# Appendix 1. *Search strings for PUBMED and EMBASE*

*Dates of searches*

- PUBMED: 6 October 2012
- EMBASE: 18 October 2012

*PUBMED search strategy*

In PUBMED the search strategy was as follows:

(cereal OR grain OR wheat OR oat OR barley OR rye OR rice OR corn OR sorghum OR triticale) AND (bran OR fiber OR fibre) AND (stool OR fecal OR faecal) AND (volume OR output OR constipation OR bulk* OR weight OR laxati* OR motor function OR gastrointestinal motility OR gastrointestinal transport time OR transit OR transit time OR bowel movemen* OR bowel function OR regularity OR consistency OR frequency OR defaecation OR bowel habit) NOT animal*

By using "NOT animal*" the search in PUBMED was limited to humans.

*EMBASE search strategy*

In EMBASE the following routine was used:

S1. CEREAL OR GRAIN OR WHEAT OR OAT OR BARLEY OR RYE OR RICE OR CORN OR SORGHUM OR TRITICALE/TI,DE,AB

S2. BRAN OR FIBER OR FIBRE/TI,DE,AB

S3. STOOL OR FECAL OR FAECAL/TI,DE,AB

S4. VOLUME OR OUTPUT OR CONSTIPATION OR BULK? OR WEIGHT OR LAXATI? OR MOTOR()FUNCTION OR GASTROINTESTINAL()MOTILITY OR GASTROINTESTINAL()TRANSPORT()TIME OR TRANSIT OR TRANSIT()TIME OR BOWEL()MOVEMEN? OR BOWEL()FUNCTION OR REGULARITY OR CONSISTE

S5. S1 A S2 AND S3 AND S4

S6. RD (unique items)

S7. S6/ENG

S8. S6/HUMAN

This search was executed on October 18, 2012.

***Criteria for relevance of publications***

Both the PUBMED search and the EMBASE search were compared for overlapping results and duplicates were eliminated. Two independent reviewers screened the titles and abstracts for relevance to the systematic review based on the following criteriaHoi Dat:

- The study performed with an intact cereal dietary fiber.
- The study was performed in humans
- The study aim corresponded with any measurement of regularity of cereal fiber or related physiological function.
- Any results of regularity of cereal fiber or related physiological function were described and discussed in the abstract.
- Stool bulking of dietary fiber or any related physiological function was framed by the search strategy as presented in table 1 (see below).
- The publication was written in English.
- Studies performed in individuals with any pathophysiological conditions, like constipation, diarrhea, irritable bowel syndrome, diverticular disease or ulcerative colitis were included in the search strategy but were excluded from detailed analysis, unless specifically mentioned.
- Studies performed in individuals up to the age of 12 months were also excluded from this review.

41 **Appendix 2.** ***PRISMA checklist***

| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | ✓ |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | After finalization manuscript |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | ✓ |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | ✓ |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | Not registered |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | Included in the database |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | ✓ |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | ✓ |

| | | | |
|---|---|---|---|
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | ✓ |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | ✓ |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | ✓ |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | Review comprises a period of more than 90 years where study reports have been published. Included studies show heterogeneity with respect to study design. |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | ✓ |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$) for each meta-analysis. | ✓ |
| **Section/topic** | **#** | **Checklist item** | Reported on page # |
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | Involvement of independent reviewer. |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | No subgroup analyses have been conducted |
| **RESULTS** | | | |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | ✓ |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | ✓ in the database, see |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | most of the studies may have be biased because of non-blinding and no randomization |

| | | | |
|---|---|---|---|
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | In the database |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | No meta-analysis! |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | ?? |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | No subgroup analyses have been conducted |
| **DISCUSSION** | | | |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | ✓ |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | ✓ |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | ✓ |
| **FUNDING** | | | |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | ✓ |

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# Appendix 3

Overview of the characteristics of included intervention studies in the comprehensive review.

