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1 **Keep it off! Maintenance is the real challenge, to benefit from**  
2 **improved weight loss methods**

3 'Comment' piece, requested by The Lancet, on the obesity treatments and lack of existing evidence  
4 around approaches for maintaining weight loss.

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9

10 The world's first evidence-based national obesity guideline<sup>1</sup> recognised that, in addition to effective  
11 government interventions for prevention, support is needed for individuals, both for weight loss and  
12 weight maintenance, for which interventions may differ. Both physiological adaptations (reducing  
13 metabolic rate and increasing appetite), and persisting obesogenic environments contribute to  
14 regain<sup>2</sup>. However, despite popular beliefs, rebound regain to exceed the starting weight is  
15 uncommon<sup>3</sup>. Most obese people know how to lose weight and identify the most difficult problem as  
16 keeping it off<sup>4</sup>. A systematic review of psychological evidence has highlighted the very high level of  
17 stress experienced by those attempting to prevent weight regain<sup>5</sup>. The greatest need is support for  
18 long-term weight loss maintenance; rather little is currently on offer and no underpinning  
19 theoretical models exist, other than relapse-prevention and correction.

20 Weight maintenance is the Cinderella component of weight management (Figure 1). Colossal  
21 amounts are spent on research, drug development and healthcare for the multiple medical  
22 complications of overweight and obesity. Spending on 'obesity treatment' has principally been for  
23 weight loss, but weight-loss maintenance, the greatest need, has attracted minimal spending.  
24 Neither FDA in US nor EMA in Europe have ever approved weight-loss maintenance, as a treatment  
25 indication. Medications should only be employed as adjuncts to diet and lifestyle programmes.  
26 Legitimising their use for those who struggle to sustain major weight loss would help to shift  
27 attention to the general need for evidence-based weight-loss maintenance programmes. That  
28 would also justify more intensive interventions for greater weight loss, in line with consumer wishes.

29

30 Maintenance only makes sense after effective weight loss. Recent guidelines have promoted  
31 bariatric surgery for severe obesity and diabetes, assuming it offers a permanent solution<sup>6</sup>, but  
32 'metabolic surgery' does not alter metabolism sufficiently to eat freely without weight regain.  
33 Assuming that massive weight loss is better than more moderate loss, most patients suffer

34 complications, serious enough to require further surgical procedures (at least 5%)<sup>7</sup>. That adverse-  
35 event rate would be unacceptable for drug licencing, though most eligible patients actually reject  
36 surgery<sup>8</sup>. Modern anti-obesity medications are safe and effective, together with a good diet  
37 programme, but weight regain occurs soon after stopping. There is a need for new non-surgical  
38 approaches to maximise acute phase weight loss. The most efficient weight loss method currently is  
39 a period of 'Total Diet Replacement' (TDR) using nutritionally-complete low-energy formula diets<sup>9</sup>.  
40 These were scorned in the past and misconceptions need to be resolved<sup>5</sup>. Thus, rapid early loss  
41 leads to less regain and better long-term results<sup>10</sup>. Results are the same with a safer, better  
42 tolerated, 800-820kcal/day TDR as a VLCD<sup>9</sup>. Medical supervision is needed to reduce or withdraw  
43 medications for diabetes and hypertension. Adverse events are uncommon with modern formula  
44 diets, but regulation is important to ensure that products and programmes are evidence-based and  
45 will optimise nutritional status and subsequent maintenance. Currently there is confusion resulting  
46 from extrapolation of non-specific evidence. A recent European Food Safety Agency report<sup>11</sup> has  
47 inexplicably required formula diets to: a) include choline (which is not accepted as required from  
48 foods by adult humans, and in excess may aggravate heart disease, b) reduce magnesium  
49 (potentially aggravating type 2 diabetes, c) increase protein to twice the minimum requirement of  
50 healthy weight-stable adults. This neglects the reduced protein requirement during weight loss, and  
51 makes products unpalatable. These measures seem misguided, given the good results, without  
52 clinical problems, using existing TDR<sup>9</sup>. The focus should be on improving maintenance, where  
53 greater protein intakes and physical activity may contribute.

