Within-trial cost and 1-year cost-effectiveness of the DiRECT/Counterweight-Plus weight-management programme to achieve remission of type 2 diabetes

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Type 2 diabetes affects 8% of adults worldwide,[1] leading to 15% excess mortality[2] and 67% excess disabilities.[3] In 2017, people with diabetes accounted for 24% of all US health-care spending: diabetes-attributable costs were US$327 billion, comprising $237 billion in direct health-care costs, equivalent to $9601 per person, plus $90 billion in losses of productivity.[4] Costs rise with age, steeply above 45 years, reflecting the large contribution from type 2 diabetes.[4] In the UK, diabetes accounts for about 10% of the total National Health Service (NHS) budget,[5] with direct costs of £2564 per patient per year at 2010–11 prices (accounting for inflation, £2801 per year in 2016–17).[5] Type 2 diabetes is being diagnosed at younger ages, with more complications, as populations become more overweight, and costs are rising rapidly with increasing prevalence and new, more expensive treatments. Management focuses heavily on pharmacotherapy but morbidity and mortality remain high.[6] Bariatric surgery, with its own complications, can induce remission of type 2 diabetes but reaches only 1% of the eligible population, so periods of remission through primary care-based interventions could be valuable. In the DiRECT trial (ISRCTN03267836), 68 (46%) of 149 participants assigned to the study intervention achieved remission of type 2 diabetes after intensive weight management in routine primary care compared with six (4%) of 149 participants assigned to usual care.[7–9] We did a cost-effectiveness analysis of the Counterweight-Plus intervention used in DiRECT, with cost per additional diabetes remission at 1 year calculated from an intention-to-treat analysis of DiRECT and the differences in costs (UK NHS perspective, 2017 prices) and effects between the Counterweight-Plus and usual care groups (appendix).

The DiRECT/Counterweight-Plus intervention involves fixed set-up costs, for Counterweight specialists to train practitioners (practice nurses or dietitians who see participants), practitioners' attendance time, dedicated training materials, and programme support including online access to a medical advisor under an annual licence fee. Resource use (table) was collected prospectively throughout the study for every participant, including formula diet sachets (as total diet replacement [soups and shakes, 825–853 kcal per day for 12–20 weeks] then reducing over stepped food reintroduction, plus optional daily meal-replacement sachets during weight loss maintenance, and for rescue packages), review appointments with a practitioner, and supporting workbooks costed in full for all randomly assigned intervention participants.[7] Total cost per intervention participant of delivering the DiRECT/Counterweight-Plus programme was £1223 (95% CI 1147–1294); the largest

See Online for appendix

	Cost per participant (£)		Cost difference per participant (intervention – control [£])
	Intervention (n=149*)	Control (n=149*)	
Intervention delivery cost			
Set-up cost (annualised over 5 years)			
Counterweight-Plus specialist training, support, and mentoring	15†	0	15
Practice nurses/dieticians' training time	33‡	0	33
Total intervention set-up cost	48	0	48
Intervention running cost CES-D			
Practice nurse/dietician visits	447 (199)§	0	447 (415 to 478)
Sachets	708 (311)¶	0	708 (659 to 757)
Counterweight-Plus booklets	20	0	20
Total intervention running cost	1175 (463)	0	1175 (1099 to 1246)
Total intervention cost	1223 (463)	0	1223 (1147 to 1294)
Cost of routine resource use			
Primary and secondary care contact			
Primary and community care visits related to diabetes			
GP	17 (31)	34 (47)	–17 (–26 to –8)
Practice nurse	19 (15)	22 (16)	–3 (–7 to 0)
Health-care assistant	1 (3)	1 (3)	–0 (–1 to 0)
Community care	16 (28)	18 (43)	–2 (–11 to 5)
Primary and community care visits not related to diabetes			
GP	149 (179)	154 (178)	–5 (–47 to 36)
Practice nurse	10 (17)	16 (30)	–6 (–11 to –1)
Health-care assistant	1 (2)	1 (6)	–0 (–2 to 1)
Community care	13 (45)	13 (92)	–0 (–20 to 14)
Outpatient visits	244 (476)	261 (407)	–17 (–111 to 83)
Hospital admission	187 (796)	157 (713)	30 (–142 to 201)
Total cost of primary and secondary care contact	656 (1047)	677 (1028)	–21 (–249 to 215)

(Table continues on next page)

