

## PROSPERO International prospective register of systematic reviews

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### **Evidence from systematic reviews for the claim that weight loss is a health care intervention for overweight individuals: protocol for an overview of Cochrane reviews**

*Jörn Jaskolowski, Nicole Juul-Hindsgaul, Beverley Shea, Arne Astrup, Mike Clark, Berit L. Heitmann, Hans Lund, Robin Christensen*

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#### **Citation**

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#### **Review question(s)**

The primary objective is to determine the quality of the evidence associated with the treatment of overweight and obesity comorbidities with weight loss interventions across all available Cochrane reviews.

A secondary aim will be to identify and prioritize research aims for prospective Cochrane reviews.

#### **Searches**

We will search the electronic bibliographic databases: The Cochrane Library (Cochrane Database of Systematic Reviews).

Reviews identified in the database search will be assessed for eligibility for review by title, abstract and description/MeSH headings.

The search strategy will include terms relating to or describing weight loss or weight reduction interventions in overweight and obese individuals.

No publication date restriction will be imposed. The last search date will be January 2016.

#### **Types of study to be included**

Only systematic reviews of studies retrieved from The Cochrane Database of Systematic Reviews will be considered eligible.

#### **Condition or domain being studied**

Weight loss in overweight and obese individuals and the resulting effects on overweight-related comorbidities (incl. surrogate outcomes) (e.g. SBP, DBP, TAG, HDL, LDL, Hba1c).

#### **Participants/ population**

Overweight and obese individuals.

Exclusion criteria: participants with diagnosed eating disorders, diseases resulting in consequential weight loss (e.g. cancer), or participants taking medication that influence weight (i.e. gain) as a side effect (e.g. antidepressants).

#### **Intervention(s), exposure(s)**

Eligible systematic reviews will include studies that investigate any desired or standardized (i.e., managed) weight loss method as the exposure.

#### **Comparator(s)/ control**

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For all practical means the control will be considered as participants (overweight or obese) who did not undergo weight loss intervention.

## **Outcome(s)**

### **Primary outcomes**

Any obesity-related comorbidities (incl. surrogate outcomes) (e.g. SBP, DBP, TAG, HDL, LDL, HbA1c).

### **Secondary outcomes**

None.

## **Data extraction, (selection and coding)**

We will use a systematic, standardized data extraction approach to gather information from all eligible systematic reviews. Major outcomes will be abstracted from the overall results reported in the Cochrane reviews.

At the level of the systematic review, we will extract data on review ID (author name, year of publication), included studies, methodology and outcome.

At the trial level, we will extract trial ID (author name, year of publication), types of participants, interventions, studies types, follow-up duration, follow-up percentage, weight loss, outcomes.

Two reviewers (JJ and NJ-H) will extract data independently, any disagreements will be resolved by discussion or by involvement of a third reviewer (RC).

## **Risk of bias (quality) assessment**

AMSTAR tool

Two authors will independently assess the quality of each review using the AMSTAR tool (Shea, Hamel et al. 2009). Each of the 11 criteria will be given a rating of 'yes' (definitely done), 'no' (definitely not done), 'can't answer' (unclear if completed) or 'not applicable'. Criteria that are rated as 'not applicable' will be removed from the denominator in the overall quality ranking.

ROBIS tool

Additionally, the risk of bias for each systematic review will be independently assessed using the ROBIS tool (Smith, Devane et al. 2011). ROBIS focuses on eligibility; identification and selection; data collection and study appraisal; and synthesis in its risk of bias assessment over three phases: assessing relevance, identifying concerns about bias in the review process, and judging risk of bias, respectfully. Each of the criteria will be given a rating of 'low risk', 'high risk' or 'unclear risk'.

Discrepancies in the ratings of the methodological reviews will be resolved by consensus between the authors and, if necessary, arbitration by a third author.

Cochrane risk of bias tool

We will aim to judge risk of bias ratings for each individual randomized controlled trial assessed using the Cochrane Collaboration's tool for assessing risk of bias. Thus, studies will be classified as high, low or unclear risk of bias based on sequence generation, allocation concealment, blinding of participants/personnel and outcome assessors, incomplete outcome data, selective outcome reporting and other sources of bias.

GRADE: judging the quality of the evidence

The GRADE approach assesses the quality of a body of evidence (QoE) defined as confidence in estimates of effects of alternative management strategies. The process will involve grading QoE for all individual outcomes included deemed to be (likely) important or critical for decision making and subsequently, for use in health care recommendations, determining the overall QoE across critical outcomes.

We will evaluate the QoE for each outcome by considering the study design (randomized trials or observational studies) and then focus on eight additional domains: risk of bias, indirectness of evidence, inconsistency of evidence, imprecision of the estimated effect, likelihood of publication bias, the presence of a dose-response effect, magnitude of the estimated effect, and issues around residual confounding. After assessing all the mentioned domains, QoE per outcome will be categorized as: high, moderate, low, or very-low (QoE). The overall QoE is determined by the QoE for each of the critical outcomes in that in most instances the overall QoE will be based on the lowest QoE for any of the (critical) outcomes.

