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Assessing the effectiveness of *If-then plans* to facilitate increased fruit and vegetable intake in adults

A systematic review and meta-analysis

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List of Abbreviations

Chi²	χ^2 – statistics/ Q-statistics
FFQ	Food Frequency Questionnaire
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HKSJ	Hartung-Knapp-Sidik-Jonkman adjustment
I²	I^2 statistics
K=	Included reports of studies in review
***k*=**	Included study comparisons in review and analysis
PRISMA	Preferred Reporting of Items for Systematic Reviews and Meta-analyses
REML	Restricted maximum likelihood estimator
RoB 2	Revised Cochrane risk-of-bias tool for randomized trials
SKM	Sanne Karlsen Melum
SMD	Standardised mean difference
SoF	Summary of Findings
Tau²	τ^2 - statistics
TiDeR	Template for intervention description and replication checklist and guide
g	Hedges *g*

Abstract

Background:

Non-communicable diseases (NCDs; e.g., cardiovascular disease, cancer) are prevalent, causing high rates of morbidity and mortality. Healthy eating behaviours and a diet rich in fruit and vegetables are important in the prevention and management of NCDs and their associated risk factors. If-then plans (i.e., *implementation intentions*) is a planning strategy that could facilitate behaviour change by creating a mental link between a cue and a response in an "If…, then…"-structure. Thus, helping adults achieve their goal of eating a healthy diet, important for good health.

Objectives:

The aim of the present systematic review was to investigate the effectiveness of if-then planning interventions to facilitate increased fruit and vegetable intake in adults. The second objective was to investigate if the effectiveness of if-then planning is related to differences in sample population or planning factors, two subgroup analyses were performed: 1) student and non-student populations; and 2) self-formulated and assigned if-then plans.

Methods:

A systematic review and meta-analysis were conducted and reported according to PRISMA 2020 guidelines. MEDLINE, Embase and PsycInfo were searched for eligible reports of studies (Nov. 2022). Included studies were randomised controlled trials, testing the effect of if-then plans on fruit and/or vegetable intake in adults, in real-life settings. Risk of bias was assessed using RoB 2. Meta-analyses were conducted using a random-effects model (REML). Certainty of the evidence was assessed with GRADE.

Results:

Ten study reports were identified as eligible and included in the review. If-then plans had a small statistically significant effect (SMD(d) = 0.23, 95% CI: 0.09, 0.37) on fruit and vegetable intake, compared to active controls without if-then planning. There was not a statistically significant difference between subgroups: 1) student and non-student populations (p = .34), and 2) self-formulated and assigned if-then plans (p = .82). The weighted risk of

bias was judged as ‘some concerns’, and the confidence in the evidence was graded to be of moderate quality.

Conclusion:

If-then plans had a small positive effect on increasing fruit and vegetable intake in adults. There was not a difference in effects between student and non-student populations, and self-formulated and assigned if-then plans. The confidence in the evidence was of moderate quality. Future research should conduct and report studies according to best-practice guidelines, to increase the certainty in the findings.

Norsk sammendrag

Bakgrunn:

Ikke-smittsomme sykdommer (eksempelvis kardiovaskulære sykdommer og kreft) er utbredte årsaker til høy sykelighet og dødelighet. Sunn spiseatferd, inkludert et kosthold med mye frukt- og grønnsaker, er viktig for å forebygge ikke-smittsomme sykdommer og dermed relaterte risikofaktorer. If-then planer (norsk: «hvis-så» planer) kan fasilitere økt frukt- og grønnsaksinntak hos voksne ved å skape en mental kobling mellom et relevant signal og en respons i en "if…, then..."-struktur.

Mål:

Målet med denne systematiske gjennomgangen var å undersøke hvor effektivt if-then planleggings intervensjoner fasiliteter økt frukt- og grønnsaksinntak hos voksne. I tillegg, for å undersøke om det var noen forskjell i effekt mellom studiepopulasjon, eller planleggingsfaktor, ble to subgruppe analyser gjennomført: 1) student og ikke-studentpopulasjon, og 2) selvformulerte og tildelte if-then planer.

Metode:

En systematisk gjennomgang og meta-analyse ble gjennomført og rapportert i henhold til PRISMA 2020 retningslinjer. Søk etter kvalifiserte studier ble foretatt i databasene: MEDLINE, Embase og PsycInfo (Nov. 22). De inkluderte studiene var randomiserte kontrollerte studier som testet effekten av if-then planer på frukt- og/eller grønnsaksinntak som utfallsmål hos voksne, i en naturlig setting. Risiko for bias ble vurdert ved bruk av RoB 2. Meta-analysen ble utført ved bruk av en tilfeldig-effekt modell (random-effects model; REML). Tilliten til resultatene ble undersøkt ved bruk av GRADE.

Resultater:

Ti studierapporter ble vurdert som kvalifiserte til å bli inkludert i denne gjennomgangen. If-then planer hadde en liten signifikant effekt (SMD(*d*) = 0.23; 95% CI: 0.09, 0.37) på frukt- og grønnsaksinntak sammenlignet med en aktiv kontroll uten if-then planlegging. Det var ingen signifikante forskjeller mellom subgruppene: 1) student og ikke-studentpopulasjon (p = .34), og 2) selvformulerte og tildelte if-then planer (p = .82). Vektet risiko for bias ble vurdert til 'noe bekymring', og tilliten til dokumentasjonen ble vurdert til moderat kvalitet.

Konklusjon:

Det ble funnet en liten positiv effekt av if-then planlegging på frukt- og grønnsaksinntak hos voksne. Det ble ikke funnet noen forskjell mellom subgruppene: 1) student og ikke-studentpopulasjon, og 2) selvformulerte og tildelte if-then planer. Dokumentasjonen ble vurdert til moderat kvalitet. Videre forskning bør tilstrebe å undersøke og rapportere studier etter gjeldende retningslinjer for randomiserte studier for å øke tilliten til funnene.

1 Background

1.1 Description of the context

Fruit and vegetable intake and health

Non-communicable diseases (NCDs; e.g., Cardiovascular disease, Cancer, Type 2 Diabetes mellitus) and their associated risk factors (e.g., overweight/obesity, high blood pressure, high blood glucose) are prevalent, causing high rates of morbidity and mortality globally (1, 2). An unhealthy diet is a modifiable risk factor, and thus promoting healthy eating behaviours and a healthy diet rich in fruit and vegetables are important in the prevention and management of non-communicable diseases (3). Afshin et al. 2017, published a review estimating 11 million deaths worldwide attributable to dietary risk factors, whereby 2 million deaths were associated with low fruit intake (4). Another review from 2013 estimated that 5.6 and 7.8 million premature deaths worldwide may be attributable to a fruit and vegetable intake below 500 g/day and 800 g/day (5).

Fruit and vegetables are low in energy, high in fibre, and are a good source of a variety of micronutrients and antioxidants that are associated with a lower risk of many non-communicable diseases (6). The current recommendation for fruit and vegetable intake for the Norwegian population is to eat at least 5 portions per day (i.e., 500 gram), whereby half of the intake should come from vegetables (7, 8). Studies on fruit and vegetable intake in the Norwegian adult population have estimated that 70-75% of women and 78-83% of men eat less fruit and vegetables than the recommended intake (9). Interventions that aim to increase fruit and vegetable intake are therefore important, if national recommendations are to be met. However, it is not easy to make sustainable and lasting dietary changes (10), and health care providers, including registered dietitians need evidence-based, time-efficient and effective strategies to guide and support patients to increase their fruit and vegetable intake.

Behaviour change theories and strategies in dietetics

A central role of the dietitian (or health provider) is to support a patient in their goal striving to make changes to eating behaviour, that are necessary for good health (e.g., increased fruit and vegetable intake). Many behaviour change techniques and strategies have been introduced to change health behaviours (11). In nutrition and dietetics there has been an

emphasis on theories and strategies that have in common that they try to explain *why* a person behaves in a certain way (12-14). Many strategies therefore target motivational- and goal setting aspects of eating behaviour change (e.g., motivational interviewing, S.M.A.R.T goals) (15, 16). Nonetheless, psychological research has found that goal setting is often not enough to lead to the required behaviours (10, 17, 18). Thus, strategies to implement the required behaviours are important, and one strategy that could be used is planning. Various types of planning strategies have been described (19), however, *implementation intentions* have demonstrated efficacy across a variety of health behaviours and populations (20), and could be particularly useful in applied settings as it is easy to use, require little effort, and are low cost.

Implementation intentions: If-then plans & Time-based plans

Implementation intentions describe a specific planning structure that are reported in two general forms in the literature: 1) if-then plans i.e., linking a relevant situational cue to a response (details below); or 2) "When, where, what, how" - plans. In this review "When, where, what, how" – plans (i.e., action plans) are defined as *time-based*. Time-based plans could easily be translated into the cue being a day or time of the week (e.g., "on Friday"), which is an abstract concept that requires conscious thought (21). Thus, the cue is not a "salient, perceptible environmental feature" that defines "a specific situation to act upon" (21). In 2016, a synergy expert group defined *implementation intentions* as: "a form of planning that specifies a critical condition linked to a goal-directed response" and recommended the use of the if-then structure (22). This recommendation was made because it was found that specifying plans in the if-then structure enhance the effectiveness (23). Consequently, if-then plans are the intervention of interest in this review.

1.2 Description of if-then plans

If-then plans is a self-regulatory planning strategy that has been developed and refined over the last 30 years (17, 18, 24). In if-then planning mental associations between a relevant situational cue are specified in advance as the "if"-part; and linked with an appropriate (goal-directed) response as the "then"-part. For example: "If I enter a grocery store, then I will first pick some fruits and vegetables". Situational cues can be an event like a critical situation or

obstacle, and a response can be a behaviour. However, the cue can also be a feeling, and the response the regulation of that feeling.

In research, if-then planning interventions have been delivered as print communication, as attachments to questionnaires (paper or online); or instructions delivered by an assistant in a face-to-face setting. In a questionnaire setting, if-then plans are usually self-guided, whereby participants go through the instructions by themselves without assistance from a helper. In a face-to-face setting, if-then planning formulation can be assisted by a helper, which is proposed to increase the quality and effectiveness of the plans (23).

In addition, if-then plans can be self-formulated or assigned. When if-then plans are self-formulated participants make their own personal plans. In contrast, assigned if-then plans are pre-specified by the researcher (or other). There are opposing views on whether self-formulated or assigned plans should be used (22), with experimental studies supporting both methods (23, 25). The following four steps have been proposed by Keller et al. 2019, to form self-formulated if-then plans (26):

1. Commit yourself to a goal intention.
2. Specify a critical situation for attaining the goal.
3. Specify a goal-directed response that can be performed in this situation.
4. Link the critical situation and a goal-directed response in an if-then format: "If___(critical situation)___, then___(goal-directed response___!"

Assigned if-then plans have pre-specified critical situations and responses, and can be delivered as a table with two columns (Table 1). The important step is to physically *draw* a link between a relevant critical situation and response that apply.

Table 1: Assigned If-then plans.

Critical situation/Obstacle	(space to *draw* a link)	Response/Solution
"If I lack time…		"then I will buy pre-cut or frozen fruit and vegetables at the grocery store!"
"If I forget to eat fruit or vegetables…		"then I will put a reminder at the refrigerator!"

Examples adapted from Vézina-Im et al., 2019 (27).

1.3 How if-then plans might work

Over the years many experimental studies have been conducted to investigate the processes of how if-then plans work, and factors that moderate the effectiveness. In a review by Keller et al. 2021, if-then plans are proposed to work based on two mental processes: 1) by specifying a situational cue in advance the cue becomes more *cognitively accessible*; consequently when cues are encountered the if-then plans are an available alternative to default responses; 2) because the relevant cue is *linked* to a response, encountering the cue enacts the response automatically (28). This is also why if-then plans have been called 'instant habits', because they share two components, i.e., the association between a cue and a response, but without the need for repetition that is usually required to change habits (18). Despite that many every-day eating behaviours are thought to be habitual, and habits are resistant to changes in motivation, if-then planning is proposed to create the required bottom-up, automaticity to change even habitual (eating) behaviours (29, 30). Therefore, it is important to assess if if-then plans are effective in increasing fruit and vegetable intake, as this is an essential part of a healthy diet.

1.4 Why it is important to do this review

Several systematic reviews and meta-analyses have been conducted to assess the effectiveness of *implementations intentions* (if-then- *and* time-based plans) in different populations for a variety of health behaviours. For example, physical activity (31), smoking cessation (32), alcohol consumption (33), and diet (34-36), with a small-to-moderate effect. Furthermore, if-then plans is the recommended planning structure by the Synergy expert group, and to my knowledge this is the first review assessing the effectiveness of *only* if-then plans (22). In a systematic review by Adriaanse et al. 2011, studying the effect of *implementation intentions* on eating behaviours, half of the included study populations were students (34). Another review found that *implementation intentions* had a higher effect on physical activity in student populations, compared to a non-student population (31). Thus, proposing the effectiveness of if-then plans in general might be dependent on population characteristics. It was therefore of interest to investigate if there were a difference in effects between student and non-student populations on fruit and vegetable intake. In addition, investigating if there were a difference between creating self-formulated personal plans, in contrast to receiving assigned, pre-specified plans, were important as research on these two

planning factors are limited according to the synergy expert group (22). Information about the effects of planning structure could inform future research prioritisation and recommendations, and might be of value to applied settings. To summarise, three important reasons for conducting this review are: 1) if-then plans could facilitate increased fruit and vegetable intake; 2) the intervention included is only *if-then* plans; 3) it is of interest to know if effects are different between sample populations, and between self-formulated or assigned planning structure.

1.5 Objectives

The primary objective of this review was to assess the effectiveness of if-then planning interventions, compared to active controls without the if-then planning, on fruit and vegetable intake in adults. The second objective was to investigate if the effectiveness of if-then planning is related to differences in sample population or planning factors: 1) student and non-student populations; and 2) self-formulated and assigned if-then plans.

2 Methods

This systematic review and meta-analysis was conducted and reported following *The Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) 2020 (37), and guided by the *Cochrane Handbook of Systematic Reviews of Interventions version 6.3* (38). The PRISMA 2020 Checklist are attached in Appendix 1. Amendments to the protocol are provided in Appendix 2, and the protocol are attached in Appendix 3. Note an important deviation from the planned protocol, where I due to feasibility (time and resources) had to focus my planned objective of assessing *all* eating behaviours to the subset of fruit and vegetable intake (refer to Appendix 2 for rationale).

2.1 Eligibility criteria

S Study design	P Population	I Intervention	C Control	O Outcome	Other criteria
Inclusion criteria:					
Experimental design with *random allocation* (RCT)	Adults ≥ 18 years*	*If-then plans* or *Implementation intentions* in the If…, then…- or 'cue'…, 'response'…- planning format, in minimum one plan	Minimum one control condition	Fruit and/or vegetable intake	*Language:* English or Scandinavian *Publication type:* Peer-reviewed journal article *Country:* No restriction *Years:* No restriction
Exclusion criteria:					
Other study designs	Psychological diagnoses.	Time-based plans; Multiple-BC-intervention**	No control condition	Plant-based/vegetarian/vegan diet; Other eating behaviours (e.g., fat, sugar, snacks)	*Setting:* Not real-life setting***

Figure 1: SPICO illustrating review inclusion and exclusion criteria.

Explanations:

**University student populations were considered eligible.*

***Multiple Behaviour Change intervention, where the effect of If-then plans cannot be assessed because several behaviour change techniques have been used, without a control condition receiving the a similar intervention without If-then plans.*

****Excluding artificial laboratory situations, where the outcome was not assessed in a natural setting.*

Study design and population

Included studies were randomised controlled trials (RCTs), i.e., experimental studies with random allocation of participants to intervention and control groups. Studies facilitating other study designs e.g., correlational studies, were not eligible. All adult populations (age ≥ 18 years) were considered eligible including university students, except for populations with

psychological diagnoses, or physiological diseases or conditions making planning difficult/impossible.

Intervention and control

Only if-then planning interventions were eligible, defined as: plans had to be created on any perceivable cue (situation, activity or feeling) as the 'If'-part; and had to describe a response aimed at facilitating the goal (i.e., increased fruit and/or vegetable intake) as the 'then'-part.

Minimum one plan had to be in the if-then format. In study reports (i.e., articles) with more than one if-then planning group (multiple-arms), the if-then groups were included in the review when there were similar active controls, but without the if-then planning. Ideally, the only difference between the intervention and control were the if-then planning factor. For studies reporting on if-then plans plus an additional co-strategy, the control condition should also include the co-strategy. Practically, not all studies provided this ideal design and summary of study comparisons are described in Table 2 (details in Appendix 4). Interventions that were described as *Implementation intentions,* but where the planning structure was time-based, were not eligible.

Outcome

The outcome of interest was fruit and/or vegetable intake (FVI) at last available follow-up. Fruit and vegetable intake were expected to be measured using dietary assessment methods e.g., 24-hour recall, food diaries, food frequency questionnaires (FFQ), single-item diaries and/or objective methods e.g., biomarkers. All dietary assessment methods were considered eligible.

Setting

Experimental studies performed in artificial laboratory settings were not eligible. Artificial setting was defined as: 1) fruit and vegetable intake were collected on the same day (e.g., amount of food eaten in the laboratory, responding to pictures of food), and 2) no follow-up assessment of fruit and vegetable intake (reflecting consumption in a natural setting). Additional other criteria are listed in Figure 1.

2.2 Information sources and search strategy

The literature searches were conducted in three electronic databases: MEDLINE, Embase, and APA PsycInfo (23.11.2022). The full search strategy for each database is attached in Appendix 5. Additional non-database searches included hand-searching reference lists of two published reviews on the topic (34, 36), and reference lists of the included study reports. The search strategy was developed in Ovid MEDLINE using key terminology, reviewing relevant literature identified from preliminary searches. It was manually adapted to each database as indexing terms varied. The literature search consisted of combining the PICO-elements 'intervention' (i.e., if-then plans OR implementation intentions) AND 'outcome' (e.g., fruit OR vegetable OR food). The searches were limited to 'abstract', 'title' and 'keywords'. No other limitations were applied. A Health Sciences Librarian was consulted.

2.3 Study selection

References retrieved from the literature searches were handled in reference manager software, where duplicates were removed. The remaining references were imported to Covidence (web-based software platform facilitating systematic review conduct), where they were screened by title and abstract for eligibility. Study reports found eligible were assessed in full-text, and those that met inclusion criteria were included in the review. The validated Cochrane RCT Classifier tool (39), which is incorporated into Covidence was used. However, all studies identified as RCTs were manually checked before being excluded. Uncertainty was discussed.

2.4 Data extraction and data items

Data items, including study methods, risk-of-bias items, participant-, intervention- and control characteristics and effects, in addition to miscellaneous (e.g., funding, ethical approval, trial registration) were extracted from the included studies. The data items were specified at the protocol phase of this review, inspired by the TIDieR checklist (40), Cochrane Handbook (38), PRISMA 2020 (41), and assessing published reviews and articles on the topic. A review-specific data extraction template was created manually in Covidence based on pre-specified data items, whereby no substantial changes were made (a list of the data items is attached in Appendix 6). Extracted outcomes were double checked.

2.5 Risk-of-bias assessment

Risk of bias was assessed using the *Revised Cochrane risk-of-bias tool for randomised trials* (RoB 2) (42). Whereby, the guidance document created by the RoB 2 Development Group (43); and the accompanying RoB 2 template (44) were used for the risk-of-bias assessments (Appendix 7). RoB 2 is outcome specific, therefore risk-of-bias assessments were performed on *one* If-then planning intervention – control comparison, for fruit and/or vegetable intake at one specific timepoint for each included study report. Because the objective was to assess the effect of if-then plans, it was the 'effect of assignment' (i.e., intention-to-teat) that was considered in the risk-of-bias assessments. All five domains i.e., risk of bias arising from the randomisation process; risk of bias due to deviations from the intended interventions; risk of bias due to missing outcome data; risk of bias in measurement of the outcome; risk of bias in selection of the reported result were assessed. Signalling questions were answered in each domain to reach a domain specific risk-of-bias judgement. This domain specific risk-of-bias judgement was reached (unless otherwise stated) using the proposed algorithms for each domain in the RoB 2 guideline document (43). Each domain was reported as 'high' or 'low' (risk of bias) or 'some concerns'. In addition, an overall risk-of-bias judgement across all domains was reached. The RoB 2-judgements are presented in figures using the software program R (45) using the robvis package (46, 47). All risk-of-bias assessments were performed by one reviewer.

2.6 Data synthesis and statistical analyses

Extracted data items from each included study was synthesised, summarised, and are presented in tables and figures in the results section. Statistical analyses were performed in the software program R version 4.2.2 (45), and the packages: tidyverse (48), meta (49) and robvis (46), guided by Harrer et al. (50).

Preparing for synthesis and meta-analysis

Similarity between studies were assessed by visual inspection, by investigating if it was reasonable to combine the effects to a pooled estimate (Appendix 8; Table 5). Last available follow-up was defined as up until and including 6-months, however, this was a post hoc decision because it was judged the most similar between studies (the protocol specified 'last available follow-up', refer to Appendix 2).

Outcome prioritisation

The outcome of interest was fruit and/or vegetable intake, but because some studies reported this in more than one way; and the protocol were unspecific, all eligible outcomes have been reported in tabular form in the results. However, I had to prioritise outcomes for the meta-analysis to avoid unit-of-analysis error. Prioritisation for the meta-analysis were as follows: 1) include fruit and vegetable intake reported as a summarised measure (FVI); 2) include only fruit intake (FI), when both were reported separately if they couldn't be combined (for similarity reasons). Sensitivity analyses were performed for several of the prioritisations to assess the effect on the pooled result (details in 'Statistical analysis' paragraph).

Effect size measure

The standardised mean difference (SMD) with 95 % Confidence intervals (CI) was calculated for each study comparison and for the pooled summary effect using reported means, standard deviation (SD), and sample size (n). SMD was chosen (at the protocol stage) because it standardises the effects of the If-then planning intervention on fruit and vegetable intake measured by different dietary assessment methods, and therefore effects can be compared between studies. SMD was calculated as Cohens' *d*, using the formula:

$$SMD(d)pooled = \frac{(Sum\ mean\ If - then) - (Sum\ mean\ Control)}{SDpooled}$$

Where SMD(d)$_{\text{pooled}}$ are the summary effect of the difference in means between the two groups, and the SD_{pooled} are the pooled standard deviation of both groups (51). Cohen's *d* was used because it is frequently reported in psychological research, and therefore comparable to other studies and reviews, and because sample sizes did not indicate a need for small sample correction (50). However, a sensitivity analysis was performed using Hedges' *g*. Because SMD(*d*) are expressed as the difference between means in two groups in units of standard deviations, a common interpretation is: 0.20 = 'small effect', 0.50 = 'medium effect', and 0.80 = 'large effect ' (52).

Data processing

An assumption of a meta-analysis with a pooled effect estimate, is that SMD(*d*) are independent across study comparisons included in the meta-analysis. Therefore, to avoid

unit-of-analysis error when dealing with study reports with multiple-arms I used one of two alternatives: 1) when there were only one control group available, I combined if-then groups (when reasonable); and 2) I excluded two if-then groups because there were no eligible control group. One study did not report on standard deviations (SDs), therefore I imputed SDs based on a pooled mean between similar studies. A sensitivity analysis was performed to assess the effect of the imputation. Other studies that had incomplete reporting or missing information, were not included in the meta-analysis (overview in Table 2 and Table 3). The protocol mentioned that I would try to obtain missing information, due to time constraints in this project I did not contact study authors to request missing information.

Statistical analyses

A meta-analysis using an inverse-variance random-effects model with restricted maximum likelihood (REML) estimator for heterogeneity (between study variance) (53), and Hartung-Knapp-Sidik-Jonkman (HKSJ) adjustment (54, 55) was performed as planned. The choice of the random-effects-model was based on the following assumption: because studies have been conducted by separate research teams, and in different populations and geographical locations, it is unlikely that all included studies are functionally identical, therefore I expect the effect sizes to be similar but not identical across studies (56) i.e., a random-effects model was considered the most appropriate. REML estimator and HKSJ adjustment was used because it was recommended in a simulation study to yield more precise estimates of heterogeneity, and confidence intervals around the pooled effect, respectively (57). Results from the meta-analyses are presented in forest plots and a drapery plot, including the prediction interval.

Robustness of the random-effects model

Robustness of the random-effects model was assessed by performing four separate sensitivity analyses: 1) removing a study with high risk-of-bias in the outcome (per protocol), 2) removing one study with imputed SDs, 3) performing a meta-analysis using Hedges *g* (small sample bias correction), and 4) performing a meta-analysis with another measure of fruit intake (where three measures were reported). The three latter analyses were run post hoc to account for prioritisations and data processing made in the meta-analysis (described above). Publication bias (small study effects) was assessed through visual inspection (asymmetry

present or not) of the drapery plot and funnel plots. Egger's regression test was performed to statistically test for asymmetry.

Assessing heterogeneity

Heterogeneity was visually inspected and tested statistically using Chi^2 and Tau^2. In addition, I^2-statistics was used as an guide on the inconsistency between studies, and can be interpreted as below 30-40% being 'low', 30-60% being 'moderate', 50-90% being 'substantial' and 75-100% being 'considerable' (58). Two subgroup analyses were performed as planned: 1) using the sample population (student and non-student populations) as subgroups, and 2) using planning construct (self-formulated or assigned if-then plans) as subgroups.

2.7 GRADE assessment

The certainty of the evidence was assessed for fruit and/or vegetable intake using the validated *Grading of Recommendations Assessment, Development and Evaluation approach* (GRADE) (59). In the GRADE approach randomised trials start at 'high' quality evidence and can be downgraded by one or two levels for five factors: Risk of bias; Inconsistency of results; Indirectness of evidence; Imprecision and Publication bias (under 'other considerations'). If the reviewer judges the evidence to be of lower quality for one or several factors, the certainty can be rated down from 'high' to 'moderate' to 'low' to 'very low'. However, certainty can also in a similar manner be rated up by one or two levels in three factors: large magnitude of effect, confounding variables, and dose-response gradient, if the quality of the evidence suggest that this is appropriate. However, this apply to studies that are non-randomised, and therefore this was not considered for this review, as there were only randomised trials included. The results from the GRADE assessment are presented in a Summary of Findings (SoF) table, and the judgements are reported in an evidence table, whereby both was created using GRADEpro Software (60).

