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1 **Lifestyle groups sustain weight loss at 12 months.**

2 **A randomised controlled trial comparing cognitive behaviour groups, individual**
3 **counselling and information only, in the management of weight and health related**
4 **variables.**

5

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14

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16 therapy

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1 **ABSTRACT**

2

3 **Objective:**

4 To investigate the effect of an 8 week group based cognitive behaviour therapy
5 intervention on change in weight and other weight related variables, change in
6 physical activity and change in health and well being compared to individualised
7 dietetic treatment or giving information only

8

9 **Design:**

10 A randomised control trial with an 8-week intervention period – two intervention
11 groups, a group based cognitive behaviour therapy intervention, Fat Booters Inc –
12 (FBI) and individualised dietetic treatment (IDT) and control group receiving an
13 information booklet only (BO). Intervention for 8 weeks with monthly follow-up to 6
14 months and further follow-up at 12 months, conducted in real practice setting.

15

16 **Subjects:**

17 A total of 176 adults with body mass index (BMI) $> 27\text{kg/m}^2$, mean ($\pm\text{SD}$) age 48 ± 13
18 years, mean BMI $34\pm 5.5\text{ kg/m}^2$.

19

20 **Main Outcome Measures:**

21 Weight, percent body fat, waist circumference, physical activity, health status, self-
22 efficacy and satisfaction with life were measured at baseline, 3, 6 and 12 months.

1

2 **Results:**

3 A statistically significant difference between groups was observed for weight change
4 over time ($p = 0.05$). The change in weight (mean \pm se) for the FBI group was
5 significantly greater than the BO group at 6 and 12 months (-2.8 ± 0.7 compared to –
6 1.0 ± 0.6 kg, $p < 0.05$ and -2.9 ± 0.9 compared to $+0.5 \pm 0.9$ kg, $p < 0.005$,
7 respectively). Change in weight in the IDT group did not differ from the FBI group at
8 any time point. For all groups, waist circumference was significantly less than
9 baseline at all time points ($p < 0.001$). Significant differences in self-efficacy were
10 observed over time ($p = 0.02$), with both intervention groups having greater self-
11 efficacy than the BO group. Significant drop-outs occurred over time for all three
12 groups.

13

14 **Conclusions**

15 A cognitive behaviour based intervention was more effective than providing
16 information alone and as effective as intensive individualised dietetic intervention in
17 weight loss and improvements in self-efficacy. The FBI group was more cost effective
18 to conduct in a real practice setting.

1 INTRODUCTION

2

3 Overweight and obesity have grown to be one of the major public health problems of
4 the 21st century, both in developed and developing countries¹. Recent national data
5 indicate that approximately 60% of the adult Australian population is overweight or
6 obese².

7

8 Obesity per se has now been recognised as an independent chronic condition, which
9 contributes over 4% to the burden of disease in Australia³. Combined with lack of
10 physical activity, which contributes 7%, this is an overall contribution of 11%. The true
11 cost of this burden of disease has been estimated at A\$680-1239m from the impact
12 of obesity and overweight alone⁴.

13

14 Intervention studies for the management of overweight and obesity have shown
15 disappointing results long term, however a review of many studies has shown
16 confounding due to poor study design^{5,6}. On the other hand, lifestyle interventions
17 resulting in weight losses of 3-5 kg, have been effective in the prevention or delay of
18 disease^{7,8,9}. Intervention studies now focus on small, sustainable losses of weight in
19 the order of 5-10%¹⁰.

20

21 Evidence based guidelines for weight management recommend energy restriction,
22 combined with increase in exercise and behaviour therapy^{11,12}. Failure of patients
23 complying with prescriptive medical advice has been linked to the style of treatment.
24 Disease management styles, which centre around the patient and their goals have

1 resulted in better adherence to treatment protocols, reduced morbidity and improved
2 quality of life¹³.

3

4 Use of chronic disease self-management and patient centred care approaches is also
5 important in the management of weight. These approaches include shared goal
6 setting, developing action plans, teaching skills and regular follow-up¹⁴.

