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Improving management of obesity in primary care: cluster randomised trial

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Abstract

Objective To evaluate a training programme intended to improve the management of obesity, delivered to general practice teams.
Design Cluster randomised trial.
Setting Northern and Yorkshire region of England
Participants 44 general practices invited consecutively attending obese adults to participate; 843 patients attended for collection of baseline data and were subsequently randomised.
Intervention 4.5 hour training programme promoting an obesity management model.
Main outcome measures Difference in weight between patients in intervention and control groups at 12 months (main outcome measure) and at 3 months and 18 months; change in practitioners' knowledge and behaviour in obesity management consultations.
Results Twelve months after training the patients in the intervention group were 1 (95% confidence interval −1.9 to 3.9) kg heavier than controls (P = 0.5). Some evidence indicated that practitioners' knowledge had improved. Some aspects of the management model, including recording weight, target weight, and dietary targets, occurred more frequently in intervention practices after the training, but in absolute terms levels of implementation were low.
Conclusion A training package promoting a brief, prescriptive approach to the treatment of obesity through lifestyle modification, intended to be incorporated into routine clinical practice, did not ultimately affect the weight of this motivated and at risk cohort of patients.

Introduction

Obesity is now a major public health problem across the world. Easy solutions are unlikely, given the complex interaction between the abundant availability of energy dense food, the ever decreasing demand for energy expenditure in the modern world, and the impact of our genetic make up. Treatment of people who are already obese is difficult; however, several systematic reviews in recent years have shown that diet, exercise, and behavioural approaches, used in combination, are effective management strategies, at least in the short term.[1 2]

The role of primary care in managing obesity in the United Kingdom is linked to achieving targets for the national service framework for coronary heart disease.[3] The Department of Health stated that primary care should "use every opportunity to promote healthy lifestyles" and should provide advice on diet, weight reduction, and exercise.[4] A survey of general practitioners and practice nurses by the National Audit Office identified several factors that they felt would assist them in the treatment of patients, including more information on effective interventions, availability of better materials for advising patients, and better training for staff.[5] Little is known about how effective such training is in helping primary care teams to manage obesity more effectively. A systematic review of interventions to improve health professionals' management of obesity in 1999 found little rigorous research from which to draw conclusions.[6]

We have evaluated, in a cluster randomised trial, a training programme (the intervention) promoting the evidence based treatment of obesity, delivered to general practice teams (unit of randomisation). Although many trials have measured the effectiveness of training, few have measured effectiveness at the level of health outcomes in patients. The primary outcome measure in this study was difference in patients' weight, but we also measured difference in practitioners' knowledge and behaviour in weight management consultations.

Methods

The method has been reported in detail elsewhere.[7] Figures 1 and 2 show the flow of practices, staff, and patients through the trial.

Recruitment

We recruited practices from four health authority areas in the Northern and Yorkshire region of England during a four month period. We invited all 161 practices in selected primary care groups to participate, of which we randomised 44 (without financial incentives): 12 in North Durham, 16 in Leeds, 10 in Newcastle, and 6 in Scarborough. All general practitioners and practice nurses in the 44 practices (a total of 245 staff) were eligible to participate. In a pre-

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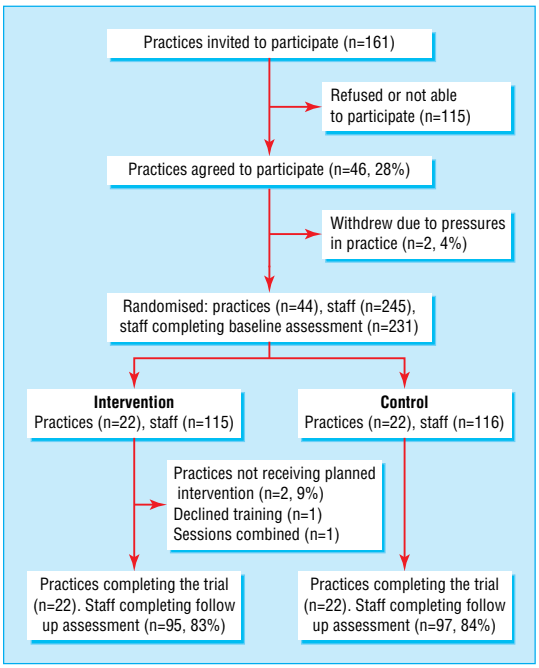

Fig 1 Flow of practices and practice staff through the trial

vious trial,[8] staff working in primary care but between practices (for example, district nurses and health visitors) were a source of contamination, so we asked for these staff to be excluded from the study.