	Cost per participant (£)		Cost difference (intervention – control [£])
	Intervention (n=149*)	Control (n=149*)	
(Continued from previous page)			
Medications			
Antidiabetes drugs	29 (86)	149 (228)	–120 (–163 to –78)
Antihypertensive drugs	5 (9)	19 (43)	–14 (–22 to –8)
Total cost of medications	34 (87)	168 (229)	–134 (–177 to –93)
Total cost of routine resource use	691 (1058)	846 (1066)	–155 (–394 to 74)
Total cost			
Cost per participant	1913 (1161)	846 (1066)	1067 (820 to 1322)

Not all total values sum precisely due to rounding. Data are mean (SD) or mean difference (95% CI). 95% CIs for the mean differences and SDs for the total costs were obtained from 1000-iteration bootstrap (appendix). *Intention-to-treat analysis (included one participant in each group who moved away from the trial-participating practice; their health-care resource use was assumed to be 0 after moving, and their medication use was assumed to continue since moving). †33 practitioners were trained and supported by the Counterweight-Plus specialist team for £300 per practitioner, giving a total cost of £9900 for all 149 participants in the intervention group, which is equal to £66·4 per participant; annualising the training cost over 5 years using the formula, equivalent annual cost = $K/([1-1/(1+r)^n]/r)$, where K = £66·4, r = 3·5%, and n = 5, gives an annual specialist training and support cost of £15 per participant. ‡33 practitioners were trained for 16 h, at £42 per h for their time, summing to a total practitioner training time cost of £22 176, which is equivalent to £149 per participant; annualising the training time cost over 5 years using the formula, equivalent annual cost = $K/([1-1/(1+r)^n]/r)$, where K = £149, r = 3·5%, and n = 5, gives an annual practitioner training time cost of £33 per participant. §Cost of practice nurse or dietician visits was calculated from the observed total duration of visits (639 min) for an average of 15·6 visits per participant, applying the standard unit cost of £42 per h from the unit cost of medical and social care 2016–17 from the UK Personal Social Service Research Unit; the mean number of visits (SD) for each stage of the intervention are 7·7 (2·9) for total diet replacement, 3·7 (1·9) for food reintroduction, 3·5 (2·7) for weight maintenance, 0·3 (0·7) for rescue package (total food replacement), and 0·4 (1·0) for rescue package (food reintroduction). ¶Cost of sachets was calculated from mean number of sachets consumed per participant (495), multiplied by the unit cost of sachets (£1·43 [£20 per 14 sachets]); the mean number (SD) of sachets per participant consumed at each stage were 383 (156) for total diet replacement, 62 (50) for food reintroduction, 30 (48) for weight maintenance, 10 (27) for rescue package (total food replacement), and 10 (31) for rescue package (food reintroduction).

Table: **Cost of intervention delivery and routine resource use per participant over the first 12 months of the DiRECT trial**

cost components were practitioner visits (£447 per participant; 37% of total intervention cost) and formula diet sachets (495 sachets [£708] per participant; 58% of total intervention cost).

Data for routine health-care contacts and medication use were collected directly from general practitioner (GP) records for both groups. Antidiabetes and antihypertensive medications, suspended on commencing the intervention and reinstated as necessary under clinical guidelines, were costed from observed individual participants' treatments. The intervention group had significantly lower cost per participant than did controls for antidiabetes drugs (mean difference £120, 95% CI 78–163), antihypertensive drugs (£14, 8–22), diabetes-related GP visits (£17, 8–26), and diabetes-unrelated practice nurse visits (£6, 1–11). No significant differences were observed for other care contacts.

Reduced routine resource use thus provides some cost offset within the first year. Mean 1-year management cost per participant (intervention delivery plus routine NHS costs; n=149 in both groups) was £1913 (SD 1161) versus £846 (1066) for controls, thus incremental intervention cost was £1067 (820–1322; figure). The incremental cost per additional 1-year remission (difference in costs divided by difference in remissions [41·6%]) was £2564 (95% CI 1867–3453).