7

8 Studies demonstrating success in weight loss are usually conducted in tightly
9 controlled clinical trial settings. Most have invested large resources in the form of
10 financial incentives for attending programs¹⁵, for meal replacements¹⁶ or for
11 medications in drug trials¹⁷. When these methods are translated to real practice
12 settings the results are often disappointing, calling experts to recommend more
13 'effectiveness' rather than 'efficacy' based research¹. Effectiveness research focuses
14 on the reach, efficacy, adoption, implementation and maintenance (RE-AIM) of a
15 program in real world settings¹⁸. This research is conducted so that its results have
16 external validity, generalisability and sustainability in real practice. Unlike efficacy
17 interventions, effectiveness based research (i) uses heterogeneous, representative
18 samples with few exclusion criteria; (ii) uses brief feasible interventions which are
19 adaptable to different settings; (iii) uses a variety of staff with competing demands to
20 implement the interventions; and (iv) focuses on maintaining the ability of the setting
21 to continue the intervention as standard practice. The current study was designed to
22 reflect real clinical practice.

23

24 This study aimed to demonstrate that (1) group based cognitive behaviour therapy
25 intervention is more effective at reducing weight and other weight related variables,

1 increasing physical activity and improving health and well-being than individualised
2 dietetic treatment or giving information only, at 3 months, and (2) group based
3 cognitive behaviour therapy intervention is more effective at maintaining these
4 changes than individualised dietetic treatment or giving information only, at 12
5 months.
6

1 **METHODS**

2

3 **Study Design**

4 The study was a randomised-controlled 12-month trial conducted between two
5 tertiary hospitals (public and private) between February 2002 and July, 2003. The
6 trial replaced the previous hospital outpatient service for weight management at the
7 public hospital but was a new service at the private facility, which previously had not
8 provided any ambulatory care services. A project manager (TD) was employed to
9 manage the recruitment, randomisation of subjects and maintenance of data. A total
10 of thirteen dietitians and nutrition staff employed by the two sites, collected patient
11 data and provided the group facilitation, dietetic intervention and follow-up. A group
12 facilitation manual was provided for the groups and all facilitators were trained prior to
13 the trial commencing. A standard protocol was developed for use in the individualised
14 dietetic treatment.

15

16 Figure 1 shows the outline of the study design. Outcome data were collected at
17 baseline, 3 months, 6 months and 12 months. The study received ethical approval
18 from the participating institutions' ethics committees. All subjects received written and
19 oral information about the study prior to consenting.

20

21 **Study Participants**

22 Overweight and obese men and women ($\text{BMI} \geq 27\text{kg/m}^2$) were recruited for
23 participation in the study from current hospital referrals and by advertising in local
24 community newspapers. Exclusion criteria included body mass index (BMI) less than
25 27 kg/m^2 , less than 18 years of age, from non-English speaking background requiring

1 an interpreter or cognitive impairment. Potential participants were not excluded based
2 on medical condition(s) or medication(s).

3

4 **Randomisation**

5 After screening for exclusion criteria and following informed consent, participants
6 were randomised by the project manager, using a random number table, into one of
7 three intervention groups at one of two hospital sites. The allocation ratio for the two
8 hospital sites (public and private) was 2:1 due to available resources for
9 implementing the intervention.

10

11 **Dietary Interventions**

12 Participants in all three groups were required to purchase a nutrition resource booklet
13 based on cognitive behaviour therapy principles¹⁹. Participants assigned to the Fat
14 Booters Incorporated (FBI) group attended an eight-week (one and a half hours per
15 week for six weeks with follow-up at 8 weeks) lifestyle behaviour management group,
16 with 10-12 participants per group.

17

18 The group program used a tri-phasic design involving knowledge and skill
19 development, cognitive behaviour therapy and relapse prevention with a focus on
20 improvements in self-concept, self-efficacy and skills mastery. It emphasised
21 empowerment, development of self-efficacy and skills, with a non-directive approach
22 taken by facilitators. While information was available about diet and exercise, it was
23 up to individuals if they acted on this information in making changes to their lifestyle.

24

1 Following completion of the program, FBI participants attended a follow-up visit at
2 week 8 and then monthly until 6 months. Attendance at each session during the initial
3 intervention and at follow-up was recorded.