3 Results

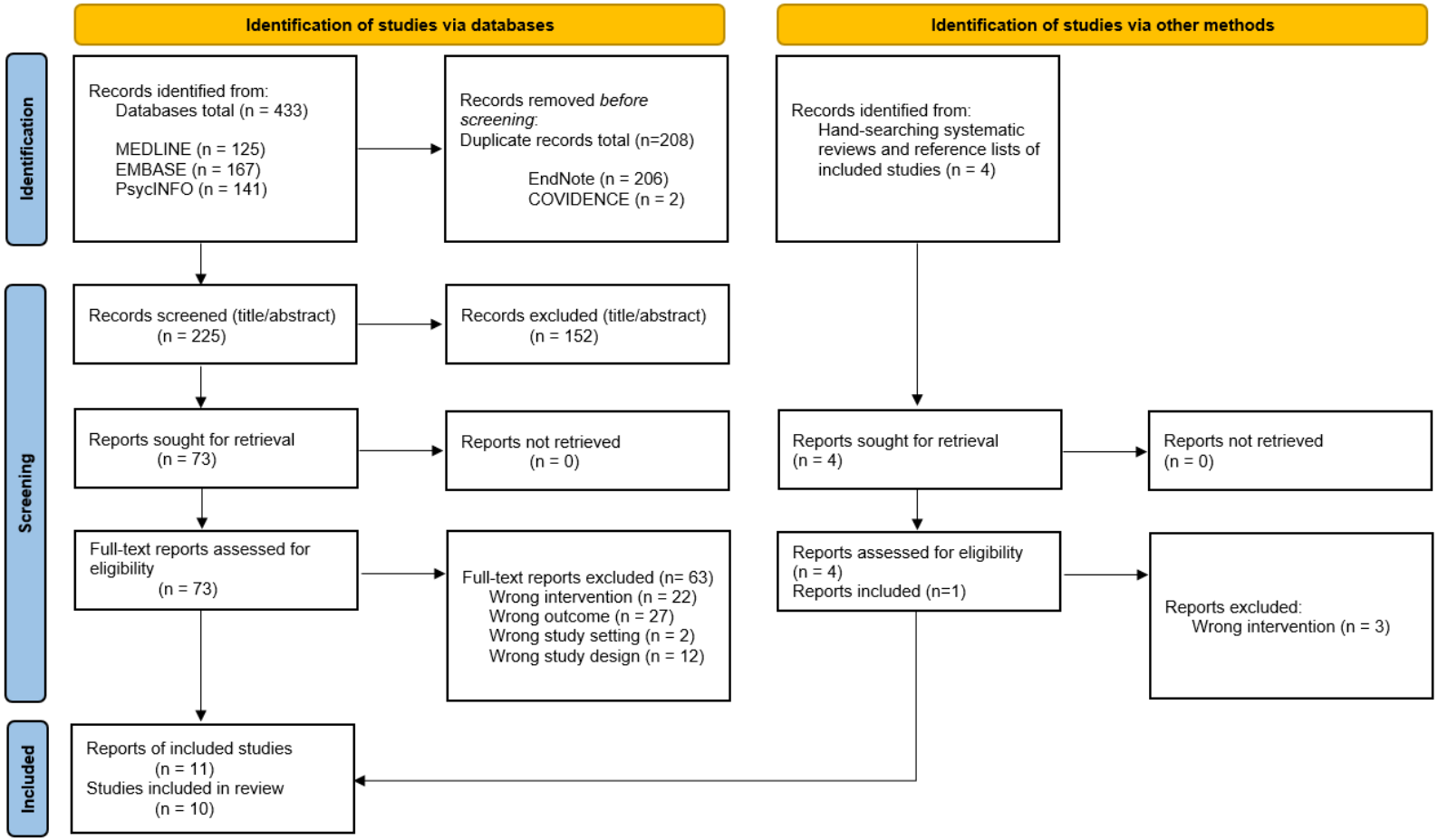

Figure 2: PRSMA 2020 Flow Diagram (37). In total 437 records were identified. Eleven reports of included studies were found eligible (i.e., citations), whereby ten unique studies were included in the review (K = 10). Note that these contained 14 eligible study comparisons (Table 2), of which nine were included in the meta-analysis (k = 9).

3.1 Search results

In total 433 records were retrieved from database searches in MEDLINE, Embase and PsycInfo (search strategies attached in Appendix 5). 208 records were identified as duplicates and removed before title and abstract screening, resulting in 225 records being screened by title and abstract. Of those, 152 records were excluded due to not meeting eligibility criteria (Figure 1). For example, not relevant to review, children or adolescent populations, protocols, non-randomised trials, physical activity, or smoking cessation as outcome. Resulting in 73 reports being assessed in full-text for eligibility, whereby 63 full-text reports were found ineligible and excluded (for details refer to Appendix 9). Reasons for exclusion were wrong intervention (e.g., time-based planning), or wrong outcome (e.g., fat-, sugar-, snack-intake), resulting in 10 eligible studies included from the database searches. In addition, two previous published systematic reviews (34, 36) and reference lists of included study reports were hand-searched, resulting in four additional studies being assessed for eligibility. One study report met eligibility criteria and was included in the review, resulting in a total of 11 reports of included studies (i.e., citations). Two included studies reported on the same trial and were therefore assessed as one publication (61, 62). In summary, a total of ten studies ($K = 10$)[1] were included in the review (61, 63-71). Five studies contained information on multiple eligible arms. Therefore, when organising the study comparisons between if-then planning group and control, a total of fourteen comparisons ($k = 14$) were found eligible (Table 2). Of those, nine study comparisons ($k = 9$) were included in the meta-analysis.

3.2 Description of included studies

Study design and population

The included studies were peer-reviewed, randomised trials published in health psychology-, behavioural- or nutrition journals (e.g., Psychology and Health; $K = 6$). The included studies were published over a thirteen-year period, between 2006 – 2019, in western countries (e.g., United Kingdom, France, Germany, Canada). The population included in the review were

[1] Note that included studies are further denoted ($K =$), and study comparisons within studies are denoted ($k =$).

recruited from universities (*K* = 6), with a median age of 20-21 years[2] (range 18-54 years) [3]; and recruited from random adult populations (*K* = 4), with a median age of 41 years[2] (range 18-65 years)[3]. All included studies had a greater proportion of females compared to men, from 62% - 100%, respectively. Median percentage of men was 26% (range 0 – 38%). In those studies reporting ethnicity, participants were predominantly Caucasian (*K* = 6). Although not all studies reported on education level, six studies had a university student sample (*K* = 6). In the four studies with a non-student population (*K* = 4), the lowest education level reported was 56% of participants with less than 10 years of education (70). In summary, the included population was predominantly from European countries, and were young -to- middle aged adults, with high literacy (Table 2). The total population included in the review is n = 2904, and n = 1864 in the meta-analysis.

[2] Based on the reported means from the included studies.

[3] Two included studies did not report on age range; but described a mean age of 20 and 18 years. They were included because university student populations were eligible.

Table 2: Summary characteristics (SPICO) of included studies (K = 10), and study comparisons (k = 14), illustrated as they were compared.

1st author, year	Study design	Population	Intervention(s)	Controls(s)	#	Outcome
Chapman et al., 2010 (64)	Six-armed parallel randomised trial (four groups incl.*)	Undergraduate students from UK University, M_{age}= 20 years (range 18-41), 71% females, 87% Caucasian (n = 432)	If-then plans (a), partially internet-based, self-guided, plans self-formulated	Questionnaire control (a), partially internet-based, self-guided	1	Retrospective (1 week), self-reported, single-item open ended question assessing FVI at 6 months + Retrospective (past year) FFQ assessing FVI at 6 months
			If-then plans + reminder at 3 months (b), partially internet-based, self-guided, plans self-formulated	Questionnaire control incl. brief encouragement (b), partially internet-based, self-guide	1	
Guillaumie et al., 2012 (61, 62)	Four-armed parallel randomised trial	Random adults from cities near Paris, France, M_{age}= 41 years (range 20-65), 85% females, 36% 'mother born abroad', 53% completed college edu., 22% BMI ≥ 30 (n = 319)	If-then plans (a), four face-to-face (individual) sessions for 1 month, facilitated by trained dietitian, plans self-formulated	Information intervention (a), brochures x4 mailed for 1 month, self-guided	1	Retrospective (1 week), self-reported FFQ with six categories assessing FVI at 6 months
			If-then plans + Self-efficacy intervention (b), four face-to-face (groups of 12) sessions for 1 month, plans self-formulated and assisted	Self-efficacy intervention (b), four face-to-face (groups of 12) sessions for 1 month	1	
Chapman et al., 2009 (66)	Three-armed parallel randomised trial (two groups incl.)	Undergraduate students from UK University, M_{age}= 20 years, 74% females, 92% Caucasian ($n = 201_{analysed}$)	If-then plans, paper-and-pencil-based, self-guided, plans self-formulated	Questionnaire control incl. prompt to plan, paper-and-pencil-based, self-guided	1	Retrospective (1 week), self-reported, single-item open ended question assessing FVI at 1 week

Armitage, 2015 (63)	Three-armed parallel randomised trial (two groups incl.)	Adult employees at private hospital, UK, M_{age}= 42 years (range 19-63), 76% females (n = 56)	If-then plans, paper-and-pencil-based, self-guided, assigned plans	Questionnaire control incl. prompt to plan, paper-and-pencil-based, self-guided	1	Retrospective (1 month), self-reported, fruit section of FFQ assessing FI at 1 month (x3 measures)**
Chapman et al., 2012 (65)	Three-armed parallel randomised trial	Undergraduate students from UK University, M_{age}= 21 years (range 18-44), 74% females, 84% Caucasian (n = 580)	Separate If-then plans***, internet-based, self-guided, plans self-formulated	Questionnaire control incl. brief encouragement, internet-based, self-guided	1	Retrospective (1 week), self-reported, single-item open ended question assessing FI and VI at 2 months
			Combined If-then plans***, internet-based, self-guided, plans self-formulated			
Vézina-Im et al., 2019 (71)	Two-armed randomised trial	Female students and university employees, Canada, M_{age}= 33 years (range 18-44), 100% females, 88% Caucasian, 62% University degree, M_{BMI} =29.5 (n = 56)	If-then plans, paper-and-pencil-based, self-guided, assigned plans	Questionnaire control, paper-and-pencil-based, self-guided	1	Retrospective (6 weeks), dietitian-assisted FFQ assessing FI, VI, FVI at 6 months
Stadler et al., 2010 (70)	Three-armed parallel randomised trial (two groups incl.)	Female adults from Germany, M_{age}= 41 years (range 30-50), 100% females, 44.3% ≥ 10 years edu. (n = 266)	If-then plans + mental contrasting and reminders, one face-to-face session (individual/groups of 2-5), plans self-formulated and assisted	Information intervention, one face-to-face session (individual/groups of 2-5)	1	Prospective (1 week), self-reported, food diary assessing FVI at 4 months
Luszczynska et al., 2006 (69)	Three-armed parallel randomised trial (two groups incl.)	Adults, M_{age}= 29 years (range 18-60), 66% females, 58.6% tertiary edu., 26% overweight/obese ($n = 285_{all\ 3\ groups}$)	If-then plans + Self-efficacy intervention, internet-based, self-guided, plans self-formulated	Self-efficacy intervention, internet-based, self-guided	0	Retrospective (2 weeks), self-reported, single item question with response

						options, assessing FVI at 6 months
Harris et al., 2014 (67)	Four-armed parallel randomised trial	Students and university employees, UK, M_{age}= 22 years (range 18-54), 72% females, 79% Caucasian, 94% students (n = 447)	If-then plans (non-affirmed) (a), internet-based, self-guided, assigned plans	Non-affirmed control (a), internet-based, self-guided	0	Retrospective (1 week), self-reported, combined, and standardised dietary assessment method, measuring FVI at 3-months
			If-then plans (self-affirmed) (b), internet-based, self-guided, assigned plans	Self-affirmed control (b), internet-based, self-guided	0	
Knäuper et al., 2011 (68)	Four-armed parallel randomised trial	First year university students, Canada, M_{age}= 18 years, 62% females, 72% Caucasian (n = 262)	If-then plans + mental imagery (a), internet-based, self-guided, plans self-formulated	Mental imagery control, internet-based, self-guided	0	Retrospective (1 week), self-reported, single-item open ended question assessing FI at 1 week
			If-then plans (b), internet-based, self-guided, plans self-formulated	Questionnaire control incl. goal intention, internet-based, self-guided	0	

Caption 1: ***Abbreviations:****. FVI: Fruit and vegetable intake; FI: Fruit intake; VI: Vegetable intake; Edu: education.*

#: Included =1, excluded =0 study comparisons (*k*) in meta-analysis.

*Two if-then groups were not reported due to no eligible control (details on the interventions are included in Appendix 4).

***3 measures of fruit intake reported: portions/day, frequency and sum.*

****Groups are combined in meta-analysis.*

Note: for transparency a table with the group names used in the original study reports, and the names used in this review are attached in Appendix 8; Table 6) .

If-then planning interventions and controls

In the present review, there were some similarities and differences in the if-then planning interventions included. For example, if-then plans given in questionnaires in printed- or online form (K = 8); or if-then planning interventions where helpers assisted participants in plan formulation (K = 2). Whereby, the latter two studies delivered the intervention in a face-to-face setting, in contrast to the other included if-then planning interventions that were self-guided (i.e., questionnaires). All studies clearly stated their planning intervention as 'if-then plans", except for the study by Luszczynska et al., 2006, which used *implementation intentions* in a "cue – response" -structure, hence included in this review (69). All included studies (K = 10) provided minimum one if-then planning example, as this was an inclusion criterion (examples in Appendix 4). For example, "If it is lunchtime at university, then I will eat an apple instead of crisps!", "If I pass the greengrocer on my way to work, then I buy apples!", or "If I am eating out for lunch, then I order a salad!" (64, 70). Furthermore, length of follow-up included in the review varied from 1 week to 6-months. In two study comparisons length of follow-up and time between if-then plan formulation (exposure), and fruit and vegetable intake assessment (outcome) were different, because participants were given planning reminders (64, 70).

In six study comparisons (k = 6) if-then plans were paired with a minor co-strategy. For example, if-then plans and self-efficacy (61, 69), if-then plans and mental contrasting (70), self-affirmed and non-affirmed if-then plans (67), and if-then plans and mental imagery (68). These were compared to the most similar control condition, for example, in the study by Guillaumie et al. 2012 the 'if-then plans and self-efficacy' intervention was compared to the self-efficacy group, i.e., an active intervention in the study report were considered a control in this review (61, 62). In all included study comparisons (k = 14) the control conditions were 'active', which means that the control group also received an intervention. The control conditions were predominantly questionnaire-based and self-guided (k = 11), whereby the baseline questionnaire given to both the intervention and control were similar except for the if-then planning factor.

Outcome

Fruit and vegetable intake (FVI) were reported in seven studies (*K* = 7), and ten study comparisons *(k* = 10) included in the overall review. Whereby, seven studies (*K* = 7) including nine comparisons (*k* = 9) were included in the meta-analysis. In the study by Vézina-Im et al., 2019 fruit and vegetable intake were reported as three variables (i.e., FVI, FI and VI) (71). Chapman et al., 2012 reported on fruit and vegetable intake separately (FI and VI) (65). Two studies reported on only fruit intake (FI) (63, 68). Fruit and/or vegetable intake were measured as portions per day or week, as servings per day, or as a combined and summarised measure (63, 67). All included study reports used self-reported dietary assessment methods, and all except Stadler et al., 2010 (70) used retrospective methods. For example, asking participants about their average daily fruit and vegetable intake over the past week (referred to as 'single-item' measure); or using fruit and vegetable sections of food frequency questionnaires (FFQ). In addition, in the study by Chapman et al., 2010, and the study by Armitage, C. J., 2015, more than one dietary assessment method was used and reported (63, 65).

3.3 Risk-of-bias (RoB 2) results

Each RoB 2 domain is described in more detail in the following paragraphs and are summarised in Figure 3. The risk-of-bias (RoB 2) assessments are attached in Appendix 7. Overall weighted risk of bias is reported in Figure 4.

Risk of bias arising from the randomisation process (domain 1)

Overall, across all study comparisons (*k* = 10) assessed for risk-of-bias (RoB 2) in domain 1, risk of bias was judged as 'low' for six- (*k* = 6), and at 'some concerns' for four (*k* = 4) study comparisons, respectively (see D1, Figure 3). Therefore, there is a greater proportion of 'low' risk of bias due to the randomisation process. In this domain insufficient information have generally been evaluated against the context of the intervention. For example, if a study was labelled as experimental and used an internet-based questionnaire, I have assumed a function of the online survey software to randomly allocate participants to intervention or control group(s); and to keep the allocation sequence concealed from participants and researchers.

Therefore, most study comparisons with ‘low’ risk of bias (Figure 3) used an online intervention. In other contexts, I have judged risk of bias to be at ‘some concerns’. For example, when the intervention was given face-to-face, and concealment of allocation was not described sufficiently. However, all study comparisons assessed for risk of bias did not report on any significant difference between groups on important baseline variables, indicating that randomisation was successfully achieved.

Risk of bias due to deviations from the intended interventions (effect of assignment to intervention, domain 2)

In domain 2 five study comparisons (k = 5) were judged as ‘low’, three were judged as ‘some concerns’ (k = 3), and two were judged as ‘high’ risk of bias (k = 2) due to deviations from the intended interventions (see D2, Figure 3). In those judged as ‘some concerns’ and ‘high’ risk of bias, information about awareness of intervention received among participants and/or researchers/assistants were incomplete reported. Also, in some cases statistical analysis methods were considered inappropriate for the objective of this review i.e., analysis was not performed according to intention-to-treat (ITT) principles. Whereby, handling of missing outcomes and exclusions were incomplete reported (e.g., many exclusions were made from the eligible baseline randomised sample).

Risk of bias due to missing outcome data (domain 3)

In domain 3, four study comparisons (k=4) were judged as ‘low’, five as ‘some concerns’ (k = 5), and one as ‘high’ risk of bias due to missing outcome data (see D3, Figure 3). Those judged as ‘some concerns’ and ‘high’ risk of bias had missing outcomes. For example: 1) high drop-out rate/low response rate; 2) incomplete reporting of reasons for dropping out, or no participant flow diagram; 3) no rationale for assumptions made in the analysis about missing outcomes. As proposed in the RoB 2 guideline document: “availability of data from 95% of participants will often be sufficient”, hence this was used as a rule of thumb (43). However, if a study provided explanations, for example, if there were equal proportions of missing outcomes in both groups and/or the study authors provided reasons for missing outcomes, they were judged as low risk of bias.

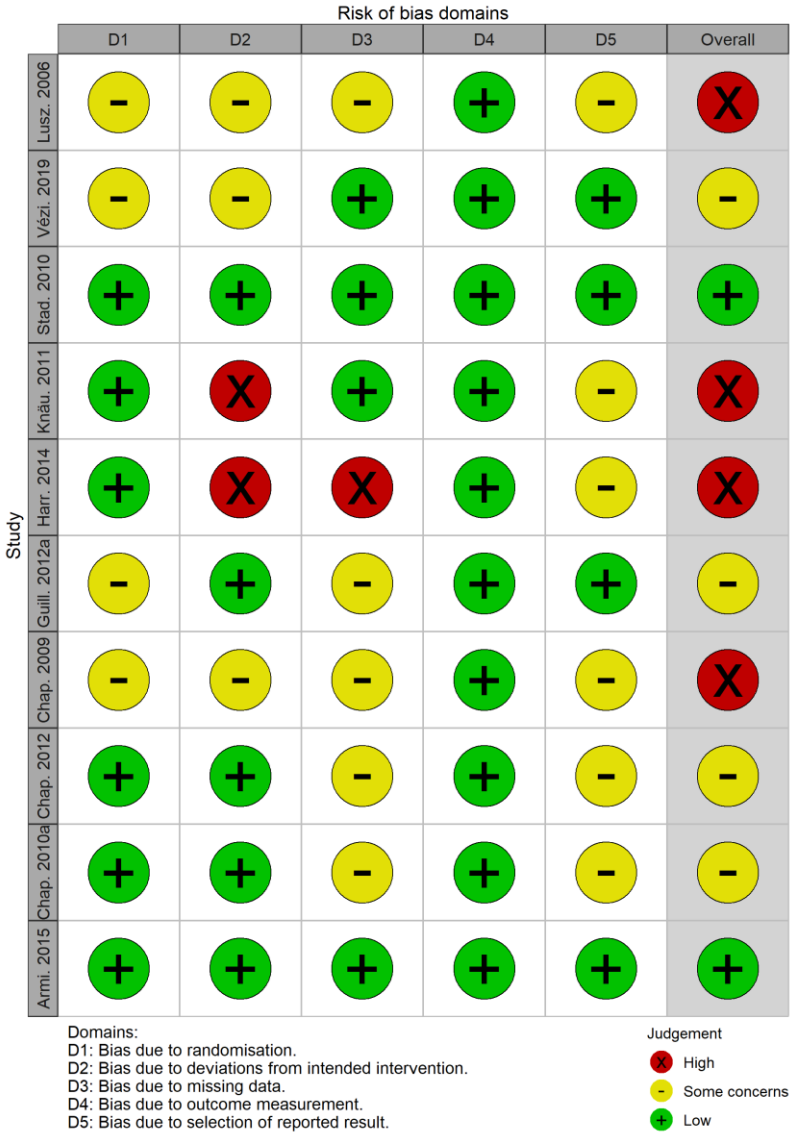

Figure 3: Traffic light plot illustrating author judgements of risk-of-bias (RoB 2) in each domain for fruit and/or vegetable intake for one study comparison from each study report (K = 10).

Risk of bias in measurement of the outcome (domain 4)

All study comparisons facilitated the same dietary assessment method for both groups that were compared. Assessment of fruit and/or vegetable intake were self-assessed i.e., the assessor was the participant, and participants were assumed to be unaware of the intervention received (based on judgements in domain 1, and the context of the studies). No dietary assessment method was considered 'inappropriate', but there were some variations in the

reporting of the validation of the methods used. However, risk of bias in domain 4 was judged as 'low' for all study comparisons (D4, Figure 3).

Risk of bias in selection of the reported result (domain 5)

In domain 5, four study comparisons (k = 4) were judged as 'low', and the other (k=6) were judged as 'some concerns' (see D5, Figure 3). Since none of the studies referenced a protocol or statistical analysis plan, I compared the results section with the methods section in the article. Those studies that reported on statistical analysis intentions in the methods, and where the results of these intentions were reported in the results, were judged as 'low' risk. In contrast, those studies that reported analysis incomplete or only in the results, were judged as 'some concerns'. The supportive evidence for judging studies to be of 'some concerns' and not 'high' risk of bias, were that there was no evidence of selective reporting for the fruit and/or vegetable measure assessed with RoB 2. All studies reported the results of fruit and/or vegetable intake as specified in the methods, and both positive and negative results were reported.

Overall risk of bias

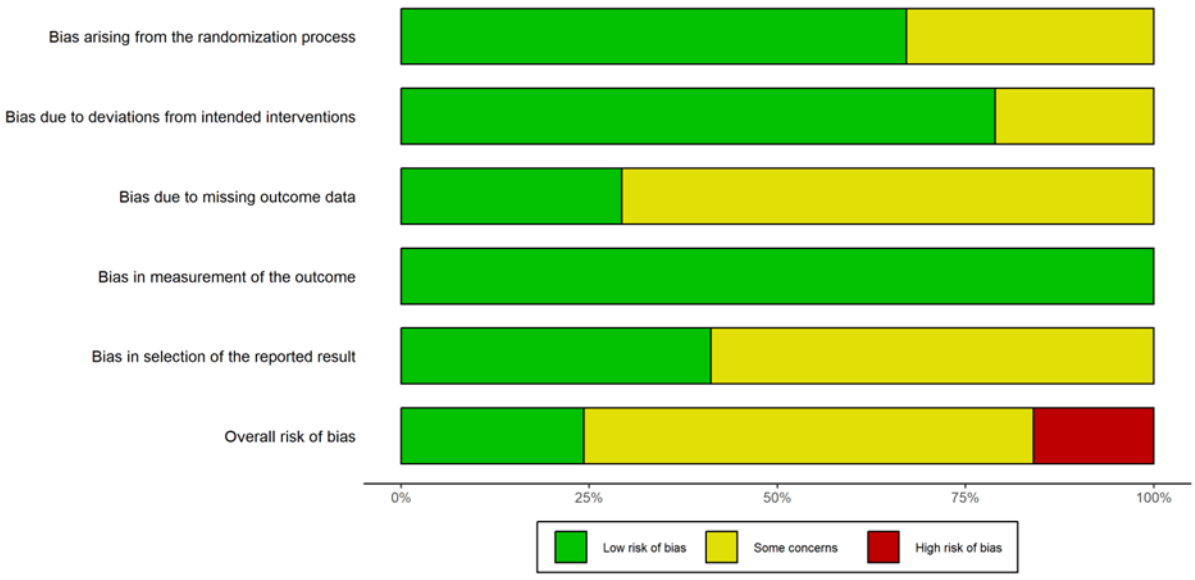

Figure 4: Weighted overall risk-of-bias (RoB 2) judgements for seven comparisons (k = 7) included in the meta-analysis.

None of the included studies provided information or reference to a study protocol, therefore, all risk-of-bias judgements are based on the information provided in the included journal articles. The overall risk of bias (RoB 2) between studies contributing to the meta-analysis is illustrated in Figure 4. The plot is weighted, as recommended by Cochrane (72). Therefore, only study comparisons that are included in the meta-analysis were given wight in this plot.[4] An unweighted plot, including one study comparison from each study report included in the review is attached in Appendix 8; Figure 14.

The weighted plot illustrates the five risk-of-bias (RoB 2) domains, including the overall risk of bias for fruit and vegetable intake. The green area of the bars illustrates 'low' risk of bias, the yellow area 'some concerns', and the red area illustrate 'high' risk of bias. In summary, the weighted plot illustrates that there is approximately equal 'low' risk of bias, and 'some concerns' in the domain-specific bars, but that the overall risk of bias has a greater proportion of 'some concerns'. In conclusion, there is 'some concerns' about the risk of bias for the reported outcome (i.e., fruit and/or vegetable intake).

3.4 Effects of If-then plans

Summary of effects

The effect of if-then plans compared to active control conditions are summarised in tables and figures in this section. Table 3 present a summary overview of all included study comparisons (k = 14), with the standardised mean difference (d), and a description of the effect.

[4] Overall, ten study comparisons (k = 10) have been assessed for risk-of-bias (RoB 2), one from each study report i.e., article (K = 10). In the weighted plot, seven study comparisons (k = 7) included in the meta-analysis contribute to the weighted risk of bias.

