Cost-effectiveness of lifestyle counselling as primary prevention of gestational diabetes mellitus: findings from a cluster-randomised trial

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study assessed the cost-effectiveness of intensive counselling on diet and physical activity to prevent gestational diabetes mellitus, in pregnant women aged 40 years or older with one or more risk factor. The authors concluded that the intervention was effective for birth weight, but not cost-effective. There were limitations in the measurement of patient benefits, and the study was not long enough to capture the long-term effects of the intervention. The results should be used with caution.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study assessed the cost-effectiveness of intensive counselling on diet and physical activity to prevent gestational diabetes mellitus, in pregnant women aged 40 years or older with one or more risk factor for diabetes.

Interventions
The intervention was five boosted visits during the recommended 11 to 15 antenatal visits received between weeks eight to 12 and 37 of gestation. The visits were conducted by public health nurses, who focused on physical activity, diet, personal goals and appropriate gestational weight gain. Programmes were customised to each patient. All patients were offered five physiotherapist-led exercise theory and practice sessions. The control group received routine care, which included some dietary and physical-activity counselling in accordance with national guidelines.

Location/setting
Finland/public health.

Methods
Analytical approach:
The economic evaluation was based on a cluster-randomised trial conducted between 2007 and 2009 in Finland. The time horizon was from eight to 12 weeks gestation until discharge from hospital after birth. The stated perspective was societal.

Effectiveness data: The trial included 399 patients from 14 maternity clinics. These clinics were matched into pairs, for randomisation, based on the number of births, socioeconomic status of patients, incidence of gestational diabetes, and size of the area's population. The effectiveness of the intervention was measured by the child's birth weight, in grams of weight avoided. This was from the maternity cards of patients in the trial and Finnish registry data. Other trial outcomes were physical activity, and quality of life on the 15D questionnaire and on the 10cm visual analogue scale (VAS). These questionnaires were completed by the women at eight to 12 weeks and 36 to 37 weeks of gestation.

Monetary benefit and utility valuations: Patients valued their utility using the 15D health-related quality of life questionnaire. Missing utility data were imputed using multivariate linear regression.

Measure of benefit:
The mean birth weight and perceived health and quality of life were the measures of benefit.

Cost data:
The analysis included the hospital costs of in-patient and out-patient days, delivery, medical salaries, administration and neonatal care; the intervention costs of nurse and physiotherapist time; and productivity lost. All cost items were measured in the trial. Resource use was from nurse and patient reports, and medical registers. The hospital costs were Finnish national averages from the hospital where 91% of infants were delivered. Productivity lost was recorded on questionnaires completed by the patients every trimester. Patient salaries were based on national averages multiplied by 1.3 to include related expenses. All costs were presented in 2009 Euros (EUR).

Analysis of uncertainty:
Bootstrapping was used to estimate the uncertainty around the costs, and confidence intervals around the incremental cost-effectiveness ratios, as well as to conduct probabilistic sensitivity analysis. The methods adjusted for the effects due to cluster randomisation. The results of the probabilistic sensitivity analysis were presented on cost-effectiveness planes and in cost-effectiveness acceptability curves. Sensitivity analysis assessed the effect of doubling the intervention costs. A subgroup of women who complied with the programme was analysed.

**Results**
The mean cost per person was EUR 7,763 (SD 4,511) with the intervention and EUR 6,994 (SD 4,326) with usual care; a mean difference of EUR 769 (p=0.14). The mean birth weight was 3,521g (SD 545) with the intervention and 3,636g (SD 500) with usual care; a mean difference of 115g (p=0.025). There were no statistically significant differences in the scores on the 15D and the VAS.

The incremental cost-effectiveness ratio for the intervention versus usual care was EUR 6.54 per gram of birth weight avoided, EUR 62.285 per point increase in 15D score, or EUR 1,697 per VAS cm improvement.

The cost-effectiveness planes showed that between 62% and 87% of simulations indicated that the intervention was more costly and more effective. Doubling the intervention costs increased the incremental cost-effectiveness ratios. For the subgroup of 55 adherent women, the intervention was less costly and more beneficial (dominant) for all outcome measures.

**Authors' conclusions**
The authors concluded that the intervention was effective for birth weight, but not cost-effective for any of the outcomes, compared with usual care.

**CRD commentary**
**Interventions:**
The intervention and comparator were well reported and appear to have been appropriate.

**Effectiveness/benefits:**
The effectiveness data were clearly reported. The birth weight that was considered a clinically significant risk for the child was not clear, making it unclear if the results were clinically meaningful. The authors noted that the outcome measures were only collected at the beginning and end of pregnancy, and no data on the intensity of physical activity were collected. The utilities from the 15D questionnaire could have been converted to quality-adjusted life-years, which would have allowed comparisons with other economic evaluations. Care should be taken when interpreting the 15D results, as they do not appear to account for patient time in each health state, so they were a limited analysis of quality of life.

**Costs:**
The cost categories and results were well reported. No resource use data were reported, which reduces the transparency and reproducibility of the analysis. The costs were from appropriate sources, which were specific to the Finnish setting; care should be used if generalising these results to other settings. Patient travel expenses and time costs were assumed to be minimal and excluded from the analysis; the validity of this assumption is unclear.

**Analysis and results:**
The results were from a randomised controlled trial, which was the gold-standard design and should minimise the risk of bias. The randomisation and techniques were used to control for clustering effects appear to have been appropriate. Appropriate sensitivity analyses were conducted. The authors imputed missing data, but only for patients with data for at least nine dimensions of the 15D. They acknowledged that the amount of missing data could have biased the results. The costs differed for each outcome, based on the number of patients with outcome data; the same cost (using all available data) could have been used for all of the cost-effectiveness ratios. The authors acknowledged that the short time horizon was insufficient to capture long-term costs and benefits, so the results are unlikely accurately reflect long-term cost-effectiveness. Care should be taken when generalising the results to all pregnant women, as inclusion was limited women who were at risk.

Concluding remarks:
The study was generally well reported, but there were limitations in the measurement of patient benefits, and the study was not long enough to capture the long-term effects of the intervention. The results should be used with caution.

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