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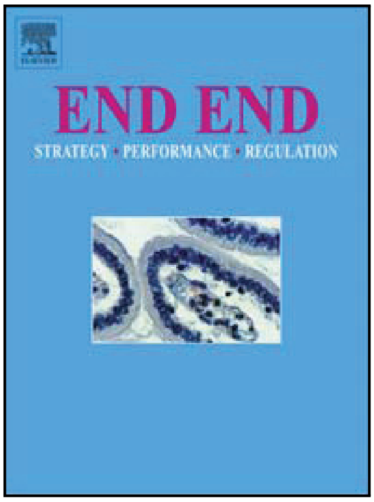

Effects of Daily Consumption of Psyllium, Oat Bran and PolyGlycopleX® on Obesity-Related Disease Risk Factors: A Critical Review

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Highlights

- Many adults do not consume the recommended 25 -30 g of dietary fibre/day
- Clinical trials have shown 10-21 g of psyllium/day to improve blood lipids
- Clinical trials have shown 6-8 g of oat bran β-glucan/day to improve blood lipids
- Clinical trials have shown 10-15 g of PolyGlycopleX /day to improve blood lipids
- Effects of these fibres on weight, hypertension, blood glucose need clarification

Title page

Title: Effects of Daily Consumption of Psyllium, Oat Bran and PolyGlycopleX® on Obesity-Related Disease Risk Factors: A Critical Review

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Abstract

The persistent obesity crisis, with the increased risk of the metabolic syndrome, type 2 diabetes and/or cardiovascular disease that ensues, continues to damage the health of populations globally, including children. Diets rich in the fibre provided by fruit and vegetables support good metabolic health, although few adults and children achieve the recommended daily target. Daily fibre supplementation, particularly with soluble fibre product, such as psyllium, oat bran, or a newer product such as PolyGlycopleX®, may provide a convenient solution. Literature searches were conducted to identify original research articles, systematic reviews and meta-analyses with the search terms ‘psyllium’, ‘oat bran’, ‘PolyGlycopleX®’, and ‘PGX®’, AND ‘adults’ and ‘children’ AND ‘overweight’, ‘obesity’ and ‘metabolic syndrome’. Data source was Embase and PubMed from 1980 to 2017. The results show that the addition of a soluble fibre product, most notably psyllium, improves blood lipid profiles, particularly total and LDL cholesterol, as well as glycaemic response, and increases satiety, and by thus improving metabolic syndrome and cardiovascular disease risk factors, may augment the processes initiated by weight reduction diets. Though less-studied than psyllium, the available evidence has shown that β-glucan present in oat bran to have a beneficial effect on metabolic syndrome and cardiovascular disease risk factors, particularly blood lipids and glycaemia. Early research has found PolyGlycopleX® to provide similar benefits to other soluble fibre products, and suggest it may also assist with weight loss. This critical review demonstrates that soluble fibre supplements used as an adjunct to dietary and lifestyle modifications may assist with the treatment of cardiovascular and metabolic syndrome risk factors. More research is needed to further clarify the benefits of PolyGlycopleX® in particular, as well as to develop safe and efficacious recommendations for fibre supplementation of all types for children in general.

Key words: soluble fibre; obesity; metabolic syndrome; psyllium; oat bran; PolyGlycopleX®, PGX®

List of abbreviations: BMI: Body Mass Index; BP: Blood pressure; CVD: Cardiovascular disease; HDL: High Density Lipoprotein; LDL: Low Density Lipoprotein; MS: Metabolic Syndrome; PGX: PolyGlycopleX; PYY: Peptide yy; SCFA: Short Chain Fatty Acid; TC: Total Cholesterol; TG: Triglycerides; T2D: Type 2 diabetes

Introduction

Obesity is the cause of many debilitating physical, emotional, social and economic consequences (1). World-wide rates of obesity have nearly doubled in the last three decades (2), a trend that shows no sign of abating (3, 4). More specifically, abdominal or central obesity is strongly associated with the development of metabolic syndrome (MS) (1). This is thought to be due to the effects of the increased release of free fatty acids, inflammatory cytokines and other by-products from the adipocytes, generated by excess adiposity (1, 5) These effects have also been observed in children that are overweight or obese (3, 6, 7).

