**Title**

A within-trial cost-effectiveness analysis of primary care referral to a commercial provider for weight loss treatment, relative to standard care – An international randomised controlled trial.

**Running Title**

Cost effectiveness of weight loss treatments

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**Trial Registration**

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**ABSTRACT**

**Background:** Due to the high prevalence of overweight and obesity, there is a pressing need to identify cost effective approaches for weight loss in primary care and community settings.

**Objective:** We evaluated the cost effectiveness of two weight loss programmes of 1 year duration, either standard care (SC) as defined by national guidelines, or a commercial provider (Weight Watchers) (CP).

**Design:** This analysis was based on a randomised controlled trial of 772 adults (87% female; age 47.4±12.9 years; BMI 31.4±2.6 kg/m2) recruited by health professionals in primary care in Australia, England (UK) and Germany. Both a health sector and societal perspective were adopted to calculate the cost per kilogram of weight loss and the incremental cost effectiveness ratio (ICER), expressed as the cost per quality adjusted life year (QALY).

**Results:** The cost per kilogram of weight loss was USD122, 90 and 180 for the CP in Australia, UK and Germany respectively. For SC, the cost was USD138, 151 and 133 for Australia, UK and Germany. From a health sector perspective, the ICER for the CP relative to SC was USD18 266, 12 100 and 40 933 for Australia, UK and Germany respectively. Societal ICER figures were USD31 663, 24 996 and 51 571 for Australia, UK and Germany.

**Conclusion:** Comparing to national standards, the CP was a cost effective approach from a health funder and societal perspective. Despite participants in the CP group attending two to three times more meetings per month than the SC group, the CP was still cost effective when including these added patient travel costs. This study indicates that it is more cost effective for GPs to refer overweight and obese patients to CPs and that this may be better value for money than spending public funds on GP visits to manage this global problem.

**Keywords:** cost effectiveness; commercial provider; standard care; weight loss; obesity

**INTRODUCTION**

The high prevalence of overweight and obesity is placing a substantial burden on health care resources, even in developed countries [1](#_ENREF_1). Overweight and obesity accounts for 44% of the global burden of type 2 diabetes mellitus, 23% of ischemic heart disease and 7-41% of certain cancers [2](#_ENREF_2). Therefore obesity management programmes which produce weight loss are needed but these must be shown to be both efficacious and cost-effective.

Policy makers are increasingly seeking evidence of cost effectiveness interventions to underpin clinical guidelines. It is important for governments to know whether it is more cost effective to support and fund the programmes already in place or subsidise others (including extant commercial weight loss programmes).

A partnership between primary care providers and commercial organisations may be a practical approach, whereby participants can benefit from early lifestyle intervention for weight management. Observational data [3](#_ENREF_3), [4](#_ENREF_4) shows that such an approach has the potential to deliver weight management programmes at the necessary scale in a community setting and at a potentially relatively low cost. Importantly, our recent 12 month international randomised controlled trial (RCT) involving three countries (Australia, UK and Germany) demonstrated that referral by a primary health care professional to a commercial weight loss community intervention programme (Weight Watchers - CP) produced greater weight loss for overweight and obese adults [5](#_ENREF_5). Similar efficacy of this CP has also been demonstrated in other randomised, controlled trials [6](#_ENREF_6), [7](#_ENREF_7). However, the cost effectiveness of commercial weight loss programs over standard care (SC) has not been estimated, and therefore we investigated this using within-trial data of GPs referring overweight and obese patients to an efficacious commercial weight loss programme rather than attempting to treat overweight and obesity alone. The cost effectiveness of Weight Watchers has previously been analysed using limited data [8](#_ENREF_8). This analysis relied on data from another trial with a smaller sample size of only six months duration, and several assumptions were made including the opportunity costs of employment.

From a societal and health care funder perspective, our aim was to evaluate the cost effectiveness of a CP compared to conventional SC in primary care for both weight loss and quality of life in an overweight and obese population group. A societal perspective was also adopted in this analysis as we previously reported that those attending the CP had more frequent visits than the SC group [5](#_ENREF_5), which may be a contributing factor to the success of the CP.

