

After enrollment, subjects were randomly allocated into 2 intervention sequences (AB or BA) using block randomization. Treatments were encoded A or B. Encoding was performed by an external dietician not involved in the study. Encoding was broken after all data analysis had been performed. Participants, trial conductors and those assessing outcomes were all blinded for the interventions.

Intervention

Participants received meal boxes to consume at home, with either food products enriched with extrinsic wheat fibre (VITACEL® wheat fibre, JRS Rettenmaier & Söhne+CO.KG, Rosenberg, Germany) or control food products containing conventional levels of fibre. The VITACEL® wheat fibre is a white, fine-fibred dietary fibre concentrate extracted from the wheat plant. The fibre-enriched and control meal boxes were iso-caloric and did not differ significantly in total protein, fat and carbohydrates (Table 1). Products had a similar taste and appearance. The boxes contained products like bread, pizza, pancakes, meat balls, pasta, pasta sauce, soup, cookies, *etc.*, accounting for ~ 800 – 1000 kcal day^{-1} . The fibre-enriched boxes contained ~ 20 grams of additional fibre per day (for more details, see ESI Tables 1 and 2†). In each intervention period, participants could choose which box they wanted to consume on which day, except for day 1 and 2 (due to step-wise increase of fibre intake: day 1; 6 grams of fibre per day and day 2; 12 grams of fibre per day). Each meal box contained accurate instructions on how to prepare and consume the products from the box. Participants were advised to drink (at least) 2 litres of water per day. Participants were instructed to maintain the same habitual dietary pattern during the two intervention periods and to maintain their normal level of physical activity. Meal boxes were integrated in the normal dietary pattern of participants.

Faecal bulk analysis

After weighing wet faecal samples (=faecal wet weight, FWW), the samples were thawed and faecal dry matter (=faecal dry



Table 1 Composition of meal boxes

	Box #	Energy (kcal)	Protein (g)	Fat (g)	CHO (g)	Fibre total (g)	Of which extrinsic wheat fibre added (g)
Control diet	1	409	11.4	6	75.3	4.5	0
	2	1236	49.1	41.8	160.4	10.4	0
	3	1563	53.2	54.6	208.6	10.8	0
	4	1563	53.2	54.6	208.6	10.8	0
	5	1575	57.3	66.8	181.1	9.5	0
	6	1831	59.7	66	241.4	14.6	0
	7	1459	42.4	58.2	186.7	8.9	0
	8	1425	44.7	63.6	164.7	8.1	0
	9	1874	66	83.6	207.1	12.9	0
	10	1288	44.3	42.6	176.5	9.4	0
	Mean (box 3–10)	1572.3	52.6	61.3	196.8	10.6	0.0
Extrinsic wheat fibre-enriched diet	1	397	11.9	7.2	65.9	10.8	6
	2	1257	48.7	48	145.9	22.3	12.4
	3	1514	49.5	52.7	181.9	32.6	20.7
	4	1514	49.5	52.7	181.9	32.6	20.7
	5	1514	53.5	63.3	157.1	31.1	20.5
	6	1849	59.1	73.4	220.2	33.7	19.5
	7	1406	40.6	57.4	167.3	28.7	19.9
	8	1375	42.7	61.1	149.2	29.3	21.2
	9	1874	64.1	87.9	189.2	32.8	19.9
	10	1244	40.7	39.9	154.5	31.3	20.3
	Mean (box 3–10)	1536.3	50.0	61.1	175.2	31.5	20.3
	<i>p</i> -Value	0.736	0.545	0.976	0.091	<0.001	<0.001

weight, FDW) was determined. For this, ten grams of the thawed wet faecal samples were oven-dried for 16 hours at 70 °C, followed by 4 hours at 103 °C. Samples were cooled-down in a desiccator for at least 30 minutes and weight was assessed on an analytical balance. FDW analyses were performed in triplicate to ensure reproducibility.

Statistical analysis

For all parameters, significant differences between the control and extrinsic wheat fibre-enriched intervention period were assessed using a Paired Samples *T*-test (IBM SPSS Statistics, Version 22). A Wilcoxon Rank sum test was also conducted for parameters that were not normally distributed (data not shown), resulting in similar outcomes that showed significant differences between the two interventions.

