Supplementary File 1 – Supplementary material

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1 Literature search strategies

RCTs for Review 1 (weight loss or weight maintenance programmes for adults with obesity and Review 5 (weight loss or weight maintenance programmes for adults with obesity compared with bariatric surgery)

MEDLINE and EMBASE

Ovid multifile search: http://shibboleth.ovid.com/

Database: Embase <1988 to 2017 Week 17>, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present> 25th April 2017

Date of Search: 25th April 2017

1 Obesity, Morbid/dh, dt, su, th use ppez
2 Morbid Obesity/dt, su, th use emed
3 Obesity, Morbid/ use ppez
4 Morbid Obesity/ use emed
5 (obes$ adj3 (morbid$ or severe$)).tw.
6 (morbid obesity or severe obesity).kw.
7 (bmi adj ("27" or "28" or "29")).tw.
8 (bmi adj ("30" or "31" or "32" or "33" or "34" or "35" or "36" or "37" or "38" or "39")).tw.
9 (bmi adj ("40" or "41" or "42" or "43" or "44" or "45" or "46" or "47" or "48" or "49")).tw.
10 (bmi adj ("50" or "51" or "52" or "53" or "54" or "55")).tw.
11 (body mass index adj ("35" or "36" or "37" or "38" or "39")).tw.
12 (body mass index adj ("40" or "41" or "42" or "43" or "44" or "45" or "46" or "47" or "48" or "49")).tw.
13 (body mass index adj ("50" or "51" or "52" or "53" or "54" or "55")).tw.
14 or/3-12
15 exp bariatric surgery/
16 bariatric.tw,kw.
(gastric adj3 (bypass or bypass or band$ or balloon$)).tw.
(gastroplast$ or gastrect$).tw.
(jejunoileal adj3 (bypass or by pass)).tw.
lipectom$.tw
diet therapy/ use ppez or caloric restriction/ use ppez or diet, carbohydrate-restricted/ use ppez or diet, fat-restricted/ use ppez or diet, reducing/ use ppez diet/ use emed or low calory diet/ use emed or low carbohydrate diet/ use emed
(diet adj3 (restrict$ or reduc$ or modif$ or calorie$)).tw.
(calori$ adj3 (reduc$ or restrict$ or limit$)).tw.
exp anti-obesity agents/ use ppez
tetrahydrolipstatin/ use emed
sibutramine/ use emed
rimonabant/ use emed
(appetite adj3 (reduc$ or depress$)).tw.
(orlistat or xenical).tw, rn.
(sibutramin$ or arcalion or reductil or medaria or meridia).tw, rn.
(rimonabant or acomplia or zimulti).tw, rn.
exp exercise/
exp sports/
(exercise or aerobic or physical activ$).tw.
weight loss/ use ppez
weight reduction/ use emed
(weight adj3 (reduc$ or loss or lose)).tw.
Weight Reduction Programs/ use ppez
exp Body Weight Management/ use emed
Behavior Therapy/
Health Education/
Counseling/ use ppez
Nutritional counseling/ use emed
Life Style/ use ppez
Lifestyle modification/ use emed
(modif$ adj3 (behavior or diet or eat? or eating)).tw.
(((diet or weight) adj3 (educat$ or counsel$))).tw.
or/15-46
1 or 2 or (14 and 49)
randomized controlled trial.pt.
controlled clinical trial.pt
randomi?ed.ab.
placebo.ab.
drug therapy.fs.
randomly.ab.
trial.ab.
groups.ab
nonhuman/ not human/
exp clinical trial/ use emed
randomization/ use emed
51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 60 or 61
exp animals/ use ppez not humans/ use ppez
nonhuman/ use emed or animal/ use emed
64 not exp human/ use emed
66 62 not (63 or 65)
67 50 and 66
68 67 not (abstract or letter or note or editorial or comment).pt.
limit 68 to yr="1990 -Current"
obesity/
(obesity adj2 (morbid or diabet$)).tw.
obesity, morbid/ use ppez
morbid obesity/ use emed
obes$.tw.
weight loss/ use ppez
weight reduction/ use emed
(weight adj1 (los$ or reduc$ or maint$ or control)).tw.
(diet adj5 weight).tw.
overweight.tw.
or/70-79
80 and 66
PsycINFO
Ovid: http://shibboleth.ovid.com/
Database: PsycINFO <1987 to April Week 3 2017>

Date of Search: 25th April 2017

1 (obes$ adj3 (morbid$ or severe$)).tw.
2 (bmi adj ("27$" or "28$" or "29$"))_.tw.
3 (bmi adj ("30$" or "31$" or "32$" or "33$" or "34$" or "35$" or "36$" or "37$" or "38$" or "39$"))_.tw.
4 (bmi adj ("40$" or "41$" or "42$" or "43$" or "44$" or "45$" or "46$" or "47$" or "48$" or "49$"))_.tw.
5 (bmi adj ("50$" or "51$" or "52$" or "53$" or "54$" or "55$"))_.tw.
6 (body mass index adj ("27$" or "28$" or "29$"))_.tw.
7 (body mass index adj ("30$" or "31$" or "32$" or "33$" or "34$" or "35$" or "36$" or "37$" or "38$" or "39$"))_.tw.
8 (body mass index adj ("40$" or "41$" or "42$" or "43$" or "44$" or "45$" or "46$" or "47$" or "48$" or "49$"))_.tw.
9 (body mass index adj ("50$" or "51$" or "52$" or "53$" or "54$" or "55$"))_.tw.
(7)
10 or/1-9
11 clinical trials/
12 randomi?ed.tw,md.
13 randomly.tw,md.
14 trial?.tw,md
15 or/11-14
16 10 and 15

CINAHL
http://search.ebscohost.com
!990- 25th April 2017
Date of Search: 25th April 2017

S1  (MH "Obesity, Morbid") OR TX ( obes[* N3 (morbid or sever*) )
S2  TX ( bmi N3 (27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39). ) OR TX ( bmi N3 (40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49). ) OR TX ( bmi N3 (50 or 51 or 52 or 53 or 54 or 55). )
S3 TX ( body mass index N3 (35 or 36 or 37 or 38 or 39). ) OR TX ( body mass index N3 (40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49). ) OR TX ( body mass index N3 (50 or 51 or 52 or 53 or 54 or 55). )
S4 S1 OR S2 OR S3
S5  (MH "Bariatric Surgery+")
S6  TX bariatric OR TX gastroplasty
S7  TX bariatric OR TX gastroplast* AND TX gastrect*
S8  TX ( gastric N3 (by pass or by pass or band* or balloon*) ) OR TX ( jejunoleal N3 (bypass or by pass ) OR TX lipectom*
S9  (MH "Diet Therapy") OR (MH "Diet, Reducing") OR (MH "Restricted Diet") OR (MH "Diet, Fat-Restricted") OR (MH "Diet, Low Carbohydrate")
S10  TX ( diet N3 (restrict* or reduc* or modif* or calorie*)) ) OR TX ( calori* N3 (reduc* or restrict* or limit*)). )
S11  (MH "Antiobesity Agents+")
S12  TX ( orlistat or xenical ) OR TX ( sibutramin$ or arcalion or reductil or medaria or meridia ) OR TX ( rimonabant or acomplia or zimulti )
S13  (MH "Exercise+")
S14  TX exercise or aerobic or physical activ*).
S15  (MH "Physical Fitness")
S16  (MH "Weight Loss")
S17  TX weight N3 (reduc* or loss or lose)).
S18  (MH "Weight Reduction Programs")
S19  (MH "Counseling")
S20  (MH "Life Style") OR (MH "Life Style Changes")
S21 TX ( modif* N3 (behavior or behaviour or diet or eat* or eating ) OR TX ( (diet or weight) N3 (educat* or counsel*)). )
S22  S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S21
S23  S4 AND S22  Limiters - Published Date: 19900101-20161231
S24  S4 AND S22  Limiters - Exclude MEDLINE records

Science Citation Index
www.webofknowledge.com
1988 - 25th April 2017

Date of Search: 25th April 2017

# 1  (TS=(morbid NEAR/3 obes$))  AND DOCUMENT TYPES: (Article)
# 2  (TS=(severe$ NEAR/3 obes$))  AND DOCUMENT TYPES: (Article)
# 3  (TS=(bmi NEAR/3 (27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39)))  AND DOCUMENT TYPES: (Article)
# 4  ((TS=(bmi NEAR/3 (40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49))))) AND DOCUMENT TYPES: (Article)
# 5  ((TS=(bmi NEAR/3 (50 or 51 or 52 or 53 or 54 or 55))))) AND DOCUMENT TYPES: (Article)
# 6  #5 OR #4 OR #3 OR #2 OR #1
# 7  (TS=(randomized or randomised or randomly))  AND DOCUMENT TYPES: (Article)
# 8  (TS=clinical trial*)  AND DOCUMENT TYPES: (Article)
# 9  #8 OR #7
# 10  #9 AND #6
# 11  (TS=(bariatric or gastroplast* or gastrect*))  AND DOCUMENT TYPES: (Article)
# 12  (TS=((gastric or jejunoileal) NEAR/3 bypass))  AND DOCUMENT TYPES: (Article)
# 13  ((TS=((gastric or jejunoileal) NEAR/3 "by pass"))) AND DOCUMENT TYPES: (Article)
# 14  (TS=(gastric NEAR/3 (band* or balloon*)))  AND DOCUMENT TYPES: (Article)
# 15 (TS=(diet NEAR/3 (restrict* or reduc* or modif* or calorie*)�)) AND DOCUMENT TYPES: (Article)
# 16 (TS=(calori* NEAR/3 (reduc* or restrict* or limit*)).) AND DOCUMENT TYPES: (Article)
# 17 (TS=(appetite NEAR/3 (reduc* or depress*).) AND DOCUMENT TYPES: (Article)
# 18 (TS=(orlistat or xenical).) AND DOCUMENT TYPES: (Article)
# 19 (TS=(sibutramin or arcalion or reductil or medaria or meridia).) AND DOCUMENT TYPES: (Article)
# 20 (TS=(rimonabant or acomplia or zimulti).) AND DOCUMENT TYPES: (Article)
# 21 (TS=(exercise or aerobic or physical active*).) AND DOCUMENT TYPES: (Article)
# 22 (TS=(weight NEAR/3 (reduc* or loss or lose))).) AND DOCUMENT TYPES: (Article)
# 23 (TS=(modif* NEAR/3 (behavior or behaviour or diet or eat? or eating)).) AND DOCUMENT TYPES: (Article)
# 24 (TS=(diet NEAR/3 (educat* or counsel*))).) AND DOCUMENT TYPES: (Article)
# 25 (TS=(weight NEAR/3 (educat* or counsel*))).) AND DOCUMENT TYPES: (Article)
# 26 #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 AND #26

Cochrane Central Register of Controlled Trials
www.thecochranelibrary.com
Issue 4 April 2017

Date of Search: 25th April 2017

#1 MeSH descriptor: [Obesity, Morbid] explode all trees and with qualifier(s): [Diet therapy - DH, Surgery - SU, Therapy - TH]
#2 MeSH descriptor: [Obesity, Morbid] explode all trees

#3 obes* near/3 (morbid* or severe*):ti,ab,kw (Word variations have been searched)

#4 bmi near/1 (27* or 28* or 29* or 30* or 31* or 32* or 33* or 34* or 35* or 36* or 37* or 38* or 39*):ti,ab,kw or bmi near/1 (40* or 41* or 42* or 43* or 44* or 45* or 46* or 47* or 48* or 49*):ti,ab,kw or bmi near/1 (50* or 51* or 52* or 53* or 54* or 55*):ti,ab,kw (Word variations have been searched)

#5 body mass index near/1 (27* or 28* or 29* or 30* or 31* or 32* or 33* or 34* or 35* or 36* or 37* or 38* or 39*):ti,ab,kw or body mass index near/1 (40* or 41* or 42* or 43* or 44* or 45* or 46* or 47* or 48* or 49*):ti,ab,kw or body mass index near/1 (50* or 51* or 52* or 53* or 54* or 55*):ti,ab,kw (Word variations have been searched)

#6 #2 or #3 or #4 or #5

#7 MeSH descriptor: [Bariatric Surgery] explode all trees

#8 bariatric:ti,ab,kw (Word variations have been searched)

#9 gastric near/3 (bypass or by pass or band* or balloon*):ti,ab,kw or gastroplast* or gastrect*:ti,ab,kw or lipectom*:ti,ab,kw or jejunoileal near/3 (bypass or by pass):ti,ab,kw (Word variations have been searched)

#10 MeSH descriptor: [Diet Therapy] explode all trees

#11 MeSH descriptor: [Diet, Reducing] explode all trees

#12 MeSH descriptor: [Diet, Fat-Restricted] explode all trees

#13 MeSH descriptor: [Diet, Carbohydrate-Restricted] explode all trees

#14 MeSH descriptor: [Caloric Restriction] explode all trees

#15 diet near/3 (restrict* or reduc* or modif* or calorie*):ti,ab,kw or calori* near/3 (reduc* or restrict* or limit*):ti,ab,kw (Word variations have been searched)

#16 MeSH descriptor: [Anti-Obesity Agents] explode all trees

#17 appetite near/3 (reduc* or depress*):ti,ab,kw or orlistat or xenical:ti,ab,kw or sibutramin or arcalion or reductil or medaria or meridia:ti,ab,kw or rimonabant or acomplia or zimulti:ti,ab,kw (Word variations have been searched)

#18 MeSH descriptor: [Exercise] explode all trees

#19 MeSH descriptor: [Sports] explode all trees

#20 exercise or aerobic* or physical activ*:ti,ab,kw (Word variations have been searched)
#21 MeSH descriptor: [Weight Loss] explode all trees
#22 MeSH descriptor: [Weight Reduction Programs] explode all trees
#23 weight near/3 (reduc* or loss or lose) :ti,ab,kw  (Word variations have been searched)
#24 weight near/3 (reduc* or loss or lose) :ti,ab,kw  (Word variations have been searched)
#25 MeSH descriptor: [Behavior Therapy] explode all trees
#26 MeSH descriptor: [Health Education] explode all trees
#27 MeSH descriptor: [Counseling] explode all trees
#28 MeSH descriptor: [Life Style] explode all trees
#29 diet near/3 (educat* or counsel*):ti,ab,kw or modif* near/3 (behaviour or behavior or diet or eat or eating):ti,ab,kw or weight near/3 (educat* or counsel*):ti,ab,kw (Word variations have been searched)
#30 #7 or #8 or #9 or #10 or #11 or #12 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29
#31 #6 and #30
#32 #1 or #31 Publication Year from 1990 to 2016, in Trials
#33 conference abstract  (Word variations have been searched)
#34 #32 not #33
REVIEW 2 UK non-randomised studies

MEDLINE and EMBASE

Ovid multilfile search: http://shibboleth.ovid.com/

Database: Embase <1980 to 2017 Week 17>, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present> 25th April 2017

Date of Search: 28th April 2017

1 *obesity/
2 morbid obesity/ use emez
3 exp obesity, morbid/ use ppez
4 (obese or obesity).tw,kw.
5 or/1-4
6 Weight Loss/ use ppez
7 weight reduction/ use emez
8 (weight adj1 (los$ or reduc$ or maint$ or control$ or manag$)).tw,kw.
9 (reduc$ adj2 (bmi or body mass index)).tw.
10 (reduc$ adj2 (waist adj3 (ratio$ or circumference))).tw.
11 (obesity adj1 manag$).tw,kw.
12 anti obesity.tw,kw
13 or/6-12
14 (obes$ adj3 (morbid$ or severe$ or extreme$)).tw,kw.
15 comparative study/ use ppez
16 follow-up studies/ use ppez
17 time factors/ use ppez
18 Treatment outcome/ use emez
19 major clinical study/ use emez
20 controlled study/ use emez
21 clinical trial/ use emez
22 (preoperat$ or pre operat$).mp. use ppez
23 (chang$ or evaluat$ or reviewed or baseline).tw.
24 (prospective$ or retrospective$).tw.
(cohort$ or case series).tw.
(compare$ or compara$).tw.
case report/ use emez
case reports.pt
or/15-26
29 not (27 or 28)
5 and 13 and 30
exp great britain/ use ppez
united kingdom/ use emez
(United kingdom or uk or Britain or scotland or England or wales or Ireland or London or Birmingham or Leeds or Glasgow or Sheffield or Bradford or Edinburgh or Liverpool or Manchester or Bristol or Wakefield or Cardiff or Coventry or Nottingham or Leicester or Sunderland or Belfast or Newcastle upon Tyne or Brighton or Hull or Plymouth or Stoke-on-Trent or Wolverhampton or Derby or Swansea or Southampton or Salford or Aberdeen or Westminster or Portsmouth or York or Peterborough or Dundee or Lancaster or Oxford or Newport or Preston or Norwich or Chester or Cambridge or Salisbury or Exeter or Gloucester or Lisburn or Chichester or Winchester or Londonderry or Carlisle or Worcester or Bath or Durham or Lincoln or Hereford or Armagh or Inverness or Stirling or Canterbury or Lichfield or Newry or Ripon or Bangor or Truro or Ely or Wells).ad.
(United kingdom or uk or Britain or scotland or England or wales or Ireland or London or Birmingham or Leeds or Glasgow or Sheffield or Bradford or Edinburgh or Liverpool or Manchester or Bristol or Wakefield or Cardiff or Coventry or Nottingham or Leicester or Sunderland or Belfast or Newcastle upon Tyne or Brighton or Hull or Plymouth or Stoke-on-Trent or Wolverhampton or Derby or Swansea or Southampton or Salford or Aberdeen or Westminster or Portsmouth or York or Peterborough or Dundee or Lancaster or Oxford or Newport or Preston or Norwich or Chester or Cambridge or Salisbury or Exeter or Gloucester or Lisburn or Chichester or Winchester or Londonderry or Carlisle or Worcester or Bath or Durham or Lincoln or Hereford or Armagh or Inverness or Stirling or Canterbury or Lichfield or Newry or Ripon or Bangor or Truro or Ely or Wells).in.
or/32-36
31 and 37
randomized controlled trial.pt.
controlled clinical trial.pt
random$.tw.
qualitative research/
exp interviews as topic/ use ppez
exp interview/ use emez
focus groups/ use ppez
grounded theory/
(qualitative or interview$ or focus group?).tw,kw.
(ethno$ or grounded or thematic or realist or interpretive or narrative or discourse analysis or discursive or mixed method$).tw,kw.
or/39-48
38 not 49
exp animals/ use ppez not humans/ use ppez
nonhuman/ use emez or animal/ use emez
52 not exp human/ use emez
50 not (51 or 53)
54 not (abstract or letter or note or editorial or comment).pt.
56 remove duplicates from 55
57 limit 56 to yr="1990 -Current
58 limit 57 to english language

PsycINFO
Ovid: http://shibboleth.ovid.com/
Database: PsycINFO <1987 to April Week 3 2017>

Date of Search: 26th April 2017

obesity/ or body weight/
(obese or obesity).tw,kw.
1 or 2
Weight Loss/ or weight control/
(weight adj1 (los$ or reduc$ or maint$ or control$ or manag$)).tw,kw.
(reduc$ adj2 (bmi or body mass index)).tw
(reduc$ adj2 (waist adj3 (ratio$ or circumference))).tw.
anti obesity.tw,kw.
(obesity adj1 manag$).tw,kw.
or/4-9
(obes$ adj3 (morbid$ or severe$ or extreme$)).tw,kw.
3 and 10
11 or 12
(United kingdom or uk or Britain or scotland or England or wales or Ireland or London or Birmingham or Leeds or Glasgow or Sheffield or Bradford or Edinburgh or Liverpool or Manchester or Bristol or Wakefield or Cardiff or Coventry or Nottingham or Leicester or Sunderland or Belfast or Newcastle upon Tyne or Brighton or Hull or Plymouth or Stoke-on-Trent or Wolverhampton or Derby or Swansea or Southampton or Salford or Aberdeen or Westminster or Portsmouth or York or Peterborough or Dundee or Lancaster or Oxford or Newport or Preston or Norwich or Chester or Cambridge or Salisbury or Exeter or Gloucester or Lisburn or Chichester or Winchester or Londonderry or Carlisle or Worcester or Bath or Durham or Lincoln or Hereford or Armagh or Inverness or Stirling or Canterbury or Lichfield or Newry or Ripon or Bangor or Truro or Ely or Wells).af.
13 and 14
random$.tw.
qualitative research/
talks/
grounded theory/
discourse analysis/
ethnography/
(qualitative or interview$ or focus group?).tw,kw.
(ethno$ or grounded or thematic or realist or interpretive or narrative or discourse analysis or discursive or mixed method$).tw,kw.
or/16-23
15 not 24
(compare$ or compara$).tw.
(cohort$ or case series).tw.
(prospective$ or retrospective$).tw.
(chang$ or evaluat$ or reviewed or baseline).tw.
(preoperat$ or pre operat$).tw.
26 or 27 or 28 or 29 or 30
25 and 31
limit 32 to (human and english language)
limit 33 to yr="1990 -Current"

REVIEW 3: Qualitative Studies

MEDLINE and EMBASE
Ovid multifile search: http://shibboleth.ovid.com/

Database: Embase <1980 to 2017 Week 31>, Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present> 26th April 2017

Date of Search 26th April 2017

1 qualitative research/
2 exp interviews as topic/ use ppez
3 exp interview/ use emez
4 focus groups/ use ppez
5 grounded theory/
6 (qualitative or interview$ or focus group?).tw,kw.
7 (ethno$ or grounded or thematic or realist or interpretive or narrative or discourse analysis or discursive or mixed method$).tw,kw.
8 or/1-7
9 *obesity/
10 morbid obesity/ use emez
11 exp obesity, morbid/ use ppez
12 (obese or obesity).tw,kw
13 or/9-12
Weight Loss/ use ppez
weight reduction/ use emez
(weight adj1 (los$ or reduc$ or maint$ or control$ or manag$)).tw,kw.
(reduc$ adj2 (bmi or body mass index)).tw.
(reduc$ adj2 (waist adj3 (ratio$ or circumference))).tw.
(obesity adj1 manag$).tw,kw
anti obesity.tw,kw
or/14-20
8 and 13 and 21
(obes$ adj3 (morbid$ or severe$ or extreme$)).tw,kw.
8 and (10 or 11 or 23)
22 or 24
25 not (abstract or letter or note or comment).pt.
remove duplicates from 26

PsycINFO
Ovid: http://shibboleth.ovid.com/
Database: PsycINFO <1987 to April Week 3 2017>
Date of Search: 26th April 2017

1 qualitative research/
2 interviews/
3 grounded theory/
4 discourse analysis/
5 ethnography/
6 (qualitative or interview$ or focus group?).tw,kw.
7 (ethno$ or grounded or thematic or realist or interpretive or narrative or discourse analysis or discursive or mixed method$).tw,kw.
8 or/1-7
9 obesity/ or body weight/
10 (obese or obesity).tw,kw
11 9 or 10
12 Weight Loss/ or weight control/
13 (weight adj1 (los$ or reduc$ or maint$ or control$ or manag$)).tw,kw.
14 (reduc$ adj2 (bmi or body mass index)).tw.
15 (reduc$ adj2 (waist adj3 (ratio$ or circumference))).tw
16 anti obesity.tw,kw.
17 (obesity adj1 manag$).tw,kw
18 or/12-17
19 8 and 11 and 18
20 (obes$ adj3 (morbid$ or severe$ or extreme$)).tw,kw.
21 8 and 20
22 "obesity (attitudes toward)"
23 19 or 21 or 22

CINAHL
http://search.ebscohost.com

!981- 25th April 2017

Date of Search: 25th April 2017

S1 (MH "Qualitative Studies")
S2  (MH "Interviews") OR (MH "Semi-Structured Interview") OR (MH "Structured Interview")
S3  (MH "Focus Groups")
S4  (MH "Narratives")
S5  TX qualitative OR TX interview* OR TX focus group*
S6  TX ( ethno* or grounded or thematic ) OR TX ( realist or interpretive or narrative ) OR TX ( discourse analysis or discursive or mixed method* )
S7  S1 OR S2 OR S3 OR S4 OR S5 OR S6
S8  (MH "Obesity") OR (MH "Obesity, Morbid")
S9  (MH "Body Weight")
S10  TX obese OR TX obesity
S11  S8 OR S9 OR S10
S12  (MH "Weight Control")
S13  (MH "Weight Loss")
S14  TX weight N1 los* OR TX weight N1 reduc* OR TX weight N1 maint* OR TX weight N1 control
S15  TX weight N1 manag* OR TX reduc* N2 bmi OR TX reduc* N2 body mass
S16  reduc* N2 waist ratio* OR TX reduc* N2 waist circumference  TX
S17  S12 OR S13 OR S14 OR S15 OR S16
S18  (S7 AND S11 AND S17)
S19  (MH "Obesity, Morbid")
S20  TX obes* N3 morbid* OR TX obes* N3 severe OR TX obes* N3 extreme*
S21  S19 OR S20
S22  S7 AND S21
S23  (MH "Attitude to Obesity")
S24  S18 OR S22 OR S23
Science Citation Index and Social Science Citation Index
www.webofknowledge.com
1980 - 28th April 2017

Date of Search: 28th April 2017

# 1 TS=(qualitative or interview* or focus group)
# 2 TS=(ethno* or grounded or thematic or realist or interpretive or narrative or discourse analysis or discursive or mixed method*).
# 3 #1 OR #2
# 4 TS=(obesity or obese)
# 5 TS=(weight NEAR/1 los*) or TS=(weight NEAR/1 reduc*) or TS=(weight NEAR/1 maint*) or TS=(weight NEAR/1 control*) or TS=(weight NEAR/1 manag*).
# 6 TS=(reduc* NEAR/2 BMI) OR TS=(reduc* NEAR/2 body mass index)
# 7 TS=anti obesity
# 8 TS= (obesity NEAR/1 manag*)
# 9 #5 or #6 or #7 or #8
10 #3 AND #4 AND #9

AND DOCUMENT TYPES: (Article)

CAB Abstracts
Ovid search: http://shibboleth.ovid.com/
Database: CAB Abstracts <1984 to 2017 Week 15>

Date of Search: 26th April 2017

1 qualitative analysis/
2 qualitative techniques/
3 (qualitative or interview$ or focus group?).tw.
4 (ethno$ or grounded or thematic or realist or interpretive or narrative or discourse analysis or discursive or mixed method$).tw.
5 or/1-4
6 obesity/
7 (obese or obesity).tw.
8 6 or 7
weight reduction/
(weight adj1 (los$ or reduc$ or maint$ or control$ or manag$)).tw.
(reduc$ adj2 (bmi or body mass index)).tw.
(reduc$ adj2 (waist adj3 (ratio$ or circumference))).tw.
(obesity adj1 manag$).tw
anti obesity.tw.
or/9-14
5 and 8 and 15
(obes$ adj3 (morbid$ or severe$ or extreme$)).tw.
5 and 17
16 or 18

**REVIEW4: Economic Evaluations**

**MEDLINE and EMBASE**

Database: Embase <1980 to 2017 Week 31>, Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present> 29th April 2017

**Date of Search 29th April 2017**

exp bariatric surgery/
bariatric.tw,kw.
(gastric adj3 (bypass or bypass or band$ or balloon$)).tw.
(gastroplast$ or gastrect$).tw.
(jejunoileal adj3 (bypass or by pass)).tw.
lipectom$.tw.
diet therapy/ use ppez or caloric restriction/ use ppez or diet, carbohydrate-restricted/ use ppez or diet, fat-restricted/ use ppez or diet, reducing/ use ppez
diet/ or low calory diet/ or low carbohydrate diet/
diet adj3 (restrict$ or reduc$ or modif$ or calori$)).tw.
(calori$ adj3 (reduc$ or restrict$ or limit$)).tw.
exp anti-obesity agents/ use ppez
tetrahydrolipstatin/
sibutramine/
rimonabant/
(appetite adj3 (reduc$ or depress$)).tw.
(orlistat or xenical).tw,rn.
(sibutramin$ or arcalion or reductil or medaria or meridia).tw,rn.
(rimonabant or acomplia or zimulti).tw,rn.
exp exercise/
exp sports/
(exercise or aerobic or physical activ$).tw.
Weight Reduction Programs/ use ppez
exp Body Weight Management/
Behavior Therapy/
Health Education/
Counseling/ use ppez
Nutritional counseling/
Lifestyle modification/
or/1-29
*obesity/
morbid obesity/ use emez
exp obesity, morbid/ use ppez
(obese or obesity).tw,kw.
or/31-34
Weight Loss/ use ppez
weight reduction/ use emez
(weight adj1 (los$ or reduc$ or maint$ or control$ or manag$)).tw,kw.
(reduc$ adj2 (bmi or body mass index)).tw.
(reduc$ adj2 (waist adj3 (ratio$ or circumference))).tw.
(obesity adj1 manag$).tw,kw.
anti obesity.tw,kw
or/36-42
(obes$ adj2 (morbid$ or severe$ or extreme$)).tw,kw.
(35 and 43) or 44
30 and 35
45 or 46
exp "costs and cost analysis"/ use ppez
exp economic evaluation/ use emez
*economics/
health economics/ use emez
exp health care cost/ use emez
exp economics,medical/ use ppez
economics,pharmaceutical/ use ppez
pharmacoeconomics/ use emez
exp models, economic/ use ppez
exp decision theory/
monte carlo method/
markov chains/
exp technology assessment, biomedical/
(cost$ adj2 (effective$ or utilit$ or benefit$ or minimis$)).ab.
economics model$.tw.
(price or prices or pricing).tw.
(value adj1 money).tw.
(expenditure$ not energy).tw.
markov$.tw.
monte carlo.tw.
(decision$ adj2 (tree? or analy$ or model$)).tw.
or/48-68
(metabolic adj cost).tw.
((energy or oxygen) adj (cost or expenditure)).tw
(letter or editorial or note or comment).pt
69 not (70 or 71 or 72)
47 and 73
*obesity/ec
*overweight/ec
77  74 or 75 or 76
78  child/ not adult/
79  (Child? or children or childhood or paediatric or pediatric).tw.
80  77 not (78 or 79)
81  limit 80 to english language
82  81 not (letter or note or comment).pt.
83  remove duplicates from 82

NHS EED and HTA Database
Centre for Reviews and Dissemination www.crd.york.ac.uk

1 MeSH DESCRIPTOR Obesity IN NHSEED,HTA
2 MeSH DESCRIPTOR Obesity, Morbid EXPLODE ALL TREES IN
NHSEED,HTA
3 (overweight ):TI OR (obese):TI OR (obesity):TI IN NHSEED, HTA
4 MeSH DESCRIPTOR weight loss EXPLODE ALL TREES IN NHSEED,HTA
5 #1 OR #2 OR #3 OR #4

CEA Registry
Date of Search 5th May 2017

Obesity or overweight or weight loss

Research papers in economic (REPEC)
http: ideas.repec.org/

Date of Search 5th May 2017

obesity or overweight or weight loss

Supplementary searches: Ongoing Studies
Clinical Trials.gov

Date of Search: 4th May 2017

Topic=Morbid Obesity (restricted to Intervention Studies, Active or Recruiting)

Supplementary Search: Systematic Reviews

MEDLINE
Ovid multifile search: http://shibboleth.ovid.com/
Database Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present> 4th May 2017

Date of Search: 4th May 2017
1 systematic$ review$.tw.
2 Meta analysis as topic/
3 meta analysis.tw,pt.
4 metanalysis.tw.
5 metaanalysis.tw.
6 meta synthesis.tw.
7 metasynthesis.tw.
8 Meta regression.tw
9 metaregression.tw.
10 (synthes$ adj3 (literature or evidence)).tw.
11 (systematic study or systematic studies).tw.
12 evidence based review.tw.
13 comprehensive review.tw.
14 or/1-13
15 review.pt,ti.
16 (medline or pubmed or cochrane or embase or cinahl or psyc?lit or psyc?info).ab.
(search adj3 (literature or database? or bibliographic or electronic or internet or computeri?ed)).ab
 included studies.ab.
 (inclusion adj3 studies).ab.
 ((inclusion or selection or predefined or predetermined) adj criteria).ab
 (assess$ adj3 (quality or validity)).ab.
 (select$ adj3 (study or studies)).ab.
 (data adj3 extract$).ab.
 extracted data.ab.
 (data adj2 abstracted).ab.
 (data adj3 abstraction).ab.
 or/16-26
 15 and 27
 14 or 28
 (letter or editorial or comment).pt.
 29 not 30
 exp animals/ not humans/
 31 not 32
 Obesity, Morbid/dh, dt, su, th
 Obesity, Morbid
 (obes$ adj3 (morbid$ or severe$)).tw.
 (morbid obesity or severe obesity).kw.
 (bmi adj ("27$" or "28$" or "29$")).tw.
 (bmi adj ("30$" or "31$" or "32$" or "33$" or "34$" or "35$" or "36$" or "37$" or "38$" or "39$"))\).tw.
 or/35-44
exp bariatric surgery/
bariatric.tw,kw
(gastric adj3 (bypass or bypass or band$ or balloon$)).tw
(gastroplast$ or gastrect$).tw.
(jeunoileal adj3 (bypass or by pass)).tw.
lipectom$.tw.
diet therapy/ or caloric restriction/ or diet, carbohydrate-restricted/ or diet, fat-restricted/ or diet, reducing/
(diet adj3 (restrict$ or reduc$ or modif$ or calorie$)).tw.
(calori$ adj3 (reduc$ or restrict$ or limit$)).tw.
exp anti-obesity agents/
(appetite adj3 (reduc$ or depress$)).tw.
(orlistat or xenical).tw, rn.
(sibutramin$ or arcalion or reductil or medaria or meridia).tw, rn
(rimonabant or acomplia or zimulti).tw, rn.
exp exercise/
exp sports/
(exercise or aerobic or physical activ$).tw.
weight loss/
(weight adj3 (reduc$ or loss or lose)).tw.
Weight Reduction Programs/
Behavior Therapy/
Health Education/
Counseling/
Life Style/
(modif$ adj3 (behavio?r or diet or eat? or eating)).tw.
(((diet or weight) adj3 (educat$ or counsel$)).tw.
or/46-61
34 or (45 and 72)
33 and 73
limit 74 to yr="2010 – 2017"
## 2 Data extraction form

### Table 1 Data extraction form

<table>
<thead>
<tr>
<th>Study details</th>
<th>General information</th>
<th>Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Title</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Publication year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Study design</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Period of study</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Length of follow-up (months)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Study ID of any linked reports</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Source of funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Competing interests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trial description</th>
<th>Information</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Setting / Location</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Population (e.g. general population, psychiatric patients, pregnant women etc.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inclusion criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exclusion criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method of recruitment and sampling</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total number of people randomised to condition (and started to receive intervention)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total number of people completing follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total number of people analysed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RCT groups (Name, type)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Baseline group/cluster differences</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Targeted population (e.g. general, diabetic, hypertensive)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participant demographics</th>
<th>Sociodemographic information</th>
<th>Age [Years (SD)]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Gender (% Female)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Education level or Years of Education</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Social Economic Status (SES) %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Income</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marital status [%]Single, Married, Divorced, Widowed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>Health data at baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental or physical conditions [% e.g. mental or physical health conditions, pregnancy]</td>
<td>Smoking status [% Never or non-smoker, Former smoker, Smoker]</td>
</tr>
<tr>
<td>Weight [kg] Mean/Median &amp; SD/Range/IQR</td>
<td></td>
</tr>
<tr>
<td>Height [cm] Mean/Median &amp; SD/Range/IQR</td>
<td></td>
</tr>
<tr>
<td>BMI [(kg/m²)] Mean/Median &amp; SD/Range/IQR</td>
<td></td>
</tr>
<tr>
<td>Risk factor data</td>
<td>Waist circumference [(cm)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Total cholesterol [(mmol/L)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
<tr>
<td></td>
<td>LDL cholesterol [(mmol/L)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
<tr>
<td></td>
<td>HDL cholesterol [(mmol/L)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
<tr>
<td></td>
<td>Triglycerides [(mmol/L)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
<tr>
<td></td>
<td>Systolic Blood Pressure [(mmHg)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
<tr>
<td></td>
<td>Diastolic Blood Pressure [(mmHg)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
<tr>
<td></td>
<td>HbA1c [(%)] SD/Range/IQR</td>
</tr>
<tr>
<td></td>
<td>Fasting plasma glucose [(mmol/L)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
<tr>
<td>Quality of life **</td>
<td>Interpretation of QoL Score [Greater the score = greater QoL or Lower score = greater QoL]</td>
</tr>
<tr>
<td></td>
<td>Score [(n)] Mean/Median &amp; SD/Range/IQR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk of bias</th>
<th>RCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Random sequence generation (selection bias) [High/Unclear/Low]</td>
</tr>
<tr>
<td></td>
<td>Allocation concealment (selection bias) [High/Unclear/Low]</td>
</tr>
<tr>
<td></td>
<td>Blinding of participants [High/Unclear/Low]</td>
</tr>
<tr>
<td></td>
<td>Blinding of personnel [High/Unclear/Low]</td>
</tr>
<tr>
<td></td>
<td>Blinding of outcome assessment (detection bias) [High/Unclear/Low]</td>
</tr>
<tr>
<td></td>
<td>Incomplete outcome data (attrition bias) [High/Unclear/Low]</td>
</tr>
<tr>
<td></td>
<td>Selective outcome reporting? (reporting bias) [High/Unclear/Low]</td>
</tr>
<tr>
<td></td>
<td>Other bias (e.g. contamination bias, conflict of interest) [High/Unclear/Low]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk of bias</th>
<th>Non-RCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Were participants a representative sample selected from a relevant patient population, e.g. randomly selected from those seeking for treatment despite of age, duration of disease, primary or secondary disease, and severity of disease? [Yes/No/Unclear]</td>
</tr>
<tr>
<td></td>
<td>Were the inclusion/exclusion criteria of participants clearly described? [Yes/No/Unclear]</td>
</tr>
<tr>
<td></td>
<td>Were participants entering the study at a similar point in their disease progression, i.e. severity of disease? [Yes/No/Unclear]</td>
</tr>
<tr>
<td></td>
<td>Was selection of patients consecutive? [Yes/No/Unclear]</td>
</tr>
<tr>
<td></td>
<td>Was data collection undertaken prospectively? [Yes/No/Unclear]</td>
</tr>
<tr>
<td></td>
<td>Were the groups comparable on demographic characteristics and clinical features? [Yes/No/Unclear]</td>
</tr>
<tr>
<td></td>
<td>Was the intervention (and comparison) clearly defined? [Yes/No/Unclear]</td>
</tr>
<tr>
<td></td>
<td>Was the intervention undertaken by someone experienced at performing the procedure? (Yes' if the practitioner received training on conducting the procedure before or conducted same kind of procedure before, i.e. no learning curve) [Yes/No/Unclear]</td>
</tr>
<tr>
<td></td>
<td>Were the staff, place, and facilities where the patients were treated appropriate for performing the procedure? (e.g. access to back-up facilities in hospital or special clinic) [Yes/No/Unclear]</td>
</tr>
<tr>
<td><strong>TiDier</strong></td>
<td><strong>Brief name</strong></td>
</tr>
<tr>
<td>-----------</td>
<td>----------------</td>
</tr>
<tr>
<td><strong>Why</strong></td>
<td>Describe any rationale, theory, or goal of the elements essential to the intervention.</td>
</tr>
<tr>
<td><strong>What</strong></td>
<td>Materials: describe materials used in the intervention (including any equipment / devices / training materials or courses used), Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.</td>
</tr>
<tr>
<td><strong>Who provided</strong></td>
<td>Number of providers, Sex of providers, Professional background, include grade if reported, Pre-existing training, Training as part of trial (include grade of trainer if reported).</td>
</tr>
<tr>
<td><strong>How</strong></td>
<td>Delivery format - How was the intervention delivered, If other please specify, Delivery mode - How was the intervention delivered.</td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td>Intervention setting (If different from recruitment setting)- Include facilities (e.g. halls etc.), Data collection setting (If different from recruitment and/or intervention setting).</td>
</tr>
<tr>
<td><strong>When and how much</strong></td>
<td>Timing of intervention (When intervention started), Duration of total intervention (period of time over which it was delivered), Number of sessions, Number of participants per session, Frequency of sessions (e.g. every second week), Duration of each session (hrs).</td>
</tr>
<tr>
<td><strong>Tailoring and modifications</strong></td>
<td>If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how; If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).</td>
</tr>
<tr>
<td><strong>Treatment fidelity and adherence</strong></td>
<td>Planned: Treatment fidelity, Actual treatment fidelity, Planned: Treatment adherence, Actual: Treatment adherence.</td>
</tr>
<tr>
<td><strong>Organizational variables</strong></td>
<td>Did treatment providers receive supervision?, If yes from who?; Did treatment providers receive intervention?</td>
</tr>
<tr>
<td>Equity evaluation</td>
<td>Co-interventions</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Costs</td>
<td>Were partial or full costs of program delivery reported?</td>
</tr>
<tr>
<td>BCT descriptions</td>
<td>Are all important intervention components described in sufficient detail to allow for BCT coding?</td>
</tr>
<tr>
<td>Equity evaluation</td>
<td>Equity pointer</td>
</tr>
<tr>
<td></td>
<td>Representativeness of sample</td>
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<tr>
<td></td>
<td>Sociodemographic differences</td>
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<tr>
<td></td>
<td>PROGRESS categories reported at baseline</td>
</tr>
<tr>
<td></td>
<td>Diversity/disadvantage</td>
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<td>Fidelity</td>
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<td>Process measures</td>
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<td>Providers</td>
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<td>Sustainability</td>
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<td>Political/organisational context</td>
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<td>Partnership</td>
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<td>Conflict of interest</td>
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<td>Adverse effects</td>
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<td>Quantitative outcomes</td>
<td>Health status at baseline</td>
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<td>Risk factor data</td>
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<tr>
<td>Quality of life **</td>
<td>Interpretation of QoL Score [Greater the score = greater QoL or Lower score = greater QoL] Score [(n) Mean/Median &amp; SD/Range/IQR]</td>
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<tr>
<td>Adverse events</td>
<td>[(n) type of adverse events per trial group]</td>
</tr>
<tr>
<td>Morbidity</td>
<td>[(n) type of morbidity registered per trial group]</td>
</tr>
<tr>
<td>Mortality</td>
<td>[(n) of participants dead per trial group]</td>
</tr>
</tbody>
</table>

**Economics**

<table>
<thead>
<tr>
<th>Methods / methodological considerations</th>
<th>Type of economic evaluation reported (e.g. CUA / CEA / CBA / CMA / CCA etc.); Study type (decision modelling / economic evaluation alongside RCT / RCT based EE extrapolated to longer term horizon).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costing considerations</td>
<td>Study time horizon – Costs; Viewpoint or costing perspective; What direct costs were measured; What indirect costs were measured; Intervention costing methodology; What resource use was included?</td>
</tr>
<tr>
<td>General costing information</td>
<td>How was resource use identified / measured; What were the sources of unit costs?; Costing year; Currency; Discount rate applied to costs; Were costs adjusted for inflation?; Were any currency conversions performed?; If yes, what conversion rates were used (include rate and source)?</td>
</tr>
<tr>
<td>Benefit considerations</td>
<td>Study time horizon – Benefits; Primary health outcome measurement; Primary economic outcome measurement; Overall summary measure of benefit (e.g. WTP / QALY / DALY / Life year gained); Source of effectiveness data (e.g. clinical trial, meta-analysis); Methods used to value benefits (e.g. EQ-5D valued using a general population sample TTO tariff); Sources of utility data (Within trial, literature review etc); Discount rate applied to benefits; Were benefits / utilities age-adjusted?</td>
</tr>
</tbody>
</table>

**Complete for RCT-based economic evaluations only**

| Framework | Primary analysis (e.g. ITT / per protocol / modified ITT); Study population; Detail the statistical analysis models for cost / outcomes / cost-effectiveness; Method to incorporate uncertainty (e.g. bootstrapping etc.), How was uncertainty presented in the study; Secondary analyses undertaken; Subgroup analyses undertaken; Sensitivity analyses undertaken. |

