The Effect of Viscous Dietary Fibre on Adiposity in Randomized Controlled Trials

By

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A thesis submitted in conformity with the requirements for the degree of Master of Science

Department Nutritional Sciences

University of Toronto

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Abstract

This project incorporates two systematic reviews and meta-analyses (SRMA) of randomized controlled trials (RCT) to evaluate the impact of viscous dietary fibre on measures of adiposity in adults. In the first study, including 62 trials (n= 3320), ad libitum diets enhanced with viscous fibre, significantly reduced body weight, BMI, waist circumference, and body fat percentage. In the second study, which had 15 trials (n= 1313), viscous fibre added to a calorie-restricted diet, significantly reduced body weight, BMI, waist circumference, and body fat percentage. The certainty of evidence for the impact of viscous fibre supplementation on markers of adiposity is low to moderate quality, as evaluated by the GRADE tool. Overall, the pooled effect of body weight and most other outcomes in these studies suggest that supplementing diet with viscous fibre produce a small but significant effect in weight management. To improve certainty of evidence, a strong need for more trials.
Acknowledgments

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LIST OF ABBREVIATIONS

Systematic reviews and meta-analysis (SRMA)

Randomized controlled Trials (RCTs)

World health organization (WHO)

Body mass index (BMI)

Basal metabolic rate (BMR)

Risk of Bias (ROB)

Cardio Vascular diseases (CVD)

Viscous fibre supplementation (VFS)

International classification of disease (ICD)

National Institutes of Health (NIH)

CAZymes (carbohydrate active enzymes)

Bacterial lipopolysaccharides (LPS)

Various inter-individual heterogeneity (genetic variations. In part)

Single-nucleotide polymorphism (SNP)

TCF7L2 SNP rs7903146 (a gene linked to diabetes)

leptin gene variant (LEP; SNPs rs4731426 and rs2071045)
PolyGlycopleX, (PGX)

Cochrane Collaboration Tool for Assessing Risk of Bias (ROB)

Review Manager (RevMan), version 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark)

Mean difference (MD)

Standard deviation (SD)

The Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Minimally important differences (MID)

Cardio vascular diseases (CVD)
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CHAPTER I - INTRODUCTION

The prevalence of obesity continues to increase worldwide, with more than 1.9 billion adults having a body mass index (BMI) > 25kg/m\(^2\) in 2016, and of these approximately 650 million are obese (World Health Organization) (1). The impact of overweight and obesity is exacerbated by higher risks of cardiovascular disease as well as all-cause mortality (2). However, evidence suggests that even a modest amount of weight loss (5-10%) has been shown to greatly improve health outcomes (3, 4). Several observational studies have shown an inverse relationship between the consumption of dietary fibres and body weight (4), but there is a lack of interventional data (5).

Dietary fibres are heterogeneous substances that can be defined as any nondigestible carbohydrate and lignin not degraded in the upper gut and are fermented by gastrointestinal microflora in the colon (6-9). Major sources of dietary fibres are whole-grain cereals, fruit, vegetables, and legumes, which typically contain diverse types of fibre. Fibre can be classified according to their physicochemical properties (e.g., solubility, viscosity, and fermentability). Whole-grain foods, by weight, generally contain approximately 12% of total (mainly insoluble cereal) dietary fibre, while fruits, vegetables and other grains such as oats and barley have 2-10% of soluble fibre content. Soluble fibre poses strong therapeutic benefits and its intake has been linked to increased satiety and improved cardiometabolic risk factors including reduction of blood lipid concentrations and glycemic response (10). Proposed mechanisms of action for these metabolic benefits include elevated bile-acid excretion and modulation of appetite-suppressing hormones that delay nutrient absorption and gastric emptying (11).

Achieving recommended fibre intake remains a challenge as dietary fibre obtained from the habitual diet (e.g., inherent in food) remains grossly inadequate, with a mean consumption barely surpassing 50% of adequate intake recommendations (12). This is especially the case with respect
to soluble, viscous dietary fibre, examples of which are beta-glucan from oats and barley, pectin, guar gum, and psyllium. which have been shown to be more metabolically active, Thus enhancing the fibre content of the food supply via supplementation of fibre isolates with known physiologic benefits may be a practical and simple strategy to improve fibre intake and health (13).

A review looking at fibre supplementation and its impact on body weight has highlighted the limited evidence available for the use of fibre supplements for weight loss. Evidence of body weight reduction through RCTs is only established for ispaghula (psyllium) husk and Glucomannan. For example, highly viscous glucomannan is the only fibre with a health claim for body weight management, approved by the European Food Safety Authority (EFSA) (14). Therefore, soluble, viscous dietary fibre may have the potential to facilitate weight reduction, possibly on the basis of its viscous properties (15, 16). Findings of clinical trials examining the association between fibre-intake and weight loss however, lacks consistency due to differences in experimental design and fibre type (3). If dietary fibres are supplemented along with a healthy diet, both exert co-influences in the metabolism of overweight or obese adults in reducing susceptibility to associated co-morbidities, yet it has been observed that taking fibre supplements only, amplify the positive impacts on health (17).

The aim of the present study is to identify and quantitatively evaluate the efficacy of soluble, viscous fibre supplementation on body weight and other markers of adiposity through a systematic review and meta-analysis of randomized controlled trials (RCT). In the first study, this effect will be assessed in habitual or ad-libitum diet, independently of calorie-restriction and in the second study, the effect in the context of a calorie- restricted diet.
CHAPTER II - LITERATURE REVIEW

2.1 Obesity

Fundamentally, positive deviation from usual energy balance incurs weight gain, which can lead to obesity. Obesity refers to a multifactorial condition marked by the excessive accumulation of fat in the human body (18). This undesirable accumulation of body fat, particularly in the abdominal region, is associated with several detrimental health consequences thereby worsening living standards and predisposing individuals to increased risk of morbidity and mortality (19, 20). Evidence from a systematic review suggests associations between obesity and many chronic diseases and conditions including type-2 diabetes, cardiovascular disease, gallbladder disease, asthmas, chronic back pain, osteoarthritis, and certain cancers (21).

2.1.1 Anthropometric-Based Obesity Classification

Until 1985, the height/weight charts available with Metropolitan Life Insurance Company were used as a reference for the approximation of ideal body weight or outlining obesity. If a 20% or more increase in the body weight above the ideal limit was registered, the condition was accepted as a health hazard (22). This system soon went out of practice because the reference used was a selected population for surmising the ideal weight value, which could not be generalized over a broad and heterogeneous population.

In 1985, BMI values were recommended by the National Institutes of Health (NIH) to physicians as the standard measurement for indexing overweight and nutritional-induced obesity in patients (18). The genesis of BMI was Quetelet's index and mathematically deduced from the equation [body weight (kg)/height meters$^2$] (23). The close association of BMI to body fatness reduces the bias of referencing a particular population, thus making comparisons among diverse populations
feasible as well as reliable. Therefore, BMI acquired preference over the previous methods to quantify fatness (24). Many population-based studies have established the correlation of BMI to co-morbidities presented by overweight individuals, and reported a relationship curve that assumes a J-shape with an increase in both the parameters rather than the expected linearity in such curve (25-27).

Less than a decade later, in 1997, BMI was endorsed by the World Health Organization (WHO) approving it as the primary determinant of obesity as well as the primary criterion for the overweight-classification in the adults (1). The WHO recommended classification includes cut-points for separate classes referring to the conditions as underweight, desired weight, overweight and obese. Since then, this classification is now widely employed by clinicians and researchers (23, 28-31). In addition to BMI, the measure of waist circumference is also recommended in specifying obesity because the excess fat in the abdominal region has been found to alleviate nutrition-associated risks independently (23, 32-35). Furthermore, the cut-points of different classes vary among different ethnic groups (36, 37). Taking the above points into account, it is clear that the current obesity-determining practice involves BMI and waist circumference measurement (23, 28). This classification of obesity is not only useful in population-based studies, but also in outlining the pronounced increase in obesity and resulting associated co-morbidities.

2.1.2 Obesity Management

Evidence suggests that a modest amount of weight loss of approximately 5-7% of initial body weight can lead to significant improvements in obesity related health risks, including type-2 diabetes and cardiovascular disease (3). Therapy for overweight and obese individuals aims to reduce total body fat and to attain and maintain a healthy body weight for the long term. Several
strategies are currently available for promoting weight loss and maintenance, including dietary, behavioural, pharmacological and surgical interventions. Lifestyle intervention, including dietary, behavioural and physical activity programs, with a goal of achieving negative energy balance remains a key strategy in the management of obesity (38). A reliable measure of energy intake is the food energy density, which is referred to as the energy content available per weight-unit (39). Many plant-derived foods are low in food energy density because they have high water and fibre contents (40). The fat (high calorific value) proportion in the food is an additional factor which determines the energy density of the food and the relative increase in the food energy density due to fat proportions surpass the contribution of carbohydrates or proteins (40). Consumption of food high in energy density promotes energy intake. In order to estimate the contribution of fat to the density, the ratio of fat: carbohydrate is manipulated in diets at a constant density or vice versa. Several studies have assessed the effects of different dietary components on weight gain and weight loss. RCTs provide robust information about the impact of individual diet-type on weight (41-43) or if the diet-intake time is relatively short (6 months to 2 years) (41, 42, 44-46). Other sources of reliable data were population-based studies which addressed specific questions in relation to the factors at the population level, responsible for the weight gain and obesity (41) . This evidence suggests that weight management strategies based on the incorporation of foods low in energy density into the regular dietary intake of obese individuals, may prove effective in minimizing energy intake and decreasing weight gain. Although diet composition has a supposed role in weight change, weight loss primarily depends upon energy reduction. Several cross-over laboratory studies have confirmed this proposition by demonstrating the association between energy-dense diets and high energy intake and, sometimes, insignificant weight gain as summarized in the paper of Drewnowski et al. (47).
2.2 Dietary fibre and obesity

A plethora of literature evidences the relationship between weight gain and diets that include fibres and whole grains (48, 49). Few studies have attempted to describe the ability of dietary fibre to impact obesity. Suggested mechanisms for weight reduction with dietary fibres include ability to reduce dietary energy density, modify oro-sensory exposure, promote gastric distention, and delay gastric emptying to modify nutrient absorption (50). Furthermore, the level of fibre-rich diet consumption, molecular structure, physicochemical properties of the fibres, and fermentability may affect body weight regulation differentially.

Dietary fibres induce early offset of durable satiation-related signals through cephalic- and gastric-phase responses. The genesis of these responses is related to the bulking effects of dietary fibre (51). Viscosity of certain soluble dietary fibres is also suggested to modify the function of the human gastrointestinal tract to delay the fat absorption in the intestine, thereby increasing the transient time and prolonging satiety (51). This gastric emptying, along with the satiety-peptides (mainly CCK, GLP-1, and PYY), releases signals to the central nervous system, reducing hunger.
as a result (52). In the context of controlling weight, studies have demonstrated positive correlation between satiety and the dietary fibres (53, 54). The fermentation of soluble dietary fibres induces the GLP-1 (55) and PYY (56) release, prolonged satiety and lower weight gain (57).

2.2.1 Characteristics of dietary fibres

The relevance of specific dietary fibre properties in predicting satiety and energy intake is not been understood completely. The illustrated effects of dietary fibres are mediated primarily through their physicochemical properties and the food matrix. However, the role of their physicochemical properties has been seldom evaluated and reported. The scarcity of relevant data makes the exact nature of the dietary fibres uncertain; making it difficult to reason out the variations observed in the findings of the various experiments conducted in different settings. Furthermore, this uncertainty does not allow the prediction of structure-function relations, an important attribute of dietary fibres.

SOLUBILITY AND VISCOSITY

Fibre functionality is mainly attributed to its quantity and viscosity (58-60). Soluble viscous fibres are responsible for partial nutrient digestion as well as the incomplete absorption of nutrients from the gut. From a stereo-chemical point of view, if the fibre constituting molecules befits structurally in a crystalline array, the thermodynamic stability of the resultant molecular structure will be greater in solid phase rather than in liquid/solution state (61). Solubility of the fibre is thought to be an indicator for its viscous effects caused by soluble fibre. However, current evidence in vitro has not established a correlation of the soluble content of fibre and its viscosity. Association of fibre viscosity and longer molecular weights and branching is suggested depending on the surface area with solution (62).

Viscosity is a fluid property related to the resistance of a fluid to flow. It is highly dependent on the chain length, and the molecular weight of the dietary fibres wherein the association is linear.
When polysaccharides combine with solvents physically and chemically, the polysaccharide molecules are enclosed by a liquid that thickens the mixture (61). Since the degree of lignification influences the water solubility, the viscosity of the dietary fibres is affected. With respect to this association, it can be inferred that fibres (e.g., wheat bran) that are high in lignin, are non-viscous and insoluble (63). The type of fibre determines its nature, such as its availability in the sol-phase, shear processing factors, pH, ionic strength and temperature (64, 65). Although long chain polymers (for example, guar and tragacanth gum) have considerable hydration properties, they exhibit high viscosity in solution. Extensively branched fibres or fibres with low molecular weights are relatively more soluble and less viscous.

While studying the impacts of wheat bran and flavour on the quality of yogurt, Aportela-Palacios et al. (2005) observed that a rise in pH accompanied by a decline in syneresis occurs when fibre concentration is increased (66). They also noticed that the impact of natural wheat bran on the consistency of the yogurt was comparatively more than the roasted bran, and that different types of flavours = influenced the viscosity of the yogurt. Similar experiments carried out by Garcia-Perez et al. reported that the rate of gel contraction, due to the addition of orange fibre to yogurt, had effects on the latter’s syneresis in a fibre concentration-dependent fashion (67). A parallel study with barley β-glucan (also referred as inulin) and guar gum demonstrated the respective fibre’s capacities to modulate viscoelastic properties as well as serum retention of low-fat yogurt (68). Poutanen et al. assessed the practicality of the fibre viscosity in mediating satiety and energy-intake effects (69). The evidence indicated that the viscosity of dietary fibres incurs substantial advantages to satiety and energy-intake. The dietary fibres tested in the included studies were psyllium, β-glucan, guar, alginate, pectin, and locust bean gum.

GELLING
The characteristic of dietary fibres to attract water and subsequently form gels in the course of digestion, lowers the variation observed in blood sugar levels by trapping the carbohydrates and down-regulating the glucose adsorption (64). It has been shown that if gels of alginates, guar gums, and other fibres were supplemented with the diet, the gels substitute fat and add viscosity, resistance to thermal stress, improve emulsion and foam, control melting properties, promote ice crystal of small size formation, reduce syneresis, and facilitate extrusion (69). For this reason, guar gum, pectins, and inulin found their practical application in cheese processing to reduce the fat percentage of the product without compromising the cheese’s texture, flavor, and other organoleptic characteristics. Similarly, fibre gels (e.g., psyllium, β-glucan) have reportedly increased the chyme viscosity in accordance with the rising fibre concentration, making the chyme thicker. The now dense/viscous chyme affects the degradation rate because the density decreases the amount of interactions between digestive enzymes and the nutrients in the gut leading to less glucose uptake (70). Evidently, the gelling property of a fibre minimizes the peak postprandial concentration of glucose in the blood. Furthermore, the increased chyme viscosity induced by fibre’s gelling behavior traps also eliminates bile, thereby lowering the cholesterol level. Bile is reabsorbed in the distal ileum for recycling and further use (71). However, when chyme enters distal lumen, the lumen membrane already absorbs most of the water, resulting in a highly concentrated or dense fibre which bile is incapable of reuptake due to the high viscosity. The unused bile is thereby lost through fecal excrement. The lost bile acid is then compensated by liver cells which activate the expression of LDL-receptors in response to stimuli. The activated receptors thus set a cascade of events at a molecular level that facilitate the rapid clearance of plasma cholesterol. The final outcome is the lowering of overall cholesterol level without the alteration of HDL-cholesterol concentration.
Comparisons of results obtained by previous studies in this context were made by Poutanen et al., who pointed out that gelling behavior has positive implications on appetite and glycemic index due to lowering of blood glucose level (69). To evaluate the suitability of the fibre gels in intervention programs, lines of evidence are available.

**SURFACE AREA**

Surface area is a relative term and often used to refer to the surface availability and porosity of the fibre. These two characteristics participate in the fermentation process of the dietary fibre such as availability of the fibre in the gut to be degraded by gut microbes (64). On the other hand, the regioselectivity of the surface layer can influence the adsorption of certain molecules, a feature which may consummate some physicochemical properties of the dietary fibres (64). Further, a fibre’s origin and processing history will further refine the fibre architecture and accessibility to porosity and surface availability (61). Poutanen et al. reviewed the dietary fibre characteristic for mediating physicochemical properties in several intervention trials (69). In this review, results of the acute studies assessing the effects of fibre viscosity having on the appetite and energy-intake are inconclusive with the majority of studies reporting no apparent effect of statistical significance. The included studies were based on the dietary fibres derived from the natural sources like inulin from barley, oligofructose, and other oligosaccharides except few wherein dietary fibres derived from rye and kernels of barley were tested.

**PARTICLE SIZE**

Nonetheless, the particle size of the dietary fibre is a crucial player in gaming several events in the gut, fermentation, time-in-transit, and the fecal excretion. Obviously, the particle size range *per se* measure of the composition of the cell walls presents in the diet and their processing degree.
The variation in the particle size of fibre is generated because of chewing, grinding and finally fermentation of the fibre along the passage of gut (72). The down-sized (or structurally modified) particle have larger surface area and more volume of pores, all these attributes confer the fibre with higher hydration properties (64). However, the decrease gradually wears off as the particle size further downsized due to grinding. Another effect of decreasing particle size is increased permeability for the fat absorption.

