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REVIEW ARTICLE **OPEN ACCESS**

Effect of Fibre Supplementation on Body Weight of Obese Adults: A Systematic review and Meta-Analysis of Double-blind RCTs

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ABSTRACT

Health benefits of dietary fibre are well known. Fibre improves gut health and provides bulk to the faecal matter; it also helps in boosting metabolism and reducing weight in overweight and obese person. This study was conducted to find out a common ground on which relationship between fibre intake and weight reduction can be placed. Systematic review was conducted by retrieving data from different database libraries. We evaluated different double blind, placebo controlled randomized trials of fibre supplementation; and studied their impact on the body weight of the obese or over weight adults through systematic review and meta-analysis. We used Scopus®, CENTRAL and PubMed as the database search library. Eligible studies (on the basis of inclusion and exclusion criteria) were selected and used to pool out the results. Jadad's score and Heyland methodological quality score (MQS) were used to assess publication bias and quality of the included studies, respectively. The effect size of 7 individual studies were pooled in meta-analysis and presented as forest plot using MS- Excel. Findings from different studies that are included in the review and meta-analysis; having participants (n), carried over varying period of 6 weeks to 52 weeks suggests fibre supplementation is an effective tool in weight loss. Though the level of heterogeneity was high between the studies, most results are coinciding. This study concludes that different fibre supplements are not equally beneficial in weight loss, some fibres are more effective in initiating more weight loss than others.

Keywords: *Obesity; fibre; forest plot; RCT; meta-analysis; double-blind*

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INTRODUCTION

Increase in the prevalence of obesity and overweight is seen well by the last few decades and is still growing at a great speed. [1] Though obesity is preventable but still as of 2016, 1.9 billion adults above the age of 18 are overweight, and 650 million out of these are obese. Obesity is present in all age groups and all parts of the world. According to a report by WHO, in 2019, 38 million children under the age of 5 are either overweight or are obese. In 2016, 39 per cent of total population was overweight and 13 per cent was obese. Its global prevalence makes it one of the most deadly life style disorders prevailing on the globe. Obesity is common not only in high income countries, but has now out stretched to middle and low income countries. [2] Because of the ever growing prevalence of it is considered as serious health concern all over world. Various chronic diseases like type II diabetes, gall bladder diseases, cardiovascular diseases, osteoarthritis, gout and various types of cancers all causes mortality because of being overweight and obesity. [3] Diet is directly a contributing factor in 30 per cent of the cancer cases in the industrialized countries, thus being the second largest modifiable risk factor after smoking cigarettes. [4] The economic burden of obesity and overweight is considerable, costing almost billions for most of the Western world. [5] With studies different aspects of different nutrients whether macro and micro have been linked either directly or indirectly with the development of obesity. With research the link between carbohydrate intake along with unsaturated fats in weight reduction has been established over time. [6] Some researchers linked reduced protein consumption to increase in body weight leading to being over-weight or obese. This is so because of the fact that by decreasing the protein fraction in diet, we increase the compensatory energy intake, thus leading to excess calorie intake causing weight gain. [7]
Many researchers have directly linked obesity with fibre intake. [8][9]Different studies that have used different types of fibres in varying amount have largely shown improvements in body composition along