We have not attempted to project precise costs for the DiRECT/Counterweight-Plus intervention under routine care conditions but, being based on observed resource use under trial conditions, the figures represent generous estimates. In DiRECT, 149 intervention participants were managed by 33 practitioners. This ratio (5:1) would be expected to be much greater in routine practice, where similar numbers of patients might be managed by a single dedicated practitioner. Such a situation would entail fewer staff undergoing training, and lower annual costs, though these intervention set-up costs formed a minor cost element (£48 per participant; table). With future research and development, seeing patients in groups rather than individually might also offer small cost savings. Substantially lower costs might be achieved if greater restrictions were placed on the number of sachets issued to each patient and by negotiating lower unit costs for large contracts. The within-trial costs reported here thus represent a conservative basis from which to estimate potential 12-month DiRECT/Counterweight-Plus implementation costs. At £1067 per participant, the cost was about half that of the intensive lifestyle intervention (2012 US$2865 per participant) in the US Look AHEAD trial; compared with Look AHEAD, DiRECT (shorter diabetes durations, but in a relatively socially deprived study population) achieved greater weight losses and an almost four times greater 1-year remission rate (46% *vs* 12%).[10,11]

The medication cost savings resulted from discontinuation of antidiabetes and antihypertensive drugs on commencing the intervention, and from the lesser likelihood of their reintroduction and effects on subsequent dose or number of drugs used (via a guideline-based protocol) if the participant lost weight. The number of prescribed antidiabetes and antihypertensive medications was more than halved at 12 months in the intervention group.[8] Use of other concomitant medications was similar across groups over the first 12 months.[8] Coupled with the low costs of most other medications, an aggregated difference between

study groups seems unlikely; detailed evaluation of concomitant medications was therefore excluded from the present 12-month analysis.

DiRECT is the first non-surgical study to set remission of type 2 diabetes as a primary outcome and is implemented entirely within primary care. The relative costs of the intervention, and of routine diabetes care, are similar in other studies. DiRECT participants were very typical of people currently living with type 2 diabetes within 6 years of diagnosis. A high proportion were from socially deprived circumstances, where type 2 diabetes is most prevalent and difficult to manage.[9] Our results are thus likely to be robust and widely transferable. However, the population studied was almost entirely of white European ethnic origin; evidence is needed for people from other ethnic backgrounds in whom type 2 diabetes has different characteristics.

Our immediate objective here is to report the costs of mounting an intervention with evident clinical benefits over the short term, potentially for a large proportion of people with type 2 diabetes, whose current management is expensive and growing. The offsetting cost savings seen in the first 12 months of the trial were modest, but reduced health-care demand might persist into future years after the initial intervention costs are completed. Remission is an incentivising target for diabetes care, but 14% (5/36) did not achieve remission despite substantial weight loss. However, weight loss has many other personal, clinical, and public health benefits. Studies with different methods suggest reduced life expectancy with type 2 diabetes of 6–7 years in younger people,[6,12] and substantial weight loss consistently improves multiple cardiometabolic risk factors, potentially extending life expectancy.[13,14] Our analysis suggests that each case of remission costs £2564 on average, as a basis for budget planning and providing a platform for long-term cost-effectiveness. Ongoing follow-up of DiRECT will inform modelling of long-term health gains, resource savings, and quality of life. Participants' abilities to maintain weight loss and to avoid relapse of diabetes will be crucial to enhance long-term cost-effectiveness, requiring appropriate research and development investment for programme improvement. However, based on this within-trial analysis, irrespective of any marginal efficiencies from delivering the weight-management programme in routine practice and the exact cost per quality-adjusted life-year gained, the case already seems strong for diabetes care budgets to offer the support for patients to attempt remission.

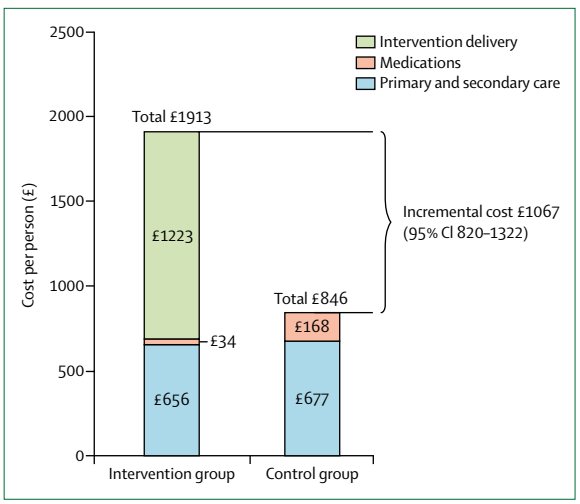

Figure: **Components of 1-year cost per participant in the intervention and control groups of the DiRECT trial**

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