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| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Holmes, A | 1919 | To examine the digestibility of wheat bran when eaten in a diet containing no wheat flour. To examine the effect of different percentages of milling of wheat upon digestibility of the protein and carbohydrates contained in the resulting flour. | Metabolic ward | No | 0% | 30% | Male | Healthy | 8 | 9 | X | | | | | |
| Cowgill, GR | 1932 | To examine the effects of bran for laxative power on human beings subsisting on suitable, carefully controlled diets. | Single arm intervention | No | 0% | 40% | Male | Healthy | 5 | 14 | X | | X | X | | |
| Williams, RD | 1936 | To examine the effect of isolated indigestible residues from naturally occurring sources with as little change as possible in their original residue on the weight of stool and laxation in man | Metabolic ward | No | 0% | 45% | Male | Healthy | 3 | 6 | X | | | | | |
| Hoppert, CA | 1942 | To examine various quantities of bran in the form of bran muffins on laxation in physiologically normal young men. | Sequential | No | 0% | 35% | Male | Healthy | 8 | 3 | | | | X | | |
| Hoppert, CA | 1945 | To obtain the coefficient of digestion with respect to crude fiber and cellulose in a set of supplementary foods, in order to determine their | Single arm intervention | No | 0% | 30% | Male | Healthy | 8 | 3 | X | X | X | | | |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | relation to laxation | | | | | | | | | | | | | | |
| McCance, RA | 1953 | To examine the effect of bread made from flours of two different extractions on the transit times of barium sulphate through the alimentary tracts of normal persons by giving a small quantity of barium sulphate mixed with a large amount of bread. | Cross-over Non-blinded placebo controlled | No | 0% | 30% | Both sexes | Healthy | 6 | 2 | | | | | X[a] | |
| Eastwood, MA | 1973 | To examine the short term effects of wheat bran on bowel habits | Single arm intervention | No | 0% | 30% | Male | Healthy | 8 | 21 | X | X | | | X[b] | |
| Payler, DK | 1973 | To examine the effect of food fiber on bowel behavior. | Single arm intervention | No | 0% | 20% | Male | Healthy | 21 | 22 | X | | | | X[b] | |
| Jenkins, DJA | 1975 | To examine the effect of supplemented wheat fiber, as whole meal bread, bran and bran-containing products, on blood lipids, fecal steroid excretion and serum iron. | Cross-over Non-blinded placebo controlled | No | 13% | 40% | Male | Healthy | 6 | 21 | X | | | | | |
| Payler, DK | 1975 | To examine the effect of bran upon intestinal transit.<br>Two studies are described:<br>* a non-blinded study without control<br>* a double blind placebo controlled study | Cross-over double blinded placebo controlled | No | 33% | 55% | Male | Healthy | 18 | 21 | | | | X | X[b] | |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Walters, RL | 1975 | To examine the effects of two different dietary fibers (residue of sugar cane, bagasse, and wheat bran) on stool weight and faecal excretion of acid, neutral steroids, and lipids. | Cross-over Non-blinded placebo controlled | No | 0% | 30% | Female | Healthy | 5 | 7 | X | X | | | X[a,b] | |
| Cummings, J | 1976 | To validatie the measurement of transit time of dietary residue through the human gut | Metabolic ward | No | 20% | 50% | Male | Healthy | 5 | 21 | | | | | X[c] | |
| Cummings, J | 1976 | The examine the effect of wheat fiber on colonic function as reflected by fecal output and composition by mean transit time of markers through the gut. | Metabolic ward | No | 0% | 35% | Male | Healthy | 6 | 21 | X | X | X | | X[c] | |
