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[Intervention Review]

Intermittent fasting for adults with overweight or obesity

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ABSTRACT

Rationale

Weight loss remains the primary strategy for reducing health risks and societal consequences associated with overweight and obesity. The most common dietary interventions are calorie-restricted diets, including various permutations of energy restriction, macronutrients, foods, and dietary intake patterns, which achieve initial but often unsustainable weight loss. Intermittent fasting involves eating patterns during which individuals take little or no energy for extended time periods, alternated with periods of normal food intake. The mechanism for weight loss is related to caloric restriction, increased fat metabolism, enhanced insulin sensitivity, and improved glucose metabolism. Intermittent fasting has been publicised in blogs and news articles but studies show inconsistent effects on health, highlighting the uncertainty faced by physicians and people with overweight or obesity when considering intermittent fasting as a feasible approach for sustained weight loss.

Objectives

To evaluate the benefits and harms of intermittent fasting versus regular dietary advice, no intervention or waiting list for adults with overweight or obesity.

Search methods

We searched CENTRAL, MEDLINE (Ovid), and two trials registers up to 5 November 2024, as well as reference checking, citation searching and contact with study authors to identify additional studies.

Eligibility criteria

We included randomised controlled trials (RCTs) and cluster-RCTs that compared intermittent fasting (including time-restricted feeding, periodic fasting, alternate-day fasting, and modified alternate-day fasting) with regular dietary advice, no intervention or waiting list in men and women with overweight or obesity, with or without associated comorbid conditions. The minimum duration of the intervention was four weeks, and the minimum duration of follow-up was six months. We excluded cross-over and quasi-RCTs.

Outcomes

Our outcomes were weight loss, quality of life, participant satisfaction, diabetes status, and adverse events. We considered outcomes measured up to and including 12 months after randomisation as short-term, and longer than 12 months as long-term.

Risk of bias

We used the Cochrane risk of bias tool (RoB 2) and the RoB2 extension for cluster-RCTs.

Synthesis methods

We synthesised results for each outcome using meta-analysis where possible, using random-effects models to calculate risk ratios (RR) and 95% confidence intervals (CI) for dichotomous outcomes, and mean differences (MD) or standardised mean differences (SMD) for continuous outcomes. Where this was not possible due to the nature of the data, we would have synthesised results using narrative synthesis, including the summary of effect estimates. We used GRADE to assess the certainty of evidence for each outcome.

Included studies

We included 22 studies with 1995 participants. All studies were conducted in an outpatient setting in North America, Australia, China, Denmark, Germany, Norway, and Brazil and were published between 2016 and 2024.

Synthesis of results

Compared to regular dietary advice, intermittent fasting may result in little to no difference in percentage from baseline weight loss (MD -0.33, 95% CI -0.92 to 0.26; 21 studies, 1430 participants; low-certainty evidence due to risk of bias). Intermittent fasting may have little to no effect on achieving a 5% reduction in body weight, but the evidence is very uncertain (RR 0.98, 95% CI 0.82 to 1.18; 4 studies, 472 participants; very low-certainty evidence due to risk of bias and imprecision). Intermittent fasting may result in little to no difference in quality of life (SMD 0.11, 95% CI -0.27 to 0.49; 3 studies, 106 participants; low-certainty evidence due to risk of bias and imprecision). Intermittent fasting may have little to no effect on adverse events but the evidence is very uncertain (RR 1.45, 95% CI 0.64 to 3.28; 7 studies, 619 participants; very low-certainty evidence due to risk of bias, inconsistency and imprecision).

Compared to no intervention or waiting list, intermittent fasting likely results in little to no difference in percentage weight loss from baseline (MD -3.42, 95% CI -4.95 to -1.90; 6 studies, 427 participants; moderate-certainty evidence due to risk of bias). Intermittent fasting may result in little to no difference in quality of life, but the evidence is very uncertain (MD 3.49, 95% CI -49.35 to 56.33, 1 study, 60 participants; very low-certainty evidence due to extreme concerns about imprecision). Intermittent fasting may result in little to no difference in adverse events, but the evidence is very uncertain (RR 1.84, 95% CI 0.88 to 3.85; 2 studies, 189 participants; very low-certainty evidence due to risk of bias and imprecision).

None of the included studies reported participant satisfaction, diabetes status or overall measure of comorbidity.

Authors' conclusions

Compared to regular dietary advice, intermittent fasting may result in little to no difference in weight loss or quality of life. Intermittent fasting may result in little to no difference in adverse events, but the evidence is very uncertain. These approaches did not differ in achieving weight loss, producing no clinically meaningful changes in most of the outcomes considered in this review. Compared to no intervention or waiting list, intermittent fasting likely results in little to no difference in weight loss and may result in little to no difference in quality of life or adverse events, but the evidence is very uncertain.

Physicians and patients may need to evaluate willingness and readiness to implement intermittent fasting as a treatment strategy, based on individual practicality and sustainability.

The included studies focused on short-term effects of the intervention (up to 12 months), limiting the applicability of the evidence in this review to inform decision-making for longer durations. It would be beneficial for future studies to extend follow-up periods beyond 12 months to build a stronger evidence base for the long-term effects.

Further research is needed to address the effect of intermittent fasting on several outcomes, including participant satisfaction, diabetes status and overall measures of comorbidities. These studies must consider different populations where obesity and overweight have different burdens, like those from low- and middle-income countries and high-income countries, men or women separately, and different body mass index categories.

Funding

This Cochrane review had no dedicated funding.

Registration

Protocol (2023): doi.org/10.1002/14651858.CD015610

PLAIN LANGUAGE SUMMARY

Intermittent fasting, traditional dietary advice or no treatment: which works better to help adults living with overweight or obesity lose weight?

Key messages

- Compared to traditional dietary advice (like restricting calories or eating different types of foods), intermittent fasting may make little to no difference to weight loss and quality of life in adults living with overweight or obesity. We are less sure about the results for unwanted events.
- Compared to no advice or being on a waiting list, intermittent fasting likely makes little to no difference to weight loss. We are less sure about the evidence for quality of life, and unwanted events (such as fatigue, headache and feeling sick).
- None of the included studies reported people's satisfaction with intermittent fasting, their diabetes status or overall measures of other health problems. We need further research to investigate them.

What is obesity and how could intermittent fasting help?

Obesity is a serious medical condition characterised by high body fat, which can cause weight-related complications and may lead to serious illness (like type 2 diabetes) and death. Worldwide obesity levels are growing, increasing the burden on healthcare systems. Weight loss remains the best way to reduce health risks and effects on society associated with overweight and obesity. Traditional dietary advice includes reducing calories, and changing eating habits to eat healthier foods or different amounts of protein, carbohydrate and fat. Intermittent fasting is a relatively new approach to weight loss. It involves periods where people eat little or no food (fasting), followed by periods when they eat normally. There are different types of intermittent fasting, such as eating only during a set time each day (time-restricted feeding), fasting on certain days of the week (periodic fasting), or alternating between days of eating normally and days of eating very little (alternate-day fasting). Intermittent fasting may improve overall health through helpful changes to some body functions, however, it may lead to unwanted events, such as fatigue, headache or nausea.

What did we want to find out?

We wanted to find out if intermittent fasting was more effective for weight loss for adults living with overweight and obesity than traditional dietary advice. We also wanted to know its effects on people's quality of life, diabetes status, and blood fat measurements, and whether people experienced unwanted effects.

What did we do?

We searched for studies in people over 18 years of age, living with overweight or obesity, who were chosen at random to do intermittent fasting, or to receive traditional dietary advice, no treatment or be on a waiting list. (People on a waiting list are scheduled to receive treatment but do not start it right away; researchers compare them to people who started the treatment immediately). We included studies in people with and without obesity-related illness, such as diabetes or kidney disease.

What did we find?

We found 22 studies with 1995 people who were treated at home or in the community. Studies took place in Europe, North America, China, Australia, and South America.

Compared to traditional dietary advice, intermittent fasting may result in little to no difference in weight loss, measured as change from starting weight (21 studies, 1430 people) and quality of life (three studies, 106 people). We are not sure about its effect on achieving a 5% reduction in body weight (4 studies, 472 people) or on unwanted events (7 studies, 619 people).

Compared to no intervention or waiting list, intermittent fasting likely makes little to no difference to weight loss (6 studies, 427 people). We are not sure about its effect on quality of life (1 study, 60 people) or unwanted events (2 studies, 189 people).

None of the included studies reported people's satisfaction with intermittent fasting, diabetes status or overall measures of other health problems.

What are the limitations of evidence?

We are moderately confident in the results for weight loss when comparing intermittent fasting with no treatment. However, our confidence is low to very low for our other points of interest because most included studies did not use the most robust methods, they included few people, and reported results that were inconclusive.

How up-to-date is this review?

The evidence is up to date to 5 November 2024.

SUMMARY OF FINDINGS

Summary of findings 1. Intermittent fasting compared to regular dietary advice for adults with overweight or obesity

Intermittent fasting versus regular dietary advice

Patient or population: adults with overweight or obesity

Settings: outpatient care in Australia, Brazil, China, Denmark, Germany, North America, and Norway

Intervention: intermittent fasting

Comparison: regular dietary advice

Outcomes	Nº of participants (studies)	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)		Comments
				Risk with regular dietary advice	Risk with intermittent fasting	
Weight loss Assessed with: % change from baseline Follow-up: range 6 months to 12 months	1430 (21 RCTs)	⊕⊕○○ Low ^a	—	Weight loss ranged from -10.56% to -0.69% of baseline weight	MD 0.33 % lower (0.92 lower to 0.26 higher)	Intermittent fasting may result in little to no difference in weight loss.
Weight loss (categorical) Assessed with: % of participants losing 5% of body weight Follow-up: range 6 months to 12 months	472 (4 RCTs)	⊕○○○ Very low ^{a,b}	RR 0.98 (0.82 to 1.18)	408 per 1000	399 per 1000 (334 to 481)	Intermittent fasting may have little to no effect on achieving a 5% reduction in body weight, but the evidence is very uncertain.
Quality of life Assessed with: AQoL-8D SF-36 and RAND-36 Scale from: 0 to 100 (higher scores indicate better quality of life) Follow-up: range 6 months to 12 months	106 (3 RCTs)	⊕⊕○○ Low ^{c,d}	—	Mean QoL ranged from 66.46 points in the AQoL-8D scale to 80 points in the RAND-36 scale	SMD 0.11 SD higher (0.27 lower to 0.49 higher)	Intermittent fasting may result in little to no difference in quality of life. This corresponds to an MD of 0.13 (95% CI -0.31 to 0.57) in the SF-36 general physical health domain, an MD of 0.12 (95% CI -0.31 to 0.57) in the RAND-36 items general physical health domain, and an MD of 0.12 (95% CI -0.30 to 0.54) in the AQoL-8D.
Adverse events Assessed with: rate of participants with any adverse event	619 (7 RCTs)	⊕○○○ Very low ^{a,d,e}	RR 1.45 (0.64 to 3.28)	279 per 1000	404 per 1000 (178 to 915)	Intermittent fasting may have little to no effect on adverse events, but the evidence is very uncertain. This analysis included two studies that reported no adverse events, for

Follow-up: range 6 months to 12 months		which the outcome was not estimable. Reported adverse events in the remaining studies included nausea, headache, dizziness, hunger, constipation, dyspepsia, cold intolerance, irritability, insomnia and impaired concentration.
Participants' satisfaction	None of the included studies reported this outcome under this comparison.	
Diabetes status	None of the included studies reported this outcome under this comparison.	

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

AQoL-8D: Assessment of Quality of Life - 8D; **CI:** confidence interval; **MD:** mean difference; **QoL:** quality of life; **RCT:** randomised controlled trial; **RR:** risk ratio; **SF-36:** Short-Form Health Survey; **SMD:** standardised mean difference

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded two levels due to risk of bias. We found an overall high risk of bias in most included studies reporting this outcome, with serious limitations in one or more criteria.

^bDowngraded one level due to imprecision. We found a low number of participants and events, and 95% CI including both benefits and harms.

^cDowngraded one level due to risk of bias. We found an overall high risk of bias in one included study and some concerns in the remaining studies reporting this outcome.

^dDowngraded one level due to imprecision. The 95% CI includes both benefits and harms.

^eDowngraded one level due to inconsistency. We found substantial heterogeneity in the effect estimates of the included studies.

Summary of findings 2. Intermittent fasting compared to no intervention or waiting list for adults with overweight or obesity

Intermittent fasting compared to no intervention or waiting list

Patient or population: adults with overweight or obesity

Settings: outpatient care in Australia, Germany, and the USA

Intervention: intermittent fasting

Comparison: no intervention or waiting list

Outcomes	Nº of participants (studies)	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	Comments
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				Risk with no intervention or waiting list	Risk with intermittent fasting	
Weight loss Assessed with: % change from baseline Follow-up: range 6 months to 12 months	427 (6 RCTs)	⊕⊕⊕○ Moderate ^a	—	Weight loss ranged from -2.79% to 1.11% of baseline weight	MD 3.42% lower (4.95 lower to 1.90 lower)	Intermittent fasting likely results in little to no difference in weight loss.
Weight loss (categorical) Assessed with: % of participants losing 5% of body weight	None of the included studies reported this outcome under this comparison.					
Quality of life Assessed with: SF-36 Scale from: 0 to 100 (higher scores indicate better quality of life) Follow-up: 12 months	60 (1 RCT)	⊕○○○ Very low ^b	—	Mean QoL was 65.04	MD 3.49 points higher (49.35 lower to 56.33 higher)	Intermittent fasting may result in little to no difference in the general physical health domain of quality of life, but the evidence is very uncertain.
Adverse events Assessed with: rate of participants with any adverse event Follow-up: range 6 months to 12 months	189 (2 RCTs)	⊕○○○ Very low ^{c,d}	RR 1.84 (0.88 to 3.85)	99 per 1000	181 per 1000 (87 to 380)	Intermittent fasting may have little to no effect on adverse events, but the evidence is very uncertain. This analysis included one study that reported no adverse events, for which the outcome was not estimable. Reported adverse events in the other study included back pain, flu, nausea, headache, dizziness, diarrhoea, and constipation.
Participants' satisfaction	None of the included studies reported this outcome under this comparison.					
Diabetes status	None of the included studies reported this outcome under this comparison.					

