ARMMS-T2D

CLINICAL TRIAL SUMMARY

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Objectives	To assess the efficacy of bariatric surgery compared to medical/lifestyle management of type 2 diabetes

https://clinicaltrials.gov/study/NCT02328599

TRIAL DESIGN

Randomized, Prospective Cohort Study

SAMPLE SIZE

228 individuals with type 2 diabetes and obesity

INCLUSION CRITERIA

- Age between 20 and 65 years
- BMI over 27 and up to 45 kg/m²
- Diagnosed with type 2 diabetes based on ADA criteria (elevated HbA1c, fasting glucose, OGTT, or diabetes medication use)
- Negative pregnancy test before surgery for women who can become pregnant

METHODOLOGY

- Researchers evaluated 228 adults with type 2 diabetes and obesity from the ARMMS-T2D study, randomly assigned to metabolic bariatric surgery (Roux-en-Y gastric bypass, sleeve gastrectomy, or gastric band; n = 152) or medical/lifestyle intervention (n = 76).

- Health-related quality of life (SF-36: Physical and Mental Component Scores) and health utility (SF-6D) were assessed annually for up to 12 years.

RESULTS

At baseline, participants had a mean age of 49.2 ± 8.0 years; 68.4% were female, with a BMI of 36.3 ± 3.4 kg/m² and HbA1c of 8.7 ± 1.6%.

Over 12 years, physical health (PCS) improved significantly more in the metabolic bariatric surgery (MBS) group than in the medical/lifestyle intervention (MLI) group (+2.37 ± 0.53 vs. −0.95 ± 0.73; difference 3.32 ± 0.85; $P < 0.001$).

MBS led to greater gains in general health ($P < 0.001$), physical functioning ($P = 0.001$), and vitality ($P = 0.003$). BMI reduction was more substantial in the MBS group ($P < 0.001$) and was moderately associated with PCS improvement ($r = −0.43$; $P < 0.001$), while changes in HbA1c showed no such association.

Mental health scores (MCS) changed minimally and were similar between groups (−0.21 ± 0.61 vs. −0.89 ± 0.84; difference 0.68 ± 0.97; $P = 0.48$). Health utility (HU) also improved more in the MBS group (+0.02 ± 0.01 vs. −0.01 ± 0.01; difference 0.03 ± 0.01; $P = 0.003$).

CONCLUSION

Metabolic surgery leads to long-term weight loss and greater improvements in physical health, general well-being, physical functioning, vitality, and health utility compared to medical therapy in people with type 2 diabetes and obesity, lasting up to 12 years post-intervention.

Simonson DC, Gourash WF, Arterburn DE, et al, Courcoulas AP, Vernon AH, Jakicic JM, Kirschling S, Aminian A, Schauer PR, Kirwan JP. Health-Related Quality of Life and Health Utility After Metabolic/Bariatric Surgery Versus Medical/Lifestyle Intervention in Individuals With Type 2 Diabetes and Obesity: The ARMMS-T2D Study. Diabetes Care. 2025 Apr 1;48(4):537-545. doi: 10.2337/dc24-2046. PMID: 39903478; PMCID: PMC11932816.