**Complete for decision analysis models only**

<p>| Type of model used; Health states / diseases modelled; Size of modelled cohort / modelled population; Base case time horizon; Other details of the model. |
|---|---|
| Results - costs | Analysis; Method of incremental comparison and additional notes were recorded. |
| Results - benefits | Analysis; Method of incremental comparison and additional notes were recorded. |
| Results - analysis | Analysis no.; Analysis; analysis – threshold; analysis – type |
| Probabilistic sensitivity | Was any probabilistic sensitivity analysis undertaken? [Yes/No]; Details Analysis No.; Title; Distribution. |
| Other methodological considerations | Was value of information analysis undertaken [Yes/No]; If yes, what type of analyses, Results of VOI analyses. Recommendations of VOI analyses. |
| Author's assessment of paper | Stated strengths; Stated limitations; Stated conclusions; Stated requirements for further research. |</p>
<table>
<thead>
<tr>
<th>Quality assessment of the decision model</th>
<th>Structure 1. Statement of decision problem / objective</th>
<th>Is there a clear statement of the decision problem? [Yes/No/Unclear]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Is the objective of the evaluation and model specified and consistent with the stated decision problem? [Yes/No/Unclear]</td>
<td></td>
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<td>Is the primary decision maker specified? [Yes/No/Unclear]</td>
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<tr>
<td>Structure 2. Statement of scope / perspective</td>
<td>Is the perspective of the model clearly stated? [Yes/No/Unclear]</td>
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<td></td>
<td>Are the model inputs consistent with the stated perspective? [Yes/No/Unclear]</td>
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<td></td>
<td>Has the scope of the model been stated and justified? [Yes/No/Unclear]</td>
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<td></td>
<td>Are the outcomes of the model consistent with the perspective, scope and overall objective of the model? [Yes/No/Unclear]</td>
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<tr>
<td>Structure 3. Rationale for structure</td>
<td>Is the structure of the model consistent with a coherent theory of the health condition under evaluation? [Yes/No/Unclear]</td>
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<td></td>
<td>Are the sources of data used to develop the structure of the model specified? [Yes/No/Unclear]</td>
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<td>Are the causal relationships described by the model structure justified appropriately? [Yes/No/Unclear]</td>
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<td>Structure 4. Structural assumptions</td>
<td>Are the structural assumptions transparent and justified? [Yes/No/Unclear]</td>
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<td></td>
<td>Are the structural assumptions reasonable given the overall objective, perspective and scope of the model? [Yes/No/Unclear]</td>
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<tr>
<td>Structure 5. Strategies / Comparators</td>
<td>Is there a clear definition of the options under evaluation? [Yes/No/Unclear]</td>
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<td>Have all feasible and practical options been evaluated? [Yes/No/Unclear]</td>
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<td>Is there justification for the exclusion of feasible options? [Yes/No/Unclear]</td>
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<tr>
<td>Structure 6. Model type</td>
<td>Is the chosen model type appropriate given the decision problem and specified causal relationships within the model? [Yes/No/Unclear]</td>
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<tr>
<td>Structure 7. Time horizon</td>
<td>Is the time horizon of the model sufficient to reflect all important differences between options? [Yes/No/Unclear]</td>
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<tr>
<td></td>
<td>Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified? [Yes/No/Unclear]</td>
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<tr>
<td>Structure 8. Disease states / pathways</td>
<td>Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions? [Yes/No/Unclear]</td>
<td></td>
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<tr>
<td>Structure 9. Cycle length</td>
<td>Is the cycle length defined and justified in terms of the natural history of disease? [Yes/No/Unclear]</td>
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<tr>
<td>Data1. Data identification</td>
<td>Are the data identification methods transparent and appropriate given the objectives of the model? [Yes/No/Unclear]</td>
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<td>Where choices have been made between data sources, are these justified appropriately? [Yes/No/Unclear]</td>
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<td>Has particular attention been paid to identifying data for the important parameters in the model? [Yes/No/Unclear]</td>
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<td>Has the quality of the data been assessed appropriately? [Yes/No/Unclear]</td>
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<td>Where expert opinion has been used, are the methods described and justified? [Yes/No/Unclear]</td>
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<tr>
<td>Data 2. Data modelling</td>
<td>Is the data modelling methodology based on justifiable statistical and epidemiological techniques? [Yes/No/Unclear]</td>
<td></td>
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</tbody>
</table>
| Data 2a. Baseline data | Is the choice of baseline data described and justified? [Yes/No/Unclear]  
|                        | Are transition probabilities calculated appropriately? [Yes/No/Unclear]  
|                        | Has a half cycle correction been applied to both cost and outcomes? [Yes/No/Unclear]  
|                        | If not, has this omission been justified? [Yes/No/Unclear] |
| Data 2b. Treatment effects | If relative treatment effects have been derived from the trial data, have they been synthesised using appropriate techniques? [Yes/No/Unclear]  
|                        | Have the methods and assumptions used to extrapolate short term results to final outcomes been documented and justified? [Yes/No/Unclear]  
|                        | Have alternative extrapolation assumptions been explored through sensitivity analysis? [Yes/No/Unclear]  
|                        | Have assumptions regarding the continuing effect of treatment once treatment is complete been documented and justified? [Yes/No/Unclear]  
|                        | Have alternative assumptions regarding the continuing effect of treatment been explored through sensitivity analysis? [Yes/No/Unclear] |
| Data 2c. Costs | Are the costs incorporated into the model justified? [Yes/No/Unclear]  
|                        | Has the source for all costs been described? [Yes/No/Unclear]  
|                        | Have discount rates been described and justified given the target decision-maker? [Yes/No/Unclear] |
| Data 2d. Quality of life weights (utilities) | Are the utilities incorporated into the model appropriate? [Yes/No/Unclear]  
|                        | Is the source for the utility weights referenced? [Yes/No/Unclear]  
|                        | Are the methods of derivation for the utility weights justified? [Yes/No/Unclear] |
| Data 3. Data incorporation | Have all data incorporated into the model been described and referenced in sufficient detail? [Yes/No/Unclear]  
|                        | Has the use of mutually inconsistent data been justified (i.e. are assumptions and choices appropriate)? [Yes/No/Unclear]  
|                        | Is the process of data incorporation transparent? [Yes/No/Unclear]  
|                        | If data have been incorporated as distributions, has the choice of distribution for each parameter been described and justified? [Yes/No/Unclear] |
| Data 4. Assessment of uncertainty | Have the four principal types of uncertainty been addressed? [Yes/No/Unclear]  
|                        | If not, has the omission of particular forms of uncertainty been justified? [Yes/No/Unclear] |
| Data 4a. Methodological | Have methodological uncertainties been addressed by running alternative versions of the model with different methodological assumptions? [Yes/No/Unclear] |
| D4b. Structural heterogeneity | Is there evidence that structural uncertainties have been addressed via sensitivity analysis? [Yes/No/Unclear]  
|                        | Has heterogeneity been dealt with by running the model separately for different subgroups? [Yes/No/Unclear] |
| Data 4d. Parameter | Are the methods of assessment of parameter uncertainty appropriate? [Yes/No/Unclear]  
|                        | If data are incorporated as point estimates, are the ranges used for sensitivity analysis stated clearly and justified? [Yes/No/Unclear] |
| Consistency 1. Internal consistency | Is there evidence that the mathematical logic of the model has been tested thoroughly before use? |
| Consistency | External consistency | Are any counterintuitive results from the model explained and justified? [Yes/No/Unclear]  
If the model has been calibrated against independent data, have any differences been explained and justified? [Yes/No/Unclear]  
Have the results of the model been compared with those of previous models and any differences in results explained? [Yes/No/Unclear] |
| Quality assessment of economic evaluations | Economic evaluations of RCTs | Was a well-defined question posed in an answerable form? [Yes/No/Questionable/Unclear]  
Was a comprehensive description of the competing alternative given? [Yes/No/Questionable/Unclear]  
Was there evidence that the programme's effectiveness had been established? [Yes/No/Questionable/Unclear]  
Were all the important and relevant cost and consequences for each alternative identified? [Yes/No/Questionable/Unclear]  
Were costs and consequences measured accurately in appropriate physical units? [Yes/No/Questionable/Unclear]  
Were costs and consequences valued credibly? [Yes/No/Questionable/Unclear]  
Were costs and consequences adjusted for differential timing? [Yes/No/Questionable/Unclear]  
Was an incremental analysis of costs and consequences of alternatives performed? [Yes/No/Questionable/Unclear]  
Was allowance made for uncertainty in the estimates of costs and consequences? [Yes/No/Questionable/Unclear]  
Did the presentation and discussion of results include all issues of concern to users? [Yes/No/Questionable/Unclear] |
| BCT coding for RCTs | 1.1 Goal setting (behaviour) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]  
1.2 Problem solving [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]  
1.3 Goal setting (outcome) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]  
1.4 Action planning [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]  
1.5 Review behaviour goal(s) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]  
1.6 Discrepancy between current behaviour and goal [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]  
1.7 Review outcome goal(s) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 1.8 | Behavioural contract [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 1.9 | Commitment [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 2.1 | Monitoring of behaviour by others without feedback [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 2.2 | Feedback on behaviour [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 2.3 | Self-monitoring of behaviour [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 2.4 | Self-monitoring of outcome(s) of behaviour [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 2.5 | Monitoring outcome(s) of behaviour by others without feedback [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 2.6 | Biofeedback [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 2.7 | Feedback on outcome(s) of behaviour [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 3.1 | Social support (unspecified) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 3.2 | Social support (practical) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 3.3 | Social support (emotional) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 4.1 | Instruction on how to perform a behaviour [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 4.2 | Information about antecedents [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 4.3 | Re-attribution [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 4.4 | Behavioural experiments [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 5.1 | Information about health consequences [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 5.2 | Salience of consequences [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 5.3 | Information about social and environmental consequences [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
5.4 Monitoring of emotional consequences [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
5.5 Anticipated regret [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
5.6 Information about emotional consequences [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
5.1 Demonstration of the behaviour [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
5.2 Social comparison [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
5.3 Information about others’ approval [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
6.1 Prompts/cues [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
6.2 Cue signalling reward [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
6.3 Reduce prompts/cues [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
6.4 Remove access to the reward [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
6.5 Remove aversive stimulus [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
6.6 Satiation [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
6.7 Exposition [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
6.8 Associative learning [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
7.1 Behavioural practice/rehearsal [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
7.2 Behaviour substitution [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
7.3 Habit formation [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
7.4 Habit reversal [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
7.5 Overcorrection [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]
<p>| 8.6 | Generalisation of a target behaviour [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 8.7 | Graded tasks [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 9.1 | Credible source [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 9.2 | Pros and cons [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 9.3 | Comparative imagining of future outcomes [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.1 | Material incentive (behaviour) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.2 | Material reward (behaviour) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.3 | Non-specific reward [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.4 | Social reward [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.5 | Social incentive [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.6 | Non-specific incentive [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.7 | Self-incentive [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.8 | Incentive (outcome) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 10.9 | Incentive (outcome) [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 11.1 | Pharmacological support [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 11.2 | Reduce negative emotions [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |
| 11.3 | Conserving mental resources [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement] |</p>
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>BCT Present/ Possibly Present</th>
<th>Targeted at: Weight Loss/ Maintenance/ Engagement</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.4</td>
<td>Paradoxical instructions</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>12.1</td>
<td>Restructuring the physical environment</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>12.2</td>
<td>Restructuring the social environment</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>12.3</td>
<td>Avoidance/reducing exposure to cues for the behaviour</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
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<tr>
<td>12.4</td>
<td>Distraction</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
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<tr>
<td>12.5</td>
<td>Adding objects to the environment</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>12.6</td>
<td>Body changes</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>13.1</td>
<td>Identification of self as role model</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>13.2</td>
<td>Framing/Reframing</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>13.3</td>
<td>Incompatible beliefs</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>13.4</td>
<td>Valued self-identity</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>13.5</td>
<td>Identity associated with changed behaviour</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>14.1</td>
<td>Behaviour cost</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>14.2</td>
<td>Punishment</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>14.3</td>
<td>Remove reward</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
</tr>
<tr>
<td>14.4</td>
<td>Reward approximation</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
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<td>14.5</td>
<td>Rewarding completion</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
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<tr>
<td>14.6</td>
<td>Situation-specific reward</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
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<tr>
<td>14.7</td>
<td>Reward incompatible behaviour</td>
<td>BCT definitely present or BCT possibly present</td>
<td>BCT targeted at: weight loss or/and weight maintenance or/and engagement</td>
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<tr>
<td>14.8</td>
<td>Reward alternative behaviour [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
<td></td>
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<tr>
<td>14.9</td>
<td>Reduce reward frequency [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
<td></td>
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</tr>
<tr>
<td>14.1</td>
<td>Remove punishment [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.1</td>
<td>Verbal persuasion about capability [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
<td></td>
<td></td>
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<tr>
<td>15.2</td>
<td>Mental rehearsal of successful performance [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
<td></td>
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</tr>
<tr>
<td>15.3</td>
<td>Focus on past success [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
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</tr>
<tr>
<td>15.4</td>
<td>Self-talk [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
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<tr>
<td>16.1</td>
<td>Imaginary punishment [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.2</td>
<td>Imaginary reward [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.3</td>
<td>Vicarious consequences [BCT definitely present or BCT possibly present; BCT targeted at: weight loss or/and weight maintenance or/and engagement]</td>
<td></td>
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</tr>
</tbody>
</table>

**If studies reported quality of life assessment for specific conditions, this was also recorded.**

Text boxes were available for free text comments and data

Denominators were provided for all outcomes.
3 List of included studies for the review of RCTs


Mingrone G, Greco AV, Giancatarini A, Scarfone A, Castagneto M, Pugeat M. Sex hormone-binding globulin levels and cardiovascular risk factors in morbidly obese
subjects before and after weight reduction induced by diet or malabsorptive surgery. *Atherosclerosis* 2002;161:455-62.


Pekkarinen T, Kaukua J, Mustajoki P. Long-term weight maintenance after a 17-week weight loss intervention with or without a one-year maintenance program: A randomized controlled trial. *Journal of Obesity* 2015;Article 651460


Tsai AG, Wadden TA, Rogers MA, Day SC, Moore RH, Islam BJ. A Primary Care Intervention for Weight Loss: Results of a Randomized Controlled Pilot Study. *Obesity* 2010;18:1614-8.


4 List of excluded studies for the review of RCTs

BMI <35 or unclear N=39


Li ZP, Treyzon L, Chen S, Yan E, Thames G, Carpenter CL. Protein-enriched meal replacements do not adversely affect liver, kidney or bone density: an outpatient randomized controlled trial. *Nutrition Journal* 2010;**9**.


Toubro S, Astrup A. Randomised comparison of diets for maintaining obese subjects' weight after major weight loss: ad lib, low fat, high carbohydrate diet v fixed energy intake. *BMJ (Clinical research Ed)* 1997;314:29-34.


**Less than 12 months follow-up data N=15**

Ahern AL, Olson AD, Aston LM, Jebb SA. Weight Watchers on prescription: An observational study of weight change among adults referred to Weight Watchers by the NHS. *BMC Public Health* 2011;11.


Freitas PD, Ferreira PG, Silva AG, Cukier A, Stelmach R, Carvalho-Pinto R. Exercise training is a determinant of weight-loss and improvement on asthma control, airway inflammation and psychosocial morbidity in obese asthmatics: A RCT. *European Respiratory Journal* 2015;46.


**Not Randomised Trial N=19**


Koohkan S, Schaffner D, Milliron BJ, Frey I, König D, Deibert P, et al. The impact of a weight reduction program with and without meal-replacement on health related quality of
life in middle-aged obese females. *BMC Women's Health* 2014;14:45.


**No relevant outcome data N=27**


Toft BS, Uhrenfeldt L. Facilitators and barriers to physical activity experienced among


**Interventions ineligible N=6**


**Secondary publication N=13**


8.

**Not obtained N=3**


### Characteristics of included studies for the review of RCTs

#### Table 2  Characteristics of included studies

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agras 1996¹</td>
<td>Country: USA Location: Stanford University School of Medicine, no further details</td>
<td>Description of interventions: All participants received an 800 kcal/day VLCD (Optifast 800, Sandoz Nutrition, Minneapolis, MN) and behaviour therapy. Groups were run by experienced doctoral-level therapists for 12 weeks prior to randomisation.</td>
</tr>
<tr>
<td></td>
<td>Period of study: Prior to June 1996 Inclusion criteria: Not reported Exclusion criteria: Recent cardiovascular event; poorly controlled type 2 diabetes on drug treatment; serious illness (bleeding stomach ulcer; liver or kidney disease); psychosis or alcohol or drug abuse; bulimia nervosa; pregnancy; medication affecting appetite Recruitment: NR Baseline age (years): Total:43.70(10); a:NR; b:NR; c:NR; d:NR Baseline BMI (kg/m²): Total:36.60(4.4); a:NR; b:NR; c:NR; d:NR Baseline Weight: Total:100.30(14); a:NR; b:NR; c:NR; d:NR</td>
<td>a: Time-dependent condition: Normal food gradually introduced, beginning with one meal each day (350 kcal equivalent to two packets of Optifast) for 2 weeks, two meals daily (700 kcal equivalent to two packets of Optifast) for the third week, and three meals each day thereafter thereafter (1200 kcal equivalent to the final packet of Optifast). b: Weight-dependent condition: As per the Time-dependent condition except participants only progressed to the next stage of food reintroduction if they were losing weight or weight was stable. c: Time-dependent, stimulus-narrowing condition: Pre-packaged foods providing equivalent nutrition to the Time- and Weight-dependent. Participants added one pre-packaged meal daily for the first week, and a second (but different) pre-packaged meal each day for the second week. A second pre-packaged meal was added in week 3 and the third meal was added in week 4 d: Weight-dependent stimulus-narrowing condition: As per the Time-dependent, stimulus-narrowing condition except participants only progressed to the next stage if they were losing weight or weight was stable.</td>
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<tr>
<td></td>
<td>Duration of active intervention: a:9 months (excluding VLCD); b:9 months (excluding VLCD); c:9 months (excluding VLCD); d:9 months (excluding VLCD) Number allocated: 194 Completed: Total:162; a:NR; b:NR; c:NR; d:NR</td>
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</tr>
<tr>
<td></td>
<td>% Drop-out: Total:16.49%; a:NR; b:NR; c:NR; d:NR</td>
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</tr>
<tr>
<td>Annesi 2017²</td>
<td>Country: USA Location: Community wellness centres</td>
<td>Description of interventions:</td>
</tr>
<tr>
<td></td>
<td>Length of follow-up (months):15 Quantitative outcomes reported: Weight</td>
<td></td>
</tr>
</tbody>
</table>

67
| Period of study: Prior to December 2015 | Both treatments employed cognitive-behavioural methods, e.g. self-regulatory skills to overcome barriers to behaviour change and increase perceptions of competence (i.e. self efficacy) and the overall self. Both treatment protocols informed participants of the recommended 150min/week of moderate exercise to gain health benefits, but also indicated that lesser amounts are also likely to hold benefits. Both groups were recommended a reduction of caloric intake (i.e. 500 to 1,000 kcal/day), and restricted fat intake (i.e. approximately 30% of total caloric intake). |
| Inclusion criteria: Women of 30-65 years, with class I or II obesity (30-39.9), physically inactive (<20 min/week average over the previous year) | a: The experimental treatment first initiated The Coach Approach exercise-support protocol which incorporated 6, 45-minute personal meetings with the same wellness leader over 6 months. Over the next 8 weeks, the group sessions transferred the learned and practiced self-regulatory skills to maintaining lost weight. The final 20 weeks of the treatment (ending at week 56) focused on applying self-regulatory methods to both losing and maintaining lost weight, based on each participant’s weight-loss goals. |
| Exclusion criteria: Present/soon-planned pregnancy; present use of medications for weight loss or a diagnosed psychiatric condition; and participation in a commercial, self-help, or medical weight-loss programme | b: The control treatment consisted of participants reviewing 1 of the 12 lessons (chapters) of a print manual entitled The LEARN (lifestyle, exercise, attitudes, relationships, nutrition) Programme for Weight Management every 2 weeks. |
| Recruitment: Participants were recruited through local print and electronic advertisements | Description of interventions: |
| Baseline age (years): Total:48.60(7.1); a:NR; b:NR | a: Self-directed: Participants in the control group met with a weight-loss coach at the time of randomisation and, if desired, after the final data-collection visit, at 24 months. They also received brochures and a list of recommended websites promoting weight loss. |
| Baseline BMI (kg/m²): Total:35.40(3.3); a:NR; b:NR | b: Remote support: Participants were offered weekly contact with coaches during the first 3 months (12 weekly calls). Individual telephone sessions were approximately 20 minutes long. For the remainder of the study, participants were offered 1 call each month. |
| Baseline weight: Total:NR; a:94.63(11.53); :95.60(10.52) | c: In-person support: Participants were offered weekly contact with coaches during the first 3 months (nine group sessions and three individual sessions). Individual sessions were approximately 20 minutes long and group sessions |
| Country: USA | Length of follow-up (months):24 |
| Location: Six clinics in primary care practices in the Baltimore metropolitan area | Quantitative outcomes reported: Weight |
| Period of study: Recruited February 2008 to February 2009 | Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose |
Recently lost 5% or more of their body weight or taking medications that cause weight gain or prevent weight loss (e.g. glucocorticoids or second-generation antipsychotic medications), MI, Stroke or ASCVD procedure within 6 months, serious medical condition likely to hinder accurate measurement of weight, or for which weight loss is contraindicated, or which would cause weight loss (e.g. ESRD on dialysis, cancer diagnosis or treatment within 2 yrs), prior or planned bariatric surgery, use of prescription weight loss medication (including off-label drugs e.g. topiramate, buproprion, byetta) or over-the-counter orlistat within 6 months, chronic use (at least past 6 months) of medications likely to cause weight gain or prevent weight loss (e.g. corticosteroids, lithium, olanzapine, risperidone, clozapine), unintentional weight loss within 6 months of enrollment (≥ 5% of body weight), intentional weight loss within 6 months (≥ 5% of body weight), pregnant or nursing within past 6 months, plans to become pregnant within 2 years, plans to relocate from area within 2 years, another member of household is a study participant or trial staff member, principal investigator discretion, self-reported average consumption of >14 alcoholic drinks/week, psychiatric hospitalization in last year, unstable angina, blood pressure >160/100 (note: individuals may be rescreened).

**Recruitment:** Participants were recruited from primary care practices, through physician referral, brochures, and targeted mailings.

**Baseline age (years):** Total:54.00(10.2); a:52.90(10.1); b:55.80(9.7); c:53.30(10.5)

**Baseline BMI (kg/m²):** Total:36.60(5.0); a:36.80(5.14); b:36.00(4.7); c:36.80(5.2)

**Baseline weight:** Total:103.40(17.9); a:104.40(18.6); b:102.10(13.9); c:105.01(20.7)

Typically lasted 90 minutes. During the next three months, participants were offered three monthly contacts (one group session and two individual sessions). For the remainder of the study, participants were offered two monthly contacts (one group session and one individual session, with the latter conducted either in person or by telephone).

Participants in the two intervention groups were encouraged to lose 5% of their baseline weight within 6 months and to maintain the reduced weight until the end of the study. Participants in both intervention groups were encouraged to log on to the study-specific website weekly. The website contained learning modules, opportunities for self-monitoring of weight, calorie intake and exercise; and feedback on progress in these key behaviours. Each participant who was assigned to an active intervention received automated monthly e-mail messages summarising his or her progress.

**Description of interventions:**

- a: Usual care: Physician advice, occasionally with referral to a dietitian, and standard educational materials during a small number of individual or group sessions, typically with little or no follow-up.

**Country:** USA

**Location:** Primary care clinic, part of a large multispecialty group practice in the San Francisco Bay Area

**Duration of active intervention:** a: No intervention; b: 24 months; c: 24 months

**Number allocated:** 415

**Completed:** Total: 394; a: 129; b: 132; c: 133

**% Dropout:** Total: 5.06%; a: 6.52%; b: 5.04%; c: 3.62%

**Length of follow-up (months):** 15

**Quantitative outcomes reported:** Weight change
**Period of study:** July 2009 to June 2010

**Inclusion criteria:**
1. All ethnic groups; 2. Men and Women; 3. Aged 18 years or more; 4. Body mass index ≥25; 5. Having pre-diabetes and/or metabolic syndrome based on the following criteria: a). Pre-diabetes: fasting plasma glucose between 100 and 125 mg/dL; b). Metabolic syndrome: Three or more of the following: Waist circumference ≥40 inches in men; ≥35 inches in women (if in Asian American ≥35 inches in men; ≥31 inches in women); Triglycerides ≥150 mg/dL; High-density lipoprotein cholesterol (HDL-C) <40 mg/dL in men; <50 mg/dL in women; Systolic blood pressure ≥130mmHg or diastolic blood pressure ≥85mmHg; Fasting plasma glucose between 100 and 125 mg/dL. 6. Having a primary care physician (PCP); 7. Able and willing to enroll and provide written, informed consent, i.e. to: 1) meet the time and data collection requirements of the study; 2) be randomized to one of the three intervention arms; 3) adhere to the recommendations of the study intervention as assigned; 4) participate in follow-up for 12 months; and 5) allow extraction of relevant information from their medical records

**Exclusion criteria:**
Inability to speak, read or understand English; no regular access to a computer with internet and email capabilities; triglycerides ≥400 mg/dL; Systolic blood pressure ≥160mmHg or diastolic blood pressure ≥100mmHg; initiation or change of drug therapy for elevated blood pressure or abnormal lipid levels within the past 3 months; initiation or change of antidepressant medication within the past 3 months; having a medical or physical condition that make moderate intensity physical activity (like a brisk walk) difficult or unsafe; use of weight-loss medications in the past 3 months; regular use (>5 days/month) of medications that affect appetite or weight (e.g. oral corticosteroids, insulin, oral hypoglycemics etc.); currently enrolled in a lifestyle intervention programme; planning to undergo bariatric surgery during

**b:** Coach-led: 12 week core curriculum session (clinic-based, small groups), online self-monitoring of weight and physical activity (preferably daily but at least twice weekly; coach routinely reviewed records) and personalized lifestyle coaching (proactive, coach-initiated). Participant goals of 7% weight loss and 150min/week of moderate physical activity. Recommended total fat reduction (to 25% of calories from fat) and calorie balance and restriction (with a goal of a 500 to 1000 calorie reduction diet). Calorie and fat goals given as a means to achieve and maintain the weight goal, rather than as a goal in and of itself.

**c:** Self-directed: 12 week core curriculum session (home-based DVD), online self-monitoring of weight and physical activity (preferably daily but at least twice weekly; coach did not routinely review records) and personalized lifestyle coaching (as needed, patient-initiated). Access to a study dietitian via secure online messaging for advice and support.

During the maintenance phase, secure online messaging was the primary mode of contact between participants in both groups and the dietitian. Based on participant progress, the dietitian provides tailored feedback to reinforce progress, recommend problem solving and relapse prevention strategies, and encourage maintenance efforts.

**Duration of active intervention:** a:unclear; b:12 weeks; c:12 weeks

**Number allocated:** 241

**Completed:** Total:; a:NR; b:NR; c:NR

**% Dropout:** Total: N/A; a:NR; b:NR; c:NR

(%);BMI kg/m²;Waist circumference
the study period; diagnosis of Type 1 or Type 2 diabetes mellitus; significant medical comorbidities, including uncontrolled metabolic disorders (e.g., thyroid, renal, liver), heart disease, stroke, and ongoing substance abuse; renal insufficiency (i.e. glomerular filtration rate <60 ml/min/1.73 m2); diagnosis of psychiatric disorders that would limit adequate informed consent or ability to comply with study protocol; diagnosis of cancer (other than non-melanoma skin cancer) that was active or treated with radiation or chemotherapy within the past 2 years; diagnosis of a terminal illness and/or in hospice care; pregnant, lactating or planning to become pregnant during the study period; enrolled or planning to enrol in a research study that would limit full participation in this study or confound the observation and interpretation of the study's findings; family/household member of another study participant or of a study staff member; no longer a patient or planning to transfer care outside of clinic during the study period; planning to move out of the area during the study period; primary care provider determination that the study is medically inappropriate or unsafe for the patient; investigator discretion for clinical safety or protocol adherence reasons

**Recruitment:** Participants were recruited from primary care practices

**Baseline age (years):** Total: 49.70(10.1); a: 47.40(10.6); b: 53.40(8.5); c: 48.60(10.4)

**Baseline BMI (kg/m²):** Total: NR; a: NR; b: NR; c: NR

**Baseline weight:** Total: 113.40(18.2); a: 116.00(20.0); b: 111.60(15.0); c: 112.60(19.4)
Bacon 2002

Country: USA
Location: Community
Period of study: NR

Inclusion criteria:
Caucasian; female; aged 30-45 years; BMI 30 or over; non-smoker; not pregnant, intending to get pregnant, or lactating; practicing birth control if heterosexually active and premenopausal; Restraint Scale score > 15, indicating a history of chronic dieting; no recent myocardial infarction; no active neoplasms, type 1 diabetes or insulin dependent type 2 diabetes, no history of cerebrovascular or renal disease

Exclusion criteria:
Participants unable to function in a group environment (e.g. personality disorders) and taking medications known to affect weight/energy expenditure, such as weight loss drugs, were excluded, with the exception of those that were on anti-depressant or selective serotonin re-uptake inhibitor (SSRI) drug therapy

Recruitment: Print, electronic and televised media

Baseline age (years): Total:39.30(4.5); a:NR; b:NR
Baseline BMI (kg/m²): Total:35.70(3.6); a:36.60(4.1) b:35.90(4.1)
Baseline weight: Total:99.00(11.4); a:101.10(13.2); b:99.60(12.0)

Description of interventions:
a: Diet: Information presented was similar to most behavioural weight loss programmes: self-monitoring, stimulus control, reinforcement and cognitive change. Participants were taught to moderately restrict their fat and energy intake and were encouraged to monitor their diet by maintaining a food diary and to monitor their weight weekly. Walking at an intensity suggested by training heart rate range was encouraged. The programme was taught by an experienced registered dietician and reinforced using the LEARN Programme for Weight Control manual.

b: Health at Every Size: There were five aspects to the treatment programme: body-acceptance, eating behaviour, activity, nutrition, and social support. Initial treatment focused on enhancing body-acceptance and self-acceptance, and participants were supported in leading as full a life as possible, regardless of their body weight or whether they succeed at weight control. The secondary phase of treatment focused on eating behaviour. The emphasis was on regulating the quality and quantity of food intake according to internal cues of hunger, appetite and satiety. The activity component of the intervention focused on helping participants to identify and transform the barriers to becoming active, such as attitudes towards their bodies, and to find activity habits that were fun and appealing. The support group element was designed to help the women see their common experiences in a culture that devalues large women, and to gain support and learn strategies for asserting themselves and effecting change. The programme was facilitated by a counsellor who has conducted educational and psychotherapeutic workshops and groups using this non-diet approach, and reinforced with a written manual.

Duration of active intervention: a:24 weeks; b:24 weeks
Number allocated: 78
Completed: Total:38; a:19; b:19
% Dropout: Total:51.28%; a:51.28%; b:51.28%

Length of follow-up (months): 24
Quantitative outcomes reported:
Weight; BMI kg/m²; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Quality of life (generic); Quality of life (condition-specific)
Country: USA
Location: 41 referral centres in the continental USA
Period of study: Pre-2002
Inclusion criteria:
BMI between 28 and 43, were taking at least one antihypertensive medication and had a sitting diastolic blood pressure (DBP) between 96mmHg and 109mmHg on two consecutive visits, antihypertensive medication dose(s) had to be stable for at least 12 weeks preceding study entry, individuals with easily controlled and stable diabetes were allowed to participate.
Exclusion criteria:
Pregnant or lactating women, women of childbearing potential were eligible only if acceptable contraceptive methods were used, unstable medical and/or psychiatric illness, recent (within 12 weeks before study entry) initiation or change in diuretic therapy, previous gastrointestinal surgery for weight reduction, and any active gastrointestinal disorders such as malabsorption syndrome except more than mild lactose intolerance, diarrhoea or constipation, history of bulimia or laxative abuse, substance abuse, including alcohol, and unwillingness or inability to comply with protocol requirements, use of nicotine replacement therapy, appetite suppressants, fish-oil supplements, oral retinoids, chronic systemic steroids other than sex hormone replacement and gonadotropin releasing hormone was prohibited during the study, as was acute antidepressant or anxiolytic therapy
Recruitment: Participants were recruited from referral centres
Baseline age (years): Total: NR; a:52.50(0.5); b:53.20(0.5)
Baseline BMI (kg/m²): Total: NR; a:35.40(4.0); b:35.80(3.9)
Baseline weight: Total: NR; a:101.50(1.0); b:101.20(1.0)
Description of interventions:
a: Nutritionally-balanced hypocaloric diet (estimated energy requirements minus 600 kcal/day) with no more than 30% of calories as fat. Lifestyle intervention literature was made available to all participants during the study and all met with a dietician periodically to review dietary instructions and food records. They were also encouraged to participate in moderate physical activity as deemed appropriate by their physician. Placebo tablet 3 times a day with meals.
b: As per control group except 120 mg orlistat three times daily with meals instead of placebo.
Duration of active intervention: a:12 months; b:12 months
Number allocated: 554
Completed: Total:266; a:106; b:160
% Dropout: Total:51.99%; a:61.59%; b:42.45%
Length of follow-up (months):12
Quantitative outcomes reported:
Weight; BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; Systolic BP; Diastolic BP
**Country:** USA  
**Location:** Community mental health centre in Concord, New Hampshire  
**Period of study:** Recruitment April 2007 to November 2008  

**Inclusion criteria:**  
Age 21 or older; diagnosis of major depression, bipolar disorder, schizoaffective disorder, or schizophrenia, (based on the Structured Clinical Interview for DSM-IV); serious mental illness, defined by an axis I disorder and persistent impairment in multiple areas of functioning (such as work, school, and self-care); BMI >25 kg/m²; and ability and willingness to provide informed consent for participation stable pharmacological treatment, defined as receiving the same psychiatric medications over the prior two months  

**Exclusion criteria:**  
Residing in a nursing home or other institution, primary diagnosis of dementia or significant cognitive impairment as determined by a Mini-Mental Status Exam score <24, terminal illness expected to cause death within one year, or current diagnosis of substance dependence (based on the substance abuse module of the Structured Clinical Interview for DSM-IV)  

**Recruitment:** NR  
**Baseline age (years):** Total:43.80(11.5); a:44.40(10.6); b:43.10(12.4)  
**Baseline BMI (kg/m²):** Total:37.60(8.2); a:38.30(8.5); b:36.80(7.8)  
**Baseline weight:** Total:105.14(24.86); a:107.18(24.68); b:103.10(25.08)  

**Description of interventions:**  
a: Free membership to the same local fitness club as IN SHAPE group and included introduction to the exercise equipment and educational materials on the health benefits of exercise and healthy diet.  
b: Health promotion intervention consisting of a free fitness club membership and a health mentor. The health mentors developed personalized fitness plans using shared goal setting. Thereafter, they met with participants once a week for 45-60 minutes at a local fitness club (YMCA) and provided fitness coaching, support, and reinforcement of physical activity. The nutrition component focused on healthy eating as opposed to caloric restriction and involved discussions at each session, individual meetings with a registered dietitian, and group cooking classes or grocery store tours (or both), depending on participant goals and preferences.  

**Duration of active intervention:** a:12 months; b:12 months  
**Number allocated:** 133  
**Completed:** Total:104; a:52; b:52  
**% Dropout:** Total:21.80%; a:22.39%; b:21.21%  

**Length of follow-up (months):** 12  
**Quantitative outcomes reported:**  
Weight; BMI kg/m²
Country: USA
Location: Three non-profit community mental health providers in the Boston area: Vinfen, Massachusetts Mental Health Center; and Bay Cove Human Services
Period of study: Recruitment 2007-2011
Inclusion criteria:
Age 21 years or older; BMI >25 kg/m²; and provision of informed consent for participation serious mental illness, defined as an axis I diagnosis of major depression, bipolar disorder; schizoaffective disorder; or schizophrenia (based on the Structured Clinical Interview for DSM-IV Axis I Disorders, Patient Edition [SCID; 16]) and persistent impairment in multiple areas of functioning (e.g., work, school, self-care); participants were on stable pharmacological treatment, defined as having received the same psychiatric medications over the previous 2 months
Exclusion criteria:
Residence in a nursing home or other institution; a primary diagnosis of dementia; presence of significant cognitive impairment, defined as a score <24 on the Mini-Mental State Examination; inability to walk one city block; pregnant or planning to become pregnant within the next 18 months; inability to speak English; terminal illness with mortality expected within 1 year; or a current diagnosis of an active substance dependence disorder (based on the substance abuse module of the SCID)
Recruitment: From the community mental health providers
Baseline age (years): Total:43.90(11.2); a:43.50(11.6); b:44.30(10.9)
Baseline BMI (kg/m²): Total:36.80(8.2); a:37.50(8.8); b:36.20(7.5)
Baseline weight: Total:106.78(24.54); a:108.36(26.26); b:105.14(22.72)

Description of interventions:
See Bartels 2013
Duration of active intervention: See Bartels 2013
Number allocated: 210
Completed: Total:163; a:83; b:80
% Dropout: Total:22.38%; a:21.70%; b:23.08%

Length of follow-up (months): 18
Quantitative outcomes reported:
Weight; BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP
Country: USA
Location: Community and health research centre
Period of study: 2008 – 2011
Inclusion criteria: Men and women aged 22 to 75 years with a BMI of 30 kg/m² to 45
Exclusion criteria: Major exclusion criteria were self-reported clinical cardiovascular disease, type 2 diabetes, or kidney disease; use of prescription weight-loss medications; surgery; and weight loss greater than 6.8 kg within 6 months of study entry.
Recruitment: From general public using mailing lists, fliers, worksite and community screenings and television advertisements
Baseline age (years): Total: NR; a:47.80(10.4); b:45.80(9.9)
Baseline BMI (kg/m²): Total: NR; a:35.60(4.5); b:35.20(3.8)
Baseline weight: Total: NR; a:97.90(13.5); b:96.30(12.7)
Description of interventions:
a: Low-fat diet: Participants were instructed to maintain less than 30% of their daily energy intake from total fat (with <7% from saturated fat) and 55% from carbohydrate, based on National Cholesterol Education Programme guidelines.
b: Low-carbohydrate diet: Participants were instructed to maintain an intake of digestible carbohydrate (total carbohydrate minus total fibre) of less than 40 g/day.
Duration of active intervention: a:12 months; b:12 months
Number allocated: 148
Completed: Total:119; a:60; b:59
% Dropout: Total:19.59%; a:17.81%; b:21.33%
Length of follow-up (months):12
Quantitative outcomes reported:
Weight; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose; Quality of life

Country: USA
Location: Three urban community health centres that served a predominately racial/ethnic minority patient population in Boston
Period of study: 1st February 2008 to 2nd May 2011
Inclusion criteria: BMI 30-50 kg/m², weight less than 180 kg, use of 1 or more antihypertensive medication, age at least 21 years, 1 or more medical visits in the 12 months before study entry, English or Spanish fluency, written informed consent, and willingness to change diet, physical activity, and weight
Exclusion criteria: History of a vascular event 6 months or less before study entry or of a medical condition that might affect measurement or trajectory of weight loss, previous or planned bariatric surgery, use of weight loss medications or medications known to increase weight, recent pregnancy or breastfeeding or plans to become pregnant
Description of interventions:
a: Usual care: Participants were provided with the National Heart, Lung, and Blood Institute's "Aim for a Healthy Weight" self-help booklet at baseline. The research team made no other attempts to influence care delivered to usual care participants. All providers were asked to use their usual weight management, and cardiovascular disease management strategies (e.g. referrals to community weight reduction programs such as Weight Watchers® etc.) for participants in the usual care group.
b: The intervention used a behavioural weight loss approach designed for use in resource-constrained settings and was designed for delivery in populations with limited literacy and numeracy and impaired access to health-promoting resources. Patients were prescribed 3 tailored goals to modify routine obesogenic lifestyle behaviours (modify lifestyle, diet and physical activity). New goals were selected at subsequent 13 week intervals. Diet goals included avoiding sugary drinks, avoiding fast food, eating 5 portions of fruit/veg every day, avoiding high fat meat and high calorie snacks. Exercise goals included doing at least 20 minutes brisk activity most days and gradually building towards walking 10,000 steps/day. For the duration of the study, participants
Length of follow-up (months):24
Quantitative outcomes reported:
Weight; Weight change (%); BMI kg/m²; Systolic BP; Diastolic BP
within 2 years, and/or plans to relocate within the 2-year study period

**Recruitment:** Research staff conducted medical chart reviews at each health center to identify potentially eligible participants

**Baseline age (years):** Total: NR; a:54.67(11.03); b:54.58(10.77)

**Baseline BMI (kg/m²):** Total: NR; a:36.99(5.24); b:37.03(4.96)

**Baseline weight:** Total: NR; a:100.60(18.67); b:99.70(16.29);

maintained a hypertension medication adherence goal (to take their medication as prescribed daily). Social support was promoted through monthly telephone coaching calls and group support sessions.

**Duration of active intervention:** a:NR; b:24 months

Number allocated: 365

Completed: Total:314; a:166; b:148

% Dropout: Total:13.97%; a:10.27%; b:17.78%

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**Berry 2014**

**Country:** USA

**Location:** Eight rural elementary schools in two counties of North Carolina

**Period of study:** Recruitment August 2007 to April 2010

**Inclusion criteria:**

Inclusion criteria for children included the ability to speak, write and read English; enrolment in the 2nd-4th grade; age 7-10 years; BMI at or greater than the 85th percentile for age and gender; at least one biological parent with a BMI of 25 kg/m² or more; self-consent and their parent's consent for their participation. Inclusion criteria for parents were ability to speak, write and read English; BMI of 25 kg/m² or more; a 2nd-4th-grade child with a BMI at or over the 85th percentile for age and gender; residence with the child; and consent to participate.

**Exclusion criteria:**

Dyads were excluded if either the parent or the child had a heart murmur, congenital heart disease, family history of sudden death, claustrophobia or if they were participating in another weight management program. Those of Asian descent were excluded because of lower BMI cut-offs for overweight and obesity.

**Recruitment:** A "pre-recruitment" presentation was made to children and parents at a "Meet the Teacher" night. Second grade children were also given a short classroom presentation and participatory permission slips to be

**Description of interventions:**

a: The control group of children and parents received usual care and had data collected at the same time points as the experimental group. After completion of the final data collection, they were offered the phase 1 classes. Families in the control group also received a monthly thank-you card and a reminder that they would be eligible to receive the intervention at the end of the trial. Children and parents received $20 each after each data collection.

b: The children and parents received a two-phase intervention. In phase 1, children and parents attended all classes together and received 60min nutrition and exercise education, and coping skills training, followed by 45min exercise weekly for 12 weeks. Education classes were taught by the same nurse practitioner/registered dietician, and the exercise classes were taught by the same certified exercise trainer. In phase 2, children and parents met once a month for 9 months for a 60min class and 45min exercise. They met in small groups with the same interventionist to problem-solve issues. Parents and children were asked to share a nutrition or exercise goal that they wanted to work on during the month. After data collection, each child and each parent received $20 each.

**Duration of active intervention:** a:NR; b:12 months

Number allocated: 346

Completed: Total: a:NR; b:NR

% Dropout: Total: N/A; a:NR; b:NR

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**Length of follow-up (months):**18

**Quantitative outcomes reported:**

BMI kg/m²; Waist circumference
signed by their parents. Leaflets and posters were also distributed around the schools.

**Baseline age (years):**
- Total: 36.90 (8.1); a: 36.80 (8.1); b: 36.90 (8.1)
- **Baseline BMI (kg/m²):**
  - Total: NR; a: 39.13 (8.27); b: 36.41 (8.27)
  - **Baseline weight:**
    - Total: NR; a: NR; b: NR;

### Berteus Forslund 2008

**Country:** Sweden  
**Location:** Three medical outpatient clinics, western and southern Sweden (Sahlgrenska Hospital, Skaraborg Hospital and Helsingborg Hospital)  
**Period of study:** September 2002 to January 2006  
**Inclusion criteria:**  
- Age 18-60 years and BMI > 30 kg/m²  
**Exclusion criteria:**  
- Previous bariatric surgery, anti-obesity drugs in previous 12 months, medication for diabetes, hypothyroidism, severe psychiatric illness, bulimia, drug or alcohol abuse  
**Recruitment:** From obesity clinics  
**Baseline age (years):**  
- Total: NR; a: 40.10 (11.5); b: 38.70 (11.6)  
- **Baseline BMI (kg/m²):**  
  - Total: NR; a: 38.40 (6.0); b: 38.30 (5.3)  
- **Baseline weight:**  
  - Total: NR; a: 112.60 (21.5); b: 113.00 (18.6)  

**Description of interventions:**  
- BOTH GROUPS: Daily kcal allowances were calculated using basal metabolic rate and physical activity levels. The minimum energy level prescribed was 1400 kcal/day. Participants were given individual diet plans and eating frequency throughout the study. Participants were encouraged to increase their physical activity, mainly by increasing walking. A diet-counselling plan was followed by the dieticians to ensure consistent treatment at study sites.  
  - a: 1400 kcal/day was divided into three meals and three snacks: breakfast 20%, lunch 25%, dinner 25% and three snacks, each on 10%.  
  - b: As per a group except daily energy intake was divided into three meals only: breakfast, 30% of daily energy intake, lunch 35% and dinner 35% and no snacks except limited fruit and zero calorie drinks.  

**Duration of active intervention:** a: 12 months; b: 12 months  
**Number allocated:** 140  
**Completed:** Total: 93; a: 44; b: 49  
**Dropout:** Total: 33.57%; a: 37.14%; b: 30.00%  
**Length of follow-up (months):** 12  
**Quantitative outcomes reported:**  
- Weight; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose

### Beutel 2006

**Country:** Germany  
**Location:** Initial rehabilitation inpatient clinic  
**Period of study:** July 1999 to March 2002  
**Inclusion criteria:**  
- BMI 35 kg/m² or over  
**Exclusion criteria:**  
- A minority of patients who were directly referred to a specific setting (usually behavioural) were excluded from randomization.  
**Recruitment:** Health insurance company referral  
**Baseline age (years):**  
- Total: 41.30 (range 20 to 64); a: 42.30 (range 20 to 60); b: 40.30 (range 20 to 64)  

**Description of interventions:**  
- a: The behavioural approach was geared to identifying functional determinants of the obesity, developing problem-solving strategies and social competence, improving body-perception and emotional expression, and promoting pleasurable eating behaviour regulated by hunger and satiety. Treatment was centred around various homogeneous groups for participants with obesity. There was less emphasis on individual therapy compared to the psychodynamic approach.  
  - b: The psychodynamic approach consisted of focal and supportive-expressive elements. This approach aimed at uncovering and resolving conflicts underlying the eating disorder, developing alternative coping strategies and

**Length of follow-up (months):** 36  
**Quantitative outcomes reported:**  
- Weight change (%); BMI kg/m²
| Baseline BMI (kg/m²): Total:44.30 (range 35.1 to 73.5); a:43.90 (range 35.2 to 73.3); b:44.60 (range 35.1 to 73.5) | improving body-perception and emotional expression. In addition to individual psychotherapy, patients with obesity participated in psychodynamic therapy in various mixed groups of patients with different psychosomatic and psychiatric disturbances. Patients received more individual and mixed group therapy in the psychodynamic treatment setting. Duration of active intervention: a:49 days; b:49 days Number allocated: 396 Completed: Total:134; a:68; b:66 % Dropout: Total:66.16%; a:65.48%; b:66.83% |
| Baseline weight: Total: NR; a:NR; b:NR | Description of interventions: a: The dietician recommended eating ordinary foods in amounts which would provide the patients with approximately 1200 kcal/day. b: Intensive VLCD formula providing 810 kcal/day for 8 weeks followed by 1200 kcal/day for 4 weeks. The formula was administered in the first 8 weeks of the programme and was followed by instruction, in groups of 8 participants, every week for another 24 weeks. The guidance was aimed to achieve 1200 kcal/day. For another 4 weeks (weeks 32-36), maintenance of the patients' weight loss was reinforced by use of the same formula diet and from weeks 36-52 by instruction in groups every second week. Duration of active intervention: a:52 weeks; b:52 weeks Number allocated: 89 Completed: Total:56; a:23; b:33 % Dropout: Total:37.08%; a:48.89%; b:25.00% |

Bliddal 2011

| Country: Denmark Location: Outpatient clinic of the Department of Rheumatology, Frederiksberg Hospital Period of study: Prior to August 5 2011 Inclusion criteria: Over 18 years of age, primary knee osteoarthritis diagnosed according to American College of Rheumatology criteria, BMI 28 kg/m² or over, explicitly expressed an unequivocal desire for weight loss, fluent Danish speakers Exclusion criteria: History of other rheumatic diseases possibly responsible for secondary OA, diabetes mellitus or other endocrine disorders, and substantial abnormalities in haematological, hepatic, renal or cardiac function Recruitment: Rheumatology outpatient clinic Baseline age (years): Total:62.60(10.8); a:64.10(10.5); b:61.10(11.1) Baseline BMI (kg/m²): Total:35.60(5.0); a:35.20(4.5); b:36.00(5.5) Baseline weight: Total:95.60(14.3); a:95.50(13.7); b:95.70(15.1) | Length of follow-up (months):12 Quantitative outcomes reported: Weight; Weight change (%); Quality of life |
Brehm 2009

Country: USA
Location: Community
Period of study: Prior to February 2009
Inclusion criteria:
BMI of 27-40 kg/m², age 30-75 years, stable body weight for the preceding 6 months, diagnosis of type 2 diabetes for at least 6 months, AIC of 6.5-9.0% and treatment by diet or oral agents only (no insulin)
Exclusion criteria:
Pregnancy or lactation; active cardiac, pulmonary, renal, liver, or gastrointestinal disease; untreated thyroid disease or hypertension; triglyceride concentrations >500 mg/dL; and use of medications that may alter lipid metabolism (other than HMG-CoA reductase inhibitors), corticosteroids and weight loss drugs
Recruitment: By advertisement
Baseline age (years): Total:56.50(8.91); a:NR; b:NR
Baseline BMI (kg/m²): Total:35.90(3.34); a:NR; b:NR
Baseline weight: Total: NR; a:102.10(14.42); b:103.70(18.36)

Description of interventions:
Both groups restricted their intake to ~1550 kcal/day throughout the study.

a: Energy was distributed as 60% carbohydrate, 15% protein, and 25% fat. Both diets included similar amounts of saturated fat and protein. Participants were instructed to maintain their level of physical activity and not to initiate more vigorous regimens during the 52 week intervention. If participants were not engaging in physical activity on a regular basis, they were encouraged to adopt a walking programme of 30min/day several days/week. Group sessions brought together all participants consuming the same diet to discuss topics, such as portion control, record keeping, cooking tips, healthy recipes, and behaviour modification.

b:Same as high carbohydrate diet but energy was distributed as 45% carbohydrate, 15% protein, and 40% fat (with 20% MUFA).