Metabolic syndrome has been defined by the International Diabetes Federation as having central obesity as well as any two of the following factors: raised blood pressure (BP; hypertension), reduced high density lipoprotein (HDL), raised triglycerides (TG; hypertriglyceridaemia), and raised fasting plasma glucose (hyperglycaemia) (8). The same applies to children and adolescents, with the presence of central obesity identified as a waist circumference greater than the 90th percentile (9). Having MS leads to an increased risk of developing type 2 diabetes (T2D) and cardiovascular disease (CVD) (1, 5, 10, 11). The risk of CVD-related mortality is also higher in those identified as having MS (11, 12).

High dietary fibre intake is known to have a protective affect against CVD, T2D, hypertension and obesity (13) - the latter being a risk factor for developing these conditions (5) - and to lower serum cholesterol (13-16). A diet rich in fibre from fruit, vegetables, legumes and whole grains is considered to be beneficial for health in adults (13, 14), and children (17, 18). It is recommended adults consume 25 to 30 g, whereas children should consume between 14 g and 28 g of dietary fibre per day (19, 20), although recommendations for children vary widely depending on the country and the evidence base used (21). However relatively few individuals achieve the targeted amount of fibre in their diets (22, 23), as demonstrated in the US Continuing Survey of Food Intakes by Individuals 1994–96, 98 (23), and more recently the 2011-12 Australian Health Survey (22). Therefore, adding fibre may provide a convenient and cost-effective alternative for increasing the fibre content of a diet without the need for other major dietary modifications.

Psyllium has been extensively researched due to its inclusion in many popular over-the-counter laxatives (24). It is known to promote bowel regularity and improve blood lipids (24, 25), however less is known regarding the role of psyllium on weight and other MS risk factors. Oat bran is another commonly consumed food product, but the potential health benefits have not been studied as widely. PolyGlycoplex® (PGX®) is a novel fibre product relatively new to the market, and early research has shown a potential for weight loss benefits, however studies relating to the effects of PGX® on other MS risk factors are limited. While the majority of research has been undertaken on adults, and those at risk of MS and CVD, the effects of dietary and/or soluble fibre products, has been less explored in children (26). The aim of this review is to critically examine the available evidence and assess the benefits of the aforementioned fibre products, and to evaluate their effects on weight loss and MS risk factors in adults and children. This is required to clarify safe and effective fibre supplementation recommendations with particular reference to improvements in weight as well as MS and CVD risk factors in adults as well as children, particularly as fibre supplementation for the prevention (and treatment) of these conditions may be more preferable to medical interventions in the young. This critical review also identifies areas where further research is needed. Literature searches were conducted to identify original research articles, systematic reviews and meta-analyses with the search terms ‘psyllium’, ‘oat bran’, ‘PolyGlycopleX®’, and ‘PGX®’, AND ‘adults’ and ‘children’ AND ‘overweight’, ‘obesity’ and ‘metabolic syndrome’. Data source was Embase and PubMed from 1980 to 2017. The bibliographies of all articles located were searched for further studies. The disproportionate amount of evidence available regarding psyllium compared to oat bran and PGX® is reflected in this review.

Commercially available soluble fibre products

Dietary fibre is derived from indigestible polysaccharides in fruit, vegetables and whole grains (24), and provides a prebiotic function in the large intestine via fermentation (15), a by-product of which is short chain fatty acids (SCFA), beneficial for gastrointestinal health (13). Diets high in fibre tend to have lower energy density and thus promote decreased energy intake (27, 28). Fibre is classified as either soluble or insoluble depending on its water-holding capacity or degree of viscosity in solution (29), and contains a number of bioactive compounds (15). A variety of soluble fibre preparations are readily available in most grocery stores, pharmacies and health food stores. For the purposes of simplifying recommendations to patients, three readily identified and accessible soluble fibre products were selected: Psyllium, oat bran and PGX®. Unprocessed psyllium and oat bran packaged in bags as a food ingredient appear to be the most cost effective option. These can be added to water, juice, yogurt, used in cooking or added to breakfast cereals or muesli. For those that find consuming unprocessed fibre inconvenient or unpalatable, flavoured powders are also available. For example, psyllium is flavoured with orange, berry, or lime under the brand name Metamucil®, a commercially available fibre supplement. Psyllium can also be obtained in capsules form.

A recent addition to the fibre product market is PGX®, a proprietary complex of three natural polysaccharides, and packaged as granules in dose-size sachets which can be added to food or drinks. Currently PGX® can only be obtained at retail outlets in the United States and Canada, but is available online in other regions. Much of the research into PGX® tested the granules. A PGX® gel capsule preparation is available, but these contain a small amount of fatty acids derived from coconut oil (30), and at this stage the effect of this particular ingredient on satiety, weight loss and MS risk factors is unclear, therefore this product has not been included in this review.