4

5 Participants assigned to the individualised dietetic treatment (IDT) group, were
6 provided with individualised weekly contact with a dietitian for eight weeks. This
7 included an initial nutrition assessment, provision of an individualised diet prescription
8 (aiming to achieve a weight loss of 0.5-1kg/week), and an exercise prescription (20 –
9 30 minutes of accumulated exercise most days of the week). IDT participants
10 attended monthly follow-up visits from week 8 to 6-months. Attendance at each
11 session during the initial intervention and at follow-up was recorded. If a patient was
12 unable to attend the clinic for an appointment, an attempt was made to provide the
13 intervention via the telephone for that appointment.

14

15 Participants in the booklet only (BO) group acted as the control group and were
16 provided with no further nutritional advice other than the nutrition resource booklet.

17

18 **Outcome Measures**

19 All outcome measures for all participants, in all groups, were assessed at baseline, 3
20 months, 6 months and 12 months. Weight and body composition were measured
21 using foot-to-foot bioelectrical impedance analysis (Model TBF-410, Tanita Inc.,
22 Tokyo, Japan). Weight and percent body fat were measured without shoes or heavy
23 clothing to the nearest 0.1kg and 0.1%, respectively. Height was measured by a fixed
24 stadiometer, without shoes, to the nearest 0.5cm. Body mass index (BMI) was
25 calculated from weight in kilograms divided by height in meters squared. Waist

1 circumference was measured with a non-expandable tape at the point of the
2 umbilicus, to the nearest 0.5 cm.
3
4 Physical activity level was assessed using the short format International Physical
5 Activity Questionnaire (IPAQ)²⁰. The questionnaire collected information on the
6 number of days and amount of time spent (when greater than 10mins) on vigorous
7 activities, moderate activities and walking in the past 7 days. Participants were
8 categorised as 'sufficiently active' or 'not sufficiently active'. Sufficient activity was
9 defined as five or more days of moderate activity or walking of at least 30 minutes per
10 day (150 minutes per week) or three or more days of vigorous activity of at least 20
11 minutes per day. These criteria are based on national and international
12 recommendations for the minimum amount of physical activity required for good
13 health²¹. The reported test-re-test reliability Spearman correlation coefficient was
14 0.80 and median criterion validity correlation against an accelerometer was 0.30²⁰.
15
16 Health status was measured using the General Health Questionnaire (GHQ-12)²².
17 The GHQ-12 is a 12-item scale for measuring non-psychotic disorders. The
18 questionnaire is usually used as a continuous scale (0 – 12) with 0 indicating good
19 health. However, due to non-normal distribution of this variable in our study
20 participants, scores on the GHQ-12 were categorised in to two categories – good
21 health (0) and not in good health (greater than or equal to 1). Self-efficacy was
22 assessed using the Generalised Self-Efficacy Scale (GSES), a 10-item, four-point
23 Likert scale²³. Overall scores range from 10 – 40, with a higher score indicating a
24 higher level of self-efficacy. General well being was measured using the Satisfaction
25 with Life Scale (SWLS)²⁴. The SWLS is a five-item, seven-point Likert scale.

1 Individual items are summed for an overall score ranging from 5 to 35, with a higher
2 score indicating better well-being. The SWLS has been shown to be a reliable and
3 valid measure of overall quality of life. Psychometric testing of the GHQ-12, GSES
4 and SWLS has indicated high level of agreement (Cronbach's alpha = 0.82 to
5 0.93)^{22,25,26}.

6

7 **Statistical Analysis**

8 General descriptive and bivariate statistical analyses were carried out using SPSS for
9 Windows (Version 11.00, 2003, SPSS Inc., Chicago, IL, USA). Continuous variables
10 were tested for normal distribution. Data are presented as means \pm sd or se for
11 continuous variables and counts (percentages) for categorical variables. Analyses
12 were carried out on an intention-to-treat basis. One-way analysis of variance
13 (ANOVA) and Fisher's exact test were used to determine whether dietary intervention
14 groups differed at baseline and whether differences existed between those subjects
15 for whom complete data was obtained and those who had missing data (incomplete
16 or drop-outs). To examine changes in intervention groups over time and to maximise
17 the amount of data that were used in the analysis the following analysis was
18 completed; repeated measures analysis of variance regression models for
19 continuous variables and repeated measures logistic regression models for
20 categorical variables, using a generalised estimating equations approach (SUDAAN
21 statistical package, Version 7.5, 1997, NC, USA). The significance was set at $P < 0.05$.