The study protocol required practice staff to invite consecutively attending obese adults (body mass index ≥ 30 kg/m^2) aged 16 to 64 years to participate in the trial over a defined six month recruitment period. Patients were asked to return a consent form to the practice by stamped addressed envelope or on their next visit. The recruitment strategy was extended to include assistance from study personnel and mail shots. Towards the end of the recruitment period, a researcher accessed the list of patients who had been recruited in the early stages and invited them to attend for collection of baseline data, so that all patients had been weighed within two months of randomisation. All practices were randomised simultaneously in June 2000.

Randomisation

Raab and Butcher did the randomisation, using the method they described in 2001, in which patient level characteristics (body mass index at recruitment, age, and sex) and practice level characteristics (practice size, socioeconomic status, and existence of dietetic service) were used to inform randomisation.[9] One permutation of treatment allocation with acceptable balance was randomly selected, a method that ensured equal numbers of practices and approximately equal numbers of patients in both treatment arms. Researchers collecting baseline data contacted a distant member of the project team to ascertain intervention status. We arranged delivery of the intervention to practices as soon as possible after completion of baseline data. Each intervention practice was allocated a control practice pair—for purposes of data collection only—to reduce any impact of seasonal variation in the main outcome variable.[10]

Intervention

At the start of the intervention period, we provided all practices with a list of their patients who had entered the trial. The educational strategy was based on a previous nutrition training programme.[8] We delivered three 90 minute sessions, intended to be delivered at intervals of no less than one week and no more than two weeks apart, to the 22 intervention practices. We asked all general practitioners and practice nurses to attend all three sessions. Four dietitians were trained in the standardised delivery of the training and then delivered the programme to small group, multidisciplinary general practice teams. The programme promoted a model approach to obesity treatment, which incorporated best evidence and was perceived to be brief enough that primary care staff could deliver it to their patients. The training covered information on the clinical benefit of weight loss and effective treatment options, including reduction of dietary energy intake, increased physical activity, and pharmaceutical intervention.

The model of obesity management entailed practitioners seeing patients regularly (about every two weeks) until they had lost 10% of their original body weight and then less regularly (about every one to two months) for maintenance of weight over a sustained period. Current and target weight and dietary and activity targets were to be recorded in the patients' records to facilitate continuity of support across practice teams. Prescription of a moderate energy deficit diet was advocated, as recommended by the Scottish Intercollegiate Guidelines Network.[11] A "ready reckoner" was produced to allow practitioners to estimate a patient's daily energy requirement and then to calculate a daily 500 kcal (2.5 MJ) deficit. Diet sheets and supporting written resources facilitated the dietary prescription to patients. At the end of the three