Table 3: Effects of If-then plans compared to control condition

1st author, year	Intervention vs. control	SMD (*d*)	Description of effect	#
Chapman et al., 2010 (64)	If-then plans (a) vs. questionnaire control (a)	**-0.01**	No difference in effect between groups on FVI at 6 months	1
		NE	No effect (FFQ)	0
	If-then plans + reminder (b) vs. questionnaire control (b)	**0.29**	Small-medium effect on FVI at 6 months favouring If-then plans	1
		NE	No effect (FFQ)	0
Guillamuie et al., 2012 (61, 62)	If-then plans (a) vs. information intervention	**0.55**	Medium effect on FVI at 6 months favouring If-then plans	1
	If-then + SE (b) vs. SE intervention	**0.00**	No difference in effect between groups on FVI at 6 months	1
Chapman et al., 2009 (66)	If-then plans vs. questionnaire control	**0.13**	Small effect on FVI at 1 week favouring If-then plans	1
Armitage, 2015 (63)	If-then plans vs. questionnaire control	**0.22**	Small effect on FI at 1 month favouring If-then plans	1
		0.54	Medium effect on FI at 1 month favouring If-then plans	0
		0.71	Medium-large effect on FI at 1 month favouring If-then plans	0
Chapman et al., 2012 (65)	If-then plans (S+C)[a] vs. questionnaire control	**0.23**	Small effect on FI at 2 months favouring If-then plans	1
		0.18	Small effect on VI at 2 months favouring If-then plans	0
Vézina-Im et al., 2019 (71)	If-then plans vs. questionnaire control	**0.29**	Small-medium effect on FVI at 6 months favouring If-then plans	1
		0.22	Small effect on FI at 6 months favouring If-then plans	0
		0.19	Small effect on VI at 6 months favouring If-then plans	0
Stadler et al., 2010 (70)	If-then plans + MC vs. information intervention	**0.44**	Medium effect on FVI at 4 months favouring If-then plans	1
Luszczynska et al., 2006 (69)	If-then plans + SE vs. SE intervention	NE	No difference in effect on FVI at 6 months	0
Harris et al., 2014 (67)	If-then plans + NA vs. NA control	NE	Effect on FVI at 3 months favouring If-then plans	0

	If-then plans + SA vs. SA control	NE	No difference in effect on FVI at 3 months	0
Knäuper et al., 2011 (68)	If-then plans vs. questionnaire control	NE	Likely no effect on FI at 1 week	0
	If-then plans + MI vs. MI control	NE	Likely no effect on FI at 1 week	0

Caption 2: SE: self-efficacy; MC: mental contrasting; NA: non-affirmed; SA: self-affirmed; MI: mental imagery. #: Included =1, excluded =0, study comparisons in meta-analysis. NE: not estimated.

Results of random-effects meta-analysis

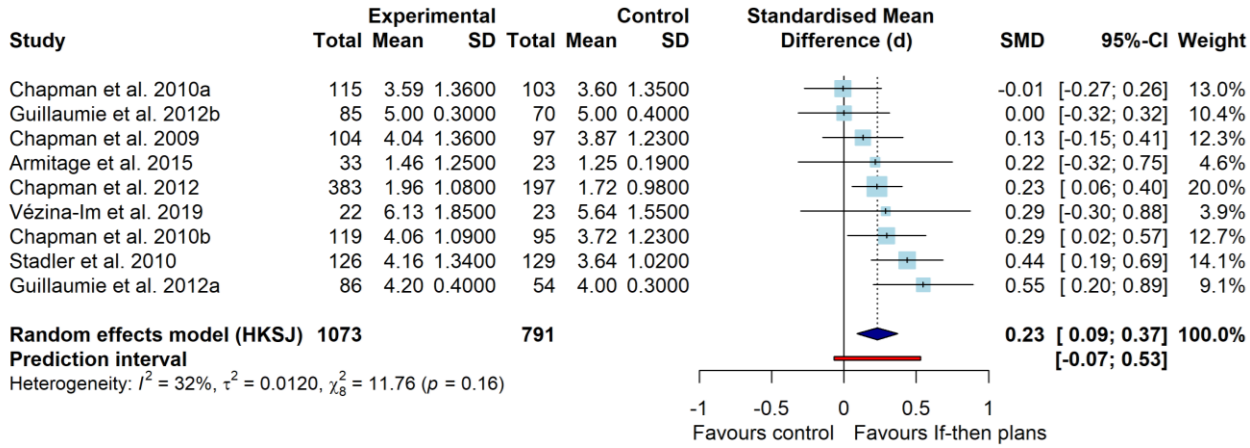

Figure 5: Forest plot illustrating the pooled standardised mean difference(d), using a random-effects model (REML), with HKSJ-adjustment.

The standardised mean difference(*d*) from a total of nine independent comparisons (*k* = 9), from seven study reports (*K* = 7) were pooled in an inverse-variance random-effects model, with restricted maximum likelihood (REML) estimator for between study heterogeneity, and Hartung-Knapp-Sidik-Jonkman (HKSJ) adjustment for confidence intervals around the pooled SMD(*d*) (Figure 5). The pooled effect estimate indicates that if-then planning interventions can be favoured compared to the control (SMD(*d*) = 0.23; 95% CI: 0.09, 0.37). The effect can be interpreted as a small, but significant effect favouring the if-then planning

intervention, compared to the control condition. However, the confidence interval for the pooled SMD(*d*) includes both small and moderate effects. Furthermore, while the point estimate indicates a small effect, the prediction interval indicates the possibility that a single future study can also find both moderately strong but also null effect. A further visual inspection of the forest plot indicate that confidence intervals are overlapping. There are no extreme outliers, thus indicating overall consistency in the results, with Chapman et al. 2010a (64) and Guillaumie et al. 2012b (62) finding no effect, and Stadler et al. 2010 (70) and Guillaumie et al. 2012a (62) finding medium effect sizes. I^2 = 32% and can be interpreted as an indication of low-to-moderate heterogeneity present, but test for heterogeneity using Tau^2 and Chi^2 are statistically unsignificant (p = .16). A drapery plot was produced to visually inspect the SMD(*d*) under varying significance levels (Figure 6). In addition, visual inspection indicate that studies are approximately equally spread at both sides around the pooled SMD(*d*) i.e., there is not an indication of small study effects (publication bias) or substantial heterogeneity (73). Overall, a small but significant effect favouring if-then planning interventions is estimated.

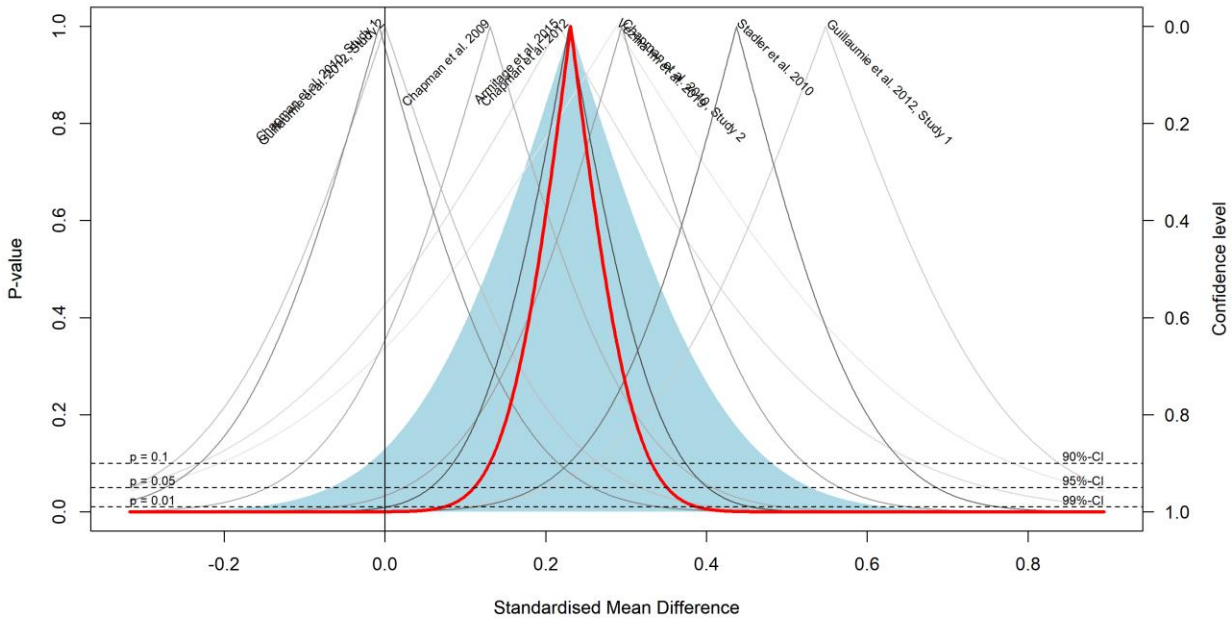

Figure 6: Drapery plot based on p-value functions. Red line: pooled SMD(d) and confidence interval (CI); grey lines: study SMD(d) and CI; blue area: prediction interval.

Robustness of the random-effects model

The robustness of the random-effects model was inspected by performing sensitivity analyses: 1) removing a study by Chapman et al., 2009, due to high risk of bias (66); 2) removing Stadler et al., 2010, due to imputed standard deviations (70); 3) running a meta-analysis with the sum measure of fruit intake, reported in Armitage, C. J., 2015 (63) ; 4) running a meta-analysis with Hedges *(g)* as effect size i.e., SMD(*g*). The forest plots are included in Appendix 8. Summary conclusion: the observed pooled effect had a similar result pattern in all analyses (SMD(*d*) = 0.20 – 0.27; all confidence intervals significant) i.e., there is a small statistically significant effect, favouring if-then planning on increased fruit and vegetable intake, compared to active control conditions.

Subgroup analyses

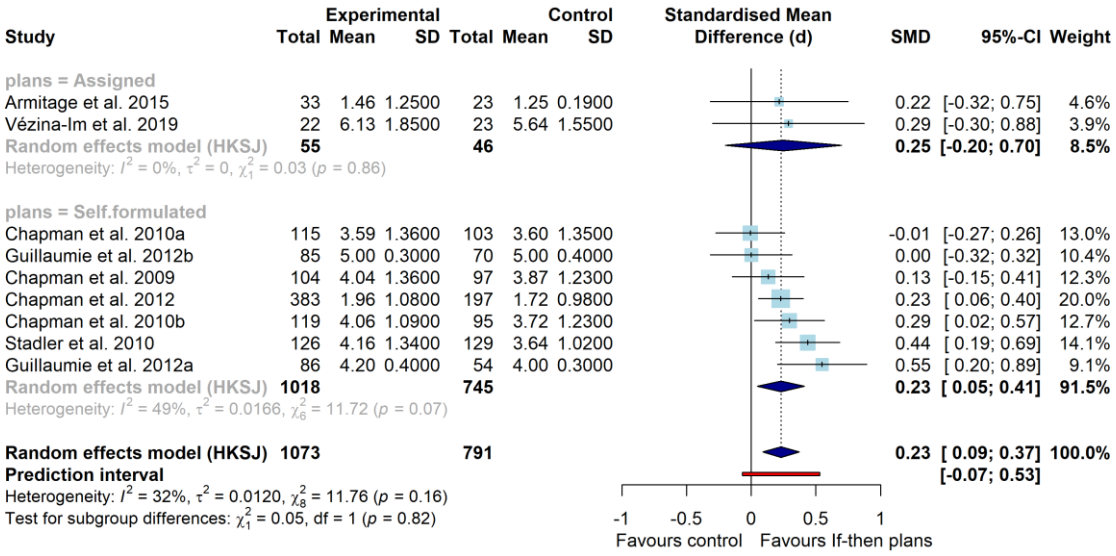

Figure 7: Forest plot with subgroups (planning factor: assigned and self-formulated), using random-effects model (REML), with HKSJ-adjustment.

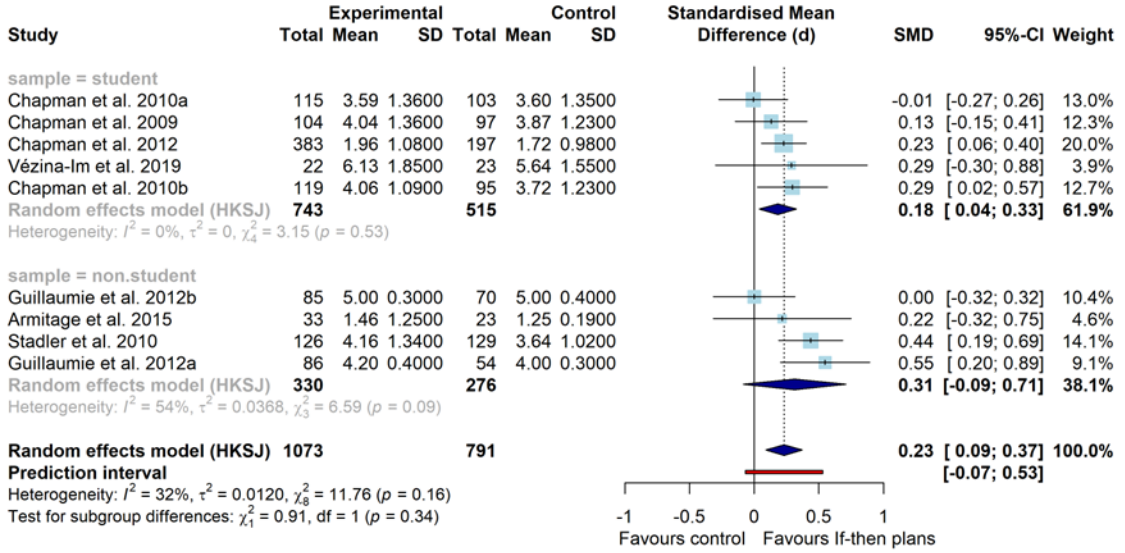

Figure 8: Forest plot with subgroups (study population: student and non-student), using random-effects model (REML), with HKSJ-adjustment.

Two subgroup analyses were performed as planned: 1) subgroup analysis on planning factor: assigned and self-formulated if-then plans (Figure 7); and 2) subgroup analysis on sample population: student- and non-student population (Figure 8). The tests for difference between subgroups: assigned and self-formulated if-then plans, was not significant (p = .82). The test for difference between subgroups: student and non-student population, was also not significant (p = .34). Hence, there were not a statistically significant difference between the pooled standardised mean difference(d) in the 1) assigned and self-formulated planning subgroups; and 2) student and non-student population subgroups. However, both subgroup analyses were underpowered i.e., there were not enough study comparisons included in the analyses to detect a significant difference, even if one existed. Therefore, the no difference results should be interpreted with caution, and future experimental studies could consider testing the effects of these factors on fruit and vegetable intake.

Publication bias assessment

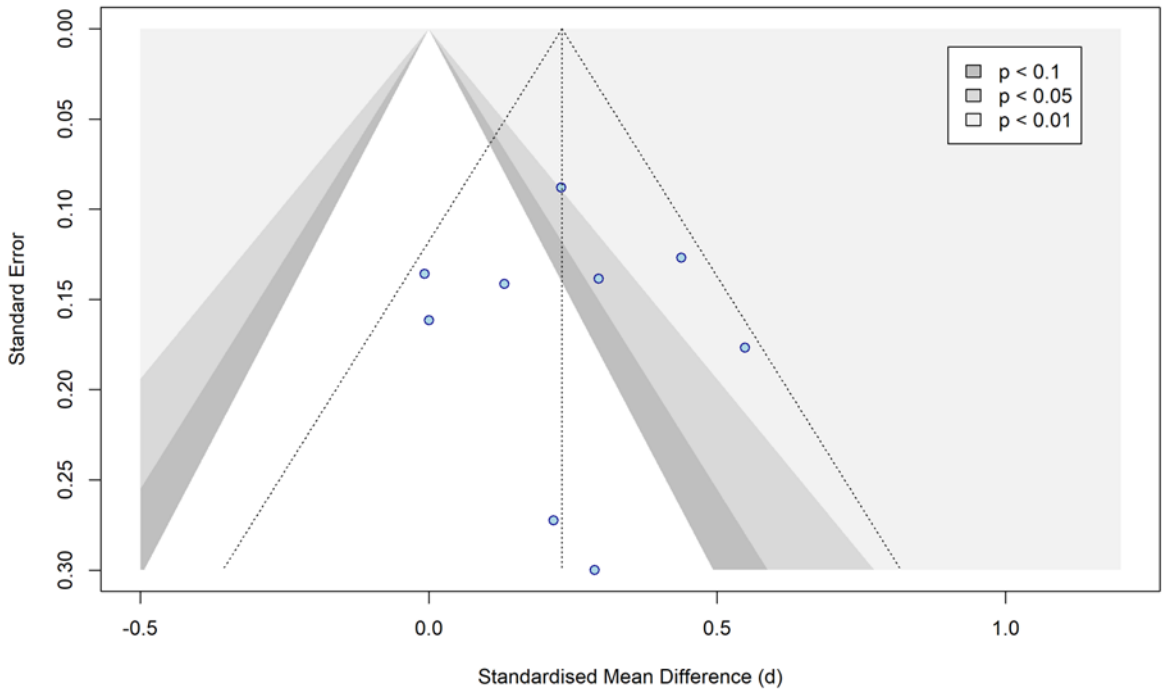

Figure 9: Contour-enriched funnel plot (k=9) illustrating risk of small study effects with shaded significance regions. The blue circles are study SMD(d) with corresponding standard error.

A contour-enriched funnel plot (Figure 9) illustrates the standardised mean difference(*d*) for each study comparison ($k = 9$) in relation to the standard error (SE) of the point estimate.[5] Generally, larger study samples are considered to have smaller standard errors, and the funnel plot can be used to assess whether it seems like studies with negative effects are missing from the review (because studies finding negative effects are less likely to be published). In the plot, four study comparisons are in the significance region of $p < .05$ to $p < .01$, and five study comparisons are in the non-significant region. Visual inspection indicate that the study effects are spread around the pooled standardised mean difference(*d*) and that they are relatively even spread on both sides within the pyramid shape. This observation indicates that

[5] A funnel plot with study labels is attached in Appendix 8; Figure 13.

there is not substantial asymmetry i.e., there is not an indication of publication bias (unpublished studies with null effects). In addition, Egger's regression test was performed, and it was not significant (p = .91) i.e., the intercept (0.153) is not significantly different from zero, thus indicating that asymmetry is not present. However, the test should be interpreted with cation when there are less than ten study comparisons (k = 10) included in the analysis due to lack of power. In conclusion, there is not supportive evidence of publication bias.

3.5 Summary of findings

The confidence in the evidence was assessed using the GRADE approach (59). It was the fruit and vegetable outcome between one week to- and including 6-months that was assessed. The evidence was downgraded by one level from 'high' to 'moderate' on the factor: risk of bias, due to overall weighted risk of bias judged as 'some concerns' (Figure 4). Removing a 'high' risk of bias study in a sensitivity analysis resulted in a similar small significant effect. The evidence was not downgraded on any of the other factors, hence the GRADE approach resulted in grading the effect estimate for fruit and vegetable intake to be of 'moderate' quality (for details refer to Appendix 10). A summary of findings table is reported in Table 4.

Table 4: Summary of findings (SoF) table

If-then plans compared to control intervention for increasing fruit and vegetable intake in adults

Patient or population: Adults (aged ≥ 18 years), and university students
Setting: Self-guided or assisted (face-to-face)
Intervention: If-then plans
Comparison: Control intervention (e.g., prompt to plan, information)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Control intervention	**Risk with If-then plans**				
Fruit and vegetable intake assessed with self-reported methods Follow-up: range 1 week to 6 months	-	SMD **0.23 SD higher** (0.09 higher to 0.39 higher)	-	1864 (9 RCTs)	⨁⨁⨁◯ Moderate[a]	I have moderate confidence that *If-then plans* increase fruit and vegetable intake with a small effect.

***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; **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.

Explanations
a. Weighted risk of bias (RoB 2) judged as 'some concerns'. Sensitivity analysis removing high risk-of-bias study resulted in a similar small effect, therefore GRADE risk of bias factor judged as 'serious' and downgraded by one level.

4 Discussion

4.1 Summary of main results

This systematic review and meta-analysis set out to assess if the self-regulatory planning strategy *if-then plans* facilitated increased fruit and vegetable intake in adults. In addition, to assess if there were a difference in effects between the subgroups: 1) assigned and self-formulated if-then plans, and 2) student and non-student populations. There are two main findings from this review. Firstly, if-then plans had a small, statistically significant positive effect on fruit and vegetable intake. Second, the difference in effects between student and non-student populations, and between self-formulated and assigned plans, were not statistically significant. The evidence was graded to be of moderate quality using the GRADE-approach.

If-then plans had a small, statistically significant effect on increasing fruit and vegetable intake, compared to active control conditions receiving a similar intervention, without if-then plans (SMD(*d*) = 0.23). The strength of this review compared to other reviews assessing the effect on eating behaviours (34-36), is that only *if-then* planning interventions were included. Over the last three decades, psychological research has found that mentally linking a "relevant situational cue" as the "if"-part, to "a goal-directed response" as the "then"-part facilitates goal-achievement (e.g., increased fruit and vegetable intake) (17, 18, 24). It is the mental link between the "cue" and "response" that is essential to if-then planning. Whereas other reviews have included if-then plans and time-based plans (*implementation intentions*) as the intervention of interest, this review made a distinction between these two forms of planning. This distinction was supported by research on habits, that have found that cues that are "perceptible", concrete and require little conscious thought work better than more abstract concepts (e.g., "time") (21). It was also the recommended planning structure by the Synergy Expert Group in 2016 (22).

The small effect found, is similar to a review published by Turton et al., 2016, that also reported a small effect (SMD(*g*) = 0.23) of *implementation intentions* on increasing healthy eating behaviours at follow-up (35). Another review by Adriaanse et al., 2011, estimated that *implementation intentions* had a medium effect on increasing healthy eating behaviours (SMD(d) = 0.51) (34). The latter finding was supported by a third review which found a

similar medium effect on decreasing fat intake (36). One possible explanation for why two previous reviews found a medium effect when investigating *implementation intentions*, as compared to the small effect found in this review, assessing only *if-then* plans is: the choice of control conditions. Thus, a strength in the present review is that it compared the intervention against active control conditions, using the most similar condition without the if-then planning strategy. For example, in the study comparison by Guillaumie et al., 2012b, the self-efficacy intervention was used as a control condition (61). This resulted in a null effect of if-then plans for this study comparison. This approach to study comparisons was made to increase confidence that the estimated pooled effect was due to the if-then planning, not other intervention components.

It was also observed that two of the included studies ($K = 2$) helped participants in formulation of the if-then plans (61, 70). Experimental research on plan formulation, have found that identifying a "relevant cue" could be challenging (25). This is much of the background for the debate of whether if-then planning in an assigned (pre-specified) structure hass a similar, or better effect compared to self-formulated (personal) if-then plans (22). Therefore, it was of interest to investigate this in a subgroup analysis. The test for differences between assigned and self-formulated if-then plans was statistically not significant ($p = .82$). Thus, assigned and self-formulated if-then plans have the same positive small effect. However, the analysis did not have enough power, and should therefore be interpreted accordingly. Experimental studies could include these factors in their design, so that future reviews have more power when testing for differences.

The other planned subgroup analysis tested the difference in effects between sample population: student and non-students. A previous review assessing *implementation intentions* on increased physical activity, observed that the effect was higher in student- than non-student populations (31). It was expected that many studies would be conducted on student populations. Hence, to increase the relevance and generalisability to other populations, it was of interest to know if the effects were different between these subgroups. The test for differences between student- and non-student populations was statistically not significant ($p = .34$). As with the other subgroup analysis on planning factor, this subgroup analysis on sample population did also not have enough power. Consequently, results should be interpreted accordingly. In addition, it could be argued that this analysis was at risk for

ecological bias, since there were "non-students" (i.e., employees in the student sample), and vice versa, I cannot know if there were students in the non-student sample, because occupation was not reported. However, only one study reported on including university employees[6], and this study was given a low weight (3.9 %) in the analysis. Therefore, this problem should not be substantial. Future research could consider clearly reporting details on their included study population to reduce the risk of bias.

4.2 Quality of the evidence

The confidence in the evidence was assessed using the GRADE approach. Because the study design inclusion criteria for this review were randomised trials, the evidence started at 'high' quality because there were no important limitations (59). However, the quality of the evidence was rated down by one factor for risk-of-bias (RoB 2) because the weighted plot (Figure 4) indicated that there were 'some concerns' of bias. This was in part due to incomplete reporting of studies. For example, insufficient information about concealment of allocation, insufficient information about reasons for dropouts and how dropouts were handled in the analysis, and lack of analysis intentions (Figure 3). Furthermore, there were no important concerns of indirectness, imprecision, or inconsistency. There was also no indication of publication bias. Hence, the certainty of the evidence was graded to be of 'moderate' quality. According to GRADE, this can be interpreted as: "the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different" (59).

One aspect of the included studies that should be elaborated, is the use of self-reported dietary assessment methods, where risk of bias was judged as 'low'. It was observed that all included studies used self-reported brief dietary assessment methods. Whereby, nine studies ($K = 9$) used retrospective methods to measure fruit and/or vegetable intake. Retrospective dietary assessment methods are dependent on memory, and are thus subject to recall bias. This could affect the reported intake of fruit and/or vegetables. Validation research have found that there is a tendency to overestimate the consumption of fruit and vegetables (i.e., healthy foods) (74). However, the strength of this review is that it included only randomised

[6] Included in the meta-analysis.

trials, and so the over- or underestimation would likely be equally present in both groups. Hence, this does not represent a serious problem when the review objective was to assess the difference in effects between to (equal) groups. Current research on dietary assessment methods in nutrition methodology describe a shift in recent years favouring repeated 24-hour recalls, multiple food records and use of biomarkers, including combined approaches (75). However, the dietary assessment methods used in the included studies was not considered 'inappropriate' (RoB 2) because: 1) brief dietary assessment methods are useful when the outcome is restricted to few food groups, 2) when resources (e.g., response burden and low cost) are important considerations (75). However, it is important that future studies use appropriate methods to measure fruit and vegetable intake (e.g., combined approaches and objective measures). Future reviews should address the appropriateness of brief dietary assessment methods in behaviour change research, considering how important it is to use quality methods.

4.3 Strengths and limitations of this review

Due to feasibility reasons, I made a change to the outcome inclusion criteria by including only studies that reported on fruit and/or vegetable intake (Appendix 2). This change was done at the screening stage of the review, before data extraction and risk-of-bias assessments. Although it is not recommended, Cochrane acknowledges that this could happen if the review turns out to be too broad (76). Furthermore, because the protocol did not specify what I would do in circumstances where the study reported on fruit and/or vegetable intake in more than one way, I have reported on all measures (Table 2 and Table 3). The outcomes could not easily be combined, thus, only one measure was included in the meta-analysis. However, sensitivity analyses were performed to observe how the outcome measure used in the analysis affected the pooled standardised mean difference(*d*). In addition, to avoid unit-of-analysis errors in the meta-analysis i.e., SMD(*d*)s are assumed to be independent; one condition (e.g., control condition) could not enter the analysis twice. Therefore, in the case of Chapman et al. 2010, two if-then planning groups were not included in the main review and meta-analysis, because: 1) there were no eligible control condition, and 2) the planning instructions were given at 3-months into the study, and this was different from all other included interventions that gave the planning instructions at baseline (details in Appendix 4) (64). Chapman et al., 2012, reported on fruit and vegetable intake separately, whereby both have been

summarised, however only fruit intake was included in the meta-analysis because this was similar to one other study (65). Stadler et al. 2010, did not report on standard deviations (SDs), therefore I made the decision to impute SDs based on the pooled mean of SDs reported in similar included studies (70). A sensitivity analysis was performed to observe how the imputation affected the pooled effect. In three other studies (66, 67, 69) I was unable to extract the outcome information needed to calculate SMD(*d*), with the comparisons I had planned for the analysis. Therefore, these studies were not included in the meta-analysis. However, they have been summarised in Table 2 and Table 3. However, the studies were rated as at high risk of bias because they did not analyse according to intention-to-treat (ITT) principles i.e., made many exclusions of eligible participants. In addition, although systematic review guidelines recommend at least two reviewers, all decisions are only based on the judgements of one reviewer (SKM).