Duration of active intervention: a:12 months; b:12 months
Number allocated: 124
Completed: Total:95; a:52; b:43
% Dropout: Total:23.39%; a:NR; b:NR

Broom 2002

Country: UK
Location: 54 GP surgeries and 12 hospital clinics
Period of study: Pre-September 2002
Inclusion criteria:
Men and non-pregnant women aged 18-80 years with a BMI of at least 28 kg/m² (both at screening and at baseline visits); at least one of the following obesity-associated cardiovascular risk factors: impaired glucose tolerance (serum glucose 8.0mmol/L or more, two hrs after a standard 75 g OGTT); dyslipidaemia (total serum cholesterol at least 5.2mmol/L or LDL-cholesterol at least 4.2mmol/L at screening); or hypertension (sitting diastolic BP 90-105mmHg); primary risk factors were defined as the most prevalent risk factor
Exclusion criteria:
Women of child-bearing potential were excluded if they were lactating or not using adequate contraception;

Description of interventions:
a: Placebo capsules three times daily with main meals and encouraged to follow a mildly hypocaloric diet providing approximately 30% of energy intake as fat. Energy content of the diet was calculated from the patient's estimated basal metabolic rate multiplied by 1.3 to estimate the total daily energy expenditure for participants with mild to moderate daily activities. From this, approximately 600 kcal/day were subtracted to give a mildly hypocaloric diet. The minimum calorie intake to be prescribed was 1200 kcal/day. After six months the energy content of the diet was reduced by a further 300 kcal/day to account for the expected reduction in energy requirements as a result of weight loss.
b:Orlistat 120 mg capsules three times daily with main meals and encouraged to follow the same mildly hypocaloric diet as the placebo group.

Duration of active intervention: a:52 weeks; b:52 weeks
Number allocated: 531
myocardial infarction, coronary artery bypass graft or percutaneous transluminal coronary angioplasty within three months before screening; gastrointestinal surgery for weight reduction, active gastrointestinal disorders, such as peptic ulcer disease or malabsorption syndromes, pancreatic disease, a history of post-surgical adhesions, excessive alcohol intake or substance abuse; patients who required any drug that might alter body weight or plasma lipids, such as appetite suppressants, lipid-lowering resins, retinoids and fish oil supplements; administration of systemic steroids, other than hormone replacement therapy; concomitant pharmacotherapy for type 2 diabetes, dyslipidaemia or hypertension

**Recruitment:** NR

**Baseline age (years):** Total: NR; a:45.30(11.5); b:46.70(11.4)

**Baseline BMI (kg/m²):** Total: NR; a:37.00(6.2); b:37.10(6.4)

**Baseline weight:** Total: NR; a:101.80(19.8); b:100.90(20.5)

### Completed: Total:347; a:161; b:186

% **Dropout:** Total:34.65%; a:39.47%; b:29.81%

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**Country:** UK

**Location:** 12 out-patient clinics

**Period of study:** Prior to 2002

**Inclusion criteria:**
- Male and female patients with obesity (BMI at least 30 kg/m²), age at least 18 years, with total plasma cholesterol at least 6.5mmol/L or LDL-C at least 4.2mmol/L, were eligible for entry into the study. Women of child-bearing potential were included if they were using adequate contraception.

**Exclusion criteria:**
- Myocardial infarction or major surgery within three months prior to screening, active gastrointestinal or pancreatic disease, type 1 diabetes, uncontrolled hypertension, histories of carcinoma, gastrointestinal surgery for weight loss, post-surgical lesions, bulimia or laxative abuse, drug or alcohol abuse, patients undergoing treatment with any of the following medications: drugs altering appetite or lipid concentrations, fish oil

**Description of interventions:**
- a: Placebo three times daily with main meals for 24 weeks, then Orlistat for 28 weeks.
- All randomised participants were advised to follow a hypocaloric diet containing 30% of calories as fat and a maximum of 300 mg/day cholesterol. Total energy expenditure was calculated by multiplying the patient's basal metabolic rate as estimated from body weight by 1.3; from this value, 600 kcal/day was subtracted. Dietary advice being provided by a state-registered dietitian. Patients also received advice on physical activity.

- b: Orlistat 120 mg three times daily with main meals for 52 weeks, otherwise as per placebo group.

**Duration of active intervention:** a:52 weeks; b:52 weeks

**Number allocated:** 142

**Completed:** Total:77; a:43; b:34

% **Dropout:** Total:45.77%; a:39.44%; b:52.11%
supplements, retinoids, systemic steroids (other than sex hormone replacements) or anticoagulants

**Recruitment:** From outpatient clinics

**Baseline age (years):** Total: NR; a:51.00(10.5); b:52.10(9.2)

**Baseline BMI (kg/m²):** Total: NR; a:37.10(6.27); b:36.50(5.48)

**Baseline weight:** Total: NR; a:101.40(20.2); b:100.60(18.1)

**Inclusion criteria:**
- Age between 18 and 65 years, men or women of an ethnic group with a BMI >40 kg/m², arterial pressure <160/100mmHg, a fasting triglycerides concentration <600 mg/dL, and a glycosylated haemoglobin (HbA1c) level <11%

**Exclusion criteria:**
- Drug or alcohol abuse, pregnancy, enrolment in other obesity interventions, previous bariatric surgery, mental disorders (depression and anxiety which were considered manageable by the principal investigator were not criteria for exclusion) and/or physical impairment, or any other criteria which could interfere with the ability to comply with treatment as previously detailed

**Recruitment:** From obesity clinics

**Baseline age (years):** Total: NR; a:47.80(11.5); b:46.90(10.3)

**Baseline BMI (kg/m²):** Total: NR; a:45.80(5.0); b:46.80(4.6)

**Baseline weight:** Total: NR; a:122.20(20.1); b:126.00(17.9)

**Description of interventions:**
- **a:** Intensive lifestyle intervention: Attended weekly group meetings, led by a registered nurse, from week 1 through week 12. Subsequently, sessions were conducted biweekly from week 13 to week 52. The group sessions were focussed on the qualitative aspects of dietary habits, as the distribution of energy intake, frequency of consumption, and food choices. Information on the benefits of the Mediterranean diet was provided. There were no restrictions in caloric intake. A sports medicine specialist prescribed daily exercise (led by a physiotherapist). Eligible participants could receive treatment with weight loss medicines, such as orlistat (Xenical, Roche, USA), or antidepressants, at the physician’s discretion. 40% of the participants in this group received treatment with sibutramine (Meridia, Abbott Laboratories, USA) for a period of only one to two months until it was withdrawn from the market in January of 2010.

- **b:** Conventional therapy: Standard nutritional education, medical treatment, and follow-up available as per the Spanish Endocrine Society protocol. Patients had regular clinic visits with an endocrinologist, dietitian, and nurse every three to six months throughout the duration of the study. Medical therapies, including the use of pharmacological agents, were determined by their endocrinologist on an individual basis. Only 15% of patients received weight loss medications.

**Duration of active intervention:** a:2 years; b:2 years

**Number allocated:** 106

**Completed:** Total:33; a:14; b:19

**% Dropout:** Total:68.87%; a:76.67%; b:58.70%

**Country:** Spain

**Location:** Obesity clinic in Son Espases University Hospital in Mallorca

**Period of study:** November 2009-May 2012

**Inclusion criteria:**
- Age between 18 and 65 years, men or women of an ethnic group with a BMI >40 kg/m², arterial pressure <160/100mmHg, a fasting triglycerides concentration <600 mg/dL, and a glycosylated haemoglobin (HbA1c) level <11%

**Exclusion criteria:**
- Drug or alcohol abuse, pregnancy, enrolment in other obesity interventions, previous bariatric surgery, mental disorders (depression and anxiety which were considered manageable by the principal investigator were not criteria for exclusion) and/or physical impairment, or any other criteria which could interfere with the ability to comply with treatment as previously detailed

**Recruitment:** From obesity clinics

**Baseline age (years):** Total: NR; a:51.00(10.5); b:52.10(9.2)

**Baseline BMI (kg/m²):** Total: NR; a:37.10(6.27); b:36.50(5.48)

**Baseline weight:** Total: NR; a:101.40(20.2); b:100.60(18.1)

**Description of interventions:**
- **a:** Intensive lifestyle intervention: Attended weekly group meetings, led by a registered nurse, from week 1 through week 12. Subsequently, sessions were conducted biweekly from week 13 to week 52. The group sessions were focussed on the qualitative aspects of dietary habits, as the distribution of energy intake, frequency of consumption, and food choices. Information on the benefits of the Mediterranean diet was provided. There were no restrictions in caloric intake. A sports medicine specialist prescribed daily exercise (led by a physiotherapist). Eligible participants could receive treatment with weight loss medicines, such as orlistat (Xenical, Roche, USA), or antidepressants, at the physician’s discretion. 40% of the participants in this group received treatment with sibutramine (Meridia, Abbott Laboratories, USA) for a period of only one to two months until it was withdrawn from the market in January of 2010.

- **b:** Conventional therapy: Standard nutritional education, medical treatment, and follow-up available as per the Spanish Endocrine Society protocol. Patients had regular clinic visits with an endocrinologist, dietitian, and nurse every three to six months throughout the duration of the study. Medical therapies, including the use of pharmacological agents, were determined by their endocrinologist on an individual basis. Only 15% of patients received weight loss medications.

**Duration of active intervention:** a:2 years; b:2 years

**Number allocated:** 106

**Completed:** Total:33; a:14; b:19

**% Dropout:** Total:68.87%; a:76.67%; b:58.70%
### Cheskin 2008

**Country:** USA  
**Location:** Clinical Research Facility  
**Period of study:** Recruited 2002 to 2003  
**Inclusion criteria:**  
Men and women aged 18 to 70, diagnosed by standard criteria with type 2 diabetes at least 3 months prior to enrolment, and had overweight or obesity, with a BMI of 25 to 40 kg/m²; if currently taking medications to control diabetes, a stable dose for at least 3 months prior to randomization was required; a normal electrocardiogram (ECG) or abnormalities deemed medically acceptable, a regular source of health care, permission of their primary care provider to enrol; women of childbearing potential were required to be using an acceptable method of birth control  
**Exclusion criteria:**  
Individuals with uncontrolled health problems (aside from obesity and diabetes), type 1 diabetes, bulimia, laxative/substance abuse, alcohol intake >10 drinks/week, or an uncontrolled psychiatric disorder (eg, major depression, bipolar disorder); a score >15 on the Beck Depression Inventory; a score of >30 on the Eating Attitudes Test; use of appetite-affecting medications (eg, certain antidepressants, steroids) unless on a stable dose for >3 months, or weight loss drugs, women who were lactating, pregnant, or seeking pregnancy  
**Recruitment:** By poster and newspaper announcements  
**Baseline age (years):** Total: NR; a:55.48(7.2); b:54.60(7.0)  
**Baseline BMI (kg/m²):** Total: NR; a:35.70(3.8); b:35.30(3.5)  
**Baseline weight:** Total: NR; a:102.70(16.6); b:101.50(15.5)  
**Description of interventions:**  
a: Standard diet: After an initial 34 week weight loss period, participants continued their diet at a maintenance energy level for 52 weeks. Both groups received diets of similar macronutrient composition: 45% to 50% carbohydrate, 25% to 30% fat, and 15% to 25% protein. A 25% of energy calorie deficit was used to construct the weight-loss phase diet, and a 10% calorie deficit (based on the new body weight after weight loss) was used to construct the weight-maintenance phase diet. All prescribed calories came from whole foods using choices from the ADA exchange lists. Each patient in both groups met 3 times for individual consultations with a dietitian or nutritionist to review their meal plans during the study. All participants were required to attend group educational sessions based on social cognitive theory.  
b: Meal replacement: After an initial 34 week weight loss period, participants were re-randomized for their 52 week maintenance phase to either 26 weeks of meal replacements followed by 26 weeks of standard diet (Portion Controlled Diet - PCD1) or vice versa (PCD2). Approximately 50-60% of prescribed calories were from low glycemic index, low sugar and soy-based meal replacements (bars, shakes, soups).  
**Duration of active intervention:** a:86 weeks; b:86 weeks  
**Number allocated:** 119  
**Completed:** Total:24; a:8; b:16  
**% Dropout:** Total:79.83%; a:NR; b:NR  
**Length of follow-up (months):** 20  
**Quantitative outcomes reported:**  
Weight; BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life

### Christensen 2013

**Country:** Denmark  
**Location:** Rheumatology outpatient clinic  
**Period of study:** November 2007 to August 2008  
**Inclusion criteria:**  
ALL GROUPS: Initially all participants went through a 16 week intensive dietary weight loss phase. Participants were randomised to either 8 weeks of low-energy diet (810 kcal/day) or VLCD (410 kcal/day) as formula. This was followed by an additional 8 week period of a hypo-energetic diet consisting of normal food plus two formula products daily (g ~ 1,200 kcal/day in total). The  
**Description of interventions:**  
ALL GROUPS: Initially all participants went through a 16 week intensive dietary weight loss phase. Participants were randomised to either 8 weeks of low-energy diet (810 kcal/day) or VLCD (410 kcal/day) as formula. This was followed by an additional 8 week period of a hypo-energetic diet consisting of normal food plus two formula products daily (g ~ 1,200 kcal/day in total). The  
**Length of follow-up (months):** 12  
**Quantitative outcomes reported:**  
Weight; BMI kg/m²; Waist circumference;
BMI 30 kg/m² or over; more than 50 years of age; diagnosed with primary knee osteoarthritis according to American College of Rheumatology criteria

**Exclusion criteria:**
Lack of motivation to lose weight, inability to speak Danish, planned anti-obesity surgery, total knee alloplasty, receiving pharmacologic therapy for obesity

**Recruitment:** Rheumatology outpatient clinic

**Baseline age (years):**
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<th>Total</th>
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**Baseline BMI (kg/m²):**
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**Baseline weight:**
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Second phase was 52 weeks where participants were randomly assigned to either a continued diet, exercise, or usual care groups.

a: Usual-care: No attention was provided to the participants after the first 16 weeks of dietary intervention.

b: Exercise: The exercise intervention was divided into four periods of 12 weeks and one period of 4 weeks (total 52 weeks). The aim was to gradually translate the intervention from facility-based exercises to home-based exercises. In this way, the participants were gradually going from supervised to unsupervised exercise. The aim of the intervention was to improve knee function and reduce pain. Functional weight-bearing exercises were applied, emulating activities of daily life - both light and more vigorous activities. The quality of the performance in each exercise was emphasised, and the level of training and progression was guided by the patient's performance

c: Diet: Participants attended educational weekly sessions lasting approximately 60 min. The participants were weighed and formula products were handed out (The Cambridge Weight Plan). Participants were advised to use one formula product a day to enhance weight loss. The group treatment provided a combination of empathy, social support, and friendly competition. The dietician aimed to maximise adherence by reinforcing positive dietary changes and addressing barriers to adherence. Attendance to the sessions was recorded. The weekly sessions included weighing and provision of formula products (1/day Cambridge Weight Plan product).

**Duration of active intervention**

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**Number allocated:** 192

**Completed:**
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**% Dropout:**
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<td>17.19%; a:18.75%; b:18.75%; c:14.06%</td>
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**Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose**
Courcoulas 2014

**Country:** USA  
**Location:** University of Pittsburgh Medical Centre  
**Period of study:** 1st October 2009 to 26 June 2014  
**Inclusion criteria:**  
- 25 to 55 years BMI 30–40 kg/m², type 2 diabetes mellitus  
- Participants with grade I obesity on antidiabetics and with permission from their physician  
**Exclusion criteria:**  
- Bariatric surgery, impaired mental state, alcohol or drug addiction, smoking, pregnancy or planning pregnancy, unfit for anaesthesia, diabetes mellitus, failed nutritional or psychological assessment, deemed unlikely to comply with study procedures  
**Recruitment:** television, newspaper, internet and other local media advertisements  
**Baseline age (years):** Total: 47.30(6.4); a: 46.30(7.2); b: 47.30(7.0); c: 48.30(4.7)  
**Baseline BMI (kg/m²):** Total: NR; a: 35.50(2.6); b: 35.50(3.4); c: 35.70(3.3)  
**Baseline weight:** Total: NR; a: 99.80(12.8); b: 99.50(14.1); c: 102.60(13.8)  
**Description of interventions:**  
- **a:** RYGB: Participants were advised to follow a recommended post-bariatric surgery diet and encouraged to exercise at least 3 to 4 times/week. All participants then followed a low-level lifestyle intervention (LLLI), based on the Look AHEAD trial for years 2 and 3. The LLLI consisted of twice-monthly contact: 1 in-person session (approximately 30–45 minutes) and 1 brief (<10 minutes) telephone contact, and regular refresher group series. Each contact focused on a specific behavioural topic related to weight loss. Participants who missed in-person sessions received written mailed materials and telephone calls. The original endocrinologist provided type 2 diabetes care. Glucose values were monitored by the study physician.  
- **b:** LAGB: As per RYGB except for LAGB procedure.  
- **c:** Lifestyle weight loss intervention (LWLI): Participants followed a 1200-1800 kcal/dau diet and a behavioural weight control programme based on the Diabetes Prevention Program and the Look AHEAD trial and adapted into a 12-month. During the first 6 months, participants attended weekly in-person sessions. During months 7 to 12, sessions in the first and third weeks of the month and participants received brief telephone calls in the second and fourth weeks. Session focused on behavioural topics. Participants engaged in moderate-intensity exercise 5 days/week. Participants followed the same low-level lifestyle intervention as the surgical groups in years 2 and 3.  
**Duration of active intervention:** a: 12 months; b: 12 months; c: 12 months  
**Number allocated:** 69  
**Completed:** Total: 52; a: 18; b: 20; c: 14  
**% Dropout:** Total: 24.64%; a: 25.00%; b: 9.09%; c: 39.13%  
**Length of follow-up (months):** 36  
**Quantitative outcomes reported:**  
- Weight; Weight change (%)  
- BMI kg/m²; Waist circumference  
- Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c%; Fasting plasma glucose

Cummings 2016

**Country:** USA  
**Location:** Seattle  
**Period of study:** July 2011 to June 2012  
**Inclusion criteria:**  
- 25–64 years old, with type 2 diabetes, a BMI of 30–45 kg/m², currently taking diabetes medications, covered by insurance that had a bariatric surgery rider (if BMI 35–45 kg/m²), and were willing to accept randomisation into either intervention group and then follow the full protocol for ≥1 year  
**Exclusion criteria:**  
- Intensive lifestyle: Gradual increase in brisk walking or other supervised and unsupervised activities of similar moderate aerobic intensity over 12 months. Participants were directed to exercise ≥45 min/day, ≥5 days/week, for 1 year. The dietary intervention was conducted by a research dietitian trained in behaviour modification. Each participant was required to attend weekly group nutrition sessions for the first 6 months. These sessions were based on DPP, with several modifications for our diabetic participants. Although reduced calorie intake and weight loss were strongly encouraged, participants were not given specific weight loss goals. In the second 6-month phase of the study, participants were contacted weekly by the dietitian via telephone or email, and

**Description of interventions:**  
- **a:** Intensive lifestyle: Gradual increase in brisk walking or other supervised and unsupervised activities of similar moderate aerobic intensity over 12 months. Participants were directed to exercise ≥45 min/day, ≥5 days/week, for 1 year. The dietary intervention was conducted by a research dietitian trained in behaviour modification. Each participant was required to attend weekly group nutrition sessions for the first 6 months. These sessions were based on DPP, with several modifications for our diabetic participants. Although reduced calorie intake and weight loss were strongly encouraged, participants were not given specific weight loss goals. In the second 6-month phase of the study, participants were contacted weekly by the dietitian via telephone or email, and

**Quantitative outcomes reported:**  
- Weight; Weight change (%)  
- BMI kg/m²; Waist circumference  
- Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c%; Fasting plasma glucose; Quality of life
Pregnancy, cancer (except non-melanoma skin cancer), ascites, peritoneal effusion, dementia, bipolar disorder, schizophrenia, cirrhosis, end-stage renal disease, human immunodeficiency virus, inflammatory bowel disease, diagnosed type 1 diabetes, diabetes secondary to a specific disease or glucocorticoid therapy, prior bariatric or major gastrointestinal surgery or organ transplantation

**Recruitment:** Potentially eligible participants were indentified from the electronic databases at Group Health Cooperative healthcare system, and approached by mail and telephone.

**Baseline age (years):** Total: NR; a:54.60(6.3); b:52.00(8.3)

**Baseline BMI (kg/m²):** Total :NR; a:37.10(3.5); b:38.30(3.7)

**Baseline weight:** Total :NR; a:112.80(16.5); b:108.80(14.9)

were encouraged to attend monthly in person group nutrition sessions.

b: RYGB: In addition to surgery, patients underwent a 4 week pre-operative and 10-month postoperative behavioural treatment regimen. In the pre-operative phase, patients had weekly telephone-based appointments with a health educator and were required to attend 2–3 bariatric support group meetings. Patients continued to have phone appointments with their health educator for 10 months after surgery. The postoperative behavioural treatment programme focused on diet and nutrition counselling, behaviour modification and exercise recommendations.

**Duration of active intervention:** a:12 months; b:11 months

**Number allocated:** 43

**Completed:** Total:32; a:17; b:15

**% Dropout:** Total:25.58%; a:15.00%; b:34.78%

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Dalle Grave 2013

**Country:** Italy

**Location:** Weight Disorder inpatient unit of Villa Garda Hospital

**Period of study:** Prior to 2012

**Inclusion criteria:**
Age 18-65 years, BMI 40 kg/m² or between 35 and 39.9 with at least one weight loss-responsive comorbidity (e.g., type 2 diabetes, cardiovascular diseases, sleep apnoea, severe joint disease, two or more risk factors defined by the Adult Treatment Panel III)

**Exclusion criteria:**
Pregnant or lactating, taking medications affecting body weight, patients with medical comorbidities associated with weight loss or severe psychiatric disorders (e.g., acute psychotic states, bipolar disorder, bulimia nervosa)

**Recruitment:** GP an other clinician referral to the weight disorder inpatient unit

**Baseline age (years):** Total: NR; a:46.70(10.3); b:46.60(12.0)

**Baseline BMI (kg/m²):** Total :NR; a:45.80(6.5); b:45.40(7.0)

**Baseline weight:** Total :NR; a: NR; b: NR;

**Description of interventions:**

BOTH GROUPS: Stage 1 included 15 CBT groups (five a week), chaired by physicians, dieticians and psychologists, 18 sessions of aerobic and 6 calisthenic sessions chaired by physical trainers. The behavioural component of the programme was based on the principles of the LEARN program for weight control. Stage 2 included 12 sessions of 45min each over 48 weeks with a CBT-trained dietitian. The first 24 weeks of stage 2 (27 weeks from treatment start) were dedicated to address barriers to weight loss, the remaining sessions to weight maintenance. In this last phase the calorie content was gradually increased to maintain the weight in 63 kg range, without changes in macronutrient composition.

a: High protein diet: 1200 kcal/day for women and 1500 kcal/day for men, with 20% energy from fats (<10% from saturated fats) and daily multivitamin supplements, 34% energy from proteins and 46% from carbohydrates.

b: High carbohydrate diet: 1200 kcal/day for women and 1500 kcal/day for men, with 20% energy from fats (<10% from saturated fats) and daily multivitamin supplements, 17% energy from proteins and 63% from carbohydrates.

**Duration of active intervention:** a:51 weeks; b:51 weeks
Number allocated: 88  
Completed: Total:69; a:32; b:37  
% Dropout: Total:21.59%; a:25.58%; b:17.78%

Damschroder 2014

Country: USA  
Location: Two Midwestern Veterans Health Association (VHA) centres  
Period of study: January 2010 to November 2012  
Inclusion criteria:  
BMI of 30 kg/m² or more (or 25-30 with at least one obesity-related chronic health condition, e.g. hyperlipidemia) without contraindications for weight loss (e.g. end-stage cancer); able to communicate in English; competent to provide informed consent; reliable access to a telephone  
Exclusion criteria:  
Current involvement in another weight-loss, nutrition or physical activity related study; currently receiving treatment or medications for weight loss; inability to complete the 6-minute walk test; pregnancy  
Recruitment: NR  
Baseline age (years): Total:55.00(10.0); a:54.60(10.5); b:54.90(9.5); c:55.40(10.0)

Description of interventions:  
a: MOVE! Participants were contacted by the study coordinator with information about available classes. Other than meeting for the 3 and 12-month assessments, study staff had no contact with participants. Participants were offered 11 or 12 weekly open-group support sessions of 90 minutes each over 3 months. During the follow-up phase (4-12 months), both sites offered drop-in follow-up groups, one with quarterly 90-minute groups and the other 60-minute groups meeting twice a month. Some patients had the option of re-enrolling in the initial series of weekly sessions. Clinical facilitators rotated from session to session.  
b: ASPIRE-group: Small-changes model specified small but cumulative improvements in lifestyle for gradual weight loss and maintenance over time. ASPIRE encourages participants to make small, self-selected goals resulting in an energy deficit as small as 200 kcal/day. Coaching sessions had four general activities: (1) review of events, progress, self-monitoring, and setbacks since the last session; (2) use of a five-stage problem-solving model to collaboratively identify and overcome barriers; (3) discussion of psychoeducational content; and (4) setting new goals. Lifestyle coaches

Length of follow-up (months): 12  
Quantitative outcomes reported:  
Weight; Weight change (%); BMI kg/m²; Waist circumference; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %
Baseline BMI (kg/m²): Total: NR; a:36.80(6.43); b:36.40(6.13); c:36.20(6.17)

Baseline weight: Total: NR; a:114.10(23.80); b:112.40(21.94); c:112.50(22.40)

The ASPIRE study encouraged patients to set their own small, manageable nutrition and physical activity goals relative to their current patterns and context. Each week, coaches and participants discussed goal attainment. Participants generally had the same lifestyle coach for 12 months.

c: ASPIRE-phone: Same as ASPIRE-group but delivered to individuals via telephone.

**Duration of active intervention:** a:12 months; b:12 months; c:12 months

**Number allocated:** 481

**Completed:** Total:361; a:119; b:122; c:120

**% Dropout:** Total:24.95%; a:25.16%; b:23.75%; c:25.93%

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**Country:** USA  
**Location:** University of California, San Francisco  
**Period of study:** July 2009 to October 2013  

**Inclusion criteria:**  
Age 18 years or older, BMI between 30-45 kg/m², waist circumference >102 cm (men) or >88 cm (women), living in San Francisco Bay Area and able to attend more than 16 classes and up to 12 assessment visits in San Francisco over an 18-month period.

**Exclusion criteria:**  
Inability to provide informed consent, a substance abuse, mental health, or medical condition that, in the opinion of investigators, will make it difficult for the potential participant to participate in the group intervention, initiation of new class of psychiatric medications in past 2 months, currently on a specific weight loss diet, active bulimia or strong history of bulimia, type 1 or 2 diabetes or fasting glucose ≥126 mg/dL or HbA1c ≥6.5; those with HbA1c between 6-6.5% may complete an OGTT to rule

**Description of interventions:**  
BOTH GROUPS: Both intervention groups received the same diet-exercise curriculum for 45-minute segments in each session. The diet component aimed for modest calorie reduction (typically 500 kcal/day) and focussed on healthy diet choices that facilitated calorie reduction. Participants were given weekly handouts that conveyed course concepts. Participants kept food records during the second week of the intervention to assess caloric intake and help identify foods they wished to eliminate, reduce, or substitute with healthier foods. All participants were given a calorie counting book, Calorie King (Family Health Publications: Costa Mesa, CA). The exercise component focused on moderate exercise by increasing daily activity and moderate intensity exercise. Participants were given pedometers to establish average daily steps and set attainable goals for increasing daily steps. The cognitive-behavioural therapy components were grounded in control theory. Participants were also asked to weigh themselves weekly and had three individual consultations with instructors to assess progress and provide feedback.

a: Active Control group: To approximate the time and social support received learning mindfulness skills in the treatment group, additional diet-exercise

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**Length of follow-up (months):** 18

**Quantitative outcomes reported:**  
Weight; BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose
out diabetes (glucose <200 mg/dL), use of systemic (oral or IV) corticosteroids in the 6 months prior to enrolment or severe autoimmune disorders or other conditions (e.g. rheumatoid arthritis, lupus), that are likely to require these medications, use of immunosuppressive or immunomodulating drugs or chronic or acute conditions that would require the use of such medications, a history of known coronary artery disease (CAD), or typical or atypical anginal chest pain requires a letter from the participant's physician that he or she has been adequately evaluated, non-English speaker, pregnant or planning to get pregnant in the next 12 months, breastfeeding or less than 6 months post-partum, initiation of new class of psychiatric medications in past 2 months, currently on a specific weight loss diet, for influenza vaccine administration: a prior allergic reaction to the influenza vaccine or eggs - these participants could be included in the trial but were excluded from participation in influenza vaccination, active bulimia or strong history of bulimia, current use of weight loss medications or supplements such as amphetamine-based drugs that are believed to have some effect on weight, history of or planned weight loss surgery, untreated hypothyroidism, use of beta blockers or alpha blockers, previous mindfulness training or participation in a program in which mindful eating was a significant focus, inability to have MRI scan, weight loss of 15 lbs or more in past 3 months

**Recruitment:** Fliers, newspaper advertisements, online postings, and referrals at UCSF clinics

**Baseline age (years):** Total: NR; a: 47.80 (12.4); b: 47.20 (13.0)

**Baseline BMI (kg/m²):** Total: NR; a: 35.60 (3.8); b: 35.40 (3.5)

**Baseline weight:** Total: NR; a: 96.70 (14.8); b: 97.70 (14.1)

content thought to be of interest to participants but not necessarily effective in promoting long term health behaviour change was introduced. Cognitive-behavioral methods for stress management were taught drawing on a standard-of-care weight loss program (Brownell, 2004) and progressive muscle relaxation was introduced. To control for food intake during the mindful eating exercises in the treatment group, participants in the control group took turns bringing healthy snacks to eat during breaks. Finally, to control for time spent meditating outside of class in the treatment group, participants were given weekly home assignments to re-enforce key concepts, exercise bands to practice strength training exercises, and a progressive muscle relaxation CD to practice at home.

b: **Mindfulness Intervention:** Mindfulness training for stress management, eating, and exercise. For stress management, participants learned formal mindfulness meditation practices including sitting meditation and yoga postures drawn from the Mindfulness-Based Stress Reduction program (Kabat-Zinn, 1990). Mindful eating components were drawn from Mindfulness-Based Eating Awareness Training. These include guided meditations, with and without food, followed by discussion to teach mindful eating practices of paying attention to physical sensations of hunger, stomach fullness, taste satisfaction, and food cravings; use of mini-meditations before meals, and for identification of emotional and other eating triggers; and self-acceptance and loving kindness practices. Mindful walking was taught using principles from Chi Walking which emphasizes posture and alignment and awareness of internal and external sensations while walking. Home practice guidelines included meditation practice for up to 30min/day 6 days a week, eating meals mindfully, and use of mini-meditations.

**Duration of active intervention**
a: 5.5 months; b: 5.5 months

**Number allocated:** 194

**Completed:** Total: 148; a: 65; b: 81

**% Dropout:** Total: 23.71%; a: 30.85%; b: 19.00%
**Country:** USA  
**Location:** Outpatient psychiatric rehabilitation setting  
**Period of study:** January 2009 and February 2011  
**Inclusion criteria:**  
Aged 18 years or over; BMI 25 kg/m² or greater; able and willing to give informed consent and participate in the intervention; on the same psychiatric medications within 30 days before baseline (dose changes allowed); able to attend at least 2 intervention sessions/week during the initial 6 month phase  
**Exclusion criteria:**  
From the trial protocol: Contraindication to weight loss (receiving active cancer treatment, liver failure, history of anorexia nervosa); Cardiovascular event within the past 6 months; prior/planned bariatric surgery; use of prescription weight loss medication or over-the-counter orlistat within 3 months; 20lb or greater weight loss in 3 months prior to baseline; inability to walk/participate in exercise class; pregnant/planning pregnancy during the study period (nursing mothers need approval from physician); alcohol or substance use disorder; planning to leave rehabilitation centre within 6 months or move out of geographic area within 18 months; investigator judgement (e.g. concerns for safety, adherence or follow-up); weight greater than 400lbs (so as not to exceed capacity of study scale)  
**Recruitment:** Study staff recruited participants by means of presentations at study sites and received referrals from rehabilitation programme staff.  
**Baseline age (years):** Total: 45.30 (11.3); a: 44.10 (11.0); b: 46.60 (11.5)  
**Baseline BMI (kg/m²):** Total: 36.30 (7.3); a: 36.50 (7.3); b: 36.00 (7.2)  
**Baseline weight:** Total: 102.70 (21.1); a: 104.00 (20.7); b: 101.30 (21.5)  
**Description of interventions:**  
a: Participants in the control group received standard nutrition and physical-activity information at baseline. Health classes were offered quarterly, with content unrelated to weight (e.g. cancer screening). Control participants also met the interventionist at 18 months (active intervention phase completed) to receive individual weight loss counselling.  
b: Dietary goals were based on DASH recommendations: reducing caloric intake by avoiding sugar-sweetened beverages and junk food (e.g. candy and high-fat snacks), eating five total servings of fruits and vegetables daily, choosing smaller portions and healthy snacks, and participating in moderate-intensity aerobic exercise. Group exercise started at a level appropriate for sedentary persons, with gradual increases in duration and intensity.  
**Duration of active intervention:** a: 18 months; b: 18 months  
**Number allocated:** 291  
**Completed:** Total: 279; a: 142; b: 137  
**% Dropout:** Total: 4.12%; a: 3.40%; b: 4.86%  
**Length of follow-up (months):** 18  
**Quantitative outcomes reported:**  
Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose
Country: USA
Location: 18 clinical research centres
Period of study: Prior to January 20 1999
Inclusion criteria:
Age >18 years, BMI 30-43 kg/m², adequate contraception in women of childbearing potential and absence of weight loss (>4 kg) in the previous 3 months
Exclusion criteria:
Unstable smoking habits, or had stopped smoking within the past 6 months, history or presence of substance abuse, excessive intake of alcohol, significant cardiac, renal, hepatic, gastrointestinal, psychiatric or endocrine disorders, drug-treated type 2 diabetes mellitus, or the concomitant use of medications that alter appetite or lipid levels
Recruitment: via the clinical research centres
Baseline age (years): Total: NR; a:44.00(10.45); b:43.30(15.38)
Baseline BMI (kg/m²): Total: NR; a:36.50(2.39); b:36.20(2.56)
Baseline weight: Total: NR; a:100.60(14.4); b:100.70(15.4)

Description of interventions:
BOTH GROUPS: A controlled-energy diet provided 30% of energy intake as fat during a 4 week, single-blind, placebo lead-in period. Participants who had a treatment compliance of 75% or more, assessed by counting placebo capsules taken during lead-in, were randomized for the 2 full years of study on day 1 to receive placebo (25% of participants) or orlistat 120 mg capsules (75% of participants) for 52 weeks. The study drug was administered with the participants’ 3 main meals and the controlled energy diet was continued. Weight change during the 4 week lead-in period was used as a measure of weight loss potential and participants were stratified accordingly at randomization to ensure an even distribution between treatment groups of individuals who lost less than 2 kg, or 2 kg or more during the run-in period. Energy intake was prescribed for each participant on the basis of estimated daily maintenance energy requirement (1.3 x calculated basal metabolic rate) minus 500-800 kcal/day. If a participant was still losing weight during the last 3 months of year 1, an increased energy intake of 200-300 kcal/day was prescribed.

a: Placebo + diet: During year 1, there were 4 behaviour modification sessions on weight-loss strategies followed during year 2 by 4 seminars on weight-maintenance strategies. Participants who had 70% or higher compliance remained taking placebo for another 52 weeks. Participants began a weight-maintenance diet during year 2. Throughout, dietitians at each site periodically provided instruction on dietary intake recording procedures as part of a behaviour modification program and then later used the participants’ food diaries for counselling.

b: Orlistat: During year 1, participants received orlistat 120 mg three times daily, with main meals and reducing diet as per placebo group. Participants who completed year 1 with a compliance of more than 70% moved to the next phase of their initial randomization to 1 of 3 groups: placebo, orlistat 120 mg, or orlistat 60 mg, for an additional 52 weeks. Maintenance diet and behaviour modification programme as per the placebo group.

Duration of active intervention: a:56 weeks; b:56 weeks
Number allocated: 892
Completed: Total:591; a:133; b:458
% Dropout: Total:33.74%; a:40.62%; b:31.44%
**Davis 2009**

**Country:** USA  
**Location:** Clinical Research Centre of Albert Einstein College of Medicine, New York  
**Period of study:** Recruitment August 2004 to November 2006  
**Inclusion criteria:**  
Adults aged > 18 years with a diagnosis of type 2 diabetes for at least 6 months, BMI of 25 kg/m² or greater, and HbA1c between 6 and 11%  
**Exclusion criteria:**  
Weight change of >10 lbs within 3 months of screening, kidney disease (defined as creatinine >1.3 mg/dL), active liver or gallbladder disease, significant heart disease, a history of severe (requiring hospitalisation) hypoglycemia, or use of weight loss medications  
**Recruitment:** Participants were recruited from the offices of primary care physicians, endocrinologists, and the local community in Bronx, New York, through physician referral, letters of invitation, and posted advertisements.  
**Baseline age (years):** Total: NR; a:53.00(7); b:54.00(6)  
**Baseline BMI (kg/m²):** Total: NR; a:37.00(6); b:35.00(6)  
**Baseline weight:** Total: NR; a:101.00(19); b:93.60(18)  

**Description of interventions:**  
BOTH GROUPS: At randomization, all participants in both groups received 45min of individual dietary instruction/counselling by a registered dietitian and were given a specific gram allowance of carbohydrates or fat to achieve a 1-pound weight loss each week. Structured menus that provided meal choices and recipes were used for the first 2 weeks. After the first 2 weeks, participants were instructed on selecting foods that met their dietary goals without using the menus.  

- a: The low-fat diet was modelled after that in the Diabetes Prevention Program. Participants received a fat gram goal, which was 25% of energy needs, based on baseline weight.  
- b: As per the low-fat diet group, except the low-carbohydrate diet was modelled after the Atkins diet and was initiated with a 2 week phase of carbohydrate restriction of 20-25 g daily depending on baseline weight. As participants lost weight, they were able to increase carbohydrate intake at 5 g increments each week.  

**Duration of active intervention:** a:12 months; b:12 months  
**Number allocated:** 105  
**Completed:** Total:91; a:44; b:47  
**% Dropout:** Total:13.33%; a:12.00%; b:14.55%  

**Length of follow-up (months):** 12  
**Quantitative outcomes reported:**  
Weight; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %

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**Delbridge 2009**

**Country:** Australia  
**Location:** Community  
**Period of study:** Up to 2008  
**Inclusion criteria:**  
18-75 years; BMI ≥30 kg/m² (or ≥27 kg/m² with comorbidities)  
**Exclusion criteria:**  
Severe disease, endocrine disease, psychiatric illness, alcohol or drug abuse;lactating women, pregnant, or planning pregnancy  
**Recruitment:** Participants were recruited by newspaper advertisement and word of mouth.  
**Baseline age (years):** Total: NR; a:44.00(9.20); b:43.70(11.80)  

**Description of interventions:**  
BOTH GROUPS: Followed a VLED meal replacement (Optifast; Nestle Nutrition) 3 times/day for 3 months. Two cups of low starch vegetables with 5 ml of oil and a minimum of 2L water or low-energy drinks were allowed to provide 500-550 kcal/day. Participants attended clinics fortnightly and had to achieve at least 10% weight loss to progress to the weight-maintenance phase. Participants were then randomised to the high-carbohydrate (HC) or high-protein (HP) diets and followed an individualised energy intake for with weight maintenance.  

- a: HC: Participants consumed 15% of their energy intake as protein and reduced their fat intake to <30% of their intake, especially reducing saturated fat. Low glycemic index (GI) carbohydrates were recommended. Behavioural issues were addressed during monthly counselling sessions. Aerobic exercise 3 or more times/week was encouraged.  
- b: HP: Participants received individualised protein and fat recommendations according to their energy intake. Saturated fat was reduced. A standardized breakfast was offered to ensure energy intake was met. Participants attended fortnightly clinics in the later phase of the study.  

**Length of follow-up (months):** 12  
**Quantitative outcomes reported:**  
Weight; BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP
| Dennison 1996<sup>30</sup> | **Country:** USA  
**Location:** Large automobile manufacturing firm  
**Period of study:** NR  
**Inclusion criteria:** NR  
**Exclusion criteria:** NR  
**Recruitment:** NR  
**Baseline age (years):** Total: 47.00(NR); a:NR; b:NR  
**Baseline BMI (kg/m²):** Total: NR; a:NR; b:NR  
**Baseline weight:** Total: NR; a:108.32(NR); b:92.35(NR) | **Description of interventions:**  
**a:** Non-computer assisted intervention (non-CAI): 8 week long "Weigh To Go" programme consisting of nutrition information.  
**b:** Computer assisted intervention (CAI): Other than hands-on experience with the computer, the activities were the same for the non-CAI and CAI groups. The CAI participants interacted directly with a microcomputer to perform computerised food intake and activity analyses. Training took place in the computer laboratory of the company's worksite training centre. | **Length of follow-up (months):** 12  
**Quantitative outcomes reported:** Weight |
| --- | --- | --- | --- |
| **Baseline BMI (kg/m²):** Total :NR; a:38.60(6.69); b:39.30(6.74)  
**Baseline weight:** Total: NR; a:109.40(21.75); b:114.00(25.28) | **b:** High protein: Same as the high-carbohydrate group except participants were instructed to consume 30% of their energy intake as protein.  
**Duration of active intervention**  
**a:** 12 months (plus 3 months lead-in) 15 months;  
**b:** 12 months (plus 3 months weight loss lead in) 15 months;  
**Number allocated:** 141  
**Completed:** Total:82; a:40; b:42;  
**% Dropout:** Total: 41.84%; a: 42.86%; b: 40.85%; | **Number allocated:** 93  
**Completed:** Total:22; a:11; b:1  
**% Dropout:** Total: 76.34%; a:NR; b:NR |
Country: USA
Location: Two Harvard Medical School-affiliated academic institutions
Period of study: January 2010 to November 2013
Inclusion criteria:
Aged 21-65 years, type 2 diabetes for at least one year, BMI 30-45 kg/m², a strong desire for substantial weight loss and commitment to lifelong medically follow-up, free from active cardiovascular disease or eye diseases prohibiting safe exercise or undergoing a bariatric surgery, HbA1c above 7% or 6.5% on two oral antihyperglycemic medications or insulin, and stable treatment for >8 weeks, non-smoker for >2 months
Exclusion criteria:
Detectable glutamic acid decarboxylase antibody, history of diabetic ketoacidosis, HbA1c >12%, gastrointestinal diseases, malignancy within 5 years, significant cardiopulmonary or renal diseases, active eating disorders, drug and/or alcohol abuse, impaired mental status, weight loss >3% within the previous 3 months, participating in an alternate weight-reduction programme, or use of weight-reduction medications
Recruitment: Participants were recruited from health centres or by advertisements
Baseline age (years): Total: NR; a:51.4 (7.5); b: 50.6 (12.6)
Baseline BMI (kg/m²): Total: NR; a:36.7 (4.2); b:36.4 (3.0)
Baseline weight: Total: NR; a:111.6 (17.9); b: 106.8 (10.4)

Description of interventions:
a: Weight Achievement and Intensive Treatment (Why WAIT) programme designed for clinical diabetes practices and run quarterly in groups of 10-15 participants. Participants receive weekly medication adjustments, up to 300 min/week graded exercise, cognitive behavioural intervention and group education. Participants followed a hypocaloric (1500-1800 kcal/day) diet with CHO (40-45%), protein (1-1.5 g/kg or ~30%) and reduced saturated fat below 7%. During the initial 6 weeks, breakfast and lunch were replaced by Boost Glucose Control nutritional drinks (calories 190; protein 16 g; CHO 16 g; fibre 3 g; fat 7 g; Nestle Nutrition Inc) and participants were instructed to eat two snacks of 100-200 kcal and select a dinner from 14 structured menus. A maintenance phase of individual monthly counselling was followed for the remainder of the year.
b: LAGB surgery. Participants were followed up 6 weeks after surgery and every 4-6 weeks thereafter. A slow diet progression (3 days of liquid/soft food) was recommended after band adjustments with counselling to eat healthy solid foods, focussing on protein. Participants were encouraged to perform physical activity as tolerated. Bariatric dietitians were available for appointments as needed but the no other formal support was provided.