| Drasar, BS | 1976 | To describe the effect of bran on the fecal flora. | Metabolic ward | No | 0% | 20% | Male | Healthy | 4 | 21 | X | | | | X[c] | |
| Fuchs, HM | 1976 | To eamine the effects of fiber on the intraluminal contents of the gut. | Metabolic ward | No | 0% | 40% | Both sexes | Healthy | 6 | 21 | X | X | X | | | |
| Reinhold, JG | 1976 | To examine the effect of bread made of flour of 80-90% extraction on mineral absorption compared to that of white bread. | Metabolic ward | No | 0% | 40% | Male | Healthy | 2 | 20 | X | X | | | | |
| Southgate, DAT | 1976 | To evaluate the importance of supplementary dietary fiber on energy balance. | Metabolic ward | No | 0% | 35% | Both sexes | Healthy | 5 | 7 | X | X | X | | | |
| Wyman, JB | 1976 | To compare the effects of two doses of raw bran, two doses of cooked bran upon intestinal transit time and upon wet and dry fecal weight, stool volume, individual stool size, frequency of bowel movements and | Parallel non-blinded placebo controlled | No | 13% | 40% | Male | Healthy | 10 | 14 | X | X | X | X | X[b] | |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | interval between bowel movements in human volunteers. | | | | | | | | | | | | | | |
| Kay, RM | 1977 | To examine the effect of brown bread, and/or wheat bran compared to white bread on plasma cholesterol. | Single arm intervention | No | 13% | 35% | Both sexes | Healthy | 6 | 21 | X | | | X | X[a] | |
| McLean Baird, I | 1977 | To examine the effects of two dietary fibers, bagasse and bran, on plasma cholesterol, fecal excretion of fats, and acid and neutral steroids. | Metabolic ward | No | 13% | 50% | Both sexes | Healthy | 4 | 7 | X | X | X | | | |
| Weinreich, J | 1977 | To examine whether wheat bran taken in physiological amounts has and effect on serum lipids, calcium and total 3a-hydroxycholanic acid and on body weight, intestinal transit time and the number of bowel movements per week. | Single arm intervention | No | 20% | 50% | Both sexes | Healthy | 25 | 35 | | | | X | X[a] | |
| Brodribb, AJM | 1978 | To examine whether a change in particle size alone affects the laxative properties of bran. | Cross-over Non-blinded placebo controlled | Yes | 7% | 35% | Both sexes | Healthy | 21 | 14 | X | | | X | | |
| Cummings, JH | 1978 | To compare the effects of a diversity of dietary fibers on colonic functions | Parallel non-blinded placebo controlled | No | 20% | 50% | Male | Healthy | 6 | 21 | X | | | | X[c] | |
| Cummings, JH | 1979 | To examine the effects of a high protein and a high wheat fiber diet on | Metabolic ward | No | 13% | 45% | Male | Healthy | 4 | 21 | X | X | X | X | X[b] | |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | fecal bile acid excretion. | | | | | | | | | | | | | | |
| Kretsch, MJ | 1979 | To examine the effects of a typical rural Guatamalan diet (high fiber), an egg formula diet (no fiber) and an egg formula with added oat bran (low fiber) on stool frequency, dye transit and retention time, bile acid and urobilinogen excretion and serum cholesterol and triglyceridees | Metabolic ward | No | 13% | 40% | Male | Healthy | 6 | 15 | X | X | | X | X[a] | |
| Heller, SN | 1980 | To examine the effects of particle size of wheat bran on gastrointestinal rate of passage and fecal output in the human. | Cross-over Non-blinded placebo controlled | Yes | 20% | 50% | Male | Healthy | 12 | 14 | X | X | | | X[b,d] | |