with enhanced metabolism. [10]Dietary fibre is derived primarily from plant sources, and is composed of non-starchy, complex carbohydrates or lignin. Dietary fibres are indigestible because of lack of enzymes which can hydrolyse the fibres. [11] Dietary fibre is defined as non-digestible carbohydrate having 3 or more monomeric units inherent in food or isolates and shows some physiological benefits. [12] Fibres include polysaccharides, lignin, some oligosaccharides (inulin), and resistance starches. [13]Fibres don't add up to the calorie intake but have a bulking action in the colon. [14] Fibre intake is recommended on the basis of gender, age and BMI or energy requirement per day. Adequate fibre intake is 14g/1000 Kcal/ day. For adult woman and men daily intake ranges from 25g/day to 40g/day. [15] Fibre has maximum health benefit when consumed in accordance with recommended levels. But most of the people eat only half the recommended levels, so supplementation is very much required to bridge the fibre gap created as a result of low intake and increased requirement. [16] Fibre has been classified as soluble and insoluble, on the basis solubility. Lignin, hemi-cellulose and cellulose are insoluble in water, while gums, pectin and mucilage are soluble in water, and become gummy when added to water. [17] Insoluble fibre provide bulk to the faecal matter, while soluble fibre is linked with improved blood sugar level, blood lipid profile and early as well as prolonged satiety because of gel formation, viscosity and fermentability. [18][19]
Different physiological effects of soluble fibre in the body are: greater viscosity in the gastro-intestinal tract, full or partial fermentation in the colon and finally excretion as a prebiotic effect.[20][21][22] Soluble dietary fibres doesn't undergo digestion, but are fermented into colon resulting in the production of SCFAs (Short Chain Fatty Acids). SCFAs regulate the secretion of various peptides, namely CCK, GLP-1 and PYY, which regulates the appetite. These peptides help in reducing food intake and improving perceived satiety. [23] Glycaemic response, body weight, metabolic diseases, inflammatory diseases and even energy intake or absorption of nutrients is affected by the presence of micro biota and its ability to ferment fibre in the lumen of gastrointestinal tract. [24]With researches, it has been also shown that fibre intake reduces insulin and glucose response in hypertensive, diabetic, hypercholesterolaemic and normal subjects. [20][25] The impetus of the study was to establish quantitatively and systematically the impact of fibre supplementation on body weight of obese or overweight adults. We hypothesised that fibre supplementation and weight reduction are positively related, that is with increased fibre intake there is a reduction in body weight.

METHODS

Study Selection Criteria

Selection of the studies was done on the basis of inclusion criteria and exclusion criteria. We selected double blind, placebo controlled, randomized trials involving participants of age ≥ 18 years; were either obese or overweight having BMI ≥ 25.0 kg/m^2, [2] or waist-to-hip ratio ≥0.90 in men and ≥ 0.85 in women,[26] or waist circumference ≥ 94 cm in men and ≥ 80 cm in women [27]; devoid of any chronic or metabolic disorder (at the time of screening); weight stable at the time of screening and were not trying to lose weight in any way (not undergoing counseling, diet therapy, pill or detox therapy to reduce weight).Double blind study is one in which neither the participant nor the researcher knows who is receiving a particular treatment, so are devoid of bias of selection, observation bias and confirmation bias. [28] RCTs (Randomized Control Trials) are selected because they are considered as corner stone in intervention of clinical researches and also offer the highest level of evidence. [29] Studies were excluded if were done on animals; studies conducted on people of age below 18 years; studies without placebo group; study involving whole food treatments for weight reduction; study conducted in less than 6 weeks; observational studies; mechanistic researches, conference proceedings and paper published in any language other than English were also excluded from the study.

Search Strategy

Electronic searches of peer reviewed articles were done from the different bibliographic databases including CENTERAL (https://www.cochranelibrary.com/collections/doi/SC000043/full), PubMed (https://pubmed.ncbi.nlm.nih.gov/) and Scopus® (https://www.elsevier.com/en-in/solutions/scopus). Additional searches using Google scholar, reference lists (backward reference search) and citation lists (forward reference search) of relevant articles were also done.CENTRAL (Cochrane Central Register of Controlled Trials) was selected as it contains largest database and is the most comprehensive source for reporting RCTs. Scopus was chosen because it contains largest database for scientific journals. While PubMed contain more than 30 million databases, from life science journals and MEDLINE. Search strategy off all the databases was done over a period of 24 days (5 May 2020 to 29 May 2020).

Data Extraction

Individual screening of the retrieved study's title and abstract were done. Full-text articles were then reviewed to check the requirements for the inclusion criteria and exclusion criteria. Primary and secondary data extraction of the selected studies was done. Primary data extraction was done so as to find out the studies investigating the effect of fibre on weight change as outcome measure. While, secondary data extraction was done to exclude studies that did not match inclusion criteria, were single blind; were devoid of placebo group or didn't fit into the definition of RCT. Data extraction included double blind, placebo controlled RCTs. The selected studies were then assessed for information including author information, study design, fibre intervention duration, fibre dosage, study population, treatment group size, study completer population, outcomes of the study, effectiveness of the study, and publication year. Outcomes of the study included results of interest like change in body weight.