**METHODS**

**Clinical Trial**

This cost effectiveness analysis was performed using data from an international study examining the change in weight among overweight and obese adults randomised to receive 12 months access to CP or 12 months SC by a primary care provider in three countries: Australia, UK, and Germany. Participants were recruited by their primary care providers and randomised to one of the two groups. A full list of inclusion and exclusion criteria, as well as a description of the two intervention groups can be found in the report of the primary findings from the study [5](#_ENREF_5). In brief, all participants were aged ≥ 18 years with a body mass index (BMI) of 27-35 kg/m2, and had at least one risk factor for obesity-related disease. Risk factors included central adiposity (waist circumference >88cm in women or >102cm in men); type 2 diabetes without insulin treatment; family history of diabetes; previous gestational diabetes; impaired glucose tolerance or impaired fasting glycemia; mild to moderate dyslipidemia (defined by national guidelines), or treatment for dyslipidemia; treatment for hypertension; polycystic ovarian syndrome or infertility without apparent cause other than weight; lower-limb osteoarthritis; or abdominal hernia. Participants randomised to the CP group received vouchers to attend a community CP meeting each week. Those randomised to the SC group received weight loss advice delivered by a general practitioner (GP)/primary care professional at their local medical practice. The regularity of these SC visits was at the discretion of the GP/primary care professional and the participant. The frequency of visits involving obesity-related advice was recorded, with GP visits only being counted for the SC group. GPs and primary care professionals were provided with and encouraged to use relevant national clinical guidelines for weight management [5](#_ENREF_5).

**Health Economic Evaluation**

A health care funder and societal perspective was adopted for the cost effectiveness evaluation. These perspectives included direct health costs to the government or patient arising from costs of intervention delivery and costs to patients for participation including transportation.

**Costing Data**

*Commercial Program*

The costing for the CP intervention group was based on a monthly payment plan to attend the CP which included unlimited access to CP meetings and online electronic web tools (which participants were entitled to access during the programme). The cost of the referral visit to the CP program was also included in the costing.

*Standard Care*

For the SC group the cost applied was the cost for a consultation lasting 20 minutes or less with a GP. In the UK, all consults provided in the SC group were by a nurse.

**Valuation of Costs**

The program cost of the CP intervention for each country was sourced directly from Weight Watchers International, Inc. Unit costs for all other intervention and conventional resources were obtained from the relevant governments/ healthcare authorities (Table 1).

**TABLE 1**. CP and SC group costs and sources

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Resource | Unit cost  | Unit cost (USD) | Unit utilised per participant (USD) | Source |
| **CP** |  |  |  |  |
| WW attendance* Australia
* UK
* Germany
 | $59.95 AUD/month£12.95 GBP/1st month then £19.99 /month€39 EUR/month | $60.55$21.24/1st month then $32.78$55.38 | $726.60$381.86$664.56 | [www.weightwatchers.com.au](http://www.weightwatchers.com.au)[www.weightwatchers.co.uk](http://www.weightwatchers.co.uk)[www.weightwatchers.de](http://www.weightwatchers.de) |
| Primary care referral* Australia
* UK
* Germany

Medication * Australia (Figure 1)

Patient travel* Australia
* UK
* Germany
 | $34.90 per participant£36 per participant€19.17 per participant\*$445.70 for 12 months $12.60 per round trip£5.00 per round trip€6.00 per round trip | $35.25$59.04$27.22$450.16$12.73$8.20$8.52 | $35.25$59.04$27.22$450.16$419.96$298.48$196.81 | MBS [9](#_ENREF_9) - Item 23 PSSRU [10](#_ENREF_10)Kassenärztliche Bundesvereinigung [11](#_ENREF_11)PBS [12](#_ENREF_12)ATO [13](#_ENREF_13)PSSRU [10](#_ENREF_10), HMRC [14](#_ENREF_14)[15](#_ENREF_15), [16](#_ENREF_16) |
| **SC** |  |  |  |  |
| General Practitioner (GP) consult* Australia
* UK (Nurse)
* Germany
 | $34.90 £12 €19.17\* | $35.25$19.68$27.22 | $377.16$261.74$307.60 | MBS [9](#_ENREF_9) - Item 23 PSSRU [10](#_ENREF_10)Kassenärztliche Bundesvereinigung [11](#_ENREF_11) |
| Dietetic/Psychology consult* Australia
* UK
* Germany

