Effect of different diets on weight and other outcomes in long term trials

Marlene Chakhtoura, Jana Jabbour, Maria Armache, Assem Khamis, Florencia Halperin

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Review question

The objective of this review is to evaluate the effect of different dietary approaches on weight change and other metabolic parameters in trials extending ? 1 year.

Searches

We will conduct a systematic search in the following electronic databases MEDLINE (1946 till present), Embase, PubMed and Cochrane Library without time restriction, using MeSH terms and keywords relevant to dietary intervention and weight loss. We will also manually search the references of systematic reviews on the topic, to identify any potentially relevant study. English

Search strategy

https://www.crd.york.ac.uk/PROSPEROFILES/103116_STRATEGY_20180710.pdf

Types of study to be included

-Inclusion criteria:

Randomized controlled trials (RCTs)

Weight loss target or not

English

Published data

No publication date restriction

-Exclusion criteria:

Prospective interventional studies that are not randomized

Condition or domain being studied

Obesity was initially recognized as a disease by the American Medical Association in 2013, and several other societies followed (Upadhyay 2018). Obesity results from a complex interaction of multiple contributing factors, including genetic, environmental, behavioral, lifestyle and others (Ahmad 2017). Obesity rates have been increasing progressively and reached epidemic rates worldwide (GBD 2015 Obesity Collaborators). Excess weight increases the risk of several co-morbidities and all-cause mortality (Guh 2009). The interventions currently available to assist patients with weight loss are lifestyle modifications, anti-obesity drugs (Apovian 2015), and weight reducing endoscopic and surgical procedures (Buschwald 2014).

Lifestyle changes, including diet, physical activity and behavioral interventions are considered the cornerstone for any approach targeting excess weight, as recommended by obesity treatment guidelines (Appendix 1). The American Association of Clinical Endocrinologist (AACE) and the American College of Endocrinologist (ACE) 2016 guidelines on the treatment of obesity recommend a reduced calorie meal plan, and potentially modifying macronutrient composition “to optimize adherence, eating patterns, weight loss, metabolic profiles, risk factor reduction, and/or clinical outcomes” (Appendix 1).

Participants/population

-Inclusion criteria:

Studies conducted on overweight or obese adults (mean BMI in individual study ? 25 kg/m2)

-Exclusion criteria

Studies conducted in patients adults with advanced liver, renal or cardiac disease

Studies conducted in diabetic patients (>75% of the population)

Studies conducted on pregnant women

Studies conducted on patients with cancer and on active cancer treatment (> 75% of the population)

Studies where ? 20% of the participants are on anti-psychotic or on any other medication that could affect weight (> 75% of the population)

Intervention(s), exposure(s)

-Inclusion criteria:

Any dietary intervention, for at least 12 months duration

-Exclusion criteria:

Studies where co-intervention differed between arms

Studies where the intensity of the intervention differed between arms

Studies that did not provide a detailed description of the intervention, such as duration, and macronutrient composition.

Studies comparing dietary to non-dietary interventions

Studies where the intervention consists of very-low-calorie diet (<800 Kcal/d), or meal replacement liquids, since such types of diets are not commonly recommended as long term interventions

Studies where diets are based on genetic testing of participants

Comparator(s)/control

Any dietary intervention or usual care

Context

The short term effect of different diets (at 6-12 months), compared to each other or to no specific dietary intervention, was assessed in a recent network meta-analysis of 48 randomized trials (total N=7,286) (Johnston 2017). Johnston's classification of diets was based on their macronutrient composition (low carbohydrates, low fat and moderate macronutrients) (National Academies Press 2005), and the cut-offs used for each of these categories were close to those recommended by the Institute Of Medicine (IOM) Acceptable Macronutrient Distribution Ranges (AMDR) (National Academies Press 2005). Compared to no dietary intervention, all diets studied resulted in significant weight loss at 6 months of 5.1 to 8.7 kg, and weight loss at 12 months was 1-2 kg less than that reported at 6 months (16). However, comparing the effects of one dietary intervention to another, a low carbohydrate diet approach was the only one to result in higher weight loss, ranging from 1.5 to 2.7 kg at 6-12 months, compared to moderate macronutrient diet and the Lifestyle, Exercise, Attitudes, Relationships, and Nutrition (LEARN) diet, while other comparisons did not yield any significant difference (Johnston 2017). In a meta-regression analysis of included studies, while exercise and behavioral therapy were found to be significant modifiers of weight loss, caloric restriction was not (Johnston 2017). This systematic review did not assess specifically the effect of diets high in unsaturated fat, such as the Mediterranean diet (Johnston 2017), which has been shown to be beneficial not only in

optimizing weight loss, but also in lowering cardiovascular risk (Dinu 2017).

