REVIEW

Effects of resistant maltodextrin on bowel movements: a systematic review and meta-analysis

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Abstract: It is well known that dietary fiber helps to relieve and prevent constipation, and there are a number of scientific papers, including systematic reviews and meta-analyses on the effects of naturally derived dietary fiber on bowel movements. In recent years, there has been an increase in the manufacture of dietary fiber ingredients obtained from food raw materials, and these are now commonly available in the market. Resistant maltodextrin (RMD), a soluble dietary fiber, is manufactured from starch, and industrially produced soluble dietary fiber is used worldwide. While there are many reports on the effects of RMD on bowel movements, no systematic review or meta-analysis has been reported. We conducted a systematic review and meta-analysis to clarify the effect of RMD on bowel movements based on stool frequency and stool volume. We also investigated the subjective evaluation of RMD effects on bowel movements. Of a total of 314 potentially relevant articles, 28 articles met the eligibility criteria, and 29 randomized controlled trials were identified. As a result of integration analyses, we found that the intake of RMD significantly increased stool volume and stool frequency compared with placebo intake. Furthermore, RMD intake tended to improve sensation of complete/incomplete evacuation. In conclusion, the evidence suggests that RMD has a positive effect on bowel movements, contributing to normal bowel function. This finding will help in the development of new criteria for choice of dietary fiber in the process of developing food products.

Keywords: resistant maltodextrin, dietary fiber, bowel movement, systematic review, meta-analysis

Introduction

Reports indicate that ~20% of the population worldwide suffers from constipation,[1] and the rate is higher in developed countries, including the USA, the UK, and Japan.[2–4] According to the Rome III diagnostic criteria, the World Gastroenterology Organization defined constipation as the presence of at least two of the following in patients who do not take laxatives in any 12-week period during the previous 12 months: 1) fewer than three bowel movements per week; 2) hard stool in >25% of bowel movements; 3) a sense of incomplete evacuation in >25% of bowel movements; 4) excessive straining in >25% of bowel movements; and 5) a need for digital manipulation to facilitate evacuation.[5] Constipation causes feelings of fatigue and weariness, adversely affects various daily activities, and reduces labor productivity.[6] Constipation could be induced by lifestyle habits, specifically diets containing substantially processed food and/or a lack of exercise. Elderly people and pregnant women, in particular, are prone to constipation. It has been reported that chronic constipation could increase the risk

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of cancer of the large intestine and reduce survival rate.[7,8] Therefore, it is postulated that the maintenance of normal defecation contributes significantly to human health and the quality of life.

It has been known that intake of dietary fiber helps to relieve and prevent constipation. Hippocrates, an ancient Greek physician, recorded the use of "wheat bran" as a laxative agent over 2000 years ago, and dietary fiber has received considerable attention through the ages.[9] In the early 1970s, Burkitt reported "the dietary fiber hypothesis" of colon cancer.[10] Since then, the research of dietary fibers has advanced significantly worldwide, and the mechanisms underlying the effectiveness of dietary fiber against constipation have been reported. Consequently, the European Food Safety Authority (EFSA) recommends consuming 25 g of dietary fiber a day for normal laxation.[11] However, actual daily consumption of dietary fiber is less than the recommended amount in many European countries,[12] in the USA, Japan, and other developed countries.[13,14] As it is not easy to consume the adequate amount of dietary fiber from daily meals, the use of added manufactured fiber will be a strategy to increase fiber ingredients available on the market.

Dietary fiber is categorized into two types: soluble dietary fiber (eg, partially hydrolyzed guar gum and resistant malto-dextrin [RMD]) and insoluble dietary fiber (eg, wheat bran and resistant starch). Numerous studies have reported that both types of dietary fiber result in improved bowel movements[15–18] although the underlying mechanisms are different. Soluble dietary fiber is pectized when hydrated and softens the stool, whereas insoluble dietary fiber absorbs water in the intestine and increases the bulk of the stool, which stimulates the bowel wall and enhances peristaltic activity.

In some countries, such as the USA, countries within the European Union, Korea, and Taiwan, there are systems in place for food labeling, indicating the function of foods, such as an improved effect on bowel movements by dietary fiber. In Japan, the system is called Foods for Specified Health Use (FOSHU),[19] and it has approved the use of 1127 products as of March 2017, including 337 products claiming benefits on gut health, including functional ingredients: RMD (182 products), dietary fiber of psyllium seed husk (35), galactooligosaccharide (16), depolymerized sodium alginate (12), polydextrose (6), partially hydrolyzed guar gum (5), and wheat bran (4). The most widely used ingredient by FOSHU for the maintenance of normal bowel functions is RMD. RMD is also widely used in Korea and Taiwan.

RMD is nonviscous water-soluble dietary fiber derived from starch. Recently, several companies have begun to produce RMD using different raw materials and/or different production processes. The effect of RMD on bowel movements is well documented,[20,21] although no systematic reviews or meta-analyses have been reported to date. McRorie and Chey conducted a literature review on the physical effects of fiber in the gut and concluded that nonviscous soluble fibers have no benefit on bowel regularity.[22]

In the present study, we conducted a systematic review and meta-analysis to determine the effect of RMD on bowel movements, which we believe will help in the development of new criteria for the choice of dietary fiber in the process of developing food products. We also investigated the subjective evaluation on bowel movements.

Methods

A systematic review and meta-analysis were performed following the guidelines of the Cochrane Handbook for systematic reviews of interventions[23] and reported in accordance with the preferred reporting items for systematic reviews and meta-analysis (PRISMA).[24]

We conducted a meta-analysis to evaluate the effect of RMD on bowel movements. Primary parameters were stool frequency and stool volume. Regarding stool frequency, the number of defecations during the study period was recorded. Stool volume was evaluated using two methods: by weight and by visual check. Measuring stool weight generates accurate figures but is a burden on subjects. Therefore, measuring stool by visual check, based on the number of eggs (or ping-pong balls), is often adopted as there is a positive correlation with weight.[25] The evaluation of stool volume and stool frequency has been validated with the guidance of EFSA[26] and FOSHU.[27] Randomized controlled trials (RCTs) evaluating stool volume by visual check were adopted in this meta-analysis study.

Formulation

The primary question was "Does intake of RMD increase stool volume and stool frequency and improve the bowel movements?" The secondary question was "Does intake of RMD improve subjective evaluation (consistency, color, odor of stool, and sensation of complete/incomplete evacuation)?"

