Diet-Related Fibers & Human Health Outcomes Database, Version 3.1 User Manual

Principal Investigator: Nicola McKeown, PhD (nicola.mckeown@tufts.edu)
Project & Data Manager: Kara Livingston, MPH (kara.livingston@tufts.edu)

Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University
711 Washington Street, Boston, MA 02111

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INTRODUCTION

The commonality to all fibers is the fact that they are non-digestible by endogenous enzymes; however, fiber is not a group of structurally similar compounds. As you can imagine, creating a comprehensive database linking fiber to a variety of health outcomes is complicated due to the complexity of defining fiber and the potential ways to classify fiber. For example, fiber includes isolated fibers (e.g. pectin and gum), fiber-enriched ingredients (oat bran, psyllium, or lupin kernel flour enriched breads), cereal fibers in whole-grains, fruit or vegetable fibers, dietary pulses, or fiber supplements. This database was developed to serve as a resource to assist health researchers in linking fibers to a variety of health outcomes in a quick and efficient manner.

A database capturing published research on fiber needs to be flexible from the standpoint of data extraction, striking a balance between standardizing data fields and adequately capturing pertinent information from individual publications. It also needs to be flexible from a user perspective. For example, a researcher using this database may be interested in searching the fibers at the level of the food source and comparing fiber from cereal sources to fiber from fruits and vegetables. On the other hand, a researcher may be interested in fiber intake at the level of the cereal components - cellulose, lignin & hemicelluloses, primarily insoluble fibers, to fruit and vegetable components such as pectins, gums, mucilages, and primarily soluble fibers. *As such, the goal of this database is to meet the needs of a variety of users, providing them with a tool to search fibers and health outcomes captured in the published literature, directing them to potential literature of interest*. In creating this database, data extractors used the description of the fiber as it was presented in the publication, and, as such, multiple fiber descriptions may capture the same type of fiber. Appendix 1 provides a list of all fiber types captured in the database, and we recommend that you review this full list before beginning your search for fiber types. We have also included, in Appendix 2, some recommendations for searching groups of fibers that you may wish to consider.

The number of publications examining fiber and health will continue to increase, and our goal is to update this database regularly, as funding allows, to incorporate new literature. Our research group will continue to work on updating this database, and we are available to help you with any aspect of using this database. We have used this database to create a fiber evidence map. An evidence map is a method of identifying, organizing, and summarizing scientific evidence on a broad topic and can provide a foundation for other work such as systematic reviews and identifying research gaps. We encourage you to provide your feedback, and we will continue to incorporate changes, where necessary, to ensure that we build a sustainable database for years to come.

DATABASE OBJECTIVES

The objectives of this database are to:

1. Systematically compile and provide access to primary, English-language, peer-reviewed science linking fiber intake in humans to one or more of 9 potential health benefits
2. Provide researchers with a tool to understand how different fibers are characterized in studies
3. Facilitate researchers in identifying gaps in the current research
4. Create a database to serve as a starting foundation of primary human literature for conducting evidence-based reviews and meta-analyses
5. Efficiently assist researchers in identifying fibers of interest

This database should serve as a foundation for future work. Specific inclusion and exclusion criteria, detailed below, were applied in determining database eligibility; thus, this database is *no*t intended to serve as a sole source for identifying all possible fiber literature for the purposes of conducting a meta-analysis or systematic review. This database contains **P**opulation, **I**ntervention, **C**omparator, and **O**utcome (PICO) data to help users formulate and narrow the focus of their research question. It is expected that secondary searches will be conducted to augment this database. If conducting a systematic review, we recommend reviewing the following source: *Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: Explanation and elaboration. PLoS Medicine 2009;6(7):e1000100.* It is important to note that for this version of the database, the screening of studies and data extraction were performed for the majority of papers by only 1 person; as such, users are strongly encouraged to confirm the data they require is captured. We imagine that the users will narrow down their search to fiber(s) of interest and will populate their version of the database with additional data (such as results).

BRIEF SUMMARY OF METHODS FOR ORIGINAL DATABASE (Version 1, capturing literature from 1946-Sept 2013)

We conducted a search in Pubmed, via the OVID Medline search engine, to identify research on fiber intervention and prospective observational studies and 9 physiological health effects identified at the Ninth Vahouny Fiber Symposium in 2010. The 9 health effects of interest were as follows:

1. Total and LDL cholesterol
2. Post-prandial glucose & insulin
3. Blood pressure
4. Increased fecal bulk and laxation
5. Transit time (time it takes food to move through digestive track)

6. Colonic fermentation & SCFA production
7. Modulation of colonic microflora
8. Weight loss, weight maintenance, and reduction in adiposity
9. Increased satiety
10. Bone health (added in 2016 with Version 3 due to growing interest, not a Vahouny outcome)

We applied the following inclusion and exclusion criteria to determine eligibility for inclusion in our fiber database:

Inclusion criteria:

- Studies published from 1946 to September 2013 identified in OVID MEDLINE® and indexed in PubMed (with a PubMed ID)
- Published in English
- Abstracts meeting the above criteria along with the specific search term criteria for a fiber term and a Vahouny health outcome term (an extensive list of search terms was developed by the research team with input from the ILSI North America Technical Committee on Carbohydrates

Specific exclusion criteria:

- Reviews, bibliographies, case reports
- Observational studies (ie. cross-sectional or prevalence studies)
- Fiber was not orally ingested (ie. administered intravenously, patients on enteral nutrition)
- Population is infants (<3 years)
- Population is pregnant and/or breastfeeding women
- Population has any type of disease (including, but not limited to, cancer, bowel disease, renal failure, ileostomy)
- Intervention has no concurrent control arm
- Fiber dose not clearly reported
- No fiber intervention
- An outcome of interest is not reported
- Intervention not sufficiently controlled to measure the effect of the fiber
- Synbiotic studies
- Animal-only studies
- In vitro studies

