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Original article

The effect of fiber supplementation on insulin resistance in children with obesity: a randomized controlled clinical trial

Shrouk Moataz Abdallah[1], Hannah Mohamed Aboulghar[1], Hend Mehawed Abdel Latif Soliman[1], Radwa Marawan Abdel Halim[2], Marwa Ahmed Sedkey[1]

[1]Department of Pediatrics, Cairo University, Cairo, Egypt

[2]Department of Clinical and Chemical Pathology, Cairo University, Cairo, Egypt

Abstract

Introduction: Childhood obesity often results in insulin resistance (IR) and may cause type 2 diabetes. Fibers are described as a dietary intervention controlling hyperglycemia; however, their effect on obese children is understudied.

Aim: To assess the effect of fiber supplementation on IR in obese children.

Methods: A randomized controlled trial was carried out at Cairo University Children's Hospital (Cairo, Egypt), including 123 obese children aged 6-13 years. Two-step double blind randomization using sealed envelopes was done. Step 1: randomization into an intervention group (82 subjects) and control group (41 subjects). Step 2: randomization of the intervention group for either receiving 10 g/day of powdered psyllium or a high fiber diet. Fasting insulin, glucose, C-peptide and homeostatic model assessment of IR (HOMA-IR) were measured at baseline and after 8 weeks for all participants.

Results: Fasting glucose, insulin, C-peptide and HOMA-IR were significantly reduced with psyllium ($p < 0.001$ for all) and natural fibers ($p = 0.001$, < 0.001, < 0.001 and < 0.001, respectively), while they were increased in the control group ($p = 0.09$, 0.006, 0.015 and < 0.001, respectively). The median percent of change from baseline for HOMA-IR was -26.47% and -42.55% compared to +9.38% for the natural fiber group, psyllium group and controls, respectively. Psyllium induced better HOMA-IR profiles as compared to the other 2 groups ($p < 0.001$). Both interventions similarly reduced BMI and waist for height z-scores compared to the control group. We report no serious side effects of psyllium; however, unpalatability was a frequent complaint (40.5%).

Conclusion: Both psyllium and natural fibers improved IR in obese children but this improvement was more pronounced in the psyllium group.

Keywords

Fiber, HOMA-IR, insulin resistance, obesity, psyllium.

Corresponding author

Shrouk Moataz Abdallah, Lecturer of Pediatrics, Faculty of Medicine, Cairo University, Cairo, Egypt; email: shroukmoataz14@gmail.com.

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Introduction

Obesity in early childhood is increasing at an alarming rate. The number of children and adolescents (5-19 years) with obesity worldwide has risen 10-fold in the past 4 decades. It was predicted to be more than underweight by 2022 [1]. It is a major risk factor for insulin resistance (IR) and type 2 diabetes mellitus (T2DM). Importantly, early T2DM has become more aggressive with severe IR, insulin hypersecretion, rapid β-cell deterioration, and unfortunately poorer response to usual therapies [2, 3]

The causes of obesity are multifactorial and include genetic predisposition, sedentary lifestyle, overeating, fast-food diet, lack of adequate nutritional education, school environment, and advertising and marketing of unhealthy foods [4]. Socioeconomic status plays also a major role in childhood obesity and is reflected in a variety of downstream characteristics. Childhood obesity is exacerbated by parental high school levels, which are linked to socioeconomic class [5]. The aim of nutritional management of IR in children with obesity is to prevent the progression of prediabetes to diabetes [6]. This may be achieved by restriction of high intake of sugars and fats and increasing dietary fibers (DF) [1]. In several studies, an increased intake of total DF was inversely associated with markers of IR [7]. This effect may be mediated by several mechanisms that may differ over acute and longer time frames, depending on specific chemical and physical characteristics of the DF and the food matrix in which the fiber is found [8, 9]. The relationship between fiber intake and IR was a point of interest to researchers. However, this relationship is understudied in children and adolescents with obesity. The current study aimed to evaluate the effect of fiber supplementation on IR in children with obesity.

We chose psyllium husk as a safe supplementary fiber that was previously studied in treatment of constipation and regulation of symptoms of irritable bowel syndrome in pediatric age group with no reported serious side effects [10]. It did not alter breath hydrogen or methane production, gut permeability, or microbiome composition as reported by Shulman et al. [10]. Being available and relatively affordable supplement is another reason for our choice. The study aimed to evaluate the benefit of adding a supplementary fiber compared to increasing DF in achieving better body mass indices and IR profiles.

Patients and methods

Patients

A total of 123 eligible children following at Cairo University Children's Hospitals (Cairo, Egypt) were recruited.