| Stasse-Wolthuis, M | 1980 | To describe the effects of isolated citrus pectin on cholesterol metabolism and colonic functions in comparison with the same amount of pectic substances contained naturally in fruits and vegetables, and also with a comparable amount of fiber from wheat bran. | Parallel non-blinded placebo controlled | Yes | 7% | 50% | Both sexes | Healthy | 16 | 35 | X | X | | X | X[b] | |
| Stephen, A | 1980 | To examine the effect of digestibility of different dietary fibers on colonic function | Parallel non-blinded placebo controlled | Yes | 0% | 30% | Male | Healthy | 6 | 21 | X | X | X | | X[c] | |
| Kurzer, M | 1981 | To examine the effect of various fibers on intestinal function provided an opportunity to investigate nitrate | Metabolic ward | Yes | 7% | 50% | Male | Healthy | 6 | 9 | X | X | | | | |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | balance in humans. | | | | | | | | | | | | | | |
| Kies, C | 1982 | To compare the effects of corn bran with the effects of wheat bran? | Parallel non-blinded placebo controlled | Yes | 13% | 40% | Male | Healthy | 11 | 7 | X | X | | | X[a] | |
| Eastwood, MA | 1983 | To examine the water holding capacity of dietary fiber and how this relates to stool-bulking ability. | Single arm intervention | No | 0% | 45% | Male | Healthy | 9 | 21 | X | X | X | | X[b] | |
| Fleming, SE | 1983 | To examine the effect of fermentability of dietary fibers and the fermentation products on colonic function.. | Metabolic ward | No | 20% | 40% | Male | Healthy | 5 | 9 | X | X | X | X | X[a] | |
| van Dokkum | 1983 | To examine the effects of wheat fiber on stool weight, stool frequency, intestinal transit time, bile acid excretion, excretion of volatile fatty acids (VFA), excretion of fecal N and phosphorus and to examine the apparent digestibility by the intestinal flora of hemicellulose, cellulose, lignin and of the total amount of dietary fiber. | Parallel non-blinded placebo controlled | No | 13% | 45% | Male | Healthy | 12 | 20 | X | X | | X | X[b] | |
| Wrick, KL | 1983 | To examine if the source, level of intake and the bulk density (particle size) of dietary fiber consumed would alter the rate of digesta passage, the total fecal output of water and dry matter (DM), the frequency of defecation and the moisture content | Cross-over Non-blinded placebo controlled | No | 0% | 30% | Male | Healthy | 12 | 14 | X | X | X | X | X[b,d,e] | |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | of the stool. | | | | | | | | | | | | | | |
| Fedail, SS | 1984 | To compare the effect of sorghum bran with wheat bran on colonic functions of healthy individuals. | Single arm intervention | No | 13% | 40% | Male | Healthy | 10 | 21 | X | | | X | X[c] | |
| Spiller, GA | 1984 | Abstract, thepurpose of study is not described. | Single arm intervention | No | 0% | 20% | Female | Healthy | 36 | 14 | X | X | | | X[f] | |
| Eastwood, MA | 1986 | To describe the effects of changing eating habits from white bread to wholemeal bread on stool parameters | Single arm intervention | No | 27% | 55% | Both sexes | Healthy | 28 | 183 | X | X | | | X[b] | |
| Miyoshi, | 1986 | To compare the effects of brown rice with white rice on fecal weight, apparent digestible energy, nitrogen and fat apparent degradation of NDF, nitrogen balance and plasma cholesterol level. | Cross-over Non-blinded placebo controlled | No | 13% | 40% | Male | Healthy | 5 | 14 | X | X | X | | X[a] | |