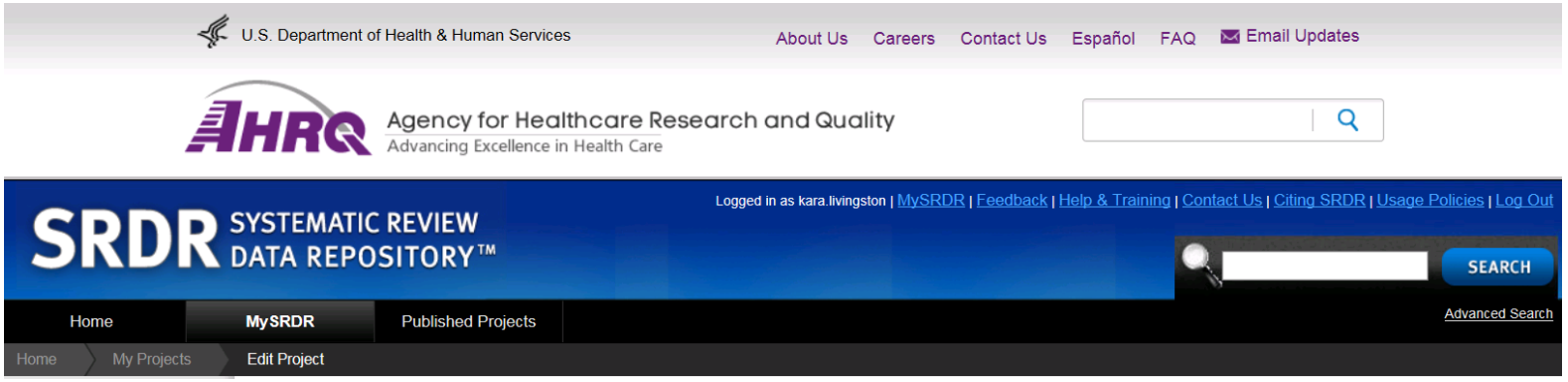
Brief summary of screening process:

We identified n=7,257 potentially relevant abstracts. These n=7,257 were screened at the abstract level, following which n=5,210 were excluded as irrelevant. The remaining n=2,047 were then full-text screened, and n=813 manuscripts were identified as relevant and included in the database. The final database contains n=868 entries due to the fact that a small number of manuscripts detailed multiple, distinct studies within the same manuscript (n=37 detailed 2 studies, n=5 detailed 3 studies). These were entered as separate entries. We also included n=8 eligible papers identified via hand search at the request of the ILSI carbohydrate committee. We anticipate adding additional papers in updated versions, identified via hand searches, upon request if they meet the inclusion criteria.

Database in SRDR

This database was created using the web-based platform, Systematic Review Data Repository (SRDR)

http://srdr.ahrq.gov/SRDR



Data is extracted into this platform, and users can output the final project in the form of an excel spreadsheet. This excel spreadsheet is searchable and can be read into statistical software packages such as SAS or STATA. Please note that SRDR outputs the database as two sheets within the final spreadsheet document- one sheet containing study design information and a second sheet containing study outcome information.

The first row of the spreadsheet contains short variable names that can be used if importing the data into a statistical software package (ie. SAS limits the number of variable name characters that can be imported). These variable names are identified in this manual , beginning in the 'Database Codebook" section, next to the variable description in the following format: variable description (short variable name). For example: What was the study design? (Design)

While many variable fields in this database offered data extractors categorical choices to help standardize data entry, nearly all fields offered an option to select 'other' and specify further using free text. This combination allowed the database to have a balance of standardization and flexibility. It is recommended that users of this database review variable frequencies to see the full spectrum of responses (both categorical and text fill-in), before searching for individual terms. For example, we would recommend reviewing a list of all fiber types included in the database before searching for a specific fiber type. In this case, users may find that they want to include multiple terms in their search (ie. psyllium, Psyllium Hydrophilic Mucilloid (Metamucil), and psyllium seed husk may be grouped), as data extractors were instructed to enter information preserving how it was detailed in the original manuscript.

General rules for data extraction

- If needed (due to space limitations of the database), information listed in the abstract was prioritized.
- Information provided is based on how authors reported in the manuscript. No interpretations or quality assessments were made during data extractions, with the exception of values presented with the approximate (~) symbol.
- Use of the ~ symbol indicates that the value was not presented in the manuscript but was able to be calculated by data extractors using available information in the manuscript.
- Use of "NR" indicates "not reported."

BRIEF SUMMARY OF METHODS FOR 2016 DATABASE UPDATE (VERSIONS 3.0 and 3.1)

Version 3.0 Update: In order to update the database in May 2016, we replicated the original Medline search, restricting to literature published from May 2015 to May 2016. Data from before this timeframe was previously captured in versions 1 and 2. The same screening and data extraction methods were applied as described above for the original database.

Addition of Bone Health Outcomes: An additional component added to version 3 was the inclusion of literature examining fiber and bone health outcomes. For this addition, the original Medline search was run specifically with bone health outcome terms included. The bone health search included literature from 1946 to May 2016, as this literature was not previously captured in versions 1 and 2.

The final database version 3.0 included n=983 entries (n=928 detailed 1 study, n=41 detailed 2 studies, n=7 detailed 3 studies).

Database Version 3.1 (current version): An additional 8 papers, identified during a hand search, were added to version 3.0 resulting in version 3.1. The final database version 3.1 includes n=991 entries (n=936 detailed 1 study, n=41 detailed 2 studies, n=7 detailed 3 studies). The 8 additional papers were the following PubMed IDs: 26860809, 26394259, 26571012, 26706043, 26500686, 23032642, 24919604, 8887030

A NOTE ON PUBMED IDs AND MULTIPLE ENTRIES FOR MANUSCRIPTS

As noted above, if a single manuscript detailed multiple, distinct studies, these studies were entered as multiple entries into the database. Such entries are denoted by numbers at the end of the title (ie. Title [1], Title [2], etc). One limitation of this is that Title, not Pubmed ID, becomes the unique field in SRDR. Thus, Pubmed IDs for manuscripts with multiple database entries are unable to upload in SRDR and will appear blank. The variable "Study ID" (different than Pubmed ID) is an auto-generated SRDR variable unique to each database entry.

DATABASE CODEBOOK

Some variables are auto-generated by SRDR, contain no data, and should be removed from the dataset. When pulled into SAS, these variables appear as: *Alt_ID_S*, *outcome*, *outcome_units*, *outcome_type*, *outcome_description, title_1 (use 'title' variable instead).*

There are two study ID variables. The first, which appears as *Study ID* on the excel sheet and *Study_ID* when pulled into SAS, is a unique identifier for each database entry (see above note on pubmed IDs, page 7). This variable can be used to link unique entries across the design and outcomes sheets. A second variable, *study_id* on the excel sheet which becomes *study_id_1* when pulled into SAS, is an auto-generated SRDR variable serving the same purpose and should be removed.