Several other reviews targeted specifically trials of at least 1 year duration (see Appendix 2)(Dinu 2017; Atallah 2014; Bueno 2013; Clifton 2014; Mancini 2016; Tobias 2015). One systematic review and meta-analysis of 53 randomized trials (total N=68,128) addressed the effect of a low fat diet [defined as a fat content range from ? 10% (very low fat) to ? 30% (moderate fat)], compared to higher fat diets (usual diet, low carbohydrate diet, or other higher fat diets) (Tobias 2015). The primary analysis, pooling all identified studies together, did not show any significant difference between these diets (Tobais 2015). Subgroup analysis, including only studies that had a weight loss goal, showed that a low fat diet performed better than usual diet (control), with a weighted mean difference (WMD) in weight loss of 5.4 (7.3; 3.5) kg, and a high heterogeneity (I^2 67.5%) (Tobias 2015). In the same analysis, a low carbohydrate diet was better than a low fat diet, with a WMD in weight loss of -1.15 (-1.8;-0.5) kg, favoring the low carbohydrate diet, with low heterogeneity (I^2 10.4%) (Tobias 2015). There was no significant difference comparing low fat to other higher fat interventions (Tobias 2015). Restricting the analysis to studies with similar intervention intensity, calorie restricted low fat diet performed worse than a high fat non-calorie restricted diet, with a WMD in weight change of -1.5 kg (-2.4;-0.5) kg, favoring the comparator- the high fat diet (Tobias 2015). Another systematic review and meta-analysis compared the long term effects of dietary interventions according to their protein content (Clifton 2014). In the included trials, a high protein diet was achieved by advising patients to increase the amount of protein intake, or to reduce the carbohydrate intake, and therefore increase the percent of protein intake (Clifton 2014). This review identified 32 randomized trials (total N=3,492) with the majority of included studies having a short active intervention, of less than 6 months, and a longer follow up time (Clifton 2014). The results showed a minimal difference in weight loss of 0.4 kg, favoring high protein diet, compared to any other diet (Clifton 2014). While the effect of a high protein diet on triglycerides and fasting insulin levels was small but significant, the effect on other metabolic markers was not (Clifton 2014). A recent systematic review, focusing on Mediterranean diet versus other diets, identified 5 studies with at least 12 months follow up (Mancini 2016). The results showed that, compared to a low fat diet, a Mediterranean diet is more efficacious in weight loss (range of mean changes in weight: -10.1 to -4.7 kg in Mediterranean diet, versus -5 to +2.9 kg in low fat diet) (Mancini 2016). Noteworthy that some of the aforementioned reviews included studies conducted in patients with chronic diseases, such as diabetes type 2, breast or colon cancer, or following a myocardial infarction, in whom response to diet therapy might be different (Mancini 2016; Tobias 2015). Furthermore, the intervention in some studies was less than 6 months, while the follow up was continued for more than 12 months (21). Accordingly, patients might have reverted to their previous usual diet during the study (Clifton 2014). Reviews focused on overweight and obese individuals, but body mass index (BMI) was missing in one of them (Tobias 2015). Only two reviews described the presence or absence of a concomitant exercise intervention in individual trials (Atallah 2014; Mancini 2016).