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **QoL:** quality of life; **RCT:** randomised controlled trial; **RR:** risk ratio; **SF-36:** short-form health survey

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

- ^aDowngraded one level due to risk of bias. We found an overall high risk of bias in most included studies, with serious limitations in one criterion or some limitations in multiple criteria.
- ^bDowngraded three levels due to extreme imprecision. The sample size was small. The 95% CI includes considerable harm, no effect, and large benefit.
- ^cDowngraded two levels due to high risk of bias in several domains in the included studies.
- ^dDowngraded one level due to imprecision. The 95% CI includes both benefits and harms.

BACKGROUND

Description of the condition

Obesity is a serious medical condition characterised by excess adiposity, which is a source of extensive morbidity and mortality, due to several weight-related complications that may impair health [1]. It is a significant public health problem in modern society that has become a leading cause of death in high-income countries (HICs) [2, 3, 4]. Between 1980 and 2013, the prevalence of obesity or overweight increased by 27.5% for adults and by 47.1% for children worldwide, with a total of 2.1 billion individuals living with overweight or obesity [5]. According to the World Health Organization (WHO), obesity has tripled globally since 1975 [6], with overweight and obesity levels across low- and middle-income countries (LMICs) approaching those found in HICs, especially in the Middle East and North Africa, and in Latin America and the Caribbean [7]. In HICs, obesity prevalence is highest among those experiencing poverty, while overweight is prevalent across all wealth groups. In contrast, the prevalence of obesity and overweight in LMICs is higher among wealthier individuals than those experiencing poverty [8]. Higher overweight rates are seen in women compared with men, in urban compared with rural settings, and in older people compared with younger people, although the urban-rural overweight differential is shrinking in many countries [9]. A recent body mass index (BMI) analysis in the USA predicted that by 2030, one in two adults will live with obesity [10].

Obesity is considered a risk factor for cardiovascular disease, type 2 diabetes, and cancer [11]. This leads to an average increase in annual healthcare costs of 36% and medication costs of 77% compared with a person of average weight [5], and imposes a large economic burden on the individual, families, and nations [12]. Besides excess healthcare expenditure, obesity also imposes costs due to lost productivity and foregone economic growth, due to lost work days, lower productivity at work, mortality, and permanent disability. In 2014, the global economic impact of obesity was estimated to be US Dollars (USD) 2.0 trillion, or 2.8% of global gross domestic product [12].

Multiple factors influence the development of obesity, including individual, social, environmental, and macro-level determinants [13]. Individual determinants include biological, psychological, and behavioural factors, such as metabolic disorders, excessive calorie consumption, physical inactivity, and psychological factors [14]. Social determinants include cultural and economic factors. Environmental determinants may consist of (but are not limited to) the lack of or barriers to accessing healthy foods and safe walking areas within the neighbourhood. Macro-level determinants relate to the influence of the media, access to health care, and government policies [13]. The diagnostic evaluation for obesity involves both an anthropometric component, such as BMI and waist circumference, and a clinical component that constitutes an assessment of the risk, presence, and severity of weight-related complications, indicating increased fat mass and the degree to which the excess adiposity is adversely affecting the health of the individual [1].

Epidemiologic studies define overweight and obesity using BMI (weight (kg)/height² (m)) to stratify obesity-related health risks at a population level. An adult with overweight is operationally defined as having a BMI between 25 kg/m² and 29.9 kg/m². An adult with obesity is defined as having a BMI exceeding 30 kg/m², which is

further subclassified into class 1 obesity (BMI 30 kg/m² to 34.9 kg/m²), class 2 obesity (BMI 35 kg/m² to 39.9 kg/m²), and class 3 obesity (BMI ≥ 40 kg/m² [15]). While BMI is widely used, it is not a reliable indicator of obesity at the individual level, particularly when comparing different ethnic groups [16]. The treatment of overweight and obesity involves weight management to reduce health risks. This includes the promotion of weight loss, weight maintenance, and prevention of weight regain, along with physical activity, behavioural therapy, pharmacotherapy, surgery, and the prevention and treatment of potential comorbidity [17].

Description of the intervention and how it might work

Intermittent fasting involves eating patterns during which individuals take little or no energy for extended time periods alternated with periods of normal food intake [18, 19]. This may imply consuming the entire daily caloric intake in a specific time window, for example, eight hours, or it may mean eating one day and completely fasting the next day [20]. During the fasting period, consuming calories frequently varies from 0% to 35% of regular caloric needs [3]. Food consumption on non-fasting days can be unrestricted, limited to a specific diet, or oriented to achieve a specific caloric intake of up to 125% of regular caloric needs [20]. Intermittent fasting can be administered alone or as part of a programme with multiple interventions (such as physical activity, behavioural therapy, etc.) [21, 22].

There are several different types of intermittent fasting [23].

- Time-restricted feeding: focuses on the duration of the fasting and eating windows within a 24-hour period; daily food intake is restricted to a certain time window (usually ≤ 10 hours), and the overnight fast is extended to at least 14 hours.
- Periodic fasting: fasting one to two days a week, with unrestricted consumption of food on the remaining five to six days [20].
- Alternate-day fasting: a regimen of 24 hours of fasting on alternate days, with modified fasting or a restricted calorie intake on fasting days and regular eating on non-fasting days [24].
- Modified alternate-day fasting: a degree of calorie restriction or modified fasting during fasting periods, such as the 5:2 diet, during which drastic energy restriction is imposed for two days a week, and food consumption is unrestricted for the remaining five days. Modified alternate-day fasting has two key elements:
 - food restriction is applied on alternate days (nominally 24 hours, although practically more varied to accommodate sleep); and
 - any energy allowed during the fast is provided in a single meal, ensuring a tangible extension of the typical overnight fast [24].

Physicians' training in intermittent fasting is essential to provide adequate information, ongoing communication, support, and potential co-interventions [25, 26].

Modifying diet and meal frequency by several fasting patterns may represent a new paradigm in today's medical approaches [27]. Intermittent fasting may lead to various physiological beneficial effects, such as weight loss, improved insulin sensitivity, reduced inflammation, increased cell repair, improved cardiovascular and cognitive health, changes in hormone production, and

enhanced immune system functionality [25, 28]. However, the exact mechanisms for these effects are poorly understood [29].

The mechanism for weight loss is related to caloric restriction, increased fat metabolism, enhanced insulin sensitivity, and improved glucose metabolism. Glucose and fatty acids are essential sources of energy for metabolism. Glucose is used for fuel after meals, and fat is stored as triglycerides. During fasting periods, triglycerides are broken down into fatty acids and glycerol, which are then converted to ketone bodies by the liver, which provides a significant source of energy for many tissues during fasting, and promotes fat loss [25], which may lead to positive changes in body composition [30]. Ketone bodies may contribute to the epigenetic control of gene expression, DNA repair, and genome stability [31], leading to cell restoration, which may positively affect cognition and survival. Intermittent fasting also restores a catabolic process that recycles nutrients in starvation, and maintains cellular energy homeostasis, enhancing the immune system's functionality [32].

Other proposed mechanisms of action are related to changes in endogenous circadian clocks, which regulate the production of metabolites and hormones, such as cortisol, insulin, and glucagon, which in turn, affect body weight and composition [33]. These changes may also positively affect the diversity of the intestinal microbiome [34]. In animal models, this promotes the browning of white adipose tissue, increases thermogenesis, and may contribute to weight loss [29]. Different types of fasting can have varying impacts on weight loss due to differences in how they affect calorie intake and metabolic processes, as longer fasting periods may not necessarily be superior and could even encourage more fat storage than other fasting approaches [35].

Adverse effects of the intervention

Potential risks of intermittent fasting include dehydration, hypoglycaemia (low blood sugar), fatigue, weakness, dizziness, hypotension (low blood pressure), insomnia, nausea, headache or migraines, presyncope or syncope (feeling faint or fainting), dyspepsia (indigestion), malnutrition, and excessive hunger. Overeating is an expected consequence, although studies show that participants maintain a regulation of intake after the fasting period [36]. Special considerations are needed in people with mental illness or undiagnosed eating disorders [37]. A dietitian or nutritionist should be consulted to ensure that the nutritional needs of the person are being met.

Why it is important to do this review

As overweight and obesity rates increase, weight loss remains the primary strategy for reducing health risks and societal consequences associated with overweight and obesity [38]. Both observational studies and controlled trials have reported that a 5% weight loss produces clinically significant improvements in obesity-associated conditions [39]. Several clinical practice guidelines and scientific societies state that current research on intermittent fasting is limited, and recommend offering a comprehensive lifestyle intervention that combines behavioural, dietary, and physical activity components as foundational elements of any weight management intervention [15, 39, 40].

Intermittent fasting involves eating patterns during which individuals take little or no energy for extended time periods alternated with periods of normal food intake [41]. Therefore, it becomes necessary to search for effective interventions that people

can follow in the long term, and which provide permanent or sustained weight loss [42].

Over recent years, intermittent fasting has been publicised in blogs and news articles [28]. Studies show inconsistent effects on health, highlighting the uncertainty faced by physicians and people with overweight or obesity when considering intermittent fasting as a feasible approach for sustained weight loss [27]. Although a recent Cochrane review addressed the effects of intermittent fasting in preventing and reducing the risk of cardiovascular disease, most included studies recruited participants without overweight or obesity, limiting their findings for this population [23]. Other non-Cochrane systematic reviews have assessed the effect of intermittent fasting in specific populations, such as people with diabetes and multiple sclerosis. They focused on surrogate outcomes, such as fasting insulin or systolic blood pressure, instead of primary clinical outcomes, such as quality of life or participants' satisfaction [3, 43]. The methodological limitations raise concerns about the generalisability and applicability of their findings in people with overweight and obesity.

OBJECTIVES

To evaluate the benefits and harms of intermittent fasting versus regular dietary advice, no intervention or waiting list for adults with overweight or obesity.

METHODS

We followed the Methodological Expectations for Cochrane Intervention Reviews (MECIR) when conducting the review [44] and the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) 2020 for the reporting [45].

We based parts of the Methods, as well as [Supplementary material 1](#) of this Cochrane review, on a standard template established by the Cochrane Metabolic and Endocrine Disorders Group.

Differences between protocol and review

We reformulated the objectives to 'To evaluate the benefits and harms of intermittent fasting versus regular dietary advice, no intervention or waiting list for adults with overweight or obesity' as suggested by the Managing Editor [46].

We deleted 'placebo' from the possible comparisons, as this comparison is very unlikely to be found in trials, and we found no studies using placebo as a comparator [46].

We simplified the definition of adverse events to 'Adverse events: defined as the number of participants experiencing adverse outcomes that occur during or after the intervention, such as fatigue, headache and nausea, or otherwise as defined by the trial authors' to better match the reported adverse events in the included studies [46].

We incorporated the subgroup analyses of gender and country income into the [Equity-related assessment](#) section. We incorporated additional detail in [Supplementary material 9](#).

We incorporated additional information on [Consumer involvement](#) in [Supplementary material 10](#).

We prioritised weight loss reported as the percentage change from baseline. We transformed the available data to this unit for the analyses when not available or reported in kg of weight loss, to maximise the use of available information and enhance interpretability.

We prioritised the short-term time point for the summary of findings tables, as most included studies had 6 to 12 months of follow-up, and only one study had data for long-term follow-up (> 12 months; Teong 2023 [47, 48, 49, 50, 51]).

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) and cluster-RCTs.

Following guidelines in Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions*, we excluded cross-over trials because they may have a potential withdrawal, rebound, or carry-over effect during or after the washout period [52]. We also excluded quasi-RCTs (any quantitative study that uses inappropriate strategies of allocating units to intervention groups).

We included studies reported as full text, those published as an abstract only, and unpublished data where it was possible to establish their eligibility for inclusion when data were limited.

Types of participants

We included trials including participants aged 18 years or older with overweight or obesity, with or without associated comorbid conditions such as diabetes, kidney disease, fatty liver disease, etc.

If we identified studies in which only a subset of participants was relevant to this review, we included these studies if data were available separately for the relevant subset or if more than 80% of participants met the inclusion criteria.

Diagnostic criteria for overweight and obesity

We used BMI as the anthropometric measurement for diagnosing obesity and overweight. BMI provides the most used population-level measure of overweight and obesity, as it is the same for both sexes and for all adult ages [6]. We used these cutoff points [1, 15]:

- overweight (BMI 25 kg/m² to 29.9 kg/m²);
- obesity (BMI ≥ 30 kg/m²).

If the included studies used different cutoff points to diagnose overweight and obesity, we used the classification defined by the study authors.

Types of interventions

We included trials that compared intermittent fasting alone or as part of a programme with multiple interventions (such as physical activity, behavioural therapy, etc.) with no intervention, waiting list or other dietary interventions, for example, the Mediterranean diet, as specified by the study authors. To establish a fair comparison, we included co-interventions, such as exercise, provided they were not part of the randomised treatment and were comparable in both the intervention and comparator groups. If a study included multiple arms, we included any arm that met the inclusion criteria for this review.

We planned to investigate the following comparisons of intervention versus control or comparator.

Intervention

- Intermittent fasting

Different types of intermittent fasting methods and details are described in [Description of the intervention and how it might work](#).

We excluded studies that report religious fasts, as their aim is not weight loss or improvement of metabolic variables [53].

Comparators

- Regular dietary advice: as defined by the study authors. This could include an eating plan emphasising fruit, vegetables, whole grains, seafood, caloric restriction, or any specific dietary advice for weight loss.
- No intervention or waiting list

Minimum duration of intervention

The minimum duration of the intervention was four weeks, which is the shortest time frame described for dietary interventions [42, 54, 55].

Minimum duration of follow-up

The minimum duration of follow-up was six months, which is the time point at which weight loss tends to plateau [38, 42, 54, 55].

Outcome measures

We did not exclude a study if it failed to report more than one of our primary or secondary outcome measures of interest. We only excluded studies if none of our outcomes of interest were measured, and provided there was evidence to support this, for example, contact with study authors, access to the original protocol, etc. When studies reported multiple outcome measures, we prioritised the most reported scale among the included studies. We prioritised weight loss reported as percentage change from baseline. We transformed the available data to this unit for the analyses when not available or reported in kg of weight loss, to maximise the use of available information and enhance interpretability.