The variable *creator* reflects the user who uploaded the final, cleaned database. This variable will always be the same within the database. Similarly, *create_date* and *last_updated* reflect the date that the final database was uploaded. Again, these dates will be the same. These variables do not reflect the original data extractor or the original date the data was extracted.

PUBLICATION INFORMATION

Study ID (Study_ID)
Study ID, auto-generated by SRDR
Unique identifier for each database entry

PubMed ID (PMID)
Pubmed Identifier
In some cases, a single manuscript detailed results from multiple, distinct studies. As noted above, in these instances, Pubmed ID will appear missing. Manuscripts with multiple entries are denoted by numbers at the end of the title (ie. Title [1], Title [2], etc).

Title of manuscript (Title)
SRDR auto-generates this variable based on pubmed ID
In cases where the study was entered more than once (previously detailed in ID field above), this was indicated in the title by adding [#] to the end of the title field. For example, the following manuscript contained two, distinct studies and, thus, titles were entered as follows:
The effect of unabsorbable carbohydrate on gut hormones. Modification of post-prandial GIP secretion by guar. [1]
The effect of unabsorbable carbohydrate on gut hormones. Modification of post-prandial GIP secretion by guar. [2]

Author list (Author)
SRDR auto-generates this variable based on pubmed ID

Publication Year (Year)
SRDR auto-generates this variable based on pubmed ID; thus, year will be missing for multiple entries with no Pubmed ID (described above).

Year of Publication (Pubyear)
Year of publication, manually entered by data extractors. No missing values unlike SRDR auto-generated (above) publication year variable.

Country of publication (Country)
Categorical variable (select one)
Data extractors were instructed to select country where study was conducted. If country where study was conducted was not detailed, extractors were instructed to use the country of the first author's affiliation.

STUDY DESIGN DETAILS

What was the study design? (Design)
Categorical variable with the following options (select one):

- Randomized Controlled Trial (Crossover)
- Randomized Controlled Trial (Parallel)
- Non-Randomized Controlled Trial
- Other (if other, please specify using text)

Was the study blinded? (Blindness)
Categorical variable with the following options (select one):

- Single blind
- Double blind
- Unspecified
- Other (if other, please specify using text)

Study diet type (Diet)
Categorical variable with the following options (select one):

- Weight loss
- Isocaloric/maintenance
- Hypercaloric
- Acute feeding study
- Unspecified
- Other (if other, please specify using text)

Level of feeding control for dietary intervention (Feedcontrol)
Categorical variable with the following options (select one):

- Food recommended
- Food partially provided
- All food provided
- Unspecified
- Other (if other, please specify using text)

Note: In some studies, all food was provided with the exception of a few hundred discretionary calories. In these cases, data extractors were instructed to select 'All food provided.'

Sample size (Sampsize)
Total sample size (fill-in text variable)
If study was randomized, extractors were instructed to use number randomized. If unable to do that, extractors were instructed to use total study population or the n presented in the abstract. If the manuscript presented multiple n's for different sample groups, extractors were instructed to sum and enter the total n in the database.

Is there a run-in period? (Runin)
Categorical variable with the following options (select one):

- Yes
- No
- Unspecified
- Not applicable

Is there a washout period? (Washout)
Categorical variable with the following options (select one):

- Yes
- No
- Unspecified
- Not applicable

Did the administered fiber dose change over the course of the study? (Dosechange)
Categorical variable with the following options (select one):

- Yes
- No

Database version? (Version)
Categorical variable with the following options (select one):

- 2013 (original database, V1)
- 2015 (V2)
- 2016, V3.0 (V3.0)
- 2016, V3.1 (V3.1)

STUDY POPULATION DETAILS

Was the study population adolescents (12-19 years)? (Age_adol)
1 indicates 'yes', missing indicates 'no'

Was the study population adults (20+ years)? (Age_adult)
1 indicates 'yes', missing indicates 'no'

Was the study population children (3-11 years)? (Age_child)
1 indicates 'yes', missing indicates 'no'

Was the study population another age group (not covered by adolescents, adults, and/or children)? (Age_oth)
1 indicates 'yes', missing indicates 'no'

Study population, mean age in years (Age_mean)
Mean age (fill-in text variable)
please note that studies where entire population was children <3 years were excluded

Study population, age range in years (Age_range)
Age range (fill-in text variable)
please note that studies where entire population was children <3 years were excluded

Study Population, mean BMI, kg/m^2 (BMI_mean)
Mean BMI of study population, kg/m^2 (fill-in text variable)

Study population, BMI Range, kg/m^2 (BMI_range)
BMI range of study population, kg/m^2 (fll-in text variable)

Was the population diabetic? (Blhealth_diab)
1 indicates 'yes', missing indicates 'no'

Was the population experiencing digestive problems? (Blhealth_digest)
1 indicates 'yes', missing indicates 'no'

Was the population healthy? (Blhealth_healthy)
1 indicates 'yes', missing indicates 'no'

Was the population hyperlipidemic/hypercholesterolemia? (Blhealth_hyperlip)
1 indicates 'yes', missing indicates 'no'

Did the population have hypertension? (Blhealth_hyperten)
1 indicates 'yes', missing indicates 'no'

Did the population have metabolic syndrome? (Blhealth_met)
1 indicates 'yes', missing indicates 'no'

Did the population have some other baseline health status not captured above? (Blhealth_oth)
1 indicates 'yes', missing indicates 'no'

If yes, please specify using text (Blhealth_othspec)

Gender, % male (Gender)
% of male participants (fill-in text variable)

INTERVENTION EXPOSURES (FIBER TYPES)
The database allowed for entry of up to 4 fiber types examined in the manuscript

GENERAL NOTES

- If "combination/mixture" was selected as fiber type, both description and dose variables were completed. For all other fiber types, description variables were left blank, and only dose 1 was completed. In a limited number of cases, dose 1 and 2 may have been completed for a non-combination fiber exposure if the paper detailed more than four exposures, requiring multiple exposures to be grouped for entry.
- In the case where several doses of the same exposure were given (for example, in increasing increments), data extractors were instructed to report the maximum dose at the maximum duration. Please note the earlier question in 'design' section indicating whether the administered fiber dose changed over the course of the study.
- If two, different groups were on different doses of the same fiber, it was entered as two exposure groups in addition to the control; vs. if the *same* group was on different doses of the same fiber during the study, one exposure was reported, and the dose reflected the maximum.
- Exposure doses are per day
- The data allowed for entry of up to 4 fiber exposures examined in the manuscript. The study team addressed cases where more than 4 exposures were examined on a case-by-case basis. In these instances, exposures were logically grouped for entry to preserve all information. See Appendix 3 for an example.