Study Evaluation and Data Synthesis

Cohen's d (effect size) was measured for studying primary outcomes of the studies. It was calculated by using difference in the mean and SD (standard deviation) for change in weight between control group and experimental group. The effect size was quantified as small, medium and large on the basis of values 0.2, 0.5 and 0.8 respectively. Both positive and negative values were obtained for the effect size. Negative value is an indication of intervention favouring treatment, while positive value favours placebo effect. [30]For the studies without exact outcome measures of mean and SD, manual calculations were done to get Cohen's d. [31] Study was excluded from the analysis, if the effect size could not be calculated.

Secondary outcomes were calculated .manually in MS-Excel. Cochran's Q and I^2 were calculated for secondary outcomes. Calculations in MS-Excel were done in accordance to Neyeloff, Fuchs and Moreira. [32] Calculation of Cochran's Q was done by taking weighted sum of squared difference between each study effects and the pooled effect across the studies with the weight used in the pooling method. Degree of freedom was represented as df, and was calculates as, df = (k-1), where k is the total number of studies used in analysis. Q value was distributed as (χ^2) (chi-square) statistic. We also assessed heterogeneity between studies by calculating I^2 statistic. [33] I^2 was calculated using formula ((Q-df)/Q)*100, where Q is Cochran's heterogeneity statistic, and df is degree of freedom. Interpretation of I^2 was done as 30% is considered low heterogeneity; 30-75% is considered as moderate and above 75% is considered as high heterogeneity. [34][35] The random-effect model will be used if the heterogeneity ≥50%, while for heterogeneity < 50% a fixed-effect model will be used. The effect size was statistically pooled manually in the meta-analysis and presented as forest plot made using MS-Excel. [32]

Study quality and Risk of bias assessment

Studies were evaluated using Heyland Methodological Quality Score (MQS) and Jadad scale. MQS quantifies methodological quality of studies on the basis of 9 criteria, namely, randomization, analysis, binding, patient selection, extent of follow up, treatment protocol, equal application of co-interventions, baseline group compatibility and outcomes. [34] Studies were score on a scale of 1-14, studies with score 8 and above were considered as high quality trials. We also used Jadad scale to assess the risk of bias. It is a 5 point scale, it takes blinding, randomization, and drop-outs into consideration. Studies with score 3 are considered as moderately biased, above 3 as low bias and below 3 are considered as highly biased. [36].

RESULTS

Study Selection

12,922 citations were generated after initial search (1280 from Scopus, 8610 from PubMed and 3032 from CENTRAL); among which 5759 studies were found to be duplicate. 7163 abstracts remained after removal of duplicate studies. Further, 6891 studies were removed on the basis of screening of title and abstract. 272 studies were selected for full text review; out of which 263 studies were rejected on the basis of study selection eligibility criteria. 9 articles met the defined study selectioneligibility criteria, and were included in the qualitative analysis. Subsets of 7 studies were included for the quantitative analysis or meta-analysis. Study selection based on PRISMA search strategy is illustrated in Figure 1.