Critical outcomes

- Weight loss
- Quality of life
- Adverse events

Important outcomes

- Participant satisfaction
- Diabetes status
- Changes in lipid profile
- Overall measure of comorbidity

Method of outcome measurement

- Weight loss: defined as a continuous outcome, such as the percentage of baseline weight lost, number of kg lost, or both; or as a categorical outcome, such as the proportion of participants achieving a 5% weight loss from baseline [56]

- Quality of life: evaluated by a validated instrument, such as the Short-Form Health Survey (SF-36), the 12-item Short-Form Health Survey (SF-12) or EuroQol-5D [56, 57]
- Adverse events: defined as the number of participants who experienced adverse outcomes that occurred during or after the intervention, such as fatigue, headache and nausea, or otherwise as defined by the study authors [56]
- Participant satisfaction: assessed by the mean Outcomes and Experiences Questionnaire (OEQ) score, adapted to suit weight-management services, or mean National Health Service Friends and Family Test (NHSFFT) score [56]
- Diabetes status: the percentage of participants with incident type 2 diabetes mellitus (based on self-report, electronic health records, or blood tests, such as a change in glycosylated haemoglobin levels or fasting glucose [56])
- Change in lipid profile: the mean change from baseline for total cholesterol levels, high-density lipoprotein (HDL) levels, and triglycerides of participants, obtained via blood test [56]
- Overall measure of comorbidity: assessed with a validated tool that assesses the burden of comorbidity, such as the Edmonton Obesity Staging System (EOSS) score [56], the Charlson Comorbidity Index [56], the Elixhauser Comorbidity Index [58], or any other tool reported by study authors

Timing of outcome measurement

We considered outcomes measured up to and including 12 months after randomisation as short-term, and those measured at more than 12 months as long-term. When multiple results were reported for each outcome, we included the longest follow-up in each category.

Minimally important difference

The minimal clinically important difference (MCID) may not have been available for all outcomes considered, but we stated it when available. We considered an absolute change of 5% in body weight as MCID [39, 59, 60]. For quality of life, we considered a mean change of 0.03 points on the EuroQol-5D, and 5 points on the SF-12 as MCID [61, 62].

Search methods for identification of studies

Electronic searches

We searched the following sources from the inception of each database to 5 November 2024; we placed no restrictions on the language of publication:

- Cochrane Central Register of Controlled Trials (CENTRAL; 2024, Issue 11) via the Cochrane Library;
- MEDLINE Ovid; MEDLINE ALL (1946 to 5 November 2024);
- ClinicalTrials.gov (www.clinicaltrials.gov);
- World Health Organization International Clinical Trials Registry Platform (ICTRP; www.who.int/trialsearch).

We did not include Embase in our search, as RCTs indexed in Embase are now prospectively added to CENTRAL via a highly sensitive screening process [63]. For detailed search strategies, see [Supplementary material 1](#). We combined the MEDLINE search with the Cochrane Highly Sensitive Search Strategy for randomised trials: sensitivity and precision-maximising version [64].

Searching other resources

We attempted to identify other potentially eligible studies or ancillary publications by searching the reference lists of included studies and systematic reviews, meta-analyses, and health technology assessment reports identified during our searches. We contacted experts in the field to identify additional unpublished materials. We also contacted the authors of the included studies to request additional information on the retrieved studies and establish whether we may have missed further studies. We searched for errata or retractions of the included studies.

Data collection and analysis

Selection of studies

Two review authors (from LG, GO, DI, MAB, PA, SR, MB and DR) independently screened the abstract, title, or both, of every record retrieved by the literature searches. We obtained the full text of all potentially relevant records. We resolved disagreements through consensus or by recourse to a third review author (EM). If we did not resolve a disagreement, we categorised the study as 'awaiting classification' and contacted the study authors for clarification. We presented a PRISMA flow diagram to show the study selection process [45]. We listed all articles excluded after full-text assessment in a 'Characteristics of excluded studies' table and provided the reasons for exclusion [45]. We used Covidence software for study selection [65].

Data extraction and management

For studies that fulfilled our inclusion criteria, two review authors (from LG, GO, DI, MAB, PA, SR, MB and DR) independently extracted key information on participants, interventions, comparators and outcomes, using a data collection form that was piloted ahead of time on at least one study in the review. We extracted the following data from the reports.

- Methods
 - Study design
- Participants
 - Inclusion and exclusion criteria
 - Participant details, baseline demographics (number of male participants, mean age, age range, gender, diagnosis criteria, BMI, severity of the condition, dyslipidaemia, diabetes mellitus, inclusion criteria and exclusion criteria)
 - The number of participants by study and by study arm
- Interventions and comparisons, according to the Template for Intervention Description and Replication (TIDieR) checklist [66, 67]
 - Name of the intervention
 - **Why:** rationale, theory or goal of the elements essential to the intervention
 - **What:** physical or informational materials used in the intervention; procedures, activities, or processes used in the intervention
 - **Who provided:** expertise, background and specific training given
 - **How:** describe modes of delivery
 - **Where:** describe the location where the intervention occurred, including infrastructure and features

- **When/how much:** the number of times the intervention was delivered over a period of time
- **Tailoring:** describe if personalisation or adaptations were planned
- **Modifications:** during the course of the study
- **How well:** measurements of adherence or fidelity
- Outcomes
 - Definitions of relevant outcomes, method and timing of outcome measurement, as well as any relevant subgroups to the review
- Study dates (start date to end date; we reported if dates were not available)
- Study settings and country, language of publication, and study identifier
- Study funding sources
- Declarations of interest by study authors

We reported these data in the 'Characteristics of included studies' table in [Supplementary material 2](#).

We contacted all authors of the included studies to enquire whether they were willing to answer questions regarding their studies. We documented these communications. We sought relevant missing information on the study from the primary study authors if required.

Dealing with duplicate and companion publications

In the event of duplicate publications, companion documents, or multiple reports of a primary study, we maximised the information yield by collating all available data, and we used the most complete data set, aggregated across all known publications. We listed duplicate publications, companion documents, multiple reports of a primary study, and trial documents of included trials (such as trials registry information) as secondary references under the study ID of the included study. We also listed duplicate publications, companion documents, multiple reports of a study, and trial documents of excluded trials (such as trials registry information) as secondary references under the study ID of the excluded study.

Data from clinical trials registers

If data from included studies were available as study results in clinical trials registers, such as ClinicalTrials.gov or similar sources, we used this information in its entirety and extracted the data. If there was also a full study publication, we collated and critically appraised all available data. If the published and unpublished data did not match, we asked the study authors for clarification; if we received no response we presented the discrepancies in the full review report. If an included study was labelled as completed in a clinical trials register but no additional information (study results, publication, or both) was available, we added this study to the 'Characteristics of studies awaiting classification' table.

Risk of bias assessment in included studies

Two review authors (from LG, GO, DI, MAB, PA, SR, MB, and DR) independently assessed the risk of bias for the results of the primary outcomes (those included in the Summary of findings tables, see below) in each study, using the Cochrane risk of bias tool (RoB 2) [68]. We resolved disagreements by consensus or by consulting a third review author (EM). If adequate information was unavailable from the publications, trial protocols, clinical study

reports, or other sources, we contacted the study authors for more details on the risk of bias items. We assessed the risk of bias according to the following domains, focusing on the effect of assignment to the intervention at baseline:

- the randomisation process;
- deviations from intended interventions;
- missing outcome data;
- measurement of the outcome;
- selection of the reported results.

We collectively used the answers to signalling questions and supporting information to reach a domain-level judgement of low risk, some concerns, or high risk of bias. These domain-level judgements informed our overall risk of bias judgement for a single outcome result as:

- low risk, if we judged all domains as low risk;
- some concerns, if we judged one or more domains as giving some concerns; or
- high risk, if we judged one or more domains as high risk, or if four domains gave us some concerns.

We provided a quote from the study report, together with a justification for our judgement, in the risk of bias table. We summarised the risk of bias judgements across different studies and domains for each outcome described. When judging the bias due to deviations from intended interventions, we focused the analyses on the effect of assignment to intervention [68]. We aimed to source trials registries, protocols, and analysis plans to assess selective reporting. Where information on the risk of bias related to unpublished data or correspondence with a study author, we noted it in the risk of bias table.

When considering treatment effects, we considered the risk of bias for the studies that contributed to that outcome. We constructed summary assessments of the risk of bias for each important outcome (across domains) within and across studies [68].

We used the RoB 2 Excel tool to manage the data supporting the answers to the signalling questions and risk of bias judgements (available at www.riskofbias.info/). All these data are publicly available, as supplementary material, in a public repository (visit <https://osf.io/9mxq5/>; DOI 10.17605/OSF.IO/9MXQ5).

For cluster-RCTs, we used the RoB 2 tool, plus a specific domain for cluster-RCTs from the archived version of the tool (Domain 1b. Bias arising from the timing of identification and recruitment of participants; available at www.riskofbias.info), with its corresponding signalling questions, following the guidance in the *Cochrane Handbook*, Section 23.1.2 and Table 23.1.a [52].

Measures of treatment effect

We expressed dichotomous data as a risk ratio (RR) with 95% confidence intervals (CIs). For continuous outcomes measured on the same scale, for example, weight loss in kg, we estimated the intervention effect using the mean difference (MD) with 95% CIs. When data were pooled from studies that used different instruments to measure the same outcome, we calculated standardised mean differences (SMDs) with 95% CIs. We entered data presented as a scale with a consistent direction of effect, and multiplied the SMD by a standard deviation (SD) that is

representative of the pooled studies, for example, the SD from a well-known scale used by several of the studies included in the analysis on which the result was based.

Unit of analysis issues

We considered the level at which randomisation occurred and multiple observations for the same outcome. If more than one comparison from the same study was eligible for inclusion in the same meta-analysis, we either combined groups to create a single pair-wise comparison, or appropriately reduced the sample size so that the same participants did not contribute data to the meta-analysis more than once (splitting the shared group into two or more groups). Although the latter approach offers some solutions for adjusting the precision of the comparison, it does not account for correlation arising from the inclusion of the same set of participants in multiple comparisons [52].

We re-analysed cluster-RCTs that had not appropriately adjusted for the potential clustering of participants within clusters in their analyses. We inflated the variance of intervention effects using a design effect. Calculating a design effect involves the estimation of an intracluster correlation coefficient (ICC), specified in Chapter 23 of the *Cochrane Handbook* [52]. We obtained estimates of ICCs by contacting study authors or by imputing ICC values, using either estimates from other included studies that reported ICCs or external estimates from empirical research. We examined the impact of clustering by performing sensitivity analyses.

Dealing with missing data

If possible, we obtained missing data from the authors of the included studies. We carefully evaluated important numerical data, such as screened, randomly assigned participants, and intention-to-treat, as-treated, and per-protocol populations in our risk of bias assessments. For this, we investigated attrition rates, such as dropouts, losses to follow-up, and withdrawals, and critically appraised issues concerning missing data and the use of imputation methods, for example, the last observation carried forward. For our primary analyses, we conducted available case analyses, considering these issues when assessing the risk of bias and the certainty of the evidence.

For studies where the outcome's SD was unavailable at follow-up, or we could not recreate it, we standardised by the mean of the pooled baseline SD from studies that reported this information.

Reporting bias assessment

If we included 10 studies or more per comparison and outcome, we used funnel plots to assess small-study effects. Several explanations may account for funnel plot asymmetry, including true heterogeneity of effect with respect to study size, poor methodological design (and hence small-study bias), and selective non-reporting [69]. Therefore, we interpreted the results carefully [70].

Synthesis methods

We undertook a meta-analysis only if we judged the participants, interventions, comparisons, and outcomes to be sufficiently similar to ensure a clinically meaningful result. Unless good evidence showed homogeneous effects across studies of different methodological quality, we primarily summarised data using a random-effects model [71]. We interpreted random-effects meta-

analyses with due consideration for the whole distribution of effects, and presented a confidence interval. We performed statistical analyses according to the statistical guidelines presented in the *Cochrane Handbook* [72]. When meta-analysis was not possible, we conducted alternative forms of synthesis, including the summary of effect estimates, the combination of P values, and vote counting, based on the direction of effects, as described in Chapter 12 of the *Cochrane Handbook* [73].

In the event of substantial clinical or methodological heterogeneity, we did not report study results as the pooled effect estimate in a meta-analysis.

We visually examined the variability in point estimates and the overlap in confidence intervals. We used the I^2 statistic to estimate the degree of heterogeneity present among the trials in each analysis. If we identified substantial unexplained heterogeneity, we reported it, and explored possible causes by prespecified subgroup analysis. We used this rough guide to interpretation, outlined in Chapter 10 of the *Cochrane Handbook* [72]:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

We avoided using absolute cutoff values but interpreted the I^2 statistic in relation to:

- the size and direction of effects; and
- the strength of evidence for heterogeneity, for example, P value from the Chi^2 test or CI for the I^2 statistic.

Investigation of heterogeneity and subgroup analysis

We expected the following characteristics to introduce clinical heterogeneity, and we planned to carry out subgroup analyses for them, including an investigation of interactions [74].

- LMICs versus HICs, based on the World Bank classification (available at the World Bank website)
- Men versus women, considering studies conducted in one gender exclusively or with over 80% of participants representing a specific gender to establish the subgroups.
- Overweight versus obesity
- Different types of intermittent fasting
- Delivery of the interventions: intermittent fasting alone versus intermittent fasting as a component of a programme with multiple interventions

We used the formal test for subgroup interactions in Review Manager (RevMan) [75], acknowledging its limitations due to its observational nature and low power to detect differences with fewer than 10 studies per category [72].

Equity-related assessment

We investigated equity-related characteristics using the PROGRESS-Plus framework [76], and following the guidance in Chapter 16 of the *Cochrane Handbook*, by assessing the effects of the intervention and exploring the potential differences between LMICs versus HICs [77]. Additionally, we explored the different effects of the intervention on men and women. We based

these analyses on the different distributions and incidences of obesity and overweight according to country incomes [7, 8], and gender [9] (see [Investigation of heterogeneity and subgroup analysis](#)). [Supplementary material 9](#) describes the equity-related characteristics of participants that led to the interpretation of the results.

Sensitivity analysis

We planned to perform sensitivity analyses to explore the influence of the following factors (when applicable) on effect sizes.

- Restricting the analysis to studies at an overall low risk of bias
- Restricting the analysis to published studies (if there were any unpublished studies)
- Excluding studies with cluster randomisation

Certainty of the evidence assessment

We presented the overall certainty of the evidence for each outcome specified below, according to the GRADE approach, which considers issues related to internal validity (overall risk of bias, inconsistency, imprecision, publication bias) and external validity (directness of results). Two review authors (from LG, GO, DI, MAB, PA, SR, MB, and DR) independently rated the certainty of the evidence for each outcome. We resolved any differences in assessment by discussion or by consulting a third review author (EM).