Medication* Australia (Figure 1)

Patient travel* Australia
* UK
* Germany
 | $59.90 £57.5 €60 $500.60 for 12 months$12.60 per round trip£5.00 per round trip€6.00 per round trip | $60.50$94.30$85.20$505.61 $12.73$8.20$8.52 | $3.99$6.23$5.62$505.61$137.01$109.60$96.84 | MBS [9](#_ENREF_9) - Items 10954/10968PSSRU [10](#_ENREF_10)Schulungs-Gemeinschaft München Ost e.V [17](#_ENREF_17)PBS[12](#_ENREF_12)ATO [13](#_ENREF_13)PSSRU [10](#_ENREF_10), HMRC [14](#_ENREF_14)[15](#_ENREF_15), [16](#_ENREF_16) |

AUD – Australian Dollar; GBP – Great Britain Pound; EUR – Euro; MBS – Medicare Benefits Schedule; PSSRU UK - Personal Social Services Research Unit; PBS – Pharmaceutical Benefits Scheme; ABS – Australian Bureau of Statistics; ONS – Office for National Statistics; ATO – Australian Taxation Office

NB: At the time of writing (early 2011), 1 AUD was 1.01 USD; 1 GBP was 1.64 USD; 1 EUR was 1.42 USD according to XE currency exchange (<http://www.xe.com>)

\*For Germany, a general GP visit was calculated as GPs are not able to charge a fee for weight loss advice.

Costs were estimated for patient travel to attend either CP or SC consultations. This was based on the assumption that patients travelled within a 10 kilometre radius to either their local CP or primary care clinic. The number of participant visits to their primary care provider for weight loss advice, or to the CP, was recorded throughout the one year study.

Opportunity costs of employment were not considered because participants could attend the CP or their primary care provider outside of work hours, during their lunch break or on weekends. Childcare costs were not considered for those with children as children of any age are welcome at the CP meetings and can accompany their parent to a SC visit.

*Australia*

The Australian government prices medical care with the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS). Professional attendances were priced under “Group A1 – general practitioner attendances to which no other item applies (level B)” – MBS item 23.

*UK*

The cost of a GP referral and a consult provided by a nurse was calculated according to the Personal Social Services Research Unit (PSSRU) - “Unit Costs of Health & Social Care 2010”.

*Germany*

Since the cost of a primary care visit has not been published for the year 2010, the costs for 2007-08 were used and indexed using the geometric mean of the increase of GP costs 2007 to 2008 [11](#_ENREF_11), according to the Working Group “Methods in Health Economic Evaluation”[18](#_ENREF_18).

**Outcomes Measured and Statistical Analyses**

The primary outcome of the study was the change in weight over 12 months. Change in Quality of Life (QOL) was also measured. In the UK and Australia, bodyweight (in light clothes without shoes) was measured with a Tanita BC-418 segmental body composition analyser (Tanita Corporation of America, Arlington Heights, IL, USA). In Germany, weight was measured in GP practices with standard scales. Participants were weighed on 6 different occasions over 12 months (baseline, month 2, 4, 6, 9 and 12) and asked to complete the Impact of Weight on Quality of Life Questionnaire-Lite (IWQOL-Lite) [19](#_ENREF_19), [20](#_ENREF_20) on 3 occasions over 12 months (baseline, months 6 and 12).

All participants who completed a baseline assessment for weight and the IWQOL-Lite questionnaire were included in the final analyses from an intention to treat (ITT) analysis using last observation carried forward (LOCF). A utility score was derived using the algorithm described by Brazier and colleagues [21](#_ENREF_21). A completer’s only analysis was also performed to calculate the mean weight loss and change in utility score between groups, however these figures were not used in the cost effectiveness calculations.

Outcomes were analysed by use of linear regression with fixed effects for continuous normal data; intervention group (CP vs. SC), and baseline measurement were used as the fixed effects.