Duration of active intervention a:12 months; b:12 months
Number allocated: 45
Completed: Total: NR; a:Unclear; b:Unclear
% Dropout: Total: NR; a:Unclear; b:Unclear

Length of follow-up (months): 12
Quantitative outcomes reported:
Weight, BMI kg/m², Waist circumference, Total cholesterol, LDL cholesterol, HDL cholesterol, Triglycerides, Systolic BP, Diastolic BP, HbA1c%, Fasting plasma glucose, Quality of life
Dixon 2008

Country: Australia
Location: The Alfred Hospital, The Avenue Hospital, and Monash University
Period of study: December 2002 to December 2006
Inclusion criteria:
Aged between 20 and 60 years, BMI of 30-40 kg/m², had been diagnosed with clearly documented type 2 diabetes within the previous 2 years, had no evidence of renal impairment or diabetic retinopathy, and able to understand and comply with the study process
Exclusion criteria:
History of type 1 diabetes, diabetes secondary to a specific disease, or previous bariatric surgery; a history of medical problems such as mental impairment, drug or alcohol addiction, recent major vascular event, internal malignancy, or portal hypertension; or a contraindication for either study group. Participants were excluded if they did not attend 2 initial information visits.
Recruitment: Recruited via newspaper advertisement
Baseline age (years): Total: NR; a: 46.60(7.4); b: 47.10(8.7)
Baseline BMI (kg/m²): Total: NR; a: 37.00(2.7); b: 37.20(2.5)
Baseline weight: Total: NR; a: 105.60(13.8); b: 105.90(14.2)
Description of interventions:
a: LAGB: Progress was reviewed by the bariatric surgical team every 4 to 6 weeks throughout the study, and adjustments to band volume were made using standard clinical criteria.
b: Best available medical practice for the treatment, education, and follow-up of patients with type 2 diabetes. Patients had open access to a general physician, dietitian, nurse, and diabetes educator and had visits with at least 1 team member every 6 weeks throughout the 2 years. Lifestyle modification programs were individually structured to reduce energy intake, to reduce intake of fat (<30%) and saturated fats, and to encourage intake of low glycaemic index and high-fibre foods. Physical activity advice encouraged 10,000 steps/day and 200 minutes/week of structured activity, including moderate intensity aerobic activity and resistance exercise. VLCDs and medications were discussed with all patients and used after consultation with the dietitian or general physician if the patient expressed a desire to use additional measures.
Duration of active intervention: a: 2 years; b: 2 years
Number allocated: 60
Completed: Total: 55; a: 29; b: 26
% Dropout: Total: 8.33%; a: 3.33%; b: 13.33%
Length of follow-up (months): 24
Quantitative outcomes reported:
Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life

Dixon 2012

Country: Australia
Location: Melbourne
Period of study: Sept 2006 to March 2009
Inclusion criteria:
Age 18 to 60 years, BMI 35-55 kg/m², apnoea-hypopnea index (AHI) of 20 events/hr or more diagnosed within the previous 6 months with recommendation to commence continuous positive airway pressure therapy, and at least 3 prior significant weight loss attempts
Exclusion criteria:
Previous bariatric surgery, obesity hypoventilation syndrome requiring bi-level positive airway pressure, and contraindications to bariatric surgery including cognitive impairment, drug or alcohol addiction, and significant
Description of interventions:
Both groups: Patients in both programmes had open access to a bariatric physician, sleep physician, and dietitian, and had their progress reviewed every 4 to 6 weeks throughout the 2 years. The management of severe obstructive sleep apnoea (OSA), the intensity, and nature of the lifestyle program were common to both groups.
a: LAGB: Participants underwent 2 weeks of VLED to reduce liver size prior to placement of an LAGB within 1 month of randomisation. Adjustments to band volume were made using standard clinical criteria.
b: Best available medical practice. Dietary, physical activity, and behavioural programs were individualized. The advice regarding physical activity encouraged walking and 200min/week of structured activity, including
Length of follow-up (months): 24
Quantitative outcomes reported:
Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life
<p>| Country: USA | Description of interventions: | Length of follow-up (months): 18 |
| Location: Community | BOTH GROUPS: Individualised dietary and exercise counselling combined with Weight Watchers for 18 months, but were randomised to receive spirituality counselling or not at the 6-month time point. | Quantitative outcomes reported: |
| Period of study: Before 2009 | a: Dietitian-led counselling: Face-to-face sessions held 6 monthly with interim telephone call contacts. The goal was to attain a weight loss of 10% of initial weight. The recommendation was for a deficit of 500-1000 kcal/day below the calculated maintenance intake for a given body weight (using an estimate of 11 kcal per pound needed for maintenance). Participants were asked to decrease fat to 20% to 25% of calories, to keep protein at about 20% of calories, to use whole grains for at least half of their daily grain intake, and include at least 6 to 8 servings of fruits and vegetables each day. Participants were also asked to exercise at least 30 minutes most days each week (at least 5). Participants were given pedometers for self-monitoring and were instructed that 10,000 steps each day is a desirable goal. | Weight change (%); Quality of life |
| Inclusion criteria: Females, age 18-70 years, diagnosed with stage I, II, or IIIA breast cancer within the last 10 years and who identified themselves as African American; BMI 30-45, completed chemotherapy or radiation therapy at least 3 months previous (with the exception of tamoxifen); willing and able to follow diet and exercise recommendations, not presently on a special diet for a medical condition (e.g. type 1 diabetes) or currently participating in a formal weight reduction programme; and having spiritual influences in their lives as determined from a spirituality index screening questionnaire (a low score on 3 or more items from a total of 6 items on the spirituality index screening questionnaire would lead to exclusion) | b: Participants received the same intervention as the dietitian-only group but, additionally, received counselling from a spiritual counsellor. Contacts with the spiritual counsellor were exclusively by telephone. The spiritual counsellor also discussed the progress of each participant with the dietitian, so that the counselling was coordinated. Participants were taught to use daily meditation, daily readings, and the recording of thoughts in a journal. The spiritual counsellor offered guidance to study participants on developing meditations that helped them observe their own actions and build better behaviours. For some participants, scripture or prayer was preferred. |
| Exclusion criteria: Women with a recurrence, a second primary tumour, or other history of malignant tumours were not eligible | |
| Recruitment: Direct solicitation of clinic patients by their providers, presentations and mailings to an African American breast cancer support group, community advertising through a local newspaper, and brochures placed in the Karmanos Cancer Institute breast care clinic. | |</p>
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<th>Description of interventions:</th>
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<td>a: Large group: During months 0-6, participants attended 24 weekly 90-minute sessions in groups of 31 participants. Each session included presentation, discussion and practice of skills related to nutrition, exercise and other self-management strategies. Participants also received training in self-monitoring, problem-solving, stimulus control, cognitive restructuring and relapse prevention. Participants were encouraged to work towards a 10% reduction in body weight during the initial six-month period and instructed to reduce caloric intake to 1200 kcal/day (for participants weighing less than 250 pounds) or 1500 kcal/day (for participants weighing over 250 pounds). Participants were also encouraged to increase levels of moderate-intensity physical activity to 180 min/week. Participants attended six monthly extended care sessions between months 6-12, which focused on maintenance of healthy lifestyle behaviours. Participants were instructed to self-monitor food intake.</td>
<td>b: Small group: Same as the large group but with 12 participants.</td>
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Country: United States  
Location: Home-based intervention, were participants received information and counselling from primary care practices in Rhode Island and south eastern Massachusetts  
Period of study: Prior to November 20, 2015  
Inclusion criteria: 
Men and women at least 18 years of age and less than 80 years old whose BMI was ≥25 kg/m²; available for the entire 24-month study period; able to read and speak English; able to provide informed consent; able to accept phone calls; able to attend study visits; and have access to a DVD player  
Exclusion criteria: 
Diagnosed or hospitalization for active CVD disease in the past 6 months; history of a significant orthopaedic limitations or other conditions that make exercise dangerous or extremely difficult; limited physical ability to be active (e.g., unable to walk briskly); another family member in the study; unstable psychiatric co-morbidity; participant requesting surgical treatment of obesity; weighing over 400 lb; participating in another clinical trial with regard to obesity or physical activity; having poorly controlled diabetes mellitus (hospitalized for poor diabetes control in the past 6 months); limited prescribed diet (e.g. gluten free diet); present treatment for an eating disorder; taking over the counter diet aids or medications for weight loss for the previous 6 months; underwent treatment for cancer in the past 5 years; end stage renal disease requiring dialysis; chronic steroid therapy; major surgery in the past month; planning a pregnancy in the next two years or delivered a baby within the past six months; exercising ≥90 min/typical week of moderate intensity activity; unwilling or unable to complete study requirements  
Recruitment: Primary care practices  
Baseline age (years): Total: NR; a:48.50(11.9); b:48.60(11.2)  
Baseline BMI (kg/m²): Total: NR; a:37.70(6.5); b:37.80(6.7)  
Description of interventions:  
BOTH GROUPS: 12 month weight loss and lifestyle programme under the guidance of registered dietitians trained as lifestyle counsellors, with a weight loss goal of 10% over six months, followed by a 12-month maintenance intervention. All participants followed a structured meal plan dependent on their starting weight to support a 500-1000 kcal/day reduced diet based on the DPP guidelines. Participants were encouraged to increase physical activity to 300min/week and to self-monitor food and physical activity. All participants also met with their lifestyle counsellor at 6 and 12 months to review progress and set new goals.  
a: Enhanced intervention: Participants in the EI group received phone calls from the lifestyle counsellor monthly for the first six months and bi-monthly for the next six. For the first 12 months, they also received weekly mailings that included print materials, feedback on food and exercise logs, and two exercise-related DVDs. Participants received four tailored nutrition reports and monthly tailored exercise feedback reports. In the second year, participants received tailored and non-tailored materials bi weekly for the first six months and monthly for the last six months. They also received four exercise feedback reports and two nutrition-related DVDs.  
b: Standard intervention: In addition to the three meetings with the lifestyle counsellors, participants received five pamphlets (3 in year 1 and 2 in year 2) on weight loss, physical activity and healthy eating.  
Duration of active intervention: a:NR; b:NR  
Number allocated: 211  
Completed: Total:148; a:73; b:75  
% Dropout: Total:29.86%; a:30.48%; b:29.25%  
Length of follow-up (months): 24  
Quantitative outcomes reported:  
Weight
| **Baseline weight**: Total: NR; a:104.80(21.6); b:102.10(18.7) | **Description of interventions**: BOTH GROUPS: 6-month intensive with 12-months follow-up. Participants received nutrition education and dietary counselling. Diets were prescribed ad libitum approach as they were intended to decrease hunger/increase satiationand therefore promote a negative energy balance. Participants did not count calories and were advised to only eat when hungry and stop before feeling too full. Physical activity recommendations were based on public health guidelines.  
  
  a: Low-glycaemic load diet: Participants followed a low-glycaemic foods diet with limited intake of high-glycaemic load foods: 40% of energy from carbohydrate, 35% from fat, and 25% from protein. Participants were given information about low-, moderate-, and high-glycaemic load foods. Dietitians also provided information during cooking demonstrations and advised on appropriate serving sizes of high-glycaemic load foods.  
  
  b: Low-fat diet: Participants followed a low-fat diet of grains, vegetables, fruits, and legumes with limited intake of fats and sweets to give 55% of energy from carbohydrate, 20% from fat, and 25% from protein. The intervention was not designed to maximise dietary glycaemic index and glycaemic load. Participants were given information about low-, moderate-, and high-fat foods. Dietitians provided information during cooking demonstrations and advised on appropriate serving sizes of high-fat foods and sweets.  
  
  **Duration of active intervention**: a:18 months; b:18 months  
  **Number allocated**: 73 |
| --- | --- |
| **Country**: USA  
**Location**: Community, Boston  
**Period of study**: September 2004 to December 2006  
**Inclusion criteria**: 18-35 years, BMI >30 kg/m², and medical clearance from a primary care provider  
**Exclusion criteria**: Weight > 140 kg, smoking, recent weight loss diet, medications affecting study outcomes, diabetes mellitus; major illness  
**Recruitment**: Fliers, newspaper and Internet advertisements, and radio broadcasts  
**Baseline age (years)**: Total: NR; a:28.20(3.8); b:26.90(4.2)  
**Baseline BMI (kg/m²)**: Total: NR; a:37.20(NR); b:36.60(NR)  
**Baseline weight**: Total: NR; a:103.50(17.3); b:103.30(15.1) | **Length of follow-up (months)**: 18  
**Quantitative outcomes reported**: Weight; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose |

Ebbeling 2007[37]
| Country: Italy | 100 |
| Location: Naples | Completed: Total:51; a:28; b:23 |
| Period of study: October 2000 - October 2003 | % Dropout: Total:30.14%; a:22.22%; b:37.84% |
| Inclusion criteria: Men with obesity who were sedentary (<1hr/week of physical activity), aged 35 to 55 years, score of 21 or less on International Index of Erectile Function questionnaire | |
| Exclusion criteria: Evidence of participation in diet reduction programs within the last 6 months, diabetes mellitus or impaired glucose tolerance, impaired renal function, including macroalbuminuria, pelvictrauma, prostatic disease, peripheral or autonomic neuropathy, hypertension (blood pressure 140/90mm Hg), cardiovascular disease, psychiatric problems, use of drugs or alcohol abuse (500 g of alcohol/week in the last year) | |
| Recruitment: Weight loss outpatient department | |
| Baseline age (years): Total: NR; a:43.00(5.1); b:43.50(4.8) | |
| Baseline BMI (kg/m²): Total: NR; a:36.40(2.3); b:36.90(2.5) | |
| Baseline weight: Total: NR; a:101.00(9.7); b:103.00(9.4) | |
| Description of interventions: a: Men in the control group were given general oral and written information about healthy food choices and exercise at baseline and at subsequent bimonthly visits, but no specific individualized programme was provided. b: Men in the intervention group were given detailed advice about how to achieve a reduction in total body weight of 10% or more. The programme consisted of reducing caloric intake, setting goals, and self-monitoring through a series of monthly small-group sessions. Behavioural and psychological counselling was also offered. The mean daily caloric intake was 1700 kcal for the first year and 1900 kcal for the second year. The recommended composition of the dietary regimen per 1000 kcal was carbohydrates, 50% to 60%; proteins, 15% to 20%; total fat, less than 30%; saturated fat, less than 10%; monounsaturated fat, 10% to 15%; polyunsaturated fat, 5% to 8%; and fibre, 18 g. Dietary advice was tailored to each man and they also received individual guidance on increasing their level of physical activity. The men had monthly sessions with the nutritionist and exercise trainer during the first year and bimonthly sessions during the second year. | |
| Duration of active intervention: a:2 years; b:2 years | |
| Number allocated: 110 | |
| Completed: Total:104; a:52; b:52 | |
| % Dropout: Total:5.45%; a:5.45%; b:5.45% | |

| Country: UK | |
| Location: Five centres | |
| Period of study: Prior to 1999 | |
| Inclusion criteria: Aged at least 18 years, BMI of between 30-43 kg/m² | |
| Exclusion criteria: Weight loss >4 kg in previous 3 months ; history of serious disease, including diabetes; uncontrolled hypertension; previous bariatric surgery ; prioropost-surgical adhesions; past or currentcancer; chronic drugsfor neurological/psychiatric illness or impacting patient compliance; alcohol or drug abuse; bulimia or laxative abuse; pregnancy or lactation (women of | |
| Description of interventions: BOTH GROUPS: Participants followed a low-energy diet during a placebo run-in period of 4 weeks. Individual energy intake was calculated from the participant’s estimated total daily energy expenditure minus 600 kcal/day to a minimum of 1200 kcal/day with 30% of energy from fat. Alcohol consumption was limited to 150 g/week. To compensate for the anticipated decrease in energy requirements following weight loss, daily energy intake was further reduced by approximately 300 kcal/day at the end of week 24. Participants completed 4-day food diaries fortnightly. A dietitian used the diaries to provide advice on food choice if necessary. a: Placebo orally three times daily with meals | |
| Length of follow-up (months): 12 | |
| Quantitative outcomes reported: Weight; Weight change (%); Total cholesterol; LDL cholesterol; HDL cholesterol | |

Finer 2000[39]
childbearing age had to sue contraceptives; post-menopausal <1y: drugs affecting weight, resins for cholesterol, anti-coagulants, digoxin or lipid-soluble vitamin supplements in past month

**Recruitment:** Local advertisement or by referral from general practitioners

**Baseline age (years):** Total: NR; a: 41.40(10.0); b: 41.50(10.5)

**Baseline BMI (kg/m²):** Total: NR; a: 36.80(3.7); b: 36.80(3.6)

**Baseline weight:** Total: NR; a: 98.40(15.0); b: 97.90(12.9)

**Description of interventions:**

a: Women in the control group received newsletters that covered general health and safety topics on a weekly basis throughout the 6-month period and monthly throughout the 12-month maintenance period. A staff member telephoned control participants once a month throughout the entire study period to allow participants to ask questions or express concerns about the information contained in the weekly newsletters. The staff member was not an interventionist and was not trained in MI. The control group received the entire written curriculum at the end of the trial.

b: The 6-month weight-loss intervention was conducted in a small group format by trained interventionists. Some of the interventionists were black and others were non-Hispanic white or Asian. The class met twice weekly on the university campus. The weight-loss goal for the first 6 months was 7% of initial body weight, which would then be maintained throughout the 12-month maintenance intervention. The recommended rate for weight loss was approximately 1-2 lb/week. All participants were taught behavioural strategies such as self-monitoring, and stimulus and portion control to help with both weight loss and weight-loss maintenance. All participants were encouraged to adopt a low-fat, high-fibre diet with increased fruit and vegetable consumption and caloric intake. Pedometers were given to encourage women to walk 10,000 steps or more a day. The intervention was tailored to the individual primarily by feedback on their self-monitoring logs. The 12-month weight-loss maintenance intervention emphasised structuring one's life in a way that supported maintenance of weight-loss behaviours. However, for many of the women who had lost minimal weight during the 6-month weight-loss intervention, weight loss continued to be a goal. Participants received monthly MI sessions throughout the 6-month weight-loss and 12-month weight-maintenance.

**Fitzgibbon 2010**

**Country:** USA

**Location:** University of Illinois, Chicago (UIC)

**Period of study:** Recruitment August 2005 to September 2006

**Inclusion criteria:**
BMI between 30–50 kg/m², female, self-identified as African American or black, aged 30–65 years, able to participate in an activity program requiring 30 min of uninterrupted moderate activity, able to attend class sessions

**Exclusion criteria:**
Unable to exercise because of emphysema, chronic bronchitis, or asthma; if they used a cane, walker, or wheelchair for mobility; planning to move out of the area; if they had been treated for cancer (excluding skin cancer other than melanoma) in the past 5 years; participating in a formal weight-loss program or taking weight-loss medications prescribed by a doctor; pregnant, nursing, or planning a pregnancy; or if using illegal drugs or consuming >2 alcoholic drinks/day on a daily basis

**Recruitment:** Mass email to UIC staff and students and face-to-face from nearby neighbourhoods, grocery stores, churches, health centres and primary care clinics

**Baseline age (years):** Total: 46.00(8.4); a: 45.50(8.4); b: 46.40(8.4)

**Baseline BMI (kg/m²):** Total: 39.20(5.7); a: 39.80(5.8); b: 38.70(5.5)

**Length of follow-up (months):** 18

**Quantitative outcomes reported:** Weight; BMI kg/m²;
**Baseline weight:** Total: 104.90 (16.6); a: 105.90 (17.4); b: 103.90 (15.7)

intervention. Throughout the 12-month maintenance period, participants received newsletters every other month, reinforcing concepts related to health behaviour change.

**Duration of active intervention:** a: 18 months; b: 18 months: 6 months weight-loss, 1 year weight-maintenance

**Number allocated:** 213

**Completed:** Total: 190; a: 97; b: 93%

**Dropout:** Total: 10.80%; a: 8.49%; b: 13.08%

**Flechtner-Mors 2010**

| Country: Germany | **Description of interventions:** BOTH GROUPS: At the randomization visit (week 0), participants received specific diet instructions. Diets were designed to deliver a total calorie intake of 500 calories less than the resting metabolic rate. Participants were then randomly assigned to one of two intervention groups. In both groups, energy derived from fat targeted 30%. All participants were advised and educated in person weekly in the first month and then monthly in groups and individually by independent dietitians. They also received instructions to maintain their usual physical activity during the study and not to undertake any new exercise programmes, but exercise was not monitored during the study.

a: Those in the conventional diet group received 0.8 g protein/kg body weight. Participants consumed three meals and two snacks with no replacements for the first 3 months. After 3 months, participants consumed one standard meal replacement, two meals, and two snacks/day, meeting the conventional protein goal. The macronutrient profile was 15% protein, 30% fat and 40% carbohydrate.

b: Participants in the high-protein diet group received a diet providing 1.34 g protein/kg body weight. In the first 3 months, participants consumed two protein-enriched meal replacements, one conventional meal, and two snacks as either a protein bar or a low-fat curd with fruit. After 3 months, participants consumed one protein-enriched meal replacement, two meals and two snacks, meeting an increased protein goal. The macronutrient profile was 15% protein, 30% fat and 40% carbohydrate. |
| Location: University Obesity Centre, Department of Medicine, University of Ulm | **Country:** Germany | **Location:** University Obesity Centre, Department of Medicine, University of Ulm | **Period of study:** Prior to June 2010 | **Inclusion criteria:** 25-70 years of age, good health, BMI 27-45 kg/m², and met the American Heart Association/National Heart, Lung, and Blood Institute criteria for the metabolic syndrome (three or more of the following: (1) waist circumference of l02cm or more in males or 88cm or more in females; (2) triglycerides 1.7 mmol/L (150 mg/dL) or greater; (3) high-density lipoprotein (HDL)-cholesterol <1.03 mmol/L (40 mg/dL) in males or <1.3 mmol/L (50 mg/dL) in females; (4) blood pressure 130/85 mmHg or more and (5) fasting glucose 5.55 mmol/L (100 mg/dL) or more); women not of childbearing potential, or using an acceptable birth control method and not pregnant or lactating |
| **Exclusion criteria:** Bariatric surgery, any disease with unknown outcome, smoking, alcohol or drug abuse, psychiatric disease, being on anti-obesity medications, and fluctuation of body weight of >2% in the 3 months prior to entering into the study; *From protocol* Intake of study drug medication during the previous 8 weeks and intolerance of meal replacements | **Quantitative outcomes reported:** Weight; Weight change (%); Waist circumference; Total cholesterol; HDL cholesterol; Triglycerides; HbA1c %; Fasting plasma glucose | **Length of follow-up (months):** 12 |
| Recruitment | Duration of active intervention: a:12 months; b:12 months | Fostert 2010
Country: USA | Number allocated: 110 |
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<td>Baseline age (years): Total: NR; a:50.20(13.0); b:49.30(12.3)</td>
<td>Completed: Total:80; a:49; b:31</td>
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<tr>
<td>Baseline BMI (kg/m²): Total: NR; a:36.30(5.0); b:36.20(4.4)</td>
<td>% Dropout: Total:27.27%; a:10.91%; b:43.64%</td>
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<tr>
<td>Baseline weight: Total: NR; a:100.50(16.6); b:100.20(16.5)</td>
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<tr>
<td>Duration of active intervention: a:2 years; b:2 years</td>
<td>Length of follow-up (months): 24</td>
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<td>Number allocated: 307</td>
<td>Quantitative outcomes reported: Weight; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP</td>
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<td>Completed: Total:194; a:105; b:89</td>
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<td>% Dropout: Total:36.81%; a:31.82%; b:41.83%</td>
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**Country:** USA

**Location:** University of Colorado Denver, Denver, Colorado; Washington University, St. Louis, Missouri; and the University of Pennsylvania, Philadelphia, Pennsylvania.

**Period of study:** March 2003 to June 2007

**Inclusion criteria:**
- Age 18 to 65 years,
- BMI 30 to 40 kg/m²
- Body weight less than 136 kg

**Exclusion criteria:**
- Serious medical illnesses, such as type 2 diabetes; lipid-lowering medications; pregnant or lactating; or medications that affect body weight, including anti-obesity agents; blood pressures of 140/90 mm Hg or more

**Recruitment:**
- Newspaper advertisements, flyers in the university or hospital setting, physician referral, and self-referral

**Baseline age (years):** Total: 45.50(9.7); a:44.90(10.2); b:46.20(9.2)

**Baseline BMI (kg/m²):** Total: 36.10(3.5); a:36.10(3.46); b:36.10(3.59)

**Baseline weight: Total: NR; a:103.50(14.4); b:103.30(15.5)**

**Description of interventions:**
- BOTH GROUPS: All participants received comprehensive, in-person group behavioural treatment weekly for 20 weeks, every other week for 20 weeks, and then every other month for the remainder of the 2-year study period. Topics included self-monitoring, stimulus control, and relapse management. All participants were prescribed the same level of physical activity (principally walking), beginning at week 4, with 4 sessions of 20 minutes each and progressing by week 19 to 4 sessions of 50 minutes each. Group sessions reviewed participants’ completion of their eating and activity records, as well as other skill builders. Participants in both groups were instructed to take a daily multivitamin supplement (provided by the study).

- a: Low-CHO diet but unrestricted consumption of fat and protein allowed. CHO intake limited to 20 g/day in the form of low–glycemic index vegetables for first 12 weeks, then gradually increased by 5 g/week, until a stable and desired weight was achieved. Dr. Atkins’ New Diet Revolution guidelines followed but participants were not provided with a copy of the book.

- b: Low-fat diet, limiting energy intake to 1200 to 1500 kcal/day for women and 1500 to 1800 kcal/day for men, with approximately 55% of calories from carbohydrate, 30% from fat, and 15% from protein. Participants were instructed to limit calorie intake, with a focus on decreasing fat intake. However, limiting overall energy intake was the primary behavioural target.

**Duration of active intervention:**
- a: 2 years; b: 2 years

**Number allocated:**
- Total: 194; a: 105; b: 89

**% Dropout:**
- Total: 36.81%; a: 31.82%; b: 41.83%
**Goodpaster 2010**

**Country:** USA  
**Location:** Pittsburgh, PA  
**Period of study:** February 2007 - March 2009  
**Inclusion criteria:**  
Age 30-55 years, severe obesity, defined as BMI 35-39.9 kg/m² for class II obesity and 40 kg/m² or greater for class III obesity; able to walk without assistance, commit to the schedule of intervention and assessment visits, and obtain medical clearance for intervention  
**Exclusion criteria:**  
History of cancer within the past 5 years, had a history of or were receiving current treatment for coronary artery disease, had enrolled within the past year in a formal weight reduction program, reported losing more than 5% of current body weight in the previous 6 months, had a history of bariatric surgery, or had uncontrolled hypertension, diabetes, or pregnancy during the previous 6 months  
**Recruitment:** Participants were recruited via television and newspaper advertisements and mass mailings.

**Baseline age (years):** Total: 47.80 (6.4); a: 46.10 (6.5); b: 47.50 (6.2)  
**Baseline BMI (kg/m²):** Total: NR; a: 43.51 (5.43); b: 43.67 (5.45)  
**Baseline weight:** Total: NR; a: 120.58 (17.69); b: 117.37 (17.68);  

**Description of interventions:**  
a: Diet and physical activity and behavioural lifestyle intervention delivered with a combination of group, individual, and telephone contacts. All participants were prescribed a diet that we have shown to result in a sustained 8% to 10% weight loss in 12 months. Energy intake was reduced to 1200 to 2100 kcal/day based on initial body weight. Targeted macronutrient composition was 20% to 30% fat, 50% to 55% carbohydrate, and 20% to 25% protein. To facilitate dietary compliance and improve weight loss, 14 liquid and pre-packaged meal replacements were. Adherence to the dietary intervention was monitored by having participants record the time of meals as well as the type and caloric value of food consumed. Moderate intensity physical activity, similar in intensity to brisk walking, was prescribed and progressed to 60 minutes, 5 days/week and were provided with a pedometer and step goals of more than 10,000 steps/day.  
b: Same dietary intervention with physical activity delayed for 6 months.  
**Duration of active intervention:** a: 12 months; b: 12 months  
**Number allocated:** 130  
**Completed:** Total: 101; a: 49; b: 52  
**% Dropout:** Total: 22.31%; a: 26.87%; b: 17.46%  

**Gorin 2013**

**Country:** USA  
**Location:** Local community in the Providence, Rhode Island area  
**Period of study:** Prior to February 6, 2012  
**Inclusion criteria:** Aged between 21 and 70 years old, BMI 25-50 kg/m², and have a household member willing to participate in the study as a support partner. These partners had to reside in the same home as the participant, be between 15 and 70 years old, have a BMI between 25 and 50, and be interested in weight loss. With the exception of the lower age limit, the same inclusion and exclusion criteria applied to both participants and partners.  
**Description of interventions:**  
a: Behavioural weight loss (BWL): To achieve the 10% weight-loss goal, all participants were placed on a standard caloric and fat-restricted diet (e.g., 1200-1800 kcal/day and 30% fat, depending on initial weight), and given sample meal plans and a calorie guidebook. Participants were instructed to gradually increase their physical activity until they achieved 200 min/week or more of moderate-intensity, physical activity. Participants received instruction in core behavioural skills, including self-monitoring, stimulus control, problem solving, goal setting, cognitive restructuring and relapse prevention. The focus of treatment shifted to weight-loss maintenance in the latter months of the program.  
b: BWL + Home: Same as the BWL group but in addition the BWL + H  
**Length of follow-up (months):** 12  
**Quantitative outcomes reported:**  
Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose; Quality of life
Exclusion criteria: Individuals were excluded from participation if they reported a heart condition, chest pain during periods of activity or rest, loss of consciousness, being unable to walk two blocks without stopping, current participation in another weight-loss program and/or taking weight-loss medication, current or planning pregnancy or becoming pregnant in the next 18 months, or any condition that in the judgment of the research team made it unlikely the individual would complete the study protocol (i.e., plans to relocate, substance abuse). Individuals endorsing joint problems, prescription medication usage, or other conditions that could limit exercise were required to obtain written physician consent to participate.

Recruitment: Advertisements in local media and direct mailings

Baseline age (years): Total: 48.90 (10.5); a: 50.40 (9.3); b: 47.50 (11.3)
Baseline BMI (kg/m²): Total: 36.40 (6.1); a: 36.10 (6.1); b: 36.70 (6.2)
Baseline weight: Total: NR; a: 101.70 (2.2); b: 101.20 (2.1)

Green 2015

Country: USA
Location: Pacific Northwest community mental health centres (Cascadia Behavioral Healthcare and LifeWorks Northwest) and a not-for-profit integrated health system (Kaiser Permanente Northwest)
Period of study: July 2009 to October 2013
Inclusion criteria: Adults (aged 18 years or over) taking anti-psychotic agents for 30 days or more prior to enrolment and with a BMI of 27 kg/m² or more
Exclusion criteria: Current or planning pregnancy/breastfeeding, inpatient psychiatric hospitalization within 30 days or less (deferred participation was allowed), history of or currently planning bariatric surgery, history of cancer (past 2 years), heart attack or stroke within 6 months, and cognitive impairment that might interfere with consent/participation

Description of interventions:
- a: Usual care: NR
- b: STRIDE: Weight loss goal of 4.5-6.8 kg (10-15 pounds) over 6 months. Adaptations made to tailor intervention content and implementation approaches for people with serious mental illnesses. STRIDE’s core was a series of weekly 2-hr group meetings with 20 minutes of physical activity delivered over 6 months. The intervention relied on engaging sessions and small-group activities to facilitate acquisition and practice of behavioural self-management and problem-solving skills and to foster social support and program ownership. Core components included increasing awareness of health-related practices through self-monitoring, creating personalized plans, reducing energy intake by reducing portions, increasing consumption of low-calorie density foods, increasing physical activity, managing high-risk eating situations, graphing progress, and addressing effects of mental health on change efforts. The maintenance phase included 6 months of group sessions focused on maintaining weight loss through problem solving and motivational enhancement. Sessions targeted the individual plus physical and social cues within their homes. The BWL + H offered these components in a comprehensive treatment package that simultaneously manipulated physical and social aspects within participants' households. BWL + H components aimed to modify the type and amount of food consumed, the availability of exercise equipment and sedentary activities, the saliency of the consequences of eating and activity choices, and to create a positive model for healthy eating and exercise in the home.

Duration of active intervention: a: 12 months; b: 18 months
Number allocated: 201
Completed: Total: 185; a: 86; b: 99
% Dropout: Total: 7.96%; a: 13.13%; b: 2.94%

Length of follow-up (months): 12
Quantitative outcomes reported: Weight; Weight change (%); BMI kg/m²; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose
Recruitment: Electronic medical records and clinician referral
**Baseline age (years):** Total:47.20(10.6); a:48.30(9.7); b:46.20(11.4)
**Baseline BMI (kg/m²):** Total:38.30(8.3); a:38.20(7.3); b:38.30(9.1)
**Baseline weight:** Total:107.70(25.1); a:106.60(22.7); b:108.60(27.2)

were supplemented with monthly individual telephone sessions with group leaders.

**Duration of active intervention:** a:NR; b:12 months
**Number allocated:** 200
**Completed:** Total:149; a:NR; b:NR
**% Dropout:** Total:25.50%; a:NR; b:NR

Hakala 1993^46

**Country:** Finland
**Location:** Rehabilitation Research Centre
**Period of study:** Prior to February 1993
**Inclusion criteria:** At least 50% overweight; aged 22-54 years
**Exclusion criteria:** Serious cardiovascular disease, metabolic disease, psychiatric disease, hypothyroidism
**Recruitment:** Local newspaper advertisement

Data for men:
**Baseline age (years):** Total:NR; a:40.00(10); b:39.00(9)
**Baseline BMI (kg/m²):** Total:NR; a:41.70(3.1); b:42.70(4.0)
**Baseline weight:** Total:NR; a:137.60(11.0); b:143.60(17.1)

Data for women:
**Baseline age (years):** Total:NR; a:37.00(6); b:41.00(8)
**Baseline BMI (kg/m²):** Total:NR; a:43.40(5.4); b:43.60(4.8)
**Baseline weight:** Total:NR; a:119.20(12.6); b:120.70(9.3)

**Description of interventions:**
a: A 1200 kcal/day diet and individual physician-led counselling in 20-minute sessions, monthly for the first year and 4-monthly over the second year. The physician provided advice and information leaflets concentrating on weight reduction for the first 6 months and changes in body weight and health status after 6 months.

b: 2 week inpatient treatment in a rehabilitation centre. Weight reduction programme consisted of a 1200 kcal/day diet and group counselling sessions led by a nutritionist, physiotherapist and occupational therapist (10 participants per group) including 15 hrs of nutrition counselling, 15 hrs of physical activity, 12 hrs of occupational therapy and 1 hr of individual nutritionist counselling. Physician-led lecture and examination. Followed by 4-monthly individual physician appointments for 2 years.

**Duration of active intervention:** a:2 years; b:2 years

Data for men:
**Number allocated:** 20
**Completed:** Total:18; a:9; b:9
**% Dropout:** Total:10.00%; a:10.00%; b:10.00%;

Data for women:
**Number allocated:** 40
**Completed:** Total:35; a:16; b:19;
**% Dropout:** Total:12.50%; a:20.00%; b:5.00%;

**Length of follow-up (months):** 60
**Quantitative outcomes reported:** Weight
| **Country:** Finland  
**Location:** Rehabilitation centre and in the community  
**Period of study:** Prior to 1 July 1994  
**Inclusion criteria:**  
20-54 years of age, a minimum of 54% overweight and no previous participation in weight reduction courses at a rehabilitation centre or a health centre during the last two years  
**Exclusion criteria:**  
Epilepsy, cardiac failure  
**Recruitment:** Sleep clinics  
Data for women:  
**Baseline age (years):** Total:NR; a:40.00(8); b:40.00(7)  
**Baseline BMI (kg/m²):** Total:NR; a:39.20(3.5); b:39.80(4.3)  
**Baseline weight:** Total:NR; a:104.30(10.6); b:104.00(12.2)  
Data for men:  
**Baseline age (years):** Total:NR; a:44.00(6); b:40.00(11)  
**Baseline BMI (kg/m²):** Total:NR; a:37.70(2.3); b:40.50(3.9)  
**Baseline weight:** Total:NR; a:120.20(9); b:121.90(10.3)  
**Description of interventions:**  
a: 10-person subgroups in weight reduction courses arranged by the Turku Health Authority. The courses were conducted by 3 public health nurses who were trained in weight reduction instruction for two days at the SII. The programme included lectures by a GP, a psychologist and a physiotherapist. After the weight reduction period each one of the participants in both study groups was to see their nearest health centre GP for motivation and support for two years at 1-2 month intervals. The follow-up of weight and health status was combined with these appointments. 27 GPs from six health centres were asked to implement the support programme. Two briefings were organised in an attempt to motivate the GPs. Drug treatment for obesity was not used in any phase of the study.

From Karvetti paper: The weight reduction course was mainly based on nutrition education and dietary counselling in an attempt to teach the clients about the use of the recommended 1200 kcal/day diet and to modify their counterproductive dietary habits. The diet was based on ordinary Finnish foods and meal patterns, but it was low in fats and sugar, moderate in milk products, cereals, meat and fish, and high in vegetables. The meal pattern consisted of breakfast, lunch, dinner and a snack in the afternoon and in the evening. The course contained three separate lectures, by a physician, a psychologist and a physiotherapist, encouraging and supporting the participants in their weight reduction efforts.

b: Three week inpatient weight reduction period: primary emphasis on modification of eating and exercise habits. 10 participants per subgroup, 21 hrs counselling on nutrition and behavioural aspects by a nutritionist, 6 hrs advice on food preparation by a dietitian, 16 hrs of recreational activation by an occupational therapist, 6 hrs of social counselling and a one-hr lecture by a physician. The participants were activated by group and individual assignments. The programme included one hr of individual counselling by a nutritionist and one individual appointment with a physician. The participants had four daily low-energy meals (1200 kcal/day). The meals were served as examples of the recommended diet. After the weight reduction period each one of the participants in both study groups was to see their nearest health centre GP for motivation and support for two years at 1-2 month intervals. The follow-up of weight and health status was combined with these appointments. 27 GPs from six health centres were asked to implement the support programme. Two briefings were organised in an attempt to motivate the GPs. Drug treatment for obesity was not used in any phase of the study.

**Length of follow-up (months):** 60  
**Quantitative outcomes reported:**  
Weight
<table>
<thead>
<tr>
<th>Duration of active intervention</th>
<th>a: 2 year; b: 2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data for women:</td>
<td></td>
</tr>
<tr>
<td><strong>Number allocated:</strong> 42</td>
<td></td>
</tr>
<tr>
<td><strong>Completed:</strong></td>
<td>Total: 39; a: 19; b: 20</td>
</tr>
<tr>
<td><strong>% Dropout:</strong></td>
<td>Total: 7.14%; a: 9.52%; b: 4.76%</td>
</tr>
<tr>
<td>Data for men:</td>
<td></td>
</tr>
<tr>
<td><strong>Number allocated:</strong> 18</td>
<td></td>
</tr>
<tr>
<td><strong>Completed:</strong></td>
<td>Total: 13; a: 6; b: 7</td>
</tr>
<tr>
<td><strong>% Dropout:</strong></td>
<td>Total: 27.78%; a: 33.33%; b: 22.22%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description of interventions:</th>
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</tr>
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<tbody>
<tr>
<td>a: Weight Achievement and Intensive Treatment (Why WAIT) programme designed for clinical diabetes practices and run quarterly in groups of 10-15 participants. Participants receive weekly mediation adjustments, up to 300 min/week graded exercise, cognitive behavioural intervention and group education. Participants followed a hypocaloric (1500-1800 kcal/day) diet with CHO (40-45%), protein (1-1.5 g/kg or ~30%) and reduced saturated fat below 7%. During the initial 6 weeks, breakfast and lunch were replaced by Boost Glucose Control nutritional drinks (calories 190; protein 16 g; CHO 16 g; fibre 3 g; fat 7 g; Nestle Nutrition Inc) and participants were instructed to eat two snacks of 100-200 kcal and select a dinner from 14 structured menus. A maintenance phase of individual monthly counselling was followed for the remainder of the year.</td>
<td></td>
</tr>
<tr>
<td>b: RYGB surgery</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Length of follow-up (months): 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative outcomes reported:</td>
</tr>
<tr>
<td>Weight; BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c%; Fasting plasma glucose; Quality of life</td>
</tr>
</tbody>
</table>
| Hauptman 2000<sup>49</sup> | Country: USA  
| Location: 17 primary care centres  
| Period of study: Prior to February 2000  
| Inclusion criteria:  
| Women and men with obesity (age >18 years), BMI 30-44 kg/m²  
| Exclusion criteria:  
| Women who were pregnant, lactating, or of childbearing potential and not taking adequate contraceptive measures; weight loss of more than 4 kg during the previous 3 months; a history of significant cardiac, renal, hepatic, or gastrointestinal disorders; uncontrolled hypertension or any other clinically significant condition; gastrointestinal surgery for weight-reducing purposes; bulimia or laxative and/or substance abuse; abnormal laboratory measures; changes in smoking habits in the previous 6 months; or use of any drug that might influence body weight or food intake during the 8 weeks before screening  
| Recruitment: NR  
| Baseline age (years): Total: NR; a:41.60(10.19); b:42.60(11.68); c:43.20(10.14)  
| Baseline BMI (kg/m²): Total: NR; a:36.10(4.4); b:35.80(4.4); c:36.00(2.9)  
| Baseline weight: Total: NR; a:101.80(14.6); b:100.40(14.6); c:100.50(14.2)  
| Description of interventions:  
| ALL GROUPS: Reduced-energy diet prescribed during the 4 week lead-in period and the first 52 weeks of treatment: nutritionally balanced; 30% of energy as fat, 50% as carbohydrate, and 20% as protein; maximum of 300 mg/d of cholesterol. Alcohol consumption was limited to a maximum of 10 drinks/week. The prescribed energy intake was 1200 kcal/day for patients who weighed less than 90 kg initially and 1500 kcal/day for those who weighed 90 kg or more initially. Year 2: the prescribed energy intake was increased by 300 kcal/day for patients who were still losing weight at the end of the first 52 weeks of treatment. No dietary adjustment was made for those whose weight remained stable. At 4 points during the first 52 weeks, patients viewed videos of behaviour modification techniques for weight control. At 4 points during the second year, they were given weight management and diet pamphlets designed to assist in weight maintenance. Throughout the study, patients were encouraged to increase physical activity by walking briskly for 20 to 30 minutes 3 to 5 times/week but were not required to keep records of their physical activity  
| a: Placebo three times daily starting from 4 weeks pre-randomisation, continuing for 2 years.  
| b: Placebo three times daily starting from 4 weeks pre-randomisation, then orlistat 60 mg three times daily for 2 years. Everything else same as placebo group.  
| c: Placebo three times daily starting from 4 weeks pre-randomisation, then orlistat 120 mg three times daily for 2 years. Everything else same as placebo group.  
| Duration of active intervention: a:108 weeks; b:108 weeks; c:108 weeks  
| Number allocated: 635  
| Completed: Total:328; a:91; b:120; c:117  
| % Dropout: Total:48.35%; a:57.08%; b:43.66%; c:44.29%  
| Length of follow-up (months): 24  
| Quantitative outcomes reported:  
| Weight; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose
### Hunt 2014<sup>50</sup>

**Country:** UK  
**Location:** Scottish Premier League Football club stadia  
**Period of study:** 2011-2012  
**Inclusion criteria:**  
Men aged 35-65 years in 2011-12; had objectively measured BMI of at least 28 kg/m²; consented to weight, height, and waist measurements; had not taken part in FFIT previously; those with blood pressure contraindicating vigorous exercise (systolic of 160mmHg or more, or diastolic of 100mmHg or more) were initially able to take part in the classroom sessions only and the incremental, pedometer-based walking programme - they were advised that they would be able to take part in more intense in-stadia training once they had provided coaches with evidence of a reduction in their blood pressure  
**Exclusion criteria:** NR

**Recruitment:**  
Club websites, in-stadiums advertising, and FFIT recruitment staff approaching potentially eligible men on match days), local and national media coverage, e-mails to staff through local employers and word of mouth. An incentive (a £50 football club shop voucher) was offered to the FFIT graduate who generated the highest enrolment rate of eligible men in the FFIT study.

**Baseline age (years):**  
Total: 47.10 (8.0); a: 47.20 (7.89); b: 47.00 (8.07)  
**Baseline BMI (kg/m²):**  
Total: 35.30 (4.9); a: 35.10 (4.8); b: 35.50 (5.1)  
**Baseline weight:**  
Total: 109.50 (17.3); a: 108.70 (16.6); b: 110.30 (17.9)

### Description of interventions:  
**BOTH GROUPS:** All men measured at baseline were informed of their weight and BMI, given a British Heart Foundation booklet, ‘So You Want to Lose Weight?’, which offered detailed advice on weight management, were advised to see their GP if baseline readings for blood pressure exceeded pre-specified levels, and met the coaches, who talked broadly about the FFIT programme and gave information of the timing of the programme at their club.

**a:** Participants were allocated to the waiting list comparison group that could do the programme 12 months later. Study measurements were held at club stadia.  
**b:** FFIT was delivered free of charge to participants by community coaching staff employed by clubs to groups of up to 30 men with overweight or obesity every week for 12 weeks at the club's home stadium. Each 90 min session combined advice on healthy diet with physical activity. The balance of classroom and physical activity sessions changed during the 12 weeks; later weeks focused on physical activity as men became fitter, and the shorter classroom sessions focused on revision. Coaches were available at the end of each session if any man wanted to discuss personal issues. Participants were also taught behavioural change techniques known to be effective in physical activity, and dietary interventions (eg, self-monitoring, specific goal setting, implementation intentions, and feedback on behaviour), and social support was promoted. The 12 week active phase was followed by a weight maintenance phase with six post-programme email prompts during 9 months and a group reunion at the club 6 months after the end of the sessions. The dietary component of FFIT was designed to deliver a 600 kcal/day deficit (from estimated daily energy requirements) through the gradual adoption of more nutrient-dense foods and reduction of portion size, particularly of energy-dense foods, as well as the reduction of snacks, sugary and alcoholic drinks.

**Duration of active intervention:**  
a: 12 months; b: 12 months  
**Number allocated:** 748  
**Completed:** Total: 688; a: 355; b: 333  
**% Dropout:** Total: 8.02%; a: 5.08%; b: 10.96%

### Iqbal 2010<sup>51</sup>

**Country:** USA  
**Location:** Veterans Affairs Medical Centre  
**Period of study:** November 2004 to April 2008  
**Inclusion criteria:**

**Description of interventions:**  
**BOTH GROUPS:** Both diet groups were invited to attend separate weekly 2-h nutrition education classes for the first month. Thereafter, participants were provided sessions every 4 weeks for the duration of the study. Participants who had questions about their intervention also had the opportunity to meet

**Length of follow-up (months):** 24  
**Quantitative outcomes reported:**  
Weight; Weight change (%); BMI kg/m²; Waist circumference; Systolic BP; Diastolic BP; Quality of life
Persons with type 2 diabetes, age 18 years or over, with a BMI of 30 kg/m² or greater (diabetes was defined as a pre-existing clinical diagnosis or by the use of insulin or oral anti-diabetic medications)

**Exclusion criteria:**
Serum creatinine concentration >1.5 mg/dL (133 μmol/L) urine albuminto-creatinine ratio >200 μg/mg, an HbA1c <6.0% or >12.0%, hypoglycaemic or hyperglycemic episodes within the past month requiring external assistance, weight loss of 5% or more in the past 3 months, participation in a weight-loss program, or the use of weight-loss medications

**Recruitment:** outpatient endocrinology, cardiology, and general medicine clinics

**Baseline age (years):**
Total: NR; a:60.00(9.5); b:60.00(8.9)

**Baseline BMI (kg/m²):**
Total: NR; a:36.90(5.3); b:38.10(5.5)

**Baseline weight:**
Total: NR; a:115.50(16.7); b:118.30(21.3)

Individuals with the dietitian at the end of the group session. All participants were encouraged to engage in at least 30min of moderate activity at least five times/week.

**a:** Low-fat group: Participants were given an individualized “fat budget” and a calorie goal, which were based on the participant's height, weight, and target calorie intake (with a deficit of 500 kcal/day to promote weight loss). In order to facilitate monitoring of fat and calories, participants in this condition were also provided with the CalorieKing Calorie, Fat, and Carbohydrate Counter. Participants received extensive education about the various types of dietary fats. Heart-healthy fats were emphasized, and participants were instructed to consume <7% of total calories from saturated fats (in accordance with the American Heart Association guidelines). Participants were specifically instructed to consume <300 mg of dietary cholesterol daily. Participants were also encouraged to increase their intake of fruits and vegetables.

**b:** Low-carbohydrate group: Participants were provided with the CalorieKing Calorie, Fat, and Carbohydrate Counter (Family Health Publications, Costa Mesa, CA) to help them achieve their target carbohydrate intake of 30 g/day. Although the glycemic index was not specifically discussed, participants were encouraged to select whole grain products and foods with a high fibre content. Participants were not instructed to restrict their total fat or caloric intake, although general advice was provided on the various types of dietary fat. They were encouraged to consume healthy fats (e.g., monounsaturated and polyunsaturated) and to minimize the intake of saturated and trans fats.

**Duration of active intervention:** a:24 months; b:24 months

**Number allocated:** 144

**Completed:** Total:68; a:40; b:28

**% Dropout:** Total:52.78%; a:45.95%; b:60.00%

**Quantitative outcomes reported:** Weight; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose

Kahleova 2014

**Country:** Czech Republic
**Location:** University research institute - Institute for Clinical and Experimental Medicine, Charles University, Prague
**Period of study:** February 2008 to May 2008

**Inclusion criteria:**
Type 2 diabetes, age 30-70 years, HbA1c between 6 and 11% (42-97 mmol/mol), BMI between 25 and 53 kg/m².

**Description of interventions:**
BOTH GROUPS: Both diets lasted 24 weeks and were designed to be isocaloric and calorie restricted (500 kcal/day deficit) with caloric intakes based on the measurement of resting energy expenditure of each participant. The second 12 weeks of the diets were combined with aerobic exercise. Participants attended weekly 1-hr meetings with lectures and cooking classes. All meals during the study were provided. Vitamin B12 was supplemented in both the experimental group and the control group (50ug/day). Alcoholic beverages were limited to one/day for women and two/day for men. Participants were
willingness to change dietary habits and follow a prescribed exercise programme

**Exclusion criteria:**
- HbA1c <6% (<42 mmol/mol) or >11 % (>97 mmol/mol), use of insulin, abuse of alcohol or drugs, pregnancy, lactation, or current-use of a vegetarian diet.