Mechanisms of action

Blood lipids

The viscosity of chyme appears to interfere with the absorption of bile acids in the large intestine, which increases faecal bile acid elimination (15), stimulating additional bile acid production intracellular cholesterol (31). The lipid-lowering effect may also occur by reducing the rate of intestinal cholesterol uptake (32), possibly trapped in the viscous gel formed (15), and reducing the amount of circulating chylomicrons (33), and thus reducing cholesterol in circulation (24). In addition, lower postprandial insulin secretion may result in reduced lipogenesis (31), and lower circulating triglycerides (24). Undigested soluble fibre is subject to bacterial fermentation in the large intestine (24). This results in the production of SCFAs, including proprianate, which travels directly via the portal vein to the liver, where it is thought to hinder cholesterol synthesis (34).

Glycaemic response

Satiety, as a result of having eaten, is a state in which continued eating is suppressed (27). Consumption of soluble fibre increases the bulk and reduces the energy density of the chyme, thus delaying gastric emptying (35). Soluble fibre also raises the viscosity of chyme, which has the effect of widening the unstirred water layer in the small intestine, thus delaying energy and nutrient (eg carbohydrate) absorption (24). These delays reduce postprandial insulin secretion (35), and moderates postprandial blood glucose concentration (24), and are thought to promote satiety (24, 35), which may assist with weight management. Supplementation with soluble fibre may improve insulin sensitivity via this and/or other as yet unidentified mechanisms, however further evidence is needed to elucidate this factor.

Blood pressure

So far, research evidence favours insoluble over soluble fibre consumption as a means of moderating blood pressure (36, 37). A variety of mechanisms have been considered to explain the effect of fibre consumption on BP, such as moderation of the glycaemic response due to enhanced insulin sensitivity (13), and increased production of the vasodilator nitric oxide, leading to improved endothelial function (38).

Soluble fibre and children

Prior to the 1990s, concern among some paediatricians was that increasing dietary fibre intake in children may displace more energy-rich carbohydrates and thus reduce the amount of energy available for normal growth and development (39); however later studies have refuted this claim (40). In addition, recent data show that many children do not get enough fibre from the diet (22). Evaluation of epidemiological evidence from Europe, Oceania and North America by Edwards et al found that most children did not consume the recommended amount of dietary fibre per day set within their country (21). While the number of studies available for review was modest, these investigators found some evidence to suggest that higher fibre intakes in children may have a protective effect against obesity, MS, insulin resistance and hypertension (21). A cohort study of Japanese children 10-11 years of age (n= 5,873) found dietary fibre consumption to be inversely associated with total cholesterol, overweight and obesity (41). Nevertheless there is insufficient evidence with which to make dietary fibre intake recommendations, specific for age and growth (42), and much of the existing recommendation appears to be extrapolated from research with adults (21). While supplementing fibre may be an acceptable alternative to pharmaceutical treatments in the treatment and prevention of MS in children (43), efficacious dosages are yet to be determined.

Psyllium

Psyllium seed husk is a viscous, water-soluble, gel-forming mucilage from the *Plantago ovata* plant and has advantages over other soluble fibre sources because it is less readily fermented and therefore causes less abdominal bloating (44). Psyllium has been shown to be an effective supplement for decreasing CVD risk (45) and blood pressure (in hypertensives) (46), improving blood lipid profiles, as well as a bowel regulator (25, 47).

Weight loss

A variety of studies have tested psyllium supplementation for weight loss. One such study showed no significant changes in BMI in 49 slightly overweight participants with T2D consuming 10.2 g of psyllium for 8 weeks, compared to a placebo (48), while other longer-term have studies produced contrasting results. A study that examined the supplementation of 21 g of psyllium a day for 3 months in 57 overweight or obese participants reported significant changes to BMI (p=0.010), weight (p=0.007) and total body fat (p=0.002) (49). In addition, improvements in these measures were greater when psyllium was combined with a healthy diet (p=0.001, for the three outcomes) (49). Another study of 141 overweight individuals with hypertension reported improvements in BMI (-1.0, p=0.01) after daily dose of 7 g of psyllium daily after 6 months compared to a standard diet (50). In addition, a 12-month study of overweight and obese adults conducted by Pal et al reported statistically significant reductions in weight (2.6%, p=0.002), body fat percentage (p=0.038), and waist circumference (p=0.01), following supplementation of 15 g of psyllium per day compared to the placebo (51). It would appear that duration of psyllium consumption may be a more influential factor than dosage, where weight loss is concerned.