Literature search and study selection

A comprehensive literature search to identify the effects of RMD on bowel movements was performed up to January 2017 using the following databases: Cochrane Central Register of Controlled Trials, the US National Library of Medicine database (MEDLINE via the PubMed portal),

Japan Medical Abstracts Society, and the National Institute of Informatics Electronic Library Service and National Diet Library.

The bibliographical search was performed by using three terms: RMD, resistant dextrin, and indigestible dextrin. The bibliographical search in Japanese was performed using the same ingredient name "nan-syoka-sei-dekisutorin" in combination with words related to bowel functions (Table 1).

Eligibility criteria for the primary question were as follows: RCTs that, 1) investigated in the general population, such as healthy adults or adults with a tendency toward constipation, but not receiving medical treatment; 2) did not include pregnant women or lactating women; 3) assessed both stool frequency and stool volume; 4) conducted statistical analysis for significance; 5) were designed as double-blind or single-blind studies; 6) received the written informed consent from subjects who fully understood the content of the clinical trial; 7) did not include RMD in the placebo; 8) were published in peer-reviewed original papers; and 9) were reported in English or Japanese language. RCTs were excluded if they, 1) included not only RMD but also other types of dietary fiber in the test food or placebo, and 2) used hydrogenated RMD.

Data extraction

Two reviewers (NW and MS) extracted the following data based on the eligibility criteria: 1) authors; 2) published years; 3) study design; 4) number of subjects; 5) age; 6) daily intake of RMD; 7) stool frequency and stool volume when test food and placebo were ingested (two occasions); and 8) subjective evaluation.

Both the reviewers independently reviewed the original papers and extracted the data. When the data extracted by the two reviewers did not coincide, they both reviewed the original papers together. When two RCTs were included in one report and each RCT included its own placebo group,

Table 1 Search formula

International database site: CENTRAL, PubMed
"resistant maltodextrin"
"resistant dextrin"
"indigestible dextrin"
Japanese database site: I-Chu-Shi Web, CiNii
"nan-syoka-sei-dekisutorin" AND "seicho"
"nan-syoka-sei-dekisutorin" AND "haiben"
"nan-syoka-sei-dekisutorin" AND "bentsu"

Notes: "nan-syoka-sei-dekisutorin," [resistant maltodextrin]; "seicho," [intestinal regulation]; "haiben," [bowel movement]; "bentsu," [laxation].
Abbreviations: CENTRAL, Cochrane Central Register of Controlled Trials; CiNii, Citations Index Portal; I-Chu-Shi Web, Japan Medical Abstracts Society.

they were counted as two RCTs. Units of stool volume and stool frequency were converted to number of stools per 7 days. Standard error was converted to standard deviation.

Risk of bias

Two reviewers (NW and MS) independently assessed the risk of bias for the following six categories based on the Cochrane Handbook for systematic review of interventions (Version 5.1.0, 2011):[23] 1) sequence generation; 2) allocation sequence concealment; 3) blinding of participants and personnel; 4) incomplete outcome data; 5) selective outcome reporting; and 6) other potential threats to validity. The risk of bias for each category was evaluated according to three grades: high risk, unclear risk, and low risk. When the risk of bias assessment by the two reviewers did not coincide, the grade was decided following discussion between the reviewers.

Statistical analysis

Mean difference (MD) was calculated as a common effect size for stool volume, stool frequency, and subjective evaluation items. When the values were not set out in the paper, inquiries were sent to the corresponding author seeking clarification. Meta-analysis was conducted using the DerSimonian–Laird method. Cochran Q-test (χ^2 test) and I^2 statistic value ($0\% \leq I^2 \leq 100\%$) were determined to evaluate heterogeneity. To evaluate the publication bias, data were corrected by the trim and fill method when the funnel plot was asymmetric. Fail-safe N was calculated to evaluate robustness.

Statistical analysis was performed by using Review Manager Version 5.3.5 (The Nordic Cochrane Centre, The Cochrane Collaboration, London, UK) and Comprehensive Meta-Analysis Version 2.2.064 (BioStat Inc., Englewood, NJ, USA).

Results

We identified 314 potentially relevant papers. Of these, 28 papers met the eligibility criteria (Figure 1). A study by Ishi et al[31] reported two independent RCTs. Therefore, finally, 29 RCTs were adopted in the present study (Table 2).

Risk of bias

The risk of bias was evaluated for six categories based on the Cochrane Handbook (Table 3).

Sequence generation

Twenty-six RCTs were classified as "low risk" as they were randomly allocated,[20,21,28–35,37–48,51–53] while three RCTs were classified as "unclear risk" as the order of allocation was not clear.[36,49,50]
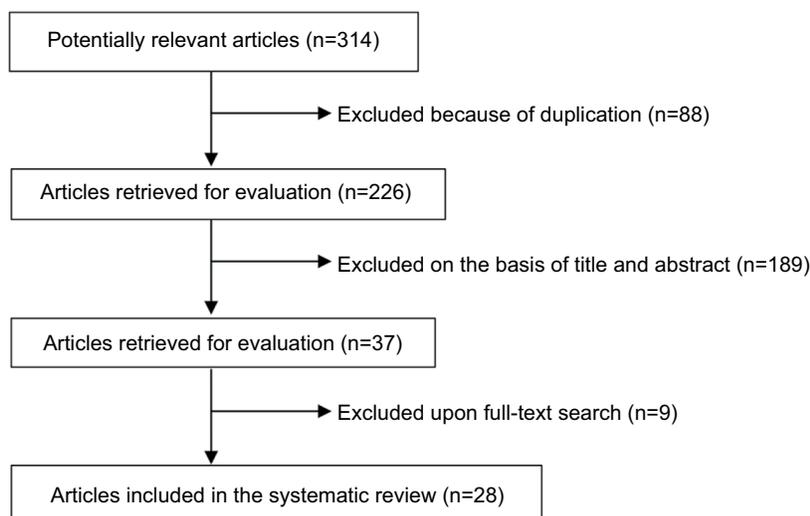
Figure 1 Flow diagram of study selection.