**Recruitment:** Pre-chosen by their endocrinologists

**Baseline age (years):** Total: NR; a:57.70(4.9); b:54.60(7.8)

**Baseline BMI (kg/m²):** Total: NR; a:35.00(4.6); b:35.10(6.1)

**Baseline weight:** Total: NR; a:100.80(17.8); b:101.10(17.1)

asked not to alter their exercise habits during the first 12 weeks. During weeks 13-24 they were prescribed an individualized exercise programme based on their history of physical activity and an initial spiroergometric examination. Participants exercised at 60% of their maximal heart rate twice a week for 1 h under professional supervision, plus once a week at home or at the sports centre with the same intensity.

a: The conventional diabetic diet contained 50% of total energy from carbohydrates, 20% protein, less than 30% fat (7% saturated fat or less, <200 mg/day of cholesterol). The conventional diabetic diet meals were provided at the Institute for Clinical and Experimental Medicine, Prague.

b: Same as the conventional diet except the vegetarian diet (~ 60% of energy from carbohydrates, 15% protein and 25% fat) consisted of vegetables, grains, legumes, fruits and nuts. Animal produces were limited to a maximum of one portion of low-fat yogurt a day. Vegetarian meals were provided in two vegetarian restaurants.

**Duration of active intervention:** a:24 weeks; b:24 weeks

**Number allocated:** 74

**Completed:** Total:44; a:23; b:21

**% Dropout:** Total:40.54%; a:37.84%; b:43.24%

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Kelley 2002[^33]

**Country:** USA

**Location:** 43 centres

**Period of study:** Prior to 2002

**Inclusion criteria:**
- 40-65 years, BMI 28-43 kg/m² and <3 kg weight change for previous 3 months, stable treatment with insulin for 6 weeks and HbA1c 7.5-12.0%, negative pregnancy test and use of contraception during the study

**Exclusion criteria:**
- Treatment with thiazolidinedione for diabetes, change in diabetes medication in last 12 months (except insulin), medical history or presence of renal, hepatic or endocrine disorders, previous bariatric surgery, use of approved/ experimental weight reduction medications or treatments, presence of malabsorption syndrome, bulimia or laxative abuse, disorders that could affect compliance with the requirements of the study.

**Recruitment:** NR

**Description of interventions:**

a: Placebo three times daily and an energy deficit diet designed for 0.25-0.5 kg loss every week. Approx. 30% of calories from fat, 50% carbohydrate, 20% protein and max. 300 mg/day cholesterol. A dietitian provided initial dietary instruction at set intervals during the 52 weeks. Dietary intake records were used to assess compliance. At week 24, calorie intake was reduced by 200 kcal/day (minimum intake 1200 kcal/day) to compensate for reduced energy requirements due to weight loss. Information about lifestyle and behaviour modification were available throughout. Moderate physical activity was encouraged.

b: Orlistat 120 mg three times daily. Diet as per placebo group.

**Duration of active intervention:** a:52 weeks; b:52 weeks

**Number allocated:** 550

**Completed:** Total:265; a:128; b:137

**% Dropout:** Total:51.82%; a:53.62%; b:50.00%

**Length of follow-up (months):** 12

**Quantitative outcomes reported:**
- Weight; Weight change (%); Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose
<table>
<thead>
<tr>
<th>Description of interventions:</th>
<th>Length of follow-up (months): 18</th>
</tr>
</thead>
<tbody>
<tr>
<td>a: The short-term counselling included two visits at a 2 week interval and included only individual dietary counselling given by a nurse who was specialized in obesity. The content of the dietary counselling was similar to intensive counselling at two first visits but no repeated counselling was included.</td>
<td>Quantitative outcomes reported: Weight; Weight change (%)</td>
</tr>
<tr>
<td>b: The intensive counselling lasted 20 weeks. It included both individual and group counselling; altogether ten visits every second week and the main idea was to help participants to solve their problems related to diet and eating behaviour. Counselling was conducted by a clinical nutritionist. The goal of eating behaviour counselling was to recognise and improve personal eating behaviour. Homework was given to the participants and they were encouraged to take the responsibility of the changes by themselves.</td>
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<tr>
<td>Duration of active intervention: a:4 weeks ; b:20 weeks</td>
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</tr>
<tr>
<td>Number allocated: 82</td>
<td>Completed: Total:50; a:30; b:20</td>
</tr>
<tr>
<td>% Dropout: Total:39.02%; a:36.17%; b:42.86%</td>
<td></td>
</tr>
</tbody>
</table>

### Baseline age (years):
- Total: NR; a:58.00(0.5); b:57.80(0.5)

### Baseline BMI (kg/m²):
- Total: NR; a:35.60(4.92); b:35.80(3.26)

### Baseline weight:
- Total: NR; a:101.80(16.4); b:102.00(16.3)

### Keranen 2009

**Country:** Finland  
**Location:** University Hospital (Oulu University Hospital)  
**Period of study:** December 2002 to November 2004  
**Inclusion criteria:**  
Age 18-65 years and BMI over 27 kg/m²  
**Exclusion criteria:**  
Simultaneous participation in another weight loss program, abnormal laboratory values (thyroid stimulating hormone or creatinine), clinically significant illness with contraindication for weight loss or physical activity  
**Recruitment:** Newspaper advertisement  
**Baseline age (years):** Total:49.00(9); a:49.00(9); b:50.00(8)  
**Baseline BMI (kg/m²):** Total:35.00(5);a:35.00(5); b:35.00(5)  
**Baseline weight:** Total:98.00(19); a:98.00(20); b:97.00(17)
Country: Australia  
Location: Community  
Period of study: June 2007 and May 2008  
Inclusion criteria: Caucasian men with type 2 diabetes, glycated haemoglobin 7% or less or receiving oral hypoglycaemic medication, BMI over 30 kg/m², waist circumference 102 cm or greater  
Exclusion criteria: Smoking, previous/current treatment for sexual problems or lower urinary tract symptoms, glomerular filtration rate <60 ml/min and alcohol intake exceeding 500 g/week in the previous 12 months  
Recruitment: Community advertisement  
Baseline age (years): Total: NR; a: 62.30 (5.9); b: 58.10 (11.4)  
Baseline BMI (kg/m²): Total: NR; a: 35.60 (4.8); b: 35.10 (4.3)  
Baseline weight: Total: NR; a: 109.60 (14.9); b: 112.70 (19.2)  

| Description of interventions: | BOTH GROUPS: All participants received a written plan with detailed diet information, menu plan, recipes and advice on cooking and eating out. Diet compliance was monitored at 2-4 weekly intervals using food diaries. All participants maintained their usual daily activity. After 8 weeks, participants were switched to or continued on the high protein (HP) diet for another 44 weeks.  
| a: The HP diet was prescribed to reduce daily energy intake by approximately 600 kcal, including 300 g of lean meat/poultry/fish, and three servings/day of cereals/bread and low-fat dairy foods and two fruit and five vegetable serves/day. Participants were permitted to consume water, tea, coffee, and diet soft drinks, and were instructed to consume at least 2L of fluids/day.  
| b: Participants consumed two sachets daily of a liquid meal replacement, providing a maximum of 450 kcal of energy, 0.8 g/kg ideal body weight of protein, and the recommended daily allowances of minerals, vitamins, and omega-3 and omega-6 essential fatty acids, plus one other small meal, for a total of approximately 900 kcal/day.  

| Length of follow-up (months): | 12  
| Quantitative outcomes reported: | Weight; Waist circumference; LDL cholesterol; HDL cholesterol; Triglycerides; Fasting plasma glucose; Quality of life  

| Duration of active intervention | a: 12 months; b: 12 months  
| Number allocated: | 31  
| Completed: | Total: 16; a: 7; b: 9  
| % Dropout: | Total: 48.39%; a: 41.67%; b: 52.63%
Country: New Zealand
Location: Community
Period of study: 2007 to 2008
Inclusion criteria:
Participants were included if they had established type 2 diabetes (WHO criteria), were between 30 and 76 years of age, and had a BMI of at least 27 kg/m²
Exclusion criteria:
Participants were excluded if they were currently on weight-reducing medications, had weight loss of >5% in the past 3 months, had a psychiatric or eating disorder, if their glycated haemoglobin (HbA1c) was >9.5% (80 nunol/mol) or they had had renal disease (estimated glomerular filtration rate <60 ml/min or urine albumin :creatinine ratio [UACR] >30 mg/nunol), abnormal liver enzymes, heart failure, known active malignancy or myocardial infarction in the preceding 6 months
Recruitment: Postal invitations through primary and secondary care
Baseline age (years): Total:57.90(9.5); a:57.70(9.9); b:58.00(9.2)
Baseline BMI (kg/m²): Total:36.60(6.5); a:36.60(6.7); b:36.70(6.4)
Baseline weight: Total:NR; a:103.40(19.7); b:101.90(20.1)

Description of interventions:
BOTH GROUPS: Individuals participated in dietitian-led group sessions every 2 weeks for the first 6 months, then every month for the second 6 months. The group sessions were identical for the two interventions, except the accompanying diet-specific information, and included an education component and time for discussion and concluded with goal setting. The aim of both interventions was to reduce total energy intake by approximately 500 kcal/day using an individualised dietary prescription based on estimation of energy requirements. Culturally appropriate recipes were made available for specific ethnic groups. No further dietary advice was offered to either intervention group by the dieticians after 12 months. Participants were asked to continue following their prescribed diets on their own in the second year.

a: A low-fat, high-protein diet (40% of total energy as carbohydrate, 30% as protein, 30% as fat).
b: A low-fat, high-carbohydrate diet (55% of total energy as carbohydrate, 15% as protein, 30% as fat).

Duration of active intervention: a:24; b:24 months
Number allocated: 419
Completed: Total:294; a:144; b:150
% Dropout: Total:29.83%; a:30.43%; b:29.25%

Length of follow-up (months): 24
Quantitative outcomes reported:
Weight; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life
Krempf 2003

Country: France  
Location: 81 hospital centres  
Period of study: Prior to May 2003  
Inclusion criteria:  
Aged 18-65 years BMI of 28 kg/m² or more  
Exclusion criteria:  
Serious eating disorders or type 1 or type 2 diabetes, pregnant or lactating women; smoking 1 or more packs/day of cigarettes or intention to stop smoking during the trial; previous surgical treatment for obesity; known or suspected substance abuse; significant thyroid, renal, hepatic, gastrointestinal or immune disorders, or concomitant use of medications that alter body weight, appetite or the absorption of food  
Recruitment: NR  
Baseline age (years): Total:41.00(10.55); a:42.00(11.22); b:40.00(11.16)  
Baseline BMI (kg/m²): Total:36.10(5.28); a:36.20(5.61); b:36.00(5.58)  
Baseline weight: Total:97.30(18.47); a:97.50(16.84); b:97.00(16.74)  

Description of interventions:  
a: Placebo three times daily for 18 months.  
Diet: Food diaries were used to assess energy intake. Initial energy intake was determined from these food diaries and a dietitian prescribed an individually tailored diet with a 20% energy reduction to begin at the start of the run-in period. Fat intake was limited to 30% of energy intake. Food diaries were repeated during the run-in period to ensure that patients had understood the dietary instructions and advice. The diet energy prescription was decreased by a further 10% (never below 1200 kcal/day) in patients with stable weight (±0.5 kg since last visit) or weight gain.  
b: Orlistat 120 mg three times daily.  
Diet: as per placebo group.  

Duration of active intervention: a:18 months + 2 weeks; b:18 months + 2 weeks  
Number allocated: 696  
Completed: Total:425; a:201; b:224  
% Dropout: Total:38.94%; a:42.57%; b:35.26%  

Length of follow-up (months): 18  
Quantitative outcomes reported:  
Weight; Waist circumference

Kumanyika 2005

Country: USA  
Location: Family practice department of urban university health system  
Period of study: July 2000 to April 2001  
Inclusion criteria:  
Self-identification as African-American, age 25-70 years, a BMI between 30 and 50 kg/m², and a personal physician in the university health system  
Exclusion criteria:  
The only exclusions were for conditions or circumstances where weight reduction would be contraindicated, inappropriate, or infeasible, or that could confound interpretation of weight loss data, e.g., pregnancy, active treatment for unstable depression or other psychiatric disorders, current use of antipsychotic medications, active chemo- or radiation therapy, alcoholism, eating disorders, or being non-ambulatory. A history of CVD, diabetes, or obesity-related comorbidities was not a basis for  

Description of interventions:  
ALL GROUPS: Phase 1: 10 week group counselling HELP programme for weight loss. No specific diet or caloric intake level was specified, except that women and men were advised to consume at least 1200 and 1500 kcal/day, respectively. Participants were encouraged to set personal goals for gradual behaviour change using provided guidance. Advice to increase physical activity was individually tailored to ability and preferences. Group sessions were adapted to increase the interactive nature and cultural salience for African-Americans. Participants who attended the 3 month post-phase 1 data collection were offered randomisation for phase 2, an additional 18 months for either additional weight loss or weight maintenance.  
a: Clinic visits only (Usual care): The only study contacts were at the semi-annual follow-up clinic visits provided to all phase 2 participants. Participants were encouraged to continue with their healthy lifestyle changes and to consult their personal physician if they had further weight management questions. Their physicians were provided with an information sheet listing websites with weight management guidelines. No study interventions were provided to these

Length of follow-up (months): 18  
Quantitative outcomes reported:  
Weight
exclusion if health status was considered stable and permission of the personal physician was obtained.

Recruitment: Hospitals and primary care

Baseline age (years): Total:45.50(10.2); a:NR; b:NR; c:NR
Baseline BMI (kg/m²): Total:37.00(5.5); a:NR; b:NR; c:NR
Baseline weight: Total:99.90(16.9); a:99.50(19.9); b:98.50(16.8); c:103.30(18.7)

participants or their physicians and participant interactions with their physicians were not tracked.

b: Self-HELP: Phase 2 participants were given a kit containing a personalized calendar, a packet describing local resources for healthy eating and physical activity, a personal diary, and a pedometer, and ad hoc telephone support from a HELP outreach worker to facilitate self-directed long term weight management.

c: Group-HELP: Phase 2 participants were offered six, 1-h group classes, twice a month (termed biweekly), followed by monthly classes through the end of follow-up. Classes were led by a subset of the Phase 1 instructors, with new topics, expansion on or review of prior topics, and an even greater focus on group discussion than in Phase 1.

Duration of active intervention: a: 21 months; b: 21 months; c: 21 months
Number allocated: 128
Completed: Total:87; a:31; b:28; c:28
% Dropout: Total:32.03%; a:26.19%; b:34.88%; c:34.88%

Kumanyika 2009

Country: USA
Location: Community/family health centres
Period of study: May 2003 to July 2004
Inclusion criteria:
Self-identified African American (not required for partners) men and women, aged 35-70 years. The partners were 16-70 years of age. All participants had a BMI of 27 to 55 kg/m²; no medical contraindications to participation; no current medications known to affect body weight; and willingness to participate in required procedures.

Exclusion criteria:
Poorly controlled hypertension; inability to engage in moderate physical activity; pregnancy; heart failure or a recent cardiovascular event; and other serious illness.

Recruitment: Newspaper advertisements, provider referrals, community presentations, word of mouth, direct mailing from a prior study, and a telephone hotline
Family data:
Baseline age (years): Total: NR; a:47.20(7.3); b:49.80(7.9)

Description of interventions:
BOTH GROUPS: The goals were achievement, by 6 months, of a 5% to 10% weight loss and then weight loss maintenance. Counselling encouraged self-monitoring of food intake and physical activity for at least the first 6 months, caloric intake of 1500 to 1800 kcal/day or 1200 to 1500 kcal/day for men and women, respectively, and a gradual increase in physical activity to 180min/week. Ninety-minute group sessions were held weekly for 6 months, biweekly for 6 months, and then monthly. Periodic personal sessions (45-60 minutes) for problem solving replaced several group sessions in each phase to allow individual tailoring. In addition to the manipulation of culturally mediated social support from family and friends, strategies to increase cultural specificity and contextual relevance included having African American programme counsellors, culturally based content within-group sessions, and community-based field workshops (eg, cooking demonstrations at grocery stores, visits to local gyms, and line dancing).

a: Family high-support: Index participants and their partners were expected to attend and participate fully in all treatment sessions. Index/partner teams were encouraged to work together during sessions, counselled on how to provide social support, and given assignments for working together between sessions.

Length of follow-up (months): 24
Quantitative outcomes reported: Weight
<table>
<thead>
<tr>
<th><strong>Baseline BMI (kg/m²):</strong></th>
<th>Total: NR; a:38.40(6.2); b:39.30(6.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline weight:</strong></td>
<td>Total: NR; a:104.60(19.8); b:107.40(17.5)</td>
</tr>
</tbody>
</table>

**Individual data:**

<table>
<thead>
<tr>
<th><strong>Baseline age (years):</strong></th>
<th>Total: NR; a:46.60(6.4); b:48.80(8.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline BMI (kg/m²):</strong></td>
<td>Total: NR; a:37.00(5.5); b:38.70(7.3)</td>
</tr>
<tr>
<td><strong>Baseline Weight:</strong></td>
<td>Total: NR; a:97.60(15.6); b:105.80(22.8)</td>
</tr>
</tbody>
</table>

**b:** Family low-support: Same as the family high-support group except that only index participants were allowed to attend group sessions. They were advised to elicit social support from and work with their partners. The partners could attend personal counselling sessions and field workshops. Written materials given to index participants at sessions were mailed to partners.

**c:** Individual low-support: Same as family low-support stratum, except people enrolled by themselves and no teams were created in this condition

| **d:** Individual high-support: Same as for the family high-support strata except participants enrolled by themselves. Participants were then assigned to or chose a team member form within their treatment group after several weeks in the programme to allow them to identify commonalities that might facilitate supportive relationships. Teams were encouraged to work together within treatment sessions and advised about ways to support each other during and between sessions

**Family data:**

<table>
<thead>
<tr>
<th><strong>Duration of active intervention:</strong></th>
<th>a:24 months; b:24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number allocated:</strong></td>
<td>130</td>
</tr>
<tr>
<td><strong>Completed:</strong></td>
<td>Total:88; a:42; b:46</td>
</tr>
<tr>
<td>% <strong>Dropout:</strong></td>
<td>Total:32.31%; a:35.38%; b:29.23%</td>
</tr>
</tbody>
</table>

**Individual data:**

<table>
<thead>
<tr>
<th><strong>Duration of active intervention:</strong></th>
<th>a:24 months; b:24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number allocated:</strong></td>
<td>63</td>
</tr>
<tr>
<td><strong>Completed:</strong></td>
<td>Total:39; a:17; b:22</td>
</tr>
<tr>
<td>% <strong>Dropout:</strong></td>
<td>Total:38.10%; a:45.16%; b:31.25%</td>
</tr>
</tbody>
</table>

**Kumanyika 2012**

<table>
<thead>
<tr>
<th><strong>Country:</strong> USA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location:</strong> Five primary care practices in the Philadelphia, Pennsylvania area Think Health! with a particular focus on practices reaching African American or Hispanic adults</td>
</tr>
<tr>
<td><strong>Period of study:</strong> November 2006 and November 2008</td>
</tr>
<tr>
<td><strong>Inclusion criteria:</strong> Aged 18-70 years with a BMI of 27 to 55 kg/m², and weighing less than 182 kg who had been patients at the</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Description of interventions:</strong> BOTH GROUPS: Think Health! advised a dietary pattern consistent with the US Dietary Guidelines. Recommended calorie levels were 1200-1499 kcal for individuals weighing less than 100 kg and usually 1500-1800 kcal for those weighing more than 100 kg. The weight loss goal was 5-10% of initial weight; the physical activity goal was to achieve at least 150 mins/week of moderate activity. The 16 core DPP sessions were modified based on a prior DPP adaptation.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>a:</strong> Basic only: Primary care provider (PCP) counselling was provided every four</td>
</tr>
</tbody>
</table>

| **Length of follow-up (months):** 24 |
| **Quantitative outcomes reported:** Weight |
practice for at least 1 year or seen at the practice at least twice.

**Recruitment:** Billing lists and clinician referrals

**Exclusion criteria:**
- Pregnant or lactating; being non-ambulatory; taking systemic steroids, second generation anti-psychotics or mood stabilising agents; undergoing active cancer treatment; and having unstable cardiovascular disease or significant mental health conditions.

**Baseline age (years):**
- Total: 47.20(11.7); a: 46.80(11.6); b: 47.60(11.9)

**Baseline BMI (kg/m²):**
- Total: 37.20(6.4); a: 37.30(6.4); b: 37.20(6.5)

**Baseline weight:**
- Total: 101.20(19.9); a: 101.60(20.9); b: 100.70(18.7)

**Description of interventions:**

**BOTH GROUPS:** All the patients, irrespective of randomization, started with an initial 16 week VLCD period with a daily energy intake of 450 kcal. After the initial VLCD period, all the patients had a 3 week refeeding phase, in which ordinary food was gradually introduced. For the remaining treatment period (up to 2 years), all the patients were recommended an individualized hypocaloric diet (minus 2.2MJ/day or 500 kcal/day).

- a: Patients in the intermittent group were scheduled to repeat the same VLCD for 2 weeks every third month.
- b: Same as the intermittent group except patients in the on-demand group were advised to use VLCD as soon as their body weight passed an individualised, predetermined cut-off level. This cut-off level was defined as the individual body weight after the initial 16 week VLCD period plus 3 kg. Patients in the on-demand group who continued to lose weight had their cut-off level reduced during the trial, whilst the cut-off level remained unchanged in participants who regained weight.

**Length of follow-up (months):** 24

**Quantitative outcomes reported:**
- Weight; Weight change (%)
<table>
<thead>
<tr>
<th>Country: USA</th>
<th>Country: United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location: Community</td>
<td>Location: Weight Control and Diabetes Research Centre in Rhode Island</td>
</tr>
<tr>
<td>Period of study: Prior to May 7, 2013</td>
<td>Period of study: Prior to 1 July 2016</td>
</tr>
<tr>
<td>Inclusion criteria: Men and women, with overweight or obesity, between the ages of 20-72, with BMI of 26 kg/m² or more</td>
<td>Inclusion criteria: Aged 18 to 70 years, BMI between 30 and 50 kg/m², and a score of 5 or higher (women) or 4 or higher (men) on the ID subscale of the Eating Inventory</td>
</tr>
<tr>
<td>Exclusion criteria: Participants were excluded from the study if they were currently in another weight control program, had a current or past weight-related medical disorder (e.g., diabetes), were taking medications affecting weight and had not been on a stable dose for at least 2 months, had a current or past severe psychiatric disorder, were planning to move in the following two years, or were pregnant or breastfeeding in the past year or were planning to become pregnant in the following 2 years</td>
<td>Exclusion criteria: Participants were excluded for current participation in another weight loss program; current pregnancy or plans</td>
</tr>
<tr>
<td>Recruitment: Community organisations</td>
<td>Description of interventions: BOTH GROUPS: Both groups had goals of 1200-1800 kcal/day with 25% energy from fat and gradually increasing physical activity to 250min/week. Both groups also self-monitored weight and food intake and were taught stimulus control, problem solving and goal setting.</td>
</tr>
<tr>
<td>Baseline age (years): Total:49.65(12.33); a:NR; b:NR Baseline BMI (kg/m²): Total:35.80(7.93); a:36.08(7.76); b:35.58(8.13) Baseline weight: Total:97.64(27.44); a:99.34(27.21); b:96.39(27.80)</td>
<td>a: Acceptance based behavioural intervention: Utilised techniques based on acceptance and commitment therapy, including mindfulness and acceptance of unwanted emotions and food cravings.</td>
</tr>
<tr>
<td>Description of interventions: a: Standard care: Both groups received the same initial 20-session behavioural treatment of obesity over a six-month period. The content of group meetings was based on the DPP treatment manual, adapted for group format and expanded by culturally tailoring the program to the unique population while retaining all key elements of the original treatment. After receiving weight-loss treatment, all participants were provided with a maintenance manual of additional behavioural strategies and skills.</td>
<td></td>
</tr>
<tr>
<td>Duration of active intervention: a:24 months; b:24 months Number allocated: 334 Completed: Total:117; a:57; b:60 % Dropout: Total:64.97%; a:64.60%; b:65.32%</td>
<td>b: Continuing care: Same as standard care except participants were additionally trained to guide mutually supportive groups of their peers in their joint efforts to maintain weight loss. During treatment, each group recruited two volunteer co-facilitators from within the group who committed to continue guiding the group in weekly meetings following treatment. These co-facilitators were assigned the responsibility of leading their group for an 18-month period.</td>
</tr>
<tr>
<td>Length of follow-up (months):24 Quantitative outcomes reported: Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Fasting plasma glucose; Quality of life</td>
<td></td>
</tr>
</tbody>
</table>

### Baseline weight: Total: NR; a:114.20(18.9); b:114.40(17.5)

### Duration of active intervention: a:24 months; b:24 months

### Number allocated: 334

### Completed: Total:117; a:57; b:60

### % Dropout: Total:64.97%; a:64.60%; b:65.32%

### Description of interventions:

- **a**: Standard care: Both groups received the same initial 20-session behavioural treatment of obesity over a six-month period. The content of group meetings was based on the DPP treatment manual, adapted for group format and expanded by culturally tailoring the program to the unique population while retaining all key elements of the original treatment. After receiving weight-loss treatment, all participants were provided with a maintenance manual of additional behavioural strategies and skills.

- **b**: Continuing care: Same as standard care except participants were additionally trained to guide mutually supportive groups of their peers in their joint efforts to maintain weight loss. During treatment, each group recruited two volunteer co-facilitators from within the group who committed to continue guiding the group in weekly meetings following treatment. These co-facilitators were assigned the responsibility of leading their group for an 18-month period.

### Duration of active intervention: a:6 months; b:24 months

### Number allocated: 90

### Completed: Total:52; a:20; b:32

### % Dropout: Total:42.22%; a:47.37%; b:38.46%

### Description of interventions:

- **a**: Acceptance based behavioural intervention: Utilised techniques based on acceptance and commitment therapy, including mindfulness and acceptance of unwanted emotions and food cravings.

- **b**: Standard behavioural treatment: Current best practice for cognitive and...
to become pregnant during the study period; reported heart condition, chest pain or inability to exercise; reported conditions that would render them unlikely to follow the protocol, including terminal illness, plans to relocate, a history of substance abuse, or a recent psychiatric hospitalization

**Recruitment:** newspaper advertisements and direct mailings

<table>
<thead>
<tr>
<th>Baseline age (years):</th>
<th>Total: 50.20 (10.9); a: 50.70 (11.3); b: 49.80 (10.7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline BMI (kg/m²):</td>
<td>Total: 37.60 (5.3); a: 37.50 (5.4); b: 37.70 (5.3)</td>
</tr>
<tr>
<td>Baseline weight:</td>
<td>Total: 102.30 (17.4); a: 102.50 (17.3); b: 102.20 (17.7)</td>
</tr>
</tbody>
</table>

**Description of interventions:**

- **a:** Weight loss only: 26 x 90 min group sessions (3-11 participants per group) over 1 year. Session content was centred on behavioural goal setting and self-monitoring of caloric intake, physical activity, and body weight. Participants were given daily caloric intake goals of 1200 or 1500 kcal as appropriate to produce weight loss of 1 to 2 lb/week, based on initial body weight. Participants were asked to restrict fat intake to 20% of daily caloric intake. Physical activity goals were increased in biweekly increments of 500 kcal/week until the goal of 2500 kcal/week was reached. Participants received structured meal plans and specific skills training in environmental stimulus control. The program did not specifically address symptoms of depression.

- **b:** Combined intervention: 26 x 120 min group sessions (4-16 per group) over 1 year. The behavioural weight loss program described above was integrated with essential elements of cognitive-behavioural treatment for depression, as drawn from the Coping with Depression manual. Approximately 55% of didactic content in the combined program addressed treatment for depression, with the remaining 45% of the content addressing behavioural weight loss treatment.

**Duration of active intervention:** a: 12 months; b: 12 months

<table>
<thead>
<tr>
<th>Number allocated:</th>
<th>162</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed:</td>
<td>Total: 127; a: 63; b: 64</td>
</tr>
<tr>
<td>% Dropout:</td>
<td>Total: 21.60%; a: 22.22%; b: 20.99%</td>
</tr>
</tbody>
</table>

**Country:** USA

**Location:** People enrolled in Group Health Cooperative, Washington state and Northern Idaho

**Period of study:** April 2003 - April 2005

**Inclusion criteria:**

- Age 40 to 65 years, BMI ≥ 30 kg/m², clinically significant depression, PHQ score ≥ 10, current or past major depressive episode, current symptoms include depressed mood or loss of interest, enrolled in Group Health Cooperative health plan

**Exclusion criteria:**

- History of treatment for bipolar disorder or schizophrenia, not willing to participate in group intervention, medical contra-indications to graded exercise programme, unable to walk for 10 minutes, receiving treatment for weight loss or psychotherapy for depression

**Recruitment:** Primary care clinics

<table>
<thead>
<tr>
<th>Baseline age (years):</th>
<th>Total: 50.10 (6.1); a: 52.10 (6.5); b: 52.30 (6.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline BMI (kg/m²):</td>
<td>Total: NR; a: 39.50 (7.7); b: 38.60 (6.8)</td>
</tr>
<tr>
<td>Baseline weight:</td>
<td>Total: 105.00 (20); a: 106.60 (22.3); b: 103.40 (17.7)</td>
</tr>
</tbody>
</table>

**Description of interventions:**

- **a:** Combined intervention: 26 x 120 min group sessions (4-16 per group) over 1 year. The behavioural weight loss program described above was integrated with essential elements of cognitive-behavioural treatment for depression, as drawn from the Coping with Depression manual. Approximately 55% of didactic content in the combined program addressed treatment for depression, with the remaining 45% of the content addressing behavioural weight loss treatment.

**Duration of active intervention:** a: 12 months; b: 12 months

<table>
<thead>
<tr>
<th>Number allocated:</th>
<th>203</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed:</td>
<td>Total: 150; a: 73; b: 77</td>
</tr>
<tr>
<td>% Dropout:</td>
<td>Total: 26.11%; a: 28.43%; b: 23.76%</td>
</tr>
</tbody>
</table>

**Length of follow-up (months):** 24

**Quantitative outcomes reported:**

- Weight
Country: UK
Location: 56 primary care practices in central and south England
Period of study: 30th January 2013 to 20th March 2014

Inclusion criteria:
Individuals aged 18 years or older with a BMI of 30 kg/m² or more (or ≥28 kg/m² with hypertension, hypercholesterolaemia, or diabetes) as identified from general practitioner (GP) routine electronic health records

Exclusion criteria:
Patients with severe mental health problems (eg, psychosis; difficulty completing outcomes), patients who were too ill to take part in a study such as this one or who were unable to change their diet (eg, individuals with severe heart, lung, kidney, bowel, or liver diseases), patients who were pregnant or breastfeeding, patients with a perceived inability to walk 100m (physical activity difficult), and patients with another member of the household taking part or no regular access to the internet

Recruitment: Primary care

Baseline age (years):
Total: NR; a:52.69(13.25); b:53.70(13.21); c:54.74(12.95)

Baseline BMI (kg/m²):
Total: NR; a:37.10(5.97); b:36.66(5.36); c:36.28(5.65)

Baseline weight:
Total: NR; a:104.38(21.11); b:102.40(16.87); c:102.93(18.26)

Description of interventions:
a: Participants assigned to the control group were directed to a set of two printable web-based pages with brief structured advice. This intervention was active, since it was intended to aid weight loss. The materials were developed by the Institute of Food Research to provide appealing strategies to minimise the pressure to cut down favourite foods, and to instead swap less healthy foods for healthier choices (healthy foods swap sheet), or to increase fruit and vegetable intake (using the NHS five-a-day sheet). To enhance retention, participants were informed that this intervention had been shown to support weight loss. Nurses arranged brief follow-up (5–10 min appointments) with sufficient time to measure weight at 6 months and 12 months, but not to provide explicit counselling.

BOTH POWeR GROUPS: POWeR+ is a theory and evidence-based intervention to teach patients self-regulation and cognitive-behavioural techniques to form sustainable eating and physical activity habits for long term weight management in a series of 24 web-based sessions over 6 months. Patients initially chose either a low-calorie (600 kcal deficit) or a low-carbohydrate eating plan (<50 g carbohydrate for 2 weeks, followed by targets intended to produce on-going weight loss (50-80 g carbohydrate), but could change plans at any stage if they wished. Patients who succeeded in losing 5% of body weight were given the choice of continuing to pursue gradual weight loss or attempting to maintain this weight loss. Participants who had lost less than 2.5 kg at 12 weeks were recommended orlistat.

b: POWeR+ Face-to-face: Automated behavioural counselling, with just three scheduled (and four optional) face-to-face nurse support sessions. In addition to weight recording every 6 months, as in the control group, participants had three scheduled face-to-face appointments in the first 3 months, and then up to four more appointments during a further 3 months if needed (ie, 6 months in total). Weight gain on two consecutive logins triggered an automated email to the nurse advising that the patient needed further support, or patients could request additional support.

c: POWeR+ Remote: Even briefer professional support for the web intervention. Patients could access the same web-based intervention as in the POWeR+Face-to-face group. In addition to weight recording every 6 months, as in the control group, participants had three scheduled phone or email

Length of follow-up (months): 12

Quantitative outcomes reported:
Weight; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life
contacts and up to two optional phone or email contacts in the first 6 months (triggered by weight gain or patient request, as in the POWeR+F group).

**Duration of active intervention:** a: 12 months; b: 6 months; c: 6 months

**Number allocated:** 826

**Completed:** Total: 666; a: 227; b: 221; c: 218

**% Dropout:** Total: 19.37%; a: 18.64%; b: 17.84%; c: 19.26%

| Look AHEAD | Country: USA
| Location: The Johns Hopkins University, Pennington Biomedical Research Centre, The University of Alabama at Birmingham, Harvard Centre, University of Colorado Anschutz Medical Campus, Baylor College of Medicine, The University of Tennessee Health Science Centre, University of Minnesota, St. Luke’s Roosevelt Hospital Centre, University of Pennsylvania, University of Pittsburgh, The Miriam Hospital/Brown Medical School, The University of Texas Health Science Centre at San Antonio, VA Puget Sound Health Care System / University of Washington, Southwestern American Indian Centre, Phoenix, Arizona and Shiprock, New Mexico, University of Southern California
| **Period of study:** August 2001 to April 2004
| **Inclusion criteria:**
45 to 75 years old, self-reported type 2 diabetes, as verified by the use of glucose-lowering medication, a physician’s report, or glucose levels; BMI 25 kg/m² or more (27.0 or greater in patients taking insulin); a glycated hemoglobin level of 11% or less; a systolic blood pressure of less than 160mmHg; a diastolic blood pressure of less than 100mmHg; a triglyceride level of less than 600 mg per deciliter (6.77 mmol/L); the ability to complete a valid maximal exercise test, suggesting it was safe to exercise; and an established relationship with a primary care provider. Patients could be using any type of glucose-lowering medication, but the percentage of those receiving insulin allowed in the trial was limited to less than 30%. Patients with and those without a history of cardiovascular disease were included to increase the generalizability of the results.

| Description of interventions: BOTH GROUPS: One-hr diabetes education class at the end of the screening process. This session provides basic education about diabetes, with particular emphasis on aspects of diabetes care related to the trial such as management of hypoglycaemia, cardiovascular disease symptoms, and foot care. The importance of eating a healthy diet and being physically active for both weight loss and improvement of glycaemic control are stressed. All individuals who smoke are encouraged to stop smoking and are provided with self-help materials and/or referral to local programs, as appropriate.

a: Participants assigned to Diabetes Support and Education are invited to attend three group educational / social support sessions each year for 4 to 6.5 years after study randomization begins. One educational or social support session annually will continue to be offered beginning with year 5 until the end of the trial. The educational sessions offered include one session each year on diet/nutrition and one session related to exercise. These sessions are informational and do not teach behavioural self-regulation skills.

b: Intensive lifestyle intervention: Individual participants were encouraged to lose >10% of their initial body weight, with the expectation that a greater number of participants would achieve the minimum 7% weight loss. During the first four weeks, participants chose from two prototype diets (one with liquid meal replacement that will replace two meals and snacks each day; the second option, for those who do not accept or tolerate the liquid/prepared meal prototypes, involves the consumption of a very structured meal plan, with the same calorie range, using foods that participants prepare themselves). Long term replacement (with a liquid supplement) of one meal and one snack a day also will be an option. Meal replacements and structured meal plans will also be options in a "tool-box," that can be used to reverse weight regain. The macronutrient composition included a maximum of 30% of total calories from fat (with a maximum of 10% of total calories from saturated fat) and a minimum of 15% of total calories from protein. The energy goal for persons less than 190% of ideal weight was 1500 kCal, and 2000 kCal for persons >190% of ideal weight. After the initial phase, participants were encouraged to use the "toolbox" as directed to maintain weight loss. Nutritional and exercise guidance continued for up to 6.5 years after randomization.

| Length of follow-up (months): 115
| **Quantitative outcomes reported:**
Weight; Weight change (%); Waist circumference; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life
Exclusion criteria:
Inadequate control of comorbid conditions (Unable or unwilling to give informed consent or communicate with local study staff, Hospitalization for depression in past 6 months, Self-report of alcohol or substance abuse within the past 12 months, Lack of support from primary health care provider or family members, In past 3 months, weight loss exceeding 10 lbs, history of bariatric surgery, small bowel resection, or extensive bowel resection, chronic treatment with systemic corticosteroids, weight greater than 350 pounds unless exercise test equipment is available at centre, current use of medications for weight loss, inability to walk two blocks); HbAlc >11%; blood pressure >= 160/100 mm Hg; fasting triglycerides >= 600 mg/dL; factors that may limit adherence to interventions or affect conduct of the trial; currently pregnant or nursing; cancer requiring treatment in the past 5 years, unless the progress is excellent; self-report of HIV-positive or active tuberculosis; CVD event within the past 3 months; documented history of pulmonary embolus in past 6 months.

Recruitment: Various site-specific recruitment plans
Baseline age (years): Total: NR; a:58.90(6.9); b:58.60(6.8)
Baseline BMI (kg/m²): Total: NR; a:36.00(5.8); b:35.90(6.0)
Baseline weight: Total: NR; a:101.00(19); b:101.00(20)

Lowe 2014
Country: USA
Location: Community/primary care
Period of study: NR
Inclusion criteria:
Aged between 18 and 70 years, have a BMI over 30 kg/m² (or 27 kg/m² with a comorbid medical condition), and have regular access to a telephone
Exclusion criteria:
Lactose intolerance, serious psychiatric disorders, and medical conditions and drug regimens know to affect body weight or appetite
Recruitment: Primary care physicians

Description of interventions:
ALL GROUPS: All participants underwent a 12 week behavioural weight loss programme. Participants were randomised into 1/4 maintenance conditions before the weight loss phase but both participants and their group leaders were kept blind about their assignment until week 13. All participants were instructed to: (1) follow a 12 week weight loss diet using two meal replacements (MR) giving 1200-1500 kcal/day, plus a controlled meal and planned snacks, (2) read weekly lifestyle change modules from the LEARN manual, and (3) implement treatment recommendations via weekly 15-min phone calls with a weight control specialist (WCS). Participants were randomly assigned to the weight maintenance interventions by crossing the two factors (1) continued use of MRs or not (+/-) and (2) introduction of a reduced energy

Duration of active intervention: a:9 years; b: 9 years
Number allocated: 5145
Completed: Total:4585; a:2275; b:2310
% Dropout: Total:10.88%; a:11.65%; b:10.12%
Baseline age (years): Total: 45.50 (11.8); a: NR; b: NR; c: NR; d: NR
Baseline BMI (kg/m²): Total: 39.50 (6.6); a: NR; b: NR; c: NR; d: NR
Baseline Weight: Total: NR; a: NR; b: NR; c: NR; d: NR
density (ED) eating programme. All participants were encouraged to gradually increase their levels of physical activity (usually brisk walking) so that they were engaging in at least 150 min/week.

b: MR+/ED-: Participants in this condition were told that MRs would constitute a significant part of their weight maintenance programme. They were taught how to build in MRs to replace one meal and one snack/day.
c: MR-/ED+: Participants were given the book Volumetrics and individual modules that complemented the material in the book. The discontinuation of MRs was explained as a necessary transition to learning how to maintain lost weight using regular foods. The goal was to change the ED of as many foods as possible in participants' personal food environments in ways that could be sustained.
d: MR+/ED+: This condition combined the use of MRs and the reduced ED diet as described in the MR+ and ED+ conditions.

Duration of active intervention: a: 12 months; b: 12 months; c: 12 months; d: 12 months
Number allocated: 132
Completed: Total: 89; a: NR; b: NR; c: NR; d: NR
% Dropout: Total: 32.58%; a: NR; b: NR; c: NR; d: NR

Ma 2015

Country: USA
Location: Community
Period of study: 16th April 2010 to 13th August 2012
Inclusion criteria:
18 to 70 years, BMI ≥30 kg/m², uncontrolled persistent asthma through a multistage screening process; Kaiser member for at least 1 year.
Exclusion criteria:
Serious medical or psychiatric disorders (e.g., chronic obstructive pulmonary disease, stroke, psychosis); pregnancy; planned relocation.
Recruitment: Primary care

Description of interventions:
a: Enhanced standard care: Participants received standard medical care from their providers, who were unaware of treatment assignment. Participants were given a pedometer, a body weight scale, a list of routinely offered weight management services, and a standard asthma self-management educational DVD. The research team made no other attempts to intervene with control participants.
b: Lifestyle intervention: Intensive (weekly in-person group sessions over 4 months), Transitional (in-person individual sessions every 2 months), and Extended (three bimonthly or more frequent phone consultations as required). Participants were advised to eat healthily with moderate calorie reductions (by 500-1000 kcal/day), engage in moderate-intensity physical activity (e.g., brisk}

Length of follow-up (months): 12
Quantitative outcomes reported:
Weight; Weight change (%); BMI kg/m²; Waist circumference; Quality of life
Baseline age (years): Total: 47.60 (12.4); a: 47.70 (12.1); b: 47.50 (12.6)
Baseline BMI (kg/m²): Total: 37.50 (5.9); a: 37.60 (5.7); b: 37.40 (6.0)
Baseline weight: Total: 104.20 (19.6); a: 104.20 (20.1); b: 104.20 (19.1)

Table:
<table>
<thead>
<tr>
<th>MacLaughlin 2014⁶⁹</th>
<th>Country: UK</th>
<th>Location: 3 university teaching hospitals in London</th>
<th>Period of study: March 2010 to June 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion criteria:</td>
<td>Male or female, aged &gt; 18 years, previously attempted weight loss, BMI 35-45 kg/m², estimated glomerular filtration rate 20-60 ml/min/1.73m² using the 4 variable modified MDRD study prediction equation, written informed consent</td>
<td>Exclusion criteria: Pregnancy, history of chronic liver disease, previous bariatric surgery, gastric surgery or large hiatus hernia, psychiatric illness including anxiety, mood and untreated eating disorders, malnutrition (assessed by Subjective Global Assessment), infection or course of antibiotics within the last month, unfit for anaesthesia or surgery, unwilling to consider surgical treatment, previous kidney transplant</td>
<td>Recruitment: Outpatient clinics</td>
</tr>
<tr>
<td>Baseline age (years): Total: NR; a: Median 51.00 (IQR 47.5 to 55); Median b: 53.00 (IQR 46.5 to 66)</td>
<td>Baseline BMI (kg/m²): Total: NR; a: 40.30 (IQR 37.3 to 43.5); b: 37.40 (IQR 35.8 to 40.0)</td>
<td>Baseline weight: Total: NR; a: Median 111.00 (IQR 104.8 to 116.0); b: Median 105.20 (IQR 101.3 to 113.0)</td>
<td>Description of interventions: a: Laparoscopic sleeve gastrectomy and dietary education and renal-specific written information prior to the procedure, or 1-2 days post-procedure as an inpatient. Dietary intake was reviewed at 1, 4, 6 and 12 weeks post-sleeve gastrectomy, then at 3-monthly intervals up to 12 months. Dietary intake progressed in texture from liquid to puree, then to soft foods over 12 weeks, before finally re-introducing most normal foods between 4-6 months postsurgery. Volume of food or fluid intake was limited to 100-150 ml per meal, up to 6 times a day, with frequent sips of fluid encouraged. Dietary energy intake was restricted to approximately 1000 kcal/day post sleeve gastrectomy.</td>
</tr>
<tr>
<td>Duration of active intervention: a: NR; b: NR</td>
<td>Number allocated: 330</td>
<td>Completed: Total: 289; a: 147; b: 142</td>
<td>% Dropout: Total: 12.42%; a: 10.91%; b: 13.94%</td>
</tr>
<tr>
<td>Length of follow-up (months): 12</td>
<td>Quantitative outcomes reported: Weight; Weight change (%); BMI kg/m²; Waist circumference</td>
<td></td>
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</tbody>
</table>

Walking, and behavioural self-management skills. Participants had a goal of achieving and maintaining a 7% weight loss and a minimum of 150 mins/week of physical activity. Participants were also advised to lower saturated fat intake to <10%; lower cholesterol intake to <300 mg/day; consume a high plant-based diet, low-fat dairy products and reduce intake of high glycemic index carbohydrates.

Duration of active intervention: a: NR; b: NR
Number allocated: 330
Completed: Total: 289; a: 147; b: 142
% Dropout: Total: 12.42%; a: 10.91%; b: 13.94%

Description of interventions:

MacLaughlin 2014⁶⁹

Country: UK
Location: 3 university teaching hospitals in London
Period of study: March 2010 to June 2011
Inclusion criteria: Male or female, aged > 18 years, previously attempted weight loss, BMI 35-45 kg/m², estimated glomerular filtration rate 20-60 ml/min/1.73m² using the 4 variable modified MDRD study prediction equation, written informed consent
Exclusion criteria: Pregnancy, history of chronic liver disease, previous bariatric surgery, gastric surgery or large hiatus hernia, psychiatric illness including anxiety, mood and untreated eating disorders, malnutrition (assessed by Subjective Global Assessment), infection or course of antibiotics within the last month, unfit for anaesthesia or surgery, unwilling to consider surgical treatment, previous kidney transplant
Recruitment: Outpatient clinics
Baseline age (years): Total: NR; a: Median 51.00 (IQR 47.5 to 55); Median b: 53.00 (IQR 46.5 to 66)
Baseline BMI (kg/m²): Total: NR; a: 40.30 (IQR 37.3 to 43.5); b: 37.40 (IQR 35.8 to 40.0)
Baseline weight: Total: NR; a: Median 111.00 (IQR 104.8 to 116.0); b: Median 105.20 (IQR 101.3 to 113.0)

Description of interventions:

a: Laparoscopic sleeve gastrectomy and dietary education and renal-specific written information prior to the procedure, or 1-2 days post-procedure as an inpatient. Dietary intake was reviewed at 1, 4, 6 and 12 weeks post-sleeve gastrectomy, then at 3-monthly intervals up to 12 months. Dietary intake progressed in texture from liquid to puree, then to soft foods over 12 weeks, before finally re-introducing most normal foods between 4-6 months postsurgery. Volume of food or fluid intake was limited to 100-150 ml per meal, up to 6 times a day, with frequent sips of fluid encouraged. Dietary energy intake was restricted to approximately 1000 kcal/day post sleeve gastrectomy.

b: Renal Lifestyle weight management programme: A low-fat energy-reduced 1400 to 1800 kcal renal diet, depending on body size, physical activity level and dietary intake at baseline, was negotiated with each patient based on food preferences and appropriate for each patient’s CKD stage. Protein intake was optimised for the stage of CKD for each patient, at 1 g protein/kg ideal body weight (IBW)/day for CKD stage 3 and 0.8-1 g protein/kg IBW/day for CKD stage 4. Fat intake was limited to less than 70 g/day, to minimise the side effects of orlistat. The remaining energy was obtained from carbohydrate sources, with higher fibre choices encouraged when possible.