| Stephen, AM | 1986 | To examine the effect of age, sex and level of intake on the colonic response to wheat fiber | Parallel non-blinded placebo controlled | No | 13% | 45% | Both sexes | Healthy | 7 | 21 | X | X | | | X[c] | |
| Balasubramanian, R | 1987 | To examine the effects of the addition of wheat bran to self-selected diets of 7 healthy independent living older adults. | Single arm intervention | No | 20% | 55% | Both sexes | Healthy | 7 | 10 | X | X | X | X | X[d,e] | |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Jenkins, DJ | 1987 | To examine the laxative effect of wheat fiber in graded doses from readily available breakfast cereals with moderate and high fiber contents. | Cross-over Non-blinded placebo controlled | No | 0% | 35% | Both sexes | Healthy | 27 | 14 | X | | | | | |
| Reddy, B | 1987 | To examine the effect of supple mental dietary whole-grain cereal fiber on fecal mutagens and bile acids in healthy individuals consuming high-fat moderately low-fiber diets and excreting high levels of fecal mutagens and bile acids. | Single arm intervention | No | 20% | 55% | Both sexes | Healthy | 15 | 28 | X | X | | | | |
| Stevens, J | 1988 | To compare the effects of psyllium and wheat bran on gastrointestinal transit time and stool characteristics. | Cross-over Non-blinded placebo controlled | No | 13% | 45% | Female | Healthy | 12 | 14 | X | X | X | X | X[b] | |
| Tomlin, J | 1988 | To compare the effects of a powdered rice bran with an available wheat bran preparation on the mass, frequency and consistency of stools and the gastrointestinal transit time in normal volunteers. | Cross-over Non-blinded placebo controlled | Yes | 27% | 55% | Male | Healthy | 8 | 10 | X | | | X | X[c] | X |
| Melcher, E | 1991 | To determine whether methane excretor status can be changed by a high-fiber diet. We hypothesized that a high-fiber diet reduces breath methane excretion, thereby decreasing risk of developing colon cancer. | Cross-over Non-blinded placebo controlled | No | 20% | 50% | Both sexes | Healthy | 24 | 20 | X | X | X | X | X[b] | X |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ziegenhage, DJ | 1991 | To compare the long-term effects of wheat bran alone versus wheat bran with fluid addition on gastrointestinal functions in healthy subjects. | Cross-over Non-blinded placebo controlled | Yes | 27% | 55% | Both sexes | Healthy | 11 | 14 | X | | | X | X[c] | |
| Lampe, JW | 1992 | To examine the effects of vegetable and cereal fiber at two doses on potential risk factors for colon cancer. | Cross-over Non-blinded placebo controlled | Yes | 33% | 50% | Both sexes | Healthy | 34 | 21 | X | X | X | | X[b] | X |
| Lampe, JW | 1993 | To compare the gastrointestinal effects of sugar beet fiber and wheat bran in healthy men consuming their habitual diets. | Cross-over Non-blinded placebo controlled | Yes | 33% | 50% | Male | Healthy | 17 | 20 | X | X | X | | X[b] | X |
| Lupton, JR | 1993 | To determine the effect of supplementation with barley bran flour on serum lipids and certain indexes of colon physiology in human beings. | Parallel non-blinded placebo controlled | Yes | 33% | 70% | Both sexes | Healthy | 22 | 14 | X | X | X | X | X[b] | |
| Bingham, SA | 1996 | To examine the effect of a 10 fold increase in protein consumption as meat on fecal N-nitroso compound excretion in humans. | Metabolic ward | Yes | 20% | 45% | Male | Healthy | 6 | 21 | X | X | | | X[c] | |