FIBER 1

Fiber 1- Type (Ftype1)
Fiber type (categorical variable with option for text fill in if 'other' is selected)
Please note there is an option to specify 'Combination/mixture' if appropriate
See Appendix 1 for full list of fiber types included in the database

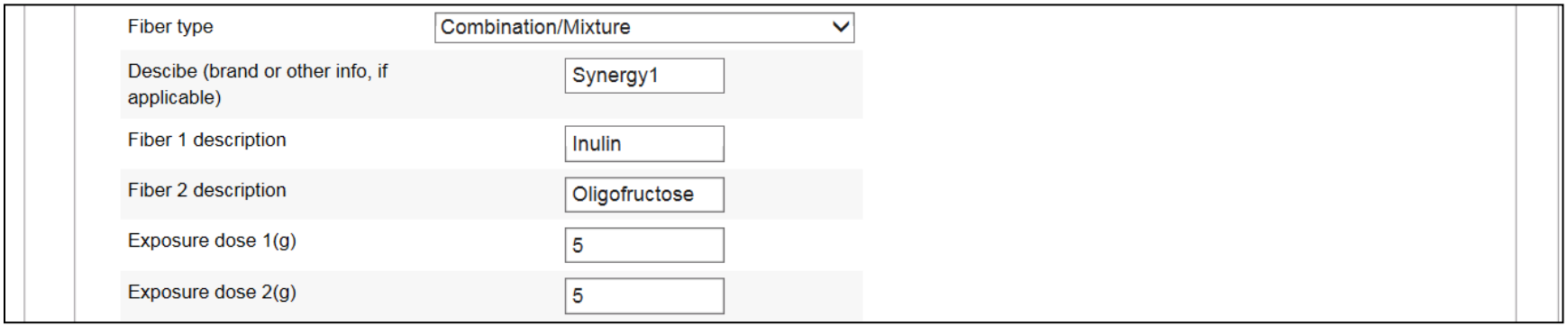
Fiber 1-if combination was selected for fiber type, 1st fiber type in combination (Descrip1_1)
Fill in text variable

Fiber 1-if combination was selected for fiber type, 2nd fiber type in combination (Descrip1_2)
Fill in text variable

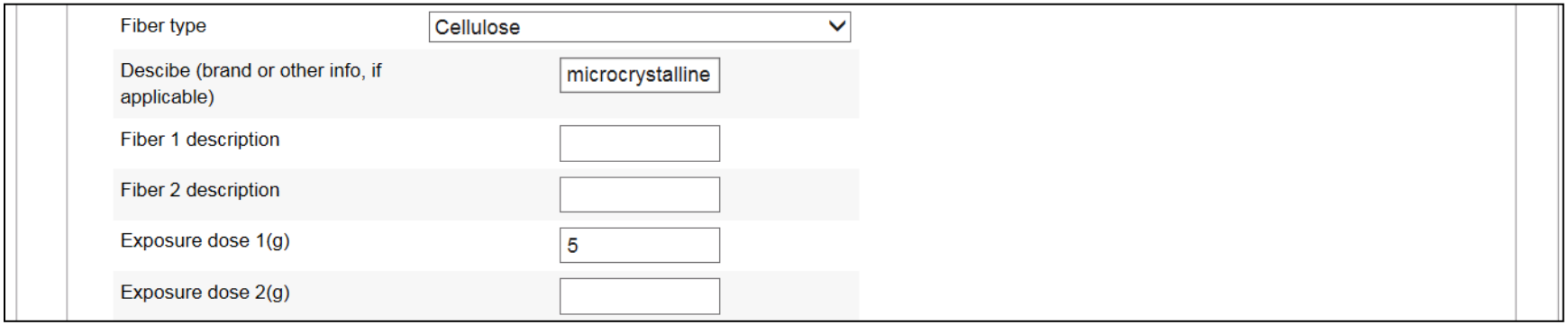
Fiber 1- Dose 1, g (Dose1_1)
Exposure dose of fiber intervention, grams unless otherwise specified (fill-in text variable)
Dose should reflect dose of fiber selected in 'fiber type' field above;
If 'Combination/mixture' was selected, dose 1 should reflect dose of fiber in 'descript1_1' variable above

Fiber 1- Dose 2, g (Dose1_2)
Exposure dose of fiber intervention, grams unless otherwise specified (fill-in text variable)
Typically used for combination/mixtures. Dose 2 would, thus, reflect dose of fiber selected in 'Descrip1_2' variable above

The screen shot of the database below illustrates entry of a 'Combination/mixture' fiber type:



The screen shot of the database below illustrates entry of a single fiber type:



Fiber 1-Duration of Intervention (Duration1)
Duration of fiber intervention (text fill-in specifying days, weeks, months, as appropriate)

Fiber 1- How was the fiber administered? (Admin1)
Categorical variable with the following options (select one):

- Diet
- Single food
- Powder
- Tablet
- Beverage
- Combination of foods
- Combination of beverage + foods
- Unspecified
- Test meal

REPEAT AS ABOVE FOR FIBERS 2-4

FIBER 2

Fiber 2- Type (Ftype2)
Fiber 2-if combination was selected for fiber type, 1st fiber type in combination (Descrip2_1)
Fiber 2-if combination was selected for fiber type, 2nd fiber type in combination (Descrip2_2)
Fiber 2- Dose 1, g (Dose2_1)
Fiber 2- Dose 2, g (Dose2_2)
Fiber 2-Duration of Intervention (Duration2)
Fiber 2- How was the fiber administered? (Admin2)

FIBER 3

Fiber 3- Type (Ftype3)
Fiber 3-if combination was selected for fiber type, 1st fiber type in combination (Descrip3_1)
Fiber 3-if combination was selected for fiber type, 2nd fiber type in combination (Descrip3_2)
Fiber 3- Dose 1, g (Dose3_1)
Fiber 3- Dose 2, g (Dose3_2)
Fiber 3-Duration of Intervention (Duration3)
Fiber 3- How was the fiber administered? (Admin3)

FIBER 4

Fiber 4- Type (Ftype4)
Fiber 4-if combination was selected for fiber type, 1st fiber type in combination (Descrip4_1)
Fiber 4-if combination was selected for fiber type, 2nd fiber type in combination (Descrip4_2)
Fiber 4- Dose 1, g (Dose4_1)
Fiber 4- Dose 2, g (Dose4_2)
Fiber 4-Duration of Intervention (Duration4)
Fiber 4- How was the fiber administered? (Admin4)

INTERVENTION COMPARATORS

The database allowed for entry of up to 4 comparators examined in the manuscript

GENERAL NOTES

- If the diets were exactly the same except for the fiber intervention, the term 'matched ' may be used to describe comparator diet
- The comparator variables were all free text variables (fill-in), with the exception of the 'how administered' question which was categorical.