We presented a summary of the evidence in the summary of findings tables, with:

- key information about the best estimate of the magnitude of effect, in relative terms and as absolute differences, for each relevant comparison of alternative management strategies;
- the numbers of participants and studies addressing each important outcome; and
- a rating of overall confidence in effect estimates for each outcome.

We created the summary of findings tables using the methods described in the *Cochrane Handbook* [78], RevMan [75], and GRADEpro GDT software [79].

When meta-analysis was impossible, we presented the results in a narrative format in the summary of findings tables. We justified all decisions to downgrade the certainty of the evidence by using informative footnotes and GRADE guidelines for informative statements [80, 81].

We created summary of findings tables for the following comparisons and outcomes:

- Comparisons
 - Intermittent fasting versus regular dietary advice
 - Intermittent fasting versus no intervention or waiting list
- Outcomes:
 - Weight loss: reported as a categorical outcome, such as the proportion of participants achieving a 5% weight loss from baseline, or as a continuous outcome, using the percentage of baseline weight lost
 - Quality of life
 - Adverse events
 - Participants' satisfaction
 - Diabetes status

Consumer involvement

Consumers were not involved in this review. We included several nutrition specialists in the author team, among other medical doctors and allied professionals who participated in all the stages of the review process. More information is in [Supplementary material 10](#).

RESULTS

Description of studies

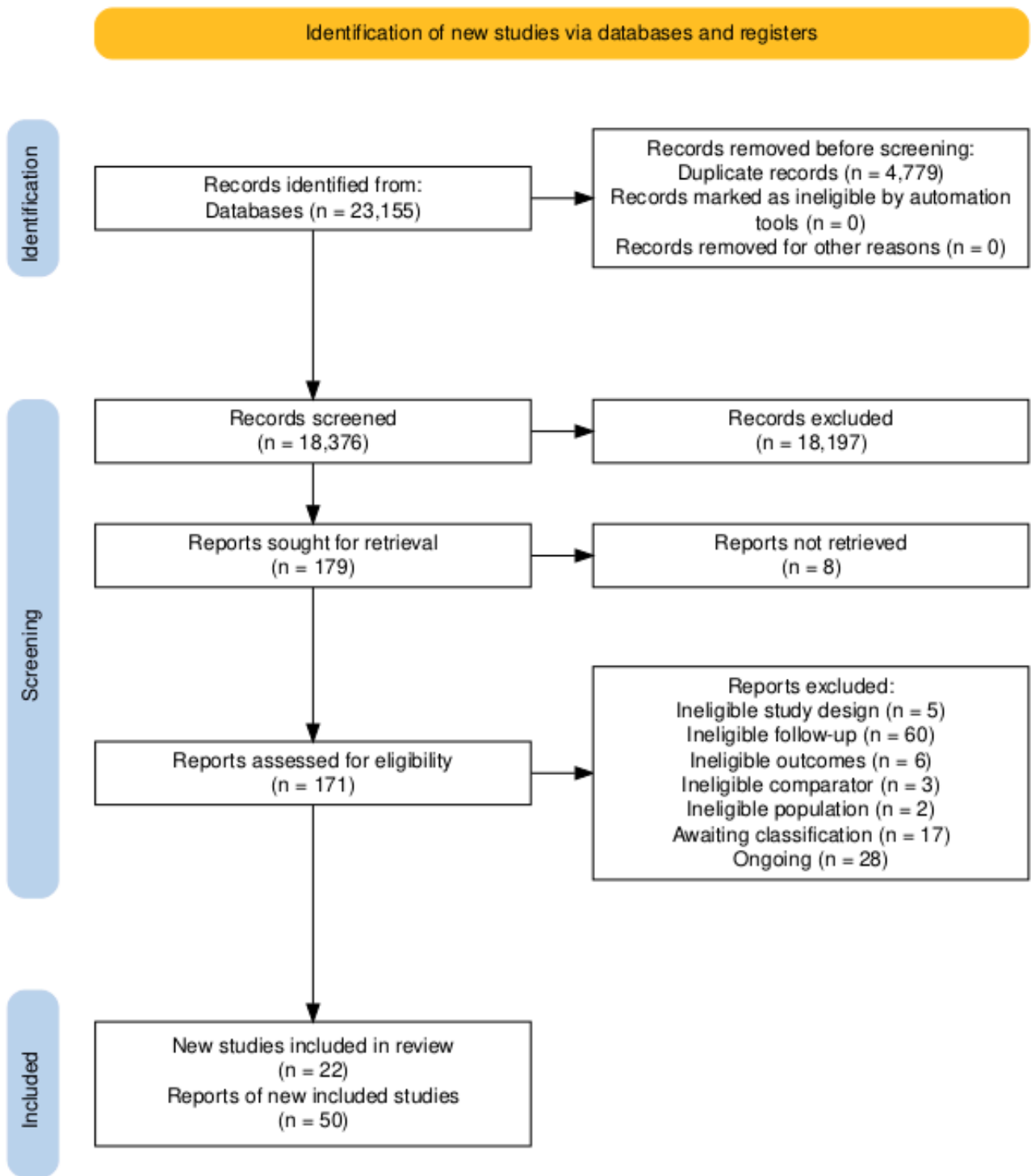
For study details, see [Supplementary material 2](#); [Supplementary material 3](#); [Supplementary material 4](#); [Supplementary material 5](#).

A complete record of all comparisons and analyses is available for this review in [Supplementary material 7](#) and a full data package is available in [Supplementary material 8](#).

Results of the search

The database searches identified 23,155 search results, of which 18,376 records remained after deduplication. We excluded 18,197 after the title and abstract screening. We sought the full texts of the remaining 179 records, eight of which were not retrieved. We excluded 76 records (representing 75 studies) (see [Supplementary material 3](#)). We classified 17 records (representing 16 studies) as awaiting classification (see [Supplementary material 4](#)) and found 22 ongoing studies (with 28 reports) (see [Supplementary material 5](#)). We finally included 22 studies with 50 reports. Our screening of the reference lists of the included publications did not reveal any additional RCTs. See the study flow diagram for a detailed description of the screening process ([Figure 1](#))^[82].

Figure 1. Study flow diagram



All studies were reported in English and published between 2016 and 2024. Twenty studies were published as full papers (Bartholomew 2021 [83]; Catenacci 2016 [84]; Conley 2018 [85, 86]; de Oliveira 2021 [87]; Dunn 2024 [88, 89]; Gray 2021 [90, 91]; Headland 2019 [92, 93]; Lin 2023 [94, 95, 96, 97]; Liu 2022 [98, 99]; Overland 2018 [100]; Parr 2024 [101]; Pavlou 2023 [102, 103]; Quist 2024 [104, 105]; Schübel 2018 [106, 107]; Sundfør 2018 [108]; Teong 2023; Thomas 2022 [109, 110]; Trepanowski 2017

[111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121]; Wei 2023 [122, 123, 124]; Yeary 2024 [125]). One study was published as a conference proceeding (Steele 2023 [126]), and another study was not published (NCT03342742 2017 [127]), but its data were available in the clinical trials register.

Included studies

Table 1 is a summary of the included studies and syntheses. We included 22 studies with a total of 1995 participants (Bartholomew 2021; Catenacci 2016; Conley 2018; de Oliveira 2021; Dunn 2024; Gray 2021; Headland 2019; Lin 2023; Liu 2022; NCT03342742 2017; Overland 2018; Parr 2024; Pavlou 2023; Quist 2024; Schübel 2018; Steele 2023; Sundfør 2018; Teong 2023; Thomas 2022; Trepanowski 2017; Wei 2023; Yearly 2024). All included studies were RCTs; one was a cluster-RCT (Yearly 2024). The median sample size was 90.68 participants (interquartile range 32.25 to 109.75). The largest sample size was 332 participants (Headland 2019), and the smallest was 10 participants (Overland 2018).

All studies were conducted in an outpatient setting and published between 2016 and 2024. Three of the included studies were multicentre studies conducted in the USA (Bartholomew 2021, Yearly 2024), and Australia (Headland 2019), while 19 were single-centre studies conducted in North America (Catenacci 2016; Conley 2018; Dunn 2024; Lin 2023; NCT03342742 2017; Pavlou 2023; Steele 2023; Thomas 2022; Trepanowski 2017), Australia (Gray 2021; Overland 2018; Parr 2024; Teong 2023), China (Liu 2022; Wei 2023), Denmark (Quist 2024), Germany (Schübel 2018), Norway (Sundfør 2018), and Brazil (de Oliveira 2021).

We contacted the authors of five of the included studies for additional information, outcome data and clarifications regarding eligibility criteria (Conley 2018; Dunn 2024; de Oliveira 2021; Overland 2018; Trepanowski 2017). All of them provided the requested information.

Participants

All studies included adults aged 18 years or older. The age of the participants in the studies ranged from 18 to 80 years. Two studies included adults with autosomal dominant polycystic kidney disease (NCT03342742 2017; Steele 2023). One study included participants with type 1 diabetes (Overland 2018), two studies included adults previously diagnosed with type 2 diabetes (Parr 2024; Pavlou 2023), and another included individuals with prediabetes (Schübel 2018). One study focused on gestational diabetes during pregnancy (Gray 2021). One study included participants with non-alcoholic fatty liver disease (Wei 2023), while another study focused on participants with non-alcoholic cirrhosis (Dunn 2024). One study focused on individuals with high levels of low-density lipoprotein (LDL) (Bartholomew 2021), and one addressed social vulnerability (de Oliveira 2021).

In seven of the 22 studies, the research focused exclusively on female participants (as an exclusive group or with more than 80% female population) (de Oliveira 2021; Gray 2021; Headland 2019; Lin 2023; Overland 2018; Thomas 2022; Trepanowski 2017). Only one study focused on male participants (as an exclusive group or with more than 80% male population) (Conley 2018), while the remaining studies included both men and women (Bartholomew 2021; Catenacci 2016; Dunn 2024; Liu 2022; NCT03342742 2017; Parr 2024; Pavlou 2023; Quist 2024; Schübel 2018; Steele 2023; Sundfør 2018; Teong 2023; Wei 2023; Yearly 2024).

Three of the included studies were conducted in LMICs (de Oliveira 2021; Liu 2022; Wei 2023) and the rest in HICs (Bartholomew 2021; Catenacci 2016; Conley 2018; Dunn 2024; Gray 2021; Headland 2019; Lin 2023; NCT03342742 2017; Overland 2018; Parr 2024;

Pavlou 2023; Quist 2024; Schübel 2018; Steele 2023; Sundfør 2018; Teong 2023; Thomas 2022; Trepanowski 2017; Yearly 2024).

Interventions

Twenty-one studies compared intermittent fasting with regular dietary advice (Catenacci 2016; Conley 2018; Dunn 2024; de Oliveira 2021; Gray 2021; Headland 2019; Lin 2023; Liu 2022; NCT03342742 2017; Overland 2018; Parr 2024; Pavlou 2023; Quist 2024; Schübel 2018; Steele 2023; Sundfør 2018; Teong 2023; Thomas 2022; Trepanowski 2017; Wei 2023; Yearly 2024), mainly in the form of caloric restriction. One study compared two types of intermittent fasting (modified alternate-day fasting and periodic fasting) with regular dietary advice (Headland 2019). Six studies compared intermittent fasting with no intervention (Bartholomew 2021; Lin 2023; Pavlou 2023; Schübel 2018; Teong 2023; Trepanowski 2017). Across the two comparisons, there was an overlap of five studies that compared intermittent fasting with both regular dietary advice and with no intervention (Lin 2023; Pavlou 2023; Schübel 2018; Teong 2023; Trepanowski 2017).

Ten studies used time-restricted feeding (de Oliveira 2021; Lin 2023; Liu 2022; Parr 2024; Pavlou 2023; Quist 2024; Steele 2023; Teong 2023; Thomas 2022; Wei 2023), four studies used alternate-day fasting (Catenacci 2016; Gray 2021; NCT03342742 2017; Trepanowski 2017), seven studies used modified alternate-day fasting (Conley 2018; Dunn 2024; Headland 2019; Overland 2018; Schübel 2018; Sundfør 2018; Yearly 2024), and two studies used periodic fasting (Bartholomew 2021; Headland 2019).

In all included studies, registered dietitians or trained study staff delivered intermittent-fasting protocols, most often through structured counselling (individual or small-group) plus written materials and periodic remote contacts. Two studies included provision of standardised meals to model the regimen, with all meals provided during the active phase (Catenacci 2016; Trepanowski 2017). Another study implemented counselling only, with scheduled check-ins by telephone or video communications led by registered dietitians (Lin 2023). These contacts taught participants how to implement the assigned fasting schedule, reinforced adherence, addressed practical barriers and guided the choice of healthy foods.

Nine studies delivered intermittent fasting as a single intervention (Bartholomew 2021; NCT03342742 2017; Parr 2024; Quist 2024; Schübel 2018; Steele 2023; Thomas 2022; Wei 2023; Yearly 2024), while the remaining 13 studies included intermittent fasting as a component of a programme with multiple interventions. These multiple interventions included counselling sessions focused on the dietary plan (Conley 2018; de Oliveira 2021; Liu 2022), teaching healthy food choices (Lin 2023; Pavlou 2023; Trepanowski 2017), and cognitive-behavioural strategies to assist with weight control (Lin 2023; Sundfør 2018). Other studies included educational materials with sample meal plans and physical activity sessions through video call (Dunn 2024), advice to maintain usual physical activity (Catenacci 2016; Teong 2023), or to engage in at least 30 minutes of physical activity on most days of the week (Gray 2021). One study combined the intervention with diabetes mellitus 1 treatment modifications, adjusting insulin doses weekly (Overland 2018).

Outcomes

All the included studies reported weight loss as a continuous outcome (Bartholomew 2021; Catenacci 2016; Conley 2018; Dunn 2024; de Oliveira 2021; Gray 2021; Headland 2019; Lin 2023; Liu 2022; NCT03342742 2017; Overland 2018; Parr 2024; Pavlou 2023; Quist 2024; Schübel 2018; Steele 2023; Sundfør 2018; Teong 2023; Thomas 2022; Trepanowski 2017; Wei 2023; Yeary 2024). Most of these studies reported weight loss as a percentage of baseline weight, while six reported weight loss in kg (Bartholomew 2021; Liu 2022; Parr 2024; Quist 2024; Sundfør 2018; Wei 2023), which we converted to the desired format for the analyses. The cluster-RCT by Yeary 2024 reported results for weight loss with an appropriate adjustment for potential clustering of participants, so we used the information as reported by the study authors in our analysis, and no re-analysis of the data was necessary. Four studies reported the rate of participants achieving a 5% weight loss from baseline (Gray 2021; Liu 2022; Quist 2024; Sundfør 2018).