| Cherbut, C | 1997 | To eamine the effects of two novel fibers, potato and maize, on fasting and postprandial blood concentrations of carbohydrate and lipid metabolites as well as on stool output and transit time. | Cross-over single blinded placebo controlled | Yes | 33% | 55% | Both sexes | Healthy | 18 | 30 | X | X | X | X | X[c] | |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Chen, HL | 1998 | To examine if the effect of oat bran on stool weight is as effectively as wheat bran. | Metabolic ward | No | 13% | 45% | Male | Healthy | 5 | 28 | X | X | X | X | | X |
| Kanauchi, O | 1998 | To examine the safety of germinated barley foodstuff when given continuously to healthy humans, and evaluate the physiologic effects f GBF by measuring various fecal parameters. | Single arm intervention | No | 13% | 50% | Both sexes | Healthy | 10 | 28 | X | | X | | | |
| Jenkins, JA | 1999 | To examine the effects of very fine particle size wheat bran on colonic function. | Cross-over Non-blinded placebo controlled | No | 20% | 45% | Both sexes | Healthy | 23 | 30 | X | | X | X | | |
| Vuksan, V | 1999 | To examine the effect of Fibrotein on fecal bulk and serum lipids of feeding healthy human subjects a high-fiber, high-protein test supplement resulting from the amylolytic digestion of wheat. | Cross-over Non-blinded placebo controlled | Yes | 20% | 55% | Both sexes | Healthy | 24 | 14 | X | X | X | | X[c] | |
| Grasten, SM | 2000 | To examine the effects of replacing customarily consumed cereal products with fiber-rich whole-meal rye bread on bowel function and the metabolic activity, compared with white wheat bread. | Cross-over Non-blinded placebo controlled | Yes | 20% | 50% | Both sexes | Healthy | 17 | 28 | X | X | | X | X[c] | |
| McRorie | 2000 | To compare and contrast the effects of wheat bran and olestra on objective measures of stool and subjective reports of or symptoms. | Parallel double blinded placebo controlled | Yes | 40% | 70% | Both sexes | Healthy | 12 | 6 | X | | X | X | | X |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hovey, AL | 2003 | To examine the effects of grinding grains on large bowel function by stool output, stool composition and whole gut transit times. | Cross-over single blinded placebo controlled | Yes | 33% | 60% | Both sexes | Healthy | 12 | 7 | X | X | X | X | X[c] | |
| Li, J | 2003 | To observe the effects of high barley (high fiber diet) intake on glucose tolerance, lipid metabolism, and bowel function in healthy women | Cross-over Non-blinded placebo controlled | Yes | 27% | 60% | Female | Healthy | 10 | 28 | | | | X | | |
| McIntosh, GH | 2003 | To evaluate the effects of < 100 g whole grain rye of whole-grain rye flour and fiber-matched whole-wheat flour and low-fiber (refined) wheat-flour foods on markers of bowel health and colon cancer risk and on postprandial glucose and insulin responses. | Cross-over Non-blinded placebo controlled | Yes | 40% | 65% | Male | Healthy | 28 | 28 | X | | | | | |
| Muir, JG | 2004 | To examine the effect of a combined wheat bran and resistant starch intervention on fecal variables (bulking, rapid transit, lower pH, higher butyrate, lower phenols, and lower ammonia) compared to wheat bran alone. | Cross-over Non-blinded placebo controlled | Yes | 40% | 55% | Both sexes | Healthy | 20 | 21 | X | X | | X | X[c] | |
| Grasten, SM | 2007 | To examine if increasing the intake of rye fiber by women, to the level observed in men in our earlier study, would produce beneficial changes in bacterial microbiota, metabolism, and bowel function also in women. | Cross-over Non-blinded placebo controlled | Yes | 47% | 70% | Female | Healthy | 39 | 28 | | | | X | | X |