COMPARATOR 1

Comparator 1- what was the comparator used in the intervention (Comparator1)
text fill-in, including any available information on comparator (may include food type, brand, food form, etc)

Comparator 1-Dose (Cdose1)
Text fill-in
Data extractors instructed to specify units and provide dose in grams whenever possible

Comparator 1-Duration of comparator intervention (Cduration1)
Duration of comparator intervention (text fill-in specifying days, weeks months, as appropriate)

Comparator 1-How was the comparator administered to participants? (Cadmin1)
Categorical variable with the following options (select one):

- Diet
- Single food

- Powder
- Tablet
- Beverage
- Combination of foods
- Combination of beverage + foods
- Unspecified
- Test meal

REPEAT AS ABOVE FOR COMPARATORS 2-4

COMPARATOR 2

Comparator 2- what was the comparator used in the intervention (Comparator2)
Comparator 2-Dose (Cdose2)
Comparator 2-Duration of comparator intervention (Cduration2)
Comparator 2-How was the comparator administered to participants? (Cadmin2)

COMPARATOR 3

Comparator 3- what was the comparator used in the intervention (Comparator3)
Comparator 3-Dose (Cdose3)
Comparator 3-Duration of comparator intervention (Cduration3)
Comparator 3-How was the comparator administered to participants? (Cadmin3)

COMPARATOR 4

Comparator 4- what was the comparator used in the intervention (Comparator4)
Comparator 4-Dose (Cdose4)
Comparator 4-Duration of comparator intervention (Cduration4)
Comparator 4-How was the comparator administered to participants? (Cadmin4)

OUTCOMES

We extracted information on up to 8 outcomes detailed in the manuscript. If more than 8 outcomes were detailed, entry of Vahouny outcomes was prioritized. Non-Vahouny outcomes were included only as space allowed, or in the list of other outcomes (variable *outcomes_other*). Extractors were also told to prioritize the central outcomes of the manuscript (for example, those highlighted in the abstract) if more than 8 Vahouny outcomes were examined.

The 'group' variables are categorical, identifying the outcome as a Vahouny vs. other type of outcome with categorical choices detailed below. 'V' indicates Vahouny outcome, 'O' indicates other outcome group. If the outcome did not fall into a 'V' or 'O' outcome group, data extractors could select "Other" and specify using text. See Appendix 4 for a list of outcomes by outcome group.

OUTCOME 1

Outcome examined #1 (Outcome1)

Categorical variable with the following options (select one):

- Appetite regulation
- Bacteria
- Blood pressure
- Blood pressure, diastolic
- Blood pressure, systolic
- Body mass index
- Body weight
- Bowel movements
- Cholesterol (blood), HDL
- Cholesterol (blood), LDL
- Cholesterol (blood), total
- Cholesterol (blood), VLDL
- Constipation
- C-peptide
- Defecation
- Fat distribution
- Fat, body fat
- Fecal weight

- Fecal weight, dry
- Fecal weight, wet
- Fermentation
- Gastric emptying
- Glucose (blood), fasting
- Glucose (blood), postprandial
- Hemoglobin A, glycosylated
- HOMA
- HOMA-IR
- Hypertension
- Insulin
- Insulin (blood), fasting
- Insulin (blood), postprandial
- Insulin sensitivity, EHGU
- Insulin sensitivity, FSVITT
- Insulin sensitivity, IST
- Insulin sensitivity, OGTT
- Laxation
- Microbiota/microflora
- Proinsulin
- Satiety-related hormones
- SCFA production
- Skinfold thickness
- Stool consistency
- Stool retention
- Subjective appetite
- Transit time
- Transit time, bowel
- Transit time, colon
- Transit time, colonic
- Transit time, gastrointestinal
- Transit time, gut

- Transit time, intestinal
- Triglycerides (blood)
- Triglycerides, postprandial
- Waist circumference
- Waist-hip ratio
- Weight loss/gain
- Other (if other, please specify using text)

Outcome is associated with which outcome group of interest? (Group1)
Categorical variable with the following options (select one):

- V: total and LDL cholesterol
- V: postprandial glycemic/insulinemia
- V: blood pressure
- V: fecal bulk/laxation
- V: transit time
- V: modulation of colonic microflora
- V: colonic fermentation/short-chain fatty acid production
- V: weight/adiposity
- V: satiety
- O: lipids
- O: glucose & insulin metabolism
- O: GI symptoms
- O: bone-related outcomes
- Other (if other, please specify using text)

REPEAT AS ABOVE FOR OUTCOMES 2-8

OUTCOME 2

Outcome examined #2 (Outcome2)
Outcome is associated with which outcome group of interest? (Group2)

OUTCOME 3

Outcome examined #3 (Outcome3)
Outcome is associated with which outcome group of interest? (Group3)

OUTCOME 4

Outcome examined #4 (Outcome4)
Outcome is associated with which outcome group of interest? (Group4)

OUTCOME 5

Outcome examined #5 (Outcome5)
Outcome is associated with which outcome group of interest? (Group5)

OUTCOME 6

Outcome examined #6 (Outcome6)
Outcome is associated with which outcome group of interest? (Group6)

OUTCOME 7

Outcome examined #7 (Outcome7)
Outcome is associated with which outcome group of interest? (Group7)

OUTCOME 8

Outcome examined #8 (Outcome8)
Outcome is associated with which outcome group of interest? (Group8)

List of other outcomes, if needed, that did not fit in outcomes 1-8 above (Outcomes_other)
Text field (fill-in)