22

1 **Results**

2

3 A total of two hundred and eight (n=208) participants were assessed for eligibility
4 between January and July 2002 (Figure 1). Seventeen subjects, with BMI<27 kg/m²
5 (n=11) and cognitive impairment or lack of language skills (n=6) were excluded. One
6 hundred and ninety one (191) participants were randomised into the three intervention
7 groups of the study, however a small number (n=14) withdrew consent following
8 randomisation and before baseline data were collected. Figure 1 shows the numbers of
9 participants at enrolment, allocation, and follow-up in each group. The intention to treat
10 analysis using Sudaan allows for the management of missing data ?????? something
11 here Marina?

12

13

14 Baseline characteristics of participants did not differ significantly between the intervention
15 groups (Table 1). Groups also did not differ with respect to employment status, highest
16 level of education, living situation, previous weight loss and dieting at commencement of
17 the study. Characteristics of participants differed slightly between the two hospital sites –
18 participants at the public hospital had a significantly higher BMI (Fisher's Exact test p =
19 0.02) and waist circumference (Fisher's Exact test p = 0.04) than participants attending
20 the private hospital.

21

22 Table 2 shows the number of participants in each intervention group for whom complete
23 data at all four time points were collected, those for whom incomplete data were
24 collected (two or three time points) and those who were classed as true drop-outs, for
25 whom only baseline data were available.

1
2 There was a significant difference in the amount of data available for participants
3 between intervention groups (Fisher's Exact test, $p = 0.01$). A greater number of
4 participants in the BO group than expected were dropout, while more participants in the
5 IDT group than expected had complete data. The amount of data available for
6 participants did not differ significantly between hospital sites. There were significant
7 differences in the data available for participants for gender, age, BMI and percent body
8 fat. Significantly more females than expected were drop outs, compared to males
9 (Fisher's Exact test, $p = 0.01$). Drop-outs tended to be younger than participants for
10 whom complete and incomplete data were available ($F_{(2,158)} = 3.248$, $p = 0.04$).
11 Participants who dropped out had a higher BMI (36.5 ± 6.1 vs 33.8 ± 5.4 kg/m²; $F_{(2,173)} =$
12 4.065 , $p=0.019$) and percent body fat (44.1 ± 6.3 vs $39.4 \pm 6.9\%$; $F_{(2,164)} = 6.331$,
13 $p=0.002$).

14

15 **Weight, Body Mass Index, Percent Body Fat and Waist Circumference**

16 Changes in weight, BMI, body fat and waist circumference between the three groups
17 over the four time points are shown in Table 3. A statistically significant difference
18 between the groups over time was evident for change in weight (Wald $F_6 = 2.13$, $p =$
19 0.05). This was reflected in a difference in change in BMI between groups, which
20 approached statistical significance (Wald $F_6 = 2.1$, $p = 0.06$). Change in weight was
21 compared to baseline and compared to FBI group. Significant differences in change in
22 weight were observed between the BO and FBI group at 3 months ($p = 0.05$) and 12
23 months ($p = 0.005$). Change in weight in the IDT group did not differ to the FBI group at
24 any of the time points.

25

1 Change in percent body fat and waist circumference did not differ between the three
2 groups over the 12 months. For all participants, waist circumference was significantly
3 lower than baseline level at each of the follow-up time points ($p < 0.001$) I could not find
4 this on the Sudaan printout, it all looks non-significant to me! however percent body fat
5 was not significantly different from baseline at 3 months, 6 months or 12 months.