**ADSORPTION OF ACTIVE FUNCTIONAL GROUPS**

Impaired mineral absorption is another dietary fibre mediated physic-chemical outcome since these polysaccharide ions contain chemically reactive species (such as carboxyl group in pectins) or associates substances such as phytates in cereal fibres which have a tendency to bond with the metal ions (64). The influence of the charged polysaccharides is not noticeable on the absorption of minerals and trace elements absorption but apparently negative when associated substances are present. The charge or the associates conforms certain polysaccharides ability to sequester and to bind bile acids chemically which may account for their hypocholesterolemic actions (64). Examples of such fibres are uronic acid-rich fibres and phenolic derivatives. Duration of exposure and other environmental factors such as pH, physical-chemistry of fibres, and basic characteristics of bile acids determines a fibre’s adsorption capacity (73, 74).

**2.2.2 Classification of dietary fibres**

Several classification systems were proposed by Tungland and Meyer (2002) to arrange groups of dietary fibre based on their simulated solubility in the human gut, based on their chemical structure, based on their defined role in the plant or their physiology, and based on site/products of digestion (75). Since the limits are not defined outright, none of the above-suggested
classification systems is convincing. However, the widely accepted dietary fibre classification is the one that is based on a degree at which these dissolves in a buffer at a fixed pH, their viscosity and/or based on the extent to which they are fermented in an in-vitro set up mimicking the sol-mix of human digestive enzymes (70). Thus, according to this system of classification, the dietary fibres are categorized in

i. insoluble/ non-viscous fibres with less fermentability (e.g., lignin, bran, cellulose and hemicellulose),

ii. the soluble, non-viscous but fermentable fibres (e.g., resistant starch, inulin, oligosaccharides, and dextrin),

iii. the soluble, viscous but non-fermentable fibres (e.g., Psyllium), and

iv. the soluble, viscous, fermentable fibres (e.g., glucomannan, Guar gum, β-glucan, and pectin).

### Classification of Dietary Fibres
(Based on Viscosity)

<table>
<thead>
<tr>
<th>Viscous (gel-forming)</th>
<th>Non-viscous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agar</td>
<td>Fructooligosaccharides (FOS)</td>
</tr>
<tr>
<td>Alginate</td>
<td>Cellulose</td>
</tr>
<tr>
<td>β-glucan</td>
<td>Resistant starch</td>
</tr>
<tr>
<td>Guar gum</td>
<td>Rice bran</td>
</tr>
<tr>
<td>Konjac</td>
<td>Inulin</td>
</tr>
<tr>
<td>Psyllium</td>
<td>Wheat bran</td>
</tr>
<tr>
<td>Pectin</td>
<td></td>
</tr>
<tr>
<td>Xanthan</td>
<td></td>
</tr>
</tbody>
</table>
2.2.3 Viscous fibre and obesity

In order to fight against obesity, dietary fibres act as physiological obstacles to energy-intake. The fibres reduce calories and nutrients in the diet. Further, they increase the time of chewing, eventually promoting the saliva and gastric juice secretion leading to the stomach extension and enhanced satiety (75). Moreover, the absorption capacity of the small intestine is reduced (75). To effect these events, the physicochemical properties such as the bulking and structure of fibre play apparent role. For this reason, viscous soluble fibres, in particular, may be useful in extending the time of nutrient digestion and absorption in the intestine (76). Time extension will facilitate greater interactions between the macronutrients and pre-absorptive satiation mechanisms, as well as the action time of post-absorptive mechanisms will be prolonged.

2.2.4 Types of viscous fibres

Guar Gum (Galactomannan)

Known by the term guar gum, these galactomannan fibres are derived from the large endosperm of the cluster beans (*Cyamopsis tetragonoloba*). Cluster beans are legume-crop cultivated majorly in India and Pakistan while other countries such as Africa, Australia, and the US do grow these legumes, however, at a small scale (77). The chemical composition of galactomannan differs in various plant sources; the difference is because the ratio in which galactose and mannose combine to form core structure of highly branched polysaccharide, galactomannan, dramatically varies among the plant species as in fenugreek, locust bean, cassia, tara and guar (77). Among the compositions in these species, guar gum is the most stable (galactose : mannose = 1:2) and economic (77). Also, the rheological characteristics of the guar gum sustain are less affected when present in low concentrations and are, therefore, highly advantageous for their use in various food
applications even without heating (77, 78). Besides being economical and stable, it is naturally available, biodegradable and safe which makes it more favorable over the synthetic food additives (77). It has found its application in food industries also, wherein it serves the purposes of a binder, thickener, stabilizer, and emulsifier without compromising the health-value of the foods processed (77, 78). Further, it is suitable for cake and cheese coating as it will not add to energy-intake, and does not contribute to the oxidation process involved in color-change and gas transfer rate. It improves texture as well as the quality of citrus fruits and delays ripening in tomato and cucumber when applied to them, thereby improving their shelf-life (77). Although the digestion of the fibre is in parts, the intestinal microbiota can efficiently ferment the Guar gum (78). Given the mentioned benefits of Guar gum use, powder and capsules made of it are used in the prophylaxis of hypercholesterolemia, diabetes, over-nutrition, hypertension and irritable bowel syndrome (IBS). The Guar-gum-derived medicines enhance the palatability and relief from the gastrointestinal discomforts (77). The physiological benefits of the Guar gum are attributed to its rheological properties. Isken et al., (2008) evaluated the protective role of a guar gum soluble fibre and compared the same with a cereal-derived insoluble fibre in obese animal models (79). They observed that after prolonged feeding with fibres, rats had gained weight and signatory molecules of insulin resistance. On the other hand, they observed that insulin sensitivity, as well as fatty acid oxidation, was improved when insoluble fibres were fed the animals.

An extensive study examined and compared mucilage solutions of galactomannan from six sources, namely guar, locust bean, Cassia, Flaxseed, tamarind, and Artemisia Sphaerocephala Krasch (80). The study grouped all the six gum samples into three categories as per the changes measured in their viscosity for a rise in the shear rate as a function of the mucilage concentration, salts and other physiological conditions such as pH and temperature. The authors reported that the
observed viscosity was apparently in positive correlation with the mucilage concentration, however, negatively affected by temperature. Among all, galactomannan of Guar and Tamarind contains more advantages which are acid-proof and alkali-proof. Moreover, the rheological behavior along with other solution properties (viscosity, and emulsification) of natural and derived galactomannans mediate their physiochemical responses in obesity by interacting with other sugar monomers or polymers (81).

**Oat β-Glucan**

Another viscous fibre, β-glucan, is generally extracted from oat (*Avena Sativa L.*) and barley (*Hordeum vulgare*). In humans, β-glucan potentiates glucose and cholesterol lowering(82). The endospermic cell-wall of oat contains β-glucan which is chemically a linear D-glucose polymer cross-linked by β-(1→4) and β-(1→3) glucosidic bonds (83, 84). Structurally, the majority of glucose units are arranged in β-(1→3)-connected cellotriosyl and cellotetraosyl blocks while few are the long segments of cellulose (83). The difference in the β-glucan structure, found in oat and barley, lies in the trisaccharides: tetrasaccharides ratios (2:1 in oat and 3:1 in barley) (85) and even a slight variation accounts for miscellaneous physical attributes as well as influences the study design and analysis outcomes (82, 85). On an average, 4.5 – 5.5 % of the oat’s total dry weight constitutes β-glucan (83). This multi-functional fibre has recently gained interest due to its bioactive properties.

The β-glucan polymers have β linkages which make them non-digestible(81). Additionally, these polymers are highly biodegraded by the microbes present in human caecum and colon (86). The β-glucan among all other oat fractions are responsible for peak rate of intestine-bacterial growth and proliferation and ameliorates the lactic acid productions to the maximum (87). Like
galactomannans, the β-glucans’ solubility is determined mainly by their structures (88). Greater the polymerization in the (1 → 3)-β-glucans, the lesser is solubility in water (89). This is because the conformation wherein the (1 → 3)-β-glucans are maximum polymerized favors stronger inter-chain interactions and associations rather than bonding with water molecules.

Further, the nature and the frequency of side-substituted branches are also a factor of the solubility of these fibres (90). A study suggests that if a β-glucan molecule is bonded with a (1 → 6)-β-glucose as its side chain, the transformation of the parent molecule will render it more soluble (91). Attributes related to the physicochemical behavior of β-glucans are in association with numerous biological functions. The ability of the β-glucans to form highly viscous solutions promotes the satiety feelings in the human gut (92). Consequently, β-glucan has found its applicability as a food ingredient. For example, Oats often supplemented with the cereal products in order to reduce water activity and eventually to sustain durability (85). The use of β-glucan as a stabilizer, emulsifier, thickening and water binding in baking products in the commercial font is well-documented in the literature (85). Beta-glucans also has probiotic effects, i.e., nourishing the intestinal bacteria. They favor the proliferation of ‘good’ bacteria, *Lactobacilli* and *Bifidobacteria*, in the human gut and discourage the growth of pathogenic bacteria (89). Therefore, in addition to the probiotic milk-based drinks, even at lower percentages, oat β-glucan promotes drink’s stability and health benefits (85). In a short-term study, β-glucan was found to reduce hunger in healthy subjects by lowering the hormone ghrelin (hunger-inducer) in blood by 23% while the level of PYY was high by 16% (93). The effects observed were prolonged satiety and attenuated glucose response.

**Konjac (Glucomannan)**
Konjac Glucomannan (KGM), is derived from tubers of *Amorphophallus konjac* and found its application in emulsification and thickening of different commercial foods (94). This viscous dietary fibre is widely used in Japan and China (95). Recently, KGM has attracted the attention of western countries given to its rheological properties which render it suitable for food industry applications (96). The fibre is essentially rich in viscous glucomannan which has potential health benefits such as weight reduction and glucose control (94). The chemical aspect of KGM comprises of D-mannopyranose bonded to D-glucopyranose via β-1,4 linkage in a proportion of 1.6:1 (94, 96). The linkage is not breakable by amylase present in human saliva and pancreatic secretions; therefore, the fibre passes through the colon undigested (97). Chain saturated with 5-10% acetyl groups branches off per 10-19 units of the glucomannan (96). These side chains accounts for the solubility of KGM; 20,000-40,000 mPa.s-1 viscosity is generated per 1.0% KGM solution at 30 °C (94). This value is prominently higher than the viscosity of guar gum and β-glucan (94). With regard to high viscosity, KGM has exceptional ability to absorb water.

In a meta-analysis, inclusive clinical trials demonstrated the beneficial effects of glucomannan on body weight (98). The weight loss effect is mediated by KGM in mechanisms similar to that other soluble, viscous and fermentable fibres. Since KGM is characterized by bulking and low energy density, it supposedly displaces the other nutrient-energy, induces satiation by the water-absorption property as well as expands in the gut (97). These attributes facilitate weight reduction in individuals. Similar findings are reported by a few clinical trials in adults (98-101). However, factors such as ineffective study designs, heterogeneous diagnoses, study population relatively small, short-termed intervention and variable KGM formulations have affected the outcomes of these trials.
Psyllium

A transparent mucilage, Psyllium, is present in the outer epidermis covering the dehydrated seed extracts of *Plantago psyllium* (102, 103). The mucilage fraction swells when comes in the contact of air-moisture and used in many commercial products. Psyllium isolates have been reported to be effective as a bulk laxative to provide relief from constipation (103, 104), management of metabolic-associated diseases (105), irritable bowel syndrome (106) and diabetes (102, 107). The molecular framework of psyllium contains arabinose, xylose in proportion of 22.6% and 74.6%, respectively, with other sugars present in traces (102). The backbone of the molecular framework is made up of repeated D-xylopyranosyl units bonded in a chain by β-(1→4)-linkages. The backbone is further branched into few chains xylopyranosyl and trisaccharide residues (102). The molecular weight of the psyllium is estimated as $7 \times 10^6$ Da, whereas the gel of the psyllium weighs in-between $10^2-20 \times 10^6$ Da (108). The calculated viscosity at room temperature was on an average of 14 300 centipoise for 1% psyllium solution (109).

The formation of viscous gel by psyllium is attributed to its hydrophilic properties that measures approximately 10 g water per gram of Psyllium (103). This attribute further renders psyllium to adsorb simple carbohydrates and other hydrophilic molecules including proteins (103). This physiology explains that despite of being a viscous fibre, psyllium is not fermented in the gut and is, therefore, successfully survive the transit in the gut (110-112) retaining energetic molecules and emulsified lipid portion of the digesta in the stomach. This delays the nutrient flux in the small bowel and laid out. In addition to this, high viscosity and solubility of the fibre contribute to improve the unstirred water layer in the gut. The mechanisms of gastric emptying and delayed
transit time by psyllium for the energy absorption in the intestine could act in several ways: (a) reducing hunger; (b) induced discomfort in abdomen; (c) increased satiety sense (103).

The satiety-effect of psyllium have been documented by several studies (113, 114). Bergmann et al. (1992) observed the delay in the psyllium-induced gastric emptying was apparent from the third hour whereas the sixth hour onward was marked with the significant rise in satiety feeling and reduced hunger (113). Psyllium effected the increase in satiation by allowing more time for the intestinal absorption of hydrosoluble nutrients rather than delaying their gastric emptying.

**PolyGlycoplex**

A proprietary functional fibre, PolyGlycopleX, PGX®, is a complex of three dietary fibres, namely \(\alpha\)-D-glucurono-\(\alpha\)-manno-\(\beta\)-D-manno-\(\beta\)-D-gluco, \(\alpha\)-Lgulurono-\(\beta\)-D mannurono, and \(\beta\)-D-gluco-\(\beta\)-D-mannan. The manufacturing process of PGX causes konjac (glucomannan), xanthan gum and sodium alginate to chemically interact in the genesis of the polysaccharide complex with viscosity greatest among all known polysaccharides (115, 116). PGX, thus formed, is a highly viscous, soluble and functional fibre with a good tolerance index as shown in animal-models (117) and human studies (118). Any mutagenic consequence related to the use was not evident in genotoxic studies that employed bacterial reverse mutation and mouse micronucleus assays (119).

PGX is known to reduce hunger more effectively than cellulose and glucamannan when given as a meal-substitute (120). Kacinik et al (2011) conducted a 3-week crossover trail on overweight and obese female subjects and showed that supplementing PGX® with low energy-dense diet reduced hunger in the subjects and intensified the feeling of fullness as compared to placebo meals (121). Reimer (2010) showed that PGX favorably facilitates satiety-related peptide hormone, PYY secretion by significantly increasing the fasting (plasma) PYY levels in plasma as compared with
placebos in healthy adults with a BMI of 23 kg/m2 (116). Several studies have indicated that the Plasma PYY concentration falls in the overweight and obese humans (54, 57) due to impaired secretion of PYY, an event associated with the progression of obesity and is believed to impede the weight loss. However, the study of Reimer (2010) was based on the observations in normal weight adults (116). In a placebo-controlled trial, it was found that PGX is effective in reducing weight gain in overweight adults by increasing PYY levels in a fashion similar to that of other soluble fibres (122).

**Alginate**

Alginate is a polysaccharide with gelling behavior and is extracted from marine brown algae (123). The molecular framework of the fibre is built by mannuronic and guluronic acids which render the fibre viscous and other physiological attributes. These attributes of alginate is responsible for the mechanical strength and flexibility of the algae. The most widely used alginate is Sodium alginate in food industry wherein it is added as additives because of its rheological properties (123). Alginates are able to form gels in the vicinity of multivalent cations such as Ca$^{2+}$ or if their solution has pH lower than the pKa of the constituent acids (123). The proportion of the constituent guluronic acids present also influence the gel-strength. Several studies have demonstrated that consuming sodium alginates in acute-settings is followed by its gel-formation in the stomach, thereby exhibiting a modulatory effect on the appetite sensation in humans (124) (56, 125-128). Authors have postulated that the mechanism of the causation (in association with Ca$^{2+}$) entails favorable modifications of fibre’s rheological properties, viscosity, gelling behavior and altering gastric milieu. The outcomes include slow rate of gastric emptying, lesser absorption of nutrients, reduced postprandial glucose intake and blunted insulin responses. The cumulative effect of all
these outcomes is enhanced satiety feeling (129). A retrospective study based on the combination of the alginate, glucomannan and xanthin gum demonstrated the positive effects on weight management of overweight subjects (130). In context of this, a contradictory finding reported by a study, which showed that no apparent promoting effects on weight loss were registered when subjects were given either guar gum or combination of guar gum, glucomannan and alginate, but the weight-loss was stimulated when isolated glucomannan fibres consumed (99). Georg et al. 2012 suggests that if in a dietary intervention, alginate supplementation is taken for long-term may stimulate weight loss benefitting the obese subjects (123).