Duration of active intervention: a: 12 months; b: 12 months
Number allocated: 16
Completed: Total: 16; a: 5; b: 6
% Dropout: Total: 0.00%; a: 37.50%; b: 25.00%
<table>
<thead>
<tr>
<th>Title</th>
<th>Country</th>
<th>Location</th>
<th>Period of study</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Baseline age (years)</th>
<th>Baseline BMI (kg/m²)</th>
<th>Baseline weight</th>
<th>Description of interventions</th>
<th>Number allocated</th>
<th>Completed</th>
<th>Dropout</th>
<th>Length of follow-up (months)</th>
<th>Quantitative outcomes reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manzoni 2016</td>
<td>Italy</td>
<td>Obesity unit of the Istituto Auxologico Italiano, Verbania</td>
<td>Prior to February 2016</td>
<td>BMI ≥40 kg/m²; 18–50 years of age and written and informed consent to participate and (f) written and informed consent to participate.</td>
<td>Other concurrent severe eating (bulimia, binge eating, or eating disorder not otherwise specified) or psychiatric disturbances (psychosis, depression with suicidal risk, or alcohol or drug abuse); concurrent involvement in other treatment, including medication; concurrent medical condition not related to the disorder</td>
<td>Total:35.63(8.04); a:NR; b:NR; c:NR</td>
<td>Total:42.24(6.01); a:NR; b:NR; c:NR</td>
<td>Total:110.33(12.27); a:110.00(15.2); b:108.00(12.1); c:112.10(15.6)</td>
<td>a: Standard behavioural inpatient programme: Consists of hospital-based living for 6 weeks. Inpatients receive medical, nutritional, physical, and psychological care. The goal was to provide practical guidelines (e.g., stressing gradual weight loss with the caloric restriction achieved largely by reductions in fat intake), plus a low-calorie diet (1200 kcal/day) and physical training (30 minutes of walking twice a week as a minimum). b: Cognitive behavioural therapy (CBT). Consists of hospital-based living for 6 weeks. As per standard care but inpatients receive medical, nutritional, physical, and psychological care the goal of which is to provide practical guidelines. The patients entered five weekly group sessions aimed at addressing weight and primary goals, and 10 biweekly individual sessions aimed at establishing and maintaining weight loss, addressing barriers to weight loss, increasing activity, addressing body image concerns, and supporting weight maintenance. c: CBT + virtual reality (VR): Consists of hospital-based living for 6 weeks. As per standard care but inpatients receive medical, nutritional, physical, and psychological care the goal of which is to provide practical guidelines. After the first inpatients week, participants entered five weekly group sessions similar to the CBT ones (focused on concerns about body weight and shape and problematic eating) and 10 biweekly VR sessions.</td>
<td>163</td>
<td>Total:118; a:31; b:40; c:47</td>
<td>27.61%; a:40.38%; b:25.93%; c:17.54%</td>
<td>12</td>
<td>Weight</td>
</tr>
<tr>
<td>Martin 2008</td>
<td>USA</td>
<td>Office of their primary care physician</td>
<td>Prior to November 2008</td>
<td>Women, between the ages of 18 and 65 years, BMI of 25 kg/m² or greater, classified as low income (&lt;$16,000 annual income), attendees of the primary care clinic for at least 1 year, and free of serious or uncontrolled medical conditions (e.g., renal or hepatic failure, cancer, immunological disease, uncontrolled hypertension).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a: Standard care participants received no special instructions regarding weight loss and were seen as needed for regular medical care. It was ultimately up to the physician (in collaboration with his/her patients) to determine how much (if any) weight loss counselling was included in primary care encounters during the study. b: Tailored interventions were derived from information provided by participants during the initial assessment. Participants received five physician - counselled office visits on a monthly basis. Topics of the monthly meetings included introductory information on weight loss (month 1), ways to decrease</td>
<td>163</td>
<td>Total:118; a:31; b:40; c:47</td>
<td>27.61%; a:40.38%; b:25.93%; c:17.54%</td>
<td>18</td>
<td>Weight</td>
</tr>
</tbody>
</table>
Women with well-controlled chronic diseases such as hypertension, diabetes, or hyperlipidaemia were included. **Exclusion criteria:** Use of weight-altering medications, pregnancy, severe psychiatric illness, alcohol intake >14 drinks/week, or serious physical illness. **Recruitment:** Primary care. **Baseline age (years):** Total: 41.80(12.0); a: 42.60(11.4); b: 40.80(12.7) **Baseline BMI (kg/m²):** Total: 38.85(7.63); a: 39.80(7.8); b: 38.30(7.5) **Baseline weight:** Total: 101.95(19.37); a: 103.40(18.0); b: 101.20(20.6)

**Description of interventions:** **ALL GROUPS:** All participants were given a study goal of achieving and maintaining a 10% weight loss over 12 months on the basis of weight measured at randomisation.

a: Usual care was delivered in 1 individual session by a study nutritionist at the beginning of the 12-month period. Information related to diet and physical activity was derived from materials developed by the American Diabetes Association and the American Dietetic Association.

b: The reimbursable-lifestyle intervention was a condensed version of the intensive-lifestyle intervention, in which key elements were delivered in 4 1-hr sessions over the course of the 12-month study and included 3 group sessions and 1 individual session.

c: The intensive lifestyle intervention was derived from the lifestyle intervention of the DPP. The programme focused on moderate weight loss with a goal of 25% of calories from dietary fat and a minimum of 150 minutes/week of physical activity that was similar in intensity to brisk walking. Energy intake goals were added as necessary. The DPP intervention was delivered primarily via individual counselling sessions, and key elements included frequent, sustained contact with a trained interventionist; a structured 16-session core curriculum composed of behavioural strategies for weight loss and physical activity, such as self-monitoring of diet and physical activity; and additional behavioural strategies to assist with achieving weight loss goals that were tailored to individual needs in a culturally appropriate manner.

**Country:** USA **Location:** Two primary health care centres in rural counties of South Carolina **Period of study:** Prior to October 2004 **Inclusion criteria:** Aged 45 years or older and having had a clinical diagnosis of diabetes. Potential participants also had to have a BMI of 25 kg/m² or greater during the previous calendar year, which was confirmed by a brief medical record review. **Exclusion criteria:** Any limitation that would prohibit full participation in the study (e.g., metastatic cancer, multiple or recent [within 6 months] myocardial infarction or stroke, dialysis for end-stage renal disease, severe psychiatric disease or dementia, or inability to walk). **Recruitment:** Letter from health centre medical director and study’s principal investigator. **Baseline age (years):** Total: 60.00(NR); a: 62.40(9.5); b: 58.90(7.8); c: 59.70(8.6) **Baseline BMI (kg/m²):** Total: 36.70(NR); a: 35.20(7.5); b: 37.50(6.7); c: 37.60(6.5) **Baseline weight:** Total: NR; a: 93.00(20.3); b: 100.00(19.8); c: 99.50(17.1)

**Quantitative outcomes reported:** Weight; BMI kg/m²; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %

**Number allocated:** 137 **Completed:** Total: 91; a: 53; b: 38 **% Dropout:** Total: 33.58%; a: 23.19%; b: 44.12%

**Length of follow-up (months):** 12
### Description of interventions:

**a:** Participants received weight management intervention from a practice nurse who had been given training in the study procedures by the research team. The nurses provided the intervention in four sessions delivered over 8 weeks. The intervention included advice on (1) diet (instructions on understanding food groups, food labels and calories; eat at least five portions of a variety of fruit and vegetables each day in place of foods higher in fat and calories; eat breakfast; watch the portion size of meals and snacks; and replace high-calorie food with healthier options); and (2) activity (make enjoyable physical activities part of everyday life; minimise sedentary activities; build activity into the working day; and take up one of the local exercise opportunities). Where appropriate, participants were given an information sheet about orlistat (based on the information provided on the NHS Choices website) and advised to see their GP if they wished to use it as part of their weight loss programme.

**b:** The Weight action programme comprised eight weekly sessions, followed by monthly follow-up visits lasting up to 1 hr each. The target weight loss was 1 lb (0.45 kg)/week and individual calorie plans, based on the Harris-Benedict formula, were given. Two advisors conducted the WAP sessions in groups of 10–20 participants. As in the control intervention, participants were not barred from using any other weight loss intervention (including pharmacological treatment from their GP). They also received information about local exercise provision and where ‘exercise on prescription’ was available, they received relevant vouchers and referrals. Participants committed to implementing each of a series of concrete and verifiable tasks for at least 1 week. Group-oriented interventions aimed to increase participant retention, involvement and adherence to weekly tasks. The target weight loss was 1 lb (0.45 kg)/week.

### Length of follow-up (months):

- Total: 12

### Quantitative outcomes reported:

- Weight
- BMI kg/m²
- Waist circumference
- Systolic BP
- Diastolic BP
- Quality of life

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<table>
<thead>
<tr>
<th>Country: UK</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Location:</strong> Two Primary Care General Practices in east London</td>
<td><strong>Location:</strong> Two Primary Care General Practices in east London</td>
</tr>
<tr>
<td><strong>Period of study:</strong> Between 2012 and 2015</td>
<td><strong>Period of study:</strong> Between 2012 and 2015</td>
</tr>
<tr>
<td><strong>Inclusion criteria:</strong> Aged ≥18 years, wanted to lose weight and had an objectively measured BMI of ≥30 kg/m² or a BMI of ≥28 kg/m² plus comorbidities</td>
<td><strong>Inclusion criteria:</strong> Aged ≥18 years, wanted to lose weight and had an objectively measured BMI of ≥30 kg/m² or a BMI of ≥28 kg/m² plus comorbidities</td>
</tr>
<tr>
<td><strong>Exclusion criteria:</strong> Unable to read/write/understand English, had a BMI of &gt;45 kg/m², had lost &gt; 5% of their body weight in the previous 6 months, were currently pregnant, were taking psychiatric medications, were not registered with a GP in the participating borough areas or were involved in a current research project</td>
<td><strong>Exclusion criteria:</strong> Unable to read/write/understand English, had a BMI of &gt;45 kg/m², had lost &gt; 5% of their body weight in the previous 6 months, were currently pregnant, were taking psychiatric medications, were not registered with a GP in the participating borough areas or were involved in a current research project</td>
</tr>
<tr>
<td><strong>Recruitment:</strong> GP referrals, mailshots from GP databases and self-referrals facilitated by posters and leaflets</td>
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</tr>
<tr>
<td><strong>Baseline age (years):</strong> Total: NR; a:45.10(14.2); b:46.60(15.0)</td>
<td><strong>Baseline age (years):</strong> Total: NR; a:45.10(14.2); b:46.60(15.0)</td>
</tr>
<tr>
<td><strong>Baseline BMI (kg/m²):</strong> Total: NR; a:35.70(4.3); b:35.00(4.2)</td>
<td><strong>Baseline BMI (kg/m²):</strong> Total: NR; a:35.70(4.3); b:35.00(4.2)</td>
</tr>
<tr>
<td><strong>Baseline weight:</strong> Total: NR; a:98.30(16.6); b:95.50(15.8)</td>
<td><strong>Baseline weight:</strong> Total: NR; a:98.30(16.6); b:95.50(15.8)</td>
</tr>
</tbody>
</table>
| Melin 2003\textsuperscript{24} | **Country:** Sweden  
**Location:** Clinic for obesity treatment.  
**Period of study:** Prior to 30 October 2002  
**Inclusion criteria:** Patients were referred to the clinic due to obesity, with complications and diagnoses like diabetes mellitus type II, hypertension, dyslipoproteinaemia, polycystic ovary disease and sleep apnoea disorder  
**Exclusion criteria:** Not reported  
**Recruitment:** Patient referral  
**Baseline age (years):** Total: NR; a:40.70 (range 25 to 60); b:39.40 (range 26 to 57)  
**Baseline BMI (kg/m\(^2\)):** Total: NR; a:35.60(4.5); b:35.20(4.6)  
**Baseline weight:** Total: NR; a:97.30(20.7); b:97.80(18.3)  
**Description of interventions:**  
**BOTH GROUPS:** The VLCD periods were 25 days. The participants were instructed to decrease their energy intake successively during 3 days from 800 kcal/day down to a level of approximately 200 kcal/day, and to keep this intake during the following 19 days. The energy intake was then progressively increased again to 800 kcal/day during the last 3 days of the VLCD period.  
a: 43 continuous intensive treatment with planned group meetings every fortnight during the first year and six meetings during the second year (including the possibility to repeat the self-monitoring and obtain more information and education in nutrition, food habits and strategies to control the eating behaviour).  
b: 27 meetings, participants met more seldom, with planned group meetings every third month. They had less contact with the supervisors, fewer repetitions with self-monitoring and less possibilities of nutrition counselling.  
**Duration of active intervention:** a:24 months ; b:24 months  
**Number allocated:** 43  
**Completed:** Total:32; a:17; b:15  
**% Dropout:** Total:25.58%; a:22.73%; b:28.57%  
**Length of follow-up (months):** 24  
**Quantitative outcomes reported:** Weight; BMI kg/m\(^2\); Systolic BP; Diastolic BP; Fasting plasma glucose |
| Mensinger 2016\textsuperscript{75} | **Country:** United States  
**Location:** Community surrounding the Reading Health System in Southeastern Pennsylvania  
**Period of study:** Prior to March 4, 2016  
**Inclusion criteria:** Aged 30-45 years old, female, BMI 30-45 kg/m\(^2\), physically inactive (i.e., scoring in one of the bottom two categories on the Stanford Brief Activity Survey), and practicing birth control if heterosexual and premenopausal.  
**Exclusion criteria:** Current smokers; did not speak fluent English; were taking medications known to effect weight; were presently participating in a weight-loss program or diet; were pregnant or intending to become pregnant; had or were planning to have bariatric surgery; had type 1 or insulin-dependent type 2 diabetes; had an active neoplasm; or had a history of myocardial infarction,  
**Description of interventions:**  
a: LEARN(Lifestyle, Exercise, Attitudes, Relationships, and Nutrition) weight loss programme. While the program emphasizes weight loss as an ultimate goal, the focus is on changing diet and lifestyle and gaining skills to overcome weight loss barriers. Groups of 20 had weekly 90-min sessions on a weekday evening for the duration of 6 months LEARN program.  
b: The weight-neutral program employed was the HUGS (Health focused, Understanding lifestyle, Group supported, and Self-esteem building) Program for Better Health. Groups of 20 had weekly 90-min sessions on a weekday evening for the duration of 6 months.  
**Duration of active intervention:** a:6 months; b:6 months  
**Number allocated:** 80  
**Completed:** Total:40; a:21; b:19  
**% Dropout:** Total:50.00%; a:47.50%; b:52.50%  
**Length of follow-up (months):** 24  
**Quantitative outcomes reported:** Weight; BMI kg/m\(^2\); Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose; Quality of life |
congestive heart failure, cerebrovascular disease, renal disease, or cirrhosis. Specific psychological contraindications included bulimia nervosa, anorexia nervosa, alcohol or substance abuse, and psychiatric disturbances that significantly disrupt daily functioning (e.g., suicide ideation, current manic episode, schizophrenia). Prior to attending the study intake session where baseline measurements occurred, applicants were required to submit a clearance form that included a description of the study and its eligibility criteria, and was signed by their primary care physician.  

**Recruitment:** advertisements placed in physician offices, local coupon magazines, and the hospital’s website  

**Baseline age (years):** Total: NR; a:39.35(4.34); b:39.83(3.91)  
**Baseline BMI (kg/m²):** Total: NR; a:35.56(3.86); b:37.42(3.86)  
**Baseline weight:** Total: NR; a:105.30(13.28); b:102.10(13.28)

| Miles 2002 | Country: USA and Canada | Location: 34 centres in the U.S. and 6 centres in Canada | Period of study: Prior to July 2002 | Inclusion criteria: Patients with type 2 diabetes who were 40-65 years of age, had a BMI of 28-43 kg/m², had maintained a stable weight for 2-3 months, had HbA1c between 7.5 and 12.0%, and had received metformin treatment at 1000-2550 mg/day for at least 6 weeks. Sulfonylurea therapy in combination with metformin was permitted as long as the sulfonylurea dose was stable for 12 weeks before study entry. | Exclusion criteria: Patients receiving insulin, thiazolidinediones, or α-glucosidase inhibitors; any clinical condition that might affect study end points, including renal, hepatic, or endocrine disorders, poorly controlled hypertension (systolic blood pressure 160mmHg or over or diastolic blood pressure 100mmHg or over), active gastrointestinal disease, previous bariatric surgery, a history of bulimia, | **Description of interventions:** a: Placebo three time daily with main meals for 12 months. A reduced-calorie diet (600 kcal daily deficit) containing 30% of calories as fat, 50% as carbohydrate, and 20% as protein, with a maximum cholesterol content of 300 mg/day, was prescribed for all patients. Daily calorie intake was reduced by an additional 200 kcal after 6 months to compensate for the reduction in energy requirements. Patients received dietary counselling at baseline and at regular intervals throughout the study and were encouraged to increase their level of physical activity.  

b: Orlistat 120 mg three time daily with main meals for 12 months and reduced calorie diet as per placebo group. | **Duration of active intervention:** a: 12 months; b: 12 months | **Number allocated:** 516 | **Completed:** Total: 311; a: 146; b: 165  
% **Dropout:** Total: 39.73%; a: 44.06%; b: 35.29% | **Length of follow-up (months):** 12 | **Quantitative outcomes reported:** Weight; Weight change (%); Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; HbA1c %; Fasting plasma glucose |
substance abuse, or the use of any weight loss medications. Women who were pregnant, lactating, or of childbearing potential were also excluded.

**Recruitment:** NR

**Baseline age (years):**
- Total: NR; a: 53.70 (6.37); b: 52.50 (6.32)
- **Baseline BMI (kg/m²):**
  - Total: NR; a: 35.20 (3.19); b: 35.60 (4.74)
- **Baseline weight:**
  - Total: NR; a: 101.10 (15.94); b: 102.10 (17.39)

**Country:** Italy

**Location:** Rome

**Period of study:** Pre-2002

**Inclusion criteria:** Unclear

**Exclusion criteria:**
- Pregnancy; history or diagnosis of diabetes, heart disease, hypertension, or other chronic diseases; hormone replacement therapy; chronic steroid therapy; a history of alcohol or drug abuse; and glucose intolerance, defined as a 2 h glucose level of 140 mg/dl after a 75 g oral glucose load and of stable weight (within 2 kg, 6 months before testing), normal electrocardiogram at rest and during an exercise test.

**Recruitment:** NR

**Data for women:**
- **Baseline age (years):** Total: NR; a: NR; b: NR
- **Baseline BMI (kg/m²):** Total: NR; a: 48.30 (6.3); b: 48.40 (8.9)
- **Baseline weight:** Total: NR; a: 125.30 (12.8); b: 121.60 (24.1)

**Data for men:**
- **Baseline age (years):** Total: NR; a: NR; b: NR
- **Baseline BMI (kg/m²):** Total: NR; a: 48.00 (5.4); b: 47.80 (8.8)
- **Baseline weight:** Total: NR; a: 151.80 (17.1); b: 147.30 (26.8)

**Description of interventions:**
- **a:** Biliopancreatic diversion. Details not reported
- **b:** Diet protocol (20 kcal/kg fat free mass (FFM), 55% carbohydrates, 30% fat, and 15% proteins). The caloric content of the diet was modified every 6 months according to the DEXA analysis of FFM.

**Duration of active intervention:** a: 12 months; b: 12 months

**Data for women:**
- **Number allocated:** 52
- **Completed:** Total: 52; a: 31; b: 21%
- **Dropout:** Total: 0.00%; a: 0.00%; b: 0.00%

**Data for men:**
- **Number allocated:** 27
- **Completed:** Total: 27; a: 15; b: 12%
- **Dropout:** Total: 0.00%; a: 0.00%; b: 0.00%

**Length of follow-up (months):** 12

**Quantitative outcomes reported:** Weight; BMI kg/m²; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Fasting plasma glucose
Mingrone 2012

**Country:** Italy  
**Location:** Catholic University diabetes centre, Faculty of Medicine Rome  
**Period of study:** April 2009 to October 2011  
**Inclusion criteria:**  
Type 2 diabetes and BMI $\geq 35$ kg/m², age between 30 and 60 years, duration of diabetes $\geq 5$ years, HbA1c $\geq 7.0\%$ in spite of medical antidiabetic therapy  
**Exclusion criteria:**  
Type 1 diabetes, secondary diabetes, previous bariatric surgery, pregnancy, medical conditions requiring acute hospitalisation, severe diabetes complications or associated medical conditions (such as blindness, end-stage renal failure, liver cirrhosis, malignancy, chronic congestive heart failure), recent (within preceding 12 months) myocardial infarction, stroke or TIA, unstable angina pectoris, psychological conditions which may hamper patient's cooperation, geographic inaccessibility, any condition which, in the judgement of the Investigator, may make risky the participation in the study or bias the results  
**Recruitment:** Day Hospital of Metabolic Diseases and Diabetology of the Catholic University in Rome  
**Baseline age (years):** Total: NR; a:43.90(7.57); b:42.75(8.06); c:43.45(7.27)  
**Baseline BMI (kg/m²):** Total: NR; a:44.85(5.16); b:45.14(7.78); c:45.62(6.24)  
**Baseline weight:** Total: NR; a:129.84(22.58); b:137.85(30.35); c:136.40(21.94)  
**Description of interventions:**  
a: Laparoscopic Roux-en-Y gastric bypass: Daily multivitamin and mineral supplementation was prescribed to the surgical groups; patients undergoing biliopancreatic diversion received additional vitamin D and calcium supplementation. No other information on diet. Medical therapy discontinued if indicated.  
b: Open biliopancreatic diversion. Daily multivitamin and mineral supplementation was prescribed. No other information on diet. Medical therapy discontinued if indicated.  
c: Assessed and treated by a multidisciplinary team that included a diabetologist, a dietitian, and a nurse, with planned visits at baseline and at 1, 3, 6, 9, 12, and 24 months after study entry. Oral hypoglycaemic agents and insulin doses were optimized on an individual basis with the aim of reaching a glycated haemoglobin level of less than 7%. Programs for diet and lifestyle modification, including reduced overall energy and fat intake (<30% total fat, <10% saturated fat, and high fibre content) and increased physical exercise (~30 minutes of brisk walking every day, possibly associated with moderate-intensity aerobic activity twice a week), were designed by an experienced diabetologist with assistance from a dietitian.  
**Duration of active intervention:** a:NR; b:NR; c:24 months  
**Number allocated:** 60  
**Completed:** Total:53; a:19; b:19; c:15  
**% Dropout:** Total:11.67%; a:5.00%; b:5.00%; c:25.00%  
**Length of follow-up (months):** 60  
**Quantitative outcomes reported:**  
Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life  

Moreno 2014

**Country:** Spain  
**Location:** Hospital Obesity Unit  
**Period of study:** Prior to 16 September 2013  
**Inclusion criteria:**  
Aged 18-65 years, BMI of 30 kg/m² or more, stable body weight in the previous 3 months, desire to lose weight, and history of failed dietary efforts.  
**Exclusion criteria:**  
Type 1 diabetes mellitus or insulin therapy, obesity induced by other endocrine disorders or by drugs, any  
**Description of interventions:**  
a: The equilibrated diet had a caloric value 10% below the total metabolic expenditure of each individual. The calories ranged between 1400 and 1800 kcal/day. The ration of macronutrients provided was 45-55% carbohydrates, 15-25% proteins, and 25-35% fat, in addition to a recommended intake of 20-40 g/day of fibre in the form of vegetables and fruits.  
b: The very low calorie ketogenic diet group, followed a a commercial weight loss program (PronoKal method) based on a high-biological-value protein preparations diet and natural foods. Each protein preparation contained 15 g  
**Length of follow-up (months):** 12  
**Quantitative outcomes reported:**  
Weight; BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides;
weight loss diet or pills in the previous 6 months, severe depression or any other psychiatric disease, abuse of narcotics or alcohol, severe hepatic insufficiency, any type of renal insufficiency or gout episodes, neoplasia (except basal cell skin cancer), previous events of cardiovascular or cerebrovascular disease, kidney failure, uncontrolled hypertension, and hydroelectrolytic alterations. Females with child-bearing potential, who were pregnant, breastfeeding, intending to become pregnant, or not using adequate contraceptive methods were excluded.

**Recruitment:** Obesity unit

**Baseline age (years):** Total:45.30(8.9); a:46.30(9.3); b:44.40(8.6)

**Baseline BMI (kg/m²):** Total:35.10(4.9); a:35.10(5.3); b:35.10(4.5)

**Baseline weight:** Total: NR; a:92.10(17.7); b:97.90(18.9)

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**Description of interventions:**

Both groups: Dietary prescriptions were implemented within a standard behavioral lifestyle intervention for weight management that included two phases:

**Phase I:** Months 0-6 involved an initial treatment period of 24 weekly group sessions. Participants were instructed to follow their prescribed condition-specific energy intake goal and adhere to a balanced diet according to recommendations from the U.S. Department of Agriculture and the National Institutes of Health’s Dietary Approaches to Stop Hypertension.

**Phase II:** Months 7-12 entailed an extended care phase with six monthly group sessions. Participants were asked to attend monthly in-person group sessions and maintain caloric intake goals and exercise behaviors prescribed during the initial treatment phase.

a: Dietary goal of 1000 kcal/day

b: Dietary goal of 1500 kcal/day

**Duration of active intervention:** a:12 months; b:12 months

**Number allocated:** 79

**Completed:** Total:53; a:26; b:27

**% Dropout:** Total:32.91%; a:35.00%; b:30.77%
<table>
<thead>
<tr>
<th>Country: Norway</th>
<th><strong>Description of interventions:</strong></th>
<th>Length of follow-up (months): 18</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location:</strong> Department of Internal Medicine, Sørlandet Hospital HF Kristiansand, Norway.</td>
<td>a: The individual group consulted the study physician at six, twelve and eighteen months after randomisation and otherwise received care from their GP as usual.</td>
<td>Quantitative outcomes reported: Weight; BMI kg/m²; Waist circumference; Total cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma</td>
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<tr>
<td><strong>Period of study:</strong> From March 2004 to September 2005</td>
<td>b: The individual plus interdisciplinary group participated in a group based program (≤ 10 participants), one day (5 hr/day) each week for six weeks and a new gathering after twelve weeks. They also consulted the study physician at six, twelve and eighteen months after randomisation and otherwise received care from their GP as usual.</td>
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<tr>
<td><strong>Inclusion criteria:</strong> Individuals aged 18-64 years with a Finnish Diabetes Risk score ≥ 9</td>
<td><strong>Duration of active intervention</strong></td>
<td></td>
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<tr>
<td><strong>Exclusion criteria:</strong> A diagnosis of diabetes mellitus, the presence of serious heart, lung, kidney or liver failure, serious psychiatric illness, substance abuse and not mastering the Norwegian language</td>
<td>a: 18 months; b: 18 months</td>
<td></td>
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<tr>
<td><strong>Recruitment:</strong> General Practitioner</td>
<td><strong>Number allocated:</strong> 213</td>
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<tr>
<td><strong>Baseline age (years):</strong> Total:46.50(11); a:45.90(11); b:47.00(11)</td>
<td><strong>Completed:</strong> Total:182; a:89; b:93</td>
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<tr>
<td><strong>Baseline BMI (kg/m²):</strong> Total:36.80(6); a:35.90(6); b:37.60(6)</td>
<td>% <strong>Dropout:</strong> Total:14.55%; a:14.42%; b:14.68%</td>
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</tbody>
</table>
Country: United States
Location: 16 U.S. sites across 13 states
Period of study: Prior to 18 March 2016
Inclusion criteria:
Type 2 diabetes, HbA1c between 7%–11%, fasting blood glucose < 240, BMI 27-50 kg/m², age 18 – 70 years, clearance on medical exam by study physician including EKG, no weight loss over the previous 3 months (5 kg loss is acceptable with physician discretion), on stable regimen of all medications (including diabetes) for at least 3 months (brief regimens of medications such as antibiotics, steroids, etc. are permitted), all diabetes medications are permitted including insulin, willing and able to commit to regular physical activity (e.g. walking) five days/week, willingness and ability to make all scheduled appointments required by study protocol, make all scheduled appointments required by study protocol, attend weekly Weight Watchers meetings in the community and to participate in Weight Watchers online program, if so randomized, follow requirements of study protocol, provide a valid email address for use in the study, able to communicate (oral and written) in English, under the care of a physician for diabetes, willing to give release to contact the MD and request MD’s agreement for participant to participate
Exclusion criteria:
1. Type 1 Diabetes, 2. Cardiovascular/Coronary Heart Disease, 3. Current severe depression or history of severe depression within the previous year, based on DSM-IV-TR criteria for Major Depressive Episode, 4. Taking prescription or OTC weight loss medications within last 4 weeks, 5. Currently taking other medications that affect weight, 6. Within the last 4 weeks, use of chromium supplements or any nutrition supplements or herbal products claimed to have a weight loss effect, 7. Participation in a weight control program within the past 3 months, 8. QTc interval >450 msec for males and QTc interval >470 msec for females, 9. PHQ-9 total score > 15, 10. Untreated thyroid disease, 11. History of a

Description of interventions:

a: Weight Watchers (WW) modified for people with type 2 diabetes. WW participants were provided free access to the ongoing, weekly, in-person WW meetings in their communities and the standard online tool.
b: Standard care participants received a nutritional consultation with a registered dietitian. Participants were instructed in healthier food choices for diabetes control and given a meal plan for a ~500 kcal/day deficit hypocaloric, carbohydrate-controlled and fibre rich diet, with other guidance regarding meal spacing and portion control.

Duration of active intervention: a:NR; b:NR
Number allocated: 563
Completed: Total: 484; a:230; b:254
% Dropout: Total: 14.03%; a:17.56%; b:10.56%

Length of follow-up (months): 12
Quantitative outcomes reported:
Weight; Weight change (%); Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose
surgical procedure for weight loss at any time, 12. History of major surgery within three months of enrolment, 13. Presence of implanted cardiac defibrillator, 14. Orthopaedic limitations that would interfere with ability to engage in regular physical activity, 15. Gastrointestinal disorders including chronic malabsorptive conditions, peptic ulcer disease, Crohn’s disease, chronic diarrhoea or active gallbladder disease, 16. Current cancer or cancer treatment, or a history of cancer or cancer treatment within the last 3 years. Persons with successfully resected basal cell carcinoma of the skin may be enrolled if treatment was completed more than 6 months prior to enrolment, 17. History, within the past five years, of clinically diagnosed eating disorders, 18. Women who are pregnant, lactating, trying to become pregnant or unwilling to use an effective means of birth control, 19. Participation in another clinical trial within 30 days prior to enrolment, 20. Currently consuming >14 alcoholic drinks (1 drink = 12 fl oz. beer, 4 fl oz. wine or 1.5 fl oz. liquor)/week and unwilling to limit intake to less than 3 drinks per drinking day during study participation, 21. Current or past drug abuse, 22. Participation in trial by another member of household, 23. Hypoglycaemic Events (Evidence of more than 1 severe hypoglycaemic event in the past 12 months, unless the participant’s treating physician provides written clearance for participation), 24. Any other condition which makes it inadvisable for the candidate to participate in the trial.

Recruitment: NR
Baseline age (years): Total: NR; a:NR; b:NR
Baseline BMI (kg/m²): Total:37.08(NR); a:NR; b:NR
Baseline weight: Total: NR; a:104.00(19.4); b:106.20(19.9)
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Location</th>
<th>Period of study</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Recruitment</th>
<th>Baseline age (years)</th>
<th>Baseline BMI (kg/m²)</th>
<th>Baseline weight</th>
<th>Description of interventions</th>
<th>Duration of active intervention</th>
<th>Number allocated</th>
<th>Completed</th>
<th>Dropout %</th>
<th>Length of follow-up (months)</th>
<th>Quantitative outcomes reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ostbye 2015&lt;sup&gt;33&lt;/sup&gt;</td>
<td>USA</td>
<td>Workplace</td>
<td>January 2011 and July 2012.</td>
<td>Employees must have a BMI &gt;30 kg/m²; benefit-eligible, enrolled in one of the health insurance programs offered through Duke, and not planning to leave Duke during the next 12 months</td>
<td>Pregnancy and enrolment in the weight management programme as a means to qualify for bariatric surgery</td>
<td>Identified by employee health nurses at complimentary health screening events</td>
<td>Total: NR; a:NR; b:NR</td>
<td>Total:37.20(6.38); a:37.02(6.14); b:37.37(6.61)</td>
<td>Total: NR; a:NR; b:NR</td>
<td>a: The weight management (WM) programme incorporated portions of the WM+ programme but without the behavioural modification coaching aspect. The WM programme relied on educating participants about weight management strategies, and is informed by constructs of the information processing paradigm. &lt;br&gt;b: WM+ involved once-a-month contacts with a health coach who provides relevant materials, helps with goal-setting, encourages self-monitoring to boost self-efficacy, and assists in problem solving and reduction of barriers. The intervention is stage-based, and counsellors work with the participant at his/her level of readiness to change using, motivational interviewing.</td>
<td>a:12 months; b:12 months</td>
<td>550</td>
<td>Total:436; a:221; b:215</td>
<td>Total:20.73%; a:19.64%; b:21.82%</td>
<td>14</td>
<td>BMI kg/m²</td>
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<tr>
<td>Pascale 1995&lt;sup&gt;34&lt;/sup&gt;</td>
<td>USA</td>
<td>Pittsburgh University</td>
<td>Prior to September 1995</td>
<td>At least 20% above ideal body weight based on the 1983 Metropolitan Life Insurance norms. High-risk participants were required to have at least one biological parent with noninsulin dependent diabetes mellitus (NIDDM). Individuals with diabetes were required to meet the criteria specified by the National Diabetes Data Group for NIDDM and had to be using diet only or oral medications to control their blood glucose levels.</td>
<td>NR</td>
<td>Newspaper advertisements</td>
<td>Total: NR; a:NR; b:NR; c:NR; d:NR</td>
<td>Total:36.40(4.7); b:36.10(5.6); c:35.00(4.4); d:36.30(4.2)</td>
<td>Total: NR; a:93.10(13.0); b:94.50(14.6); c:95.30(13.3); d:94.40(9.5)</td>
<td>a: 1000-1500 kcal/day calorie controlled diet (CAL), given general information about healthy eating and encouraged to keep their fat intake at &lt;30% of calories/day. Participants were taught about the benefits of exercise on weight, glycaemic control, and other CHD risk factors. Participants were taught behaviour modification principles to enhance self-management of calorie intake and expenditure. &lt;br&gt;b: Same as CAL groups but with fat consumption goal of 20% of total calories. &lt;br&gt;c: Identical to CAL (NIDDM) group; &lt;br&gt;d: Identical to CAL+FAT (family history) group</td>
<td>a:12 months; b:12 months; c:12 months; d:12 months</td>
<td>90</td>
<td>Total:60; a:16; b:16; c:13; d:15</td>
<td>Total:33.33%; a:27.27%; b:30.43%; c:43.48%; d:31.82%</td>
<td>12</td>
<td>Weight; BMI kg/m²; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; HbA1c %; Fasting plasma glucose</td>
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<tr>
<td>Country: Australia</td>
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<td>Period of study: Prior to December 2, 2014</td>
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<td>Inclusion criteria: BMI ≥ 27 kg/m², type 2 diabetes, aged 18-75 years, albuminuria (30-600 mg/24 h or an albumin to creatinine ratio of 3.0-60.0 mg/mmol, with an estimate glomerular filtration rate of &gt;40 ml/min/1.73 m²)</td>
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<td>Exclusion criteria: Impaired kidney function not due diabetes, coronary artery disease or any other active disease of clinical significance</td>
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<td>Recruitment: Advertisements in local newspapers, radio and television</td>
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<td>Baseline age (years): Total: NR; a:59.40(10.08); b:62.40(8.33)</td>
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<td>Baseline BMI (kg/m²): Total: NR; a:36.70(NR); b:35.40(NR)</td>
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<tr>
<td>Baseline weight: Total: NR; a:108.10(22.91); b:104.70(18.62)</td>
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<tr>
<td>Description of interventions: BOTH GROUPS: Both diet regimes aimed at reducing body weight with energy content reduced to 6000 kJ/1500 kcal with an allowance to 1800 kcal/day or less for men.</td>
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<tr>
<td>a: High protein diet patients received a prescription diet of 30% protein (90-120 g/day), 30% fat, 40% carbohydrate from the total energy.</td>
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<tr>
<td>b: Standard protein diet patients received a prescription for a diet of 20% protein (55-77 g/day), 30% fat, 50% carbohydrate from the total energy.</td>
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<tr>
<td>Duration of active intervention: a:12 months ; b:12 months</td>
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<td>Number allocated: 76</td>
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<tr>
<td>Completed: Total:45; a:21; b:24</td>
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<tr>
<td>% Dropout: Total:40.79%; a:72.37%; b:68.42%</td>
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<tr>
<td>Length of follow-up (months): 12</td>
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<tr>
<td>Quantitative outcomes reported: Weight; Weight change (%); BMI kg/m²; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose</td>
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</table>

<table>
<thead>
<tr>
<th>Country: Finland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location: At an outpatient obesity clinic, Peijas Hospital, Helsinki University Central Hospital</td>
</tr>
<tr>
<td>Period of study: Prior to March 2015</td>
</tr>
<tr>
<td>Inclusion criteria: BMI over 35 kg/m², age 18-65 years, and stable weight three months</td>
</tr>
<tr>
<td>Exclusion criteria: Contraindications to use VLCD, participating in the same treatment within five years, pregnancy, malignant disease, acute coronary event, current severe alcohol/narcotic abuse, or psychic problem/bulimia nervosa</td>
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<tr>
<td>Recruitment: Referral by primary and occupational health care</td>
</tr>
<tr>
<td>Baseline age (years): Total: NR; a:47.30(10.5); b:47.40(10.1)</td>
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<tr>
<td>Baseline BMI (kg/m²): Total: NR; a:42.10(5.7); b:41.40(6.4)</td>
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<tr>
<td>Description of interventions: BOTH GROUPS: 17 week weight loss phase with a behavioural intervention and VLCD (Nutritett, Nutrifast, or Dietta Mini) during weeks 2-11. Daily energy intake was 2200-2340 kJ (500-550 kcal).</td>
</tr>
<tr>
<td>a: No weight maintenance follow-up.</td>
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<tr>
<td>b: 1-year weight maintenance programme. Monthly behavioural sessions and two physiotherapist-led Nordic walking or gym sessions.</td>
</tr>
<tr>
<td>Duration of active intervention: a:17 weeks ; b:17 weeks + one year of maintenance programme</td>
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<tr>
<td>Number allocated: 201</td>
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<tr>
<td>Completed: Total:143; a:75; b:68</td>
</tr>
<tr>
<td>% Dropout: Total:28.86%; a:25.00%; b:32.67%</td>
</tr>
<tr>
<td>Length of follow-up (months): 17</td>
</tr>
<tr>
<td>Quantitative outcomes reported: Weight; Weight change (%); BMI kg/m²; Quality of life</td>
</tr>
</tbody>
</table>
| Perri 2001\(^{87}\) | **Country:** United States  
**Location:** Not reported  
**Period of study:** Prior to August 2001  
**Inclusion criteria:**  
21-60 years of age, BMI 27-40 kg/m\(^2\), in good health, had a physician's approval to participate in a diet-plus-exercise weight-loss intervention  
**Exclusion criteria:** NR  
**Recruitment:** Newspaper advertisements  
**Baseline age (years):** Total: NR; a:45.23(10.08); b:49.17(7.21); c:45.36(9.33)  
**Baseline BMI (kg/m\(^2\)):** Total: NR; a:36.37(4.70); b:35.00(3.96); c:36.10(4.93)  
**Baseline weight:** Total: NR; a:94.67(11.35); b:96.95(13.69); c:97.96(16.01) | **Description of interventions:**  
**ALL GROUPS:** All participants attended initial weekly standard cognitive behavioural weight-loss intervention group sessions over 20 weeks. Participants were instructed to follow a low-calorie diet (i.e. 1200 kcal/day for women), low-fat diet (i.e., 25% of total kcal/day). Participants were also instructed to complete a home-based walking program consisting of 30 min/day, 5 days/week.  
a: Standard behavioural therapy (SBT) weight-management techniques were taught during the first 20 weeks. During the year following initial treatment, the participants received no additional therapy contacts but were asked to return for follow-up assessments 6 and 12 months later.  
b: SBT + relapse prevention training participants received a year-long programme of biweekly sessions. Participants were taught cognitive and behavioural skills for anticipating, avoiding or coping with lapses in diet and exercise.  
c: SBT + problem solving therapy participants received a year-long programme | **Length of follow-up (months):** 17  
**Quantitative outcomes reported:**  
Weight |
of biweekly sessions were problem situations were described by the group members, and staff provided five-stage problem-solving model.

**Duration of active intervention:** a:20 weeks; b:17 months ; c:17 months

**Number allocated:** 103

**Completed:** Total:58; a:15; b:20; c:23

**% Dropout:** Total:43.69%; a:NR; b:NR; c:NR

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| Perri 2008[^8] | Country: USA  
Location: Local Cooperative Extension Service (CES) offices  
Period of study: June 1 2003 to May 31 2007  
Inclusion criteria: Women, aged 50 to 75 years, BMI greater than 30 kg/m² and a body weight less than 159.1 kg  
Exclusion criteria: Uncontrolled hypertension or diabetes mellitus and active (within 12 months) manifestations of cardiovascular, cerebrovascular, renal, or hepatic disease, the use of medications known to affect body weight and a weight loss of 4.5 kg, substance abuse and clinically significant depression  
Recruitment: Study announcements were mailed to households  
Baseline age (years): Total:59.40(6.1); a:58.60(6.0); b:59.80(6.2); c:59.20(6.2)  
Baseline BMI (kg/m²): Total:36.80(4.9); a:36.20(4.3); b:36.90(5.7); c:37.10(4.5)  
Baseline weight: Total:96.40(15.6); a:95.00(13.4); b:96.40(16.8); c:97.80(14.3)  
Description of interventions: ALL GROUPS: A standard 6-month lifestyle modification programme for weight loss, modelled after the DPP and included a low-calorie eating plan (1200 kcal/day), increased physical activity (30 min/day walking) and training in behaviour modification strategies. Also included issues of special concern to women from rural areas. Participants were then randomised to the extended care phase.  
a: Education control: Participants received 26 biweekly newsletters that contained tips for maintaining weight-loss progress along with recipes for low-calorie meals.  
b: Telephone counselling, including 26 biweekly sessions conducted with the same counsellors who led the initial lifestyle programme. The telephone contacts were scheduled in advance. The sessions addressed barriers to maintaining eating and exercise behaviours required for sustaining lost weight.  
c: Face-to-face counselling, including 26 biweekly group sessions, that was conducted by the same counsellors who led the initial lifestyle program. The 60-minute sessions addressed barriers to the maintenance of eating and exercise behaviours required for sustaining lost weight.  
Duration of active intervention: a:18 months; b:18 months; c:18 months  
Number allocated: 234  
Completed: Total:220; a:75; b:70; c:75  
% Dropout: Total:5.98%; a:5.06%; b:2.78%; c:9.64%  
Length of follow-up (months): 18  
Quantitative outcomes reported: Weight; BMI kg/m²; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %  |
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Location: Ten rural counties in northern Florida  
Period of study: Prior to 16 May 2014  
Inclusion criteria:  
Description of interventions: a: Sixteen nutrition education sessions. Each session included a lecture on a topic relevant to nutrition, physical activity, or weight control, followed by a group discussion of how the information was relevant to health and weight management. The schedule of sessions provided to participants in the  
Length of follow-up (months):24  
Quantitative outcomes reported: Weight change (%)  |

[^8]: Perri 2008
[^9]: Perri 2014
21-75 years of age, BMI 30 to 45 kg/m², free of uncontrolled hypertension and diabetes and no active (within 12 months) manifestations of cardiovascular, cerebrovascular, renal, or hepatic disease.

**Exclusion criteria:** use of medications known to affect body weight, a weight change of 4.5 kg or greater in the preceding six months, and musculoskeletal conditions that precluded walking for 30 min, psychosocial contraindications including substance abuse and clinically significant depression.

**Recruitment:** Study announcements were mailed to households.

**Baseline age (years):**
- Total: 52.30 (11.5)
- a: 52.00 (10.8)
- b: 51.50 (12.3)
- c: 52.80 (10.6)
- d: 53.20 (12.0)

**Baseline BMI (kg/m²):**
- Total: 36.30 (4.0)
- a: 36.30 (3.9)
- b: 36.10 (4.2)
- c: 36.20 (3.8)
- d: 36.70 (4.0)

**Baseline weight:**
- Total: 100.60 (15.3)
- a: 100.10 (14.4)
- b: 102.00 (16.6)
- c: 98.60 (15.6)
- d: 101.60 (14.8)

**CONTROL condition was identical to that of the LOW dose lifestyle condition.**

b, c, d: LOW, MODERATE AND HIGH GROUPS: The contents of the lifestyle program employed in the LOW, MOD, and HIGH conditions were modelled after the Diabetes Prevention Program (DPP) and included the following components: (a) a low-calorie eating pattern (1200 kcal/day for participants weighing <114 kg, 1500 kcal/day for those weighing 114-136 kg, and 1800 kcal/day for those weighing >136 kg); (b) increased physical activity in the form of 30 min/day of walking above baseline levels; and (c) training in behaviour modification strategies. Modifications to the DPP approach included group rather than individual counselling and home-based rather than centre-based exercise. The intervention content and the accompanying written materials provided to participants was the same for the LOW, MOD, and HIGH conditions, but the time available for discussion varied according to the dose of treatment.

**Duration of active intervention**
- a: 16 weeks (Phase 1 = 8 weeks, Phase 2 = 8 weeks)
- b: 16 weeks (Phase 1 = 8 weeks, Phase 2 = 8 weeks)
- c: 32 weeks (Phase 1 = 16 weeks, Phase 2 = 16 weeks)
- d: 48 weeks (Phase 1 = 24 weeks, Phase 2 = 24 weeks)

**Number allocated:** 612

Completed: Total: 492; a: 142; b: 112; c: 112; d: 126

% Dropout: Total: 19.61%; a: 15.98%; b: 24.32%; c: 16.42%; d: 21.74%

**Description of interventions:**
- a: Control: Will receive same lifestyle intervention as the intervention group after one year.;
- b: Orlistat + lifestyle: 120 mg orlistat three daily with meals, one vitamin and mineral capsule daily to replace fat-soluble vitamins. Participants were instructed to lower their caloric intake by at least 500 kcal/day in order to achieve a slow gradual weight loss of approximately 1 pound/week. Fat intake was limited to approximately 30% of total daily calories. 24 weekly intervention classes, six bimonthly, and three monthly maintenance classes led by a bilingual Mexican American registered dietitian with training in cognitive behavioural modification. The lifestyle intervention was designed to be culturally appropriate for the target population. The physical activity objective was to increase activity to a minimum of five times/week for 30 min per session for a total of ≥150 min/week.

**Length of follow-up (months):** 12

**Quantitative outcomes reported:** Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP
<table>
<thead>
<tr>
<th>Baseline age (years):</th>
<th>Total: NR; a:43.70(9.2); b:42.40(9.2)</th>
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<tbody>
<tr>
<td>Baseline BMI (kg/m²):</td>
<td>Total: NR; a:36.00(5.2); b:37.80(6.2)</td>
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<tr>
<td>Baseline weight:</td>
<td>Total: NR; a:92.20(15.4); b:96.40(17.3)</td>
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Exercise contracts were also used to promote physical activity and incentives provided to motivate participants to become more physically active.

**Duration of active intervention:** a:NR; b:1 year

**Number allocated:** 108

**Completed:** Total:66; a:34; b:32

**% Dropout:** Total:38.89%; a:34.62%; b:42.86%

Purcell 2014

**Country:** Australia

**Location:** Clinical Research Unit at a Melbourne metropolitan hospital

**Period of study:** Between August 2008 and July 2013

**Inclusion criteria:**
BMI ≥30 and ≤45 kg/m², otherwise healthy, aged between 18 and 70 years, weight stable for 3 months.