4.4 Implications of review findings

Implications for clinical settings and health care practitioners

In this review it was estimated that if-then planning had a *small positive* effect on increasing fruit and vegetable intake in adults. The certainty of the evidence was of moderate quality, implying that further research is warranted to increase the quality of the evidence. However, considering that a healthy diet, including fruit and vegetable intake is important in prevention and management of non-communicable diseases (NCDs), if-then plans could be a valuable strategy. If-then plans can be easily adapted to applied settings because the strategy can be delivered as print instructions, either as self-formulated or assigned planning instructions. Hence, it is a flexible tool well suited for clinical practice, where time-management and cost are important considerations.

Implications for future research

The findings of this review have important implications for future research. Firstly, to increase the quality in the evidence, future research should aim for adequate reporting of studies. For example, the CONSORT (Consolidated Standards of Reporting Trials) Statement for Randomised Trials of Nonpharmacologic Treatments, could be used as a reference guideline (77, 78). Second, choice of dietary assessment methods should be carefully considered, and future research should explore what methods are best suited for use in health

behaviour change interventions. In addition, conducting experimental studies to test the difference between assigned and self-formulated if-then plans, have implications for applicability. Lastly, this review did not include any clinical populations, thereby limiting the generalisability of the findings to clinical settings. Future research could therefore consider testing the effect of if-then plans to change eating behaviour in a clinical setting, for example in nutrition counselling.

5 Author' Conclusion

The primary objective of this systematic review and meta-analysis was to investigate the effectiveness of if-then planning interventions to facilitate increase fruit and vegetable intake in adults. The main finding was that the effect was estimated to be SMD(d) = 0.23 (95% CI: 0.09, 0.37). This is a statistically significant, small positive effect of using if-then plans as a behaviour change strategy to increase fruit and vegetable intake in adults. The second objective was to investigate if there was a difference in effects between sample population and planning structure. Thus, two subgroup analyses were performed. There was not a statistically significant difference between subgroups: 1) student and non-student populations (p = .34), and 2) assigned and self-formulated if-then plans (p = .82). However, subgroup analyses did not have sufficient power, and should be interpreted accordingly. Confidence in the evidence was of moderate quality. Future research should aim to report their studies in reproducible and transparent ways to increase the certainty in the evidence.

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Appendix 1: PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Page 1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 5-8
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 9
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Page 10
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Page 12
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix 5
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Page 12
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Page 12
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Page 11
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Page 11;14
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Page 13

Section and Topic	Item #	Checklist item	Location where item is reported
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Page 14
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Appendix 8; Table 5
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Page 14
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Table 2; Table 3; Table 4
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Page 15
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Page 15
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Page 15
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Page 13
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Page 16
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Page 17
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Page 18; Appendix 9
Study characteristics	17	Cite each included study and present its characteristics.	Page 20-21; Table 2
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Page 26; Fig. 3; Appendix 7
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Page 29; Table 3
	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Page 24-28

Section and Topic	Item #	Checklist item	Location where item is reported
Results of syntheses	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Page 30
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Page 32-33; Appendix 8
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Page 32; Appendix 9
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Page 34
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Page 36; Appendix 10
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Page 37-38
	23b	Discuss any limitations of the evidence included in the review.	Page 39-40
	23c	Discuss any limitations of the review processes used.	Page 40-41
	23d	Discuss implications of the results for practice, policy, and future research.	Page 41
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	NR; Appendix 2
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Appendix 3
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Appendix 2
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	NR
Competing interests	26	Declare any competing interests of review authors.	NR
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	NR

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Appendix 2: Amendments to the protocol

Date of change and rationale for decision

No date: The protocol was written with publication in mind; therefore, it is written in plural form. The master thesis is an individual project and have been written in singular form.

December 2022: did not register the protocol in PROSPERO due to unclarity between registry requirement (minimum two reviewers; do not support master's thesis projects) and UiT master's thesis requirement (individual project) at my study program (Clinical nutrition).

08.01.23 (before data extraction and risk of bias-assessments): Due to feasibility reasons (time and resources), I decided to narrow down the scope of the review, because it became too broad for one person to handle within the timeframe of the master's thesis. In the protocol I wrote that I would include 'all' eating behaviour outcomes (e.g., fat-, sugar-, snack-, salt intake). However, I focused the outcome inclusion criteria to fruit and/or vegetable intake. All other eligibility criteria were unchanged.

08.02.23: Updated COVIDENCE *data extraction template* according to the narrower outcome inclusion criteria (fruit and vegetable intake).

March 2023: The protocol mentioned: "In studies with outcomes measured at several time-points, we will use last available follow-up post intervention." However, when preparing for synthesis and analysis, I amended this to include the fruit and/or vegetable intake reported from 1 week to 6 months, using the outcome closest to and including 6-months, because this was the most common timeframe used in the studies (two studies reported on 12- and 24-months, these results were however biased by a large proportion of drop-outs).

In addition, the protocol mentioned: "The possibility of skewed continuous data will be assessed", this was not performed. Hartung-Knapp-Sidik-Jonkman adjustment were added to the statistical analysis. There was not time to contact study authors for missing information.

Appendix 3: Protocol

Assessing the effectiveness of If-then plans to facilitate eating behaviour change in adults: Protocol for a systematic review and meta-analysis

Last updated 25.11.2022

Authors: Sanne Karlsen Melum (SKM)[a*] and Torsten Martiny-Huenger (TMH)[a**]
Contributions: SKM drafted the protocol, including search strategy, selection criteria, risk of bias assessment strategy, data extraction items and meta-analysis strategy. TMH provided expertise on if-then plans, resolved uncertainty, and supervised all stages of the review protocol development. Both authors read, provided feedback, and approved the final protocol manuscript.
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Abstract

Background: Non-communicable diseases (NCDs; cardiovascular disease, cancer) are prevalent, causing high rates of morbidity and mortality. Healthy eating behaviours and a healthy diet are essential in both the prevention and management of NCDs and their associated risk factors. If-then plans (i.e., *implementation intentions*) is a promising self-regulatory planning strategy that could facilitate eating behaviour change in adults. By creating a mental association between a situational cue and a goal-directed response, *If-then plans* could help adults achieve and maintain their goal of eating a healthier diet, which is important for good health.

Objectives: When compared to a control condition, what is the effectiveness of *If-then planning interventions* to facilitate eating behaviour change in adult populations?
Second, what study methodological- and intervention characteristics (e.g., students versus non-students; self-formulated versus assigned If-then plans) could explain the heterogeneity expected in the results?

Methods: We will conduct and report a systematic review in accordance with PRISMA 2020 guidelines. MEDLINE, EMBASE and PsycINFO will be searched from database inception until search conduct (planned for Nov 2022). Studies eligible for inclusion are RCTs, testing the effect of *If-then plans* on eating behaviour (i.e., dietary intake) in adults (age ≥ 18) against

a control condition. COVIDENCE will be used to facilitate study screening and data extraction. Risk of bias will be assessed using RoB 2. Meta-analyses will be performed in R using the inverse-variance random effects model (REML-estimator) provided there is sufficient similarity between studies grouped for comparison. If it is not appropriate to perform meta-analyses, we will provide a structured evidence synthesis following SWiM guidelines. An evaluation of the certainty of the evidence will be conducted using GRADE. This systematic review is planned for publishing during fall 2023.

Protocol registration: This protocol will be registered in PROSPERO.

Background

Description of the condition

Non-communicable diseases (NCDs e.g., Cardiovascular disease, Cancer, Type 2 Diabetes mellitus) and their associated risk factors (e.g., overweight/obesity) are prevalent, causing high rates of morbidity and mortality globally (1, 2). An unhealthy diet is a modifiable risk factor, and thus promoting healthy eating behaviours are an important self-management strategy in NCD prevention and management (3, 4). However, there is no simple action to overcome unhealthy eating behaviours and its health-related problems. Because of its complexity, health care practitioners, including registered dietitians, need evidence-based, time-efficient and effective strategies to guide and support patients to change their unhealthy eating behaviours and maintain this change (5).

Description of the intervention

If-then plans (i.e., *implementation intentions*) is a promising self-regulatory planning strategy developed from *Implementation intentions theory* (6-8). In If-then planning, mental associations between a situational cue (or critical situation) are specified in advance and linked with an appropriate goal-directed response (7, 9). Situational cues can be an event like a situation, and a goal-directed response can be a specific behaviour, however it can also be a feeling and regulation of the feeling (10). Plans are created by mentally linking "*If"* (situational cue) with *"then"* (goal-directed response); e.g., "*If* I am on the search for a snack, *then* I will eat an apple first!"

In the structure described above, the link between "If" and "then" are supported by research to be an automatic, "bottom-up" regulation (11). Thereby, forming If-then plans can support a person's goal-striving also when the behaviours are thought to be habitual (automatic). In fact, it is likely that many of everyday eating behaviours (both healthy and unhealthy) are habitual (12). Interestingly, unhealthy eating behaviours can occur even if a person has strong motivation and goal intentions to eat healthfully (13). This phenomenon is commonly referred to as the intention behaviour "gap" (14). While motivational strategies and goal setting target the "why" of doing a behaviour, If-then plans target the "how" to do it. If-then planning can therefore be seen as a natural next step in the behaviour change process when motivation and goals are already established (11).

In the literature *implementation intention* interventions are tested in either the "when", "where" and "how"-format (also referred to as action planning), or "If-then" format.

However, experts on *implementation intentions* have advocated the use of the "If-then" format (15). The latter being the focus of the planned review. But because both formats are used interchangeably in the literature both will be included in the review to create a comprehensive picture of the available evidence. If-then plans can be either self-formulated (personal) or assigned (generic) and delivered as instructions or prompts by a health care practitioner, or as written or online print communication (9). Therefore, being well suited for use in health care consultations to facilitate eating behaviour change.
Although the aim of nutrition counselling and education interventions is to facilitate eating behaviour change, current literature and practices have emphasised psychological theories and strategies that are based in an understanding of behaviour as an outcome of deliberate choices (e.g., goal setting- and motivational strategies) (16, 17). However, motivation and goals are often not enough to change behaviour (14). If-then plans could potentially "bridge" the gap between intention and behaviour, thereby facilitating goal-achievement of healthier eating behaviours and dietary habits.

Why it is important to do this review

Making healthy changes to one's diet is important and necessary if NCDs are to be prevented and managed, and is a key factor recommended by current national guidelines (4). If-then plans is a behaviour change strategy that could facilitate healthy eating behaviours, diminish unhealthy eating, and is well suited for use in clinical practice due to its simplicity and low health literacy requirement. There are however (to our knowledge) two systematic reviews previously conducted on this topic (18, 19). One was published in 2010, and the other assess only one dietary outcome (fat intake), whereby none include risk of bias assessments. Hence, a review including newer published studies (from 2010 to present time), assessing several eating behaviours, along with conduct in accordance with current systematic review guidelines are warranted (20).

Objectives

The primary objective of this systematic review is to answer the following question: When compared to a control condition, what is the effectiveness of *If-then planning interventions* to facilitate eating behaviour change in adult populations?
The secondary objective is to answer the question: What study methodological- and intervention characteristics could explain the heterogeneity expected in the results?
Subgroups considered for analysis at the protocol stage are:
Study sample: student versus non-student population
Planning construct: Self-formulated (personal) versus assigned (generic) If-then plans

Method

This protocol follows *The Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols* (PRISMA-P) 2015 (21). The planned systematic review will follow *The Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) 2020 (22), and will be conducted with guidance from the *Cochrane Handbook for Systematic Reviews of Interventions version 6.3 (23)*. The protocol will be registered in the *International*

Prospective Register of Systematic Reviews (PROSPERO), date and registration number will be added when available. Amendments to the protocol will be documented with date, description of change and rationale. Changes will be added as separate attachments.

Eligibility criteria

P	**I**	**C**	**O**	**S**
Population	Intervention	Comparison	Outcome	Study design
Adults; age ≥ 18 years	*If-then* plans i.e., *Implementation intentions*	Active or passive comparator condition e.g., goal intentions, other intervention, no intervention	Changes in eating behaviour measured by fruit-, vegetable, fat-, salt-, sugar- and snacks intake	RCTs

Figure 1: Review inclusion criteria illustrated by PICOS. For a detailed description of each element please refer to the in-texts sections described below.

Population/participants: We will include studies examining the adult human population (18 years or older) including the general-, healthy-, student-, overweight-, obese or patient population. We will exclude studies restricted to populations with psychological diagnoses or physiological diseases or conditions that make them unable to make plans. If studies including children and adults are identified, studies will be included if outcome measures have been reported separately for adults.

Intervention: We will categorize planning interventions as event-based or time-based (e.g., 5pm, Midday, Thursday, Next Week). Interventions eligible for inclusion in the review must assess the effect of If-then planning or *implementation intentions* in the event-based format. We define event-based (If-then/*implementation intentions*) planning interventions as:
Plans should be created based on any perceivable cue (situation, activity or feeling i.e., event) as the "If"-part. Plans should describe a response, behaviour or act *linked or associated* with the cue as the "then"-part. Plans could be self-formulated (personal) or assigned (created by others). If a combination of event-based and time-based interventions are used in a study, minimum one example must be event-based to be included in the review. Interventions that do not fulfil these criteria (e.g., time-based format) will be excluded from the review. A list of excluded reports will be attached as a separate attachment. In studies where several groups of *If-then plans* have been tested, either isolated or as co-intervention with other psychological strategies, the group examining the isolated effect of *If-then plans* will be selected for meta-analysis for homogeneity reasons. If other relevant studies exist in a report, a brief description with references will be added as a separate attachment.

Comparison: We anticipate several relevant comparator conditions e.g., forming goal intentions, receiving nutrition information or education, receiving other behavioural intervention (active comparators), or being a passive control condition e.g., "waitlist"; no

intervention. If several comparators exist in a report, we will select active comparator conditions (if possible) and chose the comparator most similar to the intervention.

Outcome: The primary outcome of interest are changes in eating behaviour e.g., fruit-, vegetable-, fat-, sugar-, snack- and salt intake. These could be measured by changes in dietary intake of different foods, nutrients, biomarkers and/or surrogate outcome assessments (e.g., blood cholesterol, blood glucose). Several dietary assessment methods could be used e.g., 24-hour recall, food diaries, food frequency questionnaires (FFQ), single food item diaries, healthy eating index scores and/or objective methods e.g., biomarkers. Outcome variables could be measured by validated and reliable dietary assessment methods (e.g., validated, repeated 24-h recall) or less validated methods (e.g., unvalidated food diaries). Outcome variables could be described in different units e.g., grams, energy percentages, scores of intakes and/or blood/urine/tissue levels. Therefore, we will extract all outcome measures (e.g., continuous, categorical) to see what statistical analyses is possible. In studies with outcomes measured at several time-points, we will use last available follow-up post-intervention. We plan to extract both post-intervention (one outcome measurement) and/or change from baseline to post-intervention (two outcome measurements) from study reports. Studies assessing alcohol consumption will be excluded, as this is a complex issue beyond the scope and resources of this review. We anticipate most outcome data to be continuous variables reported as means with standard deviation or standard error, or 95% confidence intervals.

Study design: Studies eligible for inclusion are peer-reviewed randomized controlled trials (i.e., random allocation of participants to experimental or control condition) with at least one exposure to the intervention, and minimum one post-intervention outcome measurement of interest.

Delivery of intervention/setting: Provided the information is readily accessible, we will exclude studies that have been conducted in an experimental context with artificial tasks (e.g., eating in the laboratory). Included studies need to be conducted in a "everyday" life setting. If in doubt, study authors will be contacted for clarity. If we cannot obtain the information needed, we will resolve the issue by discussion until consensus is achieved. Excluded studies will be added as a separate attachment.

Language: We will include articles written in English and Scandinavian languages. Relevant articles identified in other languages will be added as a separate attachment.

Information sources

The literature search will be conducted by SKM in the following electronic databases: MEDLINE, EMBASE and PsycINFO. The searches will be conducted from database inception until the date of the final search (planned for Nov 2022). Additional non-database searches will be conducted whereby reference lists of two previously published systematic reviews on the topic will be assessed (18, 19) in addition to reference lists of included studies.

Search strategy

The search strategy was developed in Ovid MEDLINE using key terminology, reviewing relevant literature and previous systematic reviews identified from preliminary searches (refer to Appendix 1 for full search strategy). The literature search consists of combining the PICO-elements 'intervention' (i.e., implementation intentions OR if then plans) AND 'outcome' (i.e., eating behaviour OR diet OR food OR nutrition). Indexing terms will be used in combination with free text terms, and the search will be manually adapted to each database as indexing terms might vary across databases. The search will be limited to 'abstract', 'title' and 'keywords'. No other limitations will be applied. Full description of the searches along with database name, interface and dates will be attached as supplementary material. Search constraints include limited time and database searching skills. Therefore, a Health Sciences Librarian experienced in performing systematic literature searches have been consulted to increase the quality of the search strategy.

Study selection

References retrieved from the literature search will be uploaded to reference manager software (EndNote 20), where duplicates will be removed. Thereafter the remaining studies will be imported to the web-based software platform COVIDENCE (24). COVIDENCE facilitates screening, data extraction, export to the software program RevMan for statistical analysis or Excel, generation of risk assessment- and evidence tables, and collaboration between reviewers. After duplicates are removed the remaining articles will be screened by title, abstract and keywords for eligibility by SKM. Eligible studies will be assessed in full text, and those that meet the inclusion criteria will be included in the review. An accompanying *Decision rule/definition guideline* have been created (supplementary material) to support inclusion of event-based (If-then) planning interventions. The validated Cochrane RCT Classifier tool (25), which has been incorporated into COVIDENCE will be used. Excluded non-randomized studies will be double checked by SKM. When uncertainty arise in the study selection process, full text assessment will be discussed with TMH until consensus is achieved. TMH will overlook the review process in COVIDENCE. The study selection will be visually presented in a PRISMA 2020 flow diagram. Reasons for exclusion will be noted for each report and provided as supplementary material. We will attempt to link identical study reports by paying attention to details that might imply that two or more reports are published on the same study (e.g., trial registration number, intervention name, authors).

Data extraction and data items

Data items, including outcome variables and intervention characteristics will be extracted from each included study manually by SKM using COVIDENCE. A piloted *data extraction items document* (supplementary material), with an accompanying *Data extraction explanations document* (supplementary material) will be used to create the form in COVIDENCE. The *data extraction form* will be created a-priori using items from the TIDieR checklist (26), Cochrane Handbook (23), PRISMA 2020 (20), and assessing published systematic reviews and articles. The final *data extraction form* will be piloted by SKM on

one eligible study. We will also obtain information about adverse effects and/or harm if reported, although we anticipate this has not been studied. Extracted outcomes of interest will be double checked by SKM. Uncertainty will be discussed until consensus is achieved.

Outcomes and prioritisation

For a description of primary outcomes of interest please refer to section 3.1. We will extract outcomes of interest, however if a study reports on several outcomes we will extract all dietary outcomes of interest provided they have been reported separately. We will consider if study outcomes with high risk of bias should be excluded from meta-analysis. In addition, studies facilitating low quality/low validity dietary assessment methods (likely influencing outcome measures) will also be considered for exclusion from meta-analysis. However, all eligible studies will be described in a `table of characteristics`, and reasons for exclusion from meta-analysis will be reported.

Risk of bias assessment

Risk of bias in individual studies will be assessed by SKM for study outcomes using the Revised Cochrane risk-of-bias tool for randomized trials (RoB 2) (27). All five domains i.e., risk of bias arising from the randomization process; risk of bias due to deviations from intended interventions; missing outcome data; risk of bias in measurement of the outcome; risk of bias in selection of the reported result, in addition to an overall risk of bias judgement, reported as 'high', 'low' or 'some concerns'. RoB 2 will be presented in figures using the statistical software program **R** (28). Uncertainty will be discussed between SKM and TMH until consensus is achieved.

Data synthesis and statistical analyses

Data items from each included study will be synthetized, summarized, and presented in `summary of evidence` tables. Statistical analyses will be conducted in the software program **R** (packages used will be denoted and cited) with guidance from "Doing Meta-Analysis with R: A Hands-On Guide" (29). The standardized mean difference (SMD) with 95% confidence intervals (CI) will be calculated for effect sizes (Cohen's *d*). Whereby, $d = 0.20$, can be interpreted as a `small effect`, $d = 0.50$, can be interpreted as a `medium effect`, and $d = 0.80$, can be interpreted as a `large effect` (30). The possibility of skewed continuous data will be assessed. If sufficient similarity between studies is present, we will conduct meta-analyses. We plan for outcome estimates to be pooled using the generic inverse-variance method with a random-effects model (REM) with restricted maximum likelihood (REML) estimator for heterogeneity variance (31).The choice of random-effects model is based on the following assumption: because studies have been conducted by separate research teams, and in different populations and geographical locations; it is unlikely that all included studies are functionally identical and share the exact same effect size (i.e., we expect the effect size to be similar but not identical across studies).

We will consider estimating an overall intervention effect across all included studies. However, if there is not sufficient similarity between studies, planned comparisons for meta-analyses at the protocol stage are to group comparisons by the different outcome behaviours

e.g., fruit intake, vegetable intake, fat intake, sugar/snacks intake, salt intake, as reported previously in one meta-analysis on fat intake (19). But we will also consider to group comparisons by outcomes based on it being 'healthy eating behaviours that promote good health' (e.g., increased fruit and vegetable intake) or 'unhealthy eating behaviours that are negative to good health' (e.g., decreased fat-, sugar-, and salt intake), as suggested and reported elsewhere (18, 32). However, to decide on what comparisons are best suited, an exploration of similarity across PICO elements for each included study will be performed as suggested in the Cochrane Handbook.

Results from the meta-analysis will be presented in 'forest plots'. Prediction intervals will be calculated and presented to illustrate the between-study variation. To evaluate the appropriateness of the random-effects model, exploration of asymmetry will be conducted and presented as 'funnel plots' (i.e., small-study effects due to publication bias). If there is indication of asymmetry, possible explanations will be explored. The presence of heterogeneity (variability in true effect sizes) will be visually inspected (forest plots) and tested statistically using the Chi^2 statistics with corresponding p-values. Tau^2- and Tau-statistics will be calculated to give an estimate of the variation between studies, and the standard deviation in the (true) effect sizes, respectively. The I^2-statistics will be used as a guide on the inconsistency across studies (heterogeneity present) and can be interpreted as below 30-40% being *'low'*; 30-60% being `moderate`; 50-90% being *'substantial'* and 75-100% being *'considerable'* (33).

As mentioned in Section 3.6, we will consider excluding study outcomes with high risk of bias (RoB 2) and will perform sensitivity analyses to address this. Subgroup analyses and/or meta-regression will be conducted if there is indication of unexplained variance (rough guide $I^2 > 50$ %). Planned subgroups at the protocol stage are 1) study sample (students versus non-students) and 2) planning construct i.e., personal versus assigned If-then plans. The rationale for selecting these two subgroups is because previous literature has suggested that the intervention effect differ between students and non-students (e.g., general population), and if plans are self-formulated e.g., participant make If-then plans themselves based on a relevant personal dietary goal, or If-then plans are made by others (assigned). We therefore hypothesize that this could explain some of the heterogeneity expected.
If it is not appropriate to conduct meta-analyses, we will do a narrative synthesis and effect estimates will be presented in a structured tabular form in line with the Synthesis without meta-analysis (SWiM) in systematic reviews guideline (34), and SMD will be calculated for each study outcome for easier comparison.

Missing information

Study authors will be contacted once to obtain missing information. If we do not obtain correct information, especially concerns about wrongly reported standard deviations (SD) or standard errors (SE), we plan to address this by comparing the information provided in the study report (tables and text) and chose the value that align with other studies. If we are not

able to obtain missing information from the authors, we will either impute data based on the mean value from other studies or consider excluding the study from meta-analyses.

3.10 Confidence in evidence

We will assess the certainty of the evidence for all outcomes using the validated Grading of Recommendations Assessment, Development and Evaluation approach (GRADE) (35). Summaries of findings will be presented in evidence tables developed using GRADEpro Software (36).

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Draft of search strategy in MEDLINE

If-then planning interventions for eating behaviour change in adults

Sets 1-2 & 21 are the text words (words found in the title, abstract or keywords of a record) for the intervention. They are combined using OR.	1. implementation intention*.ab,kw,ti. 2. if then plan*.ab,kw,ti. 21. #1 or #2	Intervention (I)
Sets 3-20 & 22 are the MeSH & text words (words found in the title, abstract or keywords of a record). They are combined using OR.	3. exp "diet, food, and nutrition"/ 4. diet.ab,kw,ti. 5. food.ab,kw,ti. 6. nutrition.ab,kw,ti. 7. exp fruit/ 8. exp vegetables/ 9. snack*.ab,kw,ti. 10. sugar.ab,kw,ti. 11. fruit*.ab,kw,ti. 12. vegetable*.ab,kw,ti. 13. salt*.ab,kw,ti. 14. exp Sodium Compounds/ 15. exp dietary fats/ 16. fat*.ab,kw,ti. 17. exp Snacks/ 18. exp feeding behavior/ 19. eat* behavior*.ab,kw,ti. 20. eat* behaviour*.ab,kw,ti. 22. #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20	Outcome (O)
Set 23 is the combination of intervention and outcome. Population and study design will be screened manually for eligibility.	23. #21 and #22	Combination of I & O

Appendix 4: Characteristics of included studies

Ref.		Chapman et al., 2010 (64)			
METHODS					
Overall RoB 2		Some concerns			
Study design		Six-armed parallel randomised trial			
Study setting, country		In-class and internet-based, UK University			
PARTICIPANTS/POPULATION					
Participant description		Undergraduate students			
N = xx (randomly assigned)	**Mean Age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m²)**
650	19.66 years (SD = 2.05)	71	87% Caucasian	Not reported (students)	Not reported
INTERVENTION(S) & COMPARISON(S)					
Content given to all groups		All groups received equal questionnaires at each timepoint, except for the manipulations described for each group below. The questionnaires contained information about portion size, measures of Theory of Planned Behaviour (TPB), fruit and vegetable intake (FVI) and demand characteristics.			
Intervention(s) name & description		***If-then plans (a):*** at baseline participants received the questionnaire with a brief motivational encouragement to increase FVI the next 6 months, followed by If-then planning instructions in the "If..., then…" format. Intervention was self-guided and paper-and-pencil-based (baseline). At 3- and 6-month follow-up questionnaires were internet-based and did not contain If-then planning instructions.		***If-then plans + reminder (b):*** at baseline and follow-up participants were given the same If-then planning intervention as group 1, except that participants in group 2 were given a reminder If-then planning intervention in their 3-month questionnaire.	
		If-then plans (3-months) (c): at baseline participants received the internet-based questionnaire but did not receive either the brief motivational encouragement or instructions on If-then planning. At 3-months follow-up participants were given the same If-then planning intervention as group 1. At 6-months participants filled out the final questionnaire.		***If-then plans (3-months) (d):*** at baseline participants received the internet-based questionnaire and brief motivational encouragement but no instructions on If-then planning. At 3-months follow-up participants were given the same If-then planning intervention as group 1. At 6-months participants filled out the final questionnaire.	
If-then planning example		"If it is lunchtime at university, then I will eat an apple instead of crisps!"			
Planning format		Self-formulated, participants were given a blank space (in the questionnaire) to write their If-then plans.			