Pectin

Pectin, another soluble and viscous fibre, is a polymer of linearly arranged D-galacturonic acid residues inter-bonded by (1→4) links. Substituents such as α (1→2) rhamnopyranose units often present in different regions of the backbone to off-shoot the branches of neutral sugars (galactose, mannose, xylose, galactose and glucose) (131). Pectin is extracted from the peels of citrus fruits and are used as a gel or thickening agent in the commercial food applications. Similar to several other dietary fibres, pectin is not modified in the digestive tract during passage but is fermented by colonic microflora. Moreover, pectin is still capable of gelling or thickening in the milieu of the digestive tract. This property is of significance in the management of several metabolic syndromes. The gelling behavior of the pectin is also responsible for slow gastric emptying and modified transit-in-gut-time (64). In their comparative study, DiLorenzo et al. (1988) found the pectin-induced rise in the satiation feeling in 9 obese adult-patients was greater than the effect
generated by equimolar methylcellulose (132). A recent study in animal-models showed the potential of pectin in lowering the weight gain as well as attenuating obesity-risks when rats were fed daily with pectin (133). A study based on assessment of combined effects delivered by pectin in association with oligofructose pointed that the complex of both was instrumental in inciting satiety by stimulating the production of SCFA in the colon (134). In support of this, findings of the clinical trials suggest the putative role of pectin ion altering the satiety and relative hormones, glycemic index as well as rate of gastric emptying (132, 135, 136), all these mechanisms indicate the pectin’s involvement in the human weight management, which warrant further exploration.

**XANTHAN GUM**

Xanthan gum is a natural biopolymer consisting of polysaccharides with several significant industrial applications. Commercially, *Xanthomonas campestris* undergoing submerged fermentation on cruciferous vegetables in aerobic conditions produce xanthan gum (203). *X. campestris* (137) and molasses (138) are the alternative sources for the production of the xanthan gum.

Several pentasaccharide units rerun along the primary structure of this heteropolysaccharide, and their constituent molecules are glucose, mannose and guluronic acid combined in a ratio of 2:2:1 (molar ratio is 2.8:2.0:2.0) (139). At the core of the heteropolysaccharide resides b-D-glucose units bonded with each other at their 1 and 4 positions. The molecular structure of pectin shares similarity with that of cellulose molecule. Side chains are present and chemically, they are
composed of D-mannose- D-glucuronic-D-mannose trisaccharide units linked to the main chain on the third oxygen atom of the glucose residue (139). Again, the terminal D-mannose of few trisaccharides are bonded to a pyruvate acid; distribution being subjected to heterogeneity. Further, the main chain-linked D-mannose contains an acetyl group. Both the pyruvic acids and acetyl group renders the pectin molecule anionic nature (139, 140). The anionic nature of the pectin explains the highly viscous behavior of the molecules in water. Therefore, it is used as a thickener for sauces as well as prevent crystallization in ice creams (140). Further, this viscous property renders xanthan gum as a suitable fat-substitute while preparing low-calorie diets (140).
CHAPTER III - PROJECT OVERVIEW

RATIONALE

An effective diet to increase satiety and reduce food intake in weight loss interventions is needed. Dietary fibres are emerging as a potential tool to assist in appetite regulation and prevention of obesity. It has been suggested that intake of diet rich in viscous soluble dietary fibres may have beneficiary effects. Available evidence suggests that such fibre- due to ability to delay gastric emptying, affect nutrient metabolism and energy dilution (203), change gastrointestinal microbiota (211), affect energy homeostasis (208-210) - may suppress hunger and induce satiety (205-207), and thus have other therapeutic benefits of significance (138, 188, 200-202).

There has been accumulating literature describing fibre intake and its relation with obesity or weight (4, 203, 217). While these findings were not reviewed and supported in a recent meta-analysis (218), the evidence is confounding and non-conclusive.

Therefore, the present two systemic reviews and meta-analyses of evidence are conducted to synthesize knowledge from controlled intervention trials to assess the effects the viscous dietary fibre supplementation on body weight and other body anthropometry measurements. While the first study includes viscous fibre interventions independent of calorie restriction, the second one includes studies where dietary caloric restriction was applied.

The population of interest comprised three categories of adults, including overweight and obese, those at elevated CVD risk and healthy individuals.

OBJECTIVE
The overall objective is to investigate the effect of viscous fibre supplementation in context of ad libitum and restricted calorie diets in adults, by means of two systematic reviews and meta-analyses of RCTs.

Specific objectives are:

To assess the effect of viscous fibre supplementation, independent of calorie restriction on body weight, BMI, waist circumference and body fat percentage in adults through a systematic review and meta-analysis of RCTs.

To investigate the effect of viscous fibre supplementation added to a calorie restricted diet on body weight, BMI, waist circumference, and body fat percentage in adults, through a systematic review and meta-analysis of RCTs.

HYPOTHESIS

The overall hypothesis is that viscous fibre interventions would result in significant reduction in body weight and improved parameters of adiposity irrespective of background diet.

Specific Hypothesis:

Study 1: Viscous fibre supplementation will reduce body weight in adults in the context of an ad libitum setting or independent of calorie restriction.

Study 2: Viscous fibre supplementation will reduce body weight and other anthropometric parameters in the context of its inclusion to calorie restricted background diet.
CHAPTER IV – Effect of dietary viscous fibre supplementation on adiposity in individuals consuming non-restricted calorie diets: A systematic review and meta-analysis of randomized controlled trials

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Abstract:

**Background:** Dietary viscous fibre supplementation has the potential to facilitate weight management.

**Objective:** To conduct systematic review and meta-analysis of RCTs evaluating the effect of viscous fibres on body anthropometry with ad-libitum diets.

**Methods:** three databases were searched through 16-08-2018. We included randomized controlled trials ≥4 weeks assessing the effect of viscous fibre supplemented to ad-libitum diet on
adiposity parameters. Random effect method was used. (GRADE) approach used to evaluate the certainty of evidence.

**Results:** 62 eligible studies (n=3320) showed that median dose of 5 g/day (range: 0.73–36) viscous fibre supplementation significantly reduced body weight (MD= -0.33 kg [-0.51, -0.14]), BMI (MD= -0.28 kg/m2 [-0.42, -0.14]), waist circumference (MD= -0.63 cm [-1.11, -0.16]). There was no significant effect of body fat percentage (MD= 0.78 % [-1.56, 0.00]). The certainty of evidence for body weight graded “low” to “moderate”.

**Significance:** This study may help guide recommendations and direct future research.
Introduction

Obesity is a leading public health problem as rates continue to increase worldwide. Recent age-adjusted estimates of global obesity report at least 30% of men and 35% of women are obese in many countries including in North America, Western Europe, Asia, and Australia (141). Therefore, weight management is crucial in the fight against obesity. It is well-known that positive energy imbalance is the primary dietary cause of overweight and obesity (142). Lowering energy density, energy reduction, and increased fibre intake have been emphasized as a strong predictors for weight loss (142-144).

The Institute of Medicine recommends a fibre intake of 25 g/day for women and 38 g/day for men (adults aged 21–50) however, only a reported 5% of the U.S. population achieves these recommendations (145). Therefore, fibre supplementation is a practical way to increase fibre intake although, the proportion, type of fibre, and dose that is most suitable for weight management remains unclear (146).

It has been proposed that the viscosity of fibre may be associated with weight loss however, the data is inconsistent. Therefore, the objective of this study was to evaluate the effect of dietary viscous fibre supplementation in the context of an ad-libitum diet without caloric restriction on body weight and other markers of adiposity in adults, through a systematic review and meta-analysis of RCTs.
METHODS

Protocol and registration

The Cochrane Handbook for Systemic Reviews of Interventions was used to conduct this study (147). The results were reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (148). The protocol of this review is available online at ClinicalTrials.gov (NCT03257449).

Search strategy and data sources

MEDLINE, EMBASE, and Cochrane Library for Registered Controlled Trials were searched through August 16, 2018, to identify RCTs on the effect of viscous fibre supplementations in an ad-libitum diet on body anthropometric measures (body weight, BMI, waist circumference, and body fat percentage) in adults. A manual search of the included studies’ references was performed to enhance the electronic search. Supplementary Table 4.1. presents the search terms and strategy of this review.

Study eligibility

Supplementary Table 4.2. shows the study inclusion and exclusion criteria. We employed RCTs of ≥ 4 weeks that investigate the effect of viscous fibre supplementation, (agar, alginate, β-glucan, guar gum, konjac, PGX, psyllium, or xantham) in the context of an ad-libitum, non-caloric restriction diet compared to a fibre free diet or placebo on at least one of the outcomes: body weight, BMI, waist circumference, or body fat percentage. Trials that included viscous fibre supplementation in a dietary mixture or mixed with another intervention were excluded to isolate the fibre effect. However, oat and barley were an exception, they were accepted as β-glucan source.
In the multi-arms trials, we selected groups that permitted us to assess the specific effect of viscous fibre supplements. Some studies yielded more than one comparison as the control group was compared to two fibre groups to get observations as much as possible. When multiples of the same publication were found, the newest publication was used.

**Data extraction and quality assessment**

Two reviewers (NM & RK) independently extracted relevant data from eligible articles to a standardized proforma. A third impartial reviewer resolved conflicts between reviewers. Extracted study information included: fibre type (agar, alginate, β-glucan, guar gum, konjac, PGX, psyllium, or xantham), study design (cross-over or parallel), participant characteristics (number, gender, BMI, age), comparator (placebo or diet), dose of the viscous fibre (if the β-glucan content was not reported, it was estimated at 5% \(^{149}\) of the oat dose reported), duration, background diet, and funding source (agency or industry). Change from baseline as mean and SEM for both control and intervention groups were extracted or calculated from the available reported data (95% CI, SEM, or mean and SD of the baseline and endpoint values) using a standardized formulae \(^{147}\).

The Cochrane Risk of Bias (ROB) Tool was used to assess study the following domains: Random sequence generation (selection bias), Allocation concealment (selection bias), Blinding of participants and personnel (performance bias), Incomplete outcome data (attrition bias), Selective reporting (reporting bias) \(^{147}\). Each domain was considered “Low risk of bias” when the true effect of the outcome is not likely to be affected, “Unclear risk of bias” when the study does not report enough information to permit judgment, and “High risk of bias” when the true effect of the outcome is likely affected. When necessary, authors of articles were contacted for additional information \(^{150}\).
**Data management and analysis**

Review Manager (RevMan), version 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) was utilized for primary data analyses and STATA ver 14 (StataCorp, College Station, USA) for subgroup analysis. Difference between changes from baseline values for control and fibre arms were calculated for every trial for the outcomes body weight, BMI, waist circumference, and body fat percentage. A weighted average was used for multi-arm trials to create a single pair-wise comparison and reduce the unit-of-analysis error. We assumed a conservative correlation coefficient of 0.50 for standard deviation of cross-over trials. The generic inverse variance method with random effect model was used to calculate a pooled analysis. Information was expressed as MD with 95% CI and considered significant at P< 0.05. Inter-study heterogeneity was assessed and quantified utilizing the Cochrane Q-statistic and I² with significance P< 0.10. I² ≥ 50 % was considered evidence of substantial heterogeneity (147). To determine whether a single study exerted a specific influence on the overall results, a sensitivity analysis was performed by removing each study from the analysis and re-calculating the pooled effect size of the rest of the studies. Heterogeneity was investigated with *a priori* subgroup analyses (continuous and categorical) for baseline values within the fibre group, dose design, duration, fibre type, and food matrix with significance P< 0.05. Dose-response analysis was performed using meta-regressions to generate linear and non-linear dose estimates using the MKSPLINE procedure, with P< 0.05 significance. Publication bias was assessed by visual inspection of funnel plots and tested in STATA using the Egger’s and Begg’s tests, where evidence of small study effects was considered at P< 0.10. When publication bias was suspected, Trim and Fill analysis was applied to impute missing study data and correct for asymmetry.
GRADE of Recommendation Assessment, Development and Evaluation

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) (151) method was employed to evaluate the overall quality and certainty of the evidence. The grade of the evidence quality can be determined as 'very low', 'low', 'moderate', or 'high'. RCTs start with high quality evidence then may be downgraded based on the following domains:

- Risk of Bias (determined using the same domains as the ROB figure and taking in consideration the weight of studies)
- Inconsistency (determined through substantial heterogeneity, $I^2 > 50\%$)
- Indirectness (determined based on the indirectness of population, comparator, outcome, or comparison that might limit the generalizability of findings)
- Imprecision (determined by looking to the precision of the estimated effect through its width and if it cross the minimally important differences (MID))
- Publication bias (determined using the funnel plot as evidence of small-study effects).

RESULTS

Search results

The initial search yielded 8400 citations, of which 191 articles were reviewed in full and 62 articles included in the final analyses (n= 3320) (Figure 4.1.). Per outcome, body weight was reported in 51 articles (61 observations), 28 articles reported BMI (39 observations), 17 articles reported waist circumference (23 observations) and 8 articles reported on body fat percentage (10 observations).

Trials characteristics
Characteristics of the included trials are summarized in Table 4.1. All studies were conducted in an out-patient setting: with 23 in Europe (7 Finland; 6 Sweden; 3 UK; 3 Italy; 2 France; 1 Netherlands; 1 Germany), 18 in North America (11 USA; 6 Canada; 1 Mexico), 8 in Asia (2 Japan; 2 China; 2 Taiwan; 1 Thailand; 1 Singapore), 5 in Australia, 3 in Middle East (1 Iran; 1 Palestine; 1 Saudi Arabia), 1 in South America (Brazil). The majority of trials were conducted using a parallel design (64.5%; 40) and (35.5%; 22) using cross-over design. Participants were generally middle aged men and women with a median age of 51 years (range: 16-70), and are slightly overweight with a median BMI of 27 kg/m² (range: 19-33). The study population in 55% (34) of studies had elevated cardiovascular disease (CVD), 29% (18) were obese, and 16% (10) healthy (with unspecified BMI criteria). Median treatment duration was 10 weeks (range: 4-52) with median dose of 5 g/day (range: 0.73 – 36). Funding source for 48% (29) of studies was not reported, 37% (23) were agency, 12% (8) industry, and 3% (2) agency-industry.

Supplementary Table 4.3 shows the risk of bias as per each study in all domains. According to the Cochrane Risk of Bias Tool, 65% (41) of studies had unclear, 33% (20) low and 2% (1) high risk of bias for sequence generation. For allocation concealment, 81% (50) of studies had unclear, 17% (11) low, 2% (1) high risk of bias. For blinding, 59% (37), 28.5% (17), and 12.5% (8) of the studies had low, high, and unclear risk of bias, respectively. For incomplete outcome reporting, 63.5% (40) was low risk, 17.5% (10) high risk, and 19% (12) unclear risk. Data and selective reporting was low risk of bias for all included studies.
Figure 4.1. Flow of Literature
Table 4.1. Characteristics of included studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Fibre</th>
<th>Participants</th>
<th>Age (y)*</th>
<th>BMI (kg/m²)*</th>
<th>Design, Duration</th>
<th>Blinding</th>
<th>Dose (g)</th>
<th>Comparator</th>
<th>Background Diet</th>
<th>Funding</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrahamsson et al, 1994</td>
<td>B-glucan</td>
<td>24F</td>
<td>26±6</td>
<td>61±6</td>
<td>C, 5 wk</td>
<td>NA</td>
<td>1.1</td>
<td>Wheat</td>
<td>Habitual diet</td>
<td>Agency</td>
<td>Sweden</td>
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<td>98</td>
<td>30-70 †</td>
<td>75.3±10.2</td>
<td>P, 12 wk</td>
<td>DB</td>
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<td>Rice</td>
<td>Agency</td>
<td>Japan</td>
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<td>26</td>
<td>30-65 †</td>
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<td>P, 8 wk</td>
<td>DB</td>
<td>3.4</td>
<td>Cellulose</td>
<td>Habitual diet</td>
<td>Agency</td>
<td>Unite States</td>
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<td>C, 12 wk</td>
<td>DB</td>
<td>15</td>
<td>Wheat</td>
<td>Habitual diet</td>
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<td>Finland</td>
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<tr>
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<td>DB</td>
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<td>No Fibre</td>
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<td>SB</td>
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<td>18-70</td>
<td>25.3±3.2</td>
<td>P, 5 wk</td>
<td>SB</td>
<td>5.0</td>
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<td>25±3.1</td>
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<td>4.0</td>
<td>Maltodextrine</td>
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<td>Sweden</td>
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<td>79</td>
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* mean ±SD reported unless otherwise indicated
* † range provided
Effect on Body Weight

**Figure 4.2.** demonstrates the effect of dietary viscous fibre supplementation on body weight (kg). Overall, a significant reduction in body weight was observed (MD = -0.33 kg [95% CI: -0.51, -0.14], P = 0.0004) with a median dose of 5 g/d [range: 0.73 – 36] and median treatment duration of 8 weeks [range: 4 – 52]. Analysis was divided into three population groups based on health status (overweight and obese, elevated CVD risk, and healthy). Differences between population groups was significant (P= 0.01). Significance was only observed however in the overweight/obese population group (MD = -0.66 kg [95% CI: -0.99, -0.34], P < 0.0001) with no significance revealed in the elevated CVD risk group (P= 0.09) or the healthy group (P= 0.85). Substantial evidence of inter-study heterogeneity is present in the overall analysis (I^2= 66%, P<0.00001). Removing two individual studies (152, 153) systematically explained some of the heterogeneity. However, heterogeneity remained substantial (I^2= 58%, P< 0.00001 ) (I^2= 59%, P< 0.00001 ), respectively. Continuous and categorical a priori subgroup analyses are presented in Supplementary Table 4.4.(A) & 4.5. Continuous meta-regression analyses revealed a significant association between treatment duration and body weight (MD= -0.04 kg [95% CI: -0.07, 0.01], P= 0.005), with residual I^2= 48.88%. No significant association was found for viscous fibre dose or baseline body weight. Categorical meta-regression analyses revealed an effect of duration (P= 0.012), where studies ≥ 8 weeks duration showed greater reductions in body weight compared with trials < 8 weeks. After accounting for this effect, residual I^2= 64.48%. Analyses did not revealed an effect of fibre matrix (pre-mixed food, sachet, or capsule), between matrix (P= 0.119). The effect of food matrix resulted in residual I^2= 54.04%. Dose response analyses revealed no significant evidence of a linear (P= 0.79) or non-linear (P= 0.80) effect (Supplementary Figures 4.2. A1 & A2).
Effect on BMI

The effect of dietary viscous fibre supplementation on BMI (kg/m$^2$) is presented in Figure 4.3. Pooled analysis showed that median dose of 3.8 g/day [range: 0.8-15] of viscous fibre for median duration of 8 weeks [range: 4 – 52] significantly reduced BMI (MD = -0.28 kg [95% CI: -0.42, -0.14], P = 0.0001). No significant differences were observed between population groups (overweight/obese, elevated CVD risk, healthy) (P= 0.08). Within groups, reduction in BMI was significant only in those that are overweight or obese (P= 0.007). Substantial evidence of heterogeneity was observed (I$^2$= 82%, P< 0.00001). Some of the heterogeneity was explained when two studies (154, 155) were removed individually, however heterogeneity remained substantial (I$^2$= 74%, P< 0.00001) (I$^2$= 76%, P< 0.00001), respectively. Supplementary Table 4.4.(B) & 4.6. show the a priori continuous and categorical subgroup analyses. Continuous meta-regressions revealed an association between BMI reduction and study duration (-0.016 kg/m$^2$ [95% CI: -0.032, -0.0001], P= 0.047). No association was determined for fibre dose or baseline BMI.