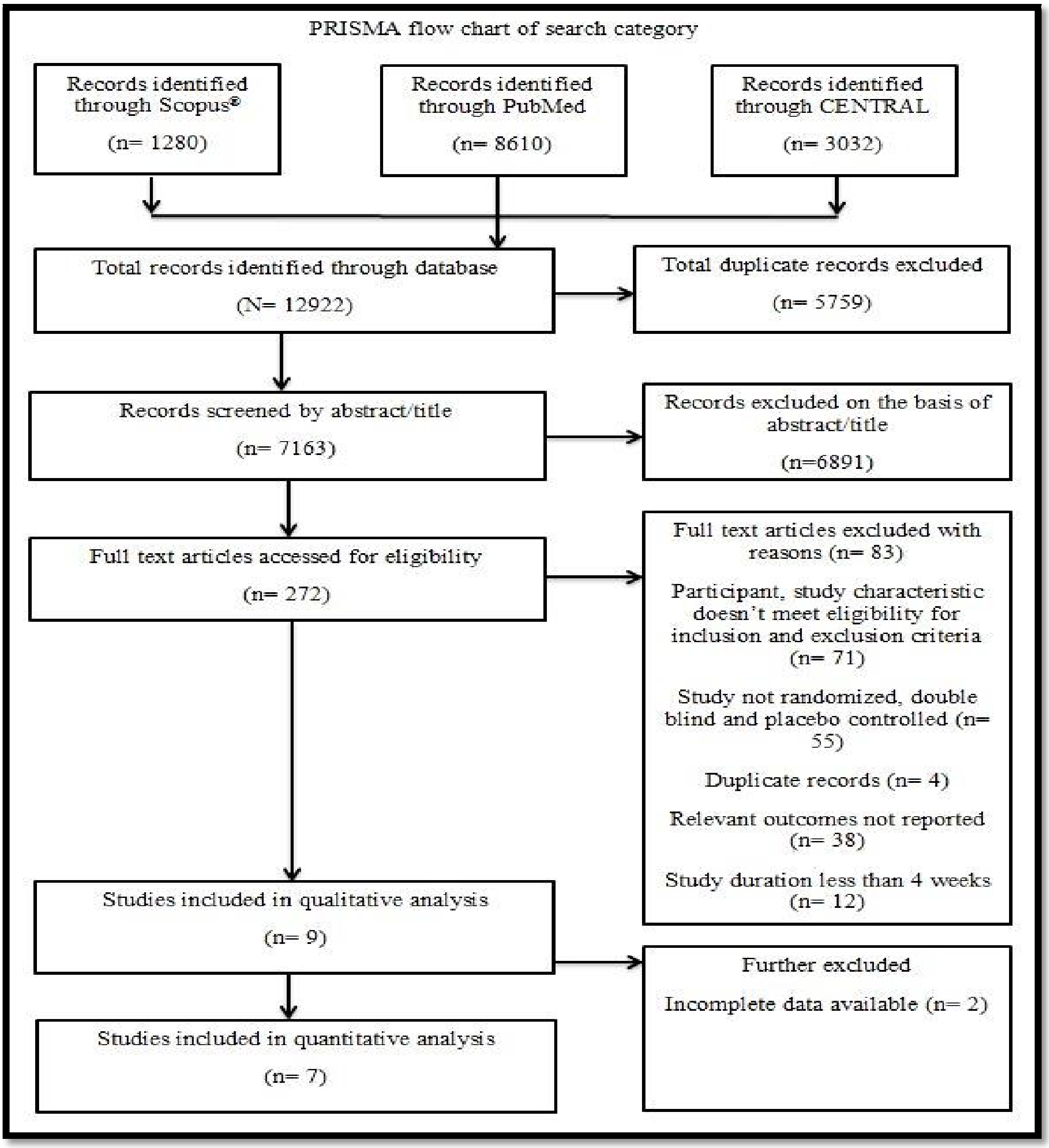

Figure 1: Search category PRISMA flow chart

Study and participant Characteristics

We included 9 studies involving 11 interventional studies with 932 (ranging from 24 to 200) participants that were published between 2003 till 2016. We assessed fibre supplementation in overweight and obese adults in both qualitative and quantitative analysis. All the included studies were double-blind and placebo-controlled RCTs, with intervention duration from 6 weeks till 52 weeks. Studies included 12 dietary fibres. [37][38][39][40][41][42][43][44][45] A total of 10 dietary fibres were identified, namely, litramine (n= 2), alginate (n=1), glucomannan (n= 3), N-oleyl-phosphatidylethanolamine (NOPE) (n=1), epigallocatechin-3-gallate (EGCG) (n= 1), PolyGlycopleX (n= 1), Psyllium (n= 1), Oligofructose (n= 1),*Plantago ovata* husk (n= 1) and chitosan (n= 1).Placebo treatment given to control groups very identical to the fibre treatment. Identified placebo given in different studies are microcrystalline cellulose (n= 4), Maltodextrin (n= 2), sucrose (n= 1) and rice flour (n= 3). All the 9 studies were carried out both on males and females. Four studies were conducted in the province of North America, four in the Europe and one in Australia. All the 9 studies were included in the qualitative analysis, but only 7 were included in the quantitative analysis. [37][38][39][40][43][44][45] Fibres were given in the form of powder (to be mixed with water) or in the form of capsules.Summary of the all 9 RCTs are given in Table 1.