54 With well-conducted studies consistently achieving mean weight losses of 12-17 kg using TDR,  
55 optimising support for long-term maintenance is vital. Programmes will always be multicomponent,  
56 comprising diet, physical activity, pharmacotherapy and surgery, but never strictly prescriptive.  
57 Emphasis will vary according to individual skills and preferences. Effective supports to improve  
58 maintenance include tailored diet and exercise approaches, behavioural and psychological  
59 techniques, meal replacements, and anti-obesity drugs<sup>12</sup>. The US National Weight Control Registry,  
60 comprising individuals who had lost at least 10% body weight has attributed avoidance of regain  
61 over 5 years to low fat (25% energy) diets, and regular physical activity, equivalent to 1 hour of  
62 moderate intensity activity daily. More disciplined meal patterns, consistent across weekdays and  
63 weekends, and self-monitoring of weight, also contributed. Physical activity contributes more  
64 towards maintenance than weight loss, but permanent changes in eating habits are vital.  
65

66 To generate the best results for the greatest number of patients, programmes must be attractive  
67 (effective, to meet consumer expectations), flexible for real-world use, and then affordable and cost-  
68 effective for health services. Not all succeed, but to establish weight maintenance as a clinical goal,  
69 agreed success criteria are needed. Arbitrary figures, eg <3% regain, have been widely used. More  
70 clinically relevant, metabolic benefits from weight loss in type 2 diabetic patients in LookAHEAD  
71 were retained at >10% below initial weight, with <1.5% regain from post-loss weight, and ≥50% of  
72 initial loss. The only known predictor of long-term maintenance results being early loss, ‘stopping-  
73 rules’ using cut-offs of inadequate early weight loss could avoid wasting effort and funds, and  
74 redirect those patients elsewhere. New non-surgical approaches are needed and as with any service  
75 development, maintenance programmes can be improved using closed-loop audit and Continuous  
76 Improvement Methodology, without needing costly, time-consuming, randomised trials.

77 Word count 895

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## 79 **Declarations of Interest**

80 The authors received no fees or other inducements to write this Comment. Professor Lean reports research  
81 grants and personal fees from Novo Nordisk, non-financial support from Cambridge Weight Plan, grants from  
82 Diabetes UK, personal fees from Orexigen and Counterweight Ltd, outside the submitted work. Dr Hankey  
83 reports no interests.

84

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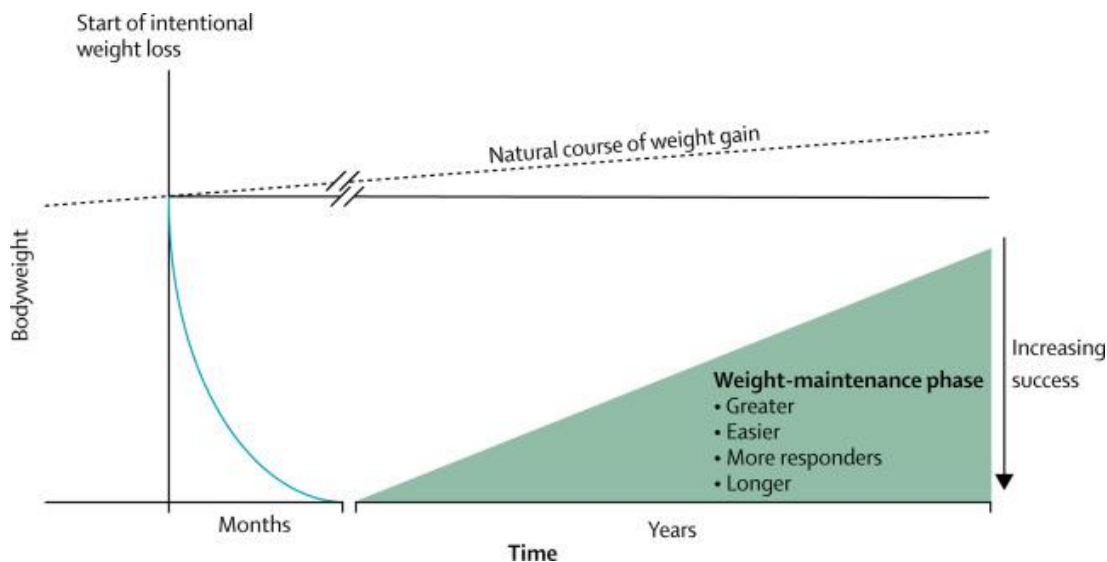
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Figure 1. Obesity and the components of medical weight management.



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138 **Footnote to Figure 1**

139 ----- broken line represents weight gain in adulthood

140 \_\_\_\_\_ solid line represents weight stability and maintenance with intervention

141 **History of weight gain and/or stability** over months and years, influenced by many factors

142 **Intentional weight loss** usually complete in 3-4 months, rarely beyond 6 months.

143 **Weight loss maintenance** months and years, ideally life-long. Requires trained, resourced, support  
144 for food reintroduction and a structured programme aiming to normalise new food choices and  
145 physical behaviours

146 **Optimisation of health and wellbeing**, *whatever the outcome for body weight*. Screen for disease  
147 risks secondary to obesity, manage cardiovascular risks while retaining appropriate weight  
148 management

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