<table>
<tr><td>Comparison(s) name & description</td><td>Questionnaire control: at baseline and follow-up participants received the internet-based questionnaire but did not receive either the brief motivational encouragement or instructions on If-then planning.</td><td>Questionnaire control: at baseline and follow-up participants received the internet-based questionnaire and the brief motivational encouragement, but no instructions on If-then planning.</td></tr>
<tr><td colspan="3">OUTCOME(S)</td></tr>
<tr><td>Outcome(s) measured</td><td colspan="2">FVI (servings/day), and psychological variables</td></tr>
<tr><td>Dietary assessment method</td><td colspan="2">1) Retrospective (1 week), self-reported, single-item open ended question assessing FVI. Assessment method used in previous research (Chapman et al. 2009) i.e., correlated with validated FFQ. “Over the past week, how many portions of fruit and vegetable have you eaten on average per day?”.
2) Retrospective (past year) FFQ assessment of FVI.</td></tr>
<tr><td>Mean, SD, N (or other) at 6- months follow-up (FVI)</td><td colspan="2">Single-item measure
<table>
<tr><td></td><td>Mean</td><td>SD</td><td>N</td><td>Timepoint</td></tr>
<tr><td>If-then</td><td>3.59</td><td>1.36</td><td>115</td><td>6 months</td></tr>
<tr><td>Control 1</td><td>3.60</td><td>1.35</td><td>103</td><td></td></tr>
<tr><td>If-then + reminder</td><td>4.06</td><td>1.09</td><td>119</td><td></td></tr>
<tr><td>Control 2</td><td>3.72</td><td>1.23</td><td>95</td><td></td></tr>
<tr><td>If-then (3)</td><td>3.80</td><td>1.25</td><td>103</td><td></td></tr>
<tr><td>If-then (4)</td><td>3.97</td><td>1.20</td><td>115</td><td></td></tr>
</table>
FFQ
<table>
<tr><td></td><td>Mean</td><td>SD</td><td>N</td><td>Timepoint</td></tr>
<tr><td>If-then</td><td>5.62</td><td>3.07</td><td>115</td><td>6 months</td></tr>
<tr><td>Control 1</td><td>5.53</td><td>2.98</td><td>103</td><td></td></tr>
<tr><td>If-then + reminder</td><td>5.81</td><td>3.40</td><td>119</td><td></td></tr>
<tr><td>Control 2</td><td>5.73</td><td>2.80</td><td>95</td><td></td></tr>
<tr><td>If-then (3)</td><td>5.36</td><td>3.67</td><td>103</td><td></td></tr>
<tr><td>If-then (4)</td><td>5.55</td><td>2.97</td><td>115</td><td></td></tr>
</table></td></tr>
<tr><td>Change in FVI from baseline to 6-months follow-up</td><td colspan="2">My calculations: 0.08 portions/day (If-then) vs. -0.02 portions/day (control 1); 0.57 portions/day (If-then + reminder) vs. 0.04 portions/day (control 2). (If-then, 3: 0.23 portions/day. If-then, 4: 0.4 portions/day).
As reported: If-then planning group decreased FVI by 0.19 portions/day. If-then planning group + reminder group increased FVI by 0.57 portions/day.</td></tr>
<tr><td>Measurement timepoints</td><td colspan="2">0, 3- and 6-months*</td></tr>
<tr><td colspan="3">EFFECT</td></tr>
<tr><td>Description</td><td colspan="2">No effect of If-then plans at 6-months compared to questionnaire control 1, significant effect of If-then plans + reminder at 6-months compared to questionnaire control 2 (single-item measure).
No significant effect of If-then plans in either group when using the FFQ-measure (p=0.59).</td></tr>
<tr><td colspan="3">OTHER</td></tr>
</table>

Motivation/intention	TPB items measured, including behavioural intention. No baseline differences in TPB measures. Brief motivational encouragement given to both intervention groups and control 2 group.
Miscellaneous	Protocol registration, author conflict of interest, funding and ethical approval not reported. Minimal participant burden. 59% response rate at 6-months.

*Indicates eligible outcome/timepoint when several are reported.

Ref.	**Guillaumie et al., 2012 (61, 62)**				
METHODS					
Overall RoB 2	Some concerns				
Study design	Four-armed parallel randomised trial				
Study setting, country	Face-to-face at intervention centre (individual and group based), Paris, France				
PARTICIPANTS/POPULATION					
Participant description	Adults (20-65 yr) from cities near Paris, eating < 5 portions FV/day, able to meet during intervention period, not pregnant or planning to become pregnant.				
N = xx (randomly assigned)	**Mean age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m²)**
319	40.8 years (SD = 10.6)	85	36% 'Mother born abroad'	53% completed college	22% BMI ≥ 30
INTERVENTION(S) & COMPARISON(S)					
Content given to all groups	Outcome measures assessed for all groups by equal paper-and-pencil questionnaires.				
Intervention(s) name & description	***If-then plans:*** Intervention given x4 for four weeks, sessions lasted 20-30 min. individual interviews (face-to-face) facilitated by trained dietitians. Intervention included several behavioural techniques e.g., 'barrier identification', 'specific goal setting', 'planning' etc. including If-then plans in the "If…, then…" format. Intervention fidelity promoted through piloted manuals, supervision and tape-recording of sessions. Goal to eat ≥ 5 FV portions/day.		***If-then plans + Self-efficacy intervention:*** Intervention given x4 for four weeks, group meetings (12 participants) lasted 2h. Participants received combined techniques from If-then (group 1) and Self-efficacy (control 2). Intervention fidelity promoted through piloted manuals, supervision and tape-recording of sessions. Goal to eat ≥ 5 FV portions/day.		
If-then planning example	"If situation x arises, then I do y".				
Planning format	Self-formulated, several plans created.				
Comparison(s) name & description	***Information intervention:*** Participants received healthy eating information brochure with		***Self-efficacy intervention:*** Intervention given x4 for four weeks, group meetings (12		

	personalised letter per mail, four times for 1 month.	participants) lasted 2h. Intervention included several behavioural techniques e.g., 'barrier identification', instructions, encouragement, strategy development etc. (not including If-then plans). Intervention fidelity promoted through piloted manuals, supervision and tape-recording of sessions. Goal to eat ≥ 5 FV portions/day.
OUTCOME(S)		
Outcome(s) measured	FI, VI, FVI* (servings/day), and psychological variables.	
Dietary assessment method	Retrospective (1 week), self-reported, validated FFQ containing 6 categories assessing FVI.	
Mean, SD, N (or other) at 6-months follow-up, FVI	*Mean* / *SD* / *N* / *Timepoint* *If-then*: 4.2 / 0.4 / 86 / 6 months *Control 1*: 4.0 / 0.3 / 54 *If-then+SE*: 5.0 / 0.3 / 85 *Control 2*: 5.0 / 0.4 / 70	
Change in FVI from baseline to 6-months follow-up	If-then: 1.0 servings/day; control 1: 0.4 servings/day. If-then + SE: 1.5 servings/day; SE-control 2: 1.6 servings/day.	
Measurement timepoints	Baseline, 1 (post-intervention), 3-, 6*- and 12-months	
EFFECT		
Description	No effect of If-then plans at 6 months in the If-then + SE compared to SE group, both groups increased FVI with approximately 1.6 servings/day. Effect of If-then compared to control 1 not reported (comparison not objective of report, but raw data reported).	
OTHER		
Motivation/intention	Only participants eating < 5 FV portions/day eligible.	
Miscellaneous	Protocol registration not reported. Ethical approval obtained, no author of conflict declared, funding reported. High attrition, high participant burden.	

*Indicates eligible outcome/timepoint when several are reported.

Ref.	Chapman et al., 2009 (66)
METHODS	
Overall RoB 2	High risk
Study design	Three-armed parallel randomised trial (two groups included i.e., one group excluded based on not If-then plans)
Study setting, country	Unclear, likely in-class, UK University
PARTICIPANTS/POPULATION	
Participant description	Undergraduate students, from different courses (aged 18-25 years)

N = xx (randomly assigned total)	**Mean age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m²)**
557 (unclear n= in included groups)	19.67 years (SD = 1.99)	74.1	91.6% Caucasian	Not reported (students)	Not reported

INTERVENTION(S) & COMPARISON(S)	
Content given to all groups	Questionnaire measuring Theory of Planned Behaviour (TPB) items, planning, demand characteristics, fruit and vegetable intake (FVI), and including information on benefits of increased FVI and portion size. Paper-and-pencil.
Intervention(s) name & description	***If-then plans:*** If-then planning instructions given in the questionnaire at baseline. Intervention aimed to increase participant FVI = 5 portions/day. Participants were encouraged to state their plans in the "If…, then…" format.
If-then planning example	"If it is lunchtime at university, then I will eat an apple instead of crisps!"
Planning format	Self-generated, space provided to write plans.
Comparison(s) name & description	***Questionnaire control:*** At baseline intervention included questionnaire with goal planning prompt i.e., encouraged participants to (generic) 'plan' to increase their FVI.
OUTCOME(S)	
Outcome(s) measured	FVI (portions/day), and psychological variables.
Dietary assessment method	Retrospective (1 week), self-reported, single-item open ended question assessing FVI. "Over the past week, how many portions of fruit and vegetable have you eaten on average per day?" Single-item measure correlated with validated FFQ.
Mean, SD, N (or other) at 1 week follow-up, FVI	*Mean* / *SD* / *N* / *Timepoint* *If-then*: 4.04 / 1.36 / 104 / 1 week *Control*: 3.87 / 1.23 / 97
Change in FVI from baseline to follow-up	My calculations: If-then: 0.5 portions/day, control: 0.01 portions/day.
Measurement timepoints	Baseline, 1 week
EFFECT	
Description	Significant effect of If-then planning intervention compared to questionnaire control intervention.
OTHER	
Motivation/intention	TPB items measured, including behavioural intention. No baseline difference in TPB variables. Information on benefits of increased FVI.
Miscellaneous	Protocol registration, author conflict of interest, funding and ethical approval not reported. Low participant burden. 54% response rate at 1 week. Not analysed according to ITT approach.

*Indicates eligible outcome/timepoint when several are reported.

<table>
<tr><th colspan="2">Ref.</th><th colspan="4">Armitage et al., 2015 (63)</th></tr>
<tr><td colspan="6">METHODS</td></tr>
<tr><td colspan="2">Overall RoB 2</td><td colspan="4">Low risk</td></tr>
<tr><td colspan="2">Study design</td><td colspan="4">Three-armed parallel randomised trial (two groups included i.e., one group excluded based on not If-then plans)</td></tr>
<tr><td colspan="2">Study setting, country</td><td colspan="4">Private hospital, UK</td></tr>
<tr><td colspan="6">PARTICIPANTS/POPULATION</td></tr>
<tr><td colspan="2">Participant description</td><td colspan="4">Adult employees at private hospital (aged 19-63)</td></tr>
<tr><td>N = xx (randomly assigned)</td><td>Mean age</td><td>Females (%)</td><td>Ethnicity</td><td>Level of education</td><td>BMI (kg/m²)</td></tr>
<tr><td>56</td><td>42.44 years (SD = 11.28)</td><td>75.9</td><td>Not reported</td><td>Not reported</td><td>Not reported</td></tr>
<tr><td colspan="6">INTERVENTION(S) & COMPARISON(S)</td></tr>
<tr><td colspan="2">Content given to all groups</td><td colspan="4">Questionnaire with brief motivational encouragement incl. prompt to plan (generic), measures of fruit intake (FI) and psychological items (incl. metacognitive processing).</td></tr>
<tr><td colspan="2">Intervention(s) name & description</td><td colspan="4">If-then plans: Participants received assigned If-then plans attached to the questionnaire i.e., ‘Volitional Help Sheet’ containing a list of ten ‘temptations/situations’ (If-statements) and ‘appropriate responses’ (then-statements). Participants were requested to link (by drawing) as many situations to responses as relevant to them.</td></tr>
<tr><td colspan="2">If-then planning example</td><td colspan="4">“If I'm tempted not to have an extra portion of fruit because I feel that I don't have the time, then I will tell myself that if I try hard enough I can have an extra portion of fruit each day."</td></tr>
<tr><td colspan="2">Planning format</td><td colspan="4">Assigned If-then plans</td></tr>
<tr><td colspan="2">Comparison(s) name & description</td><td colspan="4">Questionnaire control: at baseline participants received questionnaire with prompt to ‘plan’ and space to write their plans.</td></tr>
<tr><td colspan="6">OUTCOME(S)</td></tr>
<tr><td colspan="2">Outcome(s) measured</td><td colspan="4">FI (portions/day; frequency; sum), and psychological variables</td></tr>
<tr><td colspan="2">Dietary assessment method</td><td colspan="4">Retrospective (1 month), self-reported, fruit section (five items) of validated FFQ, quantity measure with response options on a scale from 1-5; frequency measure; and sum of quantity and frequency assessing FI.</td></tr>
<tr><td colspan="2">Mean, SD, N (or other) at 1-month follow-up, FI</td><td colspan="4">
Quantity (portions/day)*
<table>
<tr><td></td><td>Mean</td><td>SD</td><td>N</td><td>Timepoint</td></tr>
<tr><td>If-then</td><td>1.46</td><td>0.27</td><td>33</td><td>1 month</td></tr>
<tr><td>Control</td><td>1.25</td><td>0.19</td><td>23</td><td></td></tr>
</table>
Frequency
<table>
<tr><td></td><td>Mean</td><td>SD</td><td>N</td><td>Timepoint</td></tr>
<tr><td>If-then</td><td>4.34</td><td>1.55</td><td>33</td><td>1 month</td></tr>
<tr><td>Control</td><td>3.54</td><td>1.35</td><td>23</td><td></td></tr>
</table>
Sum: Quantity x Frequency
<table>
<tr><td></td><td>Mean</td><td>SD</td><td>N</td><td>Timepoint</td></tr>
<tr><td>If-then</td><td>41.09</td><td>19.63</td><td>33</td><td>1 month</td></tr>
<tr><td>Control</td><td>28.43</td><td>13.28</td><td>23</td><td></td></tr>
</table>
</td></tr>
</table>

Change in FI from baseline to 1-month follow-up	My calculations: Quantity: If-then: 0.1 portions/day; control: -0.05 portions/day
Measurement timepoints	Baseline, 1 month
EFFECT	
Description	Quantity: If-then planning intervention group ate significantly more fruit compared to control at 1 month (p=0.001). Frequency: If-then planning group ate fruit significantly more often compared to control at 1 month (p=0.002). Sum: If-then planning intervention group ate significantly more fruit than control (p=0.001).
OTHER	
Motivation/intention	Both groups received brief motivational encouragement to increase FI and plan to do so.
Miscellaneous	Protocol registration and funding not reported. No author conflict of interest declared. Ethical approval obtained. Minimal participant burden. Moderate attrition (small sample).

*Indicates eligible outcome/timepoint when several are reported.

Ref.	**Chapman et al., 2012 (65)**				
METHODS					
Overall RoB 2	Some concerns				
Study design	Three-armed parallel randomised trial				
Study setting, country	Internet-based, UK University				
PARTICIPANTS/POPULATION					
Participant description	Undergraduate students (aged 18-44)				
N = xx (randomly assigned tot.)	**Mean age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m²)**
580	21.02 years (SD = 3.91)	74	82% Caucasian	Not reported (students)	Not reported
INTERVENTION(S) & COMPARISON(S)					
Content given to all groups	Online questionnaire containing information about recommended fruit and vegetable intake (FVI), including information on portion size. Also measures of psychological items (e.g., behavioural intention), fruit- and vegetable intake (FI, VI).				
Intervention(s) name & description	***Separate If-then plans:*** at baseline participants received instructions on forming If-then plans (self-guided) attached to the questionnaire, in the "If..., then…" format. They were instructed to make *separate plans* for fruit intake and vegetable		***Combined If-then plans:*** at baseline participants received instructions on forming If-then plans (self-guided) attached to the questionnaire, in the "If..., then…" format. They were instructed to make *combined plans* for fruit intake and vegetable intake (one place to write their plans).		

	intake, at two separate places in the questionnaire.	
If-then planning example	"If it is lunchtime at university, then I will eat an apple instead of crisps!" "If it is lunchtime at the university, then I will eat a salad instead of chips!"	
Planning format	Self-generated, with space to write their plans	
Comparison(s) name & description	***Questionnaire control:*** participants in the control group received the questionnaire with a brief statement to encourage participants to increase their FI and VI.	
OUTCOME(S)		
Outcome(s) measured	FI, VI (portions/day), and psychological variables.	
Dietary assessment method	Retrospective (1 week), self-reported, single-item open ended question assessing FI* and VI. "Over the past week, how many portions of fruit have you eaten on an average day?"	

Mean, SD, N (or other) at 2-months follow-up, FI

	Mean	*SD*	*N*	*Timepoint*
If-then-S	1.94	1.07	200	2 months
If-then-C	2.14	1.03	183	
Control	1.72	0.98	197	

Mean, SD, N (or other) at 2-months follow-up, VI

	Mean	*SD*	*N*	*Timepoint*
If-then-S	2.01	1.09	200	2 months
If-then-C	1.90	1.06	183	
Control	1.75	1.00	197	

Change in FI from baseline to follow-up	My calculations (combined groups + FVI): 0.44 portions/day; -0.09 portions/day (control) Reported: 0.45 portions/day (If-then-C); 0.23 portions/day (If-then-S)
Measurement timepoints	Baseline, 2 months
EFFECT	
Description	Both If-then planning groups increased their fruit intake compared to the control (ps <0.01). Only the separate If-then group significantly increased their vegetable intake compared to combined If-then- and control group.
OTHER	
Motivation/intention	Brief motivational encouragement and information on recommended intake of FVI (5 a day). Behavioural intention measured to control for effect on plans.
Miscellaneous	Protocol registration, author conflict of interest and funding not reported. Ethical approval obtained. 68% response rate at 2-month follow up.

*Indicates eligible outcome/timepoint when several are reported.

Ref.	**Vézina-Im et al., 2019 (71)**
METHODS	
Overall RoB 2	Some concerns
Study design	Two-armed parallel randomised trial

Study setting, country		University Research Centre, Canada			
PARTICIPANTS/POPULATION					
Participant description		Female students and university employees at risk for gestational diabetes mellitus (GDM) i.e., 18-44 years, BMI ≥ 25 kg/m^2, GDM in previous pregnancy.			
N = xx (randomly assigned)	**Mean age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m^2)**
56	33.0-33.8 years (SD = 7.0-6.6)	100	87.5-88.5% Caucasian	57.7-66.7% university degree	M_{BMI} = 29.3-29.6
INTERVENTION(S) & COMPARISON(S)					
Content given to all groups		Paper-and-pencil questionnaires were given to all participants at all timepoints, except for the If-then planning intervention (only If-then group at baseline). The questionnaires contained psychological items (intention, self-efficacy), sociodemographic items and measures of FVI. In addition, anthropometric- and blood measures were taken at baseline (visits lasted 60-75 min.) and at 6-months (visits lasted 50 min.) at the research centre. Baseline and 6-month follow-up were in a face-to-face setting (3-month follow up were self-guided at home). Questionnaires where self-administrated at all timepoints, but the FFQ at baseline and 6-months was facilitated by a trained registered dietitian. The questionnaire contained information about recommended FVI (7-8 servings/day) and definition of serving size.			
Intervention(s) name & description		***If-then plans:*** At baseline participants received the If-then planning intervention, attached to a self-administrated questionnaire. The If-then plans were assigned and consisted of a table with 12 'barriers' as the "If…"-statement, and 12 'solutions' as the "then…"-statement, whereby participants were instructed to link a barrier to a solution that were relevant to them. There was also space to write one self-formulated plan. The assigned If-then planning sheet were piloted on a similar population.			
If-then planning example		"If I lack time, then I will buy pre-cut or frozen fruit and vegetables at the grocery store."			
Planning format		Assigned			
Comparison(s) name & description		***Questionnaire control:*** The control intervention was equal in all aspects to the If-then planning intervention, except for the If-then plans (control group did not receive instructions). See 'content given to all groups'.			
OUTCOME(S)					
Outcome(s) measured		FI, VI, FVI* (servings/day), and anthropometric, blood and psychological variables			
Dietary assessment method		Retrospective (length not reported, assuming 6 weeks based on validation reference), self-reported, validated semi-quantitative FFQ*, administrated by experienced dietitian assessing FVI at baseline and 6-months.			

Mean, SD, N (or other) at 6-months follow-up, FVI	*FVI*	*Mean*	*SD*	*N*	*Timepoint*
	If-then	6.13	1.85	22	6 months
	Control	5.64	1.55	23	
Mean, SD, N (or other) at 6-months follow-up, FI	*FI*	*Mean*	*SD*	*N*	*Timepoint*
	If-then	2.69	1.27	22	6 months
	Control	2.44	1.05	23	
Mean, SD, N (or other) at 6-months follow-up, VI	*VI*	*Mean*	*SD*	*N*	*Timepoint*
	If-then	3.44	1.22	22	6 months
	Control	3.20	1.28	23	
Change in FVI from baseline to 6-months follow-up	My calculations: If-then: 1.0 servings/day; Control: 0.7 servings/day.				
Measurement timepoints	Baseline, 3- and 6*-months				
EFFECT					
Description	Study reported finding no significant differences between groups at 3- and 6-months, however both groups increased their FVI from baseline compared to both follow-ups.				
OTHER					
Motivation/intention	Intention measured at all timepoints. Intention not found to moderate the effect in both groups.				
Miscellaneous	Protocol registration not reported. Ethical approval obtained, author declared no conflict of interest and funding reported. Moderate-high participant burden. Few drop-outs but small sample, therefore attrition 10 %.				

*Indicates eligible outcome/timepoint when several are reported.

Ref.		**Stadler et al., 2010 (70)**			
METHODS					
Overall RoB 2	Low risk				
Study design	Three-armed parallel randomised trial (two groups included in review, third group excluded from review due to wrong outcome, PA)				
Study setting, country	Rented conference rooms (face-to-face groups), Germany				
PARTICIPANTS/POPULATION					
Participant description	Female members of German health insurance association, between 30-50 years, no restrictions on changing their diet, not participating in similar program, available during intervention period, fluency in German.				
N = xx (randomly assigned included groups total)	**Mean age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m²)**
266	41.3 years	100	Not reported	44.3% (≥ 10 years of school)	Not reported
INTERVENTION(S) & COMPARISON(S)					

<table>
<tr><td>Content given to all groups</td><td>All participants were given one intervention session individually or in groups of 2-5, delivered by trained female interventionists. All participant received nutrition information, including serving size and benefits of a healthy diet, a dietary knowledge test, and a discussion phase during the baseline session. Intervention fidelity was promoted through standardized hand-out material, intervention manual(s) and checklists. Follow-ups were diary-based, self-guided and self-reported.</td></tr>
<tr><td>Intervention(s) name & description</td><td>If-then plans + mental contrasting and reminders: One physical session of 2 hours, where participants received the information intervention (see ‘content given to all groups’), and the If-then planning intervention. If-then planning and mental contrasting instructions were given to participants during the session, and interventionist facilitated adequate plan formulation. Plans were formulated in the “If…, then…”-format, and participants made several plans. They received food diaries to fill out for the consecutive week. Follow-ups were diary-based, self-guided and self-reported, and the If-then planning group had sections in the diary that encouraged them to practice (mentally and written) their If-then plans and mental contrasting.</td></tr>
<tr><td>If-then planning example</td><td>"If I have no fruits at work then I will buy an apple in the canteen at lunch!"
"If I pass the greengrocer on my way to work then I buy apples!"
"If I am eating out for lunch then I order a salad!"</td></tr>
<tr><td>Planning format</td><td>Self-formulated</td></tr>
<tr><td>Comparison(s) name & description</td><td>Information intervention: One physical session of 2 hours, where participants received the control nutrition information intervention (see ‘content given to all groups’) with group-based discussions. They received food diaries (without If-then planning and mental contrasting instructions) to fill out for the consecutive week. Follow-ups were diary-based, self-guided and self-reported.</td></tr>
<tr><td colspan="2">OUTCOME(S)</td></tr>
<tr><td>Outcome(s) measured</td><td>FVI (servings/week) plus other diet components, physical activity (PA), and psychological variables (e.g., intention, dietary knowledge).</td></tr>
<tr><td>Dietary assessment method</td><td>Prospective (7-day), self-reported, food diary assessing FVI (servings/day), based on validated measure. Food diary contained list of boxes to tick for each serving of FV eaten per day, plus other diet components.</td></tr>
<tr><td>Mean, SD, N (or other) at 4-months follow-up, FVI</td><td>
<table>
<tr><th></th><th>Mean</th><th>SD</th><th>N</th><th>Timepoint</th></tr>
<tr><td>If-then</td><td>29.12</td><td>Not reported</td><td>126</td><td>4 months</td></tr>
<tr><td>Control</td><td>25.49</td><td>Not reported</td><td>129</td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in FVI from baseline to 4-months follow-up</td><td>My calculations: If-then 1.0 servings/day; control 0.52 servings/day.
Reported: If-then 1.0 servings/day; control 0.47 servings/day.</td></tr>
<tr><td>Measurement timepoints</td><td>Baseline, 1 week, 1-, 2-, 4*-, 24-months</td></tr>
<tr><td colspan="2">EFFECT</td></tr>
<tr><td>Description</td><td>FVI higher in If-then planning group at 4- and 24- months compared to control ($p \leq 0.02$). Participant in both groups increased their FVI at all</td></tr>
</table>

	timepoints (p < 0.001), except at 24-months, where the If-then planning group had a higher FVI from baseline to follow-up, compared to the control (did not differ).
OTHER	
Motivation/intention	Mental contrasting i.e., motivational strategy given to the intervention group, facilitates goal commitment. Measures of intention, attitude and perceived behavioural control did not differ between groups at baseline (all ps = 0.53 – 0.94).
Miscellaneous	Protocol registration and author conflict of interest not reported. Funding reported. Ethical approval obtained. No financial incentive, but participants offered health checks. Low participant burden. Single-blinded study design (participants blinded).