**Cost Effectiveness Analysis**

The cost effectiveness analysis was performed separately for each country, incorporating national differences of the cost of the commercial intervention, medical consultation fee structure, salary structures, and other costing data [22](#_ENREF_22). An incremental cost effectiveness ratio (ICER) was undertaken whereby the net costs of CP relative to SC were calculated. The ICER represents the additional expenditure required to generate an additional unit of benefit, and in this case it was expressed as the cost per quality adjusted life year (QALY). QALYs could be calculated using the results from the IWQOL-Lite instrument. A preference based single index was estimated for each country [21](#_ENREF_21), so that country specific ICERs could be calculated. The following formula was used to calculate the cost per QALY.

ICER = Cost of CP – Cost of SC

 Difference in QALYs

A cost effectiveness analysis was also performed to calculate the cost per kilogram of weight loss, to help illustrate the value of each weight management programme. The cost per kilogram of weight loss and cost per QALY was calculated from an ITT perspective with an LOCF approach.

**Sensitivity Analysis**

One way sensitivity analyses were performed for the Australian site to include medication costs. An average costing for each patient was calculated in 3 month time periods so an annual cost could be compared between the two intervention groups (CP and SC). Drug costs were obtained from the 2011 PBS pricing index – “dispensed price for maximum quantity” and units were based on the subject’s self-reported data. A list of all medications and dosages prescribed by the GPs was collected by the research officer at each of the individual patient’s clinic visits. This additional cost effectiveness ratio was calculated as the difference in total medication costs between CP and SC plus the costs of implementing the interventions divided by the difference in QALYs.

A sensitivity analysis was also performed to include referral to allied health professionals in the SC group. Whilst it was not captured during the trial, an assumption was made that a percentage of GPs in the SC group referred their patients to a dietitian and/or psychologist for specific advice. In this analysis a 1.1% referral rate for 6 consults over a one year time period has been applied. This reflects the probability of referral to an allied health professional during a GP visit in Australia in 2009-10 [23](#_ENREF_23).

**Scenario Analysis**

Since the CP intervention costs that were sourced in Table 1 reflect commercial pricing decisions and are based on financial costs, the programme costs were re-evaluated according to opportunity costs. The CP is the same across countries, and therefore the cost to deliver the intervention should be similar. We examined the cost effectiveness consequences of reducing programme costs (to the equivalent of the Weight Watchers NHS referral scheme – GBP 45 for 12 sessions [4](#_ENREF_4)) from AUD 59.95 and EUR 39 per month to AUD 221 and EUR 156 per year in Australia and Germany respectively. This is based on an attendance of 36 CP sessions per year (GBP 135 – 12 session cost multiplied by 3). The Weight Watchers NHS referral scheme was used in this scenario for comparison to a system already in place. Despite difficulty in adjusting observed market prices, this is an estimate of likely cost and discounted to reflect likely subsidy across countries.

**RESULTS**

**Clinical Trial Results**

*Baseline Characteristics*

Baseline characteristics of participants are reported previously [5](#_ENREF_5). No statistically significant differences (p≤0.05) in baseline characteristics across treatment groups, within or between each country were observed. The mean (SD) age of subjects was 47.4 (12.9) years, the mean BMI was 31.4 (2.6) kg/m2, and the percentage of males to females was 13% and 87% respectively. A small percentage of subjects had type 2 diabetes (6.5%).

*Weight Loss*

As previously reported [5](#_ENREF_5), both treatment groups lost weight but mean 12 month weight loss was significantly greater for CP than SC in all 3 countries (CP: -5.1 ± 0.3 kg vs. SC: -2.3 ± 0.2 kg; p<0.0001). Table 2shows the mean weight loss per participant and country so that a cost per kilogram of weight loss could be calculated for each treatment group.