Three studies reported quality of life. Conley 2018 used the Assessment of Quality of Life - 8D, NCT03342742 2017 used the RAND-36 survey, and Lin 2023 used the SF-36 survey and reported disaggregated values for vitality, bodily pain, mental health and general physical health domains with no total score available.

Seven studies reported adverse events (Conley 2018; Liu 2022; NCT03342742 2017; Sundfør 2018; Teong 2023; Thomas 2022; Trepanowski 2017). Reported adverse events included nausea, headache, dizziness, hunger, constipation, diarrhoea, dyspepsia, cold intolerance, irritability, insomnia, impaired concentration, back pain and flu.

Thirteen studies reported changes in lipid profiles using total cholesterol levels (Bartholomew 2021; Conley 2018; Dunn 2024; Headland 2019; Lin 2023; Liu 2022; Overland 2018; Parr 2024; Pavlou 2023; Schübel 2018; Sundfør 2018; Teong 2023; Wei 2023), 14 studies reported changes in lipid profiles using HDL levels (Bartholomew 2021; Conley 2018; Dunn 2024; Headland 2019; Lin 2023; Liu 2022; Overland 2018; Parr 2024; Pavlou 2023; Schübel 2018; Sundfør 2018; Teong 2023; Trepanowski 2017; Wei 2023), and 15 studies reported changes in lipid profiles using triglycerides levels (Bartholomew 2021; Catenacci 2016; Conley 2018; Dunn 2024; Headland 2019; Lin 2023; Liu 2022; Overland 2018; Parr 2024; Pavlou 2023; Schübel 2018; Sundfør 2018; Teong 2023; Trepanowski 2017; Wei 2023). Studies reporting changes in lipid profile used mmol/L or mg/dL as the unit of measure. We converted all data to mg/dL for the analyses using standard formulas (128).

None of the included studies reported participant satisfaction, diabetes status, or overall measure of comorbidity.

Funding sources

Twenty studies reported funding sources (Bartholomew 2021; Catenacci 2016; Conley 2018; Dunn 2024; de Oliveira 2021; Gray 2021; Headland 2019; Lin 2023; Liu 2022; NCT03342742 2017; Overland 2018; Parr 2024; Pavlou 2023; Quist 2024; Schübel 2018; Teong 2023; Thomas 2022; Trepanowski 2017; Wei 2023; Yeary 2024). Several studies were supported by national health research agencies such as the National Institutes of Health (NIH), the National Health and Medical Research Council (NHMRC), and the National Natural Science Foundation of China. Others received grants from universities, hospital research foundations, and private organisations, including the Novo Nordisk Foundation and the

Roswell Park Alliance Foundation. Two studies did not report their sources of funding (Steele 2023; Sundfør 2018).

Conflicts of interest

Twelve studies reported no conflict of interest (Catenacci 2016; Conley 2018; Dunn 2024; de Oliveira 2021; Headland 2019; Liu 2022; Overland 2018; Schübel 2018; Teong 2023; Thomas 2022; Wei 2023; Yeary 2024). Eight studies reported conflicts of interest related to grants or support from private companies for other research projects, stipend programmes and scholarships, employment by the funding sources, travel grants, writing fees for different research not related to the included study and memberships of scientific societies related to weight management (Bartholomew 2021; Gray 2021; Lin 2023; NCT03342742 2017; Parr 2024; Pavlou 2023; Quist 2024; Trepanowski 2017). Two studies did not report their conflict of interest (Steele 2023; Sundfør 2018).

Excluded studies

We excluded 75 studies (with 76 reports). [Supplementary material 3](#) includes a detailed description of all reasons for exclusion. Common reasons for exclusion included selecting a follow-up time shorter than six months. Six studies did not consider any outcome of interest for this review. Five studies used non-randomised methods or cross-over designs. Three studies included head-to-head comparisons of different intermittent fasting strategies. We excluded two studies due to a low proportion of participants with obesity or overweight.

Ongoing studies

We found 22 ongoing studies (with 28 reports). See additional information about these studies in the [Supplementary material 5](#).

Studies awaiting classification

We classified 16 studies (with 17 reports) as awaiting classification, mainly due to limited information about the duration of the intervention and the duration of follow-up. We contacted the authors of the studies awaiting classification (when contact information was available) and received no response. See additional information about these studies in the [Supplementary material 4](#).

Risk of bias in included studies

Risk of bias assessments for each outcome are located in the risk of bias table section within [Supplementary material 6](#) and at the side of the forest plots. To access further detailed risk of bias assessment data, visit <https://osf.io/9mxq5/> (DOI 10.17605/OSF.IO/9MXQ5).

The overall risk of bias was similar across most outcomes, judged as 'high'.

For weight loss, we judged most studies reporting this outcome at overall high risk of bias, except for Schübel 2018 and Yeary 2024, which we judged at overall low risk of bias. We judged de Oliveira 2021, Lin 2023, Liu 2022, Parr 2024, and Sundfør 2018 at overall risk of bias of 'some concerns'. Most studies presented issues in risk of bias arising from the randomisation process, deviation from intended interventions and bias in the selection of the reported result.

Studies that reported weight loss as a categorical outcome were at overall high risk of bias due to issues in the selection of the reported results (Gray 2021; Liu 2022; Quist 2024; Sundfør 2018).

Of the three studies that reported quality of life, we judged one at overall high risk of bias due to issues regarding deviations from intended interventions (NCT03342742 2017). We judged the other two studies at overall risk of bias of 'some concerns' due to issues in the randomisation process and deviations from the intended intervention (Conley 2018; Lin 2023).

Most studies that reported adverse events were at overall high risk of bias (Conley 2018; NCT03342742 2017; Sundfør 2018; Teong 2023; Thomas 2022; Trepanowski 2017), except for Liu 2022, which was at overall risk of bias of 'some concerns'. The studies presented issues in almost all RoB 2 domains.

Synthesis of results

We summarised absolute and relative effects for all critical and important outcomes with their GRADE ratings, signifying confidence in the effect estimates in [Summary of findings 1](#) and [Summary of findings 2](#).

1. Intermittent fasting versus regular dietary advice

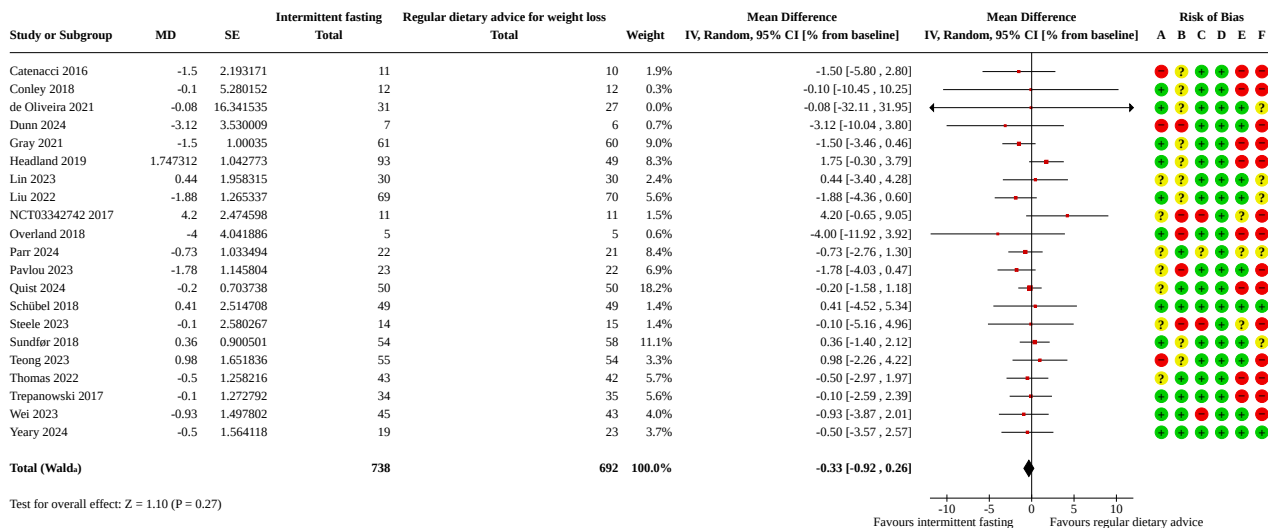
We included 21 studies with 1713 participants in this comparison.

Critical outcomes

Weight loss: continuous outcome

Twenty-one studies with 1430 participants reported this outcome. Intermittent fasting may result in little to no difference in percentage from baseline weight loss (MD -0.33, 95% CI -0.92 to 0.26; $I^2 = 0\%$; 21 studies, 1430 participants; low-certainty evidence; [Figure 2](#)). We assessed the evidence for this outcome as low certainty due to very serious concerns about risk of bias.

Figure 2. Forest plot for the outcome weight loss. Intermittent fasting versus regular dietary advice comparison

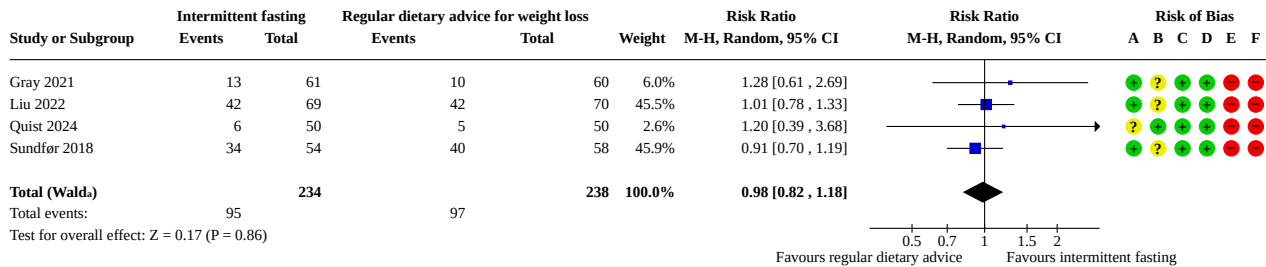


Weight loss: categorical outcome

Four studies with 472 participants reported weight loss as a categorical outcome. Intermittent fasting may have little to no effect on achieving a 5% reduction in body weight, but the evidence

is very uncertain (RR 0.98, 95% CI 0.82 to 1.18; $I^2 = 0\%$; 4 studies, 472 participants; very low-certainty evidence; [Figure 3](#)). We assessed the evidence for this outcome as very low certainty due to serious concerns about risk of bias and imprecision.

Figure 3. Forest plot for the outcome weight loss (categorical). Intermittent fasting versus regular dietary advice comparison



Heterogeneity: Tau² (DLs) = 0.00; Chi² = 1.03, df = 3 (P = 0.79); I² = 0%

Footnotes

aCI calculated by Wald-type method.
bTau² calculated by DerSimonian and Laird method.

Risk of bias legend

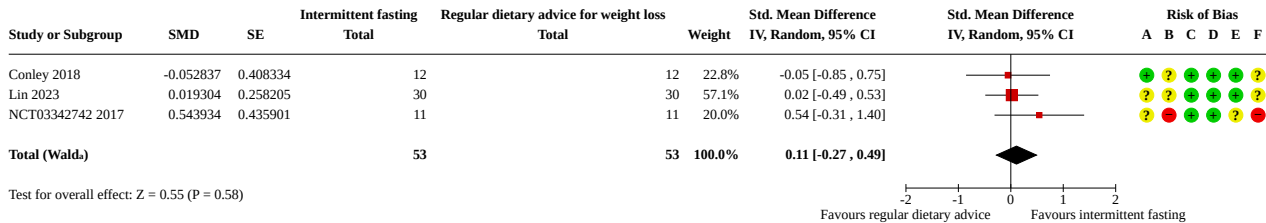
- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

Quality of life

Three studies with 106 participants reported this outcome. Intermittent fasting may result in little to no difference in quality of life (SMD 0.11, 95% CI -0.27 to 0.49; I² = 0%; 3 studies, 106 participants; low-certainty evidence; Figure 4). This corresponds to an MD of 0.13 points (95% CI -0.31 to 0.57) in the SF-36 general

physical health domain (scale range 0 to 100), an MD of 0.12 points (95% CI -0.31 to 0.57) in the RAND-36 general physical health domain (scale range 0 to 100) and an MD of 0.12 points (95% CI -0.30 to 0.54) in the AQoL-8D (scale range 0 to 100). We assessed the evidence for this outcome as low certainty due to concerns about risk of bias and imprecision.

Figure 4. Forest plot for the outcome quality of life. Intermittent fasting versus regular dietary advice comparison



Heterogeneity: Tau² (DLs, 95% CI) = 0.00 [0.00, 4.02]; Chi² = 1.27, df = 2 (P = 0.53); I² = 0%

Footnotes

aCI calculated by Wald-type method.
bTau² calculated by DerSimonian and Laird method.

Risk of bias legend

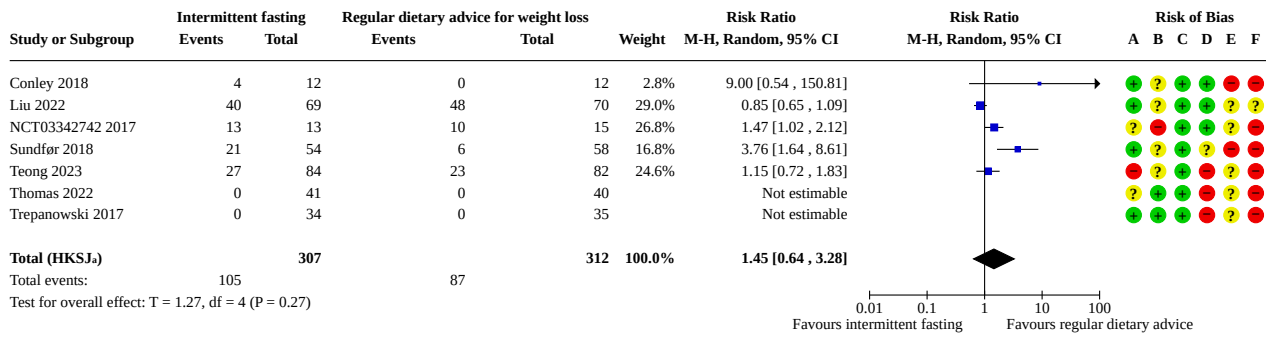
- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

Adverse events

Seven studies with 619 participants reported this outcome. Intermittent fasting may have little to no effect on adverse events, but the evidence is very uncertain (RR 1.45, 95% CI 0.64 to 3.28;

I² = 78%; 7 studies, 619 participants; very low-certainty evidence; Figure 5). We assessed the evidence for this outcome as very low certainty due to concerns about risk of bias, inconsistency, and imprecision.