*Indicates eligible outcome/timepoint when several are reported.

Ref.	**Luszczynska et al., 2006 (69)**				
METHODS					
Overall RoB 2	High risk				
Study design	Three-armed parallel randomised trial (two groups included in review, one group excluded due to being ineligible control)				
Study setting, country	Internet-based, country not reported (likely European)				
PARTICIPANTS/POPULATION					
Participant description	Adults, BMI ≥ 18, not vegetarians/vegans, no metabolic- and/or gastrointestinal diseases, valid e-mail address				
N = xx (randomly assigned)	**Mean age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m²)**
285 (unclear randomised to each group)	29 years	66	Not reported	58.6% tertiary education	26% overweight/obese
INTERVENTION(S) & COMPARISON(S)					
Content given to all groups	Internet-based questionnaire. All participants received information about self-efficacy (i.e., beliefs about ability to achieve goal intention), its importance in goal pursuit and self-efficacy instructions. Questionnaire also contained questions about other measures e.g., assessment of FVI.				
Intervention(s) name & description	***If-then plans + Self-efficacy intervention:*** all participants received the self-efficacy instructions (equal to the control group), but also received If-then planning instructions. Participants were encouraged to plan according to "what, when, where and how"-structure, and to make plans to overcome tempting situations in the "If…, then…"-format.				
If-then planning example	"If I will be in situation... (please, write down the circumstances), I plan to ... (please write down how you will react)".				
Planning format	Self-generated				
Comparison(s) name & description	***Self-efficacy intervention:*** all participants in the control group received the self-efficacy intervention (see 'content given to all groups').				

OUTCOME(S)	
Outcome(s) measured	FVI (portions/day), and psychological variables (including intention and self-efficacy items)
Dietary assessment method	Retrospective (two weeks), self-reported, single-item question i.e. "Within the last two weeks, how often have you eaten a portion of fruit and/or vegetables (excluding potatoes)?" with response options on a scale from 1-7 i.e., from 'once per week or less' to 'more than four (times per day)'.
Mean, SD, N (or other) at follow-up, FI/FVI	*Mean* / *SD* / *N* / *Timepoint* *If-then*: n.a / n.a / n.a / n.a *Control*: n.a / n.a / n.a *Results with means in Figure 1, p. 636.*
Change in FVI from baseline to follow-up	My calculations: Both groups increased their FVI by approx. 0.5 portions/day (based on visual inspection of figure 1, p. 636).
Measurement timepoints	Baseline questionnaire (without interventions), 1-month (with interventions), and 6-months
EFFECT	
Description	The If-then planning + Self-efficacy intervention did not differ from the control (self-efficacy) intervention. Both groups increased their FVI.
OTHER	
Motivation/intention	Participants in both groups received self-efficacy intervention. Measures of intention and self-efficacy; mediation tested, where self-efficacy mediated the effects (FVI) of the self-efficacy intervention, and self-efficacy and planning mediated the effects (FVI) of the If-then planning + self-efficacy intervention.
Miscellaneous	Protocol registration, ethical approval and funding not reported. Author declared no conflict of interest. Analysis not carried out by ITT. Not possible to calculate SMD. Low participant burden.

*Indicates eligible outcome/timepoint when several are reported.

Ref.		**Harris et al., 2014 (67)**			
METHODS					
Overall RoB 2		High risk			
Study design		Four-armed parallel randomised trial			
Study setting, country		Internet-based, UK			
PARTICIPANTS/POPULATION					
Participant description		University students and employees, inclusion based on FVI and motivation i.e., eligible participants reported eating < 5 portions, or eating 5 portions but finding it difficult.			
N = xx (randomly assigned)	**Mean age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m²)**
447	22.3 years	71.7	79.2% Caucasian	94% students	Not reported
INTERVENTION(S) & COMPARISON(S)					

<table>
<tr><td>Content given to all groups</td><td colspan="2">All participants received an internet-based questionnaire containing demographic questions (baseline), measures of FVI (all timepoints), intention, and nutrition information, including recommended FVI, portion size and health benefits (to promote motivation).</td></tr>
<tr><td>Intervention(s) name & description</td><td>If-then plans (non-affirmed): Participants received a non-affirmation control condition task, and instructions on how to make plans in the “If…, then…”-format. Plans were assigned in a thought bubble format, and participants could make several plans targeting different situations/obstacles of FVI. Interventionist rated plans according to plan formulation and content.</td><td>If-then plans (self-affirmed): Participants received a self-affirmation intervention task that consisted of writing down important values and their reasons, and instructions on how to make plans in the “If…, then…”-format. Plans were assigned in a thought bubble format, and participants could make several plans targeting different situations/obstacles of FVI. Interventionist rated plans according to plan formulation and content.</td></tr>
<tr><td>If-then planning example</td><td colspan="2">"If I eat out during the day, then I will have a banana after my food!"
"If I have had dinner, then [write in what fruit you will have!]"
"If I start to talk myself out of eating fruit and vegetables [write in your excuse] then [write in what you will say to yourself to prevent excuses from working!]"</td></tr>
<tr><td>Planning format</td><td colspan="2">Assigned, thought bubble format</td></tr>
<tr><td>Comparison(s) name & description</td><td>Non-affirmed control: Participants received a non-affirmation control condition task, including nutrition information (see ‘content given to all groups’).</td><td>Self-affirmed control: Participants received a self-affirmation intervention task that consisted of writing down important values and their reasons, in addition to questionnaire given to all groups.</td></tr>
<tr><td colspan="3">OUTCOME(S)</td></tr>
<tr><td>Outcome(s) measured</td><td colspan="2">FVI (standardised measure), psychological variables (including intentions).</td></tr>
<tr><td>Dietary assessment method</td><td colspan="2">FVI measured three ways (single-item, 24h-recall as portions/day and portions/week), results were standardised and combined into one estimate (all validated).</td></tr>
<tr><td>Mean, SD, N (or other) at follow-up, FVI</td><td colspan="2">
<table>
<tr><th></th><th>Z-score</th><th>SD</th><th>N</th><th>Timepoint</th></tr>
<tr><td>If-then (NA)</td><td>-0.04</td><td>0.09</td><td>43</td><td>3 months</td></tr>
<tr><td>Control-NA</td><td>-0.18</td><td>0.09</td><td>48</td><td></td></tr>
<tr><td>If-then (SA)</td><td>0.24</td><td>0.10</td><td>35</td><td></td></tr>
<tr><td>Control (SA)</td><td>0.07</td><td>0.10</td><td>36</td><td></td></tr>
</table>
Outcomes measured in z-scores with SDs, see Table 2 and Figure 1, p. 733.
</td></tr>
<tr><td>Change in FVI from baseline to follow-up</td><td colspan="2">Not calculated.
Reported: “…difference between SA and If-then-SA and NA and If-then NA approximately 1.2 portions per day.”</td></tr>
</table>

Measurement timepoints	Baseline, 1 week, 3-months
EFFECT	
Description	If-then + SA and SA interventions both increased their intake of FVI. If-then + NA and NA both decreased their intake. Linear modelling (n=250): significant overall main effects of SA and II+SA.
OTHER	
Motivation/intention	Motivational message given to all groups.
Miscellaneous	Protocol registration and conflicts of interest not reported. Ethical approval obtained. Funding reported. Exploratory analysis, not carried out by ITT. Low participant burden.

*Indicates eligible outcome/timepoint when several are reported.

Ref.	**Knäuper et al., 2011 (68)**				
METHODS					
Overall RoB 2	High risk				
Study design	Four-armed parallel randomised trial				
Study setting, country	Internet-based, Canada				
PARTICIPANTS/POPULATION					
Participant description	First year university students, living in student residence of a large North American University				
N = xx (randomly assigned)	**Mean age**	**Females (%)**	**Ethnicity**	**Level of education**	**BMI (kg/m²)**
262	18.23 years (SD = 0.72)	62.1	71.8% Caucasian	Not reported (students)	Not reported
INTERVENTION(S) & COMPARISON(S)					
Content given to all groups	All participants received equal questionnaires (except for the manipulations described below for each group).				
Intervention(s) name & description	***If-then plans + mental imagery:*** at baseline participants were given the goal intention 'to eat more fruit', and then create three If-then plans in the "If…, then…"-format, and instructed to mentally imagine (with closed eyes and details) the cues and responses outlined in their plan. At follow-up participants responded to an internet-based questionnaire assessing fruit intake (FI).		***If-then plans:*** at baseline participants were given the goal intention 'to eat more fruit', and to create three If-then plans in the "If…, then…"-format, related to this goal. At follow-up participants responded to an internet-based questionnaire assessing fruit intake (FI).		
If-then planning example	"If I see the orange juice bottles in the cafeteria at lunch, then I will take one and drink it with my lunch".				
Planning format	Self-formulated				

<table>
<tr><td>Comparison(s) name & description</td><td>Mental imagery control: at baseline participants were given the goal intention ‘to eat more fruit’, were instructed to write this goal intention down, and instructed to mentally imagine (with closed eyes and details) how to achieve this goal. At follow-up participants responded to an internet-based questionnaire assessing fruit intake (FI).</td><td>Questionnaire control: at baseline participants were given the goal intention ‘to eat more fruit’ and told to repeat this several times but were not instructed on planning. At follow-up participants responded to an internet-based questionnaire assessing fruit intake (FI).</td></tr>
<tr><td colspan="3">OUTCOME(S)</td></tr>
<tr><td>Outcome(s) measured</td><td colspan="2">FI (portions/day), and psychological variables (including behavioural intention, attitude), and measures related to mental imagery (where relevant).</td></tr>
<tr><td>Dietary assessment method</td><td colspan="2">Retrospective (1 week), self-reported, single-item open ended question assessing FI (based on Chapman et al. 2009). “In the past seven days, how many portions of fruit have you consumed on average per day?”.</td></tr>
<tr><td>Mean, SD, N (or other) at follow-up, FI</td><td colspan="2"><table><tr><th></th><th>Mean</th><th>SD</th><th>N</th><th>Timepoint</th></tr><tr><td>If-then + MI</td><td>3.96</td><td>n.a</td><td>177</td><td>1 week</td></tr><tr><td>MI control</td><td>3.94</td><td>n.a</td><td></td><td></td></tr><tr><td>If-then</td><td>3.64</td><td>n.a</td><td></td><td></td></tr><tr><td>Control</td><td>3.64</td><td>n.a</td><td></td><td></td></tr></table>Means combined for high and low fruit consumers, SD reported only for baseline FI i.e., SD = 1.66. N not reported for each group only high vs. low fruit consumers, and total. See Figure 1, p. 611.</td></tr>
<tr><td>Change in FI from baseline to follow-up</td><td colspan="2">Approximate calculations: If-then: 0.95 portions/day; Control: 0.71 portions/day. If-then + MI: 1.08 portions/day; MI control: 1.12 portions/day.</td></tr>
<tr><td>Measurement timepoints</td><td colspan="2">Baseline, 1 week</td></tr>
<tr><td colspan="3">EFFECT</td></tr>
<tr><td>Description</td><td colspan="2">Total sample (all groups) divided into low and high fruit consumers (cut-off at 2 portions), where low fruit consumers significantly increased their fruit intake ($p < 0.04$), but high fruit consumers did not. Low FI: If-then + MI group significantly increased their FI compared to the three other groups, and the If-then planning group ate more fruits compared to the questionnaire control (in the low fruit subsample).</td></tr>
<tr><td colspan="3">OTHER</td></tr>
<tr><td>Motivation/intention</td><td colspan="2">Effects on motivation tested. Indicative of MI control having higher intentions and more positive attitudes than the three other groups. Mediation analysed conducted, (weak) support for MI control being more motivated than the other groups.</td></tr>
<tr><td>Miscellaneous</td><td colspan="2">Protocol registration and author conflict of interest not reported. Funding reported. Ethical approval obtained. Not analysed according to ITT. Low drop-out rate, many exclusions. Low participant burden.</td></tr>
</table>

*Indicates eligible outcome/timepoint when several are reported.

Appendix 5: Search strategies

Embase Classic+Embase <1947 to 2022 November 23>

1	implementation intention*.ab,kw,ti.	601
2	if then plan*.ab,kw,ti.	101
3	1 or 2	626
4	exp nutrition/	2734849
5	diet*.ab,kw,ti.	884172
6	food*.ab,kw,ti.	721496
7	nutrition.ab,kw,ti.	274249
8	fruit*.ab,kw,ti.	156837
9	vegetable*.ab,kw,ti.	86965
10	snack*.ab,kw,ti.	12936
11	sugar*.ab,kw,ti.	180556
12	salt*.ab,kw,ti.	270513
13	fat*.ab,kw,ti.	1420173
14	eat* behaviour*.ab,kw,ti.	5242
15	eat* behavior*.ab,kw,ti.	12813
16	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15	4642638
17	3 and 16	**167**

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to November 23, 2022>

1 implementation intention*.ab,kw,ti. 549
2 if then plan*.ab,kw,ti. 101
3 1 or 2 575
4 exp "diet, food, and nutrition"/ 1916575
5 diet.ab,kw,ti. 380746
6 food.ab,kw,ti. 514987
7 nutrition.ab,kw,ti. 196824
8 exp fruit/ 121699
9 exp vegetables/ 35719
10 snack*.ab,kw,ti. 9673
11 sugar.ab,kw,ti. 105310
12 fruit*.ab,kw,ti. 134102
13 vegetable*.ab,kw,ti. 69074
14 salt*.ab,kw,ti. 222117
15 exp Sodium Compounds/ 107724
16 exp dietary fats/ 96891
17 fat*.ab,kw,ti. 1024050
18 exp Snacks/ 1921
19 exp feeding behavior/ 189672
20 eat* behavior*.ab,kw,ti. 9982
21 eat* behaviour*.ab,kw,ti. 3582
22 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 3541123
23 3 and 22 **125**

APA PsycInfo <1806 to November Week 2 2022>

1	implementation intention*.mp.	839
2	if then plan*.tw.	152
3	1 or 2	858
4	exp Nutrition/	68201
5	exp Eating Behavior/	25351
6	exp food intake/	15475
7	nutrition.tw.	21075
8	food*.tw.	92250
9	diet*.tw.	49499
10	fruit*.tw.	20360
11	vegetable*.tw.	6795
12	salt*.tw.	6610
13	fat*.tw.	127755
14	snack*.tw.	3146
15	eat* behaviour*.tw.	1867
16	eat* behavior*.tw.	9310
17	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16	309164
18	3 and 17	**141**

Appendix 6: Data extraction items

Data extraction items were adapted to COVIDENCE data extraction tool.

General information

- Citation
- Report ID
- Title
- Lead author contact details
- Country in which study conducted

Characteristics of included studies

Methods

- Aim of study/hypothesis
- Start and end date
- Unit of allocation
- Incentives for participation
- Sampling procedures
- Unit of analysis
- Statistical methods used (imputation of missing data, power, appropriateness of methods)
- Sequence generation, allocation sequence concealment and blinding
- Methods used to prevent and address missing data
- Likelihood of reporting and other biases
- Other concerns about bias

Participants

- Population description
- Sample population
- Eligibility criteria
- Method of recruitment of participants
- Study setting
- No. participants randomized
- Baseline sample characteristics (age, gender, ethnicity, education level, BMI)
- Baseline imbalances

Interventions and comparison

- Total no. of groups in study
- If-then plan example from report
- Mode of intervention delivery (paper-and-pencil, internet-based, face-to-face)
- Intervention manipulation assigned to all study groups
- Description of intervention(s) and comparator(s)/control(s) including names *(copy and paste for each intervention and comparison group)*
- If-then plans (self-formulated, assigned)
- Motivational component

- Co-intervention

Outcomes

- Dietary assessment method (incl. details, reference and validation)
- Outcomes and timepoints
    - Collected and reported
- For each pre-specified outcome:
    - Outcome definition/description
    - Specific metric
    - Method of aggregation (e.g., mean, SD)
    - Unit of measurement (e.g., grams, portions)
    - For scales (upper and lower limits)
- Adverse effects (e.g., 'participant burden')

Results

- Summary effect of intervention (as reported)
- For each group and each outcome at each timepoint
    - No. participants allocated to each intervention group
    - No. participants incl. in analysis
    - Summary data for each group (e.g., means, SD)
    - Attrition: No. participants who withdrew, were lost to follow-up or excluded, plus reasons for missing outcomes

Miscellaneous

- Funding source
- Potential conflict of interest
- Trial registration or protocol
- Ethical approval obtained
- Key conclusions by study authors
- Miscellaneous comments from the study authors
- References to other relevant studies
- Miscellaneous comments by review authors

Appendix 7: Risk-of-bias assessments (RoB 2)

Reference to RoB 2:

Sterne JAC, Savovic J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ. 2019;366:l4898-l.

Reference to RoB 2 Template for completion:

Higgins J, Savović J, Page M, JAC. S. Revised Cochrane risk-of-bias tool for randomized trials (RoB 2) Template for completion: RoB 2 Development Group; 2019. Available from: https://www.riskofbias.info/welcome/rob-2-0-tool/current-version-of-rob-2. (Accessed Sept. 2022)

Reference to RoB 2 Guideline document

Higgins J, Savović J, Page M, JAC. S. Revised Cochrane risk-of-bias tool for randomized trials (RoB 2) Full Guideline Document RoB 2: Development Group; 2019. Available from: https://www.riskofbias.info/welcome/rob-2-0-tool/current-version-of-rob-2. (Accessed Sept. 2022)

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration

Study details

Reference	Chapman J, Armitage CJ. Evidence that boosters augment the long-term impact of implementation intentions on fruit and vegetable intake. Psychology & health. 2010;25(3):365–81.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: If-then plans Comparator: Questionnaire control (a)

Specify which outcome is being assessed for risk of bias	FVI (single-item) at 6 months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 1, p. 374 M.e = 3.59, sd.e = 1.36 M.c = 3.60, sd.c = 1.35

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)

☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Quote: "Paper-and-pencil questionnaires sorted into random order via a random number generator were distributed at the beginning of the class by individuals who were unaware of the conditions. To reduce the risk of cross-contamination, the questionnaires were completed under examination conditions and participants were requested not to discuss the contents of the questionnaires after completion. At the end of the class, the participants were instructed to place the questionnaires into a collection box." p. 369	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No baseline differences on tested variables (all ps > 0.05).	N
Risk-of-bias judgement	Used algorithm for domain 1.	Low
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Participants "…requested to not discuss the contents of the questionnaires after completion." Thus, possible that participants talk together about the content, since trial is conducted 'in-class'. But study tested 'awareness of study hypothesis', and there was no significant difference between groups, and no significant correlation with FVI. Intervention was self-guided; internet-based follow up, with contact via (coded) email addresses.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PN
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	NA	NA
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	ITT approach. People lost to follow-up treated as no-changers. ANCOVA analysis, controlling for baseline FVI (single-item measure), and simple contrasts.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 2.	Low
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	No. Attrition from baseline to 6- months approx. 40 % missing outcomes. (Fig.1, p. 369)	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	No significant difference between those who responded and those who did not on all variables at 3- and 6 months, or drop-out rates between conditions (p. 372). Study overpowered (min. n=40 in each group with d=0.65, alpha=0.05, power=0.8). Incomplete information about reasons for missing outcomes e.g., only "withdrawal from study".	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Algorithm for domain 3 suggest 'low' risk. SKM chose to override this suggestion and judge domain 3 as 'some concerns'. Although no sig. difference between drop-out rates and responders vs. non-responders, high drop-out rate i.e., 40 % missing outcomes at 6-months.	Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No, outcome measured by single-item open ended question and FFQ.	PN
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Same outcome measurement method used in all groups at comparable timepoints.	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Probably not, outcome assessors = the participant (self-assessed), similar in all study groups.	PN
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 4.	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No protocol or SAP referenced. Comparing 'methods' section with 'results' section. Incomplete information about analysis intentions. Details on analysis primarily reported in 'results' section.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Two outcome measurement methods used, both have been reported for all groups at all pre-specified timepoints.	PN
5.3 … multiple eligible analyses of the data?	Not sufficient information about analysis intentions.	NI
Risk-of-bias judgement	Used algorithm for domain 5.	Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Domain 1, 2 and 4 judged as 'low' risk of bias, whereas domain 3 and 5 judged as 'some concerns' i.e., following RoB 2 suggestion overall risk of bias judged as 'some concerns'.	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration

Study details

Reference	Armitage CJ. Field experiment of a very brief worksite intervention to improve nutrition among health care workers. Journal of behavioral medicine. 2015;38(4):599-608.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: If-then plans (VHS) Comparator: Questionnaire control

Specify which outcome is being assessed for risk of bias: Fruit intake (FI) (quantity)

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Mean FI at 1 month (quantity):
M.e = 1.46, sd.e = 0.27
M.c = 1.25, sd.c = 0.19

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)

☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"All participants received a copy of the baseline questionnaire through the internal mail system. The manipulations were placed at the end of identical-looking questionnaires, which were sorted into random order using a web-based randomizer prior to data collection. Once the baseline questionnaire and manipulations were completed, the participant returned it to the researcher in a sealed envelope via the internal mail system. […] Baseline and follow-up questionnaires were matched using personal codes."	PY
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	'No', randomization achieved (all p-values checked > 0.05).	N
Risk-of-bias judgement	Used algorithm for domain 1.	Low
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Similar questionnaires (self-guided) given to all participants, except If-then planning manipulation (experimental group only) i.e., participants probably not aware of their assigned intervention. Since intervention was self-guided researchers probably not aware of assignment either.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		N
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	NA	NA
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Data analysed following (m)ITT principles with last observation carried forward. ANCOVAs controlling for baseline FI with condition as between participant variable, time as within participants variable, and FI as dependent variable. Including simple planned contrasts.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 2.	Low
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Outcome data at 1 month available for n=43, compared to baseline randomized (n=56) i.e., ≈ 23 % missing data. According to RoB 2 guide ≥ 95% is considered as 'nearly all' and is sufficient ('all' = all participants randomized) i.e., data not available for 'nearly all' due to small sample size and proportional large 'missing data'.	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Analyses rerun 'per protocol' and 'item imputation' with "…no substantive differences to the pattern of findings." No significant differences on baseline variables between dropouts and 1-month follow-up sample (p = .91), p. 601.	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 2.	Low
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Using the 'Fruit section' of a validated, self-administrated eight-item FFQ (reflecting last 1 month) i.e., Dietary assessment method judged as appropriate for quantity measure.	PN
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	No, both groups received the same questionnaires, except If-then planning manipulation (only experimental group).	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	No, outcome assessors = the participant (self-assessment).	N
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement	Low	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No protocol or SAP published or reported. Comparing 'methods' with reported 'results' in published article. 'Data analysis' reported in methods section align with results reported in 'results' section.	PY
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	One eligible outcome (FI) collected and *reported* three ways for all groups at comparable timepoints.	PN
5.3 … multiple eligible analyses of the data?	Multiple eligible analyses conducted based on each FVI outcome measurement, however all analyses are reported in the article.	PN
Risk-of-bias judgement	Low	Low
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Judged 'low' for all domains i.e., overall risk of bias judged as 'low' following criteria outlined in RoB 2 Short version (Cribsheet).	Low
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

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Version of 22 August 2019

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Study details

Reference	Chapman J, Armitage CJ. Do techniques that increase fruit intake also increase vegetable intake? Evidence from a comparison of two implementation intention interventions. Appetite. 2012;58(1):28-33.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Separate and combined If-then plans (II-S+C)	Comparator:	Questionnaire control (AC)

Specify which outcome is being assessed for risk of bias	Fruit intake (FI) at 2 months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 1, p. 31. II-S and II-C combined into one group for meta-analysis to avoid 'unit-of-analysis' (double counting) problem

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol

☐	Statistical analysis plan (SAP)
☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Randomised controlled design"; "The email contained a link to an online questionnaire, which randomly allocated participants to the control, combined or separate implementation intentions condition."	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	1.1 judged 'yes' based on description above; 1.2 judged 'probably yes' due to assuming online questionnaire function keeping allocation sequence concealed.	PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	'Probably no' as detailed information is missing from article, group characteristics not reported, but overall test of differences between groups where non sig., p = .67 (indicating randomization achieved).	PN
Risk-of-bias judgement	Used algorithm for domain 1.	Low
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	'Probably no' since internet-based intervention, but sample from UK university i.e., could have recruited participants from same study program/class, but incomplete information to make a judgement on this.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PN
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	NA	NA
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	ITT approach (n = 580). "Between-persons ANCOVAs controlling for baseline measures were used to examine the effects of condition (…) on fruit and vegetable intake at follow-up." Simple contrast analyses. Drop-outs treated as no changers.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 2.	Low
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	'No', 68% response rate compared to baseline i.e., 32% missing outcomes at follow-up.	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Reasons for missing outcomes not reported. But "…no significant differences were found between drop-out rates for condition" (p = .46), and no sig. diff. between non-responders and responders. No power analysis reported, however, likely oversampled.	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Algorithm for domain 3 suggest 'low' risk of bias. SKM chose to override this suggestion and judge risk of bias as 'some concerns' based on missing data. Although, no significant differences between non-responders and responders (compared on few characteristics).	Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Single-item open ended question about FI and VI, similar questions used in previous research.	PN
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	No, measured with the same method and at comparable timepoints in all groups.	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Probably no, outcome assessor = the participant. Self-reported FI and VI. Assuming participant blinded to intervention due to study design, although not explicitly stated in report.	PN
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 4.	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No protocol or SAP reported. Comparing 'methods' with 'results' section. Incomplete information in 'methods' section, analysis primarily reported in 'results' section i.e., cannot judge if analysis plan was finalised before unblinded outcome data were available based on the available evidence.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	FI reported at baseline and 2 months using one method i.e., only one eligible outcome (the same for VI), but not reported combined outcome (FVI).	N
5.3 … multiple eligible analyses of the data?	'Probably no', one analysis presented in results.	PN
Risk-of-bias judgement	Used algorithm for domain 5.	Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Judged 'low' for domain 1, 2 and 4, and 'some concerns' for domain 3 and 5 i.e., overall risk of bias judged as 'some concerns' following criteria outlined in RoB 2 Short version (Cribsheet).	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

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Study details

Reference	Chapman J, Armitage CJ, Norman P. Comparing implementation intention interventions in relation to young adults' intake of fruit and vegetables. Psychology & health. 2009;24(3):317–32.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: If-then plans (II) Comparator: Active control