Satiety is an important factor for individuals undertaking weight management. Postprandial gastrointestinal appetite hormones ghrelin and peptide yy (PYY) have been shown to decrease two hours after consumption of psyllium-enriched meals by healthy weight participants, which may explain the weight loss effects of this fibre product (52). Another study of non-restrained eaters found a significant reduction in one-hour postprandial fullness ratings, along with a decrease in total fat and energy intake during the day following two pre-meal doses of psyllium (separated by 3 h) (53). The satiety-inducing effect of psyllium has been found to be similar to other fibre sources (54).

Blood lipids

Research has suggested that psyllium supplementation may provide cardiovascular benefits via the effect of psyllium on blood lipids (13, 55-57), perhaps due to its viscosity (29). A study by Khossousi et al evaluated the 6-hour postprandial effects of the consumption of 3 g of psyllium taken with a low-fibre meal versus a high-fibre meal (15 g) in 10 overweight and obese men (58). Serum TG concentration was significantly lower four hours after the consumption of the high-fibre meal compared with the low-fibre meal ($p<0.05$); plasma concentration of Apolipoprotein B48 (a marker for chylomicrons) was significantly lower one hour after the high-fibre meal ($p<0.05$), and remained lower for the entire six-hour postprandial period (58). The authors suggest that a single acute dose of psyllium can decrease arterial exposure to TG and modify chylomicron responses in the postprandial period (58).

Longer term effects have also been observed. At the end of a 6 week study of 20 individuals with T2D given 14 g of psyllium/day in a test breakfast, researchers observed a significant decrease in TC and LDL, 7.7% and 9.2% respectively ($p<0.05$) (59). A daily dose of 10.2 g psyllium increased HDL significantly ($p<0.05$), and decreased LDL/HDL ratio (an indicator of CVD risk), in the 8 week study of T2D patients mentioned earlier (48). In 1988 Anderson et al conducted a study of 26 men with mild to moderate hypercholesterolemia, whereby participants added a total of 10.2 g per day of either psyllium or cellulose (placebo) to meals for 8 weeks, and found psyllium to reduce serum total cholesterol by

14.8%, LDL by 20.2%, and the ratio of LDL/HDL by 14.8%, relative to baseline values (60). Similar findings resulted from later studies conducted by Anderson with other researchers (56, 61).

More recently, the 12-week study by Pal et al demonstrated that supplementing 21 g of psyllium per day to a habitual diet was sufficient to see improvements in TC (-15%, p=0.003) and LDL (-23%, p=0.001), in overweight and obese individuals (49). A longer term clinical trial conducted by Pal et al found significant reductions in TC (4.8%, p=0.006), and TG (12.7%, p = 0.023) at 6 months, compared to baseline, in overweight and obese participants supplementing 15 g of psyllium per day (62).

Glycaemic response

The viscosity of soluble fibres such as psyllium has been also implicated as a moderator of the glycaemic response (29, 57, 63), as mentioned. An 8-week study of 34 male patients with T2D given a total of 10.2 g psyllium or cellulose (control) per day reported the lunch postprandial glucose concentration to be 19.2% lower and the all-day glucose concentrations to be 11% lower in the psyllium group compared to the control (64). A previously discussed 8-week study found 5.1 g per day of psyllium significantly improved fasting blood glucose and glycosylated hemoglobin compared to the control (p<0.05), in T2D patients, and although insulin levels did not change, these results suggest improved gylcaemic control (48). Nevertheless, another study found that either a healthy diet alone, or together with psyllium supplementation, reduced insulin (5%, p=0.05; 8%, p=0.02 respectively) compared the control in overweight and obese participants after 12 weeks; although psyllium added to the habitual diet did not (49). While a 12-month trial with overweight and obese adults by found no significant difference in blood glucose after 15 g of psyllium per day compared to the control, there *was* a significant difference in insulin (-9.4%, p=0.029) (62).