Figure 5. Forest plot for the outcome adverse events. Intermittent fasting versus regular dietary advice comparison



Heterogeneity: Tau² (DLs, 95% CI) = 0.21 [0.03, 6.73]; Chi² = 18.25, df = 4 (P = 0.001); I² = 78%

Footnotes

^aCI calculated by Hartung-Knapp-Sidik-Jonkman (HKSJ) method.
^bTau² calculated by DerSimonian and Laird method.

Risk of bias legend

- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

Important outcomes

Participant satisfaction

None of the included studies reported this outcome under this comparison.

Diabetes status

None of the included studies reported this outcome under this comparison.

Changes in lipid profile

- **Total cholesterol:** 12 studies with 899 participants reported this outcome. Intermittent fasting may have little to no effect on total cholesterol measured in mg/dL (MD -1.26, 95% CI -5.20 to 2.68; I² = 0%; 12 studies, 899 participants; Analysis 1.5).
- **High-density lipoprotein:** 13 studies with 968 participants reported this outcome. Intermittent fasting may have little to no effect on HDL measured in mg/dL (MD 1.71, 95% CI 0.65 to 2.77; I² = 0%; 13 studies, 968 participants; Analysis 1.6).

- **Triglycerides:** 14 studies with 989 participants reported this outcome. Intermittent fasting may have little to no effect on triglycerides measured in mg/dL (MD -1.44, 95% CI -10.29 to 7.40; I² = 45%; 14 studies, 989 participants; Analysis 1.7).

Overall measure of comorbidity

None of the included studies reported this outcome under this comparison.

2. Intermittent fasting versus no intervention or waiting list

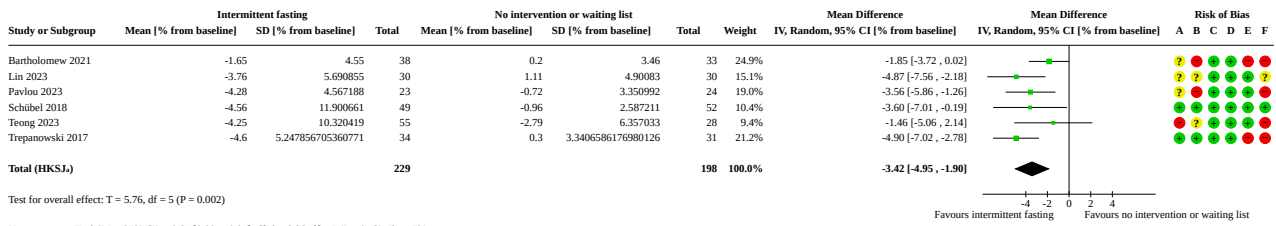
We included six studies with 448 participants in this comparison.

Critical outcomes

Weight loss: continuous outcome

Six studies with 427 participants reported this outcome. Intermittent fasting likely results in little to no difference in weight loss, measured as change from baseline weight (MD -3.42, 95% CI -4.95 to -1.90; I² = 27%; 6 studies, 427 participants; moderate-certainty evidence; Figure 6). We assessed the evidence for this outcome as moderate certainty due to concerns about risk of bias.

Figure 6. Forest plot for the outcome weight loss. Intermittent fasting versus no intervention or waiting list comparison



Test for overall effect: $T = 5.76, df = 5 (P = 0.002)$

Heterogeneity: $\tau^2 (DLA, 95\% CI) = 0.61 [0.00, 10.84]; \chi^2 = 6.86, df = 5 (P = 0.23); I^2 = 27\%$

Footnotes

.CI calculated by Hartung-Knapp-Sidik-Jonkman (HKSJ) method.
sTau² calculated by DerSimonian and Laird method.

Risk of bias legend

- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

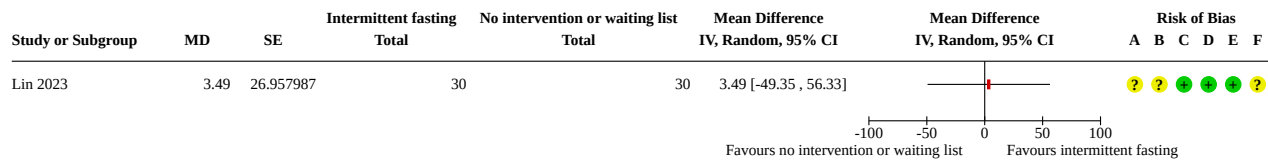
None of the included studies under this comparison reported weight loss as a categorical outcome.

Quality of life

One study with 60 participants reported this outcome, using the SF-36 (scale range 0 to 100). Intermittent fasting may result in

little to no difference in the general physical health domain of quality of life, but the evidence is very uncertain (MD 3.49 points, 95% CI -49.35 to 56.33; 1 study, 60 participants; very low-certainty evidence; Figure 7). We assessed the evidence for this outcome as very low certainty due to extreme concerns about imprecision.

Figure 7. Forest plot for the outcome quality of life. Intermittent fasting versus no intervention or waiting list comparison



Risk of bias legend

- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

Adverse events

Two studies with 189 participants reported this outcome. Intermittent fasting may have little to no effect on adverse events,

but the evidence is very uncertain (RR 1.84, 95% CI 0.88 to 3.85; 2 studies, 189 participants; very low-certainty evidence; Figure 8). We assessed the evidence for this outcome as very low certainty due to very serious concerns about risk of bias and imprecision.

of the intervention, when compared to regular dietary advice (see Analysis 2.4; Analysis 2.5; Analysis 2.6; Analysis 3.3; Analysis 3.4; Analysis 3.5; Analysis 4.5; Analysis 4.6; Analysis 4.7; Analysis 5.4; Analysis 5.5; Analysis 5.6).

Intermittent fasting versus no intervention or waiting list

Weight loss

We found no differences in the effect of intermittent fasting on weight loss between different types of intermittent fasting or delivery of the intervention when compared to no intervention or waiting list (See Analysis 7.1; Analysis 8.1).

The results from these analyses are limited due to their observational nature and low power to detect differences, as we included fewer than 10 studies per category.

Adverse events

We found that time-restricted feeding (RR 1.84, 95% CI 0.88 to 3.85) may result in more adverse events compared to alternate-day fasting, modified alternate-day fasting and periodic fasting, when compared to no intervention or waiting list (Analysis 7.2). A test for subgroup differences was not possible for this subgroup analysis, given that the outcomes for alternate-day fasting, modified alternate-day fasting and periodic fasting were not estimable, as studies reported no adverse events for these types of intermittent fasting. The results from this analysis are limited due to its observational nature and low power to detect differences, as we included fewer than 10 studies per category.

Changes in lipid profile

There were no differences in the effect of intermittent fasting on total cholesterol and HDL between different types of intermittent fasting, when compared to no intervention or waiting list (See Analysis 7.3; Analysis 7.4).

We found that periodic fasting (MD -19.20, 95% CI -42.11 to 3.71) and time-restricted feeding (MD -11.78, 95% CI -24.10 to 0.54) may decrease triglyceride levels, alternate-day fasting may increase triglyceride levels (MD 24.40, 95% CI 6.10 to 42.70), and modified alternate-day fasting may have little to no effect on triglyceride levels (MD 0.50, 95% CI -22.21 to 23.21), when compared to no intervention or waiting list (test for subgroup differences: $\text{Chi}^2 = 12.57$, $\text{df} = 3$ ($P = 0.006$), $I^2 = 76.1\%$; Analysis 7.5). The results from this analysis are limited due to its observational nature and low power to detect differences, as we included fewer than 10 studies per category.

We found no differences in the effect of intermittent fasting on total cholesterol, HDL and triglyceride levels between different methods of delivering the intervention, when compared to no intervention or waiting list (See Analysis 8.2; Analysis 8.3; Analysis 8.4).

Sensitivity analyses

The sensitivity analyses below are presented per comparison, for the outcomes for which these were feasible. See a summary of the sensitivity analyses with their effect estimates in [Supplementary material 11](#).

Intermittent fasting versus regular dietary advice

Restricting the analysis to studies at overall low risk of bias

- **Weight loss:** these results were robust when restricting the analysis to studies at overall low risk of bias. We found no differences in the effect of intermittent fasting on weight loss compared to regular dietary advice when restricting the analysis to studies with an overall low risk of bias (MD -0.25, 95% CI -2.85 to 2.36).

Restricting the analysis to published studies

- **Weight loss:** the results were robust when restricting the analysis to published studies. We found no differences in the effect of intermittent fasting on weight loss compared to regular dietary advice when restricting the analysis to published studies (MD -0.40, 95% CI -0.99 to 0.19).
- **Quality of life:** the results were robust when restricting the analysis to published studies. We found no differences in the effect of intermittent fasting on quality of life compared to regular dietary advice when restricting the analysis to published studies (SMD -0.00, 95% CI -0.43 to 0.43).
- **Adverse events:** the results were robust when restricting the analysis to published studies. We found no differences in the effect of intermittent fasting on adverse events compared to regular dietary advice when restricting the analysis to published studies (RR 1.57, 95% CI 0.41 to 6.05).

Excluding studies with cluster randomisation

- **Weight loss:** the results were robust when excluding studies with cluster randomisation. We found no differences in the effect of intermittent fasting on weight loss compared to regular dietary advice when excluding studies with cluster randomisation (MD -0.32, 95% CI -0.92 to 0.28).

Intermittent fasting versus no intervention or waiting list

Restricting the analysis to studies at overall low risk of bias

- **Weight loss:** the results were robust when restricting the analysis to studies at overall low risk of bias. We found no differences in the effect of intermittent fasting on weight loss compared to no intervention or waiting list when restricting the analysis to studies at overall low risk of bias (MD -3.60, 95% CI -7.01 to -0.19).

Equity assessment

See [Supplementary material 9](#) for a detailed description of equity-related characteristics in the included studies. We investigated equity-related characteristics by assessing the effects of the intervention, exploring the potential differences between LMICs and HICs. We found a greater prevalence of studies ($n = 19$, 86%) developed in HICs. See Analysis 2.1; Analysis 2.2; Analysis 2.3; Analysis 2.4; Analysis 2.5 and Analysis 2.6 for additional details.

We also investigated equity-related characteristics by assessing the effect of the intervention on different genders. We found a greater prevalence of studies in mixed populations including both men and women, with no disaggregated data for each gender. Only seven studies (31.81%) included predominantly women, while only one study (4.55%) included predominantly men. See Analysis 3.1; Analysis 3.2; Analysis 3.3; Analysis 3.4 and Analysis 3.5 for additional details.

Reporting biases

We created funnel plots to assess reporting bias for weight loss and changes in lipid profile (total cholesterol, HDL and triglycerides) in

the intermittent fasting versus regular dietary advice comparison, as these were the only outcomes for which we were able to include more than 10 studies (see [Figure 9](#); [Figure 10](#); [Figure 11](#) and [Figure 12](#)). We found no serious asymmetries.

Figure 9. Funnel plot for the comparison intermittent fasting vs regular dietary advice: weight loss

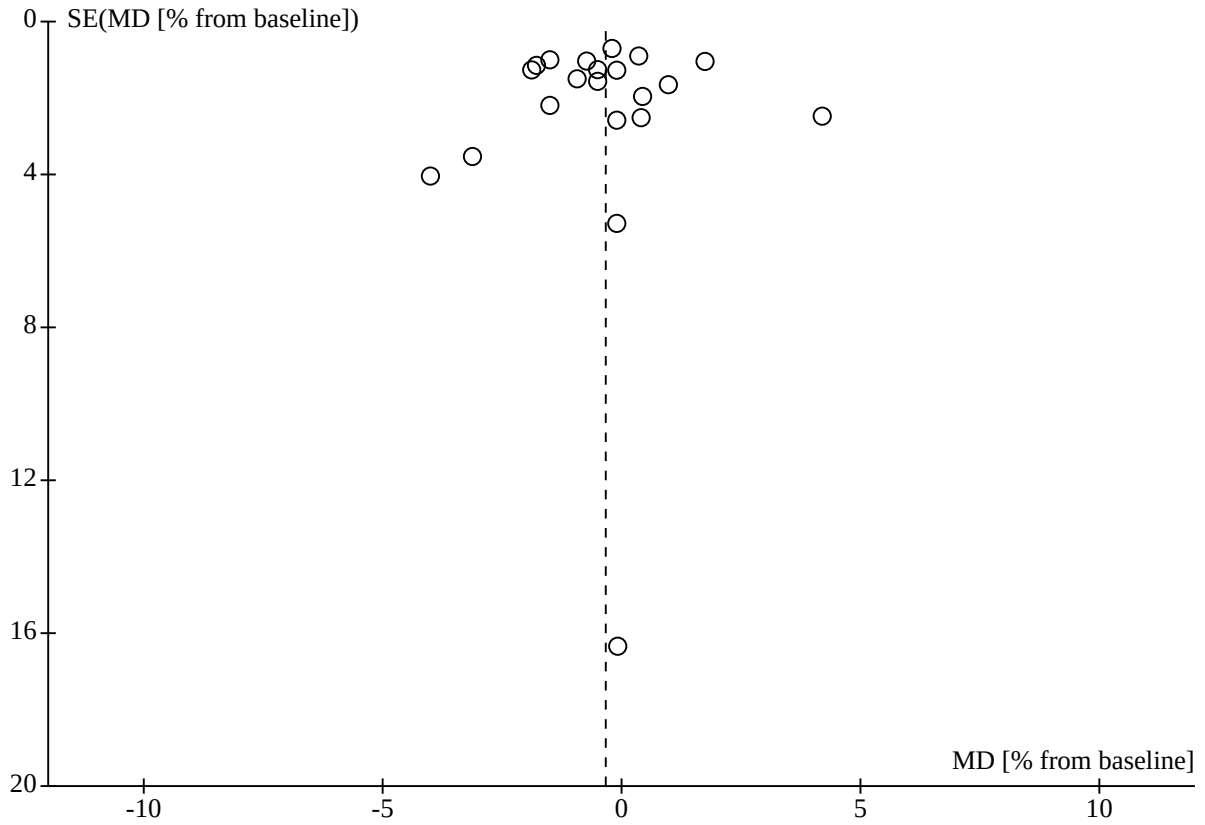


Figure 10. Funnel plot for the comparison intermittent fasting vs regular dietary advice: changes in lipid profile (total cholesterol)

