■ Living FRIendly Summaries of the Body of Evidence using Epistemonikos (FRISBEE)

## Weight loss exclusively through diet for knee osteoarthritis

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#### **Abstract**

#### Introduction

Knee osteoarthritis is a highly prevalent chronic disease, associated with various risk factors and with multiple treatment options. Overweight is among the main risk factors and also constitutes an aggravating factor of the symptoms. It has been suggested that weight loss would be able to improve symptoms and to stop the progression. It can be achieved by several methods: exercise, diet, drugs, surgery, or a combination of them. Apparently, diet is a reasonable option given its availability, low technical complexity and greater acceptability, especially in the population susceptible to developing knee osteoarthritis, but it is not clear whether the benefit of diet as the only intervention leads to symptomatic improvement.

#### Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach.

#### Results and conclusions

We identified seven systematic reviews including six primary studies overall, all corresponding to randomized trials. We concluded diet may improve functionality and quality of life, with probably minimal or no adverse effects. However, we are uncertain whether diet reduces pain as the certainty of the evidence has been assessed as very low.



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### **Problem**

Knee osteoarthritis is a highly prevalent condition produced by degeneration of the articular cartilage. It is a chronic and multifactorial disease that leads to pain, substantive functional disability and quality of life deterioration.

Among the modifiable risk factors are overweight and obesity, which, in addition to being associated with greater symptoms, contribute to progression into more severe stages. Because of the role in severity and progression of the symptoms, weight loss is recommended as a fundamental part of the treatment.

The reduction of weight would cause an improvement of the symptoms through the reduction of the mechanical stress on the joint. Additionally, it would decrease the intra-articular and serum levels of mediators such as interleukin-6 and leptin, which would be involved in the pathogenesis of the damage present in this condition.

There are different ways to achieve weight loss; currently the most recommended are diet and exercise, over drugs and surgery, mainly for its ease of implementation and lower rate of adverse effects. Exercise would also have a beneficial effect on functionality of the osteoarthritic knee, independently of the weight loss, but it presents difficulties when implemented in older patients or with clear functional limitation, so weight loss exclusively through diet could be a good alternative. Currently, there is no clarity regarding the benefit of diet as an exclusive measure to achieve symptomatic improvement in knee osteoarthritis.

## Key messages

- Weight loss exclusively through diet may improve functionality and quality of life (low certainty evidence).
- We are uncertain whether weight loss exclusively through diet reduces pain as the certainty of the evidence has been assessed as very low.
- Weight loss exclusively through diet probably has minimal or no adverse effects (moderate certainty evidence).

## About the body of evidence for this question

What is the evidence See evidence matrix in Epistemonikos later	We found seven systematic reviews <sup>1-7</sup> including six primary studies reported in 14 references <sup>8-21</sup> , of which all corresponded to randomized trials.	
What types of patients were included*	All trials included adults older than 18 years with a clinical and/or radiological diagnosis of symptomatic unilateral or bilateral knee osteoarthritis, mainly due to pain and functional limitation.	
	All trials included patients who presented some degree of overweight or obesity, with BMI values greater than 28. Two of the trials <sup>10,21</sup> recruited patients with a BMI greater than 27.	
	Three trials included patients with sedentary lifestyle <sup>8-10</sup> , while the remaining trials did not provide this information <sup>16,20,31</sup> .	
What types of interventions were included*	All trials evaluated weight loss exclusively through diet, compared mainly against placebo, exercise, other less intensive diets and healthy lifestyle education sessions.	
	One trial <sup>8</sup> evaluated a diet divided into three phases (intensive phase, transition and maintenance), each with specific goals in addition to educational sessions on healthy lifestyles.	

#### Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MED-LINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos) using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), metaanalysis of the total of studies when it is possible, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.



One trial<sup>9</sup> evaluated a diet that included the consumption of nutritional powder and weekly dietary educational sessions, compared to another diet with a higher energy content and education on a healthy diet.

One trial<sup>20</sup> evaluated a program that consisted of nutritional education and a very low energy diet (485 kcal/day), compared to a low energy diet (810 kcal/day).

In one trial<sup>10</sup>, the diet consisted of replacing regular meals of the day with meals adjusted in calories for the weight loss rate, with a goal of 10% reduction in the initial weight, compared against exercise.

One trial<sup>16</sup> evaluated a diet based on a reduction of 25% to 30% of the previous caloric level compared against placebo (they received neither diet nor exercise program).

In one trial<sup>21</sup> the diet consisted of a nutritional program for weight control, which included weekly diet diaries and information on fat intake and adequate proportions of vegetables, compared with standard care and non-specific health information.

What types of outcomes were measured The trials evaluated multiple outcomes, which were grouped by the systematic reviews as follows:

- Pain, measured through the pain subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Visual Analogue Scale (VAS) and the pain subscale of the Knee Injury and Osteoarthritis Outcome Score (KOOS)
- Functionality measured with the WOMAC physical function or KOOS function in daily living
- Quality of life, through the Short Form Health Survey (SF-36) questionnaire and its physical subscale

The average follow-up of the trials was 60 weeks with a range between 8 weeks and 18 months.