**Exclusion criteria:**
- Pregnancy or breast-feeding.
- History of surgical procedures or laxative abuse for weight loss.
- The use of any VLCD or weight lowering drugs in the past three months.
- Inability to attend scheduled examinations and visits.
- For females taking an oral contraceptive pill or hormone replacement: dose must have been stable for the past three months.
- For patients receiving thyroid hormone replacement: dose must have been stable for the past three months.
- Surgical intervention planned during the study.
- Any recent (less than six months) cessation of smoking and current smokers.
- Participation in another study, or administration of any investigational drug in the past three months.
- Uncontrolled and clinically significant disease or known malignancy that could interfere with the study conduct.
- Presence of any clinically significant renal or endocrine disease (including diabetes) according the Investigator or as revealed by screening blood tests.
- Use of anti-depressant and antiepileptic medications known to have weight gaining effect, participants with known history of alcoholism or drug abuse or dependence within 1 year prior to screening, participants had obesity in early childhood will be excluded to avoid monogenetic obesity.

**Recruitment:** Radio and newspaper advertisements and by word of mouth

**Description of interventions:**

- a: Rapid weight loss; Participants consumed a commercially available very low energy diet preparation for 12 weeks and were then instructed to follow an individualised diet for weight maintenance for 144 weeks, based on the Australian Guide to Healthy Eating”.
- Participants had individual sessions with the dietitian at weeks 4 and 12, and then every 12 weeks for 144 weeks.

- b: Gradual weight loss; Participants consumed an energy-reduced diet (400-500 kcal/day deficit), with one to two meal replacements every day. Participants were instructed to follow an individualised diet for weight maintenance for 144 weeks, based on the Australian Guide to Healthy Eating,” and Articles had individual sessions with the dietitian at weeks 4 and 12, and then every 12 weeks for 144 weeks.

**Duration of active intervention**

- a: 3 years; b: 3.5 years

**Number allocated:** 204

**Completed:** Total:104; a:61; b:43

**% Dropout:** Total:49.02%; a:39.00%; b:58.65%

**Length of follow-up (months):** 36

**Quantitative outcomes reported:**
Weight; BMI kg/m²; Waist circumference
Baseline age (years): Total: 49.80(10.9); a: 49.60(10.9); b: 50.10(11.1)
Baseline BMI (kg/m²): Total: 35.30(3.8); a: 35.20(3.7); b: 35.50(4.0)
Baseline weight: Total: 96.80(14.0); a: 96.40(13.8); b: 97.20(14.2)

| Rapoport 2000⁹² | **Country:** United Kingdom  
**Location:** The sessions of intervention and control group run in GP surgeries or local health clinics  
**Period of study:** Prior to December 2000  
**Inclusion criteria:**  
Women aged 18-65 years, BMI ≥28 kg/m², identified by their GP as suitable for participation in a group treatment for obesity, and not currently involved in any other method of weight management.  
**Exclusion criteria:**  
Serious medical or psychiatric conditions (including eating disorders), insulin dependent diabetes, and pregnancy or lactation. Patients receiving treatment for non-insulin dependent diabetes, hypertension and hyperlipidaemia were accepted provided their GP confirmed that they were not expected to change their medical treatment over the study period.  
**Recruitment:**  
Letters to general practitioners, posters in health centers and notices in the local media  
**Baseline age (years):** Total: NR; a: 49.00(10); b: 46.00(12)  
**Baseline BMI (kg/m²):** Total: NR; a: 35.40(6.3); b: 35.30(5.6)  
**Baseline weight:** Total: NR; a: 94.00(16.1); b: 94.80(16.3)  
**Description of interventions:**  
**BOTH GROUPS:** Both treatment programmes involved weekly, 2h group sessions over a 10 week period led health professionals.  

- **a:** Modified CBT; The primary aim of the M-CBT was weight management (ie prevention of further weight gain) through permanent lifestyle change. Weight loss was neither set as a goal of treatment, nor promised, although it was expected that modest weight loss might occur as a consequence of the lifestyle change. The second aim was to reduce the social and the medical health risks of obesity. The programme emphasized regular physical activity and healthy eating as means to improve overall health rather than focusing on deliberate energy restriction and rapid weight loss. The M-CBT programme used basic behavioural and cognitive principles to facilitate acceptance and change, but also incorporated elements from psychoeducational, non-dieting and feminist approaches.

- **b:** Standard CBT - The main aim of the S-CBT treatment was to achieve healthy weight loss with a moderate energy-deficit, weight-reducing diet, providing approximately 1200 kcal/day. Cognitive and behavioural methods used to achieve this included self-monitoring, stimulus control, exposure and response prevention, modifying self-defeating cognitions, social support, problem solving, goal setting, positive reinforcement and relapse prevention.

**Duration of active intervention:** a: 12 months follow-up; b: 12 months follow-up

**Number allocated:** 84  
**Completed:** Total: 58; a: 30; b: 28  
**% Dropout:** Total: 30.95%; a: 28.57%; b: 33.33%

**Quantitative outcomes reported:**  
Weight; BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose

<table>
<thead>
<tr>
<th>Length of follow-up (months): 12</th>
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**Country:** United States  
**Location:** Throughout the project, participants met once a month with project staff; in their homes or other place of their choosing.  
**Period of study:** Prior to January 2015  
**Inclusion criteria:** The sample was limited to low-income participants who (a) had a self-reported mobility impairment, (b) had BMI $\geq 25 \text{ kg/m}^2$, (c) qualified or were eligible for Medicaid, and (d) lived within 60 miles of Wichita, KS (USA).  
**Exclusion criteria:** Potential participants were excluded if they had a diagnosis of Type I diabetes, acute heart disease, cancer, or other medical conditions that would affect energy metabolism, or if they had participated in another weight loss program within the last year.  
**Recruitment:** Flyers and talking with health care and other providers in hospitals, clinics, doctor's offices, and agencies serving individuals with physical disabilities  
**Baseline age (years):** Total: NR; a: Median 52.40 (NR); b: Median 52.80 (NR)  
**Baseline BMI (kg/m$^2$):** Total: NR; a: 42.50 (NR); b: 45.90 (NR)  
**Baseline weight:** Total: NR; a: NR; b: NR  
**Description of interventions:**  
**BOTH GROUPS:** The diet programs consisted of 6 months of active dieting, followed by either 6 months of additional dieting or weight maintenance (chosen by the participant, 12 months total). Throughout the project, participants met once a month with project staff; in their homes or other place of their choosing. Each participant was randomly assigned to one of the diets with approximately 1200-1500 calories (adjusted upward based on initial weight)  

a: The modified Stop Light Diet consisted of (a) at least 5 daily servings of (fresh, canned or frozen) fruits and vegetables. (b) 2 meal replacement shakes (c) 2 packaged entrees of 300 calories or less, typically found in grocery stores.  

b: The Usual Care diet consisted of (a) At least 5 portions of fruits and vegetables  
(b) 3 portions of dairy products (c) 2 portions of protein (d) 4 portions of grains.  
**Duration of active intervention:** a: 12 months; b: 12 months total  
**Number allocated:** 126  
**Completed:** Total: 60; a: 29; b: 31  
**% Dropout:** Total: 52.38%; a: 54.69%; b: 50.00%  
**Length of follow-up (months):** 12  
**Quantitative outcomes reported:** Weight (kg); BMI kg/m$^2$
<p>| <strong>Country:</strong> Brazil  | <strong>Description of interventions:</strong>  |
| <strong>Location:</strong> University of Campinas, Sao Paulo | a: Roux-en-Y. The goals of intervention prior to surgery were: a reduction in intake of saturated fatty acid to less than 15% of energy consumed; an increase in intake of monounsaturated fatty acid to 15% or more of energy consumed; an increase in fibre intake to at least 20 g per 1000 kcal; and moderate exercise for at least 30 min/day for at least 5 days/week. Behavioural and psychological counselling was also offered. The dietary advice was tailored to each participant on the basis of 3-day food records.  |
| <strong>Period of study:</strong> Prior to October 2010 | b: Given general, oral and written information about healthy food choices and general guidance on increasing their level of physical activity at baseline and at subsequent visits, but no specific individualized programme was offered to them. In the final study, the same intervention and surgery were offered to all participants in the control group.  |
| <strong>Inclusion criteria:</strong>  | <strong>Duration of active intervention:</strong> a: 2 years; b: 2 years  |
| Male, BMI over 40 kg/m², undergoing evaluation and follow-up for gastric bypass  | <strong>Number allocated:</strong> 20  |
| <strong>Exclusion criteria:</strong>  | <strong>Completed:</strong> Total: 20; a: 10; b: 10  |
| Co-morbidities requiring regular drug usage (statin, antihypertensive, oral anti-diabetic), endocrine disease (except mild hypogonadism) or recent hormonal manipulation (thyroid/other hormonal reposition/block in the last 3 months), testicular impairment, previous history of alcohol or tobacco abuse and phosphodiesterase type-5 inhibitor usage  | <strong>% Dropout:</strong> Total: 0.00%; a: 0.00%; b: 0.00%  |
| <strong>Recruitment:</strong> From patients undergoing evaluation and follow-up for gastric bypass at University of Campinas  | <strong>Length of follow-up (months):</strong> 24  |
| <strong>Baseline age (years):</strong> Total: NR; a: 36.70 (11.5); b: 42.20 (11.0)  | <strong>Quantitative outcomes reported:</strong> Weight; BMI kg/m²  |
| <strong>Baseline BMI (kg/m²):</strong> Total: NR; a: 55.70 (7.8); b: 54.00 (6.1)  |  |
| <strong>Baseline weight:</strong> Total: NR; a: 168.60 (28.2); b: 160.40 (20.1)  |  |</p>
<table>
<thead>
<tr>
<th>Country: USA</th>
<th>Country: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location</strong>: recruited and enrolled at two study sites (University of California, San Diego; University of Minnesota, Minneapolis)</td>
<td><strong>Location</strong>: 9 clinical research centres</td>
</tr>
<tr>
<td><strong>Period of study</strong>: Recruitment between March and August 2012</td>
<td><strong>Period of study</strong>: Prior to January 2007</td>
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<tr>
<td><strong>Inclusion criteria</strong>: History of type 2 diabetes confirmed by a physician; aged ≥18 years; BMI 25–45 kg/m²; not pregnant or breastfeeding or planning to become pregnant in the next year; willing to participate in any of the study diet arms over a 1-year period; no eating disorders, food allergies, or food intolerances; no history of bariatric surgery; and willing and able to perform a step test for assessing cardiopulmonary fitness</td>
<td><strong>Inclusion criteria</strong>: Aged 18-65 years with abdominal obesity defined as a BMI 30-45 kg/m² and a waist circumference greater than or equal to 102 cm (men) or 92 cm (women) plus one of the following: impaired fasting glucose, diet-treated type 2 diabetes or dyslipidaemia, and/or serum triglycerides between 2.0 mmol/l and 10.0 mmol/l. Body weight loss of at least 5% during the VLED was required to be eligible for randomisation</td>
</tr>
<tr>
<td><strong>Exclusion criteria</strong>: Not reported</td>
<td><strong>Exclusion criteria</strong>: Not reported</td>
</tr>
</tbody>
</table>

| **Baseline age (years)**: Total: NR; a: 46.70 (range 19 to 63); b: 47.20 (range 20 to 64) | **Baseline age (years)**: Total: NR; a: NR; b: NR |
| **Baseline BMI (kg/m²)**: Total: NR; a: 97.60 (4); b: 96.20 (4.9) | **Baseline BMI (kg/m²)**: Total: NR; a: NR; b: NR |

**Description of interventions:**

**BOTH GROUPS:** Initial weight loss was induced by an 8 week very low energy diet (600-800 kcal/day). Participants who lost >5% of their body weight were then randomised to lifestyle counselling with either placebo or orlistat.

- **a:** Placebo: After the 8 week VLED, the participants were instructed to follow a standard energy restricted diet (600 kcal daily deficit) during the following 3 years of the intervention. A dietitian provided dietary and lifestyle counselling at each visit. Patients were advised to reduce fat to ~30% of total energy and increasing the intake of fruits and vegetables and limiting sweets, cookies, and desserts. Advice to increase daily physical activity was also given.

- **b:** Orlistat: As per placebo group but participants received orlistat 120 mg three times/day.

**Duration of active intervention:** a: 3 years; b: 3 years

**Number allocated:** 309

**Completed:** Total: 200; a: NR; b: NR

**% Dropout:** Total: 35.28%; a: NR; b: NR

**Length of follow-up (months):** 36

**Quantitative outcomes reported:**
- Weight; Weight change (%)
- Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose

<table>
<thead>
<tr>
<th>Rock 2014</th>
<th>Richelsen 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country: USA</strong></td>
<td><strong>Country: Scandinavia</strong></td>
</tr>
<tr>
<td><strong>Location</strong>: recruited and enrolled at two study sites (University of California, San Diego; University of Minnesota, Minneapolis)</td>
<td><strong>Location</strong>: 9 clinical research centres</td>
</tr>
<tr>
<td><strong>Period of study</strong>: Recruitment between March and August 2012</td>
<td><strong>Period of study</strong>: Prior to January 2007</td>
</tr>
<tr>
<td><strong>Inclusion criteria</strong>: History of type 2 diabetes confirmed by a physician; aged ≥18 years; BMI 25–45 kg/m²; not pregnant or breastfeeding or planning to become pregnant in the next year; willing to participate in any of the study diet arms over a 1-year period; no eating disorders, food allergies, or food intolerances; no history of bariatric surgery; and willing and able to perform a step test for assessing cardiopulmonary fitness</td>
<td><strong>Inclusion criteria</strong>: Aged 18-65 years with abdominal obesity defined as a BMI 30-45 kg/m² and a waist circumference greater than or equal to 102 cm (men) or 92 cm (women) plus one of the following: impaired fasting glucose, diet-treated type 2 diabetes or dyslipidaemia, and/or serum triglycerides between 2.0 mmol/l and 10.0 mmol/l. Body weight loss of at least 5% during the VLED was required to be eligible for randomisation</td>
</tr>
<tr>
<td><strong>Exclusion criteria</strong>: Not reported</td>
<td><strong>Exclusion criteria</strong>: Not reported</td>
</tr>
</tbody>
</table>

| **Baseline age (years)**: Total: NR; a: 46.70 (range 19 to 63); b: 47.20 (range 20 to 64) | **Baseline age (years)**: Total: NR; a: NR; b: NR |
| **Baseline BMI (kg/m²)**: Total: NR; a: 97.60 (4); b: 96.20 (4.9) | **Baseline BMI (kg/m²)**: Total: NR; a: NR; b: NR |

**Description of interventions:**

**BOTH GROUPS:** Both diet meal plans were reduced in energy relative to expenditure (typically 1,200–2,000 kcal/day).

- **a:** Low fat diet: The diet plan provided 60% energy from carbohydrates, 20% from fat, and 20% from protein. One-to-one counselling sessions with trained program staff were offered for the 1-year period, with follow-up telephone and website/message board availability. Weekly counselling visits were recommended during the first 9 months after which participants had the option to move from weekly to biweekly or monthly consultations. Increased physical activity was encouraged, with the goal of 30 min of physical activity on ≥5 days/week.

- **b:** Low CHO diet: The diet plan provided 45% energy from carbohydrates, 30% from fat, and 25% from protein. -One-to-one counselling sessions with trained program staff were offered for the 1-year period, with follow-up telephone and website/message board availability. Weekly counselling visits were recommended during the first 9 months. Increased physical activity was encouraged, with the goal of 30 min of physical activity on ≥5 days/week.

**Length of follow-up (months):** 12

**Quantitative outcomes reported:**
- Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life
<table>
<thead>
<tr>
<th>Country</th>
<th>Sweden</th>
<th>Location: Karolinska Hospital (Stockholm)</th>
<th>Period of study: Prior to January 1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion criteria:</td>
<td>BMI &gt;30 kg/m², ages between 20 and 65 years old and reported stable weights within the last two months</td>
<td>Exclusion criteria: Patients with arrhythmias, coronary artery disease, liver disease, gout, porphyria or diabetes mellitus type 1 were excluded as were patients with eating disorders, psychiatric diseases and alcohol abuse, no pregnant or breast feeding women, or participants on a continuous vegetarian diet and those with a history of lactose intolerance</td>
<td>Recruitment: From the waiting list of the obesity unit at the Karolinska Hospital</td>
</tr>
<tr>
<td>Baseline age (years):</td>
<td>Total: NR; a:43.00(NR); b:41.00(NR); c:39.00(NR)</td>
<td>Baseline BMI (kg/m²): Total: NR; a:38.60(4.0); b:39.00(5.2); c:38.40(4.3)</td>
<td>Baseline weight: Total: NR; a:112.30 (range 84.7 to 143.6); b:113.80 (range 81.0 to 158.9); c:113.80 (range 85.6 to 157.1)</td>
</tr>
</tbody>
</table>

**Rossner 199797**

**Description of interventions:**

- **a:** Patients consumed during 6 weeks Nutrilett (420 kcal/day). After the six weeks of treatment, patients were gradually switched over to a balanced hypocaloric diet (1600 kcal/day) and supervised in group sessions by a research nurse and a dietician. At week 26, the patients were again given the Nutrilett (420 kcal/day) preparation for another two weeks as a booster session.

- **b:** Patients consumed during 6 weeks VLCD (530 kcal/day). After the six weeks of treatment, patients were gradually switched over to a balanced hypocaloric diet (1600 kcal/day) and supervised in group sessions by a research nurse and a dietician. At week 26, the patients were again given the VLCD (530 kcal/day) preparation for another two weeks as a booster session.

- **c:** Patients consumed during 6 weeks LCD (880 kcal/day). After the six weeks of treatment, patients were gradually switched over to a balanced hypocaloric diet (1600 kcal/day) and supervised in group sessions by a research nurse and a dietician. At week 26, the patients were again given the LCD (880 kcal/day) preparation for another two weeks as a booster session.

**Duration of active intervention:** a:52 weeks; b:52 weeks; c:52 weeks

**Number allocated:** 93

**Completed:** Total:57; a:21; b:19; c:17

**% Dropout:** Total:38.71%; a:30.00%; b:40.62%; c:45.16%

**Length of follow-up (months):** 12

**Quantitative outcomes reported:** Weight; Waist circumference
Ryttig 1995

Country: Sweden
Location: Karolinska Hospital
Period of study: Prior to October 1995
Inclusion criteria:
BMI at least 30 kg/m², aged 19-65 years old, stable body weight (fluctuations less than 3 kg) within the last 2 months before commencing treatment
Exclusion criteria:
Known history of renal, cardiac, cerebrovascular, gastrointestinal ulcer, or gall-bladder diseases; patients suffering from diabetes mellitus type 1, gout and porphyria; and patients with psychiatric disturbances (depression, schizophrenia and behaviour disorders such as alcoholism and drug abuse), use of antihypertensives, antidepressants, anoretics and lithium, oral contraceptives and oestrogen substitution therapy (the last two only if the treatment was instituted less than 6 months before the start of the VLCD period); and pregnancy, breastfeeding, vegetarian diet and lack of informed consent
Recruitment: from the waiting list of the obesity unit at the Karolinska Hospital
Baseline age (years): Total:41.50(11.1); a:43.00(10.8); b:40.10(11.3)
Baseline BMI (kg/m²): Total:39.10(5.5); a:40.30(6.0); b:38.00(4.9)
Baseline weight: Total:112.40(19.8); a:120.10(22.5); b:108.10(15.8)
Description of interventions:
a: First 12 weeks one sachet of Cambridge diet (containing 34 g powder) three times daily as the sole source of nourishment (VLCD period). The total daily energy intake during this period was 330 kcal (1386 kJ). The energy distribution in each sachet was 11.3 g protein, 1 g fat and 14.6 g carbohydrate. Furthermore, each sachet contains one-third of the recommended daily intake of vitamins and minerals. After the VLCD period, the patients gradually increased the intake of normal food during 1 week. After this transition period, patients were assigned to a normal, well balanced hypocaloric diet containing 1600 kcal/day (20% protein, 30% fat and 50% carbohydrate).
b: As per control group except assigned to a normal, well balanced hypocaloric diet containing 1600 kcal/day, of which 220 kcal/day was provided by two sachets of the Cambridge diet.
Duration of active intervention: a:52 weeks; b:52 weeks
Number allocated: 60
Completed: Total:45; a:22; b:23
% Dropout: Total:25.00%; a:24.14%; b:25.81%
Length of follow-up (months): 12
Quantitative outcomes reported:
Weight; Weight change (%); Total cholesterol; HDL cholesterol; Triglycerides; Systolic BP

Ryttig 1997

Country: Sweden
Location: Karolinska Hospital
Period of study: Prior to July 1997
Inclusion criteria:
Stable body weight (fluctuations of 3 kg or less) in last two months, able to complete VAS concerning feeling at 3 pm daily for two weeks
Exclusion criteria:
History of renal, cardiac cerebrovascular, gastrointestinal ulcer or gallbladder disease. IDDM, gout, porphyris, psychiatric disturbances (depression, schizophrenia and behaviour disorders such as alcoholism and abuse),
Description of interventions:
a: Hypocaloric diet (6720 kJ/day) for 26 months using different recipes together with behaviour modification during the whole treatment period. The average energy content of the hypocaloric diet was approximately protein 75 g, fat 60 g and carbohydrate 180 g. Behaviour modification included strategies to prevent relapse.
b: VLCD treatment consisting of five sachets Nutrilett® (1764 kJ/day) as sole source of nourishment during the first two months. The energy content in each sachet was 12.3 g protein, 1.2 g fat and 6.1 g carbohydrate. After a one week transition period, with gradually increased intake of normal food, participants followed the same diet as group A for 24 months.
Length of follow-up (months): 26
Quantitative outcomes reported:
Weight; Weight change (%); Total cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose
treatment with hypertensives, antidepressants, anorectics, oral contraceptives < 6 months before study, oestrogen therapy < 6 months before study, pregnancy, vegetarian diet, lack of informed consent

**Recruitment:** from the waiting list of the obesity unit at the Karolinska Hospital

**Baseline age (years):** Total: NR; a:39.50(10); b:44.00(10); c:44.00(10)

**Baseline BMI (kg/m²):** Total: NR; a:37.60(5.7); b:37.70(3.9); c:37.70(3.9)

**Baseline weight:** Total: NR; a:116.20(20.8); b:113.20(17.6); c:113.20(17.6)

**Description of interventions:**

- **a:** VLCD treatment consisting of five sachets Nutrilitt® (1764 kJ/day) as sole source of nourishment during the first two months. After a one week transition period, with gradually increased intake of normal food, participants were prescribed the same total energy intake as group A, but with 1 MJ/day provided as three sachets of Nutrillett.

- **b:** Roux-en-Y gastric bypass, then a transition from initial liquid food intake through to solid food only intake over an eight week period. Plus everything as per medical therapy group.

- **c:** Sleeve gastrectomy then a transition from initial liquid food intake through to solid food only intake over an eight week period. Plus everything as per medical therapy group.

- **c:** Intensive medical therapy, including lifestyle counselling, weight management, frequent home glucose monitoring, and the use of newer drug therapies (e.g., incretin analogues). The goal of medical management was modification of diabetes medications until the patient reached the therapeutic goal of a glycated haemoglobin level of 6.0% or less or became intolerant to the medical treatment.

**Duration of active intervention:** a:24 months; b:26 months; c:26 months

**Number allocated:** 81

**Completed:** Total:42; a:16; b:11; c:15

**% Dropout:** Total:48.15%; a:NR; b:NR; c:NR

**Schauer 2012**

**Country:** USA

**Location:** Cleveland Clinic, Ohio

**Period of study:** March 2007 to January 2011

**Inclusion criteria:**

1. Is a candidate for general anaesthesia, 2. Is > 20 and < 61 years old. 3. Have a body mass index > 27 and < 43 . 4. Have biochemical evidence of type 2 diabetes confirmed by the following diagnostic criteria: a. If treated – HbA1c > 7.1%; b. If untreated - fasting 2-hr plasma glucose level of > 200 mg/dL during an oral glucose tolerance tests and a HbA1c of > 7.1%. 5. Have the ability and willingness to participate in the study and agree to any of the arms involved in the study. 6. Able to understand the options and to comply with the requirements of each program. 7. Have a negative urine pregnancy test at screening and baseline visits (prior to surgery) for women of childbearing potential. A woman of childbearing potential is one who is biologically capable of becoming pregnant. This includes women who are using contraceptives or whose sexual partners are either sterile or using contraceptives. 8. Female patients must agree to use reliable method of contraception for 2 years.

**Exclusion criteria:**

1. Prior bariatric surgery of any kind, 2. Prior complex foregut surgery including splenectomy, upper GI, Nissen, trauma, 3. Abdominal, thoracic, pelvic and/or obstetric-

**Description of interventions:**

- a: Roux-en-Y gastric bypass, then a transition from initial liquid food intake through to solid food only intake over an eight week period. Plus everything as per medical therapy group.

- b: Sleeve gastrectomy then a transition from initial liquid food intake through to solid food only intake over an eight week period. Plus everything as per medical therapy group.

- c: Intensive medical therapy, including lifestyle counselling, weight management, frequent home glucose monitoring, and the use of newer drug therapies (e.g., incretin analogues). The goal of medical management was modification of diabetes medications until the patient reached the therapeutic goal of a glycated haemoglobin level of 6.0% or less or became intolerant to the medical treatment.

**Duration of active intervention:** a:One month; b:One month; c:One month

**Number allocated:** 150

**Completed:** Total:134; a:49; b:47; c:38

**% Dropout:** Total:10.67%; a:2.00%; b:6.00%; c:24.00%

**Length of follow-up (months):** 60

**Quantitative outcomes reported:**

Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life
gynaecologic surgery within 3 months or at the discretion of the surgeon. 4. Any other surgery requiring general anaesthesia within 6 weeks prior to signing the ICF. 5. Cardiovascular conditions including significant known coronary artery disease (CAD), dysrhythmia, known peripheral vascular disease (large vessel disease), uncompensated congestive heart failure, history of stroke, or uncontrolled hypertension (defined as medically treated with the mean of 3 separate measurements SBP > 180 mm Hg or DBP > 110 mm Hg). Participants with CAD that have been successfully treated with coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI), or are 1 year after implantation of drug eluting stent, and have no evidence of active ischemia are eligible. 6. Kidney disease including renovascular hypertension, renal artery stenosis, or chronic renal insufficiency with a creatinine level > 1.8 mg/dl. 7. Known history of chronic liver disease (except for NAFLD/NASH), hepatitis, positive serologic test result for hepatitis B surface antigen and/or hepatitis C antibody, alpha-1-antitrypsin deficiency. 8. Gastrointestinal disorders including a known history of celiac disease and/or any other malabsorptive disorders or inflammatory bowel disease (Crohn’s disease or ulcerative colitis). 9. Psychiatric disorders including dementia, active psychosis, severe depression requiring > 2 medications, history of suicide attempts, alcohol or drug abuse within the previous 12 months. 10. Pregnancy. 11. Malignancy within five years (except squamous cell and basal cell cancer of the skin). Participants diagnosed with early / stage 1 cancer that have been successfully treated are eligible per Investigator discretion.

Recruitment: Electronic medical records and local media advertisements

Baseline age (years): Total: NR; a:48.30(8.4); b:47.90(8.0); c:49.70(7.4)
Baseline BMI (kg/m²): Total: NR; a:37.00(3.3); b:36.20(3.9); c:36.80(3.0)
<table>
<thead>
<tr>
<th><strong>Baseline weight:</strong> Total: NR; a:106.70(14.8); b:100.80(16.4); c:106.50(14.7)</th>
</tr>
</thead>
</table>
| **Country:** USA  
**Location:** Community  
**Period of study:** October 2010 to February 2012  
**Inclusion criteria:** Generally healthy, aged 19-65 years, BMI between 35 and 50 kg/m², blood pressure less than or equal to 160/95 mmHg, fasting serum glucose level less than or equal to 126 mg/dl, and desire to lose weight.  
**Exclusion criteria:** Participation in a weight reduction programme or other special diet within the previous 3 months; weight change of > 5% of bodyweight in the previous 6 months; prior bariatric surgery or liposuction; current medications associated with suppression or stimulation of appetite; current major disease, including diabetes, cancer, uncontrolled hypertension or other cardiovascular disease, gastrointestinal disease, renal disease, chronic pulmonary disease chronic infectious disease or psychiatric disease; unstable doses of antidepressants, steroids or thyroid medications; Brief Symptom Inventory 18 score exceeding the 90th percentile; food allergies; history of a eating disorder or Eating Attitudes Test 40 score >30; smoking within the previous 6 months; excessive alcohol intake; illicit drug use; pregnancy, recent childbirth, or nursing; and no usual source of health care.  
**Recruitment:** e-mailed flyer, campus newspaper advertisement, databases of persons interested in weight loss, and word of mouth.  
**Baseline age (years):** Total: NR; a:39.70(9.1); b:40.20(9.2)  
**Baseline BMI (kg/m²):** Total: NR; a:41.30(3.8); b:40.60(3.8)  
**Baseline weight:** Total: NR; a:112.90(12.2); b:112.60(16.8)  
**Description of intervention**  
a: Weight-loss phase (weeks 0-26): Participants were provided with a 1000 kcal/day meal plan based on regular foods selected, procured and prepared by the participants. Food lists sample menus and a portion size reference were provided.  
Weight maintenance phase (weeks 26-52): Participants’ diet remained wholly food-based.  
b: Weight-loss phase (weeks 0-26): Meal replacement plan consisting of five portion-controlled, nutritionally-balanced, low-fat meals plus one ‘Lean & Green’ meal each day. The meal replacements provided ~800-1000 kcal/day. Support consisted of online access to resources, including dietitians, trainers, recipes, message boards and chat rooms, allowing participants to interact with others on the same plan. Meal ordering was via telephone between the company and participant. Weight maintenance phase (weeks 26-52): Participants were given the option of including 0-3 meal replacements/day to reach their energy needs for weight maintenance.  
**Duration of active intervention:** a:52 weeks; b:52 weeks  
**Number allocated:** 120  
**Completed:** Total:95; a:45; b:50  
**% Dropout:** Total:20.83%; a:25.00%; b:16.67%  
**Length of follow-up (months):**12  
**Quantitative outcomes reported:** Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose |
**Country:** European countries  
**Location:** 15 European centres  
**Period of study:** Prior to July 1998  
**Inclusion criteria:**  
BMI 28-47 kg/m² men and women, aged 18 years and over, women of childbearing potential were included if they were using adequate contraception  
**Exclusion criteria:**  
Women of childbearing potential if not using adequate contraception  
**Recruitment:** hospital waiting lists or by local advertising  
**Baseline age (years):** Total: NR; a:44.30 (range 18.0 to 77.0); b:45.20 (range 20.0 to 76.0)  
**Baseline BMI (kg/m²):** Total: NR; a:36.10 (range 29.2 to 43.5); b:36.00 (range 28.3 to 47.22)  
**Baseline weight:** Total: NR; a:99.80 (range 64.2 to 137.2); b:99.10 (range 61.0 to 148.6)  

**Description of interventions:**  
a: Placebo three times daily. Diet: During the lead-in and 52 week treatment periods, patients were prescribed a hypocaloric diet containing roughly 30% of energy as fat. From energy expenditure, 600 kcal/day was subtracted to obtain a mildly hypocaloric diet. Between weeks 4 and 24, the minimum prescribed energy intake was 1200 kcal/day. To compensate for the anticipated reduction in energy expenditure accompanying the weight loss, the prescribed energy intake was further reduced by about 300 kcal/day at the end of week 24. For participants initially prescribed the minimum energy intake, energy intake was adjusted to 1000 kcal/day.  
b: Orlistat 120 mg three times daily. Diet: as per placebo group  

**Duration of active intervention:** a:56 weeks; b:56 weeks;  
**Number allocated:** 688  
**Completed:** Total:435; a:204; b:231  
% Dropout: Total:36.77%; a:40.52%; b:33.04%  

**Length of follow-up (months):** 24  
**Quantitative outcomes reported:**  
Weight; Weight change (%); Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose  

**BOTH GROUPS:** In a second 52 week double-blind period, patients were reassigned to orlistat or placebo with a weight maintenance diet.  
a: Placebo: Remained on placebo throughout the whole study period.  
b: Placebo to orlistat: Switched from placebo to orlistat 120 mg three times a day for the second 52 week period.  
c: Orlistat to placebo: Switched from orlistat 120 mg three times a day to placebo for the second 52 week period.  
d: Orlistat: Remained on orlistat 120 mg three times a day for the whole study period.  

**Duration of active intervention:** a:52 weeks; b:52 weeks; c:52 weeks; d:52 weeks  
**Number allocated:** 688  
**Completed:** Total:435; a:102; b:102; c:117; d:114  
% Dropout: Total:36.77%; a:19.05%; b:19.69%; c:15.22%; d:15.56%  

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### Smith West 2007<sup>103</sup>

**Country:** USA  
**Location:** Birmingham, Alabama  
**Period of study:** 2000 - 2002  
**Inclusion criteria:**  
Women with type 2 diabetes treated by oral diabetes medications but not insulin, were overweight (BMI 27-50 kg/m²) but generally healthy otherwise, and could walk for exercise. Women with uncontrolled diabetes (AIC > 12%) or hypertension (diastolic blood pressure >90 mmHg or systolic blood pressure > 140 mm Hg) were referred to their physicians for treatment and invited to rescreen.  
**Exclusion criteria:**  
Pregnancy, recent significant weight loss (~ 10 lbs), or a severe debilitating disease that might interfere with study participation.  
**Recruitment:** Social marketing channels, direct mail solicitation, and physician referrals  
**Baseline age (years):** Total:53.00(10); a:54.00(10); b:52.00(10)  
**Baseline BMI (kg/m²):** Total:36.50(5.5); a:36.50(5.4); b:36.50(5.5)  
**Baseline weight:** Total:97.00(16); a:97.00(15); b:97.00(17)  
**Description of interventions:**  
a: Behavioral group programme focused on attainable and sustainable changes in dietary and physical activity habits. Caloric restriction was prescribed (1200-1500 kcal/day) with a fat intake goal of 33-42 g/day. Gradual increases in physical activity were promoted with an ultimate goal of at least 150 min/week. Weight loss was emphasized in the first 6 months and weight maintenance in the subsequent 12 months.  
b: As per control group except for the individual sessions.  
**Duration of active intervention:** a:18 months; b:18 months  
**Number allocated:** 217  
**Completed:** Total:202; a:99; b:103  
**% Dropout:** Total:6.91%; a:8.33%; b:5.50%  
**Length of follow-up (months):** 18  
**Quantitative outcomes reported:**  
Weight; HbA1c %

### Soenen 2012<sup>104</sup>

**Country:** The Netherlands  
**Location:** Hengelo  
**Period of study:** Prior to 7 June 2012  
**Inclusion criteria:**  
BMI >27 kg/m², aged 18-80 years  
**Exclusion criteria:**  
Recent loss of body weight (>10%), underlying malignancy, HIV infection, psychiatric disease, pregnancy or breast feeding  
**Recruitment:** From potential clients of a weight management program of an outpatient-clinic in the city of Hengelo, The Netherlands.  
**Baseline age (years):** Total: NR; a:NR; b:NR; c:NR; d:NR  
**Description of interventions:**  
a: Normal protein and normal CHO: First 2 weeks: run-in period with energy intakes of 100%, protein/carbohydrate/fat: 10%/50%/40% of energy intake. Daily absolute protein intakes of 0.8 g/kg BW (NP) and 1.2 g/kg BW (HP) were intended to be constant during the run-in period and during the total energy restriction period of one year. After week 2: protein/carbohydrate/fat 30/35/35 of energy intake. Energy intake restriction to 33% of the participants' original energy requirements for three months to achieve significant reduction in weight. Maintenance period of nine months with an energy intake restriction to 67% of the participants' original energy requirements. Protein/carbohydrate/fat 15%/45%/40%.  
b: Normal protein and low CHO: First 2 weeks: run-in period with energy intakes of 100%; protein/carbohydrate/fat: 10%/25%/65% of energy intake. Daily absolute protein intakes of 0.8 g/kg BW (NP) and 1.2 g/kg BW (HP)  
**Length of follow-up (months):** 12  
**Quantitative outcomes reported:**  
Weight; BMI kg/m²; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose
Baseline BMI (kg/m²): Total: NR; a:36.20(4.7); b:37.00(5.4); c:37.50(5.6); d:36.60(4.6)  
Baseline weight: Total: NR; a:105.30(18.6); b:107.20(18.7); c:106.10(18.5); d:108.10(21.7)  
were intended to keep constant during the run-in period and during the total energy restriction period of one year. After week 2: protein/carbohydrate/fat of 30%/5% of energy intake. Energy intake restriction to 33% of the participants' original energy requirements for three months to achieve significant reduction in weight. Maintenance period of nine months with an energy intake restriction to 67% of the participants' original energy requirements.  
Protein/carbohydrate/fat 15%/25%/60%.  
c: High protein and normal CHO: First 2 weeks: run-in period with energy intakes of 100%, protein/carbohydrate/fat: 20%/50%/30% of energy intake.  
Daily absolute protein intakes of 0.8 g/kg BW (NP) and 1.2 g/kg BW (HP) were intended to keep constant during the run-in period and during the total energy restriction period of one year. After week 2: protein/carbohydrate/fat of 60%/35%/5% energy intake. Energy intake restriction to 33% of the participants' original energy requirements for three months to achieve significant reduction in weight. Maintenance period of nine months with an energy intake restriction to 67% of the participants' original energy requirements.  
Protein/carbohydrate/fat 30%/45%/25%.  
d: High protein and low CHO: First 2 weeks: run-in period with energy intakes of 100%, protein/carbohydrate/fat: 20%/25%/55% of energy intake.  
Daily absolute protein intakes of 0.8 g/kg BW (NP) and 1.2 g/kg BW (HP) were intended to keep constant during the run-in period and during the total energy restriction period of one year. After week 2: protein/carbohydrate/fat of 60%/5%/35% energy intake. Energy intake restriction to 33% of the participants' original energy requirements for three months to achieve significant reduction in weight. Maintenance period of nine months with an energy intake restriction to 67% of the participants' original energy requirements.  
Protein/carbohydrate/fat 30%/25%/45%.  
Duration of active intervention: a:12 months; b:12 months; c:12 months; d:12 months  
Number allocated: 139  
Completed: Total:132; a:33; b:33; c:33; d:33  
% Dropout: Total:5.04%; a:2.94%; b:5.71%; c:5.71%; d:5.71%
<table>
<thead>
<tr>
<th>Description of interventions:</th>
<th>Duration of active intervention</th>
<th>Length of follow-up (months): 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>a: Standard MOVE! Programme: Biweekly MOVE! sessions led by dieticians, psychologists, or physicians. Each session lasted approximately 1 ½ hrs and included discussion of nutrition, physical activity, and behaviour change. Participants were given a 5% to 10% weight loss goal. They were weighed at each session and encouraged to self-monitor, but personalized feedback was not provided. Calorie goals were tailored according to the participant's baseline weight. Participants who did not lose weight for two consecutive weeks were instructed to reduce calorie intake in 100 kcal increments until they reached a weight loss of 0.5-1.0% of their current weight per week. If weight loss was too rapid, the calorie goal was increased in 100 kcal increments. For safety, no participant was given an intake goal below 1200 kcal/day.</td>
<td>a: 12 months; b: 12 months</td>
<td></td>
</tr>
<tr>
<td>b: MOVE! + personal digital assistant (PDA): Biweekly MOVE! sessions led by hospital staff (as per control group) plus self-monitoring and personalised feedback via Personal Digital Assistant.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Quantitative outcomes reported: | |
|--------------------------------| |
| Weight | |
Stahre 2005

**Country:** Sweden  
**Location:** Obesity Unit, Karolinska University Hospital, Huddinge, Stockholm  
**Period of study:** Between 1998 and 1999  
**Inclusion criteria:** BMI ≥30 kg/m², Female, Aged 18–60 years  
**Exclusion criteria:** Signs of active tumour disease, pregnancy, symptoms of psychosis  
**Recruitment:** From the waiting list for non-surgical treatment at the Obesity Unit at Huddinge University Hospital  
**Baseline age (years):** Total: NR; a:45.20(11.3); b:45.40(9.8)  
**Baseline BMI (kg/m²):** Total: NR; a:39.20(NR); b:40.40(NR)  
**Baseline weight:** Total: NR; a:111.10(15.5); b:111.00(16.1)  

**Description of interventions:**  

a: Waiting list control group. Further details not reported  

b: Cognitive treatment over 10 x weekly sessions lasting three hrs. Each lesson ended with a meal based on the nutrition program, which the participants took turns preparing at home. The dietary programme component is a traditional dietary programme, compiled by a registered dietitian and based on normal food. Participants were invited to build their own personal diet consisting of 1200-1300 kcal/day with individual variation and no food restrictions.  

**Duration of active intervention:** a:NR; b:10 weeks  
**Number allocated:** 132  
**Completed:** Total:65; a:31; b:34  
**% Dropout:** Total:50.76%; a:53.03%; b:48.48%  

Stenius-Aarniala 2000

**Country:** Finland  
**Location:** University Central Hospital, Helsinki  
**Period of study:** Prior to March 25, 2000  
**Inclusion criteria:** Ability to cope with the study protocol, BMI 30-42 kg/m², age 18-60 years, previously diagnosed asthma with a spontaneous diurnal variation or a bronchodilator response of 15% or more, and being a non-smoker or having stopped smoking for two years or more before age 50  
**Exclusion criteria:** Pregnancy, history of bulimia or anorexia, unstable angina or arrhythmia, untreated thyroid disease, symptomatic liver or gall bladder disorder, any other severe disease, insulin treatment, systemic steroid treatment, or history of food allergy or of intolerance to any component of the very low energy dietary preparation that would be used in the study - such as soya, fish, chocolate, or lactose. Participants with a history of adverse reactions to peas, beans, or peanuts were  

**Description of interventions:**  

a: The control group had sessions at the same intervals as the treatment group. By the end of the first year each group had had the same amount of education about asthma and allergy. Discussions in the groups emphasized self-monitoring, goal setting, and identifying and coping with high-risk situations, and provided training in stimulus control techniques associated with eating. All participants received normal medical care throughout the study. No fixed amount of daily energy intake was recommended, but the patients were advised to diminish their previous daily energy intake by 2100 to 4200 KJ. The patients were encouraged to increase physical activity and exercise corresponding to an extra 30-minute walk daily.  

b: Same weight reduction programme as the control group but including eight weeks—“the dieting period”—in which participants took a very low energy dietary preparation (Nutrilett). The daily dose gave 1760 KJ of energy.  

**Duration of active intervention:** a:14 weeks; b:14 weeks  
**Number allocated:** 38  
**Completed:** Total:38; a:19; b:19  
**% Dropout:** Total:0.00%; a:0.00%; b:0.00%
excluded because of possible cross reactions to soya protein.

**Recruitment:** Newspaper advertisements

**Baseline age (years):**
- Total: NR; a:48.30 (range 23 to 60);
- b:49.70 (range 34 to 60)

**Baseline BMI (kg/m²):**
- Total: NR; a:36.70 (range 32.8 to 41.8); b:35.80 (range 31.3 to 39.4)

**Baseline weight:**
- Total: NR; a:98.70 (range 74.5 to 117); b:98.10 (range 86 to 117.5)

---

**Stern 2004**

**Country:** USA

**Location:** Outpatient practices of the Philadelphia Veterans Affairs Medical Centre

**Period of study:** Prior to May 2004

**Inclusion criteria:**
- Over 18 years old, BMI 35 kg/m² or more

**Exclusion criteria:**
- Serum creatine level greater than 133 µmol/L *<1.5 mg/dL), hepatic disease, severe life-limiting medical illness, inability to self-monitor glucose levels or active use of a weight loss program or weight loss medication.

**Recruitment:** From outpatient practices of Philadelphia Veterans Affairs Medical Center

**Baseline age (years):**
- Total: NR; a:54.00(9);
- b:53.00(9)

**Baseline BMI (kg/m²):**
- Total: NR; a:42.90(7.7);
- b:42.90(6.6)

**Baseline weight:**
- Total: NR; a:132.00(27);
- b:130.00(23)

**Description of interventions:**

a: Conventional diet: Regular group meetings led by experts in nutritional counselling. No instruction on restricting total fat intake was provided. Vegetables and fruits with high ratios of fibre to carbohydrate were recommended. Participants received instruction in caloric restriction sufficient to create a deficit of 500 kcal/day with 30% or less of total calories derived from fat.

b: Low-CHO diet: Regular group meetings led by experts in nutritional counselling. Instructed to restrict carbohydrate intake to 30 g/day or less. No instruction on restricting total fat intake was provided. Vegetables and fruits with high ratios of fibre to carbohydrate were recommended.