*Quality of Life*

772 participants were enrolled in and commenced the study. However, only 744 participants completed an IWQOL-Lite questionnaire at the initial baseline visit. Of these, 12 participants were excluded due to incomplete questionnaires as per the IWQOL-Lite scoring instructions. A further 73 participants were excluded due to missing data when the algorithm was applied for conversion to utility scores, leaving 659 participants who could be included in the ITT analysis. 444 participants completed the 12 month study. There was a significantly greater change in utility for CP than SC for Australian and UK patients but not for those from Germany from an ITT (LOCF) analysis. A 2.1% and 1.5% improvement in utility score for the CP relative to SC was found in Australia and Germany respectively, and a 0.9% improvement in utility score for the CP relative to SC was evident in Germany. When analysing only those who completed the programmes, there was a significantly greater change in utility for the CP than SC for Australia and Germany but not for those in the UK (possibly due to the small sample size of UK patients completing)(Table 3). From a pooled analysis of all three countries the greater change in utility for CP than SC remained significant (results not shown).

**Intervention Costs**

*Australia*

Based on the reference year for costing (2010), the cost to attend the CP was AUD 59.95 per month. The average number of visits for each participant attending the CP was 33.0 over a 12 month period. The cost of a GP visit as per MBS item 23 was AUD 34.90. The average number of visits for each participant attending their GP was 10.7 over the 12 month study period.

Unit costs were summed for each resource measurement to obtain a total cost for each intervention over the course of the one year study (Table 1).The annual cost per patient was AUD 754 and AUD 373 for the CP and SC respectively. When including patient travel the annual cost was AUD 1170 and AUD 508 for the CP and SC respectively.

*UK*

The cost to attend the CP was GBP 12.95 for the first month and GBP 19.99 for each month thereafter. The average number of visits for each patient attending the CP was 36.4 over a 12 month period. The cost of a consult provided by a nurse (GP practice) was GBP 12. The average number of visits for each patient attending their GP practice was 13.3 over a 12 month period. Therefore, the annual cost per patient was GBP 269 and GBP 160 for the CP and SC respectively. Including patient travel, costs were GBP 451 and GBP 226 for the CP and SC respectively.

*Germany*

The cost to attend the CP was EUR 39 per month. The average number of visits for each patient attending the CP was 23.1 over a 12 month period. The cost of a GP visit as per the Kassenärztliche Bundesvereinigung (The National Association of Statutory Health Insurance Physicians) was EUR 19.17. The average number of visits for each patient attending their GP was 11.3 over a 12 month period. Therefore, the annual cost per patientwas EUR 487 and EUR 217 for the CP and SC respectively. Including patient travel, costs were EUR 626 and EUR 284 for the CP and SC respectively.

**Cost-Effectiveness**

*Australia*

The cost per kilogram of weight loss was AUD 121 and AUD 137 for the CP and SC respectively. The ICER for the CP relative to SC was AUD 18 085 (Table 4).

*UK*

The cost per kilogram of weight loss was GBP 55 and GBP 92 for the CP and SC respectively. The ICER for the CP relative to SC was GBP 7378 (Table 4).

*Germany*

The cost per kilogram of weight loss was EUR 127 and EUR 94 for the CP and SC respectively. The ICER for the CP relative to SC was EUR 28 826 (Table 4).

**Sensitivity Analysis**

Whilst it did not reach statistical significance, the average medication cost per patient increased during the 12 month study period for the SC group (Figure 1). Medication costs remained the same for the CP group. The mean number of medication scripts over the 12 month period was 1.9 per patient. These were for the categories of medications for hypertension, cardiovascular disease, dyslipidemia, diabetes mellitus, thyroid disorders, arthritis and musculoskeletal disease, and all other conditions. No outliers were evident when analysing the pharmaceutical cost data which may have had the capacity to overwhelm any trends. The highest costs were associated with proton pump inhibitors, cardiovascular disease, and dyslipidemia.

When medications were included, the annual cost per patient was AUD 1200 and AUD 874 for the CP and SC respectively. With patient travel, programme costs were AUD 1616 and AUD 1009 for the CP and SC respectively. Including these medication costs resulted in a decrease in the ICER for the CP relative to SC to AUD 15 522.

Furthermore, including the costs associated with referral to a dietitian/psychologist decreased the ICER to AUD 17 901, GBP 7117, and EUR 28 403for Australia, UK and Germany respectively.

