Weight loss in a commercial setting

Susan Jebb and colleagues (Oct 22, p 1485)[1] report on weight loss in a commercial setting versus standard care. Unfortunately, as they mention, dropout rates were very high. This problem was remedied by presenting baseline observation carried forward (BOCF) and last observation carried forward (LOCF) analyses. However, these analyses could have distorted the results, since in the LOCF analysis any weight gain after the last weighing was ignored. Additionally, in the BOCF analysis all people who gained more weight than they lost with respect to baseline weight were ignored. As a result, overestimation of the effect of the sponsored weight loss programme might have occurred.

Furthermore, the baseline characteristics of the 42% of people who withdrew were not compared with those of the individuals who completed the intervention. If these groups could be identified in general practice, we might be able to assess whether an intervention like this would be useful for a particular individual.

We declare that we have no conflicts of interest.

*Theun A Hoeven, Bastiaan C de Vos
t.hoeven@erasmusmc.nl

Department of General Practice, Erasmus MC, University Medical Centre Rotterdam, 3000 CA Rotterdam, Netherlands

1 Jebb SA, Ahern AL, Olson AD, et al. Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial. *Lancet* 2011; **378:** 1485–92.

Authors' reply

Weight-loss studies have large dropout rates compared with studies of other areas. We factored in the usual level of attrition and recruited sufficient participants to ensure enough power for statistical analysis.

Handling of missing data in weight-loss studies is an ongoing debate. All methods make assumptions about what happens to participants' weight after they drop out from the study. We reported the results of each of three analysis methods typically used in weight-loss studies. We did not present these results as a solution to the missing data problem, but as part of a sensitivity analysis to show that the results are robust to different assumptions about the missing data. We have subsequently done an analysis under the assumption of missing at random, using a mixed effects model, and found the treatment effect to lie between the published analyses of completers and the baseline carried forward method.

Our paper reported the results in a way that allows the reader to do further sensitivity analyses. For example, taking the reported results and assuming that a person who dropped out gained x kg, the mean weight loss in the commercial programme becomes (–4·06+0·39x) kg and in the standard care group (–1·77+0·46x) kg, with a mean difference between the commercial programme and standard care of (–2·29–0·068x) kg. From this formula, the baseline carried forward analysis assumes a return to baseline and sets x to be 0 kg, which gives an average treatment effect of –2·29 kg (as reported in our paper). When patients who drop out actually gain 3 kg, the treatment effect is larger at –2·49 kg (–2·29–[0·068×3 kg]). Clearly, as the weight rebound gets larger, so does the apparent effectiveness of the commercial programme over standard care. The treatment effect gets smaller when we assume that the weight of dropouts is below baseline at the end of the study and would be 0 if the dropouts lost 33 kg at 12 months; but this level of bias is implausible.

Accordingly, our conclusion that the commercial programme is more effective than standard care is robust to a large range of assumptions. We agree that the baseline characteristics of the people who withdrew are of interest, but not to explain whether the treatment is effective. To reverse the conclusions of this study would require assumptions such as differential dropout bias in the two groups, and such an assumption seems unwarranted.

We declare that we have no conflicts of interest other than those stated in the original paper.

*A P Mander, A L Ahern, I D Caterson, H Hauner, *S A Jebb*
susan.jebb@mrc-hnr.cam.ac.uk

MRC Biostatistics Unit, Cambridge, UK (APM); MRC Human Nutrition Research, Cambridge CB1 9NL, UK (ALA, SAJ); Boden Institute of Obesity, Nutrition, Exercise and Eating Disorders, University of Sydney, Sydney, NSW, Australia (IDC); and Else Kroener-Fresenius-Centre for Nutritional Medicine, Faculty of Medicine, Technische Universität München, Munich, Germany (HH)

Avahan and impact assessment

AFP/Getty Images

Marie Ng and colleagues (Nov 5, p 1643),[1] in their paper on the assessment of impact of the Avahan HIV prevention programme, state: "the lack of a comprehensive, randomised, prospective assessment of the programme on HIV incidence is notable". Are Ng and colleagues suggesting that Avahan—one of the world's largest HIV prevention programmes, and one based on proven targeted interventions—should have been implemented in a randomised way?

In their accompanying Comment,[2] Ties Boerma and Isabelle de Zoysa state that: "the rapid rollout and ethical discussions in India left no room for randomisation of districts". Avahan clearly could not have been implemented easily in a randomised way, but we think it *should* not have been either. It would never have reached the high levels of coverage of essential prevention tools and services for key populations in such a short time. Nor would it have been able to allow for context-specific, community-led responses, which vary in nature and intensity between districts. And it would not have been able to apply one of its strongest assets—regular programme review and adjustments based on monitoring data from all levels. Avahan used approaches with known effectiveness, tailored to the

Indian epidemic. The assessment plan included a series of biobehavioural population-based surveys, in addition to data from mixed methods.[3] Triangulation and modelling allowed the construction of a plausible case for success for this flagship programme.

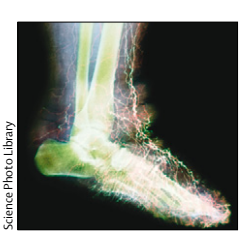
Imposition of the randomised implementation of large-scale HIV prevention programmes so that impact can be assessed is worrisome,[4] especially if such a design leads to slower scale-up or more narrow programme packages. We recognise the need for more prospective assessments of programmes, but reject the idea of randomised designs as the only way to document impact. National programmes such as tobacco control or road trauma prevention are not randomised, because they simply can't be.

We declare that we have no conflicts of interest.