Categorical meta-regression analyses showed a significant effect between doses < 3.8 g/d and ≥ 3.8 g/d (P= 0.031), where doses ≥ 3.8 g/d showed greater reductions, in BMI. Analyses also revealed an effect of study duration between < 8 weeks and ≥ 8 weeks (P = 0.020), where studies ≥ 8 weeks result in greater reduction in BMI. An effect of viscous fibre type was also observed (P= 0.0005). Analyses indicate greater reductions in BMI with guar gum and psyllium, compared with B-glucan and PGX. After accounting for effect of viscous fibre type, residual I$^2$ = 59.67%. Dose response analyses revealed no linear (P= 0.07) or non-linear (P= 0.06) association of viscous fibre supplementation dose and BMI reduction (Supplementary Figures 4.2. B1 & B2).

Effect on Waist Circumference
**Figure 4.4.** demonstrates the effect of dietary viscous fibre supplementation on waist circumference (cm). Pooled analysis of median dose of 5 g/d [range: 0.80 – 36] of viscous fibre for median duration of 12 weeks [range: 4 – 52] resulted in a significant reduction in waist circumference (MD= -0.63 kg [95% CI: -1.11, -0.16], P= 0.008). Analysis did not reveal significant difference between population groups by heath status (overweight/obese, elevated CVD risk, healthy) (P= 0.40) however, within groups, only the overweight/obese group showed significant reduction in waist circumference (MD= -0.70 cm [95% CI: -1.18, -0.22], P= 0.004). Substantial evidence of inter-study heterogeneity is present in the overall analysis (I²= 62%, P< 0.0001). After systematic removal of Solah et al 2017 (156), there remained no evidence of substantial heterogeneity (I²= 35%, P< 0.0001). Continuous and categorical *a priori* subgroup analyses are presented in the Supplementary Table 4.4.(C) & 4.7. Continuous meta-regression analyses did not reveal any association between waist circumference and dose, treatment duration, and baseline waist circumference. Categorical meta-regression analyses revealed no effect modification of dose, duration, study design, baseline waist circumference, fibre type or fibre matrix. Dose response analysis revealed no linear (P= 0.11) or non-linear (P= 0.75) association of viscous fibre supplementation dose and waist circumference reduction (Supplementary Figures 4.2, C1 & C2).

**Effect on Body Fat Percentage**

The effect of dietary viscous fibre supplementation on body fat percentage is presented in **Figure 4.3.** Pooled analysis of median dose of 5 g/day [range: 3-12] of viscous fibre for median duration
of 8 weeks [range: 4 – 52] showed no significant effect on body fat percentage (MD= -0.78 % [95% CI: -1.56, 0.00], P= 0.05). There was no significant difference between groups divided by health status (overweight/obese, elevated CVD risk, healthy) (P= 0.40). Within groups, reduction in body fat percentage was significant only in those that are overweight or obese (P= 0.04). There was no evidence of substantial heterogeneity (I²= 43%). Supplementary Table 4.4.(B) & 4.8. shows the a priori continuous and categorical subgroup analyses. Continuous meta-regression analyses revealed an association between body fat percentage and viscous fibre dose (MD= -0.05 % [95% CI: -0.09, 0.01], P= 0.021). There was no effect found for duration or baseline body fat percent. In categorical meta-regression analyses, there was a significant effect between doses < 5 g/d and ≥ 5 g/d (P= 0.029), where doses ≥ 5 g/d resulted in greater reductions in body fat percentage.

Dose response analysis revealed a linear association of viscous fibre dose with body fat percentage improvement (P= 0.02). There were not enough studies to assess non-linear dose response (Supplementary Figures 4.2. D1 & D2).

Publication bias

Figure 4.7. Shows funnel plots for body weight, BMI, waist circumference, and body fat percentage. Visual inspection of funnel plots suggested no asymmetry in Waist circumference, and body fat although, the body weight and BMI funnel plot showed major asymmetry. Formal testing using Egger’s and Begg’s tests were significant (P= 0.012, P= 0.041). Duval and Tweedie Trim and Fill analysis (Figure 4.8.) did not identify any missed studies to impute, resulting in no change to the pooled effect (MD= - 0.33 kg [95% CI: - 3.51, - 0.14]; P= 0.00) and (MD= - 0.28 kg/m² [95% CI: - 0.42, - 0.14]; P= 0.00).
Grading the evidence

A summary of the GRADE assessments is shown in Table 4.2. The certainty of evidence for body weight was graded “low” due to downgrade of inconsistency and imprecision. BMI was graded “low” quality based on a downgrade for inconsistency and imprecision. Waist circumference and body fat percentage both were graded “moderate” for downgrading in risk of bias.

Discussion

To our knowledge, this is first systematic review and meta-analysis of RCTs to assess the effect of viscous fibre supplementation on body weight, BMI, waist circumference, and body fat percentage, independent of calorie restriction. Pooled analysis of 62 trials (n= 3320) showed significant reduction in body weight (-0.33 kg), BMI (-0.28 kg/m²), and waist circumference (-0.63 cm), at a median fibre dose of 5 g/d (range: 0.73-36) for median duration of 10 weeks (range: 4-52). The reductions in anthropometric measurements were significant, mainly due to the effect in overweight and obese individuals, while the other population categories of healthy individuals and those with elevated CVD risk were not significantly reduced. The only parameter that was not significant is the percent of body fat, which approached significance -0.78% (95% CI: -1.56, 0.00; P= 0.05).

The effect of fibre as indicated in this study is small although lacking clinical significance. However, taking into consideration that the effect of weight management programs typically rely on calorie restrictive diets, the addition of viscous fibre supplements to such may be beneficial to achieve the reduction of 5-10 % of initial body weight needed to meet clinically relevant benefits (157). Another strategy to achieve this would be to increase the daily dose of viscous dietary fibre, however, this is often challenging due to unpalatability of viscous fibre (58).
Our findings are supported by a previous meta-analysis of viscous and non-viscous soluble fibre supplementation in overweight and obese individuals where BMI (-0.84 kg/m² [95% CI: 21.35, 20.32]; P= 0.001), body weight -2.52 kg (95% CI: 24.25, 20.79 kg; P= 0.004), and body fat percentage (-0.41% [95% CI: 20.58, 20.24]; P= 0.001) were significantly reduced, compared with the effects of placebo(158). Despite similar outcomes, our meta-analysis provides a more comprehensive assessment including substantially more studies while assessing the effect of dietary fibre on adiposity in a broader population (healthy, overweight/obese, increased CVD risk), improving the generalizability of the findings.

Another previous meta-analysis that assessed the effect of glucommanan on body weight and blood pressure reported no effect on body weight (MD = -0.22 kg [95% CI: -0.62, 0.19], P = 0.30). Our results show similar results however are significant, attributing the effect to the fibre viscosity. Additionally, a meta-analysis that assessed the effect of guar gum on body weight, found no effect (98, 159). It is possible that this is attributed to the inclusion of hydrolysed guar gum in the analysis that is low viscosity and thus may have weakened the effect.

There are several strengths to this study. It is the first meta-analysis to investigate the effect of fibre based on viscosity rather than solubility, and one of the first to explore the isolated effect of dietary fibre, independent of caloric restriction. This analysis also included only well designed RCTs to strengthen the quality of the evidence and trials spanning several countries, which may increase the generalizability of results. The majority of the trials also had a follow-up period of ≥10 weeks, which might be fair duration for exploratory types of trials. Finally, the certainty of evidence was assessed using GRADE.

Conversely, there are limitations in the present meta-analysis that should be considered when interpreting the results. First, some of the outcome were downgraded for risk of bias as the majority
of studies had moderate risk and the larger weighted studies had high risk. Inconsistency of the estimates across trials also resulted in substantial heterogeneity in outcomes which could not be explained through sensitivity analyses. Moreover, certainty of the evidence was downgraded for imprecision, as both bonds of the 95% CI did not meet the minimally important difference for beneficial evidence. Taking into account the strengths and limitations of the studies, the certainty of available evidence was graded low for body weight, BMI, and moderate for waist circumference and body fat percentage.

In conclusion, the present systematic review and meta-analysis of RCTs shows that a daily median intake of 5 g/d of viscous fibre supplements over a median duration of 10 weeks significantly reduced body weight, BMI, and waist circumference in a general population including healthy, overweight/obese, and individuals with elevated CVD. The overall results are limited due to a low median dose of fibre and the fact that some of the outcomes were reported as secondary outcomes in many of the included trials.

To address the current limitations of our analyses, there is a need for longer, higher quality trials with larger fibre doses of viscous fibre supplements and with a specific focus on weight endpoints as a primary outcome. Such trials may help guide the development of nutrition recommendations and health claims through future meta-analyses. It would be especially interesting if these future studies include information on measures of viscosity or molecular weight of giving fibre supplements to assess the correlations between rheological properties and prevention of body weight. Overall, our data supports the inclusion of viscous fibre supplements as part of a healthy diet for weight management in adults. It is one of the first analyses to confirm the ability of viscosity of fibre to reduce body weight even when added to ad libitum diet, with no calorie restrictions.
## Overweight/obese

<table>
<thead>
<tr>
<th>Subgroup and Study, Year (Reference)</th>
<th>VF (n)</th>
<th>Contol (n)</th>
<th>Weight (%)</th>
<th>Mean Difference (95% CI) in Body weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1983 Tuomilehto et al</td>
<td>6</td>
<td>6</td>
<td>0.60%</td>
<td>0.10 [-2.19, 2.39]</td>
</tr>
<tr>
<td>1984 Aro et al</td>
<td>14</td>
<td>14</td>
<td>0.20%</td>
<td>0.60 [-3.65, 4.85]</td>
</tr>
<tr>
<td>1984 Walsh et al</td>
<td>10</td>
<td>10</td>
<td>1.50%</td>
<td>-3.18 [-4.51, -1.85]</td>
</tr>
<tr>
<td>1991 Bremer et al</td>
<td>12</td>
<td>12</td>
<td>0.20%</td>
<td>0.30 [-3.78, 4.38]</td>
</tr>
<tr>
<td>2002 Davy et al</td>
<td>18</td>
<td>18</td>
<td>0.10%</td>
<td>0.20 [-1.20, -1.00]</td>
</tr>
<tr>
<td>2005 Robitaille et al</td>
<td>14</td>
<td>14</td>
<td>0.20%</td>
<td>0.60 [-3.65, 4.85]</td>
</tr>
<tr>
<td>2007 Wood et al</td>
<td>10</td>
<td>10</td>
<td>1.50%</td>
<td>-3.18 [-4.51, -1.85]</td>
</tr>
<tr>
<td>2010 Cicero et al</td>
<td>12</td>
<td>12</td>
<td>0.20%</td>
<td>0.30 [-3.78, 4.38]</td>
</tr>
<tr>
<td>2010 Cicero et al</td>
<td>18</td>
<td>18</td>
<td>0.10%</td>
<td>0.20 [-1.20, -1.00]</td>
</tr>
</tbody>
</table>

**Subtotal (95% CI)**

44.30% [-0.66, -0.34]

**Heterogeneity:** Tau² = 0.19; Chi² = 117.38, df = 20 (P < 0.00001); I² = 83%

**Test for overall effect:** Z = 4.00 (P < 0.0001)

## Elevated CVD risk (T2DM/MetS)

<table>
<thead>
<tr>
<th>Subgroup and Study, Year (Reference)</th>
<th>VF (n)</th>
<th>Contol (n)</th>
<th>Weight (%)</th>
<th>Mean Difference (95% CI) in Body weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980 Tuomilehto et al</td>
<td>21</td>
<td>21</td>
<td>1.60%</td>
<td>-1.20 [-2.51, 0.11]</td>
</tr>
<tr>
<td>1987 Peterson et al</td>
<td>16</td>
<td>16</td>
<td>0.20%</td>
<td>-0.20 [-1.49, 1.09]</td>
</tr>
<tr>
<td>1987 Peterson et al</td>
<td>16</td>
<td>16</td>
<td>1.40%</td>
<td>-0.50 [-1.87, 0.87]</td>
</tr>
<tr>
<td>1988 Anderson et al</td>
<td>15</td>
<td>14</td>
<td>0.10%</td>
<td>-0.70 [-7.36, 5.96]</td>
</tr>
<tr>
<td>1988 Ebeling et al</td>
<td>12</td>
<td>9</td>
<td>0.50%</td>
<td>0.11 [-2.50, 2.72]</td>
</tr>
<tr>
<td>1989 Bell et al</td>
<td>40</td>
<td>35</td>
<td>5.30%</td>
<td>-0.26 [-0.73, 0.21]</td>
</tr>
<tr>
<td>1990 Kestin et al</td>
<td>24</td>
<td>24</td>
<td>0.40%</td>
<td>-0.30 [-3.08, 2.48]</td>
</tr>
<tr>
<td>1990 Lajam et al</td>
<td>39</td>
<td>39</td>
<td>0.10%</td>
<td>0.00 [-5.70, 5.70]</td>
</tr>
<tr>
<td>1990 Neal et al</td>
<td>27</td>
<td>27</td>
<td>2.10%</td>
<td>0.50 [-0.60, 1.60]</td>
</tr>
<tr>
<td>1990 Uusitupa et al</td>
<td>9</td>
<td>9</td>
<td>0.00%</td>
<td>-0.80 [-11.19, 9.59]</td>
</tr>
<tr>
<td>1991 McIntosh et al</td>
<td>21</td>
<td>21</td>
<td>0.20%</td>
<td>0.00 [-3.94, 3.94]</td>
</tr>
<tr>
<td>1994 Braeten et al</td>
<td>19</td>
<td>19</td>
<td>2.10%</td>
<td>0.10 [-0.98, 1.18]</td>
</tr>
<tr>
<td>1994 Lupton et al</td>
<td>26</td>
<td>27</td>
<td>0.10%</td>
<td>-0.50 [-6.32, 5.32]</td>
</tr>
<tr>
<td>1996 Noakes et al</td>
<td>23</td>
<td>23</td>
<td>0.10%</td>
<td>0.00 [-5.00, 4.80]</td>
</tr>
<tr>
<td>1998 Romero et al</td>
<td>10</td>
<td>10</td>
<td>1.00%</td>
<td>1.10 [-6.58, 8.78]</td>
</tr>
<tr>
<td>1998 Romero et al</td>
<td>10</td>
<td>10</td>
<td>0.10%</td>
<td>-1.00 [-6.70, 8.70]</td>
</tr>
<tr>
<td>1999 Onnin et al</td>
<td>52</td>
<td>52</td>
<td>6.60%</td>
<td>0.00 [-0.31, 0.31]</td>
</tr>
<tr>
<td>2003 Chen et al</td>
<td>22</td>
<td>22</td>
<td>0.20%</td>
<td>0.70 [-3.08, 2.48]</td>
</tr>
<tr>
<td>2004 He et al</td>
<td>54</td>
<td>56</td>
<td>3.00%</td>
<td>0.00 [-0.70, -1.54]</td>
</tr>
<tr>
<td>2007 Queenan et al</td>
<td>35</td>
<td>40</td>
<td>0.80%</td>
<td>0.00 [-0.70, -1.54]</td>
</tr>
<tr>
<td>2012 Zhang et al</td>
<td>85</td>
<td>81</td>
<td>4.30%</td>
<td>0.00 [-0.70, -1.54]</td>
</tr>
<tr>
<td>2013 Dall’Alba et al</td>
<td>23</td>
<td>21</td>
<td>0.10%</td>
<td>-0.50 [-5.44, 6.44]</td>
</tr>
<tr>
<td>2013 Ma et al</td>
<td>62</td>
<td>57</td>
<td>0.30%</td>
<td>0.07 [-3.38, 3.52]</td>
</tr>
<tr>
<td>2013 Ma et al</td>
<td>36</td>
<td>37</td>
<td>0.30%</td>
<td>0.00 [-2.29, 2.98]</td>
</tr>
<tr>
<td>2013 Thongoun et al</td>
<td>24</td>
<td>24</td>
<td>0.10%</td>
<td>0.00 [-2.29, 2.98]</td>
</tr>
<tr>
<td>2016 Abutair et al</td>
<td>18</td>
<td>18</td>
<td>0.10%</td>
<td>0.30 [-3.73, 3.13]</td>
</tr>
<tr>
<td>2016 De souza et al</td>
<td>66</td>
<td>66</td>
<td>2.10%</td>
<td>0.10 [-3.70, 0.72]</td>
</tr>
<tr>
<td>2017 Giulati et al</td>
<td>36</td>
<td>33</td>
<td>0.30%</td>
<td>0.00 [-3.73, 3.13]</td>
</tr>
<tr>
<td>2017 Tassari et al</td>
<td>11</td>
<td>11</td>
<td>2.10%</td>
<td>0.10 [-3.70, 0.72]</td>
</tr>
<tr>
<td>2018 Soltanian et al</td>
<td>24</td>
<td>27</td>
<td>0.10%</td>
<td>-0.20 [-2.00, -0.00]</td>
</tr>
</tbody>
</table>