### **Strategy for data synthesis**

Presentation of results will align with guidelines in the Cochrane Handbook of Systematic Reviews of Interventions (Higgins JPT 2011) and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement (Moher, Shamseer et al. 2015). A PRISMA flow diagram will be used to summarize study selection. We will summarize the characteristics of included reviews in tables. Outcome data that is not quantitative will be descriptively reported. We will present data in tabular form. We will produce hierarchical lists of interventions ranked with consideration of the quality of the evidence, AMSTAR score and ROBIS score.

Where there are discrepancies or data queries related to included studies within the systematic reviews, we will search for and review the data that had been reported in the source article for

the included Cochrane review. We will resolve differences by discussion and consensus.

We plan to report the effects of strategies to reduce weight using relevant measures of effect and related 95% confidence intervals. However, as most findings could be poorly reported (with some reviews) not reporting effect sizes, we will report a descriptive summary of review findings taking into consideration the participants, weight loss, comparisons and outcomes assessed, and reported effect measures that are available.

### **Analysis of subgroups or subsets**

If the necessary data are available, subgroup analyses will be done for co-morbidities, intervention method, weight loss, age and gender.

### **Dissemination plans**

The conceptual framework used in this overview aim to clarify “what works for whom under which circumstances, and to what end”. Therefore it is essential that the quality of evidence is accurately assessed, as it will impact the quality of the conclusions drawn from research for treatment. This study will examine the evidence in the included Cochrane reviews of weight loss on overweight and obese individuals as a treatment of related comorbidities to explore the true implications on healthcare.

We believe that the findings of this review will have important implications for which overweight individuals – for instance in terms of concomitant morbidities - to recommend weight loss. Systematic reviews (frequently based on randomized controlled trials) provide the most reliable rationale for treating patients with overweight and obesity and their associated comorbidities.

As this study collects no primary data, no additional formal ethical assessment and informed consent are required.

### **Contact details for further information**

Nicole Juul-Hindsgaul

Praestoegade 16, st. tv.

njh@nexs.ku.dk

### **Organisational affiliation of the review**

Musculoskeletal Statistics Unit, The Parker Institute, Department of Rheumatology, Bispebjerg and Frederiksberg Hospital, The Capital Region of Denmark; Department of Nutrition, Exercise and Sports, Faculty of Life Sciences, University of Copenhagen, Frederiksberg C, Denmark

### Review team

Mr Jörn Jaskolowski, Department of Nutrition, Exercise and Sports, Faculty of Life Sciences, University of Copenhagen, Frederiksberg C, Denmark

Miss Nicole Juul-Hinds Gaul, Department of Nutrition, Exercise and Sports, Faculty of Life Sciences, University of Copenhagen, Frederiksberg C, Denmark

Professor Beverley Shea, Community Information and Epidemiological Technologies Institute of Population Health, Ottawa, Ontario, Canada

Professor Arne Astrup, Department of Nutrition, Exercise and Sports, Faculty of Life Sciences, University of Copenhagen, Frederiksberg C, Denmark

Professor Mike Clark, UK Cochrane Centre, National Institute for Health Research, Middle Way, Oxford, OX2 7LG, UK

Professor Berit L. Heitmann, Research Unit of Dietary Studies, Parker Institute, Bispebjerg and Frederiksberg Hospital, The Capital Region, Copenhagen, Denmark

Professor Hans Lund, SEARCH Research Group, Research Unit of Musculoskeletal Function and Physiotherapy, Institute of Sports Science and Clinical Biomechanics, Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark; Centre for Evidence-based Practice, Bergen University College, Norway

Professor Robin Christensen, Musculoskeletal Statistics Unit, The Parker Institute, Department of Rheumatology, Bispebjerg and Frederiksberg Hospital, The Capital Region of Denmark

### Anticipated or actual start date

05 January 2016

### Anticipated completion date

01 March 2016

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### Conflicts of interest

JJ: no disclosures of interest.

NJ-H: no disclosures of interest.

AA: Currently consultant or member of advisory boards for a number of companies, including: Global Dairy Platform, USA; McCain Foods Ltd., USA; McDonald's, USA; Weight Watchers, USA. Membership of extra-mural academic advisory committees: Data and safety monitoring board of the PREDIMED-PLUS multicenter trial led by University of Barcelona, Spain; International Carbohydrate Quality Consortium (ICQC) group, University of Toronto, Canada. Global Energy Balance Network (GEBN), University of Colorado, USA.

### Language

English

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Subject indexing assigned by CRD

### Subject index terms

Body Mass Index; Humans; Obesity; Overweight; Treatment Outcome; Weight Loss

### Stage of review

Ongoing

**Date of registration in PROSPERO**

12 January 2016

**Date of publication of this revision**

12 January 2016

<b>Stage of review at time of this submission</b>	<b>Started</b>	<b>Completed</b>
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

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