

## Behavioural approaches to weight loss

Obesity and its cardiovascular complications are extremely common medical problems, but evidence on how to accomplish weight loss in clinical practice is sparse.

The authors conducted a randomised, controlled trial to examine the effects of two behavioural weight-loss interventions in 415 obese patients with at least one cardiovascular risk factor. Participants were recruited from six primary care practices; 63.6% were women, 41.0% were black, and the mean age was 54.0 years. One intervention provided patients with weight-loss support remotely – through the telephone, a study-specific website, and e-mail. The other intervention provided in-person support during group and individual sessions, along with the three remote means of support. There was also a control group in which weight loss was self-directed. Outcomes were compared between each intervention group and the control group and between the two intervention groups. For both interventions, primary care providers reinforced participation at routinely scheduled visits. The trial duration was 24 months.

At baseline, the mean body mass index (the weight in kilograms divided by the square of the height in metres) for all participants was 36.6, and the mean weight was 103.8 kg. At 24 months, the mean change in weight from baseline was –0.8 kg in the control group, –4.6 kg in the group receiving remote support only ( $p < 0.001$  for the comparison with the control group), and –5.1 kg in the group receiving in-person support ( $p < 0.001$  for the comparison with the control group). The percentage of participants who lost 5% or more of their initial weight was 18.8% in the control group, 38.2% in the group receiving remote support only, and 41.4% in the group receiving in-person support. The change in weight from baseline did not differ significantly between the two intervention groups.

In two behavioural interventions, one delivered with in-person support and the other delivered remotely, without face-to-face contact between participants and weight-loss coaches, obese patients achieved and sustained clinically significant weight loss over a period of 24 months.

Appel LJ. *N Engl J Med* 2011;365:1959-1968.

## Cardiovascular biomarkers not as useful as some think they are

This study compared the reported effect sizes of cardiovascular biomarkers in datasets from observational studies with those in

datasets from randomised controlled trials using a review of meta-analyses.

Meta-analyses of emerging cardiovascular biomarkers (not part of the Framingham risk score) that included datasets from at least one observational study and at least one randomised controlled trial were identified through Medline (last update, January 2011).

Study-specific risk ratios were extracted from all identified meta-analyses and synthesised with random effects (*i*) for all studies; and (*ii*) separately for observational and for randomised controlled trial populations for comparison.

Thirty-one eligible meta-analyses were identified. For seven major biomarkers (C-reactive protein, non-HDL cholesterol, lipoprotein (a), post-load glucose, fibrinogen, B-type natriuretic peptide, and troponins), the prognostic effect was significantly stronger in datasets from observational studies than in datasets from randomised controlled trials. For five of the biomarkers the effect was less than half as strong in the randomised controlled trial datasets. Across all 31 meta-analyses, on average datasets from observational studies suggested larger prognostic effects than those from randomised controlled trials; from a random effects meta-analysis, the estimated average difference in the effect size was 24% (95% CI 7 - 40%) of the overall biomarker effect.

Cardiovascular biomarkers often have less promising results in the evidence derived from randomised controlled trials than from observational studies.

Tzoulaki I, Siontis KCM, Ioannidis JPA. *BMJ* 2011; 343 doi: 10.1136/bmj.d6829 (published 7 November 2011). Cite this as: *BMJ* 2011;343:d6829.

## Routine laboratory monitoring improves health and survival compared with clinical monitoring of HIV patients in Uganda

This study evaluated the use of routine laboratory monitoring in terms of clinical outcomes among patients receiving antiretroviral therapy (ART) in Uganda using a randomised clinical trial in a home-based ART programme in rural Uganda.

All participants were people with HIV who were members of the AIDS Support Organisation. Participants had CD4 cell counts  $< 250 \text{ cells} \times 10^6/\text{l}$ .

Participants were randomised to one of three different monitoring arms: a viral load arm

(clinical monitoring, quarterly CD4 counts, and viral load measurements), CD4 arm (clinical monitoring and CD4 counts), or clinical arm (clinical monitoring alone). The main outcome measures were serious morbidity (newly diagnosed AIDS-defining illness) and mortality.

A total of 1 094 participants started ART; median CD4 count at baseline was 129 cells  $\times 10^6/\text{l}$ . Median follow-up was three years. In total, 126 participants died (12%), 148 (14%) experienced new AIDS-defining illnesses, and 61 (6%) experienced virological failure, defined as two consecutive viral loads  $> 500 \text{ copies/ml}$  occurring more than three months after the start of ART. After adjustment for age, sex, baseline CD4 count, viral load, and body mass index, the rate of new AIDS-defining events or death was higher in the clinical arm than the viral load arm (adjusted hazard ratio 1.83,  $p = 0.002$ ) or the CD4 arm (1.49,  $p = 0.032$ ). There was no significant difference between the CD4 arm and the viral load arm (1.23,  $p = 0.31$ ).

In patients receiving ART for HIV infection in Uganda, routine laboratory monitoring is associated with improved health and survival compared with clinical monitoring alone.

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