Main outcome(s)

Primary outcomes are weight loss and bone loss at ? 1 year

Timing and effect measures

Primary outcome measures, at ? 1 year

- Mean difference in weight loss, or mean difference in percent weight loss

- Mean difference in bone mineral density loss, assessed by DXA scan

Additional outcome(s)

Secondary outcomes are metabolic parameters, body composition, muscle strength, and inflammatory markers

Timing and effect measures

Mean difference in the following, at ? 1 year:

- The change in waist circumference

- The change in glycemic parameters: Fasting glucose, fasting insulin, glycosylated hemoglobin, HOMA index

- The change in blood pressure parameters: systolic and diastolic blood pressure

- The change in lipid profile: serum High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Triglycerides (TG) and Total cholesterol

- The change in liver function tests: ALT, AST, GGT, ALT or hepatic fat content assessed by US or MRI

- The change in CRP level

- The change in muscle strength

- The change in body composition: fat mass and lean mass

- The change in satiety and hunger indices

Data extraction (selection and coding)

We will abstract relevant data from all the included studies in duplicate and independently, using data collection forms, prepared a priori. We will resolve disagreement between reviewers by discussion. If disagreement will not be reached, a content expert will intervene (FH).

We will collect data on the following variables:

-Study characteristics:

Author, Year, Journal

Center

Country

Number of centers involved

Funding

N randomized

N completed the study, and attrition rate

-Population baseline characteristics:

Age

Sex

Ethnicity

Presence or absence of co-morbities

Presence or absence of medications

Weight, height or BMI

Physical activity

Smoking status

-Intervention characteristics:

Duration

Macronutrient composition (types of fat, carbohydrates)

Intensity of intervention (delivery mode, time spent with clinician, dietician, use of pamphlets, use of a multi-component program…)

Co-intervention

-Outcomes characteristics

Before and after or change in level or RR of any of the outcomes, as detailed in the section above.

Risk of bias (quality) assessment

We will assess the risk of bias using the revised Cochrane risk of bias assessment tool 2011 (25). We will assess the risk of publication bias by doing a funnel plot of included studies. For each trial, we will plot the effect by the inverse of its standard error. The symmetry of the funnel plot will be checked visually and formally with Egger's test.

Strategy for data synthesis

For continuous variables, we will calculate the WMD and 95% confidence interval (CI), and for dichotomous variables, we will calculate the risk ratio (RR) with 95% CI. We will conduct a meta-analysis when at least 2 studies are available for a given comparison (any 2 dietary interventions, or a dietary intervention versus usual diet/control). We will conduct random-effects pairwise meta-analyses and network meta-analysis (NMA) to calculate the direct and NMA combined direct and indirect intervention effects on weight loss. We will assume 'transitivity' in NMA which propose that all pairwise comparisons have a similar distribution of the effect modifiers. 'Consistency' of NMA will be assessed whenever we have a closed loop where we will compare direct and indirect estimates.

For the other outcomes, we will conduct a simple meta-analysis when at least 2 studies are available in each comparison, using a random-effects model.

Quantitative analysis will be done as complete case analysis.

We will assess the statistical heterogeneity between studies using ?², with significance at p-value ? 0.05. We will use I² to for the quantitative assessment of heterogeneity.

In case of heterogeneity, we will conduct pre-specified sub-group analysis (see section on additional analysis, below).

Analysis of subgroups or subsets

In case of heterogeneity in results, we will conduct subgroup analysis based on covariates that we expect to affect the weight loss response to dietary interventions. These covariates are:

-overweight versus obese

-caloric restriction versus ad libitum nutrient intake

-age category [younger adults (age <65 years) versus older adults (age ? 65 years)]

-menopausal status

-compliance rate (>80% versus < 80%)

-intervention duration (1-2 years versus > 2 years)

-the presence or absence of behavioral therapy, and/or other components of a commercially available program

-diet fiber content (<14gm/1000 calories vs?14 gm/1000 calories)

Contact details for further information
Marlene Chakhtoura
mc39@aub.edu.lb

Organisational affiliation of the review
American University of Beirut - Lebanon
https://www.aub.edu.lb/

Review team members and their organisational affiliations
Dr Marlene Chakhtoura. American University of Beirut
Dr Jana Jabbour. American University of Beirut - Lebanon
Miss Maria Armache. American University of Beirut - Lebanon
Dr Assem Khamis. American University of Beirut - Lebanon
Dr Florencia Halperin. Brigham and Women's Hospital

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Conflicts of interest

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(there is not an English language summary)

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Review_Ongoing

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Body Weight; Diet; Humans

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Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Versions

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