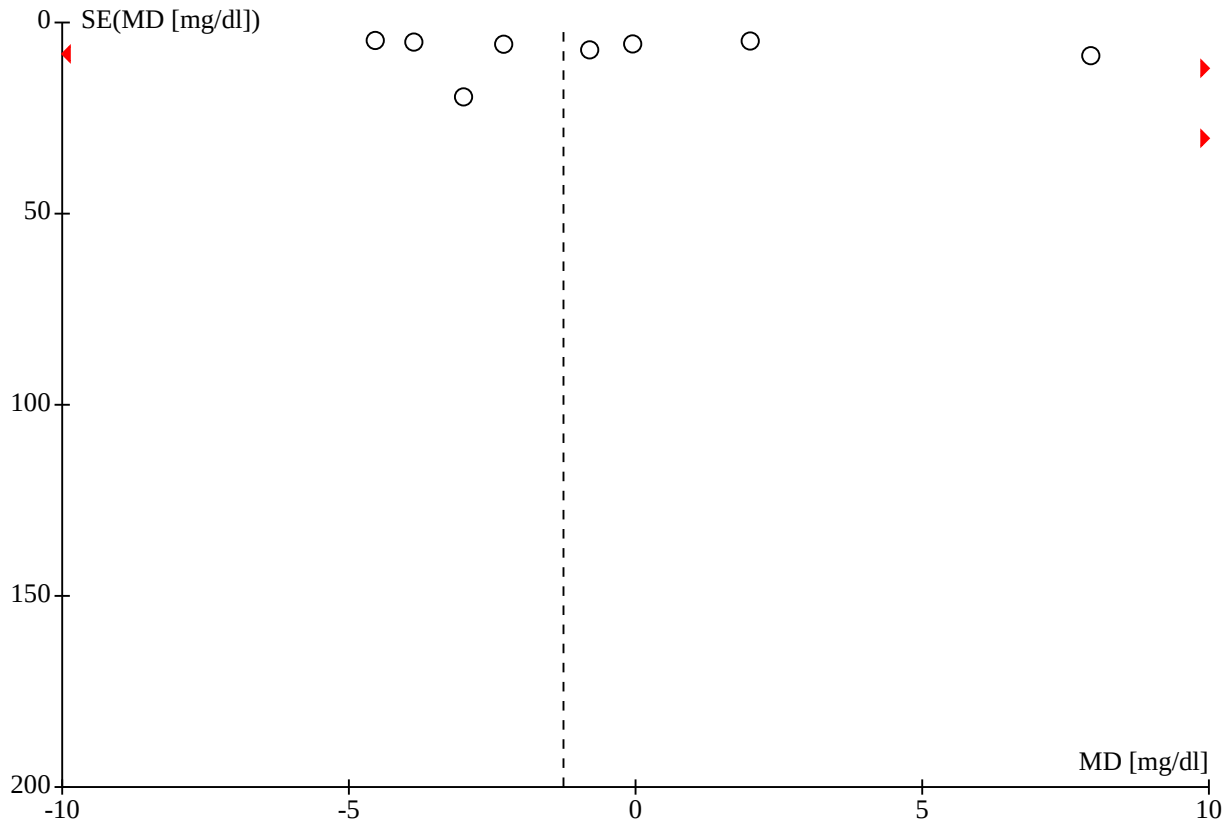


Figure 11. Funnel plot for the comparison intermittent fasting vs regular dietary advice: changes in lipid profile (high-density lipoprotein)

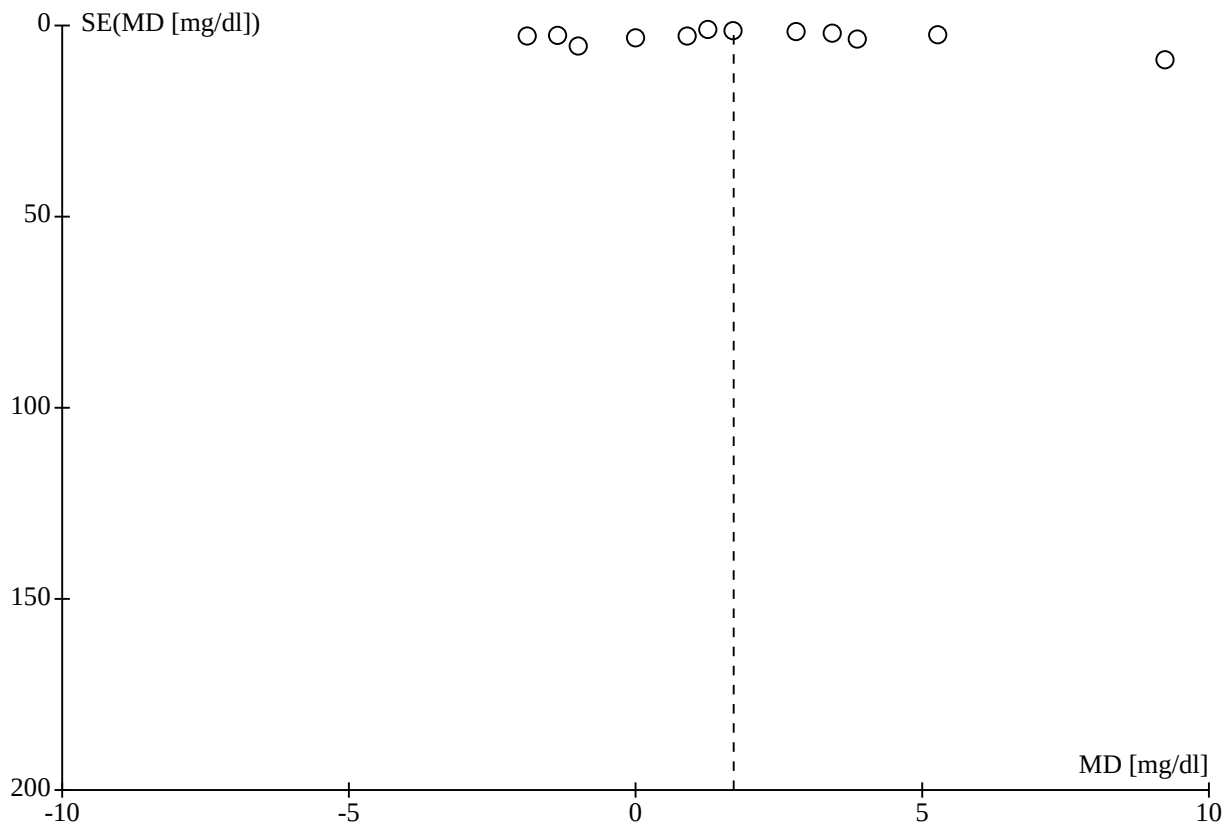
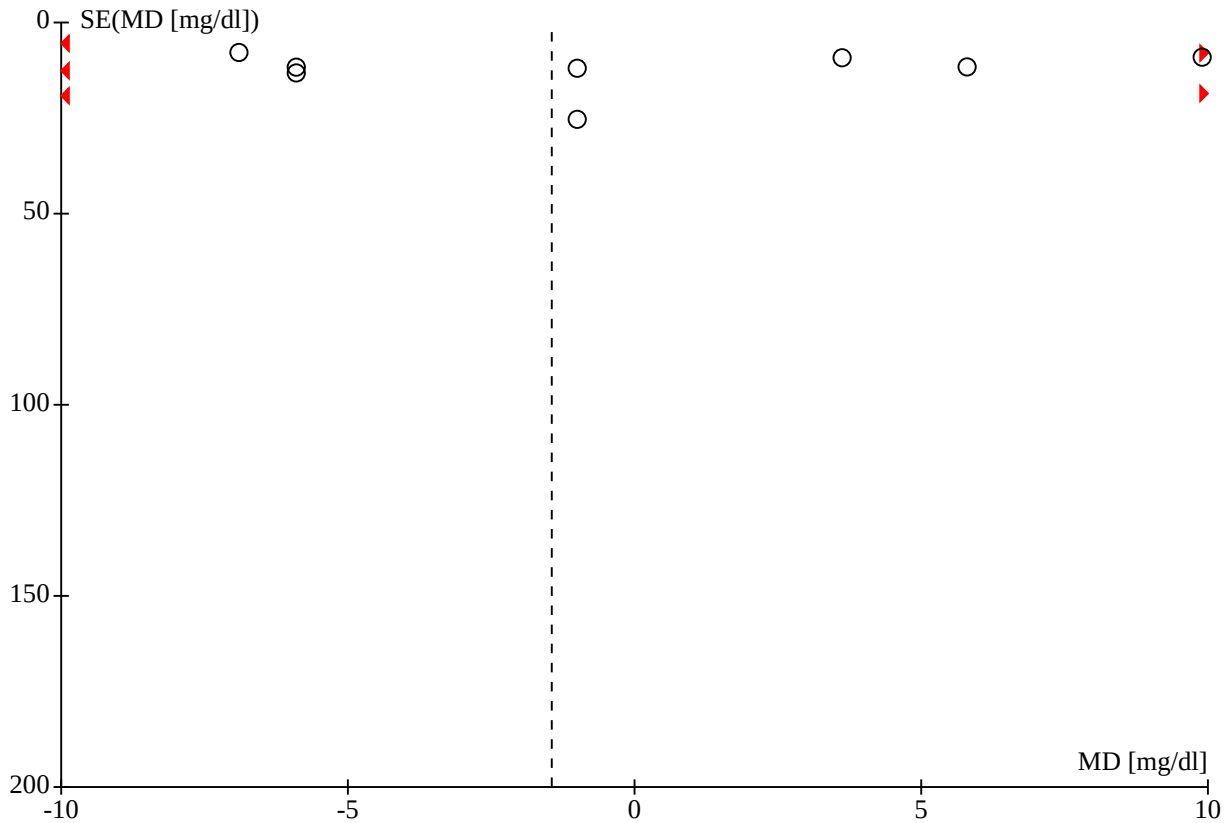


Figure 12. Funnel plot for the comparison intermittent fasting vs regular dietary advice: changes in lipid profile (triglycerides)



DISCUSSION

Summary of main results

We included 22 studies with a total of 1995 participants. The certainty of the evidence for most outcomes was low or very low, except for weight loss, when comparing intermittent fasting with no intervention or waiting list, which we assessed as moderate certainty. Intermittent fasting may result in little to no difference in weight loss (low-certainty evidence), quality of life (low-certainty evidence) or adverse events (very low-certainty evidence), when compared to regular dietary advice.

Intermittent fasting likely results in little to no difference in weight loss when compared to no intervention or waiting list (moderate-certainty evidence). Intermittent fasting may result in little to no difference in the SF-36 general physical health domain of quality of life and may have little to no effect on adverse events when compared to no intervention or waiting list, but the evidence is very uncertain (very low-certainty evidence). None of the included studies reported participant satisfaction, diabetes status or overall measure of comorbidity. See [Summary of findings 1](#) and [Summary of findings 2](#) for additional details.

Limitations of the evidence included in the review

A summary of the considerations that led to downgrading the certainty of the evidence in implementing the GRADE approach is available in [Summary of findings 1](#) and [Summary of findings](#)

2. Most included studies were at overall high risk of bias or 'some concerns' for overall risk of bias. Imprecision in the effect estimates was also a concern. For example, only four studies reported weight loss as a categorical outcome, with few participants and events. Quality of life was reported in only three studies, which used different scales and considered different time points. Other outcomes, such as adverse events, included studies reporting both benefits and harms. The certainty of the evidence was also influenced by considerable statistical heterogeneity in effect estimates, particularly for adverse events, when comparing intermittent fasting with regular dietary advice, and changes in lipid profiles when comparing intermittent fasting with no intervention or waiting list. Nevertheless, the identified evidence was in line with all the components of the review question, although some planned subgroups and settings were less represented, which may affect applicability. Nineteen of the included studies were conducted in HICs, while only three were conducted in upper-middle-income countries (de Oliveira 2021; Liu 2022; Wei 2023). No studies were conducted in low-income countries, which prevented us from analysing the effect of the intervention in very low-resource settings. Only one study assessed the intervention in men (Conley 2018), and eight studies exclusively in women. It would be desirable to have data disaggregated by sex to inform potential differences between women and men.

None of the included studies assessed participants' satisfaction with the dietary intervention, nor did they provide information on participants' diabetes status. The absence of satisfaction outcomes

limits our ability to evaluate the acceptability and long-term feasibility of intermittent fasting. Similarly, the lack of reporting on diabetes status restricts our capacity to explore potential effect modification in related overweight or obesity conditions, such as type 2 diabetes. These omissions represent important gaps in the current evidence base that should be addressed in future trials.

Only 10 of the 22 included studies reported on adherence or compliance to the assigned intervention and dietary schedule (Bartholomew 2021; Dunn 2024; Parr 2024; Pavlou 2023; Quist 2024; Schübel 2018; Thomas 2022; Trepanowski 2017; Wei 2023; Yearly 2024), mainly through patient self-reported adherence, dietary diaries, attendance at group meetings or nutritionist visits.

All included studies concentrated on short-term effects of the intervention, primarily up to 12 months, which restricts the applicability of the evidence in this review to inform decision-making for longer durations. It would be beneficial for future studies to extend follow-up periods beyond 12 months to build a stronger evidence base for the long-term effects of the intervention.

Most included studies implemented intermittent fasting as part of a programme that involved multiple interventions. These co-interventions ranged from physical activity plans to counselling sessions, aimed at helping participants with weight maintenance or making healthy food choices. Unfortunately, the additional programme components were insufficiently or inadequately described, leading to uncertainties and concerns about their potential impact on trial outcomes.

Limitations of the review processes

We faced several difficulties during the review process. First, the search strategy retrieved many reports indicating a significant workload for the review team. Nevertheless, we took all precautions possible to avoid different interpretations in the selection process, and we kept conflicts as minimal as possible, implementing regular meetings and discussions to calibrate the team. Second, we included a large body of evidence and many studies with multiple reports that we carefully appraised to avoid double-counting. Data extraction from all the included studies would have been cumbersome, but we used the standard templates provided in the RevMan Knowledge Base, simplifying the task. Nevertheless, diversity in data reporting in the included studies required special attention, which we managed by discussing within the review team and double-checking the data several times. We also needed to transform the reported data into the same unit for the analyses of several outcomes (like weight loss and lipid profiles), prioritising one unit over others reported in the included studies, to maximise the use of available information and enhance interpretability using typical effect estimates.