*Marie Laga, Rob Moodie
mlaga@itg.be

Institute of Tropical Medicine, 2000 Antwerp, Belgium (ML); and Nossal Institute for Global Health, Melbourne, VIC, Australia (RM)

1 Ng M, Gakidou E, Levin-Rector A, Khera A, Murray CJL, Dandona L. Assessment of population-level effect of Avahan, an HIV-prevention initiative in India. *Lancet* 2011; **378:** 1643–52.
2 Boerma T, de Zoysa I. Beyond accountability: learning from large-scale evaluations. *Lancet* 2011; **378:** 1610–12.
3 Chandrasekaran P, Dallabetta G, Loo V, et al. Evaluation design for largescale HIV prevention programmes: the case of Avahan, the India AIDS Initiative. *AIDS* 2008; **22:** S1–15.
4 Padian NS, Holmes CB, McCoy SI, Lyerla R, Bouey PD, Goosby EP. Implementation science for the US President's Emergency Plan for AIDS Relief (PEPFAR). *J Acquir Immune Defic Syndr* 2011; **56:** 199–203.



Science Photo Library

See Perspectives page 996

For the **WHO focus on podoconiosis** see http://www.who.int/neglected_diseases/diseases/podoconiosis/en/

Launch of the International Podoconiosis Initiative

In the past 5 years, important progress in podoconiosis research and control has been made. The global distribution of this ascending, geochemical lymphoedema has been updated, advances have been made in disease assessment and treatment, and advocacy has successfully brought podoconiosis to the global stage. We highlight some of this progress here, and announce the launch of a new international initiative.

Wanji and colleagues[1] and Ruberanziza and colleagues[2] have shown elephantiasis in the absence of filarial parasites during mapping in Cameroon and Rwanda, respectively. A new staging system for podoconiosis has been developed and validated, and used to assess the simple treatment regimen developed by a patient-led and community-based control programme in southern Ethiopia.[3] Ethical approaches to research in the remote communities in which podoconiosis patients are usually found have been developed,[4] and issues related to community attitudes, quality of life, and stigma have been documented.[5] Ongoing research in Ethiopia and Cameroon aims to identify the locus of a susceptibility gene and to characterise the minerals that trigger podoconiosis. Other studies are investigating immunological changes associated with podoconiosis, documenting overlaps with other common tropical diseases, and exploring behavioural issues that will be vital to understand as prevention programmes increase shoe distribution to high-risk children.

Much progress has also been made in terms of disease advocacy: in February, 2011, WHO included podoconiosis in its list of neglected tropical diseases (NTDs). A page focusing on the disease is available on the WHO website. On Nov 12, 2011, the first General Assembly of the Ethiopian National Podoconiosis Action Network (NaPAN) was held. The meeting brought together researchers, policy makers, clinicians, and representatives of all the groups now offering care to patients with podoconiosis in Ethiopia. NaPAN seeks to help these groups share expertise and translate research into practice, with the aim that, eventually, all patients can access treatment, and residents of all endemic areas can prevent new disease through use of shoes.

Most recently, we met to plan the public launch of "Foot*work*", the International Podoconiosis Initiative. Foot*work* aims to bring together public and private partners to prevent and treat podoconiosis, integrating control with that of other NTDs in areas of co-endemicity, and partnering with organisations that work in foot-related disorders to advocate for shoes as "the new bednets". We look forward to welcoming new partners to this group, and, further in the future, to a world free of podoconiosis.

We declare that we have no conflicts of interest.

*Gail Davey, Moses Bockarie, Samuel Wanji, David Addiss, Claire Fuller, LeAnne Fox, Mike Mycoskie, Mark Gruin, Aster Tsegaye, Fasil Tekola Ayele, Melanie Newport
g.davey@bsms.ac.uk

Brighton & Sussex Medical School, University of Sussex, Brighton BN1 9PS, UK (GD, MN); Liverpool School of Tropical Medicine, Liverpool, UK (MB); Research Foundation for Tropical Disease & Environment, Buea, Cameroon (SW); Children Without Worms, Decatur, GA, USA (DA); International Foundation for Dermatology, London, UK (CF); Centers for Disease Control and Prevention, Atlanta, GA, USA (LAF); TOMS Shoes Inc, Santa Monica, CA, USA (MM); International Orthodox Christian Charities, Baltimore, MD, USA (MG); Addis Ababa University, Addis Ababa, Ethiopia (AT); and National Institutes of Health, Bethesda, MD, USA (FTA)

1 Wanji S, Tendongfor N, Esum M, et al. Elephantiasis of non-filarial origin (podoconiosis) in the highlands of north-western Cameroon. *Ann Trop Med Parasitol* 2008; **102:** 1–12.
2 Ruberanziza E, Mupfasoni D, Karibushi B, et al. Mapping of lymphatic filariasis in Rwanda. *J Lymphoedema* 2009; **4:** 20–23.
3 Sikorski C, Ashine M, Zeleke Z, Davey G. Effectiveness of a simple lymphoedema treatment regimen in podoconiosis management in southern Ethiopia: one year follow-up. *PLoS Neglect Trop Dis* 2010; **4:** e902.
4 Tekola F, Bull S, Farsides B, et al. Tailoring consent to context: designing an appropriate consent process for a biomedical study in a low income setting. *PLoS Neglect Trop Dis* 2009; **3:** e482.
5 Yakob B, Deribe K, Davey G. High levels of misconceptions and stigma in a community highly endemic for podoconiosis in southern Ethiopia. *Trans R Soc Trop Med Hyg* 2008; **102:** 439.