Specify which outcome is being assessed for risk of bias	FVI at 1 week
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 1, p. 324 M.e = 4.04, sd.e = 1.36 M.c = 3.87, sd.e = 1.23

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)

☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Incomplete information about randomization and allocation concealment, only "randomized controlled design" and "randomly assigned to conditions". Randomization process not sufficiently described, unclear whether questionnaires are online or in-class, unclear to what extent participants are aware of other students interventions/how the study has prevented this.	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Randomization reported as successful, all ps>0.05 (pre-test planning, FVI, theory of planned behaviour variables, age, gender, ethnicity).	N
Risk-of-bias judgement	Used algorithm for domain 1.	Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Incomplete information to make a judgement. Based on reported reasons for missing data e.g., "varying attendance levels at lectures", study probably in class, and paper-and-pencil-based, although these details have not been reported clearly.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No information reported.	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	No, analyses "…based on the 300 participants for whom full data were available." 2x2x3 design ANOVA. Analyses only on participants with baseline and follow-up answers.	N
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	'Probably no', large proportion of missing data at follow-up, but no sig. diff. between responders vs. non-responders, and between drop-out rates from all groups.	PN
Risk-of-bias judgement	Used algorithm for domain 2.	Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	No, 54 % of questionnaires completed at 1 week follow up i.e., 46 % missing outcomes.	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Likely oversampled, but no power analysis. No sig. diff. between responders vs. non-responders (all ps>0.05). No sig. diff. between drop-out rates from all groups (all ps>0.05).	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Algorithm for domain 3 suggest 'low' risk, SKM chose to override this suggestion and judge this domain as 'some concerns'. Although no sig. difference between drop-out rates and responders vs. non-responders, with 46 % missing outcomes at 1 week cannot rule out that missing outcomes influences the estimated effect of the intervention.	Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Yes, single-item open ended question about FVI.	PN
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	No, the same outcome measurement method used in all groups at comparable timepoints.	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Self-assessed outcome i.e., outcome assessor = participant. Blinding not described (in-class study), and incomplete information about randomization.	NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	It is possible that knowledge of the intervention could affect reported FVI, especially due to study design. But authors did check if participants were aware of study aims, and no significant difference in awareness between groups was found (p = .21).	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement	Used algorithm for domain 4.	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No protocol or SAP referenced. Comparing 'methods' with 'results' in published report. Incomplete information reported on analysis intentions in methods section, all details reported in results.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	FVI (outcome) reported at planned follow-up for all groups.	PN
5.3 … multiple eligible analyses of the data?	One main analysis reported.	PN
Risk-of-bias judgement	Used algorithm for domain 5.	Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Domain 1, 2, 3 and 5 judged as 'some concerns', and domain 4 judged as 'low' risk of bias i.e., following RoB 2 suggestion overall risk of bias judged as 'high' (due to judged as 'some concerns' for four of five domains).	High
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	1. Guillaumie L, Godin G, Manderscheid JC, Spitz E, Muller L. The impact of self-efficacy and implementation intentions-based interventions on fruit and vegetable intake among adults. Psychology and Health. 2012;27(1):30-50. 2. Guillaumie L, Godin G, Manderscheid JC, Spitz E, Muller L. Self-efficacy and implementation intentions-based interventions on fruit and vegetable intake among adults: impact at 12-month follow-up. Global health promotion. 2013;20(2 Supplement):83-7.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: If-then plans (II) Comparator: Information control (AC)

Specify which outcome is being assessed for risk of bias: Fruit and vegetable intake (FVI) at 6 months

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

M.e = 4.20, sd.e = 0.4
M.c = 4.0, sd.c = 0.3

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)

☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"During a phone interview conducted by a research assistant (15-minute length), the study was described, inclusion criteria were specified and participants were randomly assigned to one of the study groups." "…randomised using a computer-generated randomisation list to one of the four groups." No information provided about allocation sequence concealment.	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Sig. diff. for gender $p < .001$, but not correlated to baseline FVI ($p = 0.28$) (judged as compatible with chance). In report covering 3-month follow-up, those who did not complete all questionnaires were more often male and had a mother born abroad. No diff. between baseline variables in analysed participants (n = 163). In report covering 6- and 12-month follow up (n = 291) only sig. diff. for gender (reported). No baseline characteristics table reported. Difference in control (n = 63) vs. If-then plans group (n = 93) size, not reported intended allocation ratio.	NI
Risk-of-bias judgement	Used algorithm for domain 1.	Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	"Participants were blinded to the content of the other interventions…" "A total of 14 dietitians experienced in health education were randomly assigned to an intervention type, blinded to the content of other interventions [...]"	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PN
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	NA	NA
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	"Generalized estimating equations (GEE) with five measurement times were adopted to test the impact of the intervention on FVI." ITT approach for 6-month outcome. 'Nearly all' participants included in analysis, n= 291, and efforts done to impute missing data (risk not evaluated in this domain).	PY
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 2.	Low
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	No, 39 % total missing outcomes at 6 months.	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	"Prior to performing these analyses, we used multiple imputation procedures (PROCMI and MIANALYZE in SAS software) to deal with missing data." FVI (all timepoints) = imputed variable. Predictors: sociodemographic-, behavioural-, psychosocial variables (i.e., all variables available). "Missing data assumed missing at random."	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Algorithm for domain 3 suggest 'low', but reviewer chose to override this suggestion and judge risk of bias as 'some concerns' for this domain. Although imputation procedures have been performed, missing outcomes are very high (39 %), and authors have reported missingness for the overall study (four groups) and not included participant flow diagram for 6- and 12- month outcome.	Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No, validated self-reported FFQ used for measuring FI, VI and FVI.	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	'Probably no', all groups measured by the same outcome method at comparable timepoints.	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	No, participant = outcome assessor (self-reporting); participants were blinded.	N
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 4.	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No protocol or SAP available. Methods compared with results in both reports. Same analysis method used in both reports, and outcomes reported as "planned" in methods (FI, VI, FVI) for all timepoints.	PY
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	One outcome available/defined eligible in present review i.e., FVI at 6 months.	N
5.3 … multiple eligible analyses of the data?	For 6 months outcome only ITT approach analyses available.	N
Risk-of-bias judgement	Used algorithm for domain 5.	Low
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Judged 'low' for domain 2, 4 and 5, and 'some concerns' for domain 1 and 3 i.e., overall risk of bias judged as 'some concerns' following criteria outlined in RoB 2 Short version (Cribsheet).	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Harris PR, Brearley I, Sheeran P, Barker M, Klein WMP, David Creswell J, et al. Combining self-affirmation with implementation intentions to promote fruit and vegetable consumption. Health Psychology. 2014;33(7):729-36.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Non-affirmed If-then plans Comparator: Non-affirmed control

Specify which outcome is being assessed for risk of bias: FVI at 3 months

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.: NA

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)

☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Participants in the present study were randomly assigned to [conditions]…" "Interested participants followed a link to an online site, where eligible participants obtained the link to the study pages […]" Study used online survey software (details not described). Use of online survey software probably allocated participants randomly to conditions, and kept allocation concealed until participants were enrolled and assigned.	PY
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Judged 'probably no'; No significant difference in baseline variables (age, sex, FVI) all ps>0.05. "Thus, random assignment of participants to conditions was successful."	N
Risk-of-bias judgement	Used algorithm for domain 1.	Low
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Blinding not explicitly described, however due to intervention design (internet-based), randomisation probably achieved, and active intervention given to the comparator condition, likely that participants and researchers were not aware.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PN
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	NA	NA
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	No. ITT approach not described. Explanatory ANCOVA analysis conducted, analysed those who completed at each time-point, incomplete information about exclusions. Generalised linear modelling (used n=250 of n=447 randomized).	N
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	Insufficient information about exclusions.	NI
Risk-of-bias judgement	Used algorithm for domain 2.	High
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	No, 48.8% completed the follow-up at 3 months.	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	No significant difference in drop-out rates between conditions (all *p*s > .05).	PN
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	No information. NI	NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement	Used algorithm for domain 3.	High
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No. Three dietary assessment methods used (single-item, 24h recall and portions/week), standardized and combined into consumption scores.	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	No, all groups measured with the same dietary assessment method at comparable timepoints.	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Probably no, outcome assessors = the participant (self-assessment).	PN
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 4.	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Protocol or SAP not referenced or reported. Comparing 'methods' with 'results'. Analysis intentions not described in methods.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	One outcome (FVI) collected and reported at 3 months.	PN
5.3 … multiple eligible analyses of the data?	Analysis of covariance (ANCOVA) conducted on participants who completed follow-ups and mixed model analysis (generalised linear modelling) conducted on 1 week follow-up participants (n=250) with condition x time, respectively. However, results reported for all analyses described (in results) and conducted.	NI
Risk-of-bias judgement	Used algorithm for domain 5.	Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Overall risk of bias judged as 'high', based on domain 2 and 3 being judged as at 'high' risk of bias, following RoB 2 short version (cribsheet) suggestion.	High
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

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Study details

Reference	Knauper B, McCollam A, Rosen-Brown A, Lacaille J, Kelso E, Roseman M. Fruitful plans: Adding targeted mental imagery to implementation intentions increases fruit consumption. Psychology and Health. 2011;26(5):601-17.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: II-targeted MI Comparator: Goal intentionsMI

Specify which outcome is being assessed for risk of bias	Fruit intake (portions/day) at 1 week
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	NA

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)

☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Participants were then assigned the goal to consume extra portions of fruit every day for the next 7 days and were subsequently randomly assigned to one of the four conditions." Due to the context of the study i.e., internet-based questionnaire, and randomization being facilitated by the survey website, both 1.1 and 1.2 judged as 'low' risk of bias i.e., 'yes' and 'probably yes'.	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	"Baseline fruit consumption did not differ by condition."	PN
Risk-of-bias judgement	Used algorithm for domain 1.	Low
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Participants asked if they talked to other participants about the study at follow-up, whereby 6 participants answered yes, and these were excluded from the analysis. Intervention self-guided and survey website randomised participants to study arms i.e., 2.2 judged as 'probably no'.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PN
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	NA	NA
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	'Probably no', no ITT approach described and subset n = 177 analysed (of total n = 247).	PN
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	Yes, several exclusions based on different reasons i.e., analyses conducted on a subset of participants (e.g., those who completed both questionnaires; formed goal- or If-then plans).	Y
Risk-of-bias judgement	Used algorithm for domain 2.	High
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Yes. Drop-out rate of 3.64% at follow-up (assuming all provided an answer to FI at both time-points).	PY
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	NA	NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 3.	Low
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Probably no, single-item open ended question assessing 7-day retrospective FI.	PN
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	No, same dietary assessment method used in all groups at comparable timepoints.	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Probably no, self-assessment i.e., outcome assessor = the participant (six participants answered 'yes' to talking to others about the study, these were excluded from the analysis).	PN
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 4.	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No protocol or SAP referenced/reported. Comparing 'methods' with 'results'. No information about analysis intentions, other than study design in methods section. Analysis described in results.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Probably no, outcome pre-specified to be collected at baseline and 1-week follow up, both have been reported.	PN
5.3 … multiple eligible analyses of the data?	Incomplete information to make a judgement since no analysis intentions have been described in methods. One analysis method (for FI) described in results.	NI
Risk-of-bias judgement	Used algorithm for domain 5.	Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Overall risk of bias judged as 'high' following suggestion by RoB 2 short version (cribsheet), due to domain 2 judged as 'high' risk of bias because inappropriate analysis method used in the context of review question (i.e., many exclusions of participants).	High
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Stadler G, Oettingen G, Gollwitzer PM. Intervention Effects of Information and Self-Regulation on Eating Fruits and Vegetables Over Two Years. Health Psychology. 2010;29(3):274-83.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Mental contrasting and If-then plans (MCII)	Comparator:	Information intervention (AC)

Specify which outcome is being assessed for risk of bias	Fruit and vegetable intake (FVI) (servings/week)
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Mean FVI at 4 months: M.e = 29.12, sd.e = not reported, M.c = 25.49, sd.c = not reported

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol

☐	Statistical analysis plan (SAP)
☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Telephone interviewers allocated the remaining women to the groups according to a computer-generated block-randomization list with block size 3." p.277. "[...] Single-blinded, longitudinal RCT". 1.2 judged 'no information' although using (small) block sizes; last intervention assignment within each block can be predicted, but study used "trained telephone interviewers" i.e., assuming not main research team. No further information provided in linked article: DOI: 10.1016/j.amepre.2008.09.021	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No, table 1, p.279. All *p*-values > .05 for comparing baseline group characteristics.	N
Risk-of-bias judgement	Used algorithm for domain 1.	Low
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	'No', single-blinded study, participants not aware of assigned intervention; experimental intervention compared to active comparator intervention.	N
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	'Probably yes', described as single blinded and delivered face-to-face i.e., assuming participants blinded and interventionist/facilitator unblinded.	PY
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No deviations described. Scripted intervention (manual), standardized hand-out material, and checklist to maintain intervention fidelity (see 'Design' p. 276).	PN
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes. ITT approach described: mixed-effects model that used all available data, with condition (experimental vs. comparator) as between-persons factor; follow-up time (0,1,2,4,24 months post-intervention) as within-persons factor; FVI at baseline as covariate; and FVI at follow-up as dependent variable.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 2.	Low

Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Outcome data at 4 months available for n=196, compared to baseline (n=255), and randomized (n=266) i.e., ≈ 23% drop-out rate. 4.7 % excluded from analysis (did not fill out baseline diary). According to RoB 2 guide ≥ 95% is considered as 'nearly all' and is sufficient ('all' = all participants randomized) i.e., judged as 'probably yes' due to details on exclusion from analysis with reasons (Fig. 1 Flow chart, p. 277). Analysis of attrition: similar drop-out rates at 4 months, and no significant difference in baseline characteristics between drop-outs and those who remained in the study.	PY
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	NA	NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 3.	Low
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No. The exact food diary used in study not validated, but rationale for choosing this method and validation of similar diaries for FVI provided (see 'Measures', p.278).	PN
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	No, the same method used in both groups and at comparable timepoints.	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	No, outcome assessors i.e., the individual participant filled out self-administrated food diaries, and were blinded to intervention assignment; no evidence suggest blinding was compromised.	N
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No protocol or SAP available. Comparing 'methods' with 'results' in published report. Data producing results analysed according to plan specified in methods section, but table of effects at each follow-up not reported, means reported in text, and in Fig. 2, p. 280 (both without SDs).	PN
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Outcome measured one way (food diaries) and reported at all planned timepoints.	PN
5.3 ... multiple eligible analyses of the data?	Three main analyses planned in methods, and all reported in results (all answer different research questions).	PN
Risk-of-bias judgement	Used algorithm for domain 5.	Low
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Overall risk of bias judged as 'low' following suggestion by RoB 2 short version (cribsheet), due to all domains judged as 'low' risk of bias..	Low
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Vezina-Im LA, Perron J, Lemieux S, Robitaille J. Promoting fruit and vegetable intake in childbearing age women at risk for gestational diabetes mellitus: A randomised controlled trial. Journal of health psychology. 2019;24(5):600-12.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	If-then plans + question behaviour effect intervention (QBE-II)	Comparator:	Question behaviour effect intervention (QBE)

Specify which outcome is being assessed for risk of bias	Fruit and vegetable intake (FVI) (servings/day)
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Mean FVI at 6 months: M.e = 6.13, sd.e = 1.85 M.c = 5.64, sd.c = 1.55

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol

☐	Statistical analysis plan (SAP)
☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"Women were randomly assigned to either the II or QBE group by assigning random numbers from computer-generated random number tables to the treatment conditions." p.602 No information provided about allocation sequence concealment.	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No, table 1, p. 605. Group characteristics compared, all p-values > .05.	N
Risk-of-bias judgement	Algorithm for domain 1 used.	Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Separate protocol not reported. 'Protocol' section described in methods, p. 602. No information describing participant, or researcher blinding. All participants were given identical questionnaires, except for the 'If-then' manipulation at baseline (experimental group only). Questionnaires filled out face-to-face with facilitator. Random sample from the local university i.e., assuming participants did not know each other.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No information.	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Effect of intervention on FVI measured using 2 (condition) x 3 (time) repeated-measures mixed model analyses of variance (ANOVAs) i.e., participants analysed in the group they were randomized. No information on ITT approach, or exclusion, but from flow chart (Fig. 1, p. 604) and results (Table 2, p. 606) seems like only those with missing outcomes at 6 months have been excluded.	PY
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	Excluded participants (≈ 10%, fig. 1, p. 604 and table 2, p. 606) could have had an effect on the estimated results, but outcome is not rare and not related to prognostic factors. Exclusion of participant data and handling of missing information not sufficiently described.	PN
Risk-of-bias judgement	Algorithm for domain 2 used.	Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Outcome data at 6 months available for n = 45, compared to baseline (n = 50), and randomized (n = 56) i.e., ≈ 10% and 20% missing, respectively. According to RoB 2 guide ≥ 95% is considered as 'nearly all' and is sufficient ('all' = all participants randomized) i.e., data not available for 'nearly all' due to small sample size.	PN
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	≈ Equal proportions of missing data in each group at 6 months. Participants not completing 6-month follow-up were similar to those who completed (all *p*s > 0.05).	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Algorithm for domain 3 used.	Low
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No, validated food frequency questionnaire (FFQ) (baseline and 6-months).	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	No, the same measurement of the outcome have been used in both groups at comparable timepoints.	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Outcome assessor = participant. Blinding not explicitly stated in report, but due to study design (randomized trial) and intervention vs. comparator setup (QBE-II vs. QBE), and study participants being 'randomly' recruited among students and employees (i.e., not from the same study program) risk of bias judged as 'probably no'.	PN
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement	Algorithm for domain 4 used.	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No protocol or SAP available. Comparing 'methods' with 'results' in published report p. 603-607. Judged as 'probably yes' based on reporting of 'protocol statistical analysis plan' in methods, whereby results from main analysis plan are reported in 'results'. Reporting of 'post hoc' analyses in results suggest authors are transparent in their reporting (i.e., open about what was planned and what was post hoc).	PY
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Judged as 'probably no': FVI outcome reported according to 'protocol plan' (from methods section) at all pre-specified timepoints.	PN
5.3 … multiple eligible analyses of the data?	Results reported from analyses reported as planned in methods.	PN
Risk-of-bias judgement	Used algorithm for domain 5.	Low
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Judged 'low' for domain 3, 4 and 5, and 'some concerns' for domain 1 and 2 i.e., overall risk of bias judged as 'some concerns' following criteria outlined in RoB 2 Short version (Cribsheet).	Some concerns
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
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Study details

Reference	Luszczynska A, Tryburcy M, Schwarzer R. Improving fruit and vegetable consumption: a self-efficacy intervention compared with a combined self-efficacy and planning intervention. Health education research. 2007;22(5):630–8.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Self-efficacy and If-then plans Comparator: Self-efficacy control

Specify which outcome is being assessed for risk of bias	FVI at 6-months
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	NA

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of ***adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)

☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"All participants who provided their e-mail address were randomly assigned to..." (one of three study arms). In the context of this study, 1.1. and 1.2 judged as 'no information', although internet-based, "…the experimenters sent an e-mail including either the intervention or the information for the control group." Randomization procedure and allocation concealment not described, but do not assume it is function of the online questionnaire, as experimenters *email* interventions.	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No significant difference between groups on FVI, psychological- and sociodemographic variables reported.	PN
Risk-of-bias judgement	Used algorithm for domain 1.	Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?	NA	NA

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Random adult sample, intervention internet-based i.e., 2.1 judged as 'probably not' in the context of this field of research.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Study did randomize participants to interventions, but insufficient detail on allocation procedure.	NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No information to make a judgement.	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Analysis of variance; correlational analysis. Insufficient information, no ITT approach described, drop-outs excluded from analysis. 2.6 judged 'probably no' in the context of this review.	PN
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	Participants analysed in the group they were allocated. In the analysed sample (n = 200), 2.5% data missing. No exclusions described from final analysed sample.	PN
Risk-of-bias judgement	Used algorithm for domain 2.	Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	285 participants randomized, n = 200 filled out questionnaire at follow-up i.e., 70.2% response rate and 30% drop-outs at follow-up.	PN
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	"In the final longitudinal dataset, 2.5 % of data were missing. To impute missing data, multivariate regression with self-efficacy, action plans, fruits and vegetables entered as respective predictors was employed." (n = 200) No difference between those who did not provide e-mail address at baseline and those who did. No difference between those who dropped out at follow-up and those who participated.	PY
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	Algorithm for domain 3 suggest 'low' risk of bias for this domain, reviewer chooses to override this suggestion and judge risk of bias as 'some concerns' due to 30% drop-outs at follow-up, and uncertainty if sufficient procedures have been performed to address if "results was not biased by missing outcome data".	Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	No, self-reported, single-measure item.	PN
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Same dietary assessment method used in all groups at baseline and follow-up.	PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	'No', outcome assessor = the participant (self-assessment).	N
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	NA
Risk-of-bias judgement	Used algorithm for domain 4.	Low
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Protocol or SAP not referenced/reported. Comparing 'methods' with 'results' sections in published article. No information about analysis intentions described in methods.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	No. One FVI outcome measurement, measured at baseline and follow-up.	PN
5.3 … multiple eligible analyses of the data?	One analysis of effect of intervention(s) on FVI reported.	PN
Risk-of-bias judgement	Used algorithm for domain 5.	Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA

Overall risk of bias

Risk-of-bias judgement	Overall risk of bias judged as 'high' following suggestion by RoB 2 short version (cribsheet), due to domain 1, 2, 3 and 5 judged as 'some concerns' i.e., when some concerns in multiple domains study can be judged as high risk of bias.	High
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA

Appendix 8: Supplementary data analyses and plots

Preparing for synthesis and statistical analysis

Table 5: Coded information from included studies for visual inspection of similarity

Study	Population	Intervention		Control	Outcome			Effect
Author, year	Sample	Name	Plan format		Eating behaviour + unit	Measurement timepoints (months)	Data reported	Possible to calculate SMD?
Chapman, 2010	S	If-then	S-f	AC-	FVI (portions/day)	0, 3, 6*	Mean, SD, N	Yes
		If-then x2	S-f	AC				Yes
Guillaumie, 2012	Non-s	If-then	S-f	AC-	FVI* (servings/day)	0, 1, 3, 6*, 12	Mean, SD, N	Yes
		If-then + SE	S-f	SE (AC+)				Yes
Chapman, 2009	S	If-then	S-f	AC	FVI (portions/day)	0, 1 week	Mean, SD, N	Yes
Armitage, 2015	Non-s	If-then	Ass.	AC	FI (portions/day)	0, 1	Mean, SD, N	Yes
Chapman, 2012	S	If-then[a]	S-f	AC	FI*, VI (portions/day)	0, 2	Mean, SD, N	Yes[a]
		If-then[a]						
Vézina-Im, 2019	S	If-then	Ass.	AC+	FI, VI, FVI* (servings/day)	0, 3, 6*	Mean, SD, N	Yes
Stadler, 2010	Non-s	If-then + MC	S-f	AC+	FVI (servings/week)	0, 1 week, 1, 2, 4*, 24	Mean, N	Yes**
Luszczynska, 2006	Non-s	If-then + SE	S-f	SE (AC+)	FVI (portions/day)	0, 6	F statistics, p-value	n.a/ unclear
Harris, 2014	S	If-then + NA	Ass.	NA (AC)	FVI (standardized measure)	0, 1 week, 3*	Z-scores, SD, N	n.a/ unclear
		If-then + SA	Ass.	SA (AC+)				
Knäuper, 2011	S	If-then	S-f	AC	FI (portions/day)	0, 1 week	Mean	No
		If-then + MI	S-f	MI (AC+)				

Caption 3: *Indicates eligible outcome and/or timepoint when several was reported; **SDs not reported; S-f: self-formulated; ass.: assigned; AC: active control; SE: Self-efficacy; NA: non-affirmed; SA: self-affirmed; MC: mental contrasting; MI: mental imagery; 0: baseline measurement; SD: standard deviation; Black line: studies above included in meta-analysis, studies below not included.

Sensitivity analyses

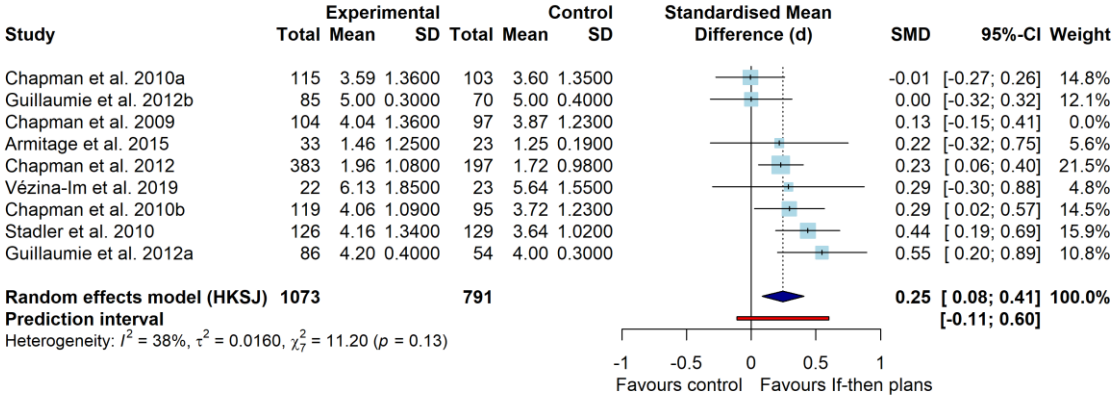

Figure 10: Sensitivity analysis (k = 8), removing Chapman et al. 2009, due to study outcome judged as at high risk of bias.

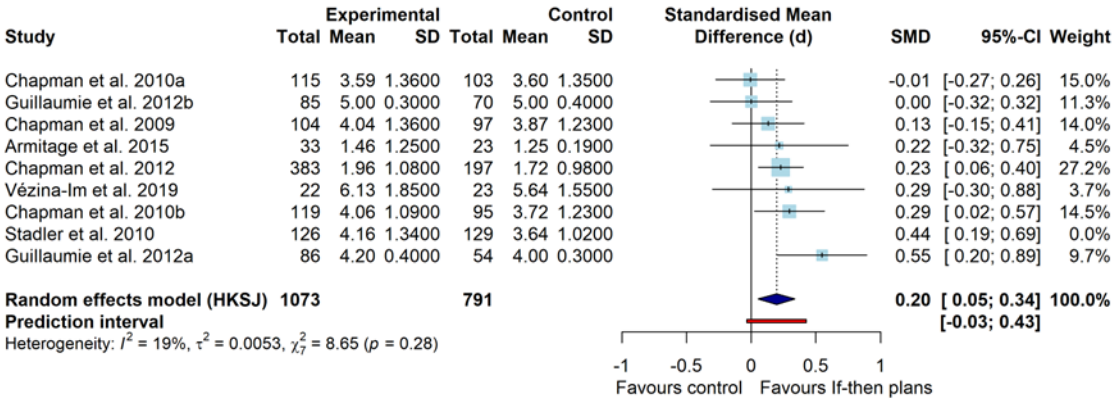

Figure 11: Sensitivity analysis (k = 8), removing Stadler et al., 2010, due to imputed standard deviations.