6

7 **Physical Activity Levels**

8 There appeared to be differences in the proportion of patients who were sufficiently
9 active between the intervention groups over time, although not statistically significant
10 (Wald $F_6 = 11.46$, $p = 0.075$). Table 4 shows the odds of being sufficiently active in the
11 IDT and BO groups at 3 months, 6 months and 12 months, relative to baseline and the
12 FBI group. Relative to the FBI group, the odds of being sufficiently active at 3 months
13 compared to baseline were 0.27 (95% CI 0.07, 1.02) times lower in the IDT group
14 ($p=0.053$) and 0.19 (95%CI 0.05, 0.77) times lower in the BO group ($p=0.021$). There
15 were no further significant differences in physical activity level at 6 months or 12 months.

16

17

18 **Health and Wellbeing Scales**

19 Health status and general wellbeing did not differ between groups over time. Significant
20 differences were observed for self-efficacy score between groups over the 12 months
21 (Wald $F_6 = 2.57$, $p = 0.02$). Table 5 shows the mean scores for the three groups. Mean
22 self-efficacy score for BO group differed significantly to FBI group at 3 months ($p = 0.01$)
23 and 12 months ($p < 0.01$).

24

25

1 **Discussion**

2 Obesity is an increasing problem worldwide, but particularly in Australia, where calls for
3 government action to address the problem are evident¹⁰. Few interventions, where
4 weight loss is sustained and which address lifestyle issues, have been designed in real
5 practice settings or have been evaluated for long enough periods¹.

6
7 Our study was designed to implement recent evidence based guidelines for the
8 management of overweight and obesity in a real practice environment. We have
9 demonstrated that an 8-week intensive lifestyle intervention, with monthly follow-up to 6
10 months could be conducted in a real practice setting and produce modest results of 3kg
11 weight loss, which were sustained over 12 months.

12 Our previous work also indicated greater weight losses in a tightly controlled research
13 setting, however these losses were not sustained over time²⁷. Other studies have
14 indicated that the effects of lifestyle interventions are often modest^{7,9}. A randomised trial,
15 which assigned 423 overweight people to a structured commercial weight loss program
16 or self help program, observed mean (\pm sd) weight loss of 4.3(\pm 6.1)kg compared to 1.3(\pm
17 6.1)kg at 12 months, and 2.9(\pm 6.5)kg compared to 0.2 \pm 6.5)kg at 2 years. Participants
18 in the structured weight loss arm received incentives in the form of vouchers for the cost
19 of the commercial program and had contact with the researchers every one to two weeks
20 over the two-year period¹⁵.

21
22 In our study, there was no significant difference in weight loss between the two
23 intervention groups over the 12 months. There was a trend however for the FBI group to
24 maintain weight loss compared to the other 2 groups. It is therefore possible that the
25 cognitive behaviour therapy program used in the group provided better strategies for

1 maintaining healthy behaviours long term. Leibbrand et al²⁸ found that weight loss
2 following a 10-week behavioural intervention was sustained after 18 months, with and
3 without follow-up support. They propose that the CBT strategies learned and reinforced
4 in the 10-week behavioural intervention were sufficient to sustain weight loss without
5 support for the follow-up period.

6

7 The FBI group-based program also took a patient centred approach, offering a structured
8 way for participants to become expert in managing their lifestyle issues and chronic
9 disease(s). Self efficacy is enhanced when patients have a collaborative plan for self
10 care which includes an assessment of beliefs, barriers and supports; a personal action
11 plan that identifies both goals and barriers; and an active follow-up plan that monitors
12 progress, while providing support for the patient throughout¹⁴.

13

14 The effectiveness of the intervention in preventing further weight gain is evident in both
15 the intervention groups compared to the control. Health authorities indicate that a mean
16 weight loss of 1 kg in the Australian population would have major impact on health
17 costs²⁹. Other studies have shown the effectiveness of dietetic intervention on minimising
18 or delaying the costs of drug and other treatment in cardiovascular disease³⁰ and
19 diabetes³¹. This study did not attempt to assess cost effectiveness using health
20 economics modelling but it is clearly evident that implementation of the FBI program in a
21 real practice setting is more cost efficient than standard individual dietetic counselling,
22 while at the same time achieving similar outcomes over a 12-month period.