| Author | Year | Hypothesis | study design | Randomi-zation | FSANZ[1] | Welch 2011[2] | Gender | Physiological characteristic | Number | Duration of study | Total stool weight | Dry stool weight | Stool water | Frequency | transit time | Consistency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bird, AR | 2008 | To determine, in free-living human volunteers, whether foods made from this barley have greater capacity to improve those indices than current wholegrain foods at equivalent levels of intake. | Cross-over single blinded placebo controlled | Yes | 47% | 75% | Both sexes | Healthy | 18 | 28 | X | | X | X | | |
| Costabile, A | 2008 | To assess the ability of WG compared with WB to selectively increase numbers of bifidobacteria and alter colonic metabolic output | Cross-over double blinded placebo controlled | Yes | 40% | 65% | Both sexes | Healthy | 31 | 21 | | | | X | | X |

[1] FSANZ: Estimate of the level of compliance to the criteria set by the Food Standards Agency Australia New Zealand (18).

[2] Welch 2011: Estimate of the level of compliance to the criteria set by Welch et all (19).

Methodology to measure transit time: [a] indigestible dye, [b] Radio-opaque pellets 80%, [c] Radio-opaque pellets MTT, [d] Poly-ethylene glycol, [e] Chromium sesquioxide, [f] not described

**Appendix 4**. Fiber intakes and effects on total stool weight, dry stool weight, percentage water in stool, stool frequency, and transit time

| | Source of intact fiber | | | | | | |
|---|---|---|---|---|---|---|---|
| | Wheat | Barley | Corn | Oat | Rice | Rye | Sorghum |
| **Total stool weight** | | | | | | | |
| *n* observations[1] | 75 | 3 | 4 | 1 | 2 | 2 | 1 |
| Fiber (g/d), mean ± SD or range[2] | 15.2 ± 8.3 | 10.2, 23 | 6.0, 42 | 14.3 | 17.1, 20.7 | 13, 20.6 | 2.5 |
| Total effect (g/d), mean ± SD or range[3] | 65.4 ± 37.8 | 49.6, 65 | 1.2, 96.3 | 64.9 | 112, 134 | 75, 92 | 34.7 |
| Fecal bulking index, Δ in g/d stool weight per g/d fiber[4] | 3.67 ± 0.09 | 2.2, 6.4 | 0.2, 3.7 | 4.5 | 5.4, 7.8 | 4.5, 5.8 | 13.9 |
| **Dry stool weight** | | | | | | | |
| *n* observations | 40 | 1 | 3 | 1 | 1 | 1 | — |
| Fiber (g/d), mean ± SD or range[2] | 14.7 ± 8.5 | 21 | 6, 42 | 14.3 | 20.7 | 20.6 | — |
| Total effect (g/d), mean ± SD or range[3] | 14.4 ± 9.4 | 15.2 | 4.8, 31 | 15.5 | 25.9 | 15.8 | — |
| Fecal bulking index, Δ in g/d stool weight per g/d fiber | 0.75 ± 0.03 | 0.72 | 0.7, 0.9 | 1.08 | 1.25 | 0.77 | — |
| **% Fecal water** | | | | | | | |
| *n* observations | 30 | 3 | 2 | — | 1 | — | — |
| Fiber (g/d), mean ± SD or range[2] | 16.0 ± 7.4 | 10.2, 23 | 15, 42 | — | 20.7 | — | — |
| Total effect (Δ% water), mean ± SD or range[3] | 1.5 ± 2.1 | -1.8, 10 | -7, 23.7 | — | -0.30 | — | — |
| **Stool frequency** | | | | | | | |
| *n* observations | 34 | 2 | 2 | — | 2 | 2 | 1 |
| Fiber (g/d), mean ± SD or range[2] | 13.6 ± 6.4 | 21, 23 | 15, 42 | — | 17.1, 20.7 | 20.6, 36.4 | 2.5 |
| Total effect (times/d), mean ± SD or range[3] | 0.34 ± 0.23 | -0.05, 0.03 | 0.11, 0.35 | — | -0.12, 0.6 | 0.3, 0.4 | 0.54 |
| **Transit time** | | | | | | | |
| *n* observations | 52 | — | — | 1 | 2 | 1 | 1 |
| Fiber (g/d), mean ± SD or range[2] | 14.8 | — | — | 2.7 | 17.1, 20.7 | 20.6 | 2.5 |
| Δ in hr per g/d fiber (those with *initial* transit time between 24-48h)[4] | 0.78 ± 0.13 | — | — | — | — | — | — |
| Δ in hr per g/d fiber (those with *initial* transit time between 48-96h)[4] | 0.75 ± 0.04 | — | — | — | — | — | — |

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[1] May include more than one observation from studies examining more than one dose or intact cereal dietary fiber.