Table 2 Characteristics of RCTs regarding effect of RMD on the bowel movements

Study	Study design	N (M/F)	Age	Daily intake of RMD(g)[a]	Duration (day)
Abellán Ruiz et al[20]	DPT	66(32:34)	21.3±2.8	13.5	21
Furukawa et al[21]	SCT	40 (7:33)	27.9±2.7	3.8	14
Ikeguchi et al[28]	DCT	42 (0:42)	28.2±6.1	4.4	14
Inafuku et al[29]	DCT	54 (12:42)	37±1.5	7.0	14
Inagi et al[30]	SCT	47 (0:47)	21.3±0.7	4.6	14
Ishi et al[31b]	SCT	40 (0:40)	43.3	5.0	20
Ishi et al[31c]	SCT	40 (0:40)	43.3	5.0	20
Ito et al[32]	DCT	56 (8:48)	36.7±5.9	5.1	14
Kasagi et al[33]	SCT	46 (2:44)	20.2±1.4	5.0	14
Kishimoto et al[34]	SCT	38 (0:38)	19.8±0.9	4.2	14
Kusaba et al[35]	DCT	50 (8:42)	M: 40.5, F: 36.3	5.1	14
Nakamura et al[36]	SCT	30 (0:30)	20–22	5.3	20
Nakamura et al[37]	SCT	30 (0:30)	20–22	5.0	20
Sato et al[38]	DCT	28 (0:28)	23.7	4.8	14
Sato et al[39]	DCT	29 (0:29)	24.8	4.8	14
Seno et al[40]	SCT	39 (2:37)	39.9±11.5	4.8	14
Shimabukuro et al[41]	SCT	28 (12:16)	M: 47.8, F: 40.1	5.2	20
Takagaki et al[42]	SCT	71 (38:33)	28.4±8.1	5.1	14
Takagaki et al[43]	DCT	40 (0:40)	37.0±12.2	5.1	14
Tanahashi et al[44]	DCT	41 (0:41)	30.4±4.5	4.7	10
Tanaka et al[45]	SCT	22 (0:22)	23.1±4.3	5.9	14
Tanaka et al[46]	SCT	40 (0:40)	20–58	6.2	14
Taniguchi et al[47]	SCT	40 (14:26)	23.0±3.2	5.0	10
Umagami et al[48]	DCT	32 (10:22)	M: 35, F: 38	5.7	20
Umekawa et al[49]	SCT	27 (6:21)	30.1±7.9	5.0	10
Unno et al[50]	CT	84 (58:26)	Undescribed	4.2	14
Unno et al[51]	SCT	42 (0:42)	21–41	4.8	14
Unno et al[52]	SCT	37 (13:24)	23–44	5.3	14
Yamamoto et al[53]	CT	29 (6:23)	M: 44.7, F: 30.1	7.7	7

Notes: [a]Amount as dietary fiber; [b]substudy 1; [c]substudy 2.
Abbreviations: CT, crossover trial; DCT, double-blind crossover trial; DPT, double-blind parallel-group trial; F, female; M, male; RCT, randomized controlled trial; RMD, resistant maltodextrin; SCT, single-blind crossover trial.

Table 3 Risk of bias of RCTs regarding effect of RMD on the bowel movements

Study	Sequence generation	Allocation sequence concealment	Blinding of participants and personnel	Incomplete outcome data	Selective outcome reporting	Other potential threats to validity
Abellán Ruiz et al[20]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Furukawa et al[21]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Ikeguchi et al[28]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Inafuku et al[29]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Inagi et al[30]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Ishi et al[31a]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Ishi et al[31b]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Ito et al[32]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Kasagi et al[33]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Kishimoto et al[34]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Kusaba et al[35]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Nakamura et al[36]	Unclear risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Nakamura et al[37]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Sato et al[38]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Sato et al[39]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Seno et al[40]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Shimabukuro et al[41]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Takagaki et al[42]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Takagaki et al[43]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Tanahashi et al[44]	Low risk	Unclear risk	Low risk	Low risk	Low risk	Low risk
Tanaka et al[45]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Tanaka et al[46]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Taniguchi et al[47]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Umagami et al[48]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Umekawa et al[49]	Unclear risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Unno et al[50]	Unclear risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Unno et al[51]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Unno et al[52]	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Yamamoto et al[53]	Low risk	Unclear risk	Unclear risk	Low risk	Low risk	Low risk

Notes: [a]Substudy 1; [b]substudy 2.
Abbreviations: RCT, randomized controlled trial; RMD, resistant maltodextrin.

Allocation sequence concealment

Twenty-seven RCTs were classified as "low risk" as the allocation sequence was appropriately concealed,[20,21,28–43,45–52] while two RCTs were classified as "unclear risk" as allocation concealment was not clear.[44,53]

Blinding of participants and personnel

Ten RCTs were classified as "low risk" as they were designed as blind clinical trials,[20,28,29,32,35,38,39,43,44,48] while 19 RCTs were classified as "unclear risk" as it was not clear whether they were blind clinical trials.[21,30,31,33,34,36,37,40–42,45–47,49–53]

Incomplete outcome data

All RCTs were classified as "low risk" as the number of dropouts and the reasons for dropouts were comparable between the test and placebo groups.[20,21,28–53]

Selective outcome reporting

All RCTs were classified as "low risk" as they were analyzed and reported as planned in the methodology.[20,21,28–53]

Other potential threats to validity

All RCTs were classified as "low risk" as they did not have any other biases.[20,21,28–53]