Outcome measures

The outcome measures in our review are weight change. All nine studies investigated the effect of fibre on the weight change between control and treatment groups. 7 studies favoured treatment, but only three studies reported significant differences in the mean weight loss of obese adults in treatment and control groups. [37][39][44]

Study, year	Fibre treatment	Placebo treatment	No. of treatment/ day	Duration	Study population	Sample size	Outcomes measured
Grube, 2013	Litramine (IQPG- 002AS)	Microcrystalline cellulose	3 (after meals)	12 weeks	Age: 18- 60 years BMI: 25- 35 Kg/m^2	125; Fibre: 62; Placebo: 61	Weight loss more in fibre group
Grube, 2015	Litramine (IQPG- 002AS)	Microcrystalline cellulose	3 (with meals)	24 weeks	Age: 18- 60 years BMI: 25- 35 Kg/m^2	50; Fibre: 25; Placebo: 24	Weight loss more in fibre group
Jensen, 2012	Alginate	Maltodextrin and sucrose	3 (before meals)	12 weeks	Age: 20- 55 years BMI: 30- 45 Kg/m^2	96; Fibre: 38; Placebo: 42	Weight loss more in fibre group
Keithley, 2013	Glucomannan	Microcrystalline cellulose	3 (1 hour before meals)	8 weeks	Age: 18- 65 years BMI: 25- 35 Kg/m^2	53; Fibre: 26; Placebo: 27	Weight loss more in fibre group
Mangine, 2012	PhosphoLean {blend of N-oleyl-phosphatidylethanolamine (NOPE) and epigallocatechin-3-gallate (EGCG)}	Rice flour	3 (1 before lunch, 2 before dinner)	8 weeks	Age: 18- 59 years BMI: 25- 40 Kg/m^2	50; Fibre: 25; Placebo: 25	No difference between the groups
Pal, 2016	I- PolyGlycopleX® (PGX®) II- Psyllium product (PgxSyl™) (PSY)	Rice flour	3 (10 minutes before meals)	52 weeks	Age: 19- 67 years BMI: 25- 47 Kg/m^2	159; PGX- 39; PSY- 43; Placebo- 45	Weight loss more in PGX followed by PSY
Parnell, 2013	Oligofructose	Maltodextrin	3 (before meals)	12 weeks	Age: 20- 70 years BMI: > 25 Kg/m^2	48; Fibre: 21; Placebo 18	No difference between the groups
Salvado, 2008	Mixed fibre (3g Plantago ovata husk and 1 g glucomannan)	Microcrystalline cellulose	Twice or thrice	16 weeks	Age: 18- 70 years BMI: 27- 35 Kg/m^2	200; b.i.d.: 53, t.i.d.: 58; Placebo: 55	Weight loss highest in t.i.d., followed by b.i.d.
Woodgate, 2003	Glucomannan, chitosan, fenugreek, *G. sylvestre*, vitamin C	Rice flour	2 capsule 3 times (1 hour before meal)	6 weeks	Age: 20- 50 years BMI: $\geq$ 30 Kg/m^2	24; Fibre: 12; Placebo: 12	Weight loss more in fibre group

Table 1: Summary of RCTs included in the systematic review (n= 9).

It was observed that maximum reduction in body weight is observed in the subjects supplemented with alginate. Effect size of different fibres on body weight showed a varying result, for Jensen's alginate effect size was found to be -0.49 (medium effect favouring treatment) and effect size of Keithley's glucomannan was 0.045 (small effect, favouring placebo). Effect size value for Grube'13 was -1.07 and for Grube'15 was -1.47. Effect values for b.i.d. and t.i.d. groups of Salvado's mixed fibre are -6.54 and -6.74 respectively. Cohen's d value for Woodgate's capsule is -1.33 and for Parnell's Oligofructose was -1.52.

Study quality and Risk of bias

Risk of bias is quantified within a study by quantifying double-blinding, randomization, drop-outs or withdrawals, method of blinding and method of randomization. [36] Risk of bias was high in studies having score below 3, moderate if score is 3 and low if score more than 3. Risk of bias was low in 4 studies [37][38][44][45] and moderate in rest of the 5 studies. [39][40][41][42][43] Calculation of Jadad score is shown in Table 2.

In accordance to the MQS, all the studies were considered as high quality with scores more than 8. 5 studies out of 9 used statistical procedure of intention-to-treat (ITT). [37][38][39][40][44] All the studies showed equal intervention to both the treatment and control groups. All the studies were double blind and randomized. About less than half (45%) of the total studies provided a detailed description of study procedures and outcomes.According to the Cochrane Risk of Bias Tool, all the studies have low risk of bias. The MQS calculations are depicted in Table 3.