Inclusion criteria

Children between 6-13 years of both sexes, with exogenous obesity (defined as body mass index [BMI] greater than 2 standard deviations "z" score) with normal height (defined as a "z" score between -2 to +2 standard deviations) on the WHO Growth Reference Standards [11].

Exclusion criteria

Patients with iatrogenic or syndromic obesity and subjects who had any co-morbid chronic diseases (except for IR).

Clinical methods

Sample size calculation

The required sample size has been calculated using the G*Power software version 3.1.9.4 (Universität Düsseldorf, Germany). The primary outcome is the change in IR as measured with homeostatic model assessment of IR (HOMA-IR). No previous study has compared the effect of fiber supplementation or high-fiber diet versus control on the change in HOMA-IR. So, the present study would target an effect size that is clinically important. Therefore, it is estimated that a sample size of 37 patients in each group (total 111 patients) would have a power of 80% to detect a medium effect size equivalent to an f(V) of 0.3 with a confidence level of 95% (alpha error = 0.05) using a multi-factorial repeated measure analysis of variance (MANOVA) test. This calculation assumed that 2 measurements will be taken on each patient (pre- and post-treatment) and that the numerator (k-1) and denominator (n-k) degrees of freedom are 2 and 108 respectively, where k is the number of groups and n is the total sample size [12]. Assuming a drop-out rate of about 10%, 123 patients will be recruited (41 patients per group).

Registration and ethical approval

The study protocol was approved by Cairo University Ethical Committee (approval code: MD-40-2019). It was registered at the Pan African Clinical Trial Registry with identification number PACTR202202746907105.

Randomization

This study is a double-blind randomized controlled clinical trial enrolling participants fulfilling the inclusion criteria. Randomization was done by one of the authors. It was done in 2 steps using sealed envelopes. Patients were randomized at step 1 into intervention (82 participants) and control groups (41 participants). The intervention group was further randomized into the psyllium group, which received 10 g of psyllium once a day, and the natural fiber group, which received high fiber diet.

Data collection

The following data were collected at baseline and after 8 weeks in the 3 studied groups.

- Anthropometric measurements: weight, height, BMI and waist circumference were obtained and z-scores were calculated using WHO AnthroPlus software for the global application of the WHO Reference 2007 for 5-19 years [11]. Measures were taken by the clinical nutrition nurses including one layer of clothes and without shoes using Clinical Nutrition Clinic scales.
- Dietary assessment through 24 h dietary recall and analysis of dietary content of total calories, proteins, fat (total fat, saturated fat, cholesterol), and fibers was performed according to the *2nd Edition* of *Food composition tables for Egypt* [13]. The recalled caloric intake was calculated as a percent of target caloric requirements of age- and sex-matched healthy children [14].
- General counseling: All the 3 groups attended a 45-min counselling session with a well-trained dietitian at Clinical Nutrition Clinic about healthy eating habits using MyPlate.gov [15, 16]. Counseling involved: benefits of healthy eating add up over time; making half the plate fruits and vegetables (whole fruits and variable veggies); making half the grains whole grains, eating a variety of protein foods (lean animal protein and plant based), ensuring adequate intake of low-fat dairy products and plenty of water.
- Daily recommended intakes (DRIs) of DF were determined according to age and gender from the Food Nutrition Board [17]. The exchange list of the *2nd Edition* of *Food composition tables for Egypt* was used to transform the required doses of DF into food servings [13].
- Administration of psyllium: 10 g of powdered psyllium husk is dissolved to 200 mL cold water or 100% unsweetened orange juice, given as a single dose before lunch. Another 200 mL of water is administered immediately after psyllium dose. Participants and caregivers were counseled about palatability and instructed to report any abnormal gastrointestinal symptoms.
- A follow-up phone call was made once weekly for all the 3 studied groups to ensure compliance to the general counseling and the prescribed regimen, and in addition, to ask about gastrointestinal side effects of psyllium or DF through a simple checklist including gastrointestinal symptoms, palatability and adherence to the prescribed doses.

Laboratory methods

Insulin resistance profile

Three mL of venous blood was collected after 8 hours of fasting in a sterile vacutainer. Samples were left to clot at room temperature and then centrifuged at 3,000 rpm for 10 minutes. Fasting blood glucose samples were analyzed on Roche Cobas 6000 c501 Chemistry Analyzer (Roche Diagnostics Corporation, Indianapolis, IN, USA). Commercially available DRG ELISA kits (DRG International, Inc., USA) were used for measurement of fasting serum insulin and C-peptide. Calculation of IR was done using HOMA-IR = fasting glucose x fasting insulin/405 for mass units (fasting glucose in mg/dL and fasting insulin in μIU/mL) [18].