## Summary of Findings

The information on the effects of weight loss exclusively through diet in the treatment of knee osteoarthritis is based on three randomized trials<sup>8-10</sup> that included 540 patients. The remaining trials did not provide the necessary information to be included in a meta-analysis.

Two trials measured pain (240 patients)<sup>8,9</sup> using the WOMAC pain scale and Visual Analogue Scale (VAS). One trial measured functionality (80 patients)<sup>9</sup> using the WOMAC function scale. Two trials measured quality of life (693 patients)<sup>8,10</sup> through the composite SF-36 scale functional subscale. Only one trial<sup>9</sup> reported adverse effects secondary to the intervention (89 patients).

The summary of findings is as follows:

- We are uncertain whether weight loss exclusively through diet reduces pain, as the certainty of the evidence has been assessed as very low.
- Weight loss exclusively through diet may improve functionality (low certainty evidence).
- Weight loss exclusively through diet may improve the quality of life (low certainty evidence).
- Weight loss exclusively through diet probably makes little or no difference to the appearance of adverse effects (moderate certainty evidence).



<sup>\*</sup> The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

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Patients Intervention Comparison	Knee osteoarthritis Weight loss exclusively through diet No intervention			
Outcomes	Absolute effect*		Certainty of evi-	
	WITHOUT diet	WITH diet	dence (GRADE)	
Pain	Pain was on average 0.59 standard deviations better in favor of weight loss		⊕⊖⊖¹.2,3 Very low	
	SMD: 0.59 better** (Margin of error: 1.66 better to 0.47 worst)			
Functionality***	506.5 units	426.4 units	<b>##</b> 001,3	
	MD: 80.1 units less (Margin of error: 302.57 less to 142.37 more)		Low	
Quality of life (SF-36 scale physical sub- scale)****	Quality of life was on average $0.39$ standard deviations better in favor of weight loss		⊕⊕○○ <sup>1,3</sup> Low	
	SMD: 0.39 better (Margin of error: 0.24 better to 0.44 worst)			
Adverse effects	The only trial [9] that reported this outcome identified adverse effects with a low energy diet *****.		⊕⊕⊕○⁴ Moderate	

Margin of error: 95% confidence interval (CI 95%).

MD: Mean difference.

SMD: Standardized mean difference\*

Diet in knee osteoarthritis

GRADE: Grades of evidence of GRADE Working Group (see later).

- \*The score WITHOUT diet was calculated from the average of the control group of the trial. The effect was calculated from the mean difference (and its margin of error).
- \*\*The standardized mean difference is calculated when the outcome has been measured with different scales, and its clinical interpretation is difficult. It is commonly accepted that values lower than 0.2 would have little clinical relevance, values of 0.5 would have moderate relevance and values higher than 0.8 would have high relevance.
- \*\*\*This outcome was measured with the WOMAC function scale, adapting each of its 17 domains to the EVA-scale from 0 to 100, where 0 is better and 100 is worse.
- \*\*\*\* This outcome was measured with the SF-36 scale, which evaluates 36 items and assigns a score from 0 to 100, where 0 is worse and 100 is better.
- \*\*\*\*\*The adverse effects reported were constipation (11%), flatulence (9%), dizziness (5%) and greater sensitivity to cold (5%).
- <sup>1</sup> The certainty of the evidence was downgraded in one level due to risk of bias, since the studies showed moderate or high risk of bias, mainly because most of them were not blind.
- $^{2}$  The certainty of the evidence was downgraded in two levels due to inconsistency, since the trials presented different conclusions ( $I^{2}$ =93%).
- <sup>3</sup> The certainty of the evidence was downgraded in one level due to imprecision, since both extremes of the confidence interval would lead to different clinical decisions.
- $^4$  The certainty of the evidence was downgraded in one level due to imprecision, since the only trial that reported this outcome had a small sample size (n = 56).

Follow the link to access the interactive version of this table (Interactive Summary of Findings – iSoF)



# About the certainty of the evidence

## (GRADE)\*

#### $\oplus \oplus \oplus \oplus$

**High:** This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

#### $\oplus\oplus\oplus\bigcirc$

**Moderate:** This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

#### $\oplus \oplus \bigcirc \bigcirc$

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

#### $\oplus$

**Very low:** This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

- \* This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.
- † Substantially different = a large enough difference that it might affect a decision

## Other considerations for decision-making

#### To whom this evidence does and does not apply

The results are applicable to adults (over 18 years) with overweight or obesity, without differences by sex, and with clinical or radiologic diagnosis of osteoarthritis in one or both knees with associated symptoms, mainly pain and loss of function.

This evidence is not applicable to patients who have received prior surgical treatment for knee osteoarthritis or who have achieved weight loss through surgery or drug use; these patients were not included in the evaluated trials.