23

1 **Cost to replicate**

2 While there appeared to be no difference between the FBI and the IDT groups in weight
3 outcomes, the group-based intervention was able to manage more overweight patients
4 over time. A conservative estimate of the amount of time required to conduct the FBI
5 group, including room set up and documentation was about 3 hours/session. The FBI
6 program accommodated 10-12 participants, over 6-8 weeks. It has continued to run at
7 least 6 sessions per year, so a minimum of 60-72 overweight people can be
8 accommodated per year. For the same time frame of a 3-hour clinic, the IDT program,
9 which includes a 1-hour initial individual consultation, followed by seven 20-minute
10 weekly review sessions and 4 monthly follow-up sessions of 20 minutes, can manage
11 only 25 people per year. It is estimated that the cost of providing dietetic service for
12 weight management would range from \$A253-415 per patient on an individual basis
13 compared to \$1A06-117 per patient on a group basis.

14
15 There were a number of limitations in this study. Firstly there was a large attrition rate,
16 particularly from the BO group, where only 37% of the initial sample had complete data.
17 In a review of randomised control trials with at least 12-month follow-up on advice on
18 low-fat diets for obesity, 40% losses to follow-up were demonstrated with only 20% of
19 subjects remaining in one study, which was extended to 18 months³². While care is
20 required in interpreting the results in such studies of weight loss, the high dropout rate is
21 not an unusual phenomenon. Every attempt was made to contact all participants at 12
22 months, unless consent had been withdrawn.

23
24 There were also significant differences in gender, age, BMI and percent body fat
25 between participants with complete data, missing data and dropouts, which have

1 decreased the representativeness of our sample. To account for the missing data, results
2 were analysed on an intention-to-treat basis using a generalised estimating equations
3 approach.

4
5 Secondly the reported levels of sufficient physical activity by participants at baseline
6 (57.9%) were considerably greater than the general Australian population (45.2%)³³. This
7 may be due to over reporting by participants in this study or due to the potential over
8 estimation of physical activity level using the IPAQ, which has been reported in other
9 studies³⁴. The measurement error may have attenuated the true effect size of physical
10 activity in this study.

11
12 Finally the study did not measure other clinical endpoints such as blood sugars, lipids or
13 other markers of disease, so no conclusions can be drawn on the impact of the weight
14 loss and increases in physical activity on improvements in health outcomes other than
15 weight.

16
17 Study strengths include being conducted under real world clinical practice conditions.
18 That is, minimal inclusion and exclusion criteria were applied, incentives were not
19 provided and dietetic staff provided the interventions within normal workplace
20 requirements. This is in contrast to previous studies, which have provided participants
21 with enticing incentives to maintain involvement¹⁵ or applied stringent eligibility
22 criteria^{16,28}, which limit generalisability of the results.

23
24 In conclusion, a group-based lifestyle program using cognitive behaviour therapy was not
25 more effective at reducing weight, increasing physical activity or improving health and

1 wellbeing at 3 months, than intensive individualised counselling or providing information
2 only. The FBI program was more effective at achieving weight loss and improving self-
3 efficacy at 12 months compared to the booklet only group. Both the FBI and IDT groups
4 sustained weight losses of 2-3kg at 12 months. The FBI program can be applied to both
5 a public and private ambulatory setting and the structured nature of the FBI program and
6 the training manual provided can easily be learnt by health professional and is flexible
7 enough to be delivered by a range of practitioners. Added to this, we have shown that
8 this type of program is possible to conduct under real work conditions, is more cost
9 efficient and provides at least as good outcomes over 12 months as an intensive
10 individualised approach.