Statistical analysis

Data were collected, revised, coded and entered into the Statistical Package for Social Science® (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when parametric and median and inter-quartile range (IQR) when data found non-parametric. The comparison between 2 groups with qualitative data was done using the Chi-square test and/or Fisher exact test, and quantitative data were compared using the t-test or Mann-Whitney test. Comparison between more than 2 groups regarding quantitative data was done by using the one-way ANOVA test followed by the LSD test or Kruskal-Wallis test followed by the Mann-Whitney test. Spearman correlation coefficients were used to assess the correlation between two quantitative parameters. The confidence interval was set to 95% and the margin of error accepted was set to 5%. The p-value was considered significant when p-value was < 0.05.

Results

The study included 123 participants fulfilling the inclusion criteria. Twelve patients were excluded due to discontinuation of the supplement, unwillingness to cooperate, family issues, and loss of follow-up (**Fig. 1**). The study was completed with 111 participants including 58 males (52.2%) and 53 females (47.7%), with a mean age of 9.68 ± 2.15 years and median (IQR) BMI z-scores of 3.56 (2.99; 4.85). They consumed a median (IQR) of 100% (65.59%; 131.47%) of their target caloric

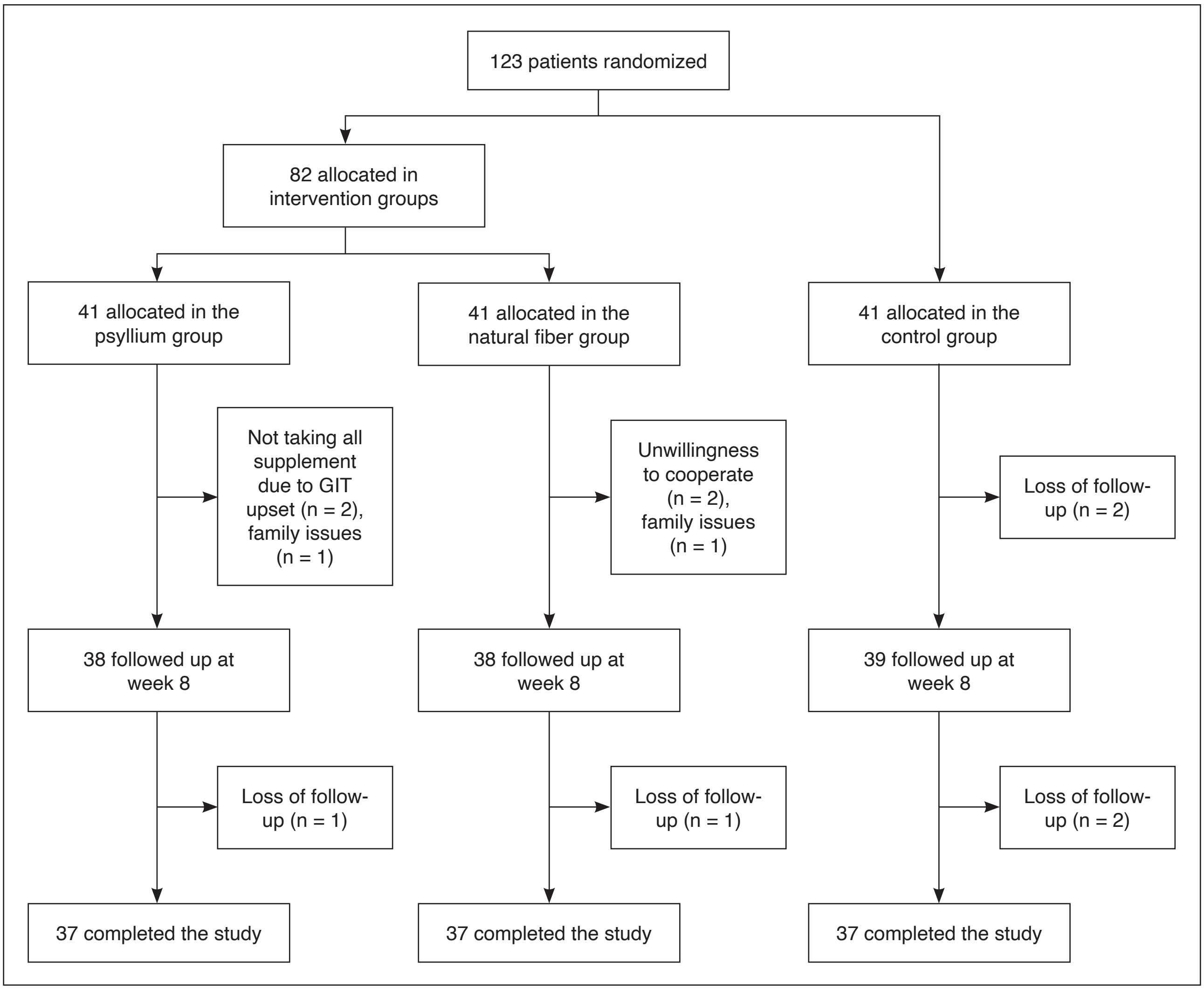

Figure 1. Flow chart of the enrolled patients in the 3 studied groups.
GIT: gastrointestinal tract.

requirements and a median (IQR) of 16.64% (13.1%; 25.81%) of their target DRIs of DF.