Primary question: effects on bowel movements

Integration analyses revealed that intake of RMD significantly increased stool volume compared with placebo intake (MD =1.65, 95% confidence interval [CI] [1.10, 2.20], $p<0.00001$), and its heterogeneity was low ($I^2=13\%$, $p=0.27$; Figure 2). Intake of RMD also significantly increased stool frequency compared with placebo (MD =0.71, 95% CI [0.48, 0.94],
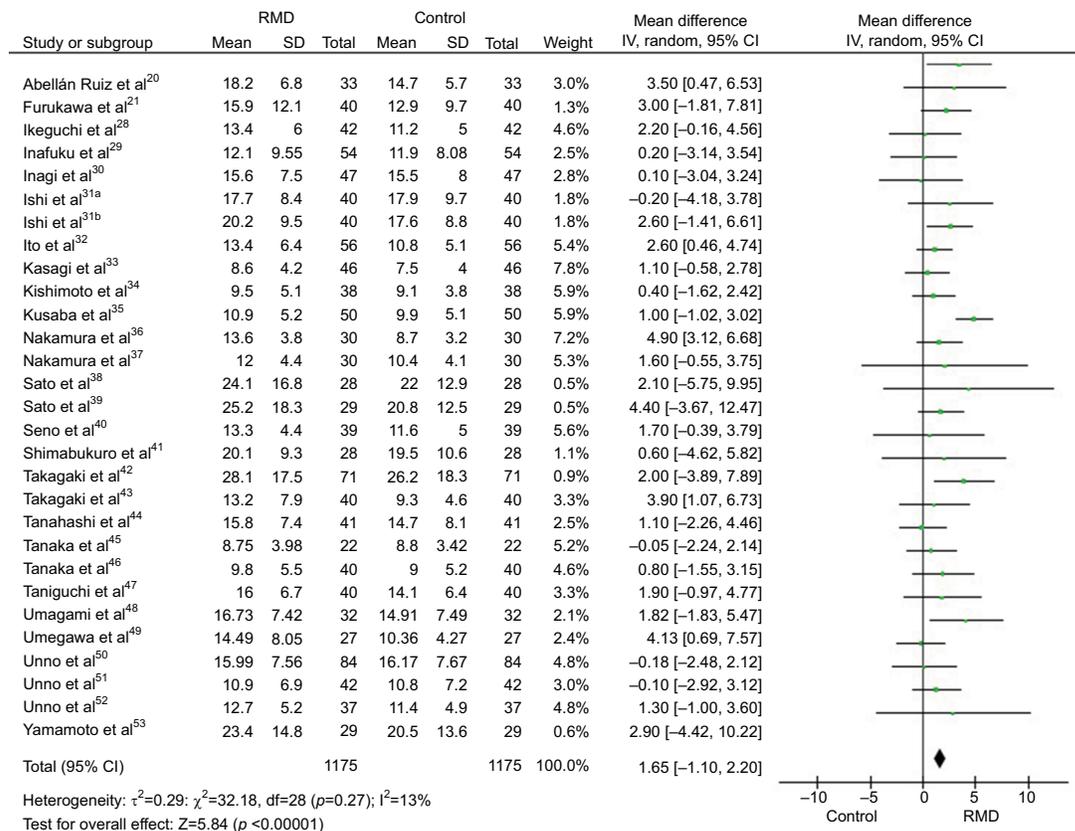
Study or subgroup	RMD Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, random, 95% CI
Abellán Ruiz et al[20]	18.2	6.8	33	14.7	5.7	33	3.0%	3.50 [0.47, 6.53]
Furukawa et al[21]	15.9	12.1	40	12.9	9.7	40	1.3%	3.00 [−1.81, 7.81]
Ikeguchi et al[28]	13.4	6	42	11.2	5	42	4.6%	2.20 [−0.16, 4.56]
Inafuku et al[29]	12.1	9.55	54	11.9	8.08	54	2.5%	0.20 [−3.14, 3.54]
Inagi et al[30]	15.6	7.5	47	15.5	8	47	2.8%	0.10 [−3.04, 3.24]
Ishi et al[31a]	17.7	8.4	40	17.9	9.7	40	1.8%	−0.20 [−4.18, 3.78]
Ishi et al[31b]	20.2	9.5	40	17.6	8.8	40	1.8%	2.60 [−1.41, 6.61]
Ito et al[32]	13.4	6.4	56	10.8	5.1	56	5.4%	2.60 [0.46, 4.74]
Kasagi et al[33]	8.6	4.2	46	7.5	4	46	7.8%	1.10 [−0.58, 2.78]
Kishimoto et al[34]	9.5	5.1	38	9.1	3.8	38	5.9%	0.40 [−1.62, 2.42]
Kusaba et al[35]	10.9	5.2	50	9.9	5.1	50	5.9%	1.00 [−1.02, 3.02]
Nakamura et al[36]	13.6	3.8	30	8.7	3.2	30	7.2%	4.90 [3.12, 6.68]
Nakamura et al[37]	12	4.4	30	10.4	4.1	30	5.3%	1.60 [−0.55, 3.75]
Sato et al[38]	24.1	16.8	28	22	12.9	28	0.5%	2.10 [−5.75, 9.95]
Sato et al[39]	25.2	18.3	29	20.8	12.5	29	0.5%	4.40 [−3.67, 12.47]
Seno et al[40]	13.3	4.4	39	11.6	5	39	5.6%	1.70 [−0.39, 3.79]
Shimabukuro et al[41]	20.1	9.3	28	19.5	10.6	28	1.1%	0.60 [−4.62, 5.82]
Takagaki et al[42]	28.1	17.5	71	26.2	18.3	71	0.9%	2.00 [−3.89, 7.89]
Takagaki et al[43]	13.2	7.9	40	9.3	4.6	40	3.3%	3.90 [1.07, 6.73]
Tanahashi et al[44]	15.8	7.4	41	14.7	8.1	41	2.5%	1.10 [−2.26, 4.46]
Tanaka et al[45]	8.75	3.98	22	8.8	3.42	22	5.2%	−0.05 [−2.24, 2.14]
Tanaka et al[46]	9.8	5.5	40	9	5.2	40	4.6%	0.80 [−1.55, 3.15]
Taniguchi et al[47]	16	6.7	40	14.1	6.4	40	3.3%	1.90 [−0.97, 4.77]
Umagami et al[48]	16.73	7.42	32	14.91	7.49	32	2.1%	1.82 [−1.83, 5.47]
Umegawa et al[49]	14.49	8.05	27	10.36	4.27	27	2.4%	4.13 [0.69, 7.57]
Unno et al[50]	15.99	7.56	84	16.17	7.67	84	4.8%	−0.18 [−2.48, 2.12]
Unno et al[51]	10.9	6.9	42	10.8	7.2	42	3.0%	−0.10 [−2.92, 3.12]
Unno et al[52]	12.7	5.2	37	11.4	4.9	37	4.8%	1.30 [−1.00, 3.60]
Yamamoto et al[53]	23.4	14.8	29	20.5	13.6	29	0.6%	2.90 [−4.42, 10.22]
Total (95% CI)			1175			1175	100.0%	1.65 [−1.10, 2.20]

Heterogeneity: $\tau^2=0.29$; $\chi^2=32.18$, df=28 (p=0.27); $I^2=13\%$
Test for overall effect: Z=5.84 (p <0.00001)

Figure 2 Forest plot for the effect of RMD on stool volume.
Abbreviations: RMD, resistant maltodextrin; IV, inverse variance.

p<0.00001), and its heterogeneity was low ($I^2=34\%$, p=0.04; Figure 3). These results indicate that RMD had a beneficial effect on bowel movements.