Study	Randomization	Double- blind	Withdrawal and drop-outs	Method of randomization	Method of blinding	Scores
Grube, 2013	1	1	1	1	0	4
Grube, 2015	1	1	1	1	0	4
Jensen, 2012	1	1	1	0	0	3
Keithley, 2013	1	1	0	1	0	3
Mangine, 2012	1	1	1	0	0	3
Pal, 2016	1	1	1	0	0	3
Parnell, 2013	1	1	1	0	0	3
Salvado, 2008	1	1	1	1	0	4
Woodgate, 2003	1	1	1	1	0	4

Table 2: Jadad score of RCTs (n= 9)

Study, Year	Randomization	Analysis	Blinding	Patient Selection	Treatment Protocol	Comparability of groups at baseline	Extent of follow-up	Equal application of co-interventions	Outcomes	Total
Grube, 2013	2	2	2	0	1	1	2	2	2	14
Grube, 2015	2	2	2	0	1	1	2	2	2	14
Jensen, 2012	2	2	2	0	1	1	2	2	2	14
Keithley, 2013	2	2	2	0	1	1	2	2	2	14
Mangine, 2012	2	1	2	0	1	1	1	2	1	11
Pal, 2016	2	1	2	0	1	1	2	2	1	12
Parnell, 2013	2	1	2	0	1	1	2	2	1	12
Salvado, 2008	2	2	2	0	1	1	2	2	1	11
Woodgate, 2003	2	1	2	0	1	1	2	2	1	12

Table 3: MQS of RCTs (n= 9)

Meta-analysis on body weight

There was a high heterogeneity in the studies selected for meta-analysis (I^2= 95.79%), so we selected the random effect model for the analysis of the studies. The effect size ranges from very small (d= -0.49, p= 0.03) to very large (d= -6.74, p= 0.03). One study favoured control group with positive effect size (d= 0.045, p= 0.05). Mean weight loss favours no particular group, because of close similarities in result, but for individual series, Jensen, 2012 [39] favours treatment group the most. Three other studies favours the mean weight loss [37][38][45], while rest of the 5 slightly favours the placebo or no effect between the groups are seen. [40][41][42][43][44] In 31.81% cases, fibre supplementation helps in the body weight reduction in obese or overweight adults. However, the overall effect of weight loss can be contributed to exercise, hypo calorie diet and other dietary interventions. A forest plot was drawn using MS-Excel and is depicted in the Figure 3. Results on the positive side of the mean weight loss effect line favours treatment, while values on the negative scale of left side favours placebo. The results on the left side of the graph show that there is no specific effect of dietary fibre on weight loss.