At baseline, there were no statistically significant differences between the 3 studied groups in demographic characteristics, dietary intakes or anthropometric measurements. Regarding the IR profile, the control group showed significantly lower levels of insulin (median [IQR]: 14.2 [9.3; 21.2] μIU/mL) and C-peptide (median [IQR]: 2.49 [1.8; 3.7] ng/mL) at baseline than both intervention groups (p = 0.046 and 0.013, respectively), with no similar significant differences in fasting glucose or HOMA-IR.

All parameters of IR (fasting glucose, insulin, C-peptide and HOMA-IR index) were significantly reduced in both intervention groups after 8 weeks (**Tab. 1**) compared to the control group (**Tab. 2**). Median percentage change from baseline for glucose was -5.26% and -7.61% in the natural fiber group and psyllium group, respectively, compared to +2.97% in controls. It was -21.13% and -33.76% compared to +7.14% for insulin, -14.29% and -20.51% compared to +10.87% for C-peptide, and finally -26.47% and -42.55% compared to +9.38% for HOMA-IR (**Tab. 2**, **Fig. 2**).

Table 1. Comparison of data of at baseline and 8-week after intervention for the 3 groups.

Group	Variable		At baseline	8-week after intervention	p
Psyllium group	Dietary recall (24 h), median (IQR)	Total calories/target calories per day (%)	98.1 (71.1; 133.53)	67.65 (50.53; 93.24)	**< 0.001**
		Fat calories/total calories per day (%)	32 (19.23; 38.55)	23.79 (18.04; 30)	**< 0.001**
		Fibers/DRI for age (%)	21.78 (12.21; 26.57)	67 (61.26; 78)	**< 0.001**
		Fiber g/1,000 kcal (g)	3.05 (1.71; 3.72)	13.66 (10.45; 18.75)	**< 0.001**
	Anthropometry, median (IQR)	BMI (z-scores)	3.25 (3.09; 4.85)	3.21 (2.73; 4.56)	**< 0.001**
		Waist for height (z-scores)	2.04 (1.85; 2.33)	1.78 (1.47; 2.02)	**< 0.001**
	Fasting glucose (mg/dL), mean ± SD		97.11 ± 9.21	87.7 ± 10.58	**< 0.001**
	Fasting insulin profile, median (IQR)	Insulin (μIU/mL)	15.7 (12.4; 22)	9.75 (7.6; 13.6)	**< 0.001**
		C-peptide (ng/mL)	33 (2.7; 4)	2.8 (2.2; 3.2)	**< 0.001**
		HOMA-IR	3.6 (2.9; 5.2)	2.1 (1.6; 2.7)	**< 0.001**
Natural fiber group	Dietary recall (24 h), median (IQR)	Total calories/target calories per day (%)	95.58 (64.19; 131.47)	64.71 (49.87; 49.12)	**< 0.001**
		Fat calories/total calories per day (%)	29.85 (23.67; 34.78)	33.33 (27.8; 38.92)	**< 0.001**
		Fiber g/DRI for age (%)	13.87 (11.5; 21.68)	36.32 (31.54; 44.13)	**0.001**
		Fibers/1,000 kcal (g)	2.32 (1.62; 3.42)	8.92 (5.19; 10.01)	**< 0.001**
	Anthropometry, median (IQR)	BMI (z-scores)	3.44 (2.86; 4.13)	3.22 (2.36; 3.53)	**< 0.001**
		Waist for height (z-scores)	2.15 (1.88; 2.45)	1.91 (1.64; 2.21)	**< 0.001**
	Fasting glucose (mg/dL), mean ± SD		97.76 ± 8.77	1.35 ± 10.24	**0.001**
	Fasting insulin profile, median (IQR)	Insulin (μIU/mL)	17.8 (10.5; 28.3)	11.6 (9.2; 17.4)	**< 0.001**
		C-peptide (ng/mL)	3.5 (2.6; 4.1)	2.6 (2.1; 3.5)	**< 0.001**
		HOMA-IR	4.2 (2.5; 6.2)	2.6 (2.1; 4.5)	**< 0.001**
Control group	Dietary recall (24 h), median (IQR)	Total calories/target calories per day (%)	101.47 (75.57; 114.29)	94.51 (80.39; 131.48)	0.703
		Fat calories/total calories per day (%)	31.39 (23.79; 33.62)	30 (27.27; 36.4)	0.509
		Fibers/DRI for age (%)	19.44 (15.32; 25.37)	17.56 (14.21; 23.84)	0.313
		Fiber g/1,000 kcal (g)	4.7 (3.75; 7)	2.46 (1.99; 3.34)	0.245
	Anthropometry, median (IQR)	BMI (z-scores)	3.7 (2.99; 5.29)	3.82 (2.95; 5.22)	0.613
		Waist for height (z-scores)	2.19 (1.85; 2.62)	2.28 (1.95; 2.66)	**< 0.001**
	Fasting glucose (mg/dL), mean ± SD		93.73 ± 9.48	96.54 ± 9.75	0.09
	Fasting insulin profile, median (IQR)	Insulin (μIU/mL)	14.2 (9.3; 21.2)	15.9 (12.9; 23.5)	**0.006**
		C-peptide (ng/mL)	2.49 (1.8; 3.7)	2.9 (2.2; 4.2)	**0.015**
		HOMA-IR	3.1 (2.1; 4.9)	3.9 (3.1; 5.2)	**< 0.001**

