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Benefit assessment of non- drug treatment strategies in patients with type 2 diabetes: increase in physical activity¹

Executive Summary

¹ Translation of the executive summary of the rapid report “Nutzenbewertung nichtmedikamentöser Behandlungsstrategien bei Patienten mit Diabetes mellitus Typ 2: Steigerung der körperlichen Aktivität” (Version 1.0; Status: 19.09.2011). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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IQWiG thanks the external reviewer for her comments on the rapid report. However, she was not involved in the preparation of the rapid report. Individual sections and conclusions in the rapid report therefore do not necessarily reflect her opinion.

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Background

The treatment of type 2 diabetes is usually started with a non-drug intervention that often includes the recommendation to change dietary habits, as well as to reduce weight and increase physical activity. If these measures do not lead to an adequate reduction in blood glucose, then pharmacotherapy can be introduced as well. Various studies have indicated that favourable effects of increased physical activity on patient-relevant outcomes are likely, but the extent to which these expected favourable effects on patient-relevant outcomes are also actually demonstrated in intervention studies remains unclear.

Aim of the investigation

The aim of this investigation was to assess, with regard to patient-relevant outcomes, the benefit of interventions for increasing physical activity compared to no such intervention in patients with type 2 diabetes.

Methods

The assessment was conducted on the basis of relevant randomized controlled trials (RCTs). For this purpose, a systematic literature search was performed in the following databases: MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials (Clinical Trials). In addition, a search for relevant systematic reviews was carried out in the databases MEDLINE, EMBASE, Cochrane Database of Systematic Reviews (Cochrane Reviews), Database of Abstracts of Reviews of Effects (Other Reviews), and the Health Technology Assessment Database (Technology Assessments). The identified systematic reviews were screened for further relevant studies. The literature search covered the period up to 6.12.2010.

Studies of at least 24 weeks examining an intervention to increase physical activity in adult patients with type 2 diabetes were included. Studies were excluded in which the increase in physical activity as a primary intervention was compared to another antidiabetic treatment as a primary intervention (e.g. increased physical activity versus diet or blood glucose-lowering drugs).

The following outcomes were pre-defined in the rapid report: “all-cause mortality”, “cardiovascular mortality”, “cardiovascular morbidity”, “health-related quality of life”, “end-stage renal disease”, “amputations”, “blindness or vision-relevant retinal changes”, “severe hypoglycaemia”, and “other adverse events” such as problems of the musculoskeletal system.

Results

Nine relevant RCTs were identified by the systematic literature search, of which 2 were excluded from the assessment on methodological grounds. Ultimately, 7 studies were used for the benefit assessment. Six studies investigated the effect of a supervised training programme lasting several weeks or months and 1 study investigated independent, home-based training.

The study populations consisted of persons with a mean age of about 60 years and a mean Body Mass Index (BMI) of more than 30 kg/m². The studies lasted 6 to 24 months. In most

cases, the results were considered to have a high risk of bias; only in 1 study was the risk of bias rated as low.

The included RCTs provided no, or only insufficient, results on the patient-relevant outcomes “all-cause mortality”, “cardiovascular mortality and morbidity”, “end-stage renal disease”, “amputations”, “blindness” and “severe hypoglycaemia”, so that an assessment of the benefit or harm of an increase in physical activity in patients with type 2 diabetes was not possible for these outcomes.

Four of the 7 studies contained information about the outcome “health-related quality of life”. No study reported a statistically significant effect. Overall, there was neither proof nor an indication of a benefit or harm from increased physical activity for this outcome.

Results on the outcome “other adverse events” were available from 6 studies. However, due to incomplete information in 4 of these studies, a group comparison was only possible for 2 RCTs, in which no statistically significant differences between the study groups were found. Hence, neither proof nor an indication of a benefit or harm from increased physical activity could be derived in respect of this outcome.

Conclusions

No studies are available that provide sufficient data to assess the benefit of interventions to increase physical activity in patients with type 2 diabetes regarding the patient-relevant outcomes “all-cause mortality”, “cardiovascular mortality and morbidity”, “end-stage renal disease”, “amputations”, “severe hypoglycaemia”, and “blindness or vision-relevant retinal changes”. There is also no indication or proof of an effect on the patient-relevant outcomes “health-related quality of life” or “other adverse events”.

Therefore, from the existing studies, there is neither proof nor an indication of a benefit or harm from increased physical activity in patients with type 2 diabetes with regard to the patient-relevant outcomes investigated.

Keywords: diabetes mellitus – type 2, physical education and training, exercise, exercise therapy, benefit assessment, systematic review

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