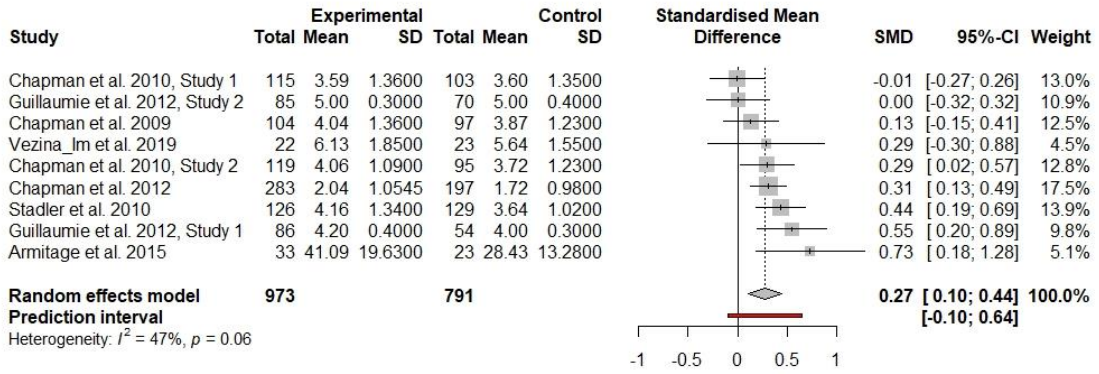

Figure 12: Sensitivity analysis with Armitage, C.J., 2015 sum measure (quantity x frecuency) of fruit intake.

Results from random-effects model

Random-effects model with Hedges g: SMD(*g*) = 0.23 (95% CI: 0.09, 0.37).

Funnel plot

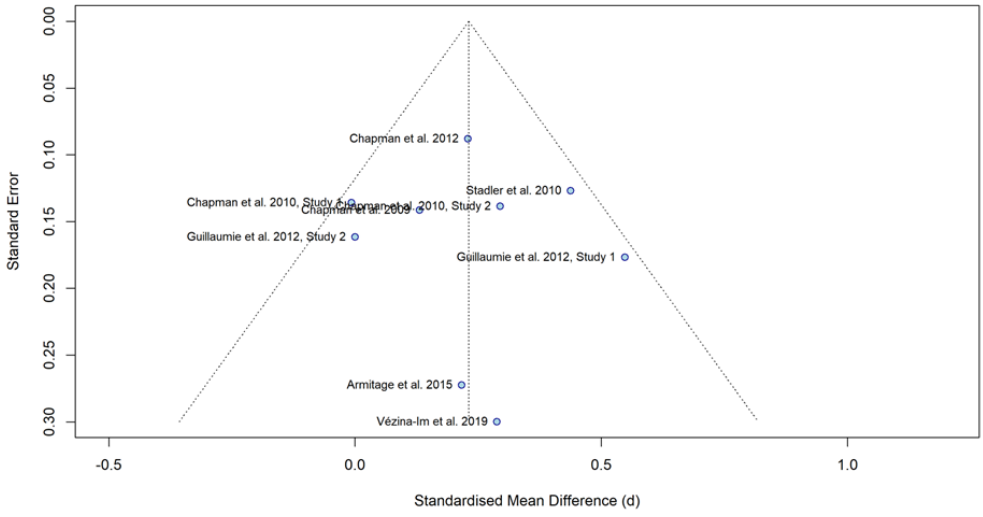

Figure 13: Funnel plot (k = 9) illustrating the 'risk of small study effects'. The blue circles are study SMD(d) with corresponding standard error.

Table 6: Overview of study group names used in report, compared to the names used in this review

Author, year	Report abbreviations Intervention(s)	Report abbreviations Comparison(s)	Name used in review Intervention(s)	Name used in review Comparison(s)
Chapman et al., 2010	II	PC	If-then plans	Questionnaire control (a)
	II+II	AC	If-then plans + reminder	Questionnaire control (b)
	PC+II	n.a	If-then plans (3-months)	n.a
	AC+II	n.a	If-then plans (3-months)	n.a
Guillaumie et al., 2012	II	Control	If-then plans	Information intervention
	II+SE	SE	If-then plans + Self-efficacy intervention	Self-efficacy intervention
Chapman et al., 2009	If-then	Control	If-then plans	Questionnaire control
Armitage, 2015	Volitional help sheet condition	AC	If-then plans	Questionnaire control
Chapman et al., 2012	Separate II	Control	Separate If-then plans	Questionnaire control
	Combined II		Combined If-then plans	
Vézina-Im et al., 2019	II	QBE	If-then plans	Questionnaire control
Stadler et al., 2010	Information + self-regulation group	Information group	If-then plans + mental contrasting and reminders	Information intervention
Luszczynska et al., 2006	Self-efficacy and plans	Self-efficacy	If-then plans + Self-efficacy intervention	Self-efficacy intervention
Harris et al., 2014	Non-affirmed Imps	Non-affirmed control	If-then plans (non-affirmed)	Non-affirmed control
	Self-affirmed Imps	Self-affirmed control	If-then plans (self-affirmed)	Self-affirmed control
Knäuper et al., 2011	II-targeted MI	Goal intention MI	If-then plans + mental imagery	Mental imagery control
	II	Control	If-then plans	Questionnaire control

Unweighted risk of bias plot

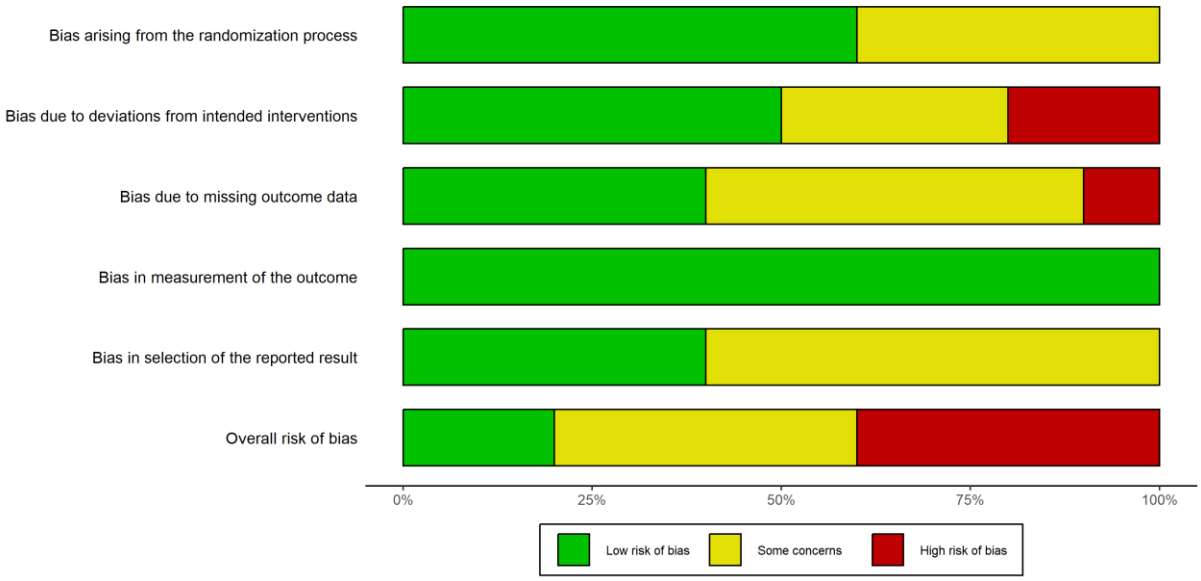

Figure 14: Unweighted risk-of-bias (RoB 2) plot. All study comparisons (k = 10) from all included studies are given weight (also those k = 3 with 'high' RoB 2, not included in meta-analysis).

Appendix 9: Excluded full-text reports

Excluded study reports: If-then planning interventions with wrong outcome

	Citation	Reason(s) for exclusion
1	Shreedhar G, Galizzi MM. Personal or planetary health? Direct, spillover and carryover effects of non-monetary benefits of vegetarian behaviour. J Environ Psychol. 2021;78.	Wrong outcome: number of vegetarian days
2	Knauper B, Carriere K, Frayn M, Ivanova E, Xu Z, Ames-Bull A, et al. The Effects of If-Then Plans on Weight Loss: Results of the McGill CHIP Healthy Weight Program Randomized Controlled Trial. Obesity. 2018;26(8):1285-95.	Wrong outcome: weight loss, fat- and caloric intake
3	Achtziger A, Glas A, Kenning P, Rudolph T. Comparing the effects of financial incentives and implementation intentions on unhealthy snacking behavior in employees. Curr Psychol. 2021;40(10):4770-84.	Wrong outcome: unhealthy snacking behaviour
4	Bradbury D, Upsher R, Chilcot J. A pilot randomised test of a self-affirmation implementation intention intervention to reduce dietary salt intake. Journal of health psychology. 2018;23(6):765-75.	Wrong outcome: salt intake
5	Prestwich A, Ayres K, Lawton R. Crossing two types of implementation intentions with a protection motivation intervention for the reduction of saturated fat intake: A randomized trial. Soc Sci Med. 2008;67(10):1550-8.	Wrong outcome: fat intake
6	Ayre J, Bonner C, Cvejic E, McCaffery K. Randomized trial of planning tools to reduce unhealthy snacking: Implications for health literacy. PLoS One. 2019;14(1):e0209863.	Wrong outcome: unhealthy snacking
7	de Freitas Agondi R, Cornelio ME, Rodrigues RCM, Gallani M-C. Implementation Intentions on the Effect of Salt Intake among Hypertensive Women: A Pilot Study. Nursing research and practice. 2014;2014:196410.	Wrong outcome: salt intake
8	Prestwich A, Conner MT, Lawton RJ, Ward JK, Ayres K, McEachan RRC. Partner- and planning-based interventions to reduce fat consumption: randomized controlled trial. British journal of health psychology. 2014;19(1):132-48.	Wrong outcome: fat intake
9	Kroese FM, Adriaanse MA, Evers C, De Ridder DTD. "Instant success": Turning temptations into cues for goal-directed behavior. Personality and Social Psychology Bulletin. 2011;37(10):1389-97.	Wrong outcome: chocolate
10	Lacroix K, Gifford R. Targeting interventions to distinct meat-eating groups reduces meat consumption. Food Qual Prefer. 2020;86.	Wrong outcome: meat intake
11	Zandstra EH, den Hoed W, van der Meer N, van der Maas A. Improving compliance to meal-replacement food regimens. Forming implementation intentions (conscious IF-THEN plans) increases compliance. Appetite. 2010;55(3):666-70.	Wrong outcome: meal replacement products
12	van Koningsbruggen GM, Stroebe W, Papies EK, Aarts H. Implementation intentions as goal primes: Boosting self-	Wrong outcome: unhealthy food

	control in tempting environments. European Journal of Social Psychology. 2011;41(5):551-7.	
13	Verhoeven AAC, Adriaanse MA, De Ridder DTD, De Vet E, Fennis BM. Less is more: The effect of multiple implementation intentions targeting unhealthy snacking habits. European Journal of Social Psychology. 2013;43(5):344-54.	Wrong outcome: unhealthy snacking
14	Gregorio-Pascual P, Mahler HIM. Effects of interventions based on the theory of planned behavior on sugar-sweetened beverage consumption intentions and behavior. Appetite. 2020;145:104491.	Wrong outcome: sugar-sweetened beverage
15	O'Connor DB, Armitage CJ, Ferguson E. Randomized test of an implementation intention-based tool to reduce stress-induced eating. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine. 2015;49(3):331-43.	Wrong outcome: stress-induced eating
16	Adriaanse MA, Oettingen G, Gollwitzer PM, Hennes EP, De Ridder DTD, De Wit JBF. When planning is not enough: Fighting unhealthy snacking habits by mental contrasting with implementation intentions (MCII). European Journal of Social Psychology. 2010;40(7):1277-93.	Wrong outcome: unhealthy snacking
17	Adriaanse MA, De Ridder DTD, De Wit JBF. Finding the critical cue: Implementation intentions to change one's diet work best when tailored to personally relevant reasons for unhealthy eating. Personality and Social Psychology Bulletin. 2009;35(1):60-71.	Wrong outcome: unspecific healthy snacks
18	Hayes JF, Balantekin KN, Graham AK, Strube MJ, Bickel WK, Wilfley DE. Implementation intentions for weight loss in college students with overweight and obesity: A proof-of-concept randomized controlled trial. Translational Behavioral Medicine. 2021;11(2):359-68.	Wrong outcome: weight loss, calories and HEI-score
19	Achtziger A, Gollwitzer PM, Sheeran P. Implementation intentions and shielding goal striving from unwanted thoughts and feelings. Personality and Social Psychology Bulletin. 2008;34(3):381-93.	Wrong outcome: unhealthy snacking
20	Verhoeven AA, Adriaanse MA, de Vet E, Fennis BM, de Ridder DT. Identifying the 'if' for 'if-then' plans: combining implementation intentions with cue-monitoring targeting unhealthy snacking behaviour. Psychology & health. 2014;29(12):1476-92.	Wrong outcome: snacking intake, calories; Wrong study design: not randomised
21	Adriaanse MA, van Oosten JMF, de Ridder DTD, de Wit JBF, Evers C. Planning what not to eat: Ironic effects of implementation intentions negating unhealthy habits. Personality and Social Psychology Bulletin. 2011;37(1):69-81.	Wrong outcome: unhealthy snacks; wrong study setting
22	Loy LS, Wieber F, Gollwitzer PM, Oettingen G. Supporting Sustainable Food Consumption: Mental Contrasting with Implementation Intentions (MCII) Aligns Intentions and Behavior. Frontiers in psychology. 2016;7:607.	Wrong outcome: meat intake
23	Rees JH, Bamberg S, Jager A, Victor L, Bergmeyer M, Friese M. Breaking the habit: On the highly habitualized nature of	Wrong outcome: meat reduction

	meat consumption and implementation intentions as one effective way of reducing it. Basic Appl Soc Psych. 2018;40(3):136-47.	
24	Judah G, Mullan B, Yee M, Johansson L, Allom V, Liddelow C. A Habit-Based Randomised Controlled Trial to Reduce Sugar-Sweetened Beverage Consumption: the Impact of the Substituted Beverage on Behaviour and Habit Strength. International journal of behavioral medicine. 2020;27(6):623-35.	Wrong outcome: sugar-sweetened beverage; no control condition
25	Knauper B, Shireen H, Carriere K, Frayn M, Ivanova E, Xu Z, et al. The effects of if-then plans on weight loss: Results of the 24-month follow-up of the McGill CHIP Healthy Weight Program randomized controlled trial. Trials. 2020;21(1):40.	Wrong outcome: weight loss, fat- and caloric intake (linked to Knaüper et al., 2018)
26	Achtziger A, Gollwitzer PM, Sheeran P. Implementation intentions and shielding goal striving from unwanted thoughts and feelings. Personality and Social Psychology Bulletin. 2008;34(3):381-93.	Wrong outcome: unhealthy eating behaviours

Excluded study reports: Time-based interventions with fruit and vegetable intake as outcome

	Citation	**Reason(s) for exclusion**
27	Troop NA. Brief report: effect of dietary restraint on fruit and vegetable intake following implementation intentions. Journal of health psychology. 2013;18(7):861-5.	Wrong intervention: time-based
28	Luszczynska A, Haynes C. Changing nutrition, physical activity and body weight among student nurses and midwives: Effects of a planning intervention and self-efficacy beliefs. Journal of Health Psychology. 2009;14(8):1075-84.	Wrong intervention: time-based
29	Kendzierski D, Ritter RL, Stump TK, Anglin CL. The effectiveness of an implementation intentions intervention for fruit and vegetable consumption as moderated by self-schema status. Appetite. 2015;95:228-38.	Wrong intervention: time-based
30	Churchill S, Jessop DC. Too impulsive for implementation intentions? Evidence that impulsivity moderates the effectiveness of an implementation intention intervention. Psychology and Health. 2011;26(5):517-30.	Wrong intervention: time-based
31	de Bruijn GJ, Nguyen MH, Rhodes RE, van Osch L. Effects of preparatory and action planning instructions on situation-specific and general fruit and snack intake. Appetite. 2017;108:161-70.	Wrong intervention: time-based
32	Kellar I, Abraham C. Randomized controlled trial of a brief research-based intervention promoting fruit and vegetable consumption. British Journal of Health Psychology. 2005;10(4):543-58.	Wrong intervention: time-based

33	Armitage CJ. Effects of an implementation intention-based intervention on fruit consumption. Psychology & Health. 2007;22(8):917-28.	Wrong intervention: time-based
34	de Nooijer J, de Vet E, Brug J, de Vries NK. Do Implementation Intentions Help to Turn Good Intentions into Higher Fruit Intakes? J Nutr Educ Behav. 2006;38(1):25-9.	Wrong intervention: time-based

Excluded study reports: all reasons

	Citation	**Reason(s) for exclusion**
35	Luszczynska A, Scholz U, Sutton S. Planning to change diet: A controlled trial of an implementation intentions training intervention to reduce saturated fat intake among patients after myocardial infarction. J Psychosom Res. 2007;63(5):491-7.	Wrong intervention: time-based, wrong outcome: fat intake
36	Verplanken B, Faes S. Good intentions, bad habits, and effects of forming implementation intentions on healthy eating. European Journal of Social Psychology. 1999;29(5-6):591-604.	Wrong intervention: time-based
37	Sullivan HW, Rothman AJ. When Planning Is Needed: Implementation Intentions and Attainment of Approach Versus Avoidance Health Goals. Health Psychology. 2008;27(4):438-44.	Wrong intervention: time-based
38	Sheeran P, Orbell S. Implementation intentions and repeated behaviour: Augmenting the predictive validity of the theory of planned behaviour. European Journal of Social Psychology. 1999;29(2-3):349-69.	Wrong intervention: time-based; wrong outcome: vitamin C pill
39	Kothe EJ, Mullan BA. Acceptability of a theory of planned behaviour email-based nutrition intervention. Health promotion international. 2014;29(1):81-90.	Wrong intervention: time-based; wrong outcome: feasibility study
40	Luszczynska A, Cieslak R. Mediated effects of social support for healthy nutrition: Fruit and vegetable intake across 8 months after myocardial infarction. Behav Med. 2009;35(1):30-8.	Wrong study design: not randomised trial
41	Plaete J, De Bourdeaudhuij I, Verloigne M, Crombez G. The use and evaluation of self-regulation techniques can predict health goal attainment in adults: an explorative study. PeerJ. 2016;4:e1666.	No comparator condition; wrong intervention: time-based; wrong outcome: feasibility study
42	Tam L, Bagozzi RP, Spanjol J. When Planning Is Not Enough: The Self-Regulatory Effect of Implementation Intentions on Changing Snacking Habits. Health Psychology. 2010;29(3):284-92.	Wrong intervention: time-based; wrong outcome: unhealthy snacking
43	Tapper K, Jiga-Boy G, Maio GR, Haddock G, Lewis M. Development and preliminary evaluation of an internet-based healthy eating program: randomized controlled trial. Journal of medical Internet research. 2014;16(10):e231.	Multi-BCT-program without proper control condition

44	Armitage CJ. Evidence that implementation intentions promote transitions between the stages of change. J Consult Clin Psychol. 2006;74(1):141-51.	Wrong intervention: time-based; wrong outcome: fat intake
45	Armitage CJ. Evidence That Implementation Intentions Reduce Dietary Fat Intake: A Randomized Trial. Health Psychology. 2004;23(3):319-23.	Wrong intervention: time-based; wrong outcome: fat intake
46	Allan JL, Sniehotta FF, Johnston M. The best laid plans: planning skill determines the effectiveness of action plans and implementation intentions. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine. 2013;46(1):114-20.	Wrong intervention: time-based; wrong outcome: completion of food diary
47	Gohner W, Schlatterer M, Seelig H, Frey I, Berg A, Fuchs R. Two-year follow-up of an interdisciplinary cognitive-behavioral intervention program for obese adults. Journal of Psychology: Interdisciplinary and Applied. 2012;146(4):371-91.wrog	Wrong intervention: time-based; Multi-BCT-program without proper control condition
48	Bagozzi RP, Edwards EA. Goal-striving and the implementation of goal intentions in the regulation of body weight. Special Issue: Methods and Models in Health Psychology. 2000;15(2):255-70.	Wrong study design: not randomised trial; wrong intervention: self-efficacy
49	Adriaanse MA, Gollwitzer PM, de Ridder DTD, de Wit JBF, Kroese FM. Breaking habits with implementation intentions: A test of underlying processes. Personality and Social Psychology Bulletin. 2011;37(4):502-13.	Wrong study setting: laboratory experiment; wrong outcome
50	Hopstock LA, Deraas TS, Henriksen A, Martiny-Huenger T, Grimsgaard S. Changes in adiposity, physical activity, cardiometabolic risk factors, diet, physical capacity and well-being in inactive women and men aged 57-74 years with obesity and cardiovascular risk - A 6-month complex lifestyle intervention with 6-month follow-up. PLoS One. 2021;16(8 August):e0256631.	Multi-BCT-program without control condition; unclear If-then or time-based plans; unclear if FVI assessed
51	Kothe EJ, Mullan BA, Amaratunga R. Randomised controlled trial of a brief theory-based intervention promoting breakfast consumption. Appetite. 2011;56(1):148-55.	Wrong intervention: time-based; wrong outcome: breakfast consumption
52	Verhoeven AAC, Kindt M, Zomer CL, de Wit S. An experimental investigation of breaking learnt habits with verbal implementation intentions. Acta psychologica. 2018;184:124-36.	Wrong study setting: laboratory experiment; wrong outcome
53	Churchill S, Jessop D. Spontaneous implementation intentions and impulsivity: can impulsivity moderate the effectiveness of planning strategies? British journal of health psychology. 2010;15(Pt 3):529-41.	Wrong intervention: time-based; no control condition
54	Epton T, Norman P, Dadzie AS, Harris PR, Webb TL, Sheeran P, et al. A theory-based online health behaviour intervention for new university students (U@Uni): results from a randomised controlled trial. BMC Public Health. 2014;14:563.	Multi-BCT-program without proper control

55	Anderson AS, Dunlop J, Gallant S, Macleod M, Miedzybrodzka Z, Mutrie N, et al. Feasibility study to assess the impact of a lifestyle intervention (a LivingWELL') in people having an assessment of their family history of colorectal or breast cancer. BMJ Open. 2018;8(2):e019410.	Multi-BCT-program, feasibility study; wrong outcome: fibre and fat intake
56	Cameron D, Epton T, Norman P, Sheeran P, Harris PR, Webb TL, et al. A theory-based online health behaviour intervention for new university students (U@Uni: LifeGuide): Results from a repeat randomized controlled trial. Trials. 2015;16(1):555.	Multi-BCT-program without proper control
57	Oh HJ, Larose R. Tell Me a Story About Healthy Snacking and I Will Follow: Comparing the Effectiveness of Self-Generated Versus Message-Aided Implementation Intentions on Promoting Healthy Snacking Habits Among College Students. Health Commun. 2015;30(10):962-74.	No control condition; wrong outcome: snack intake
58	Chatzisarantis NLD, Hagger MS, Wang JCK. Evaluating the effects of implementation intention and self-concordance on behavior. British Journal of Psychology. 2010;101(4):705-18.	Wrong intervention: time-based; Wrong outcome: multivitamin
59	Churchill S, Pavey L, Sparks P. The Impact of Autonomy-Framed and Control-Framed Implementation Intentions on Snacking Behaviour: The Moderating Effect of Eating Self-Efficacy. Appl Psychol Health Well Being. 2019;11(1):42-58.	No control condition; wrong outcome snack intake
60	Pirolli P, Mohan S, Venkatakrishnan A, Nelson L, Silva M, Springer A. Implementation Intention and Reminder Effects on Behavior Change in a Mobile Health System: A Predictive Cognitive Model. Journal of medical Internet research. 2017;19(11):e397.	Feasibility study; wrong outcome: reminders
61	Brittain M, Consedine N, Bagot KL, Booth N, Rodda SN. Sugar Habit Hacker: Initial evidence that a planning intervention reduces sugar intake. J. 2021;10(3):471-81.	Wrong study design; no comparator
62	Vinkers CD, Adriaanse MA, Kroese FM, de Ridder DT. Better sorry than safe: Making a Plan B reduces effectiveness of implementation intentions in healthy eating goals. Psychology & health. 2015;30(7):821-38.	Wrong study setting
63	White SC, Agurto I, Araguas N. Promoting healthy behaviors to prevent chronic disease in Panama and Trinidad & Tobago: Results of the women as agents of change project. Journal of Community Health. 2006;31(5):413-29.	Wrong study design; not RCT

Appendix 10: GRADE evidence profile

Author(s): SKM
Question: If-then planning intervention compared to control intervention for increasing fruit and vegetable intake in adults
Setting: Self-guided or assisted (face-to-face)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies (*k*)	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	If-then plans	Control intervention	Relative (95% CI)	Absolute (95% CI)		
Fruit and vegetable intake (follow-up: range 1 week to 6 months; assessed with: self-reported dietary assessment methods												
9	randomised trials	serious[a]	not serious[b]	not serious[c]	not serious[d]	none[e]	1073	791	-	SMD **0.23 SD higher** (0.09 higher to 0.39 higher)	⨁⨁⨁◯ Moderate	IMPORTANT

CI: confidence interval; **SMD:** standardised mean difference

Explanations

a. Weighted risk of bias (RoB 2) judged as 'some concerns'. Sensitivity analysis removing high risk study resulted in a similar small effect. *Risk of bias* domain assessed as 'serious' and downgraded by one level.

b. Visual inspection of forest plot reveals overlapping CI, and effect estimates are in the range from zero to moderate effect. No extreme outliers on either side of the plot. I^2 = 32%, Chi^2 and Tau^2 unsignificant (at both significance levels: p > 0.05 and p > 0.10). Overall, I judge *Inconsistency* domain as 'not serious'.
c. Overall population included in review do not sufficiently represent the 'average' adult. However, If-then planning instructions were generally similar across studies (and only studies facilitating 'If-then plans' were included). If-then plans were compared to active comparisons with some differences (which was expected). Fruit and vegetable intake was assessed in a similar way (self-reported brief dietary assessment methods). Overall, despite some indirectness I judge *Indirectness* domain as 'not serious'.
d. According to Cochrane interactive learning course > 800 participants in total indicates that there is enough 'information sources' (79). My review included 1864 participants. The direction of effect is positive (i.e., significant small effect), and there is not an indication that the intervention decreases fruit and vegetable intake. Overall, I judge *Imprecision* domain as 'not serious'.
e. No indication of publication bias based on visual inspection of funnel plot and Egger's test (*p* = .91).