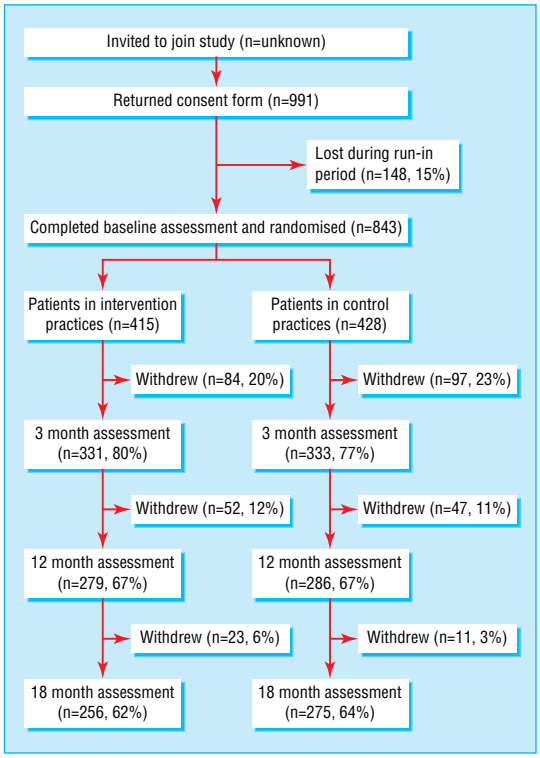

Fig 2 Flow of patients through the trial

training sessions, practices devised individualised weight management protocols based on the model and were encouraged to implement this with patients recruited to the study. Control practices were asked to provide usual care to their patients.

Outcome measures

The primary outcome measure was difference in mean weight of patients between intervention and control practices 12 months after the intervention. We also measured difference in weight at three months and 18 months post-intervention. We measured knowledge of obesity management and self reported behaviour in obesity management consultations for all practice staff before and after the intervention. We gathered this information by using a questionnaire designed by us and field tested with staff from non-participating practices.

Process assessment

Practices had no trial specific responsibility to see patients once the training intervention had been delivered. We used process assessment to provide insight into the implementation of the weight management protocol. Researchers extracted information from the medical records of those patients still participating in the trial, in both arms, one year after the intervention. These data included whether patients had been seen about their weight and whether weight, diet, and exercise targets had been recorded as advocated in the intervention.

Sample size and analysis

A clinically significant effect of intervention can be achieved with as little as 5% (or 3-5 kg) weight loss in obese people.[1 2] We designed the study to have 80% power to detect a mean difference in weight between treatment arms of approximately 3-5 kg, assuming 5% significance and a within practice correlation coefficient of 0.05. Allowing for withdrawal and loss to follow up of 15%, this gave a required number of patients per treatment arm of approximately 660, equivalent to 22 practices recruiting 30 patients each. We collated all data on a purposefully designed database by using Microsoft Access software. We analysed change in both continuous and categorical outcome variables by using STATA to account for both within cluster and between cluster variation. We did analyses on an intention to treat basis, where possible.

Blinding

Patients were not aware of the intervention status of their practice, and researchers collecting outcome measurements from patients were blind to the intervention status of the practices, both before and after the intervention. Double blinding was not possible in this trial, as practice staff were inevitably aware of whether or not they had been trained.

Results

All 44 practices completed the trial. One practice (allocated to the intervention group) declined the training intervention but agreed to continue with outcome assessment, and one would only consent to the training if two of the three sessions were combined. Training was delivered between June and November 2000. This extended intervention period was due to difficulties in arranging training sessions in practices.

Table 1 Baseline characteristics of patients and practices

	Intervention	Control
Patients	**(n=415)**	**(n=428)**
Mean (SD) weight (kg)	100.8 (18.1)	100.2 (17.4)
Mean (SD) body mass index (kg/m^2)	37.0 (5.7)	36.9 (5.8)
Mean (SD) age (years)	48.4 (10.9)	48.8 (12.2)
No (%) male	104 (25)	116 (27)
Practices	**(n=22)**	**(n=22)**
No (%) with dietetic input	9 (41%)	9 (41%)
Median (interquartile range) socioeconomic status	3.4 (–0.9-5.8)	2.4 (0.1-7.1)
Median (interquartile range) No of general practitioners	4 (3-6)	4 (2-6)

Table 2 Difference in weight and body mass index between patients from intervention and control practices

	Intervention	Control	Difference (intervention–control) (95% CI)	P value
Weight (kg)				
Three months after training (n=664)	100.4	99.8	+0.6 (–2.1 to 3.2)	0.7
12 months after training (n=565)	100.3	99.3	+1.0 (–1.9 to 3.9)	0.5
18 months after training (n=531)	100.8	99.5	+1.3 (–1.8 to 4.4)	0.4
Body mass index (kg/m^2)				
Three months after training (n=663*)	36.8	36.9	–0.2 (–1.2 to 0.8)	0.7
12 months after training (n=564*)	36.9	36.8	0 (–1.0 to 1.0)	0.96
18 months after training (n=530*)	37.1	36.9	0.1 (–1.0 to 1.1)	0.9

*Height missing from data for one patient.