BMI: body mass index; DRI: daily recommended intake; HOMA-IR: homeostatic model assessment for insulin resistance; IQR: interquartile range; SD: standard deviation.

Table 2. Comparison of the 3 studied groups at week 8 of the intervention.

Variable		Control group	Natural fiber group	Psyllium group	p
Dietary recall (24 h), median (IQR)	Total calories/target calories per day (%)	95.51 (80.39; 131.48)[a]	64.71 (49.87; 49.12)[b]	67.65 (50.53; 93.24)[b]	**0.001**
	Fat calories/total calories per day (%)	30 (27.27; 36.4)[a]	33.33 (27.8; 38.92)[a]	23.79 (18.04; 30)[b]	**0.001**
	Fibers/DRI for age (%)	18 (14.24; 24.64)[a]	36.32 (31.54; 44.13)[b]	67 (61.26; 78)[c]	**< 0.001**
	Fiber g/1,000 kcal (g)	2.46 (1.99; 3.34)[a]	8.92 (5.19; 10.01)[b]	13.66 (10.45; 18.75)[c]	**< 0.001**
Anthropometry, median (IQR)	BMI (z-scores)	3.82 (2.95; 5.22)[a]	3.22 (2.36; 3.53)[b]	3.21 (2.73; 4.56)[b]	**0.02**
	Percentage change	0.83 (-3.01; 3.24)	-10.83 (-15.7; -5.32)	-10.19 (-12.56; -6.96)	**< 0.001**
	Waist for height (z-scores)	2.28 (1.95; 2.66)[a]	1.91 (1.64; 2.21)[b]	1.78 (1.47; 2.02)[b]	**< 0.001**
	Percentage change	1.96 (0.45; 5.07)	-8.06 (-13.79; -5.74)	-11.43 (-18.92; -6.39)	**< 0.001**
Fasting glucose (mg/dL), mean ± SD		96.54 ± 9.75[a]	91.35 ± 10.24[b]	87.7 ± 10.58[b]	**0.001**
Percentage change		2.97 (-3.45; 7.95)	-5.26 (-13.21; 2.04)	-7.61 (-18.18; -4.85)	**< 0.001**
Fasting insulin profile, median (IQR)	Insulin (μIU/mL)	15.9 (12.9; 23.5)[a]	11.6 (9.2; 17.4)[b]	9.75 (7.6; 13.6)[b]	**< 0.001**
	Percentage change	7.14 (0.99; 22.08)	-21.13 (-35.8; -11.76)	-33.76 (-51.36; -25)	**< 0.001**
	C-peptide (ng/mL)	2.9 (2.2; 4.2)	2.6 (2.1; 3.5)	2.8 (2.2; 3.2)	0.25
	Percentage change	10.87 (-5.26; 30.3)	-14.29 (-27.78; -6.67)	-20.51 (-30.3; -7.5)	**< 0.001**
	HOMA-IR index	3.9 (3.1; 5.2)[a]	2.6 (2.1; 4.5)[b]	2.1 (1.6; 2.7)[c]	**< 0.001**
	Percentage change	9.38 (0; 19.35)	-26.47 (-44.83; -15.79)	-42.55 (-55.56; -30)	**< 0.001**

The same small letters denote no statistically significant difference between the 2 groups; different small letters denote a statistically significant difference between the 2 groups.
BMI: body mass index; DRI: daily recommended intake; HOMA-IR: homeostatic model assessment for insulin resistance; IQR: interquartile range; SD: standard deviation.

