

The Fasting Hyperglycaemia Study: II. Randomized controlled trial of reinforced healthy-living advice in subjects with increased but not diabetic fasting plasma glucose.

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Self-referred subjects (N = 227) thought to be at risk of developing non-insulin-dependent diabetes mellitus (NIDDM) and with fasting plasma glucose (FPG) in the range of 5.5 to 7.7 mmol.L⁻¹ on two consecutive tests 2 weeks apart were randomized to reinforced or basic healthy-living advice. They were simultaneously allocated either to a sulfonylurea group or a control group in a two-by-two factorial design. A total of 201 subjects in three English and two French centers completed 1 year's follow-up study. Reinforced advice recommending dietary modification and increased exercise was given every 3 months, and basic advice was given once at the initial visit. Glycemia was monitored by FPG, dietary compliance by body weight and food diaries, and fitness compliance by bicycle ergometer assessment and exercise diaries. Both reinforced and basic advice groups had a significant mean reduction in body weight (1.5 kg) at 3 months, although the weight subsequently returned to baseline. After 1 year, subjects allocated to reinforced advice versus basic advice (1) reported a lower fat intake (34.1% v 35.8%, P = .04) with no difference in lipid profiles, (2) had improved fitness as shown by increased calculated maximal oxygen uptake ([Vo₂max] 2.39 v 2.18 L.min⁻¹, P = .007) with no change in insulin sensitivity, (3) showed no change in FPG, glucose tolerance, or hemoglobin A1c (HbA1c), and (4) showed a greater tendency to withdraw from the study (16% v 7%, P = .03). In conclusion, reinforced healthy-living advice given to self-referred subjects with increased FPG did not encourage sufficiently pronounced life-style changes for significantly greater effects on body weight and glycemia in a 1-year study than basic healthy-living advice.