11

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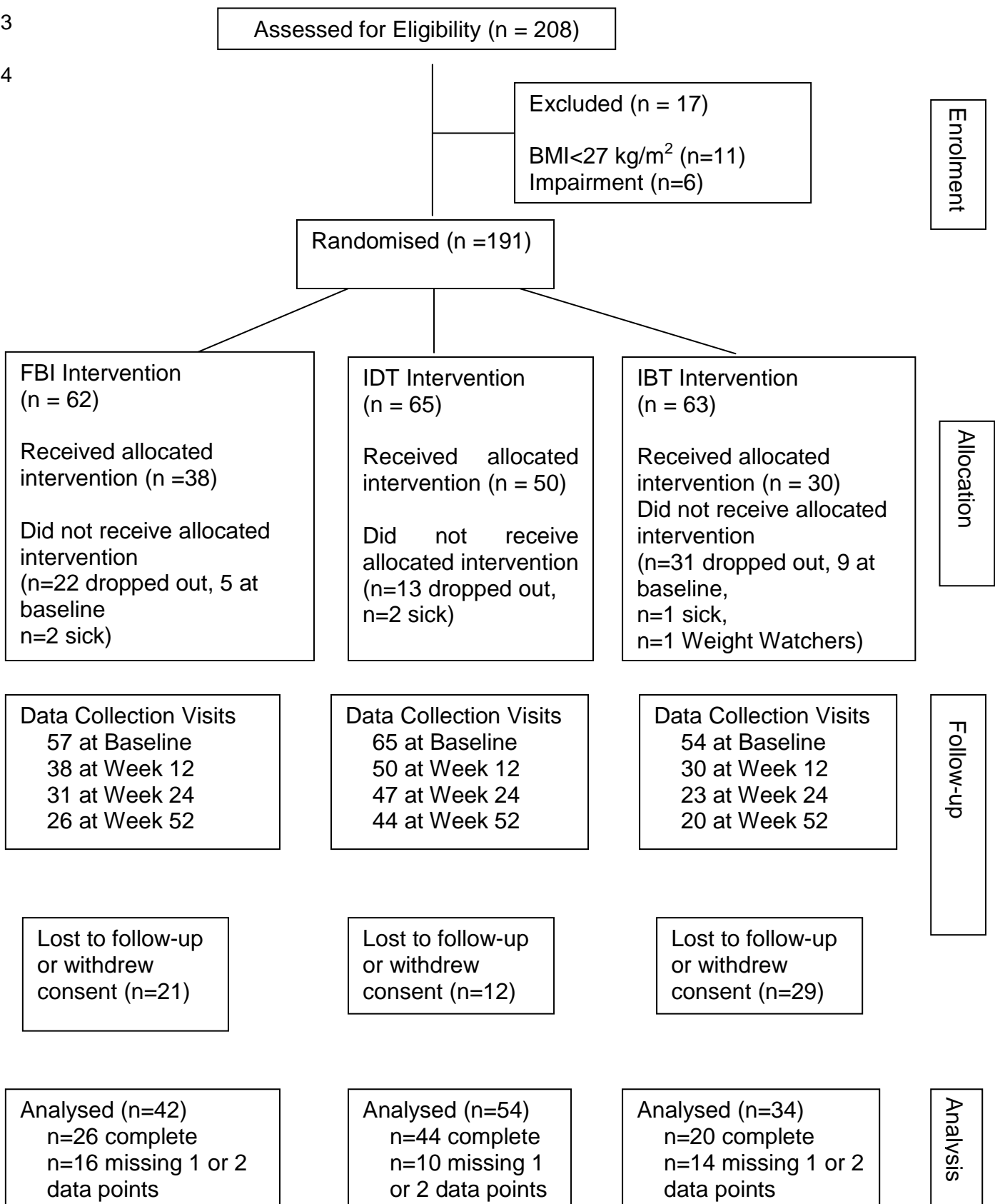
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1 Figure 1. Study design and intention to treat analysis protocol

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1 **Table 1** Baseline characteristics of participants by intervention group

	FBI	IDT	BO
N	57	65	54
Age (y)	49 ± 13	48 ± 13	47 ± 14
Gender (M:F)	19:38	16:49	12:42
Weight (kg)	94.6 ± 16.8	95.4 ± 20.7	101.6 ± 18.4
BMI (kg/m ²)	33.7 ± 4.6	34.2 ± 5.9	35.8 ± 6.2
Body Fat (%)	39.6 ± 6.4	41.4 ± 7.1	41.9 ± 7.4
Waist (cm)	111.5 ± 13.3	111.5 ± 16.2	114.3 ± 17.3
GHQ-12			
Good Health	24 (42.1%)	27 (41.5%)	22 (40.7%)
Not Good Health	33 (57.9%)	38 (58.5%)	32 (59.3%)
GSES	31 ± 5	30 ± 5	31 ± 6
SWLS	22 ± 8	20 ± 7	22 ± 7
Activity			
Insufficient	22 (40.0%)	27 (41.5%)	21 (40.4%)
Sufficient	33 (60.0%)	38 (58.5%)	31 (59.6%)