**Scenario Analysis**

If program costs are re-evaluated in Australia and Germany to the equivalent of the Weight Watchers NHS referral scheme, the ICER for the CP relative to SC becomes cost saving (more health benefit at a lower cost) in both countries, from a health sector perspective. In the UK, the ICER is lowered to GBP 655. The cost per kilogram of weight loss for the CP becomes AUD 41, GBP 35 and EUR 46 in Australia, UK, and Germany respectively.

**DISCUSSION**

This analysis suggests that the CP can provide a cost effective immediate option, calculated for a time period of 1 year, for weight management in persons within a BMI range of 27 to 35 kg/m². Whilst the SC group also achieved a significant weight loss from baseline to month 12 in all three countries in this RCT, it is not clear whether this would apply in routine practice, and therefore WW may be an accessible programme to which primary care providers can refer their patients. It can also be said that the efficacy of the CP may be in part attributable to the shared care approach as the subject was initially referred into the study by their GP, and of which has been demonstrated in similar settings [24](#_ENREF_24).

In Australia and the UK, the cost per kilogram of weight loss was lower for the CP than the SC group, indicating a cost saving compared to current SC practice. In Germany, the cost per kilogram of weight loss was lower for SC than the CP. It is difficult to compare these data to other weight loss studies due to the different costing methodologies used. Previous lifestyle intervention studies did not include indirect costs such as patient travel and vary in terms of duration of outcome measures, and produced costs from USD 61 [25](#_ENREF_25) to USD 133 per kilogram of weight loss [26](#_ENREF_26), and USD 6.40 [27](#_ENREF_27) to USD 48 per pound lost [28](#_ENREF_28). There is also data showing a AUD 7.30 per kilogram of weight loss for a 12 month dietician supervised weight loss programme [29](#_ENREF_29). When we adjusted for the CP financial costs based on commercial pricing decisions, and costed according to economic prices, the cost per kilogram of weight loss was lower for the CP compared to SC in all three countries.

Since the cost per kilogram of weight loss is not a metric commonly used by decision makers, a cost per QALY gained was also calculated. Furthermore, as an example of health resources used by this demographic group, medication usage was estimated for the Australian sample. When medications were included, the cost per QALY was lowered. Regardless of the inclusion or exclusion of medication usage, and using the commonly accepted threshold of less than $50 000 per QALY [30](#_ENREF_30), [31](#_ENREF_31), the CP proved to be a cost effective programme from both a health sector and societal perspective in Australia.

In the UK, the ICER level that the National Institute of Health and Clinical Excellence (NICE) has adopted is GBP 20 000 to GBP 30 000 per QALY gained [32](#_ENREF_32). Our results show, using this standard, that the CP in the UK is a cost effective programme from both a health care funder and societal perspective.

In Germany, obesity is not considered as a disease in the health care system. Therefore, obesity treatment is not usually undertaken in primary care. Comparing to what is regarded to be cost effective for pharmaceutical and surgical interventions in Europe (<€50 000) [33](#_ENREF_33), the CP is again a cost effective programme when both perspectives were adopted.

The cost disparity of the CP between countries, and the difference in GP/nurse costs, had a large effect on the outcome, indicating that the results (cost per kilogram of weight loss and cost per QALY gained) are sensitive to the costs of the programme. In the UK, the cost to attend the CP was the lowest amongst the three countries. When the CP costs were lowered to the equivalent of the UK NHS referral scheme, the ICER for the CP relative to SC becomes cost saving (more health benefit at a lower cost) in both countries (Australia and Germany), from a health sector perspective. Therefore, the intervention (CP) generated a better health outcome and cost less than the comparison intervention (SC). In the UK, this lowers the ICER to GBP 655.

Furthermore, despite the data not being collected within this randomised controlled trial, it seems foreseeable that the SC group would have higher rates of referral to allied health due to greater contact with the GP. Whilst attempting to compensate for these associated allied health costs in the SC group by applying a 1.1% referral rate [23](#_ENREF_23), the only data available relates to the general population rather than specifically for the overweight and obese population, for which the referral rate is likely to be much higher. Including these costs associated with referral to allied health decreased the ICER in each country. Since the CP subjects were not allowed to participant in other weight loss program or seek other assistance for weight loss, these associated costs were not included for the CP group.