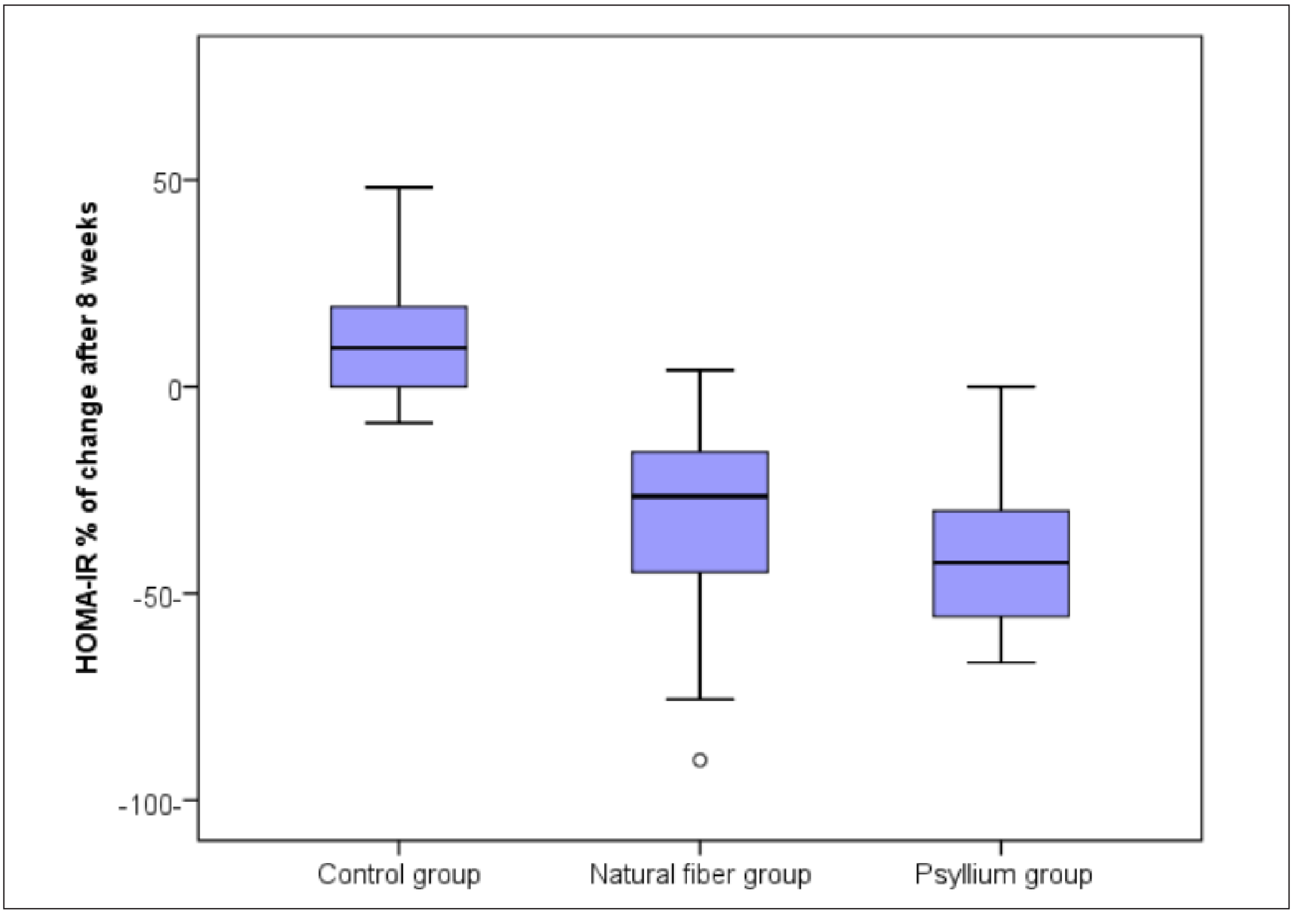

Figure 2. Percentage change from baseline of HOMA-IR index for the 3 studied groups after 8 weeks.

There were no significant differences between the 2 types of intervention in reducing fasting glucose, insulin and C-peptide. This was different with HOMA-IR, where psyllium induced a very highly significant reduction than natural fiber; $p < 0.001$ (**Tab. 2**).