By visual judgment of the forest plot (Figures 2 and 3) and funnel plot (Figure 4) of 29 RCTs, it was estimated that the study by Nakamura et al[36] was an outlier and affected heterogeneity. When this RCT was excluded and we analyzed 28 RCTs, the increase in stool volume was significant (MD =1.38, 95% CI [0.85, 1.90], p<0.00001), and there was no heterogeneity ($I^2=0\%$, p=0.89). The increase in stool frequency was also significant (MD =0.62, 95% CI [0.44, 0.80], p<0.00001) with no heterogeneity ($I^2=0\%$, p=0.54; figure not shown). While the MDs of both stool volume and stool frequency were slightly decreased by excluding the study of Nakamura et al,[36] the beneficial effect of RMD on bowel movements was still statistically significant.

Regarding publication bias, the funnel plot of stool frequency was asymmetric; therefore, nine RCTs were added for correction by the trim and fill method (Figure 4). The increase in stool frequency was significant, and MD was even greater (MD =0.95, 95% CI [0.73, 1.17]). Therefore, the effect of publication bias was not great.

Robustness of the results was evaluated by the fail-safe N. Fail-safe Ns for stool frequency and stool volume were 348 and 225, respectively, indicating that the effectiveness of RMD is significant unless there is further unpublished literature existing in more than the above mentioned numbers, concluding that RMD is ineffective. In conclusion, it appears that RMD has a beneficial effect on bowel movements.

Secondary question: effects on subjective evaluation

Subjective evaluation (consistency, color, odor of stool, and sensation of complete/incomplete evacuation) was conducted in 17 of 29 RCTs. In 13 of 17 extracted RCTs, higher scores indicated beneficial changes, and we conducted a meta-analysis of subjective evaluation on these 13 RCTs.

Sensation of complete/incomplete evacuation

The intake of RMD tended to improve the sensation of complete/incomplete evacuation compared with placebo intake (MD =0.041, 95% CI [−0.007, 0.088], p=0.096),
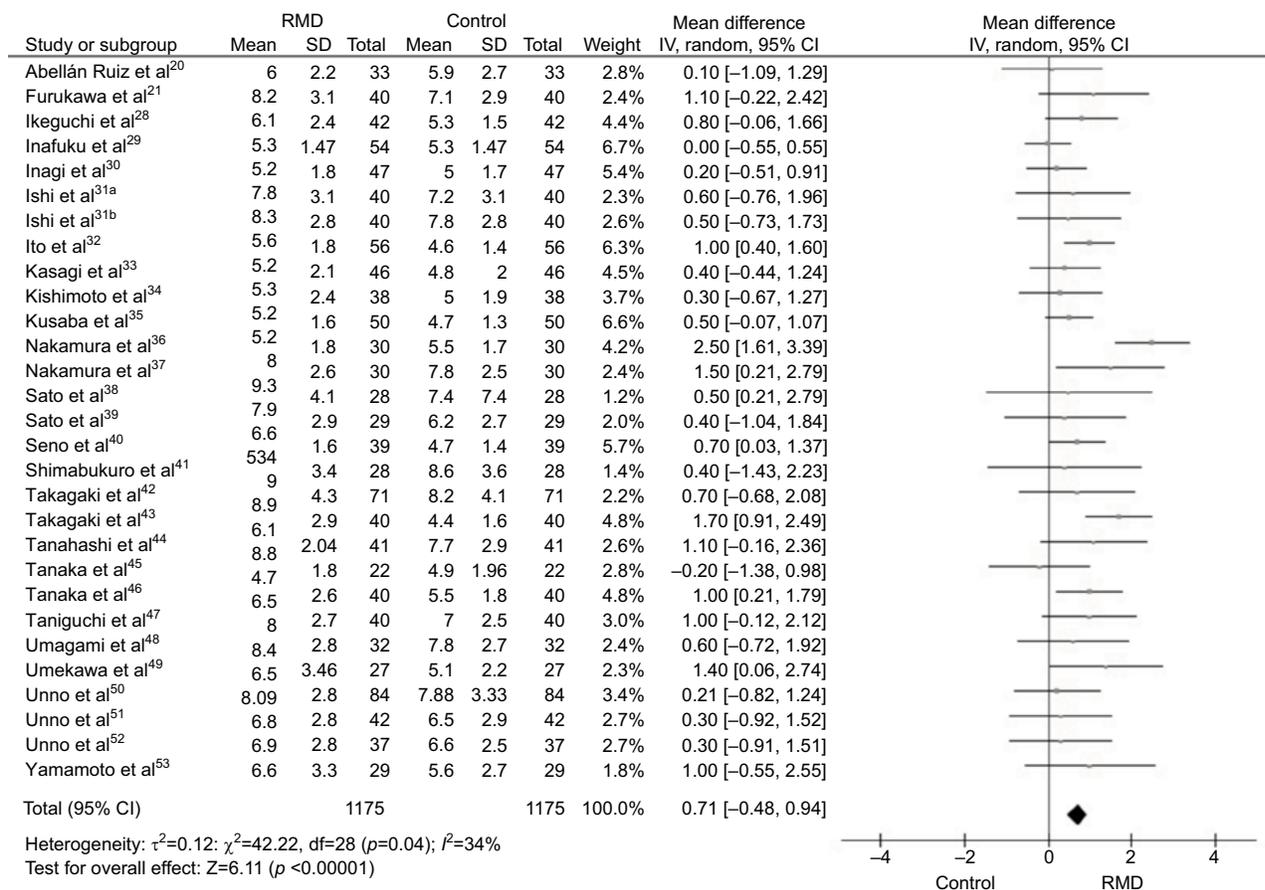
Study or subgroup	RMD Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, random, 95% CI	Mean difference IV, random, 95% CI
Abellán Ruiz et al[20]	6	2.2	33	5.9	2.7	33	2.8%	0.10 [–1.09, 1.29]	
Furukawa et al[21]	8.2	3.1	40	7.1	2.9	40	2.4%	1.10 [–0.22, 2.42]	
Ikeguchi et al[28]	6.1	2.4	42	5.3	1.5	42	4.4%	0.80 [–0.06, 1.66]	
Inafuku et al[29]	5.3	1.47	54	5.3	1.47	54	6.7%	0.00 [–0.55, 0.55]	
Inagi et al[30]	5.2	1.8	47	5	1.7	47	5.4%	0.20 [–0.51, 0.91]	
Ishi et al[31a]	7.8	3.1	40	7.2	3.1	40	2.3%	0.60 [–0.76, 1.96]	
Ishi et al[31b]	8.3	2.8	40	7.8	2.8	40	2.6%	0.50 [–0.73, 1.73]	
Ito et al[32]	5.6	1.8	56	4.6	1.4	56	6.3%	1.00 [0.40, 1.60]	
Kasagi et al[33]	5.2	2.1	46	4.8	2	46	4.5%	0.40 [–0.44, 1.24]	
Kishimoto et al[34]	5.3	2.4	38	5	1.9	38	3.7%	0.30 [–0.67, 1.27]	
Kusaba et al[35]	5.2	1.6	50	4.7	1.3	50	6.6%	0.50 [–0.07, 1.07]	
Nakamura et al[36]	5.2	1.8	30	5.5	1.7	30	4.2%	2.50 [1.61, 3.39]	
Nakamura et al[37]	8	2.6	30	7.8	2.5	30	2.4%	1.50 [0.21, 2.79]	
Sato et al[38]	9.3	4.1	28	7.4	7.4	28	1.2%	0.50 [0.21, 2.79]	
Sato et al[39]	7.9	2.9	29	6.2	2.7	29	2.0%	0.40 [–1.04, 1.84]	
Seno et al[40]	6.6	1.6	39	4.7	1.4	39	5.7%	0.70 [0.03, 1.37]	
Shimabukuro et al[41]	534	3.4	28	8.6	3.6	28	1.4%	0.40 [–1.43, 2.23]	
Takagaki et al[42]	9	4.3	71	8.2	4.1	71	2.2%	0.70 [–0.68, 2.08]	
Takagaki et al[43]	8.9	2.9	40	4.4	1.6	40	4.8%	1.70 [0.91, 2.49]	
Tanahashi et al[44]	6.1	2.04	41	7.7	2.9	41	2.6%	1.10 [–0.16, 2.36]	
Tanaka et al[45]	8.8	1.8	22	4.9	1.96	22	2.8%	–0.20 [–1.38, 0.98]	
Tanaka et al[46]	4.7	2.6	40	5.5	1.8	40	4.8%	1.00 [0.21, 1.79]	
Taniguchi et al[47]	6.5	2.7	40	7	2.5	40	3.0%	1.00 [–0.12, 2.12]	
Umagami et al[48]	8	2.8	32	7.8	2.7	32	2.4%	0.60 [–0.72, 1.92]	
Umekawa et al[49]	8.4	3.46	27	5.1	2.2	27	2.3%	1.40 [0.06, 2.74]	
Unno et al[50]	6.5	2.8	84	7.88	3.33	84	3.4%	0.21 [–0.82, 1.24]	
Unno et al[51]	8.09	2.8	42	6.5	2.9	42	2.7%	0.30 [–0.92, 1.52]	
Unno et al[52]	6.8	2.8	37	6.6	2.5	37	2.7%	0.30 [–0.91, 1.51]	
Yamamoto et al[53]	6.9	3.3	29	5.6	2.7	29	1.8%	1.00 [–0.55, 2.55]	
Total (95% CI)			1175			1175	100.0%	0.71 [–0.48, 0.94]	