Blood pressure

Studies measuring changes in BP following psyllium consumption have produced contradictory results. A systematic review and meta-analysis found that psyllium consumption was not associated with lower BP (65). No significant improvements in vascular function or BP were found by Pal et al in their 12-week study of the effect of consuming 21 g psyllium per day in obese and overweight individuals (66). Another study examined the effect of dietary protein (raised to 25% of total energy intake) and/or 12 g psyllium added to a low fibre diet in 41 treated hypertensive patients, and found that systolic BP and diastolic BP decreased with exposure to either protein (systolic: -2.9 mmHg; diastolic: -2.5 mmHg) or fibre (systolic: -2.4 mmHg; diastolic: -1.9 mmHg); an additive effect was found when the two were combined (systolic: -10.5 mmHg; diastolic: -3.6 mmHg) in the 24-hour postprandial period, relative to a low fibre, low protein control (67). A concomitant reduction in hypertension may not necessarily be found with improvements to blood lipids due to the influence of other factors on BP (68).

Children

Studies examining the effect of psyllium supplementation on weight and other MS risk factors in children are scarce. Early indications suggest that psyllium improves lipid profiles and glycaemic response in children and adolescents that are overweight or obese (7). More recently, a 6-week study of 45 healthy adolescent participants (aged 15-16 years; 44% overweight or obese), given 6 g of psyllium per day, reported improvements in LDL (p=0.042), and a 4% reduction in android to gynoid fat ratio (or adiposity) (p=0.019), but no meaningful changes to BP (69). Further studies are needed to determine the health benefits of psyllium supplementation in children of all age groups, given that it has a lipid, glucose and insulin lowering effects in adults.

Oat bran

Oat bran has attracted the attention of food and nutrition scientists in recent years, however studies examining the health benefits of this fibre source are less abundant compared to psyllium. Oats, derived from the *Avena sativa* plant, is a cereal containing a complex array of compounds (70). One constituents of interest is β-glucan, a viscous, soluble fibre found in the endosperm, consisting of glucose molecules with β-(1→3) and β-(1→4) linkages (70). It is thought that these physiochemical properties may assist with the reduction of hypertension, thus reducing CVD and stroke risk (70, 71) as well as MS risk factors (72). Oat bran may contribute to stool weight by delivering highly viscous β-glucan to the large intestine for fermentation, but not appears not to contribute to improved laxation (24). Consumption of oat bran β-glucan has been shown to result in dose-dependent improvements in the blood lipid profiles of middle aged adults (73), as well as increase glycaemic control in patients with T2D (74).

Weight loss

Studies regarding the impact of oat bran on weight are few, with most trials assessing changes to blood glucose and blood lipid profiles following oat bran consumption. A 3-month trial with 56 overweight women randomised into groups adding either 0 g, 5–6 g or 8–9 g of β-glucan to an energy-restricted diet, showed a significant reduction in weight (m=4.1 kg, $p<0.001$) and waist circumference ($p<0.001$) in *all* groups (75). The amount of weight loss expected in the 8-9 g group was 6-6.5 kg, therefore the authors were unable to draw any firm conclusions about the impact of β-glucan consumption on weight (75).

To examine the effect of oat bran on weight management, Juvonen et al assessed pre-prandial and postprandial plasma levels of appetite-regulating hormones ghrelin and peptide yy, along with self-reported appetite ratings of three test meals of varying fibre composition (10 g oat bran, 5 g oat bran with 5 g wheat bran, or 10 g wheat bran, and a control), with 20 young, healthy weight participants (76).

This study reported no significant between-group differences in plasma ghrelin, PYY measurements or self-rated appetite, however the researchers postulate that different results may be achieved with overweight and obese individuals (76).

A 12-week trial examined the effect of oat bran on weight loss in 144 hypercholesterolaemic overweight and obese individuals, whereby an oat-based cereal product (3 g of β-glucan per day) was added to a weight loss programme and compared to a low fibre control (77). Statistically significant reductions in waist circumference were, however weight loss was not significant, therefore this cannot be attributed to the effect of β-glucan, as the decrease in waist circumference may have been due to improved gastrointestinal health as opposed to a reduction in abdominal adiposity (77).

Blood lipids

Several studies have found oat bran to increase bile acid excretion and synthesis, and reduce serum TC (71). More specifically, β-glucan has been shown to reduce fasting and postprandial lipoproteins (70). One possible mechanism is that β-glucan consumption increases the viscosity of the outer layer of chyme, which hinders the absorption of cholesterol and the reabsorption of bile acids in the small intestine (71), thus increasing bile acid excretion and stimulating bile acid synthesis, and reducing serum LDL (70, 71), similar to the actions of soluble fibre in general (15).