**Subtotal (95% CI)**

28.70% [-0.19, -0.42, 0.03]

**Heterogeneity:** Tau² = 0.00; Chi² = 16.79, df = 29 (P = 0.00001); I² = 83%

**Test for overall effect:** Z = 3.00 (P = 0.00001)
Figure 4.2. Shows the effect of viscous fiber supplements on body weight. Diamonds represent the pooled effect estimates for overall and stratified analyses. Data are represented as MD with 95% CI, using the generic inverse variance random effects models. Inter-study heterogeneity quantified by $I^2$ with significance $P < 0.10$. N = number of participants in each intervention group. VF, viscous fibre.
<table>
<thead>
<tr>
<th>Subgroup and Study, Year (Reference)</th>
<th>VF (n)</th>
<th>Contol (n)</th>
<th>Weight (%)</th>
<th>Mean Difference (95% CI) in BMI (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2.1 Overweight/obese</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002 Davy et al</td>
<td>18</td>
<td>18</td>
<td>0.70%</td>
<td>-0.10 [-1.67, 1.47]</td>
</tr>
<tr>
<td>2005 Robitaille et al</td>
<td>18</td>
<td>16</td>
<td>6.60%</td>
<td>0.11 [0.05, 0.17]</td>
</tr>
<tr>
<td>2011 Pal et al</td>
<td>16</td>
<td>15</td>
<td>4.60%</td>
<td>-0.67 [-1.04, -0.30]</td>
</tr>
<tr>
<td>2011 Pal et al</td>
<td>14</td>
<td>12</td>
<td>5.20%</td>
<td>-0.15 [-0.44, 0.14]</td>
</tr>
<tr>
<td>2012 Lu et al</td>
<td>29</td>
<td>25</td>
<td>1.10%</td>
<td>-0.30 [-1.55, 0.95]</td>
</tr>
<tr>
<td>2013 Chang et al</td>
<td>16</td>
<td>18</td>
<td>4.90%</td>
<td>-0.96 [-1.29, -0.63]</td>
</tr>
<tr>
<td>2013 Reimer et al</td>
<td>32</td>
<td>32</td>
<td>5.90%</td>
<td>-0.14 [-0.34, 0.06]</td>
</tr>
<tr>
<td>2016 Pal et al</td>
<td>26</td>
<td>32</td>
<td>3.90%</td>
<td>-0.93 [-1.40, -0.46]</td>
</tr>
<tr>
<td>2016 Pal et al</td>
<td>36</td>
<td>32</td>
<td>3.00%</td>
<td>-0.52 [-1.13, 0.09]</td>
</tr>
<tr>
<td>2017 Aoe et al</td>
<td>50</td>
<td>48</td>
<td>2.10%</td>
<td>-0.40 [-1.20, 0.40]</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td>38.00%</td>
<td>-0.41 [-0.72, -0.11]</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Heterogeneity: Tau² = 0.16; Chi² = 79.29, df = 9 (P &lt; 0.00001); I² = 89%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 2.69 (P = 0.007)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2.2 Elevated CVD risk (T2DM/MetS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1992 Uusitupa et al</td>
<td>20</td>
<td>16</td>
<td>0.90%</td>
<td>0.10 [-1.27, 1.47]</td>
</tr>
<tr>
<td>1998 Romero et al</td>
<td>10</td>
<td>10</td>
<td>0.60%</td>
<td>0.40 [-1.40, 2.20]</td>
</tr>
<tr>
<td>1998 Romero et al</td>
<td>10</td>
<td>10</td>
<td>0.50%</td>
<td>0.60 [-1.36, 2.56]</td>
</tr>
<tr>
<td>2000 Lovegrove et al</td>
<td>31</td>
<td>31</td>
<td>0.50%</td>
<td>0.80 [-1.20, 2.80]</td>
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<tr>
<td>2005 Biörklund et al</td>
<td>19</td>
<td>20</td>
<td>0.70%</td>
<td>0.00 [-1.57, 1.57]</td>
</tr>
<tr>
<td>2005 Biörklund et al</td>
<td>15</td>
<td>20</td>
<td>5.90%</td>
<td>0.10 [-0.10, 0.30]</td>
</tr>
<tr>
<td>2005 Biörklund et al</td>
<td>19</td>
<td>20</td>
<td>0.60%</td>
<td>0.10 [-1.66, 1.86]</td>
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<td>2005 Biörklund et al</td>
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<td>5.90%</td>
<td>0.10 [-0.10, 0.30]</td>
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<td>45</td>
<td>45</td>
<td>4.40%</td>
<td>-0.90 [-1.29, -0.51]</td>
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<tr>
<td>2007 Cicero et al</td>
<td>45</td>
<td>45</td>
<td>4.60%</td>
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<tr>
<td>2008 Shimizu et al</td>
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<td>1.20%</td>
<td>-0.30 [-1.48, 0.88]</td>
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<td>24</td>
<td>24</td>
<td>0.40%</td>
<td>-0.09 [-2.40, 2.22]</td>
</tr>
<tr>
<td>2016 Abutair et al</td>
<td>18</td>
<td>18</td>
<td>1.10%</td>
<td>-1.20 [-2.47, 0.07]</td>
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<tr>
<td>2016 Connolly et al</td>
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<td>30</td>
<td>0.50%</td>
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<td>2016 De souza et al</td>
<td>66</td>
<td>66</td>
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<tr>
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<td>-0.10 [-1.35, 1.15]</td>
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<td>2018 Soltanian et al</td>
<td>24</td>
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<tr>
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<td>43.40%</td>
<td>-0.28 [-0.58, 0.03]</td>
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<td>Heterogeneity: Tau² = 0.23; Chi² = 98.43, df = 20 (P &lt; 0.00001); I² = 80%</td>
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<td>Test for overall effect: Z = 1.79 (P = 0.07)</td>
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<td>1.2.3 Normal weight</td>
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<tr>
<td>1994 Abrahamsson et al</td>
<td>24</td>
<td>24</td>
<td>2.40%</td>
<td>0.00 [-0.74, 0.74]</td>
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<td>1998 Romero et al</td>
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<td>0.30 [-1.48, 2.08]</td>
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<td>1998 Romero et al</td>
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<td>2005 Katz et al</td>
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<td>2017 Solah et al</td>
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<td>0.14 [-0.04, 0.32]</td>
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<tr>
<td>2017 Solah et al</td>
<td>19</td>
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<td>Subtotal (95% CI)</td>
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<td>18.50%</td>
<td>-0.02 [-0.23, 0.19]</td>
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<td>Heterogeneity: Tau² = 0.02; Chi² = 12.61, df = 7 (P = 0.08); I² = 45%</td>
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<td>Test for overall effect: Z = 0.21 (P = 0.83)</td>
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<tr>
<td>Total (95% CI)</td>
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<td></td>
<td>100.00%</td>
<td>-0.28 [-0.42, -0.14]</td>
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<td>Heterogeneity: Tau² = 0.08; Chi² = 213.47, df = 38 (P &lt; 0.00001); I² = 82%</td>
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<td>Test for overall effect: Z = 3.85 (P = 0.0001)</td>
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<tr>
<td>Test for subgroup differences: Chi² = 4.91, df = 2 (P = 0.09), I² = 59.2%</td>
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</table>
Figure 4.3. Shows the effect of viscous fiber supplements on BMI. Diamonds represent the pooled effect estimates for overall and stratified analyses. Data are represented as MD with 95% CI, using the generic inverse variance random effects models. Inter-study heterogeneity quantified by I² with significance P < 0.10. N = number of participants in each intervention group. VF, viscous fibre.
**Figure 4.4.** Shows the effect of viscous fiber supplements on Waist circumference. Diamonds represent the pooled effect estimates for overall and stratified analyses. Data are represented as MD with 95% CI, using the generic inverse variance random effects models. Inter-study heterogeneity quantified by $I^2$ with significance $P < 0.10$. N = number of participants in each intervention group. VF, viscous fibre.

<table>
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<tr>
<th>Subgroup and Study, Year (Reference)</th>
<th>VFS (n)</th>
<th>Control (n)</th>
<th>Weight (%)</th>
<th>Mean Difference (95% CI) in Body fat percentage (%)</th>
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<tr>
<td>1.4.1 Overweight/obese</td>
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<td>2007 Wood et al</td>
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<td>15.40%</td>
<td>0.50 [-0.85, 1.85]</td>
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<td>2011 Pal et al</td>
<td>16</td>
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<td>21.20%</td>
<td>-2.19 [-3.05, -1.33]</td>
</tr>
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<td>2011 Pal et al</td>
<td>14</td>
<td>12</td>
<td>19.40%</td>
<td>-1.08 [-2.08, -0.08]</td>
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<td>2012 Lu et al</td>
<td>29</td>
<td>25</td>
<td>6.70%</td>
<td>-0.30 [-2.93, 2.33]</td>
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<td>2013 Chang et al</td>
<td>16</td>
<td>18</td>
<td>5.80%</td>
<td>-1.32 [-4.20, 1.56]</td>
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<tr>
<td>2016 Pal et al</td>
<td>26</td>
<td>32</td>
<td>1.10%</td>
<td>-2.92 [-10.19, 4.35]</td>
</tr>
<tr>
<td>2016 Pal et al</td>
<td>36</td>
<td>32</td>
<td>1.70%</td>
<td>-1.95 [-7.77, 3.87]</td>
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<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>71.30%</strong></td>
<td><strong>-1.05 [-2.03, -0.07]</strong></td>
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</table>

Subgroup and Study, Year (Reference) | VFS (n) | Control (n) | Weight (%) | Mean Difference (95% CI) in Body fat percentage (%) |
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<td>1.4.2 Elevated cvd risk (T2DM/MetS)</td>
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<tr>
<td>2011 Soo-wan chea et al</td>
<td>40</td>
<td>39</td>
<td>14.90%</td>
<td>0.00 [-1.39, 1.39]</td>
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<tr>
<td>2013 Thongoun et al</td>
<td>24</td>
<td>24</td>
<td>9.20%</td>
<td>0.00 [-2.12, 2.12]</td>
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<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>24.10%</strong></td>
<td><strong>0.00 [-1.16, 1.16]</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subgroup and Study, Year (Reference) | VFS (n) | Control (n) | Weight (%) | Mean Difference (95% CI) in Body fat percentage (%) |
<table>
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<td>1.4.3 Normal weight</td>
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<td>2012 De bock et al</td>
<td>45</td>
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<td>4.60%</td>
<td>-0.40 [-3.73, 2.93]</td>
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<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>4.60%</strong></td>
<td><strong>-0.40 [-3.73, 2.93]</strong></td>
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</table>

Total (95% CI) | 100.00% | -0.78 [-1.56, 0.00] |

**Figure 4.5.** Shows the effect of viscous fiber supplements on Body fat percentage. Diamonds represent the pooled effect estimates for overall and stratified analyses. Data are represented as MD with 95% CI, using the generic inverse variance random effects models. Inter-study

Heterogeneity: Tau² = 0.69; Chi² = 11.87, df = 6 (P = 0.07); $I^2 = 49$

Test for overall effect: Z = 2.10 (P = 0.04)

1.4.2 Elevated cvd risk (T2DM/MetS)

2011 Soo-wan chea et al             | 40      | 39          | 14.90%     | 0.00 [-1.39, 1.39]                                  |
2013 Thongoun et al                 | 24      | 24          | 9.20%      | 0.00 [-2.12, 2.12]                                 |
Subtotal (95% CI)                   | 24.10%  | 0.00 [-1.16, 1.16] |

Heterogeneity: Tau² = 0.00; Chi² = 0.00, df = 1 (P = 1.00); $I^2 = 0$

Test for overall effect: Z = 0.00 (P = 1.00)

1.4.3 Normal weight

2012 De bock et al                  | 45      | 45          | 4.60%      | -0.40 [-3.73, 2.93]                                 |
Subtotal (95% CI)                   | 4.60%   | -0.40 [-3.73, 2.93] |

Heterogeneity: Not applicable

Test for overall effect: Z = 0.24 (P = 0.81)

Total (95% CI)                      | 100.00% | -0.78 [-1.56, 0.00] |

Heterogeneity: Tau² = 0.55; Chi² = 15.72, df = 9 (P = 0.07); $I^2 = 43$

Test for overall effect: Z = 1.96 (P = 0.05)

Test for subgroup differences: Chi² = 1.85, df = 2 (P = 0.40), $I^2 = 0$

Test for overall effect: Z = 1.96 (P = 0.05)

Test for subgroup differences: Chi² = 1.85, df = 2 (P = 0.40), $I^2 = 0$
heterogeneity quantified by $I^2$ with significance $P < 0.10$. $N =$ number of participants in each intervention group. VF, viscous fibre.

**Figure 4.7.** Publication bias funnel plots assessing publication bias and effect of small and/or imprecise study effects for (a) Body weight, (b) BMI, (c) Waist circumference, and (d) Body fat percentage. The horizontal line represents the pooled effect estimate expressed as the mean difference for each analysis. Diagonal lines represent the pseudo-95% CI. P-values are derived from quantitative assessment of publication bias by Egger and Begg tests.
Figure 4.8. Trim and Fill funnel plot evaluating publication bias and effect of small study effects in randomized controlled trials investigating the effect of viscous fibre supplementation on (A) Body weight, (B) BMI. The horizontal line represents the pooled effect estimate expressed as MD, the diagonal lines represent the pseudo-95% CIs of the MD, the clear circles represent effect estimates for each included studies, and black squares represent imputed “missed” studies. Imputed MD, accounting for publication bias and p-values are provided where p < 0.10 is considered evidence of small-study effects.
Figure 4.9. Risk of Bias

Studies were rated “Low Risk of Bias” if the study design is unlikely to have little influence over the true outcome; “High Risk of Bias” if the design is likely to have an influential effect on the true outcome; “Unclear Risk of Bias” if insufficient information was given to assess risk.
### Table 4.2. GRADE Assessment

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<th>Certainty assessment</th>
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<td>serious a</td>
<td>not serious</td>
<td>serious b</td>
</tr>
<tr>
<td>BMI</td>
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<td>34 randomised trials</td>
<td>not serious</td>
<td>serious d</td>
</tr>
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<td><strong>Waist Circumference</strong></td>
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<td></td>
<td></td>
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<tr>
<td>23 randomised trials</td>
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<td>not serious</td>
<td>not serious</td>
<td>not serious</td>
</tr>
<tr>
<td><strong>Body Fat Percentage</strong></td>
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<td></td>
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</tr>
<tr>
<td>10 randomised trials</td>
<td>serious h</td>
<td>not serious</td>
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<td>not serious</td>
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</tbody>
</table>

CI: Confidence interval; MD: Mean difference

**Explanations**

a. Downgraded for serious inconsistency. Although the heterogeneity was partially explained by removing two studies; Change et al and Solah et al, (I²=58%, p<0.00001) (I²=65%, p<0.00001), respectively, and fibre differences. Evidence of substantial heterogeneity remained (I²=66%, p<0.00001).

b. Downgraded for imprecision. The upper bond of the 95% CI (-0.51) overlapped the minimally important difference of 0.5 kg.

c. No downgrade for publication bias. Although visualization of funnel plot and Egger and Begg test suggest evidence of publication bias, Trim and Fill analysis imputed 0 studies and the adjusted mean difference did not change.

d. Downgraded for serious inconsistency. Although the heterogeneity was partially explained by removing two studies; Ceciro et al and Robitaille et al, (I²=74%, p<0.00001) (I²=76%, p<0.00001), respectively, and fibre differences. Evidence of substantial heterogeneity remained (I²=82%, p<0.00001)

e. Downgraded for imprecision. The lower bond of the 95%CI (-0.42) does not meet the minimally important difference of 0.2 kg/m2.

f. Downgraded for Risk of Bias. The majority of studies have moderate risk of bias and the two largest weighted studies have a high risk of bias.

g. No downgrade for inconsistency. The heterogeneity was explained by Solah et al. After removing the study, no evidence of substantial heterogeneity remained (I²=35%, p<0.00001).