The available literature makes it difficult to determine the effects and to apply the information to decision-making, since there is wide variation in the diet in terms of duration and nutritional content, and there is not a common comparator among the different trials included in the reviews.

#### About the outcomes included in this summary

We decided to include pain, functionality, mobility and quality of life as outcomes given its relevance for the decision-making process of knee osteoarthritis treatment. These outcomes are easy to measure clinically and they are part of the treatment expectations for both patients and clinicians. On the other hand, we made a search of relevant outcome sets for knee and hip osteoarthritis in the COMET Initiative (Core Outcome Measures in Effectiveness Trials), where one set<sup>22</sup> included the first three outcomes selected for this summary.

Additionally, the adverse effects of the intervention were investigated, which were reported by a single trial. According to this, the risks to be expected would be constipation, flatulence, dizziness and increased sensitivity to cold.

#### Balance between benefits and risks, and certainty of the evidence

The benefit of the diet itself in these patients translates into a possible improvement in functionality and quality of life. The effect on pain is uncertain due to the limitations of the existing evidence.

The risks, with a moderate certainty of the evidence, are probably of low frequency and severity, among them constipation, flatulence, dizziness and cold intolerance. Although

there is a high degree of uncertainty, the balance between benefits and risks would be favorable for the diet in this context.

#### Resource considerations

Given the potential benefits, weighed against the slight risks described previously, it seems reasonable to consider weight loss through diet as a part of the treatment. This benefit could increase if it is associated with other measures that pursue the same objective: exercise, education, analgesia, physical therapy.

It is not possible to accurately determine the cost-effectiveness of the intervention, due to the existing uncertainty.

#### What would patients and their doctors think about this intervention

Currently, most doctors recommend comprehensive weight management through programs that include both diet and exercise. Although the recommendation is well supported, problems arise when standardizing both the diet and the exercises to be implemented. Further trials are necessary to standardize the diets that achieve some benefit, which could be implemented without associated exercise in patients limited in their ability to perform physical activity, such as the elderly or disabled.

On the other hand, the prescription of diet is not technically complex and is generally well received by overweight patients. However, the prolonged periods of time required to achieve some clinical benefit hinder the adherence.

#### Differences between this summary and other sources

The reviews included in this summary, although differ in terms of the included trials, type of diet implemented and comparison studied, coincide in the beneficial effect of weight loss through diet for some outcomes such as functionality and quality of life. The conclusion of the reviews, both those that interpreted the differences as negative (not statistically significant)<sup>3-5</sup>, and those that interpreted them as positive (statistically significant)<sup>2,6,7</sup> coincide with the conclusion of this summary: there is a possibility of benefit, but with a low certainty of evidence.



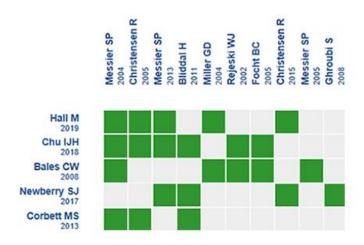
The international guidelines for knee osteoarthritis management of the American Academy of Orthopaedic Surgeons (AAOS)<sup>23</sup> recommend weight loss in symptomatic patients with a BMI greater than 25, mainly through diet associated with exercise. The recommendation of the Osteoarthritis Research Society International (OARSI)<sup>24</sup> is similar; suggesting programs for weight management in patients who have osteoarthritis of the knee and overweight, intending to achieve a reduction of 5% in 20 weeks, but in this recommendation diet alone is not mentioned as an option.

#### Could this evidence change in the future?

Future evidence is likely to change the conclusions derived from this summary, given the uncertainty that currently exists.

There are at least two reviews on this topic that are in progress<sup>25,26</sup>, registered in the International Prospective Register of Systematic Reviews (PROS-PERO).

In addition, at least two ongoing trials<sup>32,33</sup> evaluating the effect of diet alone were identified, according to the International Clinical Trials Registry Platform of the World Health Organization.



An evidence matrix is a table that compares systematic reviews that answer the same question.

Rows represent systematic reviews, and columns show primary studies. The boxes in green correspond to studies included in the respective revisions

The system automatically detects new systematic reviews including any of the primary studies in the matrix, which will be added if they actually answer the same question.

Follow the link to access the interactive version: Weight loss through diet only in knee osteoarthritis treatment.

#### Notes

The upper portion of the matrix of evidence will display a warning of "new evidence" if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier.

After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

This article is part of the Epistemonikos Evidence Synthesis project. It is elaborated with a pre-established methodology, following rigorous methodological standards and internal peer review process. Each of these articles corresponds to a summary, denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos), whose main objective is to synthesize the body of evidence for a specific question, with a friendly format to clinical professionals. Its main resources are based on the evidence matrix of Epistemonikos and analysis of results using GRADE methodology. Further details of the methods for developing this FRISBEE are described here (http://dx.doi.org/10.5867/medwave.2014.06.5997)

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database

www.epistemonikos.org.

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