Results

Subject characteristics, compliance & product liking

In total thirty-three healthy males that met the inclusion and exclusion criteria were screened for their habitual fibre intake. Twenty-two volunteers with a fibre intake of less than 23 grams per day were included in the trial, of which eighteen subjects successfully completed the two intervention periods (ESI Fig. 1†). The average age of these remaining 18 volunteers was 55.4 ± 3.7 , ranging from 20–69 years old. Their average fibre intake at start of the study was 17.6 ± 1.0 grams per day. In both intervention periods, 11 out of 18 volunteers were 100% compliant with the diet, meaning consumption of all the products provided in the meal boxes. The others showed an

overall compliance between 90–99%. Individual compliance was highly balanced between the two intervention periods. In each intervention, the volunteers also had to score their liking of the products in the meal boxes. Liking-scores for each product were highly comparable for the fibre-enriched intervention and control period, with an average product-liking score of 6.0 ± 0.4 and 5.9 ± 0.4 (on a scale from 0–10), respectively.

Effect of extrinsic wheat fibre consumption on faecal bulk

To assess faecal bulk, FWW and FDW were determined of the faecal samples collected during the two intervention periods. Table 2 shows that the fibre-enriched diet significantly increased the absolute amounts of FWW and FDW compared to the control diet ($p < 0.01$). FWW and FDW increased by 1.41 ± 0.1 and 1.55 ± 0.1 times, respectively. The fibre-enriched diet led to an increase of FDW in all subjects (Fig. 1). From the absolute values of FWW (Table 2), the increase in FWW per day for each gram of supplemented dietary fibre was calculated, resulting in a 2.7 grams-increase of FWW per gram of dietary fibre added to the diet ($229.4-175.2/20$). Also percentage of faecal dry weight (= faecal dry weight/faecal wet weight $\times 100\%$) was significantly higher on the extrinsic wheat fibre-enriched diet compared to the control diet.

Effect of extrinsic wheat fibre consumption on stool pattern, gastrointestinal complaints & satiety

During the intervention periods, stool frequency, stool consistency, gastrointestinal complaints and satiety were scored. Table 2 shows that stool frequency was significantly higher by the fibre-enriched diet compared to the control diet (1.3 versus 1.1 bowel movements per day, respectively). Stool consistency

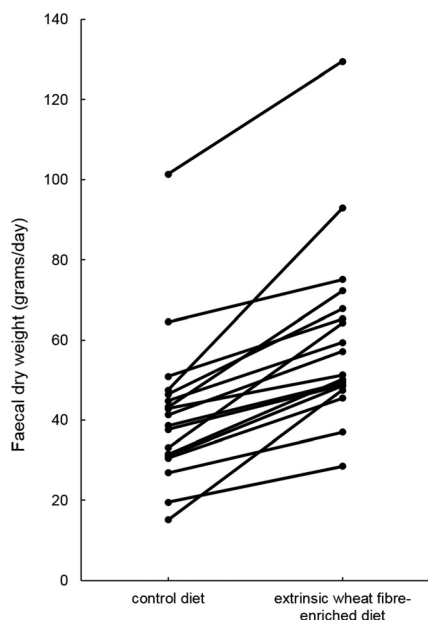


Table 2 Effect of dietary intervention on faecal bulk, stool pattern, satiety, gastrointestinal complaints and product liking

	Control diet	Extrinsic wheat fibre-enriched diet ^a	<i>p</i> -Value ^b
Faecal bulk			
Faecal wet weight (gram per day)	175.2(21.0)	229.4(24.8)	<0.001
Faecal dry weight (gram per day)	41.5(4.5)	60.5(5.4)	<0.001
Faecal dry weight (%)	26.0(1.3)	28.3(1.1)	0.002
Stool pattern			
Stool frequency (per day)	1.1(0.1)	1.3(0.1)	0.018
Stool consistency ^c	3.4(0.2)	3.6(0.2)	0.503
Satiety			
Satiety before diner ^d	3.5(0.4)	3.8(0.3)	0.386
Satiety after diner ^d	7.4(0.4)	7.3(0.4)	0.821
Gastrointestinal complaints			
Cramps	1.4(0.1)	1.4(0.1)	0.593
Bloating	1.8(0.3)	1.6(0.2)	0.290
Flatulence	1.4(0.1)	1.5(0.1)	0.477
Product liking^e			
Average score of all products	6.0(0.4)	5.9(0.4)	0.244

^a Results are displayed as means (SE). ^b Paired student *T*-test.

^c According to Bristol Stool Chart; scale 1–7. ^d Measured as feeling of fullness; scale 1–10. ^e Scale 1–10.