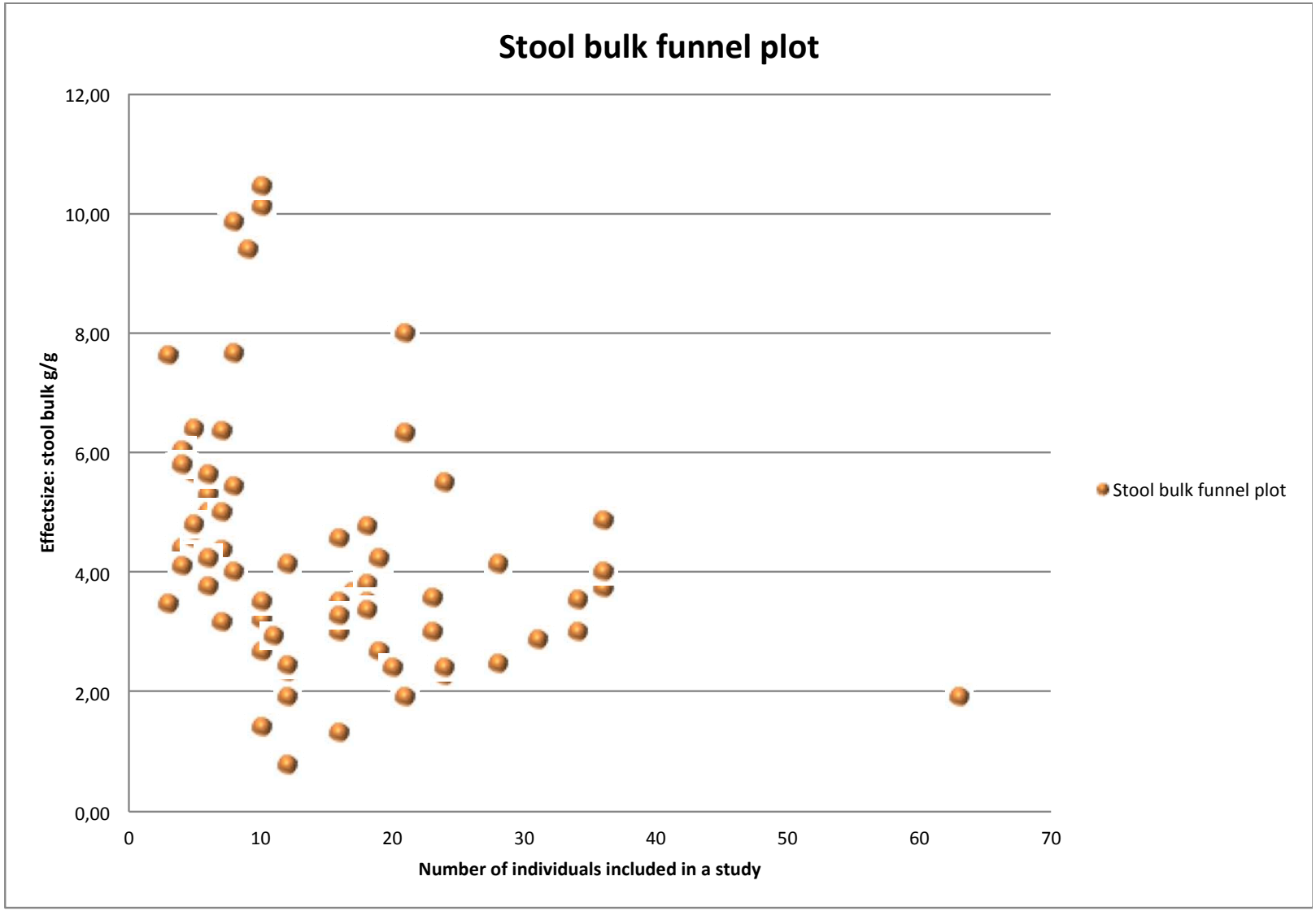
[2] Fiber intakes are shown as mean ± SD of all observations if ≥ 5 observations were available, the range of values from individual studies if 2-4 observations were available, and a single estimate if only one observation was available.

[3] Effects are shown as non-weighted mean ± SD of all observations if ≥ 5 observations were available, the range of values from individual studies if there were 2-4 observations, and a single estimate if only one observation was available.

[4] The change per g/d of fiber was first calculated for each individual observation; next, the overall change per g/d of fiber was generated using weighted regression analysis if ≥ 5 observations were available. The range from individual studies is shown if there were 2-4 observations and a single estimate is shown if only one observation was available.

# Appendix 5.

Funnel plot of the observations on total stool weight.



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