To examine this effect in the short-term, a 3-day study of 9 outpatients with conventional ileostomies, tested two types of extruded oat bran cereal (75 g), one with native β-glucan (11.6 g), the other with hydrolysed β-glucan (4.5 g) and measured bile acid and cholesterol excretion (78). The results showed that native β-glucan cereal increased median bile acid excretion by 144% (p=0.008), and lowered cholesterol absorption by 19% (p=0.013) (78). Native β-glucan may perform these functions better than an extruded analogue, as the extraction process may alter the physiochemical properties of β-glucan (79).

In a 2-week study of 24 healthy individuals provided with a diet containing 10.2 g of oat bran (equivalent to 6 g of soluble fibre per day) per day versus a low fibre reported that oat bran reduced circulating TC by 14% compared to the low fibre control (4%, $p<0.001$) and LDL by 33% compared to the control (9%, $p<0.01$), (and also reduced haemostatic factors, blood-clotting regulators implicated in CVD) (80).

Although the duration and sample sizes in the above studies are small, they support the view that β-glucan in food can positively alter blood lipids, and thus reduce CVD risk factors, in a relatively short timeframe. Further evidence from a longer term trial with 204 overweight and obese participants given 3 g of β-glucan per day compared to a low fibre control, demonstrated a significant reduction in LDL (-8.7±1.0 vs -4.3±1.1%, $p=0.005$), and TC (-5.4±0.8 vs -2.9±0.9%, $p=0.038$) after 12 weeks (77), and further support these results.

Glycaemic Response

Oat bran may lower the glycaemic index of a meal by reducing its energy digestibility, in a similar manner to fibre in general. Juvonen et al reported a reduction in postprandial plasma glucose ($p=0.001$) and insulin ($p<0.001$) with 10 g of oat bran in a meal, in their study mentioned above (76). Another study has shown β-glucan to reduce the postprandial glycaemic response ($p<0.002$) in 12 patients with T2D, after adding 30 g of oat bran flour to a 25 g glucose load (81). However whether there is a long-term or additive effect on glycaemic response or T2D with regular consumption of oat bran/β-glucan remains to be validated by further studies.

Blood pressure

Although one systematic review reported less convincing results with regard to the impact of oat bran β-glucan on blood pressure (82), a slightly more recent systematic review and meta-analysis (cited earlier), reported an inverse association between higher β-glucan intake and lower BP (65). Specifically, diets higher in β-glucan (median difference of 4 g between high and low) were shown to reduce systolic and diastolic BP by averages of 2.9 mmHg and 1.5 mmHg, respectively (65). However differing results can be found in individual trials. A 12-week study of 110 participants with moderately high BP demonstrated non-significant decreases in systolic BP (1.8 mmHg) and diastolic BP (0.8 mmHg) after 8 g/day of oat bran compared to a low-fibre diet control (83). In addition, a 6-week study with a total of 100g oat bran added to daily meals compared to the low-fibre meal equivalent found no significant effect on either systolic BP or diastolic BP on normotensive participants (84).

Children

Minimal evidence exists of the effects of oat bran supplementation on MS risk factors in children, however some studies conducted in the early 1990s examined its effects in children with elevated cholesterol provide limited information. One such study of 20 hypercholesterolaemic children 5-12 years of age reported a significant reduction in LDL and a significant increase in HDL following the daily consumption of oat bran compared to soy (dosages: 1 g per kg body weight) after 7 months (p<0.05) (85). Another study of 49 children (mean age: 10 years) with elevated cholesterol, found that although the overall lipid profiles did not differ significantly, 38 g of oat bran per day for 4 weeks to significantly reduce apolipoprotein B (p=0.05), as well as greater improvements in apolipoprotein A1, compared to the control (86). These results may suggest that over a longer duration, oat bran consumption may improve lipid profiles in children with high cholesterol.

PGX®

PolyGlycopleX® is a non-starch polysaccharide product consisting of three natural fibre components (glucomannan, sodium alginate, and xanthan gum), manufactured by a proprietary process known as EnviroSimplex® (87). Together these constituents form a highly fermentable complex with a very high viscosity, high water-holding and gel-forming properties, making it approximately seven times more viscous than psyllium (87).