After 8 weeks of intervention, participants in both psyllium group and natural fiber group had consumed significantly lower calories and fats compared to the control group. Fat intake was significantly less in the psyllium group than in the natural fiber group (**Tab. 1** and **Tab. 2**). Looking at BMI and waist for height z-scores, they were significantly reduced in both the psyllium group and natural fiber group compared to controls. Both interventions exerted the same effect on anthropometry with no significant differences (**Tab. 1** and **Tab. 2**).

After 8 weeks with no intervention, insulin, C-peptide and HOMA-IR were significantly increased in the control group. Percentage change from baseline (median [IQR]) was +7.14% (0.99%; 22.08%) for insulin, +10.87% (-5.26%; 30.3%) for C-peptide and +9.38% (0%; 19.35%) for HOMA-IR ($p = 0.006$, 0.015, and < 0.001, respectively) (**Tab. 1** and **Tab. 2**). Fasting glucose, caloric intake, fat intake, and BMI z-scores did not show significant changes from baseline after 8 weeks (**Tab. 1**).

Added to the significant difference found between the 3 studied groups regarding week-8 HOMA-IR, we found a significant direct negative correlation between the fiber percent achieved from the DRI and HOMA-IR profile ($R = -0.277$, $p = 0.017$).

Regarding the potential side effects of psyllium, it was reported in 54.1% of patients in the psyllium group. Unpalatability was the most frequently reported complaint (40.5%), followed by abdominal pain, vomiting and constipation (**Fig. 3**). Adding psyllium to orange juice and yoghurt, instead of water, improved palatability. Increasing water intake and symptomatic treatment with antispasmodics and antiemetics relieved gastrointestinal upset in 48.6% of patients. Two patients discontinued psyllium before 8 weeks (4.9%) due to unrelieved upset (**Fig. 1** and **Fig. 3**).

Discussion

The effect of fibers on IR and obesity was not studied for the first time in the current study; however, psyllium in particular was chosen due to being available, affordable and relatively safe supplement with a hypothesized benefit for obese children [19].

Psyllium supplementation and natural DF were associated with significant improvement of IR after 8 weeks. The beneficial effect of fibers (in both groups) extended to reducing caloric intake, fat intake and anthropometric indices (BMI and waist for height z-scores) despite the short study period. Lack of intervention in the control group led to worsening of IR and may predispose to T2DM if left untreated.

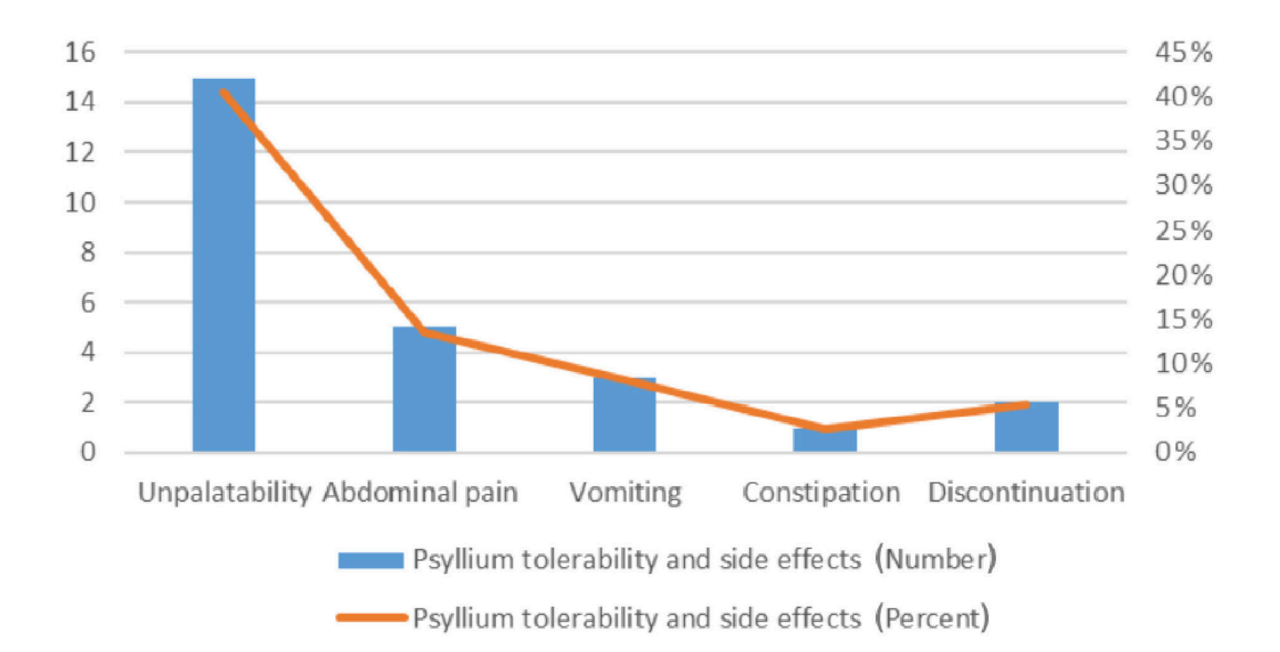

Figure 3. Tolerability and side effects of psyllium supplementation.