Heterogeneity: τ^2=0.12; χ^2=42.22, df=28 (p=0.04); I^2=34%
Test for overall effect: Z=6.11 (p <0.00001)

Figure 3 Forest plot for the effect of RMD on stool frequency.
Abbreviations: RMD, resistant maltodextrin; IV, inverse variance.

and heterogeneity was low (I^2=0%, p=0.984; Figure 5). The funnel plot (data not shown) of thirteen RCTs[28,31,32,34,35,40,42,43,45,46,51,52] was asymmetric; therefore, three negative data were added for correction by the trim and fill method. Fail-safe N was not obtained as there was no significant difference. Publication bias was not high because no significant difference (p=0.49: two-sided test) was obtained by Egger regression, and the symmetry of the plot was not denied. No other significant difference was observed regarding subjective evaluation.

Discussion

The majority of the RCTs included in the preset systematic review were conducted in Japan. A number of studies on RMD have been conducted and published in Japan because RMD was first developed in that country and has been used in many FOSHU products. Food products recognized as FOSHU contain a key ingredient that provides a physiological function and benefit to health. To be accepted as a

FOSHU product by the Japanese governmental agency, an RCT should be conducted in humans to prove the efficacy of the functional ingredient, which needs to be published in a peer-reviewed journal.[54] Therefore, many scientific papers reporting the efficacy of food products containing RMD have been published in Japan. A meta-analysis of RCTs with foods containing RMD was conducted to determine the effect of RMD on postprandial blood glucose elevation and concluded that RMD attenuated the glycemic response to foods.[55] As many RMD studies were published in Japanese scientific journals, terms related to bowel movements were used to narrow the search in Japanese. As there were limited studies published in English, it was possible to screen the relevant papers on the basis of the titles and abstracts. Therefore, the terms related to RMD and their variations were used for the search in English.

