Original Article

The Lighten Up trial – A Critical Appraisal

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Abstract

This paper attempts to present a critical appraisal of a randomised controlled trial to compare a range of commercial or primary care led weight reduction programmes with a minimal intervention control for weight loss in obesity: the Lighten Up trial as presented in BMC Public Health. 2010;10:439. doi:10.1186/1471-2458-10-439. At the outset, an overview of the paper is presented including its purpose, funding, methods, statistical analysis, discussion, conclusions, etc. In this appraisal, the aspects of the original paper are critically analyzed and reviewed. Shortcomings in the design of weight loss programs are discussed. It is identified that better outcomes for primary care interventions could have been possible with better training, more commitment, fidelity checks and monitoring by research team. It is observed that higher motivation for patients to embark on and adhere to interventions can be ensured by counselling and referral by the concerned physician as indicated by NHS Stop Smoking service and other studies.

Keywords: Obesity, Commercially provided weight management services, primary care based services, weight loss, physical activity, dietary regimen.

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INTRODUCTION

Obesity is a global epidemic and is the leading risk factor for deaths. Obesity and the consequent non-communicable diseases (44% of diabetes, 23% of IHDs, 7- 41% of some cancers, etc.) are a huge burden on any economy, and are preventable.[1] Changes in lifestyle are major contributors to the current epidemic of overweight and obesity and hence the need to test the effect of weight reduction by various dietary manipulations and increased physical activity in preventing and reducing health risks across the population.[2] In UK, obesity has a prevalence of 25%[3], and is expected to double in next 50 years.[4] UK Government has identified that there is a paucity of effective weight loss services delivered through Primary care5. There is no nationally available NHS weight management service akin to NHS Stop Smoking Service for the general population except for a few referrals to Commercial Weight Management Program (CWMPs), offered free by the Primary Care Centres.[5] A paper comparing the effectiveness of short term CWMP with Primary care intervention is reviewed in the following section.

OVERVIEW OF THE ORIGINAL PAPER

Purpose: To compare the effectiveness of short term CWMP (Commercial Weight Management Program) with Primary care intervention.

Funding: The study is funded by NHS South Birmingham.

Methods: Lighten Up study is an eight arm randomised controlled trial comparing

(i) 3 CWMPs
- Weight Watchers (WW),
- Slimming World (SW) and
- Rosemary Conley (RC)

(ii) 3 NHS programs
- Size Down, which is a community based dietary plan,
- general practice(GP) nurse led 1to 1 support, and
- pharmacist 1 to 1 support,

(iii) Choice of intervention (allowed to choose) and

(iv) Minimal intervention comparator group.

Population: Patients registered with 17 practices from South Birmingham Primary Care Trust.

Inclusion criteria:
- Age > 18 years, of both sexes with BMI >30 recorded in the registries since 15 months.
- White European - BMI >30 with no co-morbidities, >28 with co-morbidities

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- S. Asians - BMI > 25 with no co-morbidities, >23 with co-morbidities

Exclusion criteria

- Pregnant women
- Participants not knowing English
- Participants with medical contraindications

Randomisation

- Eligible patients invited by letters
- Consent taken
- Baseline data collected by nurses at the call centre.
- Ratio of allocation was 1:1 in 6 trial arms
- Ratio in GP and Pharmacist arms was limited to 1: 0.7 for lack of spaces.
- 740 participants recruited
- 100 each into 6 arms
- 70 each to GP and Pharmacist arm

Study Outcomes

Primary outcome: weight loss at the end of 3 months

Secondary outcomes

- self reported physical activity,
- weight loss at one year, and
- % weight loss at the end of 3 months and one year.

Interventions

Commercial Weight Management Programs:

- Group-based
- Weekly sessions lasted one hour to 90 minutes
- Varied in the one-to-one contact availability, website access and goal-setting.

Size Down

- six weekly two-hour sessions
- Follow-up sessions at 9 and 12 weeks.

GP and Pharmacist

- 12 one to one sessions
- First session was for 30 minutes
- Remaining sessions lasted for 15 to 20 minutes.

Choice arm: according to the intervention arm chosen

- Exercise only comparator group were provided with 12 free vouchers for a local fitness centre.

Statistical Analysis

The statistical analysis was done by STATAv11.0 and SPSSv17.0

Results

All the programs achieved a weight loss ranging from 4.4 (SD 4.3Kg) in Weight Watchers to 1.4 (SD 4.1Kg) in General practice.

Weight Watchers and Rosemary Conley arms had statistically significant weight loss vis-a-vis the comparator group.