h. Downgraded for Risk of Bias. The majority of studies have moderate risk of bias and the two largest weighted studies have a high risk of bias.

i. No downgrade for indirectness. Although there is only one study in the healthy group, study results can still be generalized.
Supplementary Material
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**Supplementary Table 4.1.** Search Strategy. For all databases, searches were performed through April 2016 and updated August 16, 2018.
### Inclusion Criteria

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<td>1</td>
<td>Randomized controlled clinical trial with either a parallel or cross-over design</td>
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<td>2</td>
<td>Treatment period of 4 weeks or more</td>
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<td>3</td>
<td>Adults or adolescent either healthy, overweight and obese individuals or individuals with diabetes and cardiovascular disease (CVD), were all acceptable</td>
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<td>4</td>
<td>Have one of the selected viscous fibre, (Agar, Alginate, B-glucan from oat or barley, Guar gum, Konjac, Pectin, Psyllium, or PGX), as a supplemented treatment</td>
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<td>5</td>
<td>Appropriately controlled</td>
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<td>6</td>
<td>Measure one of outcomes: body weight, BMI, waist circumference, or Body fat percentage. These anthropometry measures can be either primary or secondary outcomes</td>
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<td>7</td>
<td>Enough information provided to calculate the magnitude of effect, i.e. end of treatment measures and/or change from baseline measures</td>
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<td>8</td>
<td>Background diet is ad-libitum diet meaning that participant’s diet have no calorie restriction</td>
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### Exclusion Criteria

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<td>Soluble fibre was not one of the selected viscous fibre or a combination supplement where this fibres could not be isolated each one alone</td>
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<td>Study was insufficiently controlled, i.e. the control was another soluble fibre</td>
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<td>Outcome measures did not include body weight, BMI, waist circumference, or Body fat percentage</td>
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<td>Study protocol maintains baseline weight</td>
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<td>Secondary information such as reviews, editorials, commentaries, were excluded</td>
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<td>Diet is energy restricted diet</td>
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**Supplementary Table 4.2. Eligibility Criteria**
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Supplementary Table 4.3. Cochrane risk of bias tool
### A. Body Weight

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<th>N</th>
<th>β [95% CI]</th>
<th>Residual I² (%)</th>
<th>P-value</th>
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### B. BMI

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<th>Residual I² (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscous Fibre Dose (g/d)</td>
<td>39</td>
<td>2742</td>
<td>-0.040 [-0.083, 0.003]</td>
<td>76.84</td>
<td>0.066</td>
</tr>
<tr>
<td>Duration (wk)</td>
<td>39</td>
<td>2742</td>
<td>-0.016 [-0.032, -0.0002]</td>
<td>73.26</td>
<td>0.047</td>
</tr>
<tr>
<td>Baseline BMI (Kg/m²)</td>
<td>33</td>
<td>2384</td>
<td>-0.085 [-0.208, 0.038]</td>
<td>80.47</td>
<td>0.167</td>
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</table>

### C. Waist Circumference

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>No. of Trials</th>
<th>N</th>
<th>β [95% CI]</th>
<th>Residual I² (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscous Fibre Dose (g/d)</td>
<td>23</td>
<td>1727</td>
<td>0.055 [-0.014, 0.123]</td>
<td>63.63</td>
<td>0.112</td>
</tr>
<tr>
<td>Duration (wk)</td>
<td>23</td>
<td>1727</td>
<td>-0.025 [-0.113, 0.062]</td>
<td>62.65</td>
<td>0.552</td>
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<tr>
<td>Baseline Waist Circumference (Cm)</td>
<td>17</td>
<td>1369</td>
<td>0.019 [-0.071, 0.109]</td>
<td>26.73</td>
<td>0.663</td>
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</table>
### D. Body Fat Percentage

<table>
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<tr>
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<th>No. of Trials</th>
<th>N</th>
<th>β [95% CI]</th>
<th>Residual I² (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscous Fibre Dose (g/d)</td>
<td>10</td>
<td>509</td>
<td>-0.050 [-0.092, -0.010]</td>
<td>00.00</td>
<td>0.021</td>
</tr>
<tr>
<td>Duration (wk)</td>
<td>10</td>
<td>509</td>
<td>-0.047 [-0.174, 0.079]</td>
<td>45.52</td>
<td>0.412</td>
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<tr>
<td>Baseline Body Fat Percentage (%)</td>
<td>6</td>
<td>266</td>
<td>-0.015 [-0.44, 0.411]</td>
<td>00.00</td>
<td>0.925</td>
</tr>
</tbody>
</table>

**Supplementary Table 4.4.** Continuous *a priori* subgroup analyses. β is the slope derived from meta-regression analyses and represents the treatment effect of viscous fiber for each subgroup for A. Body weight, B. BMI C. Waist circumference, D. Body fat percentage. The residual I² value indicates heterogeneity unexplained by the subgroup and is reported as a percent value, where I² ≥ 50% indicated “substantial” heterogeneity. P-value significance for heterogeneity was set as P < 0.10. N = number of participants in each treatment group.
<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Level</th>
<th>No. of Trials</th>
<th>N</th>
<th>Within Subgroups</th>
<th>P-Value</th>
<th>Between Subgroups</th>
<th>Residual $I^2$ (%)</th>
<th>$P$-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td></td>
<td>61</td>
<td>3224</td>
<td></td>
<td></td>
<td></td>
<td>-0.32 [-0.51, -0.14]</td>
<td>65.00</td>
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<tr>
<td>Dose</td>
<td>&lt; 5.3</td>
<td>27</td>
<td>1447</td>
<td>-0.44 [-0.92, 0.03]</td>
<td>0.068</td>
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<td>-0.06 [-0.70, 0.58]</td>
<td>59.90</td>
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<tr>
<td></td>
<td>≥ 5.3</td>
<td>34</td>
<td>1777</td>
<td>-0.50 [-0.93, -0.08]</td>
<td>0.021</td>
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<tr>
<td>Duration</td>
<td>&lt; 8.0</td>
<td>29</td>
<td>1569</td>
<td>-0.08 [-0.49, 0.34]</td>
<td>0.713</td>
<td></td>
<td>-0.74 [-1.31, -0.17]</td>
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<tr>
<td></td>
<td>≥ 8.0</td>
<td>32</td>
<td>1655</td>
<td>-0.82 [-1.21, -0.42]</td>
<td>&lt; 0.001</td>
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<tr>
<td>Study Design</td>
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<td>-0.09 [-0.72, 0.54]</td>
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<td>&lt; 78.6</td>
<td>27</td>
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<td>-0.38 [-0.85, 0.09]</td>
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<td>-0.12 [-0.84, 0.59]</td>
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<td>Viscous Fibres (1)</td>
<td>B-glucan</td>
<td>26</td>
<td>1740</td>
<td>-0.32 [-0.80, 0.16]</td>
<td>0.189</td>
<td>1 vs 2</td>
<td>-0.58 [-1.51, 0.36]</td>
<td>57.07</td>
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<tr>
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<td>Psyllium</td>
<td>13</td>
<td>658</td>
<td>-0.89 [-1.70, -0.09]</td>
<td>0.029</td>
<td>1 vs 3</td>
<td>-0.05 [-1.05, 0.95]</td>
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<tr>
<td></td>
<td>Guar Gum</td>
<td>11</td>
<td>313</td>
<td>-0.37 [-1.25, 0.51]</td>
<td>0.407</td>
<td>1 vs 4</td>
<td>-0.10 [-1.07, 0.87]</td>
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<td>1 vs 5</td>
<td>-0.45 [-1.56, 0.65]</td>
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<td>3 vs 4</td>
<td>0.05 [-1.17, 1.27]</td>
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<td>4 vs 5</td>
<td>0.36 [-0.95, 1.66]</td>
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<td>19</td>
<td>906</td>
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<td>0.001</td>
<td>1 vs 3</td>
<td>-0.24 [-1.10, 0.62]</td>
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<td>0.280</td>
<td>2 vs 3</td>
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<td>P-Value</td>
<td>Between Subgroups</td>
<td>Residual I^2 (%)</td>
<td>P-Value</td>
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<td>1313</td>
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<td>&lt; 0.001</td>
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<td>Duration &lt; 8.0</td>
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<td>1382</td>
<td>0.01 [-0.29, 0.30]</td>
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<td>-0.45 [-0.82, -0.07]</td>
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<tr>
<td>Baseline BMI</td>
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<td>1.000</td>
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<td>-0.25 [-2.14, 1.65]</td>
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<tr>
<td></td>
<td>≥ 26.72</td>
<td>18</td>
<td>1089</td>
<td>-0.25 [-0.49, -0.00]</td>
<td>0.048</td>
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<tr>
<td>Viscous Fibres</td>
<td>(1) B-glucan</td>
<td>24</td>
<td>1866</td>
<td>-0.09 [-0.30, 0.12]</td>
<td>0.390</td>
<td>1 vs 2</td>
<td>-0.42 [-0.80, -0.03]</td>
<td>59.67</td>
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<tr>
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<td>(2) Psyllium</td>
<td>10</td>
<td>514</td>
<td>-0.51 [-0.83, -0.18]</td>
<td>0.003</td>
<td>1 vs 3</td>
<td>-0.12 [-0.50, 0.26]</td>
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<tr>
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<td>(3) PGX</td>
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<td>272</td>
<td>-0.21 [-0.53, 0.10]</td>
<td>0.180</td>
<td>1 vs 4</td>
<td>-1.61 [-2.34, -0.88]</td>
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<tr>
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<td>(4) Guar Gum</td>
<td>1</td>
<td>90</td>
<td>-1.7 [-2.40, -1.00]</td>
<td>0.000</td>
<td>2 vs 3</td>
<td>-0.29 [-0.75, 0.16]</td>
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<td></td>
<td></td>
<td></td>
<td>2 vs 4</td>
<td>1.19 [0.42, 1.96]</td>
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<tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>3 vs 4</td>
<td>1.49 [0.72, 2.25]</td>
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<tr>
<td>Matrix</td>
<td>(1) Pre-mixed Food</td>
<td>25</td>
<td>1824</td>
<td>-0.18 [-0.44, 0.09]</td>
<td>0.190</td>
<td>1 vs 2</td>
<td>-0.26 [-0.68, 0.16]</td>
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<tr>
<td></td>
<td>(2) Sachet</td>
<td>11</td>
<td>716</td>
<td>-0.44 [-0.76, -0.11]</td>
<td>0.010</td>
<td>1 vs 3</td>
<td>-0.007 [-0.78, 0.76]</td>
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<tr>
<td></td>
<td>(3) Capsule</td>
<td>3</td>
<td>163</td>
<td>-0.18 [-0.90, 0.54]</td>
<td>0.612</td>
<td>2 vs 3</td>
<td>0.25 [-0.54, 1.04]</td>
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</tr>
</tbody>
</table>

**Supplemental Table 4.6 Categorical *a priori* subgroup analyses for BMI.** The residuals I^2 value indicates heterogeneity unexplained by the subgroup. Between subgroup differences represent differences between Viscous Fibres and control group. Within subgroup differences represent the difference between end and baseline values. N = number of participants in each treatment group; PGX = PolyGlycopleX®.
<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Level</th>
<th>No. of Trials</th>
<th>N</th>
<th>Within Subgroups</th>
<th>P-Value</th>
<th>Between Subgroups</th>
<th>Residual I² (%)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td></td>
<td>23</td>
<td>1727</td>
<td></td>
<td></td>
<td></td>
<td>-0.63 [-1.11, -0.16]</td>
<td>62.00</td>
</tr>
<tr>
<td>Dose (g/d)</td>
<td>&lt; 5.0</td>
<td>9</td>
<td>848</td>
<td>-1.07 [-1.99, -0.14]</td>
<td>0.026</td>
<td>0.85 [-0.39, 2.08]</td>
<td>63.61</td>
<td>0.169</td>
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<tr>
<td></td>
<td>≥ 5.0</td>
<td>14</td>
<td>879</td>
<td>-0.22 [-1.04, 0.60]</td>
<td>0.584</td>
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<tr>
<td>Duration (wk)</td>
<td>&lt; 12.0</td>
<td>8</td>
<td>859</td>
<td>-0.98 [-2.03, 0.07]</td>
<td>0.066</td>
<td>0.60 [-0.71, 1.90]</td>
<td>63.51</td>
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<tr>
<td></td>
<td>≥ 12.0</td>
<td>15</td>
<td>868</td>
<td>-0.38 [-1.15, 0.39]</td>
<td>0.320</td>
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<td>Study Design</td>
<td>Crossover</td>
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<td>0.083</td>
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<tr>
<td>Baseline WC (Cm)</td>
<td>&lt; 98.0</td>
<td>8</td>
<td>882</td>
<td>-1.06 [-1.70, -0.42]</td>
<td>0.003</td>
<td>0.28 [-0.96, 1.53]</td>
<td>29.08</td>
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<tr>
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<td>487</td>
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<td>Viscous Fibres</td>
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<tr>
<td></td>
<td>(1) B-glucan</td>
<td>8</td>
<td>913</td>
<td>-0.80 [-1.88, 0.29]</td>
<td>0.141</td>
<td>1 vs 2 0.53 [-1.51, 2.56]</td>
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<td>278</td>
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<td>0.746</td>
<td>1 vs 3 -1.00 [-3.45, 1.46]</td>
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<tr>
<td></td>
<td>(3) Guar Gum</td>
<td>3</td>
<td>175</td>
<td>-0.79 [-4.00, 0.41]</td>
<td>0.104</td>
<td>1 vs 4 -0.55 [-1.01, 2.11]</td>
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<td>(4) PGX</td>
<td>6</td>
<td>331</td>
<td>-0.25 [-1.36, 0.87]</td>
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<td>(5) Konjac</td>
<td>1</td>
<td>30</td>
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<td>1.000</td>
<td>2 vs 3 1.52 [-1.27, 4.32]</td>
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<td>2 vs 4 -0.02 [-2.08, 2.03]</td>
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<td>3 vs 4 -1.55 [-4.02, 0.92]</td>
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<td>3 vs 5 -1.79 [-5.54, 1.95]</td>
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<td>4 vs 5 -0.25 [-3.47, 2.98]</td>
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<td>12</td>
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<td>-0.90 [-2.10, 0.30]</td>
<td>0.134</td>
<td>1 vs 3 0.30 [-1.48, 2.08]</td>
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<td></td>
<td>(3) Capsule</td>
<td>4</td>
<td>153</td>
<td>-0.22 [-1.72, 1.29]</td>
<td>0.767</td>
<td>2 vs 3 0.68 [-1.22, 2.61]</td>
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**Supplemental Table 4.7 Categorical a priori subgroup analyses for Waist Circumference.** The residuals I² value indicates heterogeneity unexplained by the subgroup. Between subgroup differences represent differences between Viscous Fibres and control group. Within subgroup differences represent the difference between end and baseline values. N = number of participants in each treatment group; PGX = PolyGlycopleX®.
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<th>N</th>
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<th>Between Subgroups I^2 (%)</th>
<th>Residual I^2 (%)</th>
<th>P-Value</th>
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<tr>
<td>Total</td>
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<td>509</td>
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<td>-0.78 [-1.56, -0.00]</td>
<td>-1.60 [-2.99, -0.21]</td>
<td>43.00</td>
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<td>167</td>
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<td>6</td>
<td>342</td>
<td>-1.54 [-2.41, -0.67]</td>
<td>0.004</td>
<td>-0.78 [-1.56, -0.00]</td>
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<tr>
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<td>123</td>
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<tr>
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<td>386</td>
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<td>69</td>
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<td>-0.73 [-3.49, 2.03]</td>
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<td>45</td>
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<td>0.826</td>
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<td></td>
<td>≥ 78.6</td>
<td>5</td>
<td>221</td>
<td>0.05 [-1.09, 1.18]</td>
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<td>(1) Psyllium</td>
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<td>(2) B-glucan</td>
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<td>(4) PGX</td>
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**Supplemental Table 4.8 Categorical a priori subgroup analyses for Body Fat Percentage.** The residuals I^2 value indicates heterogeneity unexplained by the subgroup. Between subgroup differences represent differences between Viscous Fibres and control group. Within subgroup differences represent the difference between end and baseline values. N = number of participants in each treatment group; PGX= PolyGlycopleX®.
Supplementary figure 4.2 (A1 & A2). Linear and non-linear VF dose-response analyses on Body weight.

Supplementary figure 4.2 (B1 & B2). Linear and non-linear VF dose-response analyses on BMI.
Supplementary figure 4.2 (C1 & C2). Linear and non-linear VF dose-response analyses on Waist circumference.