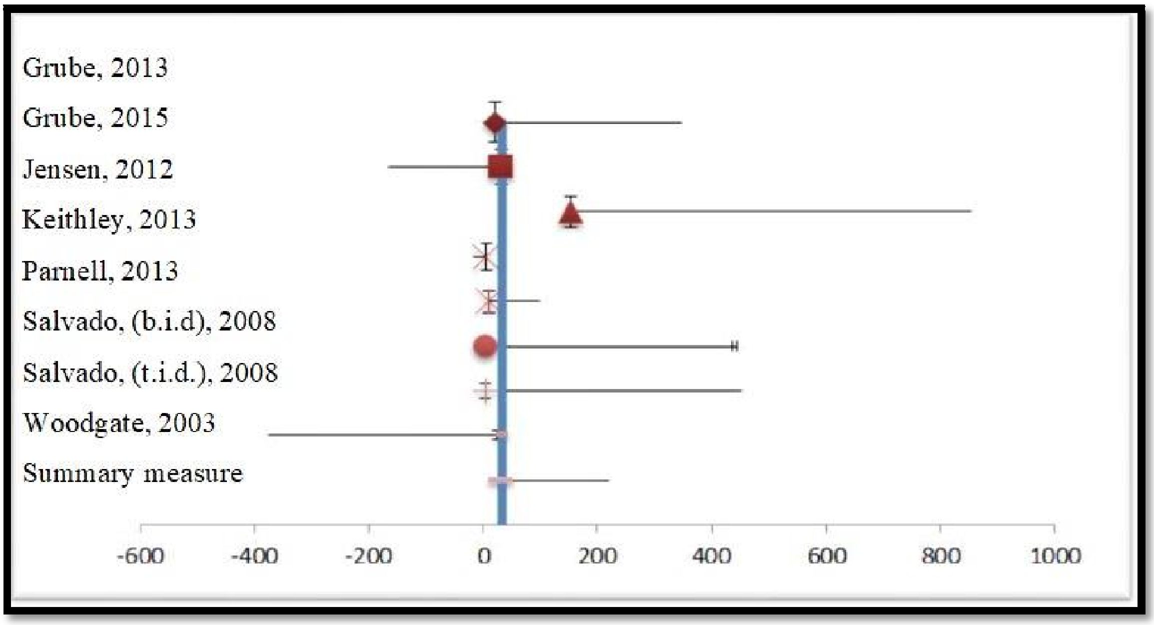

Figure 2: Forest plot depicting effect of different fibres on the weight loss in obese and over-weight adults.

DISCUSSION

Ten different fibres were identified from different literature. Identified fibres are alginate, litramine, NOPE, EGCG, PolyGlycopleX, glucomannan, Psyllium, Oligofructose, *Plantago ovata* husk and chitosan. Maximum body weight loss was achieved by alginate consuming fibre, followed by a mixed supplement of *Plantago ovata* husk and glucomannan. The risk of bias was high in the studies; five out of nine studies clearly depicted the method of randomisation used.

Our systematic review and meta-analysis of double blind, placebo controlled RCTs revealed significant reduction in the body weight of obese and over-weight adults after consuming fibre supplementation. Meta-analysis performed on body weight revealed significant and clinically meaningful reduction in body weight, when compared to the placebo group, by -3.33 (-2.78, -1.57) kg (here minus sign indicates reduction in the body weight). Improvement in the metabolic reactions of the body can be seen even with the slightest reduction in the body weight. With reduction in one kilogram of body weight, risk of getting type II diabetes is decreased by 16 per cent. [46] Reducing weight by 2-5 per cent of the total reduces the risk of getting cardio vascular diseases (CVD) by improving the fasting blood glucose levels and gylcated haemoglobin. [47] Viscous, fermentable and soluble fibre is advised for controlling calorie intake and reducing body weight. [48] With some researches it has been also found that consuming non-viscous, fermentable fibre also helps in reducing body weight and improving metabolic reactions in the similar was as done by the viscous fermentable fibre. [49] The weight loss mechanism and improvement in the metabolic reactions can be related to the difference in the length of the polymer chain and degree of fermentability between different types of fibres. Glucomannan has found to be more effective than soluble dextrin, when compared on the basis of impact per gram on metabolic or anthropometric outcomes. [50][51]

In this review we focused on the primary outcome of weight loss of obese and over-weight, otherwise healthy adults. All the studies had control group and placebo group. 7 studies had one group each of placebo and control. [37][38][39][40][41][43][45] While, 2 studies had two placebo and one control group. [42][44]
Limitations of the study conducted were: the number of the studies included was small. The level of heterogeneity was high among the studies. Only one outcome measure was taken into consideration for evaluation, that is, body weight. Despite proper intake of fibres, some studies showed no impact of fibre on the body weight when compared to placebo. [41][43] Our study considered only over-weight and obese otherwise healthy adults, so our findings may not be generalised to adults with normal BMI or to obese/over-weight children and on to people with chronic diseases.
Our study had various methodological strengths as well. We included high-quality studies with the low risk of biasness. We selected studies over a fine drawn exclusion and inclusion criteria. We removed the confounding variables such as weight loss counselling and chronic diseases by taking into consideration only health adults with BMI greater than 24.9, and devoid of any chronic disease.

CONCLUSION
In this review and meta-analysis, it is evident that fibre can be used potentially as an ingredient for the formulation of supplements for achieving weight loss. Fibres might play a role in decreasing energy intake by helping in achieving early satiety, and hence should be considered while planning diets for weight loss. However, all fibres do not act in a similar manner, and some may not help in reducing energy intake. Further researches should be done so as to get the maximum benefit on improving body weight and metabolic rate of the body by the action of different fibres. We suggest that the supplement should be given as preload, and its food matrix is important in reducing body weight. In conclusion, because we observed improvement in body weight of the selected population fibre supplementation can be given for reducing body weight and improving metabolic rate of the body.

WORD OF CAUTION
Supplementation of fibre should only be taken after consulting a physician or any dietician.

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