Discussion

The weight loss achieved at the end of program was greater in Commercial Weight Management Programs. In all arms there was weight loss at the end of one year but significant only in Weight Watchers arm. Lighten Up trial was a short duration - 12 week study, but the results proved to be clinically beneficial and more effective than other long duration trials. The sessions in Primary care were not conducted as per study protocol due to scheduling problems. Population studied was diverse, compared to other studies. Self-reported physical activity (based on International Physical Activity Questionnaire), though an overestimate, was evaluated for the first time. Sex and choice of intervention had no effect on weight loss. The total cost of interventions ranged from 71.37 (£) in Slimming world to 112.73 (£) in General practice.

Conclusions

The author aptly concluded that 12 week group based weight management intervention could result in meaningful weight loss in an unselected primary care population; CWMPs were more effective and economical than Primary Care Intervention arms.

CRITICAL APPRAISAL

Purpose of the study

The present study is intended to compare the cost effectiveness of weight management offered by prevailing Commercial Programs with Primary care interventions as there is no sufficient evidence. In the past, Counterweight [6] program showed good results but was an uncontrolled trial and Moore et al [7] failed to show promising results for Primary Care intervention. The study chose to address an unselected primary care population by recruiting those who responded to invitation letter from their GP as previous studies were based on highly motivated people who responded to advertisements from Commercial Weight Management Programs.

Methods

The eight arm randomised controlled study design with inclusion of available Commercial Weight Management Programs is appropriate to provide comparison for the local decision makers. Sample size of 70 with allowance for 20% drop out (which is good practise), was estimated to give a power of 90%, for a statistical significance of 5% to detect a 2Kg (SD: 3.2Kg) weight loss. Weight loss of 2Kg is considered clinically beneficial, as evidence shows that a loss of 5 - 10% of body weight is adequate to reduce the progression of diabetes to 58% in 4 years time.[8,9]

There is no maximum age limit set for the participants in inclusion criteria. The co-existent medical conditions for exclusion from the trial were mentioned in the protocol as serious co-morbidities such as terminal illness. Participants with hormone replacement therapy who tend to be refractory to weight loss measures may also be excluded. Those who participated in the recent (3 months) weight loss programs also may be excluded.

Interventions

Author gave details about fidelity checks in all programmes except in General Practice and Pharmacist arms. Fidelity checks and periodic monitoring could have ensured uniformity, high patient adherence/follow-up and better results in GP arm.

The sessions were more regularly held in all arms except in the GP and Pharmacist arms due to scheduling problems, as also conceded by the author.

Statistical Analysis

Last-Observation-Carried-Forward (LOCF) (single imputation method) method was used for imputing missing data and sensitivity analysis of the results obtained from assumptions was done. National Academy of Sciences (2010) has advised against using single imputation methods (LOCF and Baseline-Observation-Carried-Forward [BOCF]) as primary approaches to the treatment of missing data, unless the assumptions that underlie them are scientifically justified. Instead, it recommended multiple imputation methods such as Boot Strapping, etc.

DISCUSSION AND CONCLUSION

The study population consisted of 30.67% men and 69.33% women; other baseline characteristics are fairly comparable between groups. WW and RC achieved a statistically significant weight loss at the end of study period. Proportion of patients showing 5% weight loss at the end of 12 weeks was comparable in the 3 Commercial Weight Management Programs (46%, 45%, and 35%) and Choice group (35%) but was found to be lowest in the GP arm (15.7%). Self-reported Physical Activity showed a great variation in pharmacy group from 1112kcal/wk at 12 weeks to -285kcal/wk at the end of one year. The commercial programs were more economical than the services provided by the GP and Pharmacist arms. More than 50% of participants in the Weight Watchers and Choice intervention arms have attended >50% of sessions as reflected in the results. The weight loss at the end of 12 weeks in Commercial Weight Management Program - Weight Watchers was greater probably due to group based interventions, well trained group leaders, fidelity checks, regular sessions, easy booking of first session and no subsequent scheduling. Weight loss at the end of 1 year decreased in all arms in this study. Obesity is a chronic, relapsing condition. The weight loss achieved in short term interventions can only be sustained through assiduous counselling on avoidance of sedentary life and poor dietary habits.[12] The weight loss outcomes of General practice and Pharmacist arms simply seemed prescient because they were less well equipped to deliver weight management interventions, caused by less expertise, shortage of resources and competing demands[5]. Better outcomes for Primary care interventions could have been possible with better training, more commitment, fidelity checks and monitoring by research team. Higher motivation for patients to embark on and adhere to interventions can be ensured by brief counselling and referral by the concerned physician as indicated by NHS Stop Smoking service and other studies.

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