2 Data are mean ± standard deviation or n(%).

3

1 **Table 2** Amount of available data on participants by intervention group

	FBI	IDT	BO
N	57	65	54
Complete Data	26 (45.6%)	44 (67.7%)	20 (37.0%)
Incomplete Data [†]	16 (28.1%)	10 (15.4%)	14 (25.9%)
Drop out [‡]	15 (26.3%)	11 (16.9%)	20 (37.0%)

2 [†] Missing data for one or two time points (at month 3, 6 or 12)

3 [‡] Baseline data only available

4

5

1 **Table 3** Change in anthropometric variables over time

	3 Months	6 Months	12 Months
Weight (kg)			
FBI	-1.9 (0.5)	-2.8 (0.7)	-2.9 (0.9)
IDT	-2.6 (0.4)	-2.6 (0.5)	-1.8 (0.8)
BO ¹	-1.4 (0.5)	-1.0 (0.6)	0.5 (0.9)
BMI (kg/m²)			
FBI	-0.7 (0.2)	-1.0 (0.2)	-1.0 (0.3)
IDT	-0.9 (0.1)	-0.9 (0.2)	-0.6 (0.3)
BO ²	-0.5 (0.2)	-0.4 (0.2)	0.2 (0.3)
Body Fat (%)			
FBI	-0.2 (0.7)	0.0 (0.5)	-0.2 (0.8)
IDT	-0.4 (0.4)	-1.6 (0.5)	-1.3 (0.6)
BO	0.7 (0.5)	-0.4 (0.4)	0.0 (0.5)
Waist (cm)			
FBI	-3.5 (0.6)	-4.3 (0.9)	-5.8 (1.2)
IDT	-4.6 (0.9)	-4.8 (1.1)	-4.5 (1.1)
BO	-3.5 (0.9)	-4.6 (1.5)	-3.1 (1.0)

2 Values are mean (standard error) for change from baseline

3 FBI Fat Booters Inc group

4 IDT Individual Dietetic Intervention group

5 BO Booklet Only group

6 ¹ Overall Wald $F_6 = 2.13$, $p = 0.05$ (Not sure how to report the difference stated in the
 7 text of $p < 0.05$ between FBI and BO at 3 months and $p < 0.005$ at 6 months)

8 ² Overall Wald $F_6 = 2.1$, $p = 0.06$

9

1 **Table 4** Odds ratio (95% Confidence Interval) of being sufficiently active compared to
2 baseline

	3 Months	6 Months	12 months
FBI	1.00	1.00	1.00
IDT	0.27 (0.07, 1.02)	0.62 (0.20, 1.92)	0.73 (0.24, 2.22)
BO ¹	0.19 (0.05, 0.77)	0.47 (0.13, 1.69)	2.15 (0.52, 8.84)

3

4 ¹ p=0.021

5

6

7

1 **Table 5** Mean (\pm standard error) Self-Efficacy Scores

	Baseline	3 Months	6 Months	12 Months
FBI	30.7 (0.6)	32.2 (0.8)	30.8 (1.0)	33.0 (0.8)
IDT	30.5 (0.6)	31.7 (0.6)	31.6 (0.6)	32.9 (0.6)
BO ¹	30.6 (0.8)	29.6 (1.0)	29.5 (0.9)	29.4 (1.2)

2

3 ¹ Wald $F_6 = 2.57$, $p = 0.02$ (again not sure how to report the difference at 3 months of
4 $p=0.01$ and 12 months $p<0.01$, it actually looks like $p=0.006$) I might not have the final
5 sudaan printouts for this and exercise only what Angela had.

6