This cost of such an early prevention approach targeting overweight and obese adults is low when compared to the cost associated with the burden of type 2 diabetes. The average annual cost in 2003 per person with type 2 diabetes was AUD 5360 [34](#_ENREF_34). Prevention of type 2 diabetes among high risk individuals, as well as intensive glycaemic, hypertensive, and cholesterol control, has been shown to vary considerably between interventions and country [35](#_ENREF_35). As shown by previous lifestyle interventions, the degree of weight loss evident from this study prevents the progression to type 2 diabetes in those at high risk [36](#_ENREF_36). Despite weight regain being inevitable over time, a so-called ‘metabolic memory effect’ has been shown previously in Diabetes Treatment and Prevention Outcome Studies [36](#_ENREF_36), [37](#_ENREF_37) and it could be anticipated that such metabolic benefit would occur with the weight loss achieved in our trial . Therefore, adopting cost effective weight management programmes such as demonstrated here with this CP, an intervention which has the capacity to be large scale, may be an effective way to help reduce the prevalence of obesity associated diseases such as type 2 diabetes and their costs.

*Strengths and Limitations*

Whilst a key strength of this analysis is the ability to draw on the results of a randomised controlled trial to perform a within trial cost, it also acts as a limitation as the cost effectiveness analysis is restricted to a one year time period. Importantly, the QALY metric is not all that applicable over a one year time horizon, however it has been used in this study for demonstration purposes such that results can be compared to cost effectiveness thresholds.

Another key strength of our study was the use of the societal perspective to take in to consideration all intervention costs. This follows the recommended approach for cost effectiveness analyses [38](#_ENREF_38). However, as the available data from the RCT did not enable us to capture several cost offsets including reduced rates of obesity-related disease, frequency of hospitalisations averted, or reduction in sick leave, the true cost effectiveness of the intervention programme may have been underestimated.

Whilst it was assumed that no patient required time off from work to attend WW meetings or GP consultations, this information was not specifically captured. A large benefit of the CP programme and GP consults is that they are available out of work hours, at lunchtimes, and on weekends, minimising the opportunity costs of employment. An assumption may also be made that a percentage of patients are commenced on other weight loss assistance therapies by their GP in a SC real life setting, but such treatments were not included in our analysis. Similarly the limitations of the trial design meant that other costs such as food products endorsed by the CP and out of pocked expenses for the SC group (e.g. allied health professional consultations) were ignored.

For the Australian sensitivity analysis, medications were grouped as a whole and therefore it was not possible to determine whether there was a change in costs relating to obesity or disease specific drugs. However, as reported by the Counterweight Programme in the UK, the range of prescribing areas being affected by obesity was greater than expected [39](#_ENREF_39). An increased prescription rate was found for categories such as gastrointestinal, infections, skin conditions, antihistamines, hypnotics, and drugs used in the treatment of nausea and vertigo. Most clinicians would not typically associate these with obesity [39](#_ENREF_39). Therefore there is a wide range of clinical conditions for which obesity is a contributory factor.

In Australia, despite the GP treated (SC) group showing an increase in mean medication prescription over the 12 month period (not reaching significance), this may reflect better control of risk factors by GPs as SC patients were required to see their primary care professional on a more regular basis than the CP group. However, despite an increase in prescriptions noted for this group of patients, they had no better control of risk factors for obesity related conditions at the end of the 12 month study. Patients in the CP group had significantly greater improvements in insulin, and total to HDL cholesterol ratio than the SC group, and weaker evidence existed of improvements in glucose, and HDL and LDL cholesterol for the CP group. Small reductions in blood pressure were noted for both treatment groups [5](#_ENREF_5). All these improvements may be related to, or influenced by, degree of weight loss. As patients were recruited via their GPs with a BMI of 27-35 kg/m2 and one or more additional risk factors for obesity-related disease, a slightly higher average number of medication scripts per person may be expected, and consequently a higher mean medication cost per patient. Results from a random Australian community sample of 3015 respondents with a mean age of 45.3 years, found that 1411 (46.8%) were taking one or more prescribed medications [40](#_ENREF_40). In this trial it was 1.9 prescribed medications per patient.