Supplementary figure 4.2 (D). Linear VFS dose-response analyses on Body fat percentage. Non-linear dose was not applicable.
### Viscous Fiber & Weight Loss Meta-Analysis Proforma

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<td>Psyllium</td>
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### The Cochrane Collaboration Tool for Assessing Risk of Bias:

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- **Sequence Generation**
- **Allocation Concealment**
- **Blinding of participants, personnel and outcome assessors**
- **Incomplete outcome data**
- **Selective outcome reporting**

69
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### Table 4.9 PROFORMA-sheet

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<th>Intervention 3 (within treatment)</th>
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<td>End Values</td>
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<th>Intervention 2 vs. Intervention 4 (between treatment)</th>
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<td>∆ End Values</td>
<td>P-Values</td>
<td>∆ Change Values</td>
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Results: (Expressed as means ± SD (SD = SEM x √n))

**Weight:** kg X 2.2 = lbs  **BMI:** [BMI] = kg/m²  **Height or Waist Circumference:** cm/0.39 = in
CHAPTER V – Effect of dietary viscous fibre supplementation on adiposity in individuals receiving calorie-restricted diets: A systematic review and meta-analysis of randomized controlled trials

Nourah Mazhar1,5, Rana Khayyat1,5, Hoang Vi Thanh Ho1, Allison Komishon1, Sonia Blanco Mejia2,5, Lucia Zurbau1,5, Elena Jovanovski1,5, John Sievenpiper1,2,3,5, Alexandra Jenkins1,5, and Vladimir Vuksan1,2,3,5

1Clinical Nutrition and Risk Factor Modification Centre, St. Michael’s Hospital, 193 Yonge Street, Toronto, ON, Canada
2Li Ka Shing Knowledge Institute, St. Michael’s Hospital, 30 Bond Street, Toronto, ON, Canada, M5B 1W8
3Division of Endocrinology & Medicine, St. Michael’s Hospital, 30 Bond Street, Toronto, ON, Canada, M5B 1W8
4Toronto 3D Knowledge Synthesis and Clinical Trials Unit, St. Michael’s Hospital, Toronto, ON, Canada, M5B 1W8
5Department of Nutritional Sciences, Faculty of Medicine, University of Toronto, 27 King’s Circle, Toronto, ON, Canada, M5S 1A1

Abstract:

Background: Obesity is worldwide pandemic. Potentially, viscous fibres have positive effect.

Objective: To quantify the effects of dietary viscous soluble fibre on adiposity parameters in a calorie deficit diet, through systematic review and meta-analysis.

Methods: Three databases searched through 16-08-2018 for randomized controlled trials (RCT)s assessing the effect of viscous fibre supplementation with restricted-caloric diet of 4 weeks on adiposity. Analysis using random-effects models. (GRADE) approach used to evaluate the evidence’s certainty.
**Results:** 15 studies (n= 1313) showed that a median dose of 6g/d (range: 0.5–15) of viscous fibre supplementation with a calorie-restricted diet for a median duration of 12 weeks (range: 4-48), significantly decreased body weight (-0.81 kg [-1.20, -0.41]), BMI (-0.25 kg/m2 [-0.46, -0.05]), and body fat percentage (-1.39% [-2.61, -0.17]). No effect on waist circumference found. The certainty of the evidence graded “moderate” to “low” for downgrades of inconsistency and imprecision.

**Significance:** This analysis may help guide recommendations in weight management.
Introduction

Approximately 650 million individuals worldwide are obese (World Health Organization) (1). Modern obesity management strategies involve diet as a key factor to facilitate weight loss. Even a modest amount of weight loss such as 5-10% of initial body weight has been shown to greatly improve health outcomes and morbidity (3, 4). Numerous studies have examined the effects of macronutrients on obesity, on energy intake, but studies assessing the role of dietary fibre on this process are more limited (160). Increased fibre intake has been suggested as a strong predictors for weight loss, possibly through its viscous properties (142, 144). Evidence suggests that high viscosity of the gastric chyme improves cholesterol level, regulates glucose level in individuals with diabetes, and has positive impacts on the other lipoprotein profile, weight loss, and blood pressure (10). The recommendation for fibre intake according to The Institute of Medicine is 25 g/day for women and 38 g/day for men (adults aged 21–50). It is difficult however to achieve this recommended level of fibre within a typical Western diet and it is estimated that only 5% of the population meet current recommendations (145). Fibre supplements may help to achieve targets as they provide a more convenient and concentrated source of fibre (10, 58, 161, 162). We have previously shown through a systematic review and meta-analysis of RCTs that viscous fibre supplementation significantly improves body weight and additional markers of adiposity when taken in the context of a non-restrictive ad-libitum diet. It is unknown whether this effect would be different when taken with a more restricted caloric diet. Therefore, the objective of this study was to evaluate the effect of viscous fibre supplementation on body weight and additional anthropometric parameters when consumed along with a calorie deficit diet.
METHODS

Protocol and registration

The Cochrane handbook for systemic reviews of Interventions was utilized to conduct this meta-analysis (147). Results was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (148). The protocol for this study is available online at ClinicalTrials.gov (registration number: NCT03257449).

Search strategy and data sources

**Supplementary Table 4.1.** presents the search terms and strategy of this review. MEDLINE, EMBASE, and the Cochrane Library for Registered Controlled Trials were searched through August 16, 2018, to identify RCTs that assess the effect of viscous fibre supplementation with deficit caloric diet on body anthropometric measures (body weight, BMI, waist circumference, and body fat percentage). A manual search of included trials references was performed to enhance the electronic search.

Study eligibility

**Supplementary Table 4.2.** shows the study inclusion and exclusion criteria. We employed RCTs ≥ 4 weeks that investigate the effect of dietary viscous fibre supplementation, (agar, alginate, β-glucan, guar gum, konjac, PGX, psyllium, or xantham) consumed while on a calorie deficit diet, in comparison to a free fibre diet or placebo, on at least one of the outcomes: body weight, BMI, waist circumference, or body fat percentage. Trials that included viscous fibre supplementation in a dietary mixture or mixed with another intervention were excluded, as the effect of fibre could not be isolated. However, oat and barley were an exception, they were accepted as β-glucan
source. In the multi-arms trials, we selected groups that permitted us to assess the specific effect of viscous fibre supplements. Some studies yielded more than one comparison as the control group was compared to two fibre groups to get observations as much as possible. When multiples of the same publication were found, the newest publication was used.

**Data extraction and quality assessment**

Two reviewers (NM & RK) independently extracted data from eligible articles to a standardized proforma. A third impartial reviewer solved conflicts between reviewers. Extracted information included: fibre type (agar, alginate, β-glucan, guar gum, konjac, PGX, psyllium, or xantham), design (cross-over or parallel), participant characteristics (number, gender, BMI, age), comparator (placebo or diet), dose of viscous fibre (if the β-glucan content was not reported, it was estimated at 5% (149) of the oat dose reported), duration (four weeks or more), background diet, funding source (agency or industrial). Change from baseline mean and SEM for both control and intervention groups were extracted or calculated from the available reported data (95% CI, SEM, or mean and SD of the baseline and endpoint values) using a standardized formulae (147).

The Cochrane Risk of Bias (ROB) Tool (147) was used to assess the following domains: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), incomplete outcome data (attrition bias), selective reporting (reporting bias). Each domain was considered “Low risk of bias” when the true effect of the outcome is not likely to be affected, “Unclear risk of bias” when the study do not report enough information to permit judgment, and “High risk of bias” when the true effect of the outcome is likely affected. If necessary, authors of articles were contacted for additional information.

**Data management and analysis**
Review Manager (RevMan), version 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) was utilized for primary data analyses and STATA ver. 14 (StataCorp, College Station, USA) for subgroup analyses. Difference between changes from baseline values for control and fibre arms was calculated for every trial. A weighted average was used for multi-arm trials to create a single pair-wise the comparison and reduce the unit-of-analysis error. We assumed a conservative correlation coefficient of 0.50 for standard deviation of cross-over trials. The generic inverse variance method with random effects model was used to calculate a pooled analysis. Information was expressed as MD with 95% CI and P-value were considered significant at P< 0.05. Inter-study heterogeneity was assessed and quantified utilizing the Cochrane Q-statistic and $I^2$ with a significance P< 0.10. $I^2 \geq 50\%$ was considered evidence of substantial heterogeneity (147). To determine whether a single study exerted a specific influence on the overall results, sensitivity analysis was performed by removing every study from the analysis and re-calculating the pooled effect size of the remaining studies. Heterogeneity sources were investigated with a priori subgroup analyses (continuous and categorical) for baseline values of each outcome, dose, design, duration, fibre type, and food matrix with a significance level P< 0.05. Dose-response analysis was performed using meta-regressions to generate linear and non-linear dose estimates using the MKSPLINE procedure, with P< 0.05 significance. Publication bias was tested with visual inspection of funnel plots and tested in STATA using Egger’s and Begg’s tests, where evidence of small study effects was considered at P < 0.10. Trim and Fill tests were applied to correct for asymmetry when publication bias was suspected.

**GRADE of Recommendation Assessment, Development and Evaluation**
The Grading of Recommendations Assessment, Development and Evaluation (GRADE) (151) method was employed to evaluate the overall quality and certainty of the evidence. The grade of the evidence can be 'very low', 'low', 'moderate', or 'high'. RCTs start with high quality of evidence and may be downgraded based on the following domains:

- Risk of Bias (determined as of the same domains of the ROB taking in consideration the weight of studies )
- Inconsistency (determined through substantial heterogeneity, $I^2 > 50\%$)
- Indirectness (determined based on the indirectness of population, comparator, outcome, or comparison that might limits the generalizability of findings)
- Imprecision (determined by looking to the precision of the estimated effect through its width and if it cross the minimally important differences (MID))
- Publication bias (determined using the funnel plot as evidence of small-study effects).

RESULTS

Search results

The initial search yielded 8400 citations, of which 162 articles were reviewed in full and 15 articles were included in the final analyses (n= 1313) (Figure 5.1.). Body weight was reported in 13 articles, BMI in 11 articles, 4 reported waist circumference and 3 reported on body fat percentage.

Trials characteristics

Characteristics of the included trials are summarized in Table 5.1. All studies were conducted in out-patient setting: with 6 in Europe (1 UK; 1 Italy; 1 Norway; 1 Denmark;1 Poland; 1 Germany), 2 in North America (1 USA; 1 Mexico), 2 in Asia (1 Japan; 1 China; ) 1 in Australia, 3 in Middle
East (3 Iran), 1 in South America (Venezuela). The majority of trials (93%;14) of trials were conducted using a parallel design and 7% (1) using cross-over design. Participants are generally middle aged men and women, with a median age of 50 years (range: 32-64), and slightly overweight (median = 29 kg/m² (range: 26-34)). Approximately 47% (7) of studies had elevated cardiovascular disease (CVD), and 53% (8) were overweight/obese. Median treatment duration was 8 weeks (range: 4-48) with median dose of 6 g/d (range: 0.5 – 15). Funding source was not reported in 53% (8) of trials, agency in 33% (5), industry in 7% (1), and agency-industry in 7% (1).

According to the Cochrane Risk of Bias Tool 60% (9) of trials had unclear risk and 40% (6) low risk of bias for sequence generation. For allocation concealment, 87% (13) of trials had unclear risk, and 13% (2) low risk of bias. In 60% (9) of trials there was low risk for blinding, in 13.3% (2) high risk, and in 26.7% (4) unclear risk for blinding. Incomplete outcome reporting was low risk in 80% (12) of trials, high risk in 7% (1), and unclear risk in 13% (2). Moreover, data and selective reporting was low risk of bias in 93% (14) of trials and high risk of bias in 7% (1) of trials. **Supplementary Table 5.3.** shows the risk of bias for all domains.
Figure 5.1. Flow of Literature
Table 5.1. Characteristics of included studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Fibre</th>
<th>Participants</th>
<th>Age (y)*</th>
<th>BMI (kg/m²)*</th>
<th>Design, Duration</th>
<th>Blinding</th>
<th>Dose (g)</th>
<th>Comparator</th>
<th>Background Diet</th>
<th>Funding</th>
<th>Country</th>
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<tbody>
<tr>
<td>Akbarzadeh et al, 2015</td>
<td>Psyllium</td>
<td>75</td>
<td>46.1±17</td>
<td>29.4±3.4</td>
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<td>10.0</td>
<td>Wheat</td>
<td>Energy-deficient diet</td>
<td>Agency</td>
<td>Iran</td>
</tr>
<tr>
<td>Beattie et al, 1988</td>
<td>Guar Gum</td>
<td>24</td>
<td>64 †</td>
<td>30±5.2</td>
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<td>19-45</td>
<td>25-32 ‡</td>
<td>P, 12 wk</td>
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<td>0.48</td>
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<td>52±8</td>
<td>29.5±4.9</td>
<td>P, 8 wk</td>
<td>SB</td>
<td>7.0</td>
<td>Corn starch</td>
<td>Energy-deficient diet</td>
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<td>Iran</td>
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<tr>
<td>Jensen et al, 2012</td>
<td>Alginate</td>
<td>80 (25M:54F)</td>
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<td>&gt;30 ‡</td>
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<td>DB</td>
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<td>OL</td>
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<td>No Fibre</td>
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<td>Agency</td>
<td>United States</td>
</tr>
<tr>
<td>Moran et al, 1997</td>
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<td>36 (6M:30F)</td>
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<td>35±4.0</td>
<td>P, 8 wk</td>
<td>DB</td>
<td>15.0</td>
<td>Placebo (unspecified)</td>
<td>Energy-deficient diet</td>
<td>Agency-Industry</td>
<td>Mexico</td>
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<tr>
<td>Reyna-villasmil et al, 2007</td>
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<td>38M</td>
<td>59.8±1</td>
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<td>SB</td>
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<td>32.5±2</td>
<td>22.38±2.3</td>
<td>P, 12 wk</td>
<td>OL</td>
<td>0.5</td>
<td>No Fibre</td>
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<td>60F</td>
<td>51.1±9</td>
<td>28.9±3.5</td>
<td>P, 4 wk</td>
<td>OL</td>
<td>6.0</td>
<td>Wheat</td>
<td>Energy-deficient diet</td>
<td>NA</td>
<td>Iran</td>
</tr>
</tbody>
</table>

* mean ±SD reported unless otherwise indicated
† median value provided
‡ range provided
Effect on Body Weight

Figure 5.2. demonstrates the effect of viscous fibre supplementation with deficit caloric diet on body weight (kg). Overall, a significant reduction in body weight was observed (MD = -0.81 kg [95% CI: -1.20, -0.41], P< 0.0001) with a median dose of 5.3 g/d [range: 0.48 – 15] and median treatment duration of 12 weeks [range: 4 – 48]. Analysis was divided into three population groups based on health status (overweight and obese, elevated CVD risk, and healthy). Differences between groups was not significant (P= 0.73). Within population groups, significance was observed in overweight/obese individuals (MD= -0.74 kg [95% CI: -1.28, -0.21], P= 0.006) and those individuals with elevated CVD risk (MD = -0.89 kg [95% CI: -1.53, -0.25], P= 0.006). Substantial evidence of inter-study heterogeneity is present in the overall analysis (I²= 71%, P<0.00001). Removing two individual studies, systematically, explained some of the heterogeneity (99, 163). However, heterogeneity remained (I²= 24%, P<0.00001) and (I²= 39%, P<0.00001), respectively. Continuous and categorical a priori subgroup analyses are presented in the Supplementary Table 5.4(A) & 5.5. Continuous subgroup analyses did not reveal any association with dose, duration, baseline body weight or supplement matrix. In categorical subgroup analyses did not reveal any relation for dose, duration and baseline body weight. There was an effect of fibre type (P= 0.0003) with konjac, agar, alginate, then B-glucan showing the greatest to less reductions in body weight accounting for fibre differences resulted in residual I²=58.52%. Dose response analyses revealed no linear (P= 0.66) or non-linear (P= 0.55) association of viscous fibre supplementation dose and body weight (Supplementary Figures 5.2, A1 & A2).
Effect on BMI

Pooled effect of viscous fibre supplementation on BMI (kg/m^2) in adults is presented in Figure 5.3. Median dose of 5.3 g/d (range: 0.48-15) with median treatment duration of 10 wk (range: 4-48) resulted in a significant reduction in BMI (MD = -0.25 kg/m^2 [95% CI: -0.46, -0.05], P = 0.01). Substantial evidence of inter-study heterogeneity is present in the overall result (I^2 = 71%, P<0.00001). Substantial evidence of inter-study heterogeneity is present in the overall result (I^2 = 71%, P<0.00001). Pooled analysis was divided into two groups based on health status (overweight and obese, and elevated CVD risk). Difference between groups was significant (P= 0.01). Within the elevated CVD group, a significant reduction was observed (MD = -0.45 kg/m^2 [95% CI: -0.64, -0.26], P < 0.00001), but overweight/obese groupe was not significant (P = 0.54). Evidence of substantial heterogeneity was explained through sensitivity analysis when two studies were removed individually, (I^2 = 37%, P<0.00001) and (I^2 = 42%, P<0.00001). Supplementary Table 4.4.(B) & 4.6. show the a priori subgroup analyses (continuous and categorical). Continuous subgroup analyses revealed no association of dose, duration, and baseline =. In the categorical analyses, an effect of duration was found (MD = -0.43 kg [95% CI: -0.66, 0.21], P= 0.001) for a duration of ≥ 10 weeks. Dose response analysis revealed no linear (P= 0.22). In non-linear, (P= 0.02) association of viscous fibre supplementation dose with BMI reduction revealed. Visual inspection shows dose response with doses up to 5g/d but this effect is not observed with doses greater than 5g/d (Supplementary Figures 5.2. B1 & B2).
Effect on Waist Circumference

Figure 5.2 demonstrates the effect of viscous fibre supplementation on waist circumference (cm). Overall, a median dose of 6g/d (range: 3 – 15) and median treatment duration of 12 weeks (range: 4 – 12) had no effect on waist circumference (MD= 0.24 cm [95% CI: -1.73, 2.20], P= 0.81). Differences between groups (overweight/obese vs elevated CVD) was not significant (P= 0.93). Within groups, there was no significant effect on waist circumference. Substantial evidence of inter-study heterogeneity is present in the overall result (I² = 91%, P< 0.0001) that was not explained through removal of individual studies. A priori subgroup analyses (continuous and categorical) could not be conducted as the number of included studies was too small (< 10 trials). Dose response revealed no linear (P= 0.762) association of viscous fibre dose and waist circumference. Non-linear dose response analysis could not be performed due to the small numbers of trials (< 10 trials) (Supplementary Figures 5.2. C1 & C2).