APPENDIX 1: COMPREHENSIVE LIST OF ALL FIBER TYPES INCLUDED IN DATABASE (FROM EXPOSURES 1-4 COMBINED)

Agar
Alginates
Alphacyclodextrin
Arabinogalactan
Arabinoxylan
Arabinoxylan-Oligosaccharides
Atta Mix
Balsamodendron Mukul
Barley B-Glucan (Bbg)
Barley Beta Glucan
Barley Bran
Barley Bran Flour
Barley Dietary Fiber
Barley Fiber
Barley Fiber (Hull-Less)
Barley Flour
Barley Grain
Barley Kernels
Barley Tempe
Bdg (1,3)(1,6)-_x001A_-D-Glycans
Bean Fiber
Beta-Glucans
Birch
Bran
Bran, Added
Buckwheat Flour
Butyrylated High Amylose Maize Starch
Calcium Polycarbophil
Carboxymethylcellulose Gum
Carob Fiber
Carrageenans
Cellulose
Cereal Fiber
Chia Seed

Chitin-Glucan
Chitosan
Cocoa Bran
Cocoa Husk
Coconut Fiber
Coconut Flour
Combination Of Fibers
Combination/Mixture
Corn Bran
Corn Fiber
Corn Starch
Corn Starch/Cornflour/Maize Starch
Dextrin
Dietary Fiber
Flaxseed Fiber
Flour, Citrus
Flour, Lupin
Flour, Wheat
Fructan
Fructooligosaccharide
Fruit Fiber
Galactooligosaccharide
Germinated Fenugreek Seeds
Glucomannan
Guava Fruit
Gum, Arabic
Gum, Carboxymethyl Cellulose
Gum, Carob
Gum, Flaxseed
Gum, Guar
Gum, Karaya
Gum, Vegetable
Gum, Xanthan
Gum,locust Bean

High Amylose Starch
High-Amylose Maize Starch
Hydroxypropyl Methylcellulose
Inulin
Irvingia Gabonesis Fiber
Isapgol
Ispaghula
Ispaghula Husk
Konjac Mannan
Legume Fiber
Legume Fiber/Bean Fiber
Lignin
Lupin Bread
Lupin Kernel Fiber
Lupin Kernel Flour
Methylcellulose
Non-Starch Polysaccharides
Oat B-Glucan
Oat Bran
Oat Fiber
Oat Kernels
Oat Tempe
Oats
Oligofructose
Oligofructose-Enriched Inulin (Of-In)
Pea Fiber
Pectin
Polydextrose
Polyglycoplex (Pgx)
Polysaccharide, Non-Starch
Potato Fiber
Promitor Soluble Corn Fiber
Psyllium
Psyllium Hydrophilic Mucilloid (Metamucil)

Psyllium Seed Husk
Pullulan
Resistant Dextrin
Resistant Maltodextrin
Resistant Starch
Resistant Starch Type 2
Resistant Starch Type 3
Resistant Starch Type 4
Retrograded Resistant Starch (Rs3)
Rice Bran
Rice Fiber
Rye Bran
Rye Fiber
Short-Chain Fructo-Oligosaccharides (Scfos)
Soluble Corn Fiber
Soluble Fiber
Soluble Fiber Dextrin
Soluble Gluco Fiber
Soy Cotyledon Fiber
Soy Fiber
Soy Hulls
Soy Kernel Fiber
Soy Polysaccharide
Soybean Polysaccharide
Sugar Beet Fiber
Sugar Cane Fiber
Tannin-Rich Fiber
Tragacanth
Vegetable Fiber
Viscous Fiber
Viscous Fiber Blend
Wheat Bran
Wheat Dextrin
Wheat Fiber

Wheat Germ
Wheat Kernels
Wheat Starch
Whole Grain
Whole Wheat Flour
Wholemeal Flour
Xylans
Xylo-Oligosaccharide

APPENDIX 2: SUGGESTIONS FOR SEARCHING FIBER TYPES

If you are interested in:	Consider also searching for:
Barley or barley beta-glucans	barley kernels, barley glucans, beta-glucans unspecified, barley flour, barley grain, barley tempe, barley bran
Cellulose and/or modified cellulose-based gums	cellulose, hydroxypropyl methylcellulose (HPMC), hydroxyproply cellulose (HPC), methy cellulose (MC), carboxymethyl cellulose (CMC/cellulose gum), microcrystalline cellulose (MCC)
Glucomannan	konjac-mannan
Gums	balsamodendron mukul, acacia, tragacanth, karaya, ghatti, extracts from plants and animals (pectins, alginates, agar, carrageenan, chitin), flours (seeds)
High amylose starch	resistant starch
Inulin-type fructans	fructans, fructooligosaccharide, inulin, oligofructose, oligofructose-enriched inulin, short-chain fructooligosaccharide
Legume fiber	legume fiber/bean fiber, bean fiber, pea fiber
Locust bean gum	gum, carob
Novel functional ingredients	rice bran
Pectin	sugar beet fiber, sugar cane fiber, beet fiber, citrus peel fiber, apple
Psyllium	psyllium seed husk, ispagula husk, ispaghula, isabgol
Resistant dextrins	resistant maltodextrin, resistant dextrin, dextrin, cyclodextrin, wheat dextrin, soluble fiber dextrin
Resistant starch	resistant starch, resistant starch type 2, resistant starch type 3, resistant starch type 4, retrograded resistant starch, high amylose maize starch, high amylose starch, corn starch/corn flour/maize starch, wheat starch
Seaweed gums	carrageenans
Seed gums	galactomannans - locust bean gum, guar gum, tara gum, fenugreek, mesquite gum, cassia gum and others, psyllium seed gum, tamarind kernel powder, flaxseed gum, quince seed gum, oat gum
Soy bean fiber	soy cotyledon fiber, soy fiber, soybean, soy hulls
Wheat bran	bran, wheat kernels, wheat fiber, wheat bran, bran added, arabinoxylans, arabinogalactan, arabinoxylan-oligosaccharides, cereal fiber

APPENDIX 3: DATA ENTRY EXAMPLE

The following example is provided to illustrate the complexity of data extraction for some entries. It also serves to illustrate, first-hand, some of the data entry notes described throughout the manual pertaining to capturing more than 4 fibers and approximating doses in grams.