The present study revealed that both stool frequency and stool volume were significantly increased by RMD intake compared with placebo. Although the meta-analysis of the
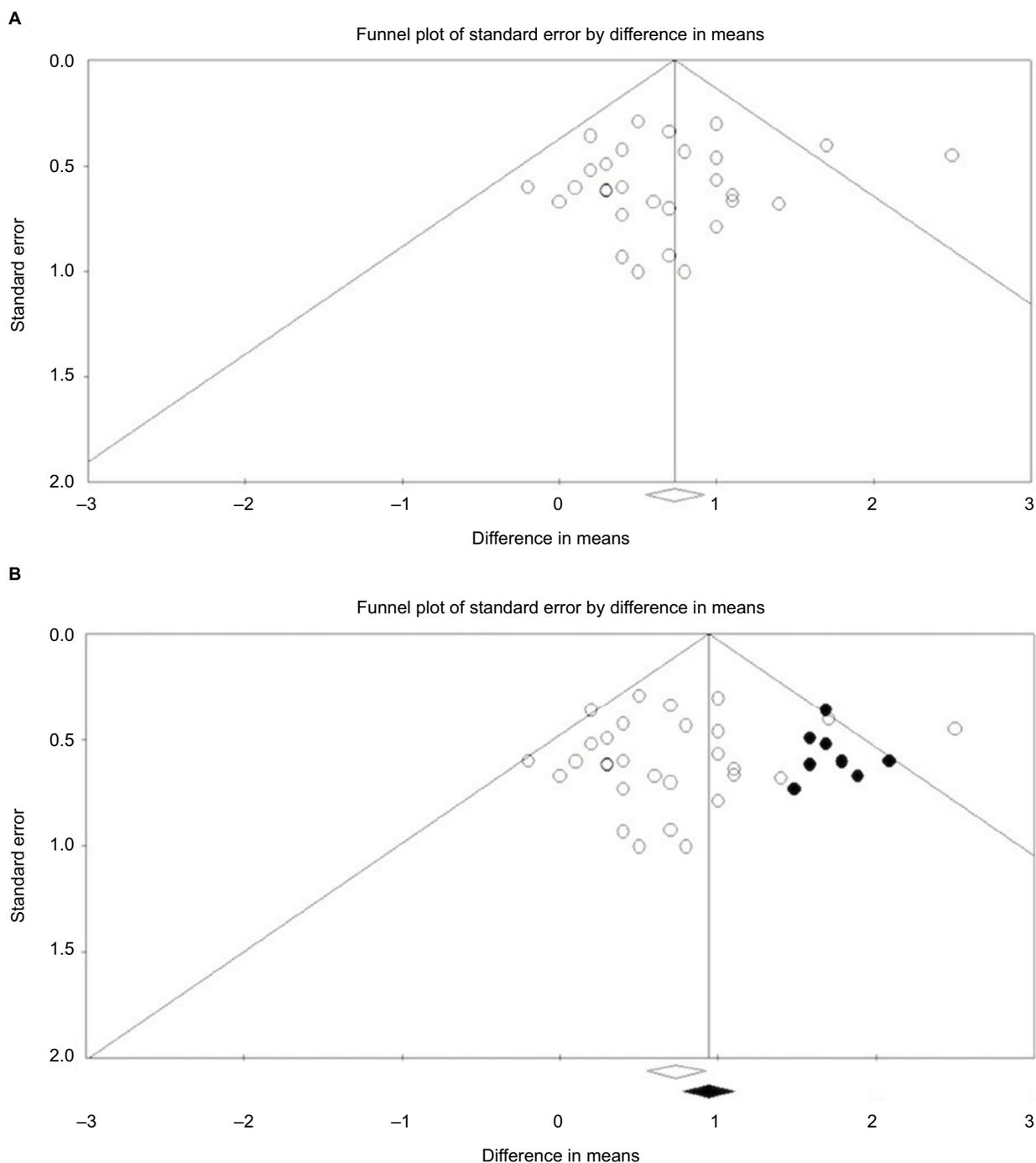
A

B

Figure 4 Funnel plot of publication bias for the effect of RMD on stool frequency.
Notes: (**A**) Original data; (**B**) after correction by the trim and fill method.
Abbreviation: RMD, resistant maltodextrin.

29 RCTs revealed the significance of RMD, the heterogeneity (I^2) values for stool volume and stool frequency were 13% and 34%, respectively. This indicated that one extreme outcome may have affected all the results. Therefore, we conducted a further meta-analysis excluding the outlier (Nakamura et al[36]); heterogeneity for both stool volume and

stool frequency was 0%, and the significant effect of RMD remained. These results confirmed that the effect of RMD on bowel movements was significant even after deleting the outlier from the analysis.

Of the 29 RCTs, 10 RCTs were double-blinded, 18 RCTs were single-blinded, and one RCT did not report

Model	Study name	Statistics for each study							Difference in means and 95% CI				
		Difference in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	P-Value	−0.50	−0.25	0.00	0.25	0.50
	Ikeguchi et al[28]	0.080	0.074	0.006	−0.066	−0.226	1.076	0.282					
	Ishi et al[31a]	0.000	0.089	0.008	−0.175	−0.175	0.000	1.000					
	Ishi et al[31b]	0.000	0.089	0.008	−0.175	−0.175	0.000	1.000					
	Ito et al[32]	0.000	0.062	0.004	−0.121	−0.121	0.000	1.000					
	Kishimoto et al[34]	0.100	0.161	0.026	−0.215	−0.415	0.623	0.533					
	Kusaba et al[35]	0.110	0.077	0.006	−0.041	−0.261	1.427	0.153					
	Seno et al[40]	0.100	0.091	0.008	−0.078	−0.278	1.104	0.270					
	Takagaki et al[42]	0.000	0.067	0.005	−0.132	−0.132	0.000	1.000					
	Takagaki et al[43]	0.000	0.089	0.008	−0.175	−0.175	0.000	1.000					
	Tanaka et al[45]	0.000	0.151	0.023	−0.295	−0.295	0.000	1.000					
	Tanaka et al[46]	0.000	0.112	0.013	−0.219	−0.219	0.000	1.000					
	Unno et al[51]	0.100	0.109	0.012	−0.114	−0.314	0.917	0.359					
	Unno et al[52]	0.100	0.096	0.009	−0.088	−0.288	1.043	0.297					
Random		0.041	0.024	0.001	−0.007	−0.088	1.664	0.096					

Model	Effect size and 95% confidence interval						Test of null (2-tail)		Heterogeneity				τ^2			
Model	Number studies	Point estimate	Standard error	Variance	Lower limit	Upper limit	Z-value	P-value	Q-value	df (Q)	P-value	I^2	τ^2	Standard error	Variance	τ
Fixed	13	0.041	0.024	0.001	−0.007	0.008	1.664	0.096	3.962	12	0.984	0.000	0.000	0.003	0.000	0.000
Random	13	0.041	0.024	0.001	−0.007	0.008	1.664	0.096								

Figure 5 Forest plot for the effect of RMD on the sensation of complete/incomplete evacuation.
Abbreviation: RMD, resistant maltodextrin.

blinding. Therefore, 19 RCTs were classified as "unclear risk" because they were not double-blinded. However, we evaluated that the risk of bias was low as the 19 RCTs were conducted as placebo-controlled trials. As a result of the evaluation of the publication bias, nine RCTs for stool frequency were added, based on the correction by the trim and fill method, which corroborated the hypothesis regarding the beneficial effect on bowel movements. Ten double-blinded RCTs were selected, and the meta-analysis was performed. Increases in stool volume and stool frequency were significant. The failsafe Ns were over 200 for both stool frequency and stool volume, which means that the positive effect of RMD on bowel movements is significant unless there are over 200 unpublished papers, concluding that RMD has no effect. We searched the following clinical trial registration systems to identify any relevant unpublished papers: University Hospital Medical Information Network Center (http://www.umin.ac.jp/), Clinical Trials. Gov (https://clinicaltrials.gov/), International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/Default.aspx), and International Standard Randomised Controlled Trial Number Register (https://www.isrctn.com/). We found no registered clinical trials for the effect of RMD on bowel movements, indicating that there were no unpublished

papers. Therefore, the effect of publication bias was not high, which strongly supports the effect of RMD on improving bowel movements.