Effect on Body Fat Percentage

The effect of dietary viscous fibre on body fat percentage is presented in Figure 5.3. Pooled effect of 10 g/d [range: 4.5-15] viscous fibre supplementation with median treatment duration of 12 weeks [range: 4 – 12] resulted in a significant reduction in body fat percentage (MD= -1.39% [95% CI: -2.61, -0.17], P= 0.03). There was substantial evidence of I inter-study heterogeneity I²= 61% (P= 0.08) in the pooled analysis. A priori subgroup analyses (continuous and categorical) could not be conducted as the number of included studies was too small (< 10 trials). Dose response analysis revealed no linear association of viscous fibre dose on body fat percentage (P= 0.26). Non-linear dose response analysis was not performed due to the small numbers of included trials (< 10 trials) (Supplementary Figures 5.2. D1 & D2).
Publication bias

Figure 5.7. shows the funnel plots for body weight and BMI. Visual inspection of funnel plots did not present asymmetry. Formal testing using Egger’s and Begg’s tests were not significant (Egger’s test P= 0.212 and Begg’s test P= 1.000) for body weight, and (Egger’s test P= 0.207 and Begg’s test P= 0.519) for BMI. Publication bias could not be analyzed for waist circumference and body fat percentage, as there were < 10 trial comparisons available.

Grading the evidence

A summary of the GRADE assessments for each endpoint is shown in Table 5.2. The evidence for body weight and BMI were graded “moderate” due to downgrades for imprecision. Waist circumference was graded “low” for downgrades of inconsistency and imprecision. Body fat percentage was graded “moderate” for downgrading in imprecision. Grading based on publication bias was not applicable for waist circumference and body fat percentage.

Discussion

This systematic review and meta-analysis quantified the effect of viscous fibre supplementation in adults consuming a calorie restricted diet on indices of obesity and body composition in 15 RCTs. Pooled analyses demonstrate significant reduction in body weight (MD= -0.81 kg [95% CI: -1.20, -0.41], P< 0.0001), BMI (MD = -0.25 kg/m² [95% CI: -0.46, -0.05], P =0.01), and body fat percentage (MD= -1.39 % [95% CI: -2.61, -0.17], P= 0.03). There was no effect found for waist circumference (MD= 0.24 cm [95% CI: -1.73, 2.20], P = 0.81). Analysis based on health status, demonstrated a significant reduction in body weight in those individuals reported as overweight
or obese (MD= -0.74 kg [95% CI: -1.28, -0.21], P= 0.006), and those with elevated risk of CVD (MD= -0.89 kg [95% CI: -1.53, -0.25], P= 0.006). However, for BMI, only those with elevated CVD showed a significant improvement (P < 0.00001). In subgroup analysis, fibre type appeared to have an effect on body weight (P= 0.0003). Subgroup analyses of waist circumference and body fat percentage could not be conducted due to small numbers of trials (< 10 trials). Our findings revealed that viscosity of fibre may be clinically meaningful in weight management along with a restricted caloric diet as the reduction in body weight, BMI, and waist circumference exceeded the MID (157). Our findings may facilitate dieting and weight management through its ability to reduce weight, and by increasing satiety as earlier studies have previously showed (164). Our findings are supported by a meta-analysis, by Thompson et al. (158) of soluble fibre on body weight that demonstrated a significant reduction in body weight (MD= -2.52 kg [95% CI: -4.25, -0.79], P= 0.004), other parameters such as BMI, waist circumference, and body fat percentage also was reported in their meta-analyses and all were significant too but waist circumference. This reduction effect may be attributed to viscous fibre if compared to our study. Comparison of results between this study and ours is difficult due to variance in the study criteria, and the inclusion of soluble non-viscous fibre.

The strength of this study is that to our knowledge, this first systematic review and meta-analyses of RCTs to investigate the effect of viscous fibre supplementation in addition to a restricted caloric diet on body weight, BMI, waist circumference, and body fat percentage. Additionally, no prior study has investigated dietary fibre on the basis of its viscosity with the company of a deficit caloric diet on body anthropometry. Included RCTs included participants with multiple health conditions and spanned multiple countries around the world allowing for generalizability of the results. Finally, the overall quality of evidence was assessed using the GRADE approach.
Limitations of the study should be considered and the results interpreted carefully. First, some of the outcomes were downgraded for inconsistency of the estimates across trials, which resulted in evidence of substantial heterogeneity, which could not be explained through sensitivity analyses. Moreover, certainty of the evidence was downgraded for imprecision as the 95% CI bounds overlapped the MID for beneficial evidence. Subgroup analyses could not be explored for some of the outcomes because there were too few trial comparisons available for analyses. Based on the strengths and limitations of the study, the overall certainty of available evidence was graded as moderate for body weight, BMI, and body fat percentage and as low for waist circumference.
Figure 5.2. Shows the effect of viscous fiber supplements with restricted-caloric diet on body weight. Diamonds represent the pooled effect estimates for overall and stratified analyses. Data are represented as MD with 95% CI, using the generic inverse variance random effects models. Inter-study heterogeneity quantified by $I^2$ with significance $P < 0.10$. N = number of participants in each intervention group. VF, viscous fibre.
Figure 5.3. Shows the effect of viscous fiber supplements with restricted-caloric diet on BMI. Diamonds represent the pooled effect estimates for overall and stratified analyses. Data are represented as MD with 95% CI, using the generic inverse variance random effects models. Inter-study heterogeneity quantified by $I^2$ with significance $P < 0.10$. N = number of participants in each intervention group. VF, viscous fibre.
Figure 5.4. Shows the effect of viscous fiber supplements with restricted-caloric diet on Waist circumference. Diamonds represent the pooled effect estimates for overall and stratified analyses. Data are represented as MD with 95% CI, using the generic inverse variance random effects models. Inter-study heterogeneity quantified by $I^2$ with significance $P < 0.10$. N = number of participants in each intervention group. VF, viscous fibre.
Figure 5.5. Shows the effect of viscous fiber supplements with restricted-caloric diet on Body fat percentage. Diamonds represent the pooled effect estimates for overall and stratified analyses. Data are represented as MD with 95% CI, using the generic inverse variance random effects models. Inter-study heterogeneity quantified by I² with significance P < 0.10. N = number of participants in each intervention group. VF, viscous fibre.
Figure 5.7. Publication bias funnel plots assessing publication bias and effect of small and/or imprecise study effects for (a) Body weight, (b) BMI. The horizontal line represents the pooled effect estimate expressed as the mean difference for each analysis. Diagonal lines represent the pseudo-95% CI. P-values are derived from quantitative assessment of publication bias by Egger and Begg tests.
Figure 5.9. Risk of Bias

Studies were rated “Low Risk of Bias” if the study design is unlikely to have little influence over the true outcome; “High Risk of Bias” if the design is likely to have an influential effect on the true outcome; “Unclear Risk of Bias” if insufficient information was given to assess risk.
Table 5.2. GRADE Assessment
<table>
<thead>
<tr>
<th>Viscous Fibre</th>
<th>Control</th>
<th>Relative (95% CI)</th>
<th>Absolute (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Weight</td>
<td>17</td>
<td>1642 lower 0.33 kg</td>
<td>0.51 lower to 0.14 lower</td>
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<tr>
<td>BMI</td>
<td>15</td>
<td>1147 lower 0.28 kg/m²</td>
<td>0.42 lower to 0.14 lower</td>
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<tr>
<td>Waist Circumference</td>
<td>6</td>
<td>717 lower 0.63 cm</td>
<td>1.11 lower to 0.16 lower</td>
</tr>
<tr>
<td>Body Fat Percentage</td>
<td>3</td>
<td>261 lower 0.78 %</td>
<td>1.56 lower to 0</td>
</tr>
</tbody>
</table>

**Explanations**

a. No downgrade for inconsistency. The heterogeneity was explained by Birketvedt et al and Maki et al. After removing the studies individually, no evidence of substantial heterogeneity remained (I²=24%, p<0.0000 and I²=39%, p<0.0000, respectively.)

b. Downgraded for imprecision. The upper bound of the 95% CI (-0.41) does not meet the minimally important difference of 0.5 kg.

c. No downgrade for inconsistency. The heterogeneity was explained by Berg et al and Meada et al. After removing the studies individually, no evidence of substantial heterogeneity remained (I²=37%, p<0.0000 and I²=42%, p<0.0000, respectively)

d. Downgraded for imprecision. The upper bound of the 95% CI (-0.05) does not meet the minimally important difference of 0.2 kg/m².

e. Downgraded for serious inconsistency that was not explained by removing individual studies (I²=91%, p<0.00001).

f. Downgraded for imprecision. The upper bound of the 95% CI (-2.20) does not meet the minimal important difference of 2 cm.

g. No downgrade for publication bias: Publication bias could not be assessed due to lack of power for assessing funnel plot asymmetry and small study effects (<10 RCTs)

h. The heterogeneity was explained by Akbarzadeh et al. After removing the study, no evidence of substantial heterogeneity remained (I²=0%, p<0.0000).

i. Downgraded for imprecision. The lower bound of the 95% CI (MD -2.61) does not meet the minimally important difference of 2%.

j. No downgrade for publication bias: Publication bias could not be assessed due to lack of power for assessing funnel plot asymmetry and small study effects (<10 RCTs)
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#### Supplementary Table 5.1. Search Strategy. For all databases, searches were performed through August 16, 2018
### Inclusion Criteria

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<td>Adults or adolescent either healthy, overweight and obese individuals or individuals with diabetes and cardiovascular disease (CVD), were all acceptable</td>
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<td>have one of the selected viscous fiber, (Agar, Alginate, B-glucan from oat or barley, Guar gum, Konjac, Pectin, Psyllium, or PGX), as a supplemented treatment</td>
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<td>appropriately controlled</td>
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<td>#6</td>
<td>measure one of outcomes: body weight, BMI, waist circumference, or Body fat percentage. These anthropometry measures can be either primary or secondary outcomes</td>
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<td>Enough information provided to calculate the magnitude of effect, i.e. end of treatment measures and/or change from baseline measures</td>
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<td>#8</td>
<td>Background diet is a caloric deficit diet meaning that participant’s diet have calorie restriction</td>
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### Exclusion Criteria

| #1 | soluble fiber was not one of the selected viscous fiber or a combination supplement where this fibers could not be isolated each one alone |
study was insufficiently controlled, i.e. the control was another soluble fiber

outcome measures did not include body weight, BMI, waist circumference, or Body fat percentage

intervention was a diet with no supplemented fiber

study provided insufficient information to calculate a magnitude of effect

study protocol maintains baseline weight

Secondary information such as reviews, editorials, commentaries, were excluded

diet is not energy restricted diet

No clinical drug introduced with fibre supplementation

**Supplementary Table 5.2.** Eligibility Criteria

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**Supplementary Table 5.3.** Cochrane risk of bias tool
A. Body Weight

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<td>17</td>
<td>1354</td>
<td>-0.022 [-0.083, 0.126]</td>
<td>71.46</td>
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<tr>
<td>Duration (wk)</td>
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<td>Baseline Body Weight (Kg)</td>
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B. BMI

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<th>P-value</th>
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<td>43.80</td>
<td>0.998</td>
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Supplementary Table 5.4. Continuous *a priori* subgroup analyses. β is the slope derived from meta-regression analyses and represents the treatment effect of viscous fiber for each subgroup for A. Body weight, B. BMI. The residual I² value indicates heterogeneity unexplained by the subgroup and is reported as a percent value, where I² ≥ 50% indicated “substantial” heterogeneity. P-value significance for heterogeneity was set as P < 0.10. N = number of participants in each treatment group.
Supplemental Table 5.5 Categorical *a priori* subgroup analyses for Body weight. The residuals $I^2$ value indicates heterogeneity unexplained by the subgroup. Between subgroup differences represent differences between Viscous Fibres and control group. Within subgroup differences represent the difference between end and baseline values. N = number of participants in each treatment group; PGX = PolyGlycopleX®.

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**Supplemental Table 5.5 Categorical a priori subgroup analyses for BMI.** The residuals $I^2$ value indicates heterogeneity unexplained by the subgroup. Between subgroup differences represent differences between Viscous Fibres and control group. Within subgroup differences represent the difference between end and baseline values. N = number of participants in each treatment group; PGX = PolyGlycopleX®.
Supplementary figure 5.2 (A1 & A2). Linear and non-linear VF dose-response analyses on Body weight.

Supplementary figure 5.2 (B1 & B2). Linear and non-linear VF dose-response analyses on BMI.
### Viscous Fiber & Weight Loss Meta-Analysis PROFORMA

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The Cochrane Collaboration Tool for Assessing Risk of Bias:

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- Sequence Generation
- Allocation Concealment
- Blinding of participants, personnel and outcome assessors
- Incomplete outcome data
- Selective outcome reporting
### Table 4.9 PROFORMA-sheet

<table>
<thead>
<tr>
<th></th>
<th>Intervention 1 (within treatment)</th>
<th>Intervention 2 (within treatment)</th>
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<tr>
<td>Waist Circumference</td>
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<td>Body Fat Percentage</td>
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### Results

Expressed as mean±SD (SD = SEM×SQRT(n))

- **Weight**: kg × 2.2 = lbs
- **BMI**: (kg/m²) × 703 = kg/m²
- **Height or Waist Circumference**: cm/2.54 = in

Table 4.9 PROFORMA-sheet
CHAPTER VI - Overall Discussion

The two systematic review and meta-analyses presented in this thesis include different scenarios by which dietary viscous fibre was used as an interventional material to understand its role on weight; in the first, viscous fibre was consumed along with an isocaloric diet, and in the second scenario, the interventional material was given in the background of calorie restriction. To our knowledge, these studies are the first to focus on a specific fibre type where, it was hypothesized that consumption of various types of purified viscous fibre analogues and b-glucan from oat and barley might improve body weight and markers of adiposity in a period of four weeks or more. This period is not established by literature, but it has been discussed that it is not ideal to consider the first four weeks as it is the period when the body loses weight of water. The results from both studies showed that there was a small but significant reduction in body weight with twice the reduction (-0.81 kg vs. -0.33 kg) in studies where viscous fibre was supplemented along with a calorie restrictive diet. Thus, simplifying, but not scientific, the overall findings, the difference of approximately 0.5 kg between the two dietary scenarios favoring calorie restriction could be attributed to the effect of calorie restriction, whereas reduction of -0.3 kg may be solely related to the addition of viscous fibre supplementation, per see.

Despite extensive research on the effect of many single nutrients and/or particular dietary patterns in obesity, none have been shown to be effective in body weight management to a significant degree. Adherence to a low calorie diet appears to be a significant predictor of weight loss, with barriers including lack of motivation and difficulties sustaining the willpower to consume a lesser amount of food. One of the nutrients that might be an effective intervention in weight loss management is dietary fibre, especially viscous dietary fibre. Several reviews have suggested that
increased fibre intake is associated with greater satiety and reduced energy intake when provided in an isocaloric setting (165). Our study 1 demonstrated that adding viscous fibre to diet that did not include calories restriction resulted in a small but significant reduction of body weight (MD= -0.33 kg [95% CI: -0.51, -0.14], P= 0.0004).

Viscous soluble fibres have been shown to be more effective metabolically than non-viscous types, including energy intake, as they can increase the viscosity of the digestive contents to promote satiety by lowering the gastric emptying rate and modifying nutrient absorption (129). Increased meal viscosity from gel-forming fibres has been associated with prolonged satiety and a heterogeneous effect on body weight. Potential mechanisms leading to reduction of body weight remain unexplained, however, the presented data indicate that viscous soluble fibres, including psyllium, guar, konjac blend (PGX) and b-glucan from oats and barley, are likely to be physiologically active components that can be utilized as part of a dietary program in regulation of human adiposity, thus may be interesting candidates for future research, included in dietary guidelines and used in practical application in weigh management programs.

More RCTs are needed for other viscous fibre types (i.e. agar, alginate, pectin, and xanthan). Furthermore, studies that focus on the association between weight loss parameters and that evaluate the level of fibre viscosity is of interest. In addition, the duration of the majority of studies in our meta-analysis range from 4 to 24 weeks with the exception of two studies being 48 weeks and 52 weeks, should be considered going forward. It is recommended that weight loss studies are of longer duration, preferably > 1 year. Therefore, our median duration of 8 weeks may not be sufficient to capture a true effect on weight over time, which may be over or underestimated. The latter of which is especially relevant in the ad libidum setting, where weight loss could be compounded over time. Moreover, future RCTs are encouraged to be of higher quality so that
future systematic reviews and meta-analyses can effectively address Cochrane Risk of Bias Tool and utilize the GRADE approach. As body composition parameters were generally under-reported, future RCTs should include these measurements more often.

In conclusion, viscous fibre supplementation may very modestly, but significantly facilitate weight management, thus it may be encouraged as adjunctive therapy to a low-calorie diet, but could also be advised as part of regular dietary regime that is independent of calorie restriction. Higher quality evidence is still needed for a more precise estimate of the effect of viscous fibre on weight.


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