**Fig. 1** Individual changes in faecal dry weight induced by the extrinsic wheat fibre-enriched diet. Faecal dry weight (grams per day) obtained from faeces collected during the last 5 days of the control or extrinsic wheat fibre-enriched intervention period, for each individual.

was not significantly changed during the extrinsic wheat fibre intervention compared to control. No differences were observed between the intervention periods for gastrointestinal complaints. Satiety was scored before and after the evening-dinner, but could not be directly linked to the products in the meal boxes, as dinner was mostly combined with other food

products that could be chosen freely by the participants. No significant differences in satiety were found between the control and fibre-enriched intervention.

Discussion

In a double-blind crossover randomized controlled trial, the effect of extrinsic wheat fibre was studied on faecal bulk (primary outcome) and stool frequency, stool consistency, gastrointestinal complaints, satiety and product liking (secondary outcomes). It was found that consumption of food products enriched with this extrinsic wheat fibre increased faecal bulk (FWW and FDW), as well as stool frequency.

Outcomes of this study are highly comparable to studies using intact wheat fibre supplementation. For instance, similar to Jenkins *et al.*¹¹ we found an increase of 2.7 grams of FWW for each gram of supplemented dietary fibre. Moreover, we found an increase of 0.95 grams of FDW per day and an increase in stool frequency of 0.006 times per day for each gram of dietary fibre added to the diet, which is in line with data reported in the review of de Vries *et al.*² For the effect of intact wheat fibre on stool consistency, previous results are inconsistent as some studies show that wheat fibre 'loosens stool',¹³ whereas others report no significant effect.¹⁴ The latter fits our results. In addition to a significant increase in absolute values of FWW and FDW, we also found that consumption of extrinsic wheat fibre increases the percentage of FDW (= FDW/FWW × 100%). This indicates that extrinsic wheat fibre not only increased water content, but also the organic fraction in stool (consisting of *e.g.* bacterial biomass and indigestible food compounds) is elevated.

In previous studies, wheat fibre was predominantly offered daily in one dose, often processed in breakfast cereals.² In this study, extrinsic wheat fibre was incorporated into more diverse products (*e.g.* meatballs, pizza, bread, sandwiches, cookies, instant soup, pancakes) and by doing this, fibre intake was spread more evenly throughout the day. Incorporating the extrinsic wheat fibre in multiple products and thus processing it in several ways may affect the faecal bulk capacity, as it has previously been shown that for instance cooking can reduce the effect of wheat fibre on faecal bulk.¹⁵ However, our study shows that processing of the extrinsic VITACEL® wheat fibre in different ways does not seem to substantially affect its faecal bulk capacity.

In our study only men were included. Stephen *et al.* previously reported that there might be a difference in response to dietary fibre related to stool weight between men and women.¹⁶ Women seem to have a lower stool weight and higher transit time at basal conditions, and also have a lower increase in faecal weight after a high-fibre diet. Nevertheless, still an increase in stool weight was seen in that study and various other studies also report a substantial beneficial effect of dietary fibre in women.² Based on these data we assume that the results of extrinsic wheat fibre found in this study can also be translated to women, although the effects might be less strong. The extrinsic VITACEL® wheat fibre was also pre-



viously studied for its effect on insulin sensitivity.^{17,18} As Type 2 diabetes is a growing health issue, these studies focused on glucose clearance and insulin levels, and especially on faster clearance of glucose due to improvement of insulin sensitivity. Insulin sensitivity is a highly relevant marker to assess the effects of fibres on metabolic health and the potential prevention of metabolic disease. So, in addition to its beneficial effect on faecal bulk and stool frequency, consumption of the extrinsic wheat fibre can also improve insulin sensitivity.

In conclusion, the consumption of extrinsic wheat fibre significantly improves stool pattern, including faecal bulk and stool frequency. It does this without inducing gastrointestinal complaints like bloating, cramps and flatulence, and without affecting liking of food products. As this extrinsic wheat fibre can be easily incorporated in various food products, without compromising on the appearance or taste, it is an interesting dietary fibre to increase fibre intake in the general population, in an attractive and low-threshold way. It might thereby contribute to intestinal health and potentially even overall metabolic health.

Abbreviations

FWW	Faecal wet weight
FDW	Faecal dry weight
EWf	Extrinsic wheat fibre

Conflicts of interest

Anne Fischer and Juergen Sieg are employed by J. Rettenmaier & Sohne GmbH & Co. KG, which funded this study. All other authors received salary support from their respective institutions and declare that they have no conflict of interest.

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