Table 3 Change in practitioners' knowledge of obesity management

Question (correct response)	Odds ratio (95% CI) of providing correct response (intervention *v* control)	P value
By 1997, the prevalence of obesity in England was? (17% men, 20% women)	2.0 (1.1 to 3.5)	0.02
What rate of weight loss would you recommend for obese adults? (0.5-1 kg a week)	1.5 (0.5 to 3.9)	0.4
The recommended energy deficit for long term weight loss is? (500 kcal)	3.0 (1.6 to 5.8)	0.001
Which of the following meals has the highest fat content? (Minced meat pie, chips, and peas)	0.56 (0.3 to 1.02)	0.06
Adults trying to lose weight should be advised to eat less starchy food? (False)	1.3 (0.5 to 2.9)	0.6

In total, 991 patients gave consent, of whom 843 (85%) attended for collection of baseline data and were subsequently randomised. Table 1 shows the characteristics of the practices and patients after randomisation. Table 2 shows the difference in patients' weight after the training. Twelve months after the training the patients in the intervention group were 1 (95% confidence interval −1.9 to 3.9) kg heavier than the controls (P = 0.5).

Two hundred and thirty one (95%) practitioners completed the questionnaire at baseline, and 192 (83%) of these completed the post-intervention assessment. Table 3 shows the difference in knowledge levels between control and intervention practitioners after the training. The odds ratio of providing the correct response was higher for trained practices for all but one of the five questions, but only two of these reached statistical significance.

We collected process information from the medical records of 670 patients. Table 4 shows the difference in activities between intervention and control practices one year after the training intervention. Patients in trained practices consulted, on average, on two more

occasions than patients in control practices in the year after the delivery of the training. Trained practices were more likely to discuss weight (odds ratio 2.0, P = 0.003), and the records of patients from trained practices were more likely to include weight (odds ratio 2.0, P = 0.004), target weight (13.6, P ≤ 0.001), and dietary targets (4.5, P = 0.02).

Discussion

The rapid increase in the incidence of obesity and associated comorbidities presents a major challenge to health care in the United Kingdom. The National Audit Office reported a lack of "buy in" towards management of obesity on the part of general practitioners, but also that training, information on the effectiveness of interventions, and resources to use with patients would assist them in the task.[5] Our findings indicate that a training package promoting a brief and prescriptive approach to the treatment of obesity by using lifestyle modification, and intended to assist primary care staff incorporating such treatment into routine care, did not ultimately affect the weight of this motivated and at risk cohort of patients.

Impact of the intervention

The training was well received and was based on an acceptable model applied in a previous study.[8] Practitioners' knowledge of the principles of obesity management improved, and trained practitioners were more likely to implement weight management strategies promoted in the training. Patients from trained practices were seen more often and were more likely to have weight, target weights, and dietary targets documented in their records, but in absolute terms the level of implementation was low. Target weights were recorded for only 14% of participating patients in trained practices, compared with just 3% of participating patients in control practices, in the year after delivery of the training. Patients in trained practices attended two more consultations than did those in control practices, averaging eight consultations in the year after the intervention. Treatment as per protocol would entail fortnightly follow up until 10% of initial body weight was lost, potentially some 20 or more consultations in the year. The low level of implementation of the obesity management model means that we cannot draw conclusions about its effectiveness.

The training programme was realistic in terms of the type of training that might be delivered to primary care teams by NHS dietitians. Obesity management is complex, and strategies that have shown promise in the literature include the application of behaviour change techniques, antiobesity drugs, and promotion of higher levels of physical activity. Undoubtedly, a four and a half hour training programme can only scratch the surface of these issues. Even so, several general practitioners from these motivated practices expressed misgivings about the need to devote so much time to the subject, and indeed more in-depth training for practice teams is unlikely to be feasible, set against competing educational priorities in general practice.