Although we did not find large clinical heterogeneity in the included studies, we identified considerable statistical heterogeneity in some critical outcomes, like adverse events, or other important outcomes, like changes in lipid profile.

We classified a substantial number of records as awaiting classification, due to insufficient information in abstracts or uncertainties about the duration of the intervention or follow-up. This high number of records awaiting classification introduces uncertainties in the completeness of the evidence, and may alter the overall conclusions of the review if we find that these records

contribute relevant data. This underscores the importance of ongoing efforts to retrieve and classify these records, and the need for timely updates of the review as new evidence becomes available.

Agreements and disagreements with other studies or reviews

We found that intermittent fasting likely results in little to no difference in weight loss when compared to no intervention or waiting list, contrasting with the findings by Liu and colleagues, who analysed 17 studies on time-restricted feeding [129]. In a subgroup analysis by weight category (people with normal weight, people with overweight, and people with obesity), the authors reported that those in the overweight category lost more weight than those in the normal or obese categories.

Additionally, the systematic review by Chen and colleagues included nine studies on time-restricted feeding in adults with overweight or obesity and reported greater weight loss in the intervention (time-restricted feeding) versus hypocaloric diet or unrestricted diet, with a greater proportion of weight loss in the studies with longer duration [130]. Moreover, the Cochrane review by Allaf in 2021 reported that intermittent fasting led to greater weight loss than unrestricted eating in the short term [23]. Notably, the authors reported weight change as a secondary outcome, did not limit the population to people with overweight or obesity, and the magnitude of weight change was not clinically relevant.

Clinical practice guidelines recommend decreasing at least 5% of body weight to manifest risk reduction for other chronic diseases [59, 131, 132]. Most clinical practice guidelines for managing overweight and obesity do not recommend intermittent fasting [6, 15, 133], and only one mentions it as a possible approach [134], highlighting the limited evidence on the long-term effects of this kind of intervention. Healthcare clinicians, specifically dietitian nutritionists, may be able to counsel patients and clients on strategies for weight management using a patient-centred, evidence-based approach to achieve optimal outcomes [135, 136]. As such, we found little to no difference in weight loss outcomes between intermittent fasting and regular dietary advice, similar to the findings of Welton and colleagues, who reported little to no difference in weight outcomes in their analysis of 18 RCTs comparing intermittent fasting to calorie restriction, which may be one form of dietary advice for weight loss [41].

We found little to no difference in the SF-36 general physical health domain of quality of life between intermittent fasting and no intervention or waiting list. These findings are similar to those of Teong and colleagues, who found no differences in quality of life between intermittent fasting and calorie restriction, although that study was limited to an eight-week follow-up [137]. Furthermore, it is important to highlight the types of intermittent fasting in terms of the number of consecutive days of restrictive eating and the duration of the regimen, which may not reflect clinically significant aspects of diet-related daily life among people living with overweight and obesity. This may also reflect the sustainability of implementing a time-restrictive eating pattern every day over the long term.

We found little to no effect on adverse events with intermittent fasting compared to no intervention or waiting list. These findings align with the safety of intermittent fasting reported in several

narrative reviews and opinion articles [138, 139, 140], which may affect the implementation of intermittent fasting in the clinical setting.

Regarding blood lipid profile, our analysis aligns with that of Chen and colleagues [130], but contrasts with that of Liu and colleagues [129]. It is possible that the additional research findings since the publication of the earlier review strengthen the conclusions by including more studies and, thus, a larger collective sample.

AUTHORS' CONCLUSIONS

Implications for practice

When compared to regular dietary advice, intermittent fasting may result in no difference in weight loss, quality of life or adverse events. These approaches did not differ in achieving weight loss, producing no clinically meaningful changes in most of the outcomes considered in this review.

When compared to no intervention or waiting list, intermittent fasting likely results in little to no difference in weight loss. Intermittent fasting may result in little to no difference in the Short-form Health Survey (SF-36) general physical health domain of quality of life and adverse events. None of the included studies reported participant satisfaction, diabetes status or overall measure of comorbidity.

Physicians and patients may need to evaluate willingness and readiness to implement intermittent fasting as a treatment strategy, based on individual practicality and sustainability.

Equity-related implications for practice

We are uncertain about the effect of intermittent fasting in LMICs, as most of the included studies enrolled predominantly white populations and were conducted in HICs, which prevented us from analysing the effect of the intervention in very low-resource settings and may limit the applicability of our findings in the clinical setting or for policy development. Some ongoing studies will help in filling this gap, as they are planned to be conducted in low and middle-income settings (CTRI/2022/02/040292 2022 [141]; CTRI/2022/11/047684 2022 [142]; CTRI/2024/07/070430 2024 [143]).

We are uncertain about the potential different effects of intermittent fasting in men and women, as only one study assessed the intervention in men (Conley 2018), and eight studies exclusively in women, which may affect the applicability of intermittent fasting in different genders. We found one ongoing study that will help fill this gap (NCT05629858 2022 [144]), as it is planned to include women with polycystic ovarian syndrome. Most ongoing studies will enrol mixed populations but may report disaggregated data for each gender.

Implications for research

Further research is needed to address the effect of intermittent fasting on several outcomes, such as participant satisfaction, diabetes status and overall measure of comorbidities. Future research should also focus on loss of lean body mass as a potential relevant long-term outcome, which could be relevant for specific populations, such as those with eating disorders or sarcopenia. These studies must consider different populations where obesity and overweight have different burdens of disease,

like those from LMICs and HICs, men or women separately, and different body mass index categories; and report the results for all these relevant subgroups. These population characteristics would provide insights into contextual influences, such as cultural acceptability and access to food, that may modify the effects of intermittent fasting. New studies need to assess various types of intermittent fasting and guarantee a long-term follow-up beyond 12 months to facilitate conclusions on durability and weight loss maintenance. These studies must also address several methodological limitations found in the included studies in this review, such as prospective registration or a detailed randomisation process to enhance transparency. Studies must provide an appropriate definition for all outcomes considered and must use valid tools for assessment in all the study groups, harmonising outcome measures to facilitate comparability across studies and strengthen the evidence base. Additionally, future research must define in advance the relevant time points for outcome assessment and report data for all the agreed time points when presenting their results, using adequate reporting guidelines for randomised controlled trials. It is essential for studies to evaluate dietary adherence or compliance since this is a crucial aspect of dietary interventions. Understanding adherence can help clarify the intervention's effects when followed properly and identify any potential signs of intolerance as adverse effects. Additionally, assessing adherence will help determine the intervention's feasibility and applicability in real-world settings. Studies must also assess the nutritional adequacy of the fasting approach, especially addressing the different types of intermittent fasting that may affect its feasibility in the real world.

Equity-related implications for research

New research assessing the effect of intermittent fasting in adults with overweight or obesity needs to determine the potential differences the intervention may have in different genders, reporting disaggregated data for women and men. This research also needs to focus on the effect of intermittent fasting in different income scenarios, where the burden of disease and treatment resources are different, and the potential impact of intermittent fasting may exacerbate any nutritional inadequacies.

SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: [10.1002/14651858.CD015610.pub2](https://doi.org/10.1002/14651858.CD015610.pub2).

Supplementary material 1 Search strategies

Supplementary material 2 Characteristics of included studies

Supplementary material 3 Characteristics of excluded studies

Supplementary material 4 Characteristics of studies awaiting classification

Supplementary material 5 Characteristics of ongoing studies

Supplementary material 6 Risk of bias

Supplementary material 7 Analyses

Supplementary material 8 Data package

Supplementary material 9 Summary of the characteristics of participants we expected to see in the evidence and the actual participant characteristics extracted from the included studies

Supplementary material 10 Consumer involvement

Supplementary material 11 Sensitivity analyses summary

ADDITIONAL INFORMATION

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Editorial and peer-reviewer contributions

Cochrane Metabolic and Endocrine Disorders supported the authors in the development of this review.

The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Brenda Bongaerts, Institute of General Practice, Medical Faculty of the Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Jenny Bellorini, Cochrane Central Editorial Service;
- Editorial Assistant (conducted editorial policy checks, selected peer reviewers, collated peer-reviewer comments and supported the editorial team): Cynthia Stafford, Cochrane Central Editorial Service;
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- Peer-reviewers (provided comments and recommended an editorial decision): Dr Melyssa Roy, University of Otago, Dunedin, New Zealand (clinical/content review); Jo-Ana Chase, Evidence Production and Methods Directorate (methods review); Jo Platt, Central Editorial Information Specialist (search review). Two additional peer reviewers provided clinical/content and patient and public peer review but chose not to be publicly acknowledged.

Contributions of authors

All review authors read and approved the final draft of the review.

LG: Conceptualisation, methodology, data curation, formal analysis, investigation, visualisation, writing – original draft, writing – review & editing, supervision, project administration

GO: Methodology, investigation, data curation, writing – review & editing

DI: Methodology, investigation, data curation, writing – review & editing

MAB: Investigation, data curation, writing – review & editing

History

Protocol first published: Issue 9, 2023

Intermittent fasting for adults with overweight or obesity (Review)

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PA: Investigation, data curation, writing – review & editing

SR: Investigation, data curation, writing – review & editing

MB: Investigation, data curation, writing – original draft, writing – review & editing

DR: Investigation, data curation, writing – original draft, writing – review & editing

CE: Methodology, data curation, formal analyses (search strategies), writing – original draft, writing – review & editing

EM: Conceptualisation, methodology, data curation, formal analysis, investigation, writing – original draft, writing – review & editing, supervision, project administration

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LG: none known

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PA: is a member of the Cochrane Hepato-Biliary Editorial Team. She was not involved in the editorial process for this review.

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Data, code and other materials

As part of the published Cochrane review, the following are made available for download for users of the Cochrane Library: full search strategies for each database; full citations of each unique report for all studies included, ongoing or awaiting classification, or excluded at the full-text screen, in the final review; study data, including study information, study arms, and study results or test data; consensus risk of bias assessments; and analysis data, including overall estimates and settings, subgroup estimates, and individual data rows. Analyses and data management were conducted using Cochrane's authoring tool, Review Manager (RevMan). Templates for data extraction are available from the RevMan Knowledge Base. See [Supplementary material 8](#) for additional details.

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ADDITIONAL TABLES

Table 1. Overview of included studies and syntheses

Study ID (Country)	Study design	Population (sample size)	Intervention	Duration of the intervention	Outcome domains with available data	Time point of measurement
Bartholomew 2021 (USA)	RCT	Men and women (n = 103)	Periodic fasting	6 months	Weight loss Changes in lipid profile	6 months
Catenacci 2016 (USA)	RCT	Men and women (n = 29)	Alternate-day fasting	2 months	Weight loss Changes in lipid profile	8 months
Conley 2018 (USA)	RCT	Men (n = 24)	Modified alternate-day fasting	6 months	Weight loss Quality of life Adverse events Changes in lipid profile	6 months
de Oliveira 2021 (Brazil)	RCT	Women (n = 58)	Time-restricted feeding	12 months	Weight loss	12 months
Dunn 2024 (USA)	RCT	Adults with non-alcoholic cirrhosis (n = 20)	Modified alternate-day fasting	6 months	Weight loss Changes in lipid profile	6 months
Gray 2021 (Australia)	RCT	Women with gestational diabetes (n = 121)	Alternate-day fasting	12 months	Weight loss	12 months
Headland 2019 (Australia)	RCT	Men and women (> 80% women) (n = 332)	Modified alternate-day fasting Periodic fasting	12 months	Weight loss Changes in lipid profile	12 months
Lin 2023 (USA)	RCT	Men and women (> 80% women) (n = 90)	Time-restricted feeding	12 months	Weight loss Quality of life Adverse events Changes in lipid profile	12 months
Liu 2022 (China)	RCT	Men and women (n = 139)	Time-restricted feeding	12 months	Weight loss Adverse events Changes in lipid profile	12 months

Table 1. Overview of included studies and syntheses (Continued)

NCT03342742 2017 (USA)	RCT	Men and women with Autosomal dominant polycystic kidney dis- ease (n = 28)	Alternate-day fasting	12 months	Weight loss Quality of life Adverse events	12 months
Overland 2018 (Australia)	RCT	Men and women (> 80% women) with type 1 dia- betes (n = 10)	Modified alter- nate-day fasting	3 months	Weight loss Changes in lipid profile	9 months
Parr 2024 (Australia)	RCT	Men and women with type 2 diabetes (n = 51)	Time-restricted feeding	6 months	Weight loss Changes in lipid profile	6 months
Pavlou 2023 (USA)	RCT	Men and women with type 2 diabetes (n = 75)	Time-restricted feeding	6 months	Weight loss Changes in lipid profile	6 months
Quist 2024 (Denmark)	RCT	Men and women (n = 100)	Time-restricted feeding	3 months	Weight loss	6 months
Schübel 2018 (Germany)	RCT	Men and women with prediabetes (n = 150)	Modified alter- nate-day fasting	3 months	Weight loss Changes in lipid profile	12 months
Steele 2023 (USA)	RCT	Adults with autosomal dominant polycystic kidney disease (n = 29)	Time-restricted feeding	12 months	Weight loss	12 months
Sundfør 2018 (Norway)	RCT	Men and women (n = 112)	Modified alter- nate-day fasting	12 months	Weight loss Adverse events Changes in lipid profile	12 months
Teong 2023 (Australia)	RCT	Men and women (n = 209)	Time-restricted feeding	6 months	Weight loss Adverse events Changes in lipid profile	18 months
Thomas 2022 (USA)	RCT	Men and women (> 80% women) (n = 85)	Time-restricted feeding	10 months	Weight loss Adverse events	10 months
Trepanowski 2017 (USA)	RCT	Men and women (> 80% women) (n = 100)	Alternate-day fasting	6 months	Weight loss Changes in lipid profile	12 months
Wei 2023 (China)	RCT	Men and women with non-alcoholic fatty liver disease (n = 88)	Time-restricted feeding	12 months	Weight loss Adverse events Changes in lipid profile	12 months
Yeary 2024 (USA)	Cluster-RCT	Men and women (n = 42)	Modified alter- nate-day fasting	6 months	Weight loss	6 months

RCT: randomised controlled trial