A study with healthy individuals to determine the tolerability of PGX® found no major adverse events, with participants reporting gastrointestinal discomfort (eg. flatulence, bloating, intestinal rumbling, or abdominal pain), which was no different to the effects of the placebo (skimmed milk powder) (88). Such gastrointestinal responses to higher fibre consumption are well documented in the literature (24), and are considered normal consequences of increasing dietary intake of fruits and vegetables and fibre in general (89). The small number of studies of PGX® available for review reflect the relatively recent addition of this product on the fibre supplement market.

Weight loss

Recent trials have examined the effect of PGX® on weight loss. Solah et al found that when participants consumed 12.2 g PGX® daily for 12 weeks per protocol they experienced 1.4 kg weight loss compared to the rice flour control (p<0.01), however this change was not significant with intention-to-treat analysis (90). A 14-week study of 29 overweight and obese participants supplementing 15 g of PGX® per day, along with weight loss dietary and lifestyle modifications, experienced a significant reduction of body weight of 6.44%, total body fat of 6.02% and waist circumference of 11.65%, compared to baseline (p<0.05) (91). However, without a control group to offset the effect the diet and lifestyle modifications it is not possible to determine the exact role of PGX® in these outcomes. Nevertheless similar results were reported in another 14-week placebo controlled trial of 64 overweight and obese adults in Japan, with significant reductions waist circumference of 1.96 cm ($p<0.008$), and visceral adiposity (in females only; $p=0.045$), observed after consumption of 15 g of PGX® per day (92). A 15-week study examining the effect of daily consumption of 15 g PGX® on weight in 60 overweight and obese men and women, compared to 15 g inulin per day, reported a significant weight loss of 1.6 kg in the women of the PGX® group (n=14; $p=0.016$) (93).

A 12-month trial by Pal and colleagues compared the effects of either 15 g of PGX® or 15 g psyllium daily against a placebo with measurements collected at three-month intervals and found both PGX® and psyllium improved weight and total body fat, although participants in PGX® group had slightly better results (-2.8%, $p=0.012$, and $p=0.008$, respectively), and these changes were maintained more consistently throughout the trial period (51).

Blood Lipids

More seems to be known regarding the influence of PGX® on blood lipids, which has been shown to have a lipid-lowering effects in both healthy and overweight or obese participants. A trial with 54 healthy participants given 5 g of PGX® a day for the first week followed by 10 g a day of PGX® for the following two weeks reported a significant reduction of TC of 0.70 mmol/L and LDL of 0.48 mmol/L compared to controls (*p*-values not reported) (88). The first of the 14-week trials discussed above showed significant reductions in TC and LDL levels of 19.26% and 25.51%, respectively, after 15 g of PGX® daily compared to baseline measurements ($p<0.05$) (91). Similarly, the other 14-week trial cited above reported significant reductions in TC of 6.6% and LDL of 12.2% after 15 g of PGX® per day over for the trial period ($p<0.05$) (92).

Further results from the long-term trial mentioned earlier found both PGX® and psyllium to improve blood lipids however the PGX® group showed better results for the 12-month duration (62). The cholesterol-lowering effects found in these studies may be due to SCFAs produced by microbiotic digestion of PGX® in the large intestine, as demonstrated in a simulation experiment conducted by Reimer et al (94).

Glycaemic Response

Some of the studies conducted so far have also examined the effect of PGX® on glycaemic response. One study has shown that 2.5 to 5 g of PGX® added to a meal to be effective in lowering the glycaemic index of food, thus reducing postprandial glycaemia and modifying appetite-regulating hormones ghrelin and PYY (p=0.043) in healthy adults (95). A study of 10 participants compared meals containing either 2.5 g, 5 g or 7.5 g PGX®, or 5 g inulin (control) found increased self-rated satiety following the PGX® meals, as well as a dose-dependent reduction in glycaemic response over a two-hour post-prandial period, compared to the control meal (96). However matching inulin dosages in the control meals may yield different results.

Blood pressure

The available studies have not reported any effects regarding PGX® supplementation and blood pressure.

Children

To date, there have been no studies examining the effects of PGX® supplementation in young or overweight children. Interestingly however, a postprandial study of 31 healthy adolescent participants (16–17 years of age) compared the effects of one of three 5 g fibre preloads - PGX®, glucomannan or cellulose - on appetite, administered 90 min prior to an *ad libitum* pizza meal, and found PGX® to produce a significantly greater reduction in subsequent pizza consumption (in grams), compared to the two comparison preloads (*p*=0.008) (97). No other outcome measures were collected in this study. Further studies are required to clarify the effects of PGX® supplementation in children of different ages.