It is known that the contents of the large intestine (ie, stool) are transported by the peristalsis and excreted. Peristaltic activity is induced by the gastrocolic reflex, which occurs when foods enter the stomach, and by the physical stimulus of the stool volume. Peristaltic activity is also stimulated by acetic acid, propionic acid, and butyric acid.[56] These short-chain fatty acids (SCFAs) are produced by intestinal bacterial fermentation. Ingested RMD reaches the large intestine, where RMD is fermented by intestinal bacteria and SCFAs are produced.[57] SCFAs produced in the large intestine stimulate mucosa of the large intestine and promote peristaltic activity. Intestinal bacteria proliferate by degrading RMD and increase in number.[16] It is postulated that peristaltic activity is promoted by the physical stimulus of increased stool volume, including increased intestinal bacteria and undigested RMD. Intake of RMD has been reported to shorten gastrointestinal transit time and improve stool volume and stool consistency in humans.[20]

Regarding the secondary question examined in this study, the sensation of complete/incomplete evacuation tended to be improved by RMD intake compared with placebo intake (*p*=0.096). Straining during defecation,

sensation of incomplete evacuation, and sensation of ano-rectal obstruction/blockage are caused by hard stool and defined by the Rome III diagnostic criteria. Hard stool is caused by prolonged gastrointestinal transit time and reduced stool moisture, which is absorbed from the intestinal wall. RMD intake shortens the gastrointestinal transit time, with defecation of softer stools that retain moisture. Consequently, the sensation of complete/incomplete evacuation is improved.

Twenty-eight of 29 RCTs (except for the study of Abellán Ruiz et al[20]) were conducted by the crossover comparison method. The crossover comparison method can eliminate individual differences and can make it possible to estimate the effect with a small number of subjects. However, if the washout period is insufficient, a carryover effect occurs, which affects the result. In the 28 RCTs, the washout period range was between 7 and 14 days, and the average was 9.9 days. In general, normal bowel movements will be passed between 24 and 72 hours after foods are ingested. Breath hydrogen gas, a marker of intestinal fermentation, was not detected at the 24-hour time point after RMD intake,[58] indicating that RMD is fermented and/or excreted within 24 hours. Therefore, it is unlikely that there were studies with carryover effects among the 28 RCTs, and it is considered that the washout periods were appropriate.

Some systematic reviews on bowel movements have been reported regardless of raw materials and properties of dietary fibers. Yang et al[59] conducted a meta-analysis of five RCTs on bowel movements by the ingestion of different dietary fibers (glucomannan, wheat bran, and cocoa husk) and concluded that stool frequency was significantly increased by the intake of dietary fibers. de Vries et al[60] conducted meta-analyses to evaluate the effect of dietary fibers derived from cereals on bowel movements, based on the raw material, and reported that the intake of dietary fiber derived from wheat significantly increased stool volume, stool frequency, and stool moisture and significantly shortened the gastrointestinal transit time. All these meta-analyses involved natural and unprocessed dietary fibers. In the current meta-analysis study, we investigated dietary fibers manufactured from starch, ie, RMD, which has been used in the processed food market worldwide. The results based on the RCTs focusing only on human subjects suggested that RMD improves bowel movements. Therefore, in relation to bowel movements, RMD effectively works in the same way as unprocessed dietary fibers.

Baer et al[61] observed increased wet and dry stool weight by RMD intake (25 and 50 g) in a dose-dependent relation. Satouchi et al[62] observed that RMD intake (3.0 and 5.9 g) increased both stool frequency and stool volume. Both RCTs were not included in the present study as the former RCT reported stool volume by weight, and the latter RCT did not have a placebo group. However, these two RCTs showed that the intake of RMD increases both stool volume, by weight, and stool frequency, dose-dependently. Meanwhile, there is a concern that transient diarrhea may be caused by the intake of large doses of indigestible saccharides. When indigestible saccharides flow into the large intestine in high volume at once, osmotic pressure will be increased. To decrease the pressure, water is pumped into the intestinal tract and transient diarrhea occurs. The relevant doses differ according to the specific substances. The maximum no-effect level of RMD (1.0 g/kg body weight for men and 1.1 g/kg body weight for women)[63] is higher than that of lactitol (0.075 g/kg for men and 0.15 g/kg for women)[64] and galactooligosaccharide (0.3 g/kg for men and 0.3 g/kg for women).[65] The intake of RMD in the present study ranged from 3.8 g to 13.5 g per day. It has been postulated that the common use of RMD rarely causes transient diarrhea.

Currently, there are several companies producing RMD from different raw materials and/or by different manufacturing processes. Therefore, dietary fiber content, molecular structure, and/or disposition in the human body could differ among products. We conducted a meta-analysis for the effect of RMD on bowel movements irrespective of the raw material and the manufacturing process. We identified some papers regarding RMD manufactured by different processes during the literature search. However, some were animal studies, and others had different objectives, which did not meet the study criteria and were finally eliminated. Consequently, all the papers adopted in the current study involved the same RMD product. There are different RMD products available on the market with different physical and physiological properties; therefore, further studies are required to investigate the differences in efficacy of each RMD product on different physiological functions, including the effect on bowel movements.

Regular bowel movements are an important factor affecting the quality of healthy life and could be achieved by consuming more dietary fiber and performing moderate exercise. When the intake of dietary fiber is not sufficient, the use of foods containing RMD is a practical strategy, which could contribute to normal bowel function.

Conclusion

The intake of RMD significantly increased stool volume and stool frequency compared with placebo intake. RMD intake tended to improve the sensation of complete/incomplete evacuation. Therefore, RMD improves bowel movements and contributes to normal bowel function.

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Disclosure

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