Strengths and weaknesses of the study

Several previously recognised characteristics of obesity treatment trials were evident in our study.[12] Samples are usually biased towards women, and our sample was predominately female. In addition, our sample was skewed towards more extreme obesity. Retention of participants in obesity trials is recognised as problematic,[12] and it was potentially an even greater problem in our study, as the intervention was aimed at practices and it may have been difficult for patients to see any benefit from participation. Despite the observed loss to follow up of patients, the study maintained 80% power owing to a negligible within practice correlation coefficient for the main outcome variable.

Using the general practice as the unit of randomisation reduces the possibility of contamination between treatment arms by minimising the risk of contact between health professionals from different arms. As stated earlier, in an effort to further eliminate contamination, we offered training only to general practitioners and practice nurses. In reality, enforcing this research condition was difficult, and many additional practice staff, including district nurses and health visitors, turned up for the training. We detected no evidence of contamination between intervention groups, but this cannot be ruled out.

Conclusion

This training programme resulted in only limited implementation of an approach to obesity management and did not achieve improved patient weight loss. A more in-depth training programme might be more successful at changing practitioners' behaviour but is unlikely to be generalisable to most general practices in the United Kingdom. Other strategies to manage obesity in primary care urgently need to be considered and evaluated. These might include motivated and dedicated obesity specialists placed at the level of the primary care trust, use of leisure services, and use of the commercial weight loss sector.

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Table 4 Difference in process outcomes between patients from intervention and control practices after training. Values are numbers (percentages) responding "Yes" unless stated otherwise

Question	Intervention	Control	Odds ratio (95% CI)	P value
Has patient been seen since end of intervention? (n=668)	317 (94)	318 (96)	0.6 (0.3 to 1.3)	0.23
Median No of times (n=626)	8	6	1.3 (1.0 to 1.6)*	0.05
Is there evidence that weight has been discussed? (n=650)	186 (57)	129 (40)	2.0 (1.3 to 3.2)	0.003
Has weight been recorded? (n=650)	197 (61)	137 (42)	2.0 (1.3 to 3.3)	0.004
Has a target weight been recorded? (n=643)	46 (14)	9 (3)	13.6 (4.2 to 44.3)	<0.001
Have dietary targets been recorded? (n=648)	48 (15)	14 (4)	4.5 (1.2 to 16.7)	0.02
Have exercise targets been recorded? (n=648)	46 (14)	25 (8)	1.9 (0.7 to 5.0)	0.2

*Estimate and confidence interval for attendance rate ratio.

What is already known on this topic

Most obesity management in the United Kingdom takes place in primary care, but the approach is not coordinated or consistent

Evidence shows that lifestyle modification can be effective in the treatment of obesity

The Department of Health expects primary care to deliver weight management to obese patients

What this study adds

A brief training programme delivered to primary care improved practitioners' knowledge and behaviour but did not result in improved weight loss in obese patients

Implementation of the brief, prescriptive weight management model promoted in the training was low

This raises questions about the feasibility of primary care practitioners incorporating weight management into routine clinical care

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Contributors: HM was responsible for the conception, design, analysis, interpretation, and project management of the study and produced the first draft of this manuscript. CDS contributed to the design and was involved in project management, interpretation of results, and the second draft of the manuscript. DCG contributed to the design, supervised and helped to conduct the analysis, and contributed to the manuscript. PT contributed to the design of the study, was part of the advisory committee, and contributed to the manuscript. JG, MH, KH, and SW contributed to the project design, helped to develop and deliver the intervention, carried out data collection, and contributed to interpretation of results and to the manuscript. AJA was the principal investigator, supervised HM, shared responsibility for conception, design, interpretation, and project management, and contributed to the manuscript. HM and AJA are the guarantors.

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Competing interests: None declared.

Ethical approval: The Northern and Yorkshire regional medical research ethics committee and five local research ethics committees approved the study.

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