Pubmed ID 19155430
Kendall et al (2008) 'Effect of novel maize-based dietary fibers on postprandial glycemia and insulinemia'

This acute study supplied participants with 7 test beverages containing the 7 products illustrated in the table below. Test beverages were composed of 25g (dry weight) of the test fiber product added to an identical base of sucralose and citric acid (lemonade).

Table 1. Composition of the Test Products

Test Meal	Product	Average MW (Da)	% Fiber (dsb)	AOAC Method
A	Pullulan	486000	85	991.43
B	Pullulan & Soluble Corn Fiber-70	233800	77	2001.03
C	Soluble Corn Fiber-70	1600	70	2001.03
D	Resistant Starch-60	100000	58	991.43
E	Resistant Starch-75	8000	78	991.43
F	Soluble Corn Fiber-70 & Resistant Starch-60	51000	64	2001.03
G	Soluble Fiber Dextrin	6500	64	2001.03

As the database is able to capture up to 4 exposures, and this study used 7, exposures were logically grouped for entry as indicated in the table below.

In addition, as the % fiber per product was provided, rather than fiber in grams, doses in grams were calculated for entry (indicated in the database using the ~ symbol). Since fibers had to be grouped, the maximum dose was entered for the exposure group as indicated in red. As noted throughout this manual, doses correspond to fiber type selected in the relevant fiber 1-4 exposure fields. Despite the need to group, users would still be directed to this manuscript upon searching for any of the four following fibers examined: pullulan, corn fiber, resistant starch, or dextrin.

		% Fiber	Approximated fiber dose (g)
Exposure 1 Fiber type: Pullulan	Pullulan	85	~ 21.3
	Pullulan and soluble corn fiber-70	77	~ 19.3
Exposure 2 Fiber type: Soluble corn fiber	Soluble corn fiber-70	70	~ 17.5
	Soluble corn fiber-70 and RS-60	64	~ 16.0
Exposure 3 Fiber type: Resistant starch	Resistant starch-60	58	~ 14.5
	Resistant starch-75	78	~ 19.5
Exposure 4 Fiber type: Dextrin	Soluble fiber dextrin	64	~ 16.0

Fiber type and dose information entered into the database for exposures 1-4 are identified in red.

APPENDIX 4: LIST OF OUTCOMES BY ASSOCIATED OUTCOME GROUP

V-Blood Pressure

Blood Pressure
Blood Pressure, Diastolic
Blood Pressure, Systolic

V-Colonic Fermentation/SCFA Production

Acetate
Bacteria
Branched Chain Fatty Acids
Breath H2 Production
Breath Hydrogen
Butyrate
Butyrate, Propionate, Acetate
Colonic Ph
Equol Production
Fecal Butyrate
Fecal Ph
Fecal Scfa Excretion
Fermentation
Glucagon-like Peptide-1
Microbiota/Microflora
Monosaccharides & Oligosaccharides in faecal sample
Propionate
Scfa Production
Stool Ph
Total Fecal Scfa Excretion

V-Fecal Bulk/Laxation

Bowel Movement Frequency
Bowel Movements
Children With <3 Bms
Constipation
Daily Stool Frequency

Defecation
Defecation Frequency
Fecal Consistency
Fecal Incontinence
Fecal Moisture
Fecal Moisture Content
Fecal Output
Faecal Ph
Fecal Weight
Fecal Weight, Dry
Fecal Weight, Wet
Frequency And Volume Of Bowel Habit
Frequency Of Bms/Wk
Frequency Of Defecation
Laxation
Stool Consistency
Stool Frequency
Stool Output
Stool Output And Defacation Frequency
Stool Output And Stool Water Output
Stool Retention
Stool Size
Stool Volume

V-Modulation of Colonic Microflora

Bacteria
Fecal Bifidobacterium
Fecal Ph
Fecal Water Ph
Microbiota/Microflora
Ph
Stool Ph

V-Postprandial Glycemic/Insulinemia

Acute Insulin Response
Glucose (Blood), Postprandial

Glucose Effectiveness
Hemoglobin A, Glycosylated
Insulin (Blood), Postprandial
Insulin Sensitivity, Fsvitt
Insulin Sensitivity, Ist
Insulin Sensitivity, Ogtt
Interstitial Glucose Response

V-Satiety

Appetite Regulation
Consumption of Fiber, Energy, and Macronutrients
Daily Energy Intake
Dietary Intake
Energy Intake
Fiber & Energy Intake
Food Intake
Free-Living Intake
Nutrient Intake
Nutritional Intake
Satiety
Satiety-Related Hormones
Subjective Appetite
Total Daily EI
Total Energy Intake

V-Total & LDL Cholesterol

Cholesterol (Blood), Ldl
Cholesterol (Blood), Total

V-Transit Time

Bowel Movements
Defecation
Gastric Emptying
Transit Time
Transit Time, Bowel

Transit Time, Colon
Transit Time, Gastrointestinal
Transit Time, Gut
Transit Time, Intestinal
Viscosity

V-Weight/Adiposity

% Body Fat, Total Fat Mass, Lean Body, Mass, Abdominal
Body Fat
Body Mass Index
Body Weight
Fat Distribution
Fat, Body Fat
Hip Circumference
Skinfold Thickness
Visceral Fat Area
Waist Circumference
Waist Circumference, Subcutaneous Fat Area
Waist-Hip Ratio
Weight Loss/Gain

O-GI Symptoms

Abominal Pain
Adverse Events
Adverse Reactions
Constipation
Diarrhoea
Digestive Symptoms
Gastrointestinal Intolerance
Gastrointestinal Symptoms
Gastrointestinal Tolerance
Gi Discomfort
Gi Side Effects
Gi Symptoms
Gi Tolerance
Gi Tolerance Symptoms

Side Effects
Tolerance
Total Gastrointestinal Side Effects

O-Glucose & Insulin Metabolism

Blood Glucose And Insulin
C-Peptide
C-Peptide-To-Insulin Molar Ratio
Day-Long Average Glucose
Day-Long Glucose And Insulin
Fasting Endogenous Glucose Turnover
Fasting Glucose And Insulin
Forearm Muscle Glucose Clearance During Mtt
Gip
Glp-1
Glp-1, Plasma
Glucagon
Glucose (Blood), Fasting
Glucose (Urine, 24 Hr)
Glucose Kinetics
Glucose Oxidation
Glucose, Insulin, Insulin Resistance
Glucose-Dependent Insulinotropic Polypeptide
Glycaemic Index
Glycemic Index
Glycemic Load
Hemoglobin A, Glycosylated
Homa
Homa%s And Homa%b
Homa-Ir
Insulin
Insulin (Blood), Fasting
Insulin Sensitivity
Insulin Sensitivity, Ehgu
Insulin Sensitivity, Ist
Insulin Sensitivity, M/I Ratio