The quantitative results discussed above are presented in *Table 1. Range of the effects of the different fibre supplements on key disease factors*.

Conclusions

Overall, soluble fibre preparations such as psyllium have demonstrated positive improvements in serum TC, LDL and body composition as well as postprandial glycaemic response. Based on the above evidence, 10-15 g of psyllium per day added to a weight management programme for a minimum of six months may augment the improvements in MS risk factors desired for overweight and obese individuals. While the effects of psyllium and to a lesser degree oat bran have had relatively more attention from researchers, a small number of studies with PGX® have reported improvements to some of the abovementioned disease risk factors. Many unknowns remain regarding the effect of specific fibre products on BP, another risk factor for both metabolic syndrome and CVD. Elucidating these effects appears problematic, possibly due to the difficulty in separating the effect of other dietary and lifestyle factors on BP.

The results of this critical review demonstrate that the addition of a fibre product to the daily diet, most notably psyllium, can improve blood lipid profiles, particularly total and LDL cholesterol, as well as moderate glycaemic response, and increase satiety. While the weight loss results are inconsistent, by improving these cardiovascular and metabolic syndrome risk factors, this fibre product may augment the processes initiated by dietary and lifestyle modifications. PGX® is a relatively new fibre product and therefore more research is needed to confirm the effects noted here, and should include an examination of the different types available (eg. granules versus gel capsules) as well as the required dosages.

While it is still unclear whether fibre supplementation will reduce overall MS and CVD risk on its own, it may be a useful strategy to support other risk reduction measures such as lifestyle changes and/or pharmaceutical treatments (98). The heterogeneity of studies into fibre supplementation for the treatment of obesity-related risk factors should be taken into consideration when evaluating the evidence presented in this review. Further randomised controlled clinical trials are needed before any definitive safe and efficacious recommendations can be made regarding fibre supplementation of all types in children of all age groups.

Recommendations for clinical practice

The following is a list of recommendations based on the evidence discussed.

Psyllium

Psyllium supplementation may be a suitable alternative to lipid-lowering medication with minimal side effects, particularly for overweight/obese adults and children at low-to-moderate risk. Adding psyllium to a healthy diet or weight management program would maximise the benefits of this strategy. A minimum of 10 g of psyllium husk or powder (approximately 2 teaspoons) or the equivalent in capsules, taken with 250 mL of water twice daily would be suitable for adults, and a minimum of 5 g of psyllium taken with 250 mL of water once or twice per day may be suitable for children (12 years and over) of low risk. If palatability is a problem, psyllium powder or husks can be added to meals, however extra water should be consumed throughout the day.

Oat bran

A 10 g dose of oat bran (approximately 6 teaspoons) added to a meal appears to be sufficient to moderate the glycaemic response following a meal, and may to assist adults of low risk to manage blood glucose levels. No recommendations can yet be made for oat bran supplementation in children.

PGX®

Although preliminary evidence suggests that 5 g supplementation of PGX® taken with at least 250 mL of water two to three times per day may augment a weight management program in overweight adults, further research is required to determine recommendations to assist with MS risk factors. No recommendations can yet be made about supplementation of PGX® in children. In addition, this product is only available online in some places and the price may be prohibitive for some.

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Table 1. Range of the effects of the different fibre supplements on key disease factors

	PSYLLIUM		OAT BRAN/β-GLUCAN		POLYGLYCOPLEX	
	Dose (g/day)	**Effect**	**Dose (g/day)**	**Effect**	**Dose (g/day)**	**Effect**
Total Cholesterol (%)	10 - 21	-4.8 - -15	3 - 6	-5.4 - -14	10 - 15	-6.6 - -19.3
LDL-Cholesterol (%)	10 - 21	-9.2 - -23	3 - 6	-8.7 - -33	10 - 15	-12.0 - -25.5
Fasting Blood Glucose (%)	10	19.2*	IC	IC	IC	IC
Systolic BP (mmHg)	12	-2.4*	8	-1.8*	NE	NE
Diastolic BP (mmHg)	12	-1.9*	8	-0.8*	NE	NE

*Data sourced from a limited number of studies; BP: blood pressure; LDL: low density lipoprotein; IC: studies inconclusive; NE: no evidence

CHECK/CORRECT after MA CHECK