Missing data was dealt with from an ITT perspective using last observation carried forward. Despite a mixed model or multiple imputation approach now being more commonly used to deal with missing data [41](#_ENREF_41), the last observation carried forward approach was adopted as it was found to produce more robust and higher cost findings than the mixed model results previously reported in an interim analysis of this RCT. For example, with respect to weight loss, under all four missing data assumptions, 12 month change in mean weight compared to baseline was significantly greater for the CP versus SC. Under the missing at random assumption the CP achieved on average 3.0kg greater weight loss than SC (p<0.001); under the missing completely at random assumption the CP achieved 3.2kg greater weight loss (p<0.001); under the baseline observation carried forward assumption, the CP achieved 2.3kg greater weight loss than SC (p<0.001); and under the last observation carried forward assumption the CP achieved 2.8kg greater weight loss than SC (p<0.001) [42](#_ENREF_42).

The models by which IWQOL-Lite values are transformed into utilities (especially to other countries) has its weaknesses and such a mapping exercise is always second preference compared to the direct use of, for example, the EuroQoL Europe or the AQoL Australia. Important to note however, is that the IWQOL-Lite is an obesity-specific measure of quality of life which is sensitive to obesity related quality of life effects and performs well in terms of conventional psychometric criteria in obese populations [19](#_ENREF_19), [43](#_ENREF_43), [44](#_ENREF_44). Despite the concerns with this mapping approach, it is possible to estimate a robust model for predicting SF-6D index values from the IWQOL-Lite [21](#_ENREF_21), however the ability to transfer utility values of health states to other countries must be acknowledged.

It has been argued that there is too much reliance on health professionals such as GPs to treat overweight and obesity [45](#_ENREF_45). This is in part because GPs have not been given enough additional or alternative resources to manage this issue beyond a standard GP consultation. The ability to be able to refer to cost effective commercial programmes may assist with this issue[\_ENREF\_41](#_ENREF_41). However due to the out of pocket cost it may still be beyond the financial reach of a substantial proportion of the population, particularly those who need it most [46\_ENREF\_46](#_ENREF_46). Thus governments may consider funding cost effective commercial programmes in preference to GP visits for managing overweight and obesity. In Australia, for example, the addition of items to Medicare and private health insurance, which could provide financial incentives to better treatment, could help support individuals in changing their lifestyle behaviours [45](#_ENREF_45).

This study provides data from three different countries showing consistent results. The cost per kilogram of weight loss was lower for the CP versus SC in Australia and the UK. When we adjusted for the CP financial costs based on commercial pricing decisions, and costed according to economic prices, the cost per kilogram of weight loss was lower for the CP compared to SC in all three countries. The CP is cost effective when assessed by the commonly accepted threshold of a cost <$50 000 per QALY. Importantly, despite participants in the CP group attending on average three meetings per month in the UK and Australia, and two meetings per month in Germany, compared to only one appointment per month for the SC group, the CP program was still cost effective when including these added patient travel costs.

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**Conflicts of Interest**

NRF and IDC have received research grants for other clinical trials funded by Sanofi-Aventis, Allergan, Eli Lilly, and Novo Nordisk. IDC was a board member for the SCOUT trial and has received payment for lectures from iNova Pharmaceuticals, Eisai Pharmaceuticals, Pfizer Australia, and Servier Laboratories (Australia). SAJ has received research grants for other clinical trials from Sanofi-Aventis and Coca Cola, and is a member of the Tanita Medical Advisory Board and receives a fee for nutrition articles and lectures for Rosemary Conley Enterprises. HH is on the Advisory Board for Weight Watchers International and has received payment for lectures from Sara Lee, Novartis, Sanofi Aventis, and Bristol-Myers Squibb.

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**FIGURE LEGENDS**

Figure 1**.** Mean medication cost in AUD per patient by group for each 3 month time period.