Insulin Sensitivity, Mtt (Meal Tolerance Test)
Insulin Sensitivity, OGTT
Insulin:glucose Ratio
Insulinaemic Index
Insulinemic Index
Whole-Body Glucose Disposal

O-Lipids

Adiponectin
Apo A-I
Apo B
Apo B Concentrations; Apo A-I Concentrations
Apoa-1
Apob
Apolipoprotein A-I; Lipoprotein(A); Vldl
Apolipoprotein A1
Apolipoprotein A1 And B And Lipoprotein (A)
Apolipoprotein A1 And B Levels
Apolipoprotein B
Apolipoprotein B:a-I
Beta-Lipoprotein
Cholesterol (Blood), Hdl
Cholesterol (Blood), Vldl
Cholesterol Ester Transfer Protein
Cholesterol Ester Transfer Protein Activity
Cholesterol Precursors
Chylomicron Triglyceride Concentrations
Ffa
Free Fatty Acids
Hdl And Triglycerides
Hdl Choelsterol; Total Cholesterol/Hdl Cholestero
Hdl-C, Hdl2-C, Hdlc3-C, B-Apoprotein
Hdl-C, Ldl-C/Hdl-C, Tg
Hdl-C, Tg
Hdl-C; Triacylglycerol

Hdl-Cholesterol, Triglyceride
Hdl/Ldl Ratio
Hdlc, Vldlc, Tg
Isotopic Cholesterol Ratio And Concentration
Ldl Oxidation
Ldl-Apo B
Ldl/Hdl Cholesterol Ratio
Ldl/Hdl Cholesterol Ratio
Ldl/Hdl Ratio
Ldl:hdl Cholesterol Ratio
Lecithin-Cholesterol Acyltransferase
Lecithin-Cholesterol Acyltransferase
Lipoprotein A
Long-Term Lipid Metabolism
Nefa
Non-Essential Fatty Acids, Postprandial
Oxidized Ldl
Plasma Triacylglycerol
Post-Prandial Lipids: Vldl, Ffa, Ldl
Postprandial Lipids: Tg, Rlp-C
Ratio Of Ldl To Hdl
Serum Hdl-Cholesterol, Hdl/Ldl-Chol. Ratio
Tc/Hdl-C Ratio, Ldl-C/Hdl-C Ratio
Total Cholesterol/Hdl-C
Total Cholesterol: Hdl Ratio
Total Serum Lipids, Triglycerides, Pre-B Lipoprot
Total:hdl Ratio
Triacylglycerol
Triglyceride, Hdl Cholesterol
Triglycerides (Blood)
Triglycerides, Hdl, Apolipoprotein A, Apolipoprot
Triglycerides, Hdl-C, Ratio Hdl/Tc
Triglycerides, Postprandial
Triglycerides; Vldl

O-Bone-related outcomes

Absolute apparent calcium absorption
Absolute apparent magnesium absorption
Absolute calcium absorption
Apparent calcium absorption
Apparent calcium balance
Apparent calcium retention
Apparent copper retenttion
Apparent iron absorption
Apparent iron balance
Apparent magnesium absorption
Apparent magnesium balance
Apparent magnesium retention
Apparent zinc absorption
Apparent zinc balance
Bone alkaline phosphatase (BAP)
Bone Mineral Content
Bone mineral density
Calcium absorption
Calcium absorption efficiency
Calcium absorption index
Calcium absorption, urine
Calcium accretion
Calcium balance
Calcium retention
Calcium specific activity
Copper retention
Fecal calcium excretion
Fecal copper excretion
Fecal iron excretion
Fecal magnesium excretion
Fractional calcium absorption
Iron absorption, serum
Iron balance
Iron retention
Iron utilization
Magnesium absorption
Magnesium balance
Magnesium retention
N-telopeptides of type I collagen

Net calcium absorption
Net magnesium absorption
Net nitrogen absorption
Net phosphorus absorption
Nitrogen balance
Parathyroid Hormone
Parathyroid hormone
Phosphorus balance
Rate of total bone turnover (Vt)
Relative apparent calcium absorption
Relative apparent magnesium absorption
Serum C-telopeptide of type I collagen (CTX)
Serum calcium concentration
Serum copper concentration
Serum iron concentration
Serum magnesium concentration
Serum osteocalcin
Serum phosphorus concentration
Serum procollagen I carboxyterminal propeptide (P
Serum zinc concentration
Stronium retention
Stronium:Calcium Retention Ratio
Total serum alkaline phosphatase
True calcium absorption
True magnesium absorption
Urinary calcium excretion
Urinary chromium excretion
Urinary copper excretion
Urinary deoxypyridinoline cross-links
Urinary deoxypyridinoline cross-links (DPD)
Urinary hydroxyproline/creatinine ratio (OHPr:Cr)
Urinary iron excretion
Urinary magnesium excess
Urinary magnesium excretion
Urinary phosophorus excretion
Urinary phosphorus excretion
Urinary potassium excretion
Urinary pyridinoline
Urinary sodium excretion
Urinary zinc excretion

Vitamin D
Zinc balance
Zinc retention

Other outcomes (from text fill in for variables "outcome1" through "outcome8") and associated group ("group1" through "group8")

Outcome	**group**
Bile Acid Concentrations	Bile Acids
Bile Acid Kinetics	Bile Acid Kinetics
Biochemical markers of bone turnover	Biochemical markers of bone turnover
Cholecystokinin	Digestion
Cholesterol Absorption And Synthesis	Cholesterol Absorption And Synthesis
Diet-Induced Thermogenesis	Diet-Induced Thermogenesis
Factor Vii	Coagulation Factor
Fecal Bile Acid Output	Fecal Composition
Fecal Bile Acids	Fecal
Fractional Ca absorption	Calcium absorption
Iron	Micronutrient Levels
Sodium, Potassium, Creatine In Urine	Urinary Measurements
Urinary Ca excretion	Calcium excretion
Urinary Phosphorus And Urinary Calcium Excretions	Micronutrient Balance

This table does not specify outcomes listed as free text under the additional variable 'list of other outcomes (if needed)'