Psyllium supplementation had a unique influence on HOMA-IR index compared to increasing DF.

Although several studies investigated the association between fiber intake and reduced risk of T2DM in adults, children were understudied. It was reported that psyllium improved glucose homeostasis in children with diabetes; however, they assessed postprandial and not fasting glucose [20]. Several studies on adults with obesity and T2DM reported glucose reduction with a percentage change of -27.9% [21].

Regarding IR profile, the effect of psyllium was compared versus standard diet in patients with metabolic syndrome [22]. They reported significant improvement in insulin (-20.4% vs. -10.8%) and HOMA-IR (-39.2% vs. -16.7%), similar to our current study where fasting insulin significantly improved in psyllium group as compared to natural fiber group (-33.76% vs. -21.13%) as well as HOMA-IR (-42.55% vs. -26.47%). It was reported that increasing DF consumption was associated with a predictable decrease of fasting glucose, fasting insulin and HOMA-IR [23]. Also, a better glycemic response with combining 10 g psyllium to the normal diet was reported by a similar study. Similarly, psyllium significantly improved IR in non-diabetic women with polycystic ovary disease compared to placebo [24].

The results of the current study came contradictory to an older study where psyllium was not associated with important changes in insulin (5%) and C-peptide levels [25]. They found that psyllium decreased glucose absorption and excretion, which was beyond our scope.

The positive effect on BMI and waist circumference reduction produced by psyllium supplementation in our study was found to be in line with one study and contradictory to another one in adults with obesity [26].

No serious side effects for psyllium were found in the current study, which agreed with an earlier report [27]. Unpalatability was a frequent complaint with psyllium (40.5%) in our study; however, this was not the same in the report by Ribas et al. [28]. We reported some gastrointestinal symptoms, which might be induced by psyllium. Yet, we consider psyllium a safe and tolerable treatment, as symptoms are mild, improved with simple advice and led to a minimal discontinuation rate (4.9%). Side effects were frequent and this might be another indirect effect of psyllium in reducing caloric intake and subsequently improving anthropometric parameters and IR profile (in addition to their bulking effect on the gastrointestinal tract).

Among limitations of this study, it was not possible to measure dietary intake objectively and directly in such large samples, individuals can overreport all or selected foods, introducing reporting bias. However, this was compensated by interviewing by a skilled dietitian who took recall with different methods to minimize the effect of this bias.

Several points of strength existed in the current study. Involving a control group helped to highlight the fact that IR increased within 8 weeks with lack of intervention and was not simply stationary. This emphasized the importance of fiber supplementation in general and psyllium in particular for children with obesity and IR. Being a randomized clinical trial with a relatively large sample size is another point of strength. Comparing psyllium supplementation to increasing DF showed an extra benefit of adding a fiber supplement to the standard diet in improving IR of children with obesity.

Long-term studies are required to evaluate the role of psyllium in the prevention of diabetes, accelerating weight loss and improving the quality of life in children with obesity. Tolerability and potential side effects of psyllium should be examined on a larger scale of symptoms over a longer period of time.

The accidental finding of worse insulin and C-peptide in the control group highlighted the great importance of involving fibers either dietary or with supplements to have better IR profiles in children with obesity.

Conclusion

IR improved significantly with both psyllium and natural DF, with a more pronounced effect of psyllium on HOMA-IR. Lack of intervention resulted in worsening of IR profile that may progress to T2DM in children with obesity if not properly treated. The better improvement of HOMA-IR induced by psyllium compared to DF needs further investigation on a larger scale and longer duration studies.

Abbreviations

BMI: body mass index

DF: dietary fibers

DRI: daily recommended intake

ELISA: enzyme-linked immunosorbent assay

HOMA-IR: homeostatic model assessment of insulin resistance
IQR: interquartile range
IR: insulin resistance
SD: standard deviation
T2DM: type 2 diabetes mellitus
WHO: World Health Organization

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Cairo University (Date 7 August 2019 /No. MD-40-2019).

Clinical trial registration

Registration number is PACTR202202746907105.

Consent to participate

Written informed consent was obtained from the parents or legal guardian of participants included in the study.

Consent to publish

The Authors affirm that human research participants provided informed consent for publication.

Declaration of interest

The Authors have no relevant financial or non-financial interests to disclose.

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