**Duration of active intervention:**
- a: 6 months; b: 6 months

**Number allocated:**
- Total: 132

**Completed:**
- Total: 87; a:43; b:44

**% Dropout:**
- Total: 34.09%; a:36.76%; b:31.25%

**Length of follow-up (months):**
- 12

**Quantitative outcomes reported:**
- Weight; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %
Country: Germany  
Location: University of Wurzburg  
Period of study: October 2008 to November 2009  
Inclusion criteria:  
BMI between 30 and 44 kg/m², had started inpatient medical rehabilitation with the goal of reducing their body weight, aged between 18 and 65 years  
Exclusion criteria:  
Type 1 diabetes or a disorder precluding participation in sports therapy, had or were planning to have bariatric surgery, not able to see, hear, read or understand German, severe psychiatric disorders, such as psychotic and substance abuse disorders  
Recruitment: From inpatient medical rehabilitation centre  
Baseline age (years): Total: 48.28 (9.76); a: 48.03 (9.77); b: 48.54 (9.77)  
Baseline BMI (kg/m²): Total: 36.33 (3.50); a: 36.26 (3.44); b: 36.41 (3.56)  
Baseline weight: Total: NR; a: 109.70 (16.1); b: 109.80 (15.6)  
Description of interventions:  
a: Usual care: Complete medical check-up with assessment of cardiovascular risk factors; Nutrition therapy (supervised selection of healthy food at daily special buffets; cooking seminars; group counselling about healthy food); Physical exercise (daily group training courses for people with obesity only including swimming; regular use of step counter; individualized gym for improvement of endurance and muscular function); Psychoeducation (group seminar about life style change and barriers to reduce body weight.  
b: As per usual care group but additionally received a planning intervention provided in a group setting (50 min), followed by an individual counselling session (10 min) 1 week later, before discharge, and 6 phone calls of 5-10 min duration for up to 6 months after discharge.  
Duration of active intervention: a: 3 weeks; b: 27 weeks  
Number allocated: 467  
Completed: Total: 341; a: 164; b: 177  
% Dropout: Total: 26.98%; a: 31.38%; b: 22.37%  
Length of follow-up (months): 12  
Quantitative outcomes reported:  
Weight; BMI kg/m²
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Location</th>
<th>Period of study</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Recruitment</th>
<th>Baseline age (years)</th>
<th>Baseline BMI (kg/m²)</th>
<th>Baseline weight</th>
<th>Description of interventions</th>
<th>Duration of active intervention</th>
<th>Number allocated</th>
<th>Completed</th>
<th>Dropout (%)</th>
<th>Length of follow-up (months)</th>
<th>Quantitative outcomes reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swinburn 2005</td>
<td>Australia and New Zealand</td>
<td>Eight clinical research centres in Australia and New Zealand</td>
<td>Prior to 21 July 2004</td>
<td>Men and women, aged 40–70, with a BMI between 30 and 50 kg/m² and one of the following: hypercholesterolemia (serum total cholesterol of &gt;5.5 mmol/l and/or LDL-cholesterol of &gt;3.5 mmol/l and clinically stable if on treatment); or hypertension (systolic &gt;140mmHg and/or diastolic &gt;90mmHg and clinically stable if on treatment); or type 2 diabetes treated with dietary modification or any oral hypoglycaemic agent for at least 6 months and clinically stable (glycated haemoglobin: 6.5–10%).</td>
<td>A history of significant cardiac, renal, hepatic, gastrointestinal or endocrine disorders; uncontrolled hypertension; previous gastrointestinal surgery for weight reduction; a history of post-surgical adhesions; smoking; a history or presence of substance abuse, bulimia, type 1 diabetes, psychiatric disorders or active gastrointestinal disease.</td>
<td>NR</td>
<td>Total: NR; a:52.50(7.4); b:52.00(7.5)</td>
<td>Total: NR; a:38.00(4.9); b:37.60(5.1)</td>
<td>Total: NR; a:106.90(17.8); b:103.30(17.8)</td>
<td>a: Participants received advice from a dietician about identifying the sources of dietary fat (such as through label reading) and reducing them as much as possible. The aim was to reduce daily dietary fat intake to be between 25 and 30% of total daily energy intake or about 40 g/day. Advice was also given about undertaking regular, moderate-intensity physical activity of at least 30 min a day on most days. Plus placebo tablet 3 times daily. b: As per control group but with 120 mg orlistat 3 times daily instead of placebo.</td>
<td>a:56 weeks; b:56 weeks</td>
<td>339</td>
<td>Total:269; a:137; b:132</td>
<td>20.65%; a:18.93%; b:22.35%</td>
<td>12</td>
<td>Weight; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life</td>
</tr>
<tr>
<td>Torgerson 1997</td>
<td>Sweden</td>
<td>Department of medicine outpatient clinics</td>
<td>November 1991 to December 1993</td>
<td>NR</td>
<td>NR</td>
<td>From the Swedish Obese Subjects (SOS) study. SOS participants are recruited by advertisements in newspapers</td>
<td></td>
<td></td>
<td></td>
<td>a: Hypocaloric diet participants were advised to consume an individualised hypocaloric diet aiming at a daily energy intake of 1200-1400 kcal for women or 1400-1800 kcal for men with 15-20 percent of the energy intake (E%) from protein, 25-30 E% from fat and 50-55 E% from carbohydrates. At randomisation and every six months (major visits) patients met a dietitian for individual nutritional counselling. b: Participants in the VLCD-group were provided with Modifast and were</td>
<td>24</td>
<td>269; a:137; b:132</td>
<td>20.65%; a:18.93%; b:22.35%</td>
<td>24</td>
<td>Weight; Weight change (%)</td>
<td></td>
</tr>
</tbody>
</table>
Baseline age (years): Total: NR; a:46.90(5.8); b:47.30(6.7)
Baseline BMI (kg/m²): Total: NR; a:40.50(4.3); b:40.20(3.3)
Baseline weight: Total: NR; a:116.60(16.7); b:116.20(16.3)

Recommended 456-608 kcal/day. The higher kcal level was recommended to men with high energy expenditure. The VLCD-treatment lasted for 12 weeks and thereafter the same hypocaloric diet followed by the non-VLCD group was gradually introduced. The VLCD participants followed the same supportive behavioural programme as the non-VLCD participants except participants in the VLCD-group restarted the visit schedule after the 12 weeks, when shifting to the hypocaloric diet, to facilitate refeeding. They were thus offered three more visits during the study period than the non VLCD-patients.

**Duration of active intervention:** a:20 months; b:24 months
**Number allocated:** 113
**Completed:** Total:55; a:26; b:29
**% Dropout:** Total:51.33%; a:52.73%; b:50.00%

| Torgerson 1999112 | **Country:** Sweden  
**Location:** Clinical Metabolic Laboratory, Sahlgrenska University Hospital  
**Period of study:** Recruited February 1994 - April 1995  
**Inclusion criteria:** Age 20-60, BMI 30 kg/m² or more  
**Exclusion criteria:** Severe somatic/mental disorder, previous bariatric surgery, abuse, probably non-compliance or participation in another clinical trial of obesity  
**Recruitment:** Clinic referral  
**Baseline age (years):** Total: NR; a:45.40(9.6); b:41.40(10.8); c:41.10(11.7)  
**Baseline BMI (kg/m²):** Total: NR; a:37.90(5.0); b:38.50(4.5); c:37.70(4.3)  
**Baseline weight:** Total: NR; a:109.30(16.0); b:111.40(15.5); c:107.20(16.0) |
| --- | --- |
| **Description of interventions:**  
ALL GROUPS: Modifast: 3 sachets/day (456 kcal/day) and recommendation to drink at least 2.5l of non-caloric fluid/day.  
| a: VLCD-plus: Two small meals per week - free choice of food items, but encouraged to eat as little as possible. After the VLCD period, ordinary food was gradually introduced during a three week refeeding phase. All patients were then advised to consume an individualised hypocaloric diet aiming at an energy deficit of approximately 2100 KJ/d (500 kcal/day), with 15-20% of the energy intake (%E) from protein, 25-30% E% from fat and 50-55 E% from carbohydrates.  
| b: VLCD-strict: Recommended to strictly adhere to the VLCD and avoid other food items. After the VLCD period: as per VLCD-plus group.  
| c: VLCD metabolic ward: Hospitalised on a metabolic ward for first week, in a locked, single room with 30 min walk twice daily accompanied by staff members, who gave support and guidance. Then recommended to strictly adhere to the VLCD and avoid other food items. After the VLCD period: as per VLCD-plus group.  
| **Duration of active intervention:** a:12 months; b:12 months; c:12 months  
**Number allocated:** 121  
**Completed:** Total:69; a:27; b:19; c:23  
**% Dropout:** Total:42.98%; a:34.15%; b:53.66%; c:41.03% |
| **Length of follow-up (months):** 12  
**Quantitative outcomes reported:** Weight; Weight change (%) |
Torgerson 2004

Country: Sweden  
Location: 22 Swedish medical centres  
Period of study: February 1997 to September 1999  
Inclusion criteria:  
30–60 years old and with at least BMI 30 kg/m². The stipulated sex distribution was 55% women and 45% men. Also, participants had to be non-diabetic as determined by a 2-hr oral glucose tolerance test (OGTT) at the baseline examination. However, at least 10% of the participants were requested to have impaired glucose tolerance (IGT).  
Exclusion criteria:  
A change in body weight > 2 kg between the screening and baseline examinations and a blood pressure above 165 mm Hg systolic or 105 mm Hg diastolic on the same two consecutive visits. Diabetes mellitus, myocardial infarction within 6 months, symptomatic cholelithiasis, gastrointestinal surgery for weight reduction or peptic ulcer, active gastrointestinal disorder or pancreatic disease, malignancy, significant psychiatric or neurologic disorder, abuse or previous participation in any trial of orlistat were not allowed.  
Recruitment: Newspaper advertisements  
Baseline age (years): Total: NR; a: 43.70 (8.0); b: 43.00 (8.0)  
Baseline BMI (kg/m²): Total: NR; a: 37.40 (4.5); b: 37.30 (4.2)  
Baseline weight: Total: NR; a: 110.60 (16.5); b: 110.40 (16.3)  

Description of interventions:  
a: Reduced-calorie diet (~800 kcal/day deficit) containing 30% of calories from fat and not more than 300 mg/day of cholesterol. The prescribed energy intake was readjusted every 6 months to account for any weight lost during the preceding months. Participants received dietary counselling every 2 weeks for the first 6 months and monthly thereafter. Patients were also encouraged to walk at least 1 extra kilometre a day in addition to their usual physical activity. Plus placebo three times daily with breakfast, lunch and dinner.  
b: As per placebo group but with 120 mg Orlistat three times daily instead of placebo.  
Duration of active intervention: a: 4 years; b: 4 years  
Number allocated: 3305  
Completed: Total: 1414; a: 564; b: 850  
% Dropout: Total: 57.22%; a: 65.92%; b: 48.48%  
Length of follow-up (months): 48  
Quantitative outcomes reported:  
Weight; Waist circumference; Systolic BP; Diastolic BP; Fasting plasma glucose; Quality of life

Tsai 2010

Country: USA  
Location: Two academic primary care offices in the University of Pennsylvania Health System  
Period of study: Prior to 27 August 2009  
Inclusion criteria:  
BMI of 27-50 kg/m² and willingness to keep food and activity records  
Exclusion criteria:  
Medical conditions that contraindicated weight loss, use of medications associated with weight gain or loss of ≥5%  

Description of interventions:  
a: Quarterly visits with primary care providers (PCPs). The weight management component of each PCP visit lasted 2-3 min. PCPs were instructed to encourage patients to lose weight but they did not give participants specific behavioural strategies for weight management.  
b: Same schedule of PCP visits and received the same materials as individuals in the control group. In addition, these participants received a series of eight brief (15-20min) individual visits with a medical assistant at weeks 0, 2, 4, 8, 12, 16, 20, and 24. Visits were conducted using handouts adapted from the  
Length of follow-up (months): 12  
Quantitative outcomes reported:  
Weight change; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP
<table>
<thead>
<tr>
<th>Description of interventions:</th>
<th>Diabetes Prevention Program. Patients were instructed to consume 1,200-1,500 kcal/day (if &lt;250 lb) or 1500-1800 kcal/day (if~250 lb) and to gradually increase their physical activity to 175 min/week.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of active intervention:</td>
<td>a: 12 months; b: 12 months</td>
</tr>
<tr>
<td>Number allocated:</td>
<td>50</td>
</tr>
<tr>
<td>Completed:</td>
<td>Total: 47; a: 25; b: 22</td>
</tr>
<tr>
<td>% Dropout:</td>
<td>Total: 6.00%; a: 3.85%; b: 8.33%</td>
</tr>
</tbody>
</table>

| Length of follow-up (months): | 12                                                                                             |
| Quantitative outcomes reported: | Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose |

| Inclusion criteria: | Women between 18 and 65 years of age with at least one risk factor for diabetes, including BMI greater than or equal to 30 kg/m², a family history of type 2 diabetes, a history of gestational diabetes mellitus, a child born <9 pounds (4 kg), or a diagnosis of hypertension, dyslipidemia, or cardiovascular disease |
| Exclusion criteria: | NR                                                                                             |

| Recruitment: | The center’s electronic patient registry (Patient Electronic Care System [PECSYS]) was used to identify women with the inclusion characteristics. |
| Baseline age (years): | Total: NR; a: 43.00(9.7); b: 43.80(10.8) |
| Baseline BMI (kg/m²): | Total: NR; a: 35.20(7.3); b: 35.40(8.5) |
| Baseline weight: | Total: NR; a: 87.10(22.8); b: 84.80(24.8) |

<table>
<thead>
<tr>
<th>Van Name 2016115</th>
<th>Country: USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location:</td>
<td>Fair Haven Community Health Centre, New Haven, CT</td>
</tr>
<tr>
<td>Period of study:</td>
<td>2008 to 2012</td>
</tr>
</tbody>
</table>

| Inclusion criteria: | Women between 18 and 65 years of age with at least one risk factor for diabetes, including BMI greater than or equal to 30 kg/m², a family history of type 2 diabetes, a history of gestational diabetes mellitus, a child born <9 pounds (4 kg), or a diagnosis of hypertension, dyslipidemia, or cardiovascular disease |
| Exclusion criteria: | NR                                                                                             |

<p>| Recruitment: | The center’s electronic patient registry (Patient Electronic Care System [PECSYS]) was used to identify women with the inclusion characteristics. |
| Baseline age (years): | Total: NR; a: 43.00(9.7); b: 43.80(10.8) |
| Baseline BMI (kg/m²): | Total: NR; a: 35.20(7.3); b: 35.40(8.5) |
| Baseline weight: | Total: NR; a: 87.10(22.8); b: 84.80(24.8) |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Location</th>
<th>Period of study</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Recruitment</th>
<th>Baseline age (years)</th>
<th>Baseline BMI (kg/m²)</th>
<th>Baseline weight</th>
<th>Description of interventions</th>
<th>Length of follow-up (months)</th>
<th>Quantitative outcomes reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Villareal 2008&lt;sup&gt;116&lt;/sup&gt;</td>
<td>USA</td>
<td>Washington University School of Medicine</td>
<td>January 2003 to July 2004</td>
<td>65 years or older, BMI 30 kg/m² or greater, sedentary (did not participate in regular exercise more than twice a week), stable body weight (±2 kg) over the past year, and treatment with medications was unchanged for at least 6 months before enrolment. Mild to moderate frailty, based on meeting at least two of the three following criteria: 1) physical performance test score of 18-32, 2) peak 0 2 consumption of ll-18 ml/kg·min, and 3) difficulty or need for assistance in two instrumental activities of daily living or one basic activity of daily living.</td>
<td>Severe cardiopulmonary disease, neuromuscular impairments that preclude ET, visual, hearing, or cognitive impairments, history of malignant neoplasm, and treatment with bone-acting drugs (e.g. bisphosphonates, glucocorticoids, sex-steroid compounds) during the previous year.</td>
<td>Local advertisements</td>
<td>Total: NR; a:71.10(5.1); b:69.40(4.6)</td>
<td>Total: NR; a:39.00(5.0); b:38.50(5.3)</td>
<td>Total: NR; a:103.20(19.8); b:99.70(13.6)</td>
<td>a: Participants randomized to the control group were instructed to maintain their usual diet and activities during the study period and were asked not to participate in any weight-loss or exercise programs. b: A combination of an energy-deficit diet, behaviour therapy, and a multi-component exercise therapy. Participants met weekly as a group with a study dietitian, who was experienced in group behavioural therapy. Participants were prescribed a balanced diet to provide an energy deficit of 500-750 kcal/day, which contained about 30% of energy as fat, 50% as carbohydrate, and 20% as protein. Total calorie intake was adjusted to prevent more than a 1.5% loss of body weight each week. The goal was to achieve a 10% weight loss at 6 months, followed by weight maintenance for an additional 6 months. Exercise sessions were conducted as a group on three non-consecutive days each week at our exercise facility.</td>
<td>12</td>
<td>Weight change (%)</td>
</tr>
<tr>
<td>Villareal 2011&lt;sup&gt;117&lt;/sup&gt;</td>
<td>USA</td>
<td>Washington University School of Medicine</td>
<td>April 2005 to August 2009</td>
<td>65 years BMI &gt;30 kg/m², sedentary lifestyle, body weight during the previous year (i.e., had not fluctuated more than 2 kg), medications stable for 6 months before enrolment. All participants had to have mild-to-moderate frailty, on the basis of meeting at least two of the following operational criteria: score on the modified</td>
<td>Severe cardiopulmonary disease, neuromuscular impairments that preclude ET, visual, hearing, or cognitive impairments, history of malignant neoplasm, and treatment with bone-acting drugs (e.g. bisphosphonates, glucocorticoids, sex-steroid compounds) during the previous year.</td>
<td>Local advertisements</td>
<td>Total: NR; a:71.10(5.1); b:69.40(4.6)</td>
<td>Total: NR; a:39.00(5.0); b:38.50(5.3)</td>
<td>Total: NR; a:103.20(19.8); b:99.70(13.6)</td>
<td>a: Control: All participants were given supplements to ensure an intake of approximately 1500 mg/day of calcium and approximately 1000 IU/day of vitamin D. Participants did not receive advice to change their diet or activity habits and were prohibited from participating in any weight-loss or exercise program. They were provided general information about a healthy diet during monthly visits with the staff. b: Diet only: Supplements as per control. Balanced diet with energy deficit of 500 to 750 kcal/day from their daily energy requirement. The diet contained approximately 1 g of high-quality protein per kilogram of body weight per day.</td>
<td>12</td>
<td>Weight; Quality of life</td>
</tr>
</tbody>
</table>
Physical Performance Test of 18 to 32; a peak oxygen consumption (VO\textsubscript{2peak}) of 11 to 18 ml per kilogram of body weight per minute; or difficulty in performing two instrumental activities of daily living or one basic activity of daily living.

**Exclusion criteria:**
Severe cardiopulmonary disease; musculoskeletal or neuromuscular impairments that preclude exercise training; visual, hearing, or cognitive impairments; or a history of cancer, as well as persons who were receiving drugs that affect bone health and metabolism or who were current smokers.

**Recruitment:** Advertisements

**Baseline age (years):**
- Total: NR; a:69.00(4); b:70.00(4); c:70.00(4); d:70.00(4)

**Baseline BMI (kg/m\textsuperscript{2}):**
- Total: NR; a:37.30(4.7); b:37.20(4.5); c:36.90(5.4); d:37.20(5.4)

**Baseline weight:**
- Total: NR; a:101.00(16.3); b:104.10(15.3); c:99.20(17.4); d:99.10(16.8)

Participants met weekly as a group with a dietitian for adjustments of their caloric intake and for behavioural therapy. The goal was to achieve a weight loss of approximately 10% of their baseline body weight at 6 months and to maintain that weight loss for an additional 6 months.

c: Exercise only: Supplements as per control. Participants were given information regarding a diet that would maintain their current weight and participated in three group exercise-training sessions per week. Each session was approximately 90 minutes in duration and consisted of aerobic exercises, resistance training, and exercises to improve flexibility and balance. The exercise sessions were led by a physical therapist.

d: Diet + exercise: Supplements as per control. Diet as per diet-only group, exercise as per exercise-only group.

**Duration of active intervention:**
a:12 months; b:12 months; c:12 months; d:12 months

**Number allocated:** 107

**Completed:** Total:93; a:23; b:23; c:22; d:25

**% Dropout:** Total:13.08%; a:14.81%; b:11.54%; c:15.38%; d:10.71%
| von Gruenigen 2008<sup>118</sup> | **Country:** USA  
**Location:** Cleveland, Ohio  
**Period of study:** July - December 2005  
**Inclusion criteria:** Histologically confirmed diagnosis of stage I or II endometrial cancer, received surgery consisting of a total abdominal hysterectomy, and bilateral salpingo-oophorectomy (most with lymph node sampling), had no evidence of disease at the time of enrolment, performance status of 0-2, and a body mass index (BMI) >25 kg/m²  
**Exclusion criteria:** Clear cell or papillary serous histology  
**Recruitment:** An invitation letter was sent to women included in the cancer registry at the Ireland Cancer Center diagnosed from 2001 - 2004  
**Baseline age (years):** Total: NR; a:55.40(7.50); b:54.00(9.59)  
**Baseline BMI (kg/m²):** Total: NR; a:41.10(10.32); b:43.50(10.07)  
**Baseline weight:** Total: NR; a:107.10(24.7); b:115.40(29.4)  
**Description of interventions:**  
**a:** Usual care (UC): Both groups received counselling regarding overall health concerns. UC participants did not receive any advice related to weight loss, physical activity or nutrition at these visits. To reduce attrition, UC participants were offered a modest monetary incentive ($20.00) for each completed data collection point as this group was not receiving any active intervention.  
**b:** Lifestyle intervention (LI): In addition to counselling regarding overall health concerns, LI participants received specific reinforcement of group session topics on weight loss. The LI group met weekly for 6 weeks, bi weekly for 1 month, and monthly for 3 months. The weight loss goal, or clinically important difference (CID) was 5% weight loss in 6 months. Participants were coached to gradually increase walking or other aerobic activity to 5 days a week for 45 min or more, if able.  
**Duration of active intervention:** a:NR; b:6 months  
**Number allocated:** 45  
**Completed:** Total:38; a:18; b:17  
**% Dropout:** Total:15.56%; a:18.18%; b:26.09%  
**Length of follow-up (months):** 12  
**Quantitative outcomes reported:** Weight; Weight change |  
| Wadden 1994<sup>119</sup> | **Country:** USA  
**Location:** University of Pennsylvania  
**Period of study:** 1987-1989  
**Inclusion criteria:** Female, at least 25 kg overweight, as determined by the height-weight tables of the Metropolitan Life Insurance Company (1983), ability to pay $600 to participate ($300 of which was refunded at 6-month intervals for completing the program)  
**Exclusion criteria:** Recent myocardial infarction or evidence of cardiac abnormalities, history of cerebrovascular, kidney or liver disease, cancer, T1DM, bulimia nervosa or significant psychiatric illness  
**Recruitment:** Newspaper advertisements  
**Baseline age (years):** Total: NR; a:42.86(10.12); b:36.82(8.87)  
**Description of interventions:**  
**a:** Balanced deficit diet (BDD): Participants were instructed for the first 52 weeks to consume a 1200 kcal/day diet of which approximately 15-20% of the calories were derived from protein, no more than 30% from fat and the remainder from carbohydrate. They were instructed in food preparation, proper nutrition and behavioural methods of weight control. Participants were told to adjust their caloric intake during the 26 week maintenance program, depending on their desired weight change, but not consume fewer than 1200 kcal /day. From Week 8; participants were instructed initially to exercise for 10-20 mins, 2-3 times a week at 40-60%, of estimated maximum heart rate. By Week 52, participants were to exercise for 20-40 minutes, 3-5 times a week, at 60-70% of maximum heart rate.  
**b:** VLCD: Participants followed a 1200 kcal/day diet for the first week then a liquid VLCD formula during weeks 2-17, providing 420 kcal/day (70 g protein, 30 g CHO, 2 g fat), 2990 mg/day potassium and 100% of US RDA of essential vitamins and minerals. Participants were instructed to drink at least 2 litres of non-caloric fluid daily and to avoid all other foods. Weeks 8-23: conventional  
**Length of follow-up (months):** 20  
**Quantitative outcomes reported:** Weight |
food were gradually reintroduced and the amount of liquid formula reduced, so that by week 23 patients consumed a 1000 kcal/day diet of conventional food. Refeeding was supervised by the dietitian, who co-led groups from weeks 18-27 and provided further information on food preparation and nutrition (as per BDD group). Weeks 24-52: conventional reducing diet of 1200 kcal/day. The 26 week weight maintenance program was as per BDD group.

**Duration of active intervention:** a:NR; b:NR
**Number allocated:** 49
**Completed:** Total:37; a:16; b:21
**% Dropout:** Total:24.49%; a:23.81%; b:25.00%

### Description of interventions:

**BOTH GROUPS:** All participants followed a 1 week run-in period (i.e., week 0) during which they maintained their usual eating and activity habits and completed assessments of appetite, mood, and other measures.

**a:** Physician visits: Patients were prescribed 20 mg/day of dl-fenfluramine the first week, 40 mg/day the second week, and 60 mg/day the third week. Fifteen mg/day of phentermine were added the third week. All patients were instructed to consume a self-selected diet of approximately 1200 kcal/day (with no more than 30% of calories from fat) and to increase their energy expenditure by walking or other aerobic activity.

**b:** Group behaviour therapy: As per the physician visits condition but with weekly group behaviour modification classes for the first 18 weeks. Sessions included six to seven participants, lasted 75 minutes, and were conducted using the LEARN Manual for Weight Control. From weeks 19 to 40, patients attended every-other week weight maintenance classes. Sessions were conducted using the Weight Loss Maintenance Survival Guide.

**Duration of active intervention:** a:52 weeks; b:52 weeks
**Number allocated:** 26
**Completed:** Total:22; a:11; b:11
**% Dropout:** Total:15.38%; a:15.38%; b:15.38%

**Length of follow-up (months):** 12
**Quantitative outcomes reported:** Weight
<table>
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<tr>
<th>Country: USA</th>
<th>Description of interventions:</th>
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</thead>
</table>
| Location: Syracuse University and University of Pennsylvania | **a:** Diet: Weekly group behaviour modification sessions for the first 28 weeks and every-other week meetings from week 30 to week 48, once every 3 months in the year following treatment. During the first week, they were instructed to consume their usual diet of conventional foods. From week 2 to week 17, they were prescribed a 900-925 kcal/day portion-controlled diet that consisted of four servings/day of a liquid diet, combined with a shelf-stable dinner entree and two cups of salad. Each serving of the liquid diet provided 150 kcal, 15 g of protein, 11.2 g of carbohydrate (CHO), and 5 g of fat. The dinner entrees provided 280 kcal, 300 kcal, 20 g of protein, 35 to 40 g of CHO, and 7 g of fat. Beginning at week 18, patients gradually decreased their consumption of the liquid diet which they replaced with conventional foods, so that by week 20 they consumed approx 1250 kcal/day. From week 22 to week 48, participants were instructed to consume approx 1500 kcal/day, with 12% to 15% of calories from protein, 55% to 60% from CHO, and 25% to 30% from fat. Participants were instructed not to participate in any aerobic or strength training.  
| **b:** Diet + aerobic exercise: As per diet alone group but with three/week on-site, supervised training sessions for the first 28 weeks and two workouts/week from Weeks 29 to 48. All exercise sessions lasted approximately 1 hr and included 5- to 10-min warm-up and cool-down periods. Participants were assisted in developing a program of home exercise to replace the third supervised training session that was deleted during this time. Aerobic exercises were designed to expend approximately 300 to 400 kcal per session (by the end of the program). Participants agreed not to engage in resistance training at any time during the study.  
| **c:** Diet + strength training: as per diet + aerobic exercise group except aerobic exercises were replaced with strength training. Participants performed the exercises with a resistance that allowed them to do 10 or more repetitions, but not more than 14. By the end of week 14, participants engaged in weight training for approximately 40 minutes per session. Participants agreed not to initiate aerobic training at any time during the study.  
| **d:** Diet + aerobic exercise and strength training: as per diet alone and exercise groups. Approximately 40%/60% time split between aerobic activity and strength, and expended approximately 225 to 275 kcal per session. | **Length of follow-up (months): 25**  
| **Quantitative outcomes reported:** Weight; Weight change (%) |
### Description of interventions:

**a:** Usual care: Weight < 113.4 kg: prescribed a balanced diet of 1200 to 1500 kcal/day. Weight 113.4 kg or more: 1500 to 1800 kcal/day. Participants followed a diet giving approximately 15 to 20% kcal from protein, 20 to 35% kcal from fat, and the remainder from carbohydrate. All participants were instructed to gradually increase their physical activity to 180 minutes/week. Quarterly primary care provider (PCP) visits during the 24 months of the study to address coexisting illnesses.

**b:** Brief lifestyle counselling: As per usual care plus 10 to 15 minutes each month with an auxiliary health care provider, who delivered treatment by following abbreviated lessons from the DPP.

**c:** Enhanced lifestyle counselling: As per brief lifestyle counselling plus, in consultation with their PCP, participants also chose to take sibutramine, orlistat, or meal replacements to increase weight loss, beginning 1 month after treatment began.

### Length of follow-up (months):

24 months

### Quantitative outcomes reported:

- Weight
- Weight change (%)
- BMI kg/m²
- Waist circumference
- Total cholesterol
- LDL cholesterol
- HDL cholesterol
- Triglycerides
- Systolic BP
- Diastolic BP
- Fasting plasma glucose
with a study participant or staff member, PI or PCP deems an individual should not participate in the study. **Recruitment**: Multiple methods, including PCP referral and self-referral in response to in-clinic advertisements.  
**Baseline age (years)**: Total: 51.50 (11.5); a: 51.70 (12.1); b: 52.00 (12.2); c: 51.00 (10.1)  
**Baseline BMI (kg/m²)**: Total: 38.50 (4.7); a: 39.00 (4.8); b: 38.50 (4.6); c: 37.80 (4.7)  
**Baseline weight**: Total: 107.70 (18.3); a: 111.20 (20.0); b: 106.30 (17.3); c: 105.40 (17.2)

### Description of interventions:

**BOTH GROUPS**: DPP materials were adapted for delivery by telephone. Written materials were provided to participants at baseline and educators followed scripts as per DPP materials.  

#### a: Individual
Educators initiated individual calls with participants at mutually agreed times. Educators served as liaisons to the PCPs and were asked to provide quarterly feedback to them about patient progress. Coaches (registered dietitians) made monthly calls (after first 5 weeks) alternating with educators. During year 2, each participant could request up to six coach contacts. Participants used “keeping track logs” to quantify diet and activity behaviours and review progress. They mailed these monthly for dissemination to their educator and coach.  

#### b: Conference calls
As per the individual group but group conference calls were held at mutually convenient times, mediated by a telephone conferencing service.

### Duration of active intervention: a: 24 months; b: 24 months

**Number allocated**: 257  
**Completed**: Total: 132; a: NR; b: NR  
**% Dropout**: Total: 48.64%; a: NR; b: NR

### Length of follow-up (months): 36

**Quantitative outcomes reported:** Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose

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Weinstock 2013

**Country**: USA  
**Location**: Five diverse primary care provider (PCP) sites in upstate New York  
**Period of study**: June 2009 - November 2010  
**Inclusion criteria**:  
> 18 years old, presence of metabolic syndrome (IDF criteria) and BMI ≥30 kg/m². The International Diabetes Federation definition requires central obesity, measured by waist circumference (WC) with ethnicity-based cutoffs, plus two of four other criteria: triglyceride level ≥150 mg/dl or triglyceride treatment, HDL-cholesterol <40 mg/dl (males) and <50 mg/dl (females) or HDL treatment, elevated blood pressure (systolic ≥130 or diastolic ≥85 mmHg) or treatment of diagnosed hypertension, and high fasting plasma glucose (≥100 mg/dl).  

**Exclusion criteria**:  
Diagnosed diabetes and presence of severe medical problems that could interfere with participation (e.g., severe current psychiatric illness).  
**Recruitment**: Potential volunteers were offered study involvement by their PCP at office visits or were identified (chart review) and contacted (letter/phone).  
**Baseline age (years)**: Total: 52.00 (NR); a: 50.70 (13.1); b: 52.70 (12.8)  
**Baseline BMI (kg/m²)**: Total: 39.00 (NR); a: 38.90 (7.6); b: 39.70 (8.3)  
**Baseline weight**: Total: NR; a: 105.80 (23.6); b: 109.40 (26.1)
Inclusion criteria:
Women least 30 years of age, had a BMI between 25 and 50 kg/m², reported 10 or more episodes of urinary incontinence on a 7-day voiding diary, and were able to walk for exercise

Exclusion criteria:
Medical conditions that contraindicated weight loss, pregnancy or parturition in the previous 6 months or history of current or persistent urinary tract infection or other medical conditions of the genitourinary tract

Recruitment: NR

Baseline age (years): Total:53.00(10); a:53.00(10); b:53.00(10); c:53.00(11)
Baseline BMI (kg/m²): Total:36.00(6); a:36.00(5); b:37.00(6); c:36.00(5)
Baseline weight: Total:97.00(17); a:95.00(16); b:100.00(19); c:95.00(15)

Description of interventions:
a: Control: Seven education sessions that provided general information about physical activity, healthy eating habits and weight loss, following a structured protocol.
b+c: The same 6-month weight loss program was offered to all individuals randomized to behavioural weight control regardless of the maintenance condition. The 24-session program was modelled after DPP and the Look AHEAD lifestyle interventions. A reduced calorie balanced diet was prescribed and meal replacement product coupons were provided to replace two meals and one snack/day throughout. Graded exercise goals progressed to 200 min/week or more of moderate physical. To encourage adoption of the dietary and physical activity recommendations, training in specific behavioural skills was provided. After the initial weight loss program, all lifestyle participants received a 12-month weight maintenance intervention with bi weekly group meetings. The overall aim for both programs was to achieve and maintain at least a 10% weight loss.
b: Skill-based maintenance: A standard behavioural maintenance programme focused on reviewing and refining behavioural skills in problem solving, goal setting, social support and relapse prevention. New skill development topics introduced included reversing small weight gains, improving body image and self-esteem, and expanding exercise options.
c: Motivation-based maintenance: Same as skill-based maintenance group except the novel maintenance intervention focused on increasing and sustaining motivation to use the dietary, physical activity and behavioural skills introduced in the initial weight loss phase rather than on improving and fine-tuning those skills.

Duration of active intervention: a:NR; b:12 months; c:12 months

Number allocated: 338
Completed: Total:289; a:88; b:98; c:103
% Dropout: Total:14.50%; a:21.43%; b:13.27%; c:8.85%
Wing 1991a

Country: USA  
**Location:** University of Pittsburgh School of Medicine, Pennsylvania  
**Period of study:** Prior to July 1991  
**Inclusion criteria:** 35 to 70 years of age, 30% or more above ideal body weight based on the Metropolitan Life Insurance norms, type 2 diabetes as defined by the National Diabetes Data Group, and with no evidence of liver disease, renal disease, or heart disease that would contraindicate the use of VLCDs.  
**Exclusion criteria:** NR  
**Recruitment:** NR  
**Baseline age (years):** Total: NR; a:51.90(9.9); b:50.60(7.7)  
**Baseline BMI (kg/m²):** Total: NR; a:38.10(5.7); b:37.34(4.7)  
**Baseline weight:** Total: NR; a:104.50(21.5); b:102.10(11.7)  
**Description of interventions:**  
a: Behaviour therapy (BT): Group therapy including instruction in diet, exercise, and behaviour modification. Participants were given weekly exercise goals, starting at 210 J/week (equivalent to walking 0.5 mile for a 67.5 kg person), and increasing to 4200 J/week (approximately 10 miles/week). Calorie goals were 4200 to 6300 J/day depending on initial body weight, and were instructed to remain at this calorie goal throughout the program unless ideal body weight was achieved. Participants were encouraged to increase their complex carbohydrate, especially fibre while decreasing dietary fat.  
b: Same as BT group for the first month, then participants followed a VLCD for months 2 and 3. While on the VLCD, participants were instructed to consume 1680 J/day of lean meat, fish, or fowl, and had the option of using Optifast 70 (Sandoz Nutrition) for occasional meals. Participants receiving insulin started the VLCD in the hospital, where insulin was either withdrawn or sharply reduced. After 8 weeks on the VLCD, other foods were gradually reintroduced and calories increased so that by week 17 participants had returned to a 4200 to 6300 J/day, balanced diet, which they were instructed to consume for the remainder of the study.  
**Duration of active intervention:** a:20 weeks; b:20 weeks  
**Number allocated:** 36  
**Completed:** Total:33; a:16; b:17  
**% Dropout:** Total:8.33%; a:15.79%; b:0.00%  
**Length of follow-up (months):** 18  
**Quantitative outcomes reported:** Weight; BMI kg/m²; Total cholesterol; HDL cholesterol; Triglycerides; HbA1c %; Fasting plasma glucose

Wing 1991b

Country: USA  
**Location:** University of Pittsburgh School of Medicine, Pennsylvania  
**Period of study:** Prior to February 1991  
**Inclusion criteria:** 20% or more above ideal body weight, aged 30-65 years, met the National Diabetes Data Group (1979) criteria for Type 2 diabetes (These criteria include fasting glucose >= 140 mg/dl or the two hr and one other value >= 200 mg/dl after an oral glucose load). Spouses were required to be > 15% above ideal weight and aged 30-70 years.  
**Exclusion criteria:** NR  
**Recruitment:** Newspaper advertisements  
**Baseline age (years):** Total: NR; a:51.20(7.3); b:53.60(7.7)  
**Description of interventions:**  
BOTH GROUPS: A 20 week, group behavioural weight loss programme. Participants self-monitored calorie intake and were directed to stay within a goal of 1200-1500 kcal/day. Decreasing total fat and simple carbohydrates and increasing complex carbohydrates and fibre were stressed. Participants were given stepwise goals for a walking program with a final goal of expending at least 1000 calories/week in exercise. A $150 deposit was required from each couple.  
a: Spouses in the alone condition were not permitted to attend treatment meetings but attended an assessment session after the 20 week program and at 1-year follow-up. The deposit was refunded contingent on the participant's weight loss ($2/lb lost up to 25 lb. $50). Fifty dollars was refunded if both the patient and spouse attended the post-assessment and $50 if both attended the 1-year follow-up assessment.  
**Length of follow-up (months):** 18  
**Quantitative outcomes reported:** Weight; BMI kg/m²; HbA1c %; Fasting plasma glucose
Baseline BMI (kg/m²): Total: NR; a:36.64(5.77); b:35.68(5.76)
Baseline weight: Total: NR; a:103.19(18.51); b:96.84(19.69)

**b:** In the together condition, both the diabetic patients and the spouse participated in the behavioural weight control programme and both were targeted for weight loss. The spouses participated in all aspects of the programme and no distinction was made between patient and spouse. Spouses were taught to provide each other with positive reinforcement in the form of praise for appropriate changes in diet and exercise behaviour and were taught appropriate listening skills and to identify joint problems (e.g. family dinners) and to work together to develop mutually agreeable solutions. The patient and spouse each deposited $75 and could each earn back the money by losing weight ($2/lb up to 25 lb) and attending the 1-year assessment ($25).

**Duration of active intervention:** a:NR; b:NR
**Number allocated:** 49
**Completed:** Total:43; a:23; b:20
**% Dropout:** Total:12.24%; a:4.17%; b:20.00%

**Wing 1994**

**Country:** USA
**Location:** University of Pittsburgh, Pennsylvania
**Period of study:** Pre-1994
**Inclusion criteria:**
National Diabetes Data Group criteria for type 2 diabetes, either more than 30% or more than 18 kg above ideal body weight based on Metropolitan Life Insurance norms, were aged 30 to 70 years, with no health problems that would preclude use of a VLCD

**Exclusion criteria:**
Health problems that would preclude use of a VLCD

**Recruitment:** Newspaper advertisements

**Baseline age (years):** Total: NR; a:51.30(8.7); b:52.30(10.7)
**Baseline BMI (kg/m²):** Total: NR; a:38.31(6.52); b:37.42(6.13)
**Baseline weight:** Total: NR; a:107.70(18.7); b:105.80(19.4)

**Description of interventions:**
**BOTH GROUPS:** Both groups participated in a year-long behavioural treatment program, with weekly group meetings conducted by a multidisciplinary team of therapists. Nutrition topics focused on the importance of reducing dietary fat and increasing complex carbohydrates and fibre. Patients were given weekly exercise goals, which were gradually increased over time, until they were asked to walk 10 miles each week (2 miles/day on 5 days/week).

**a:** The LCD group was assigned a calorie intake goal of 1000 to 1200 kcal/day throughout the program. Participants were able to select the food items they wished, but were encouraged to spread their calories over the day and to limit their dietary fat intake to less than 30% of calories.

**b:** The VLCD group was prescribed a diet of 400 to 500 kcal/day for weeks 1 through 12 and 24 through 36 of the program. During these VLCD periods, participants were instructed to consume no more than 500 kcal/day. These calories could be consumed in the form of liquid formula or as lean meat, fish, and fowl. After 12 weeks on the VLCD, other foods were gradually reintroduced, and the prescribed number of calories was gradually increased over the next 4 to 1000 kcal of balanced diet. Participants were restarted on the VLCD at week 24 unless ideal body weight had already been reached.

**Length of follow-up (months):** 24
**Quantitative outcomes reported:**
Weight; BMI kg/m²; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; HbA1c %; Fasting plasma glucose; Quality of life
| Country: USA |
| Location: University of Pittsburgh, Pennsylvania |
| Period of study: Prior to 1997 |

**Inclusion criteria:**
30-100% of ideal body weight, aged 40-55 years, nondiabetic, and had one or two biological parents with type 2 diabetes.

**Exclusion criteria:** Diabetes

**Recruitment:** Newspaper advertisements

**Baseline age (years):**
- Total: 45.70(4.4); a: 45.30(4.9); b: 45.00(4.7); c: 46.40(4.5); d: 46.30(3.8)

**Baseline BMI (kg/m²):**
- Total: 35.90(4.3); a: 36.00(5.4); b: 36.10(4.1); c: 36.00(3.7); d: 35.70(4.1)

**Baseline weight:**
- Total: NR; a: 97.40(16.0); b: 99.60(13.0); c: 99.30(15.3); d: 98.70(15.9)

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### Description of interventions:

**a: Control:** Participants were given a copy of the Learn Manual. They were not invited to any treatment meetings but participated in all assessments.

**b: Diet:** Weekly group meetings for the first 6 months, and then biweekly meetings for 6 months. In addition, two 6 week refresher courses were held during year 2. Group meetings were led by a multidisciplinary team of therapists, and focused on behavioural strategies to help modify intake and nutrition information related to the diet. Participants followed a 800-1000 kcal/day diet, with 20% of calories as fat, for weeks 1-8 of the program; the diet was gradually made more flexible over the course of the program, with calorie goals adjusted to 1200-1500 kcal/day at week 16.

**c: Exercise:** Meetings on the same contact schedule as the diet condition. Again, meetings were conducted by a multidisciplinary staff, but the primary therapists were a behaviour therapist and an exercise physiologist. Each meeting for these participants included a lecture on a topic related to changing exercise behaviour. Participants took a 50-60-min walk with the therapist at each of the weekly meetings. During weeks 1-10 of the program, a second supervised walk session was available each week. Participants were encouraged to gradually increase their physical activity to 1500 kcal/week. Activity level was increased gradually in biweekly increments of 250 kcal/week.

**d: Diet + exercise:** Participants received both the diet and exercise interventions.

### Duration of active intervention:
- a: NR; b: 24 months; c: 24 months; d: 24 months

### Number allocated:
- a: 154

### Completed:
- Total: 129; a: 31; b: 35; c: 31; d: 32

### Dropout:
- Total: 16.23%; a: 22.50%; b: 5.41%; c: 16.22%; d: 20.00%
<table>
<thead>
<tr>
<th>Country: USA</th>
<th>Description of interventions:</th>
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<tbody>
<tr>
<td>Location: University of Virginia Health System and General Clinical Research Centre</td>
<td>a: Usual care participants received educational material and were free to join other weight management or diabetes care programmes.</td>
</tr>
<tr>
<td>Period of study: Prior to July 2004</td>
<td>b: One registered dietitian met with participants individually, in groups, and by phone for assessment, goal setting, education, and support. Goals were tailored but based on national dietary recommendations for people with type 2 diabetes and obesity. Goals of the intervention were modest weight loss (5% of initial weight) and dietary intake as well as physical activity reflecting national recommendations.</td>
</tr>
<tr>
<td>Inclusion criteria: Type 2 diabetes, use of diabetes medications, BMI ≥27 kg/m², age ≥20 years, ability to comprehend English, and membership in the Southern Health Services health plan</td>
<td><strong>Duration of active intervention:</strong> a: 12 months; b: 12 months</td>
</tr>
<tr>
<td>Exclusion criteria: Pregnancy, cognitive limitations, or medical reasons precluding dietary and physical activity modifications</td>
<td><strong>Number allocated:</strong> 147</td>
</tr>
<tr>
<td>Recruitment: Members in the Southern Health Services (SHS) health plan</td>
<td>Completed: Total: 115; a: 61; b: 54</td>
</tr>
<tr>
<td>Baseline age (years): Total: NR; a: 53.40(8.0); b: 53.30(8.6)</td>
<td><strong>% Dropout:</strong> Total: 21.77%; a: 16.44%; b: 27.03%</td>
</tr>
<tr>
<td>Baseline BMI (kg/m²): Total: NR; a: 37.50(6.4); b: 37.60(7.7)</td>
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<tr>
<td>Baseline weight: Total: NR; a: 106.70(24.3); b: 107.10(25.5)</td>
<td><strong>Quantitative outcomes reported:</strong> Weight; Waist circumference</td>
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<table>
<thead>
<tr>
<th>Country: USA</th>
<th>Description of interventions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location: Freestanding Health Maintenance Organization, Albert Einstein College of Medicine, Long Island</td>
<td>a: Workbook only: Designed for use as a standalone (do-it-yourself) programme in which participants completed self-help sheets that guided them to sections of the workbook most salient to their needs. The workbook also served as an integral component of the more intensive intervention modalities.</td>
</tr>
<tr>
<td>Period of study: Prior to October 2001</td>
<td>b: Workbook + computer: An expert software programme was written to guide participants in using the workbook and tailor behavioural goals based on their prior computer use and the answers they provided on baseline questionnaires. The computer system addressed nutrition, fitness, and psychobehavioral content.</td>
</tr>
<tr>
<td>Inclusion criteria: BMI of more than 25 (or a BMI of 24 kg/m² or more plus 1 cardiovascular risk factor) and the willingness to follow the study protocol, which included a refundable $100 deposit.</td>
<td>c: Workbook + computer + staff: 6 closed-group workshop sessions and up to 18 telephone or face-to-face consultations with a registered dietitian and/or a cognitive behavioral therapist. The workshop curriculum focused on specific activities and assignments in the workbook, and it encouraged use of the computer to identify problems and issues. Thus, the consultation reinforced and amplified the content of the computer system and the workbook.</td>
</tr>
<tr>
<td>Exclusion criteria: Intention to move beyond commuting distance within the next 12 months, medical conditions that would interfere with study participation, and unwillingness to follow the study protocol. Recruitment: Newsletter articles, flyers, posters, and local media news coverage via cable television and newspapers</td>
<td><strong>Duration of active intervention:</strong> a: 12 months; b: 12 months; c: 12 months</td>
</tr>
<tr>
<td>Baseline age (years): Total: 52.20(NR); a: 52.50(11.50); b: 52.70(11.27); c: 51.60(12.14)</td>
<td></td>
</tr>
<tr>
<td>Baseline BMI (kg/m²): Total: NR</td>
<td><strong>Quantitative outcomes reported:</strong> Weight; Weight change (%); BMI kg/m²; Waist circumference; Total cholesterol; LDL cholesterol; HDL cholesterol; Triglycerides; Systolic BP; Diastolic BP; Fasting plasma glucose</td>
</tr>
</tbody>
</table>
Baseline BMI (kg/m²): Total:35.60(6.5); a:36.50(6.0); b:35.70(6.7); c:35.16(6.5)
Baseline weight: Total:97.16(20.00); a:100.15(20.68); b:96.75(19.96); c:96.07(19.69)
Number allocated: 588
Completed: Total:474; a:97; b:183; c:194
% Dropout: Total:19.39%; a:16.38%; b:22.46%; c:17.80%

Country: USA
Location: Middle class community in Lower Naugatuck Valley, CT
Period of study: Prior to December 2003
Inclusion criteria:
Age 30-65, with obesity or overweight, as defined by BMI greater than 25 kg/m², the participants were required to be the primary person in the household who purchases groceries and prepares meals.
Exclusion criteria:
Unstable medical condition affecting ability to participate fully in the study, participating in another weight reduction program at the time of enrolment, pharmacologically treated diabetes, or were using medications known to affect weight gain or loss.
Recruitment: Local newspaper advertisements, and flyers in hospitals and grocery stores
Baseline age (years): Total: NR; a:51.00(11.0); b:48.00(9.0)
Baseline BMI (kg/m²): Total: NR; a:36.30(5.4); b:37.90(6.7)
Baseline weight: Total: NR; a:96.57(15.4); b:99.16(19.0)

Description of interventions:
a: Standard counselling: Dietary counselling provided by a licensed dietitian.
The content of the sessions was determined by the dietitian based on interactions with each participants. Each participants received individualized counselling based upon their diet history, medical history, and psychosocial concerns. During the initial session the clients were instructed in a low-calorie meal plan and, during subsequent sessions, received instruction regarding meal planning, food label reading, recipe modification, dining out, and physical activity.
b: Skills based intervention: Two 90-min didactic sessions delivered to groups of approximately 20 participants, followed by skill building sessions over a 4-month period. Each didactic session consisted of 60 min for presentation and 30 min for question and answer. Following the didactic sessions, participants began technical skill building sessions including: Two 2-hr trips to the supermarket in groups of 10 supervised by the dietitian in which participants received aisle-by-aisle instruction in the selection of healthful items, and in the interpretation of food labels; Two dinners at local restaurants. Each of the dinners was attended by 5 participants and the dietitian. Participants received instruction in the selection of healthful dishes from the menu, and in obtaining information from restaurant staff about menu options. A 2-hr private session at each of the participants’ homes with the dietitian supervising the preparation of a meal. The dietitian provided instruction in ingredient selection, pantry stocking, food preparation methods, and portion sizing. Following completion of the skill-building phase of the intervention, participants had telephone and E-mail access to the dietitian for the remainder of the year.

Duration of active intervention: a:NR; b:6 months
Number allocated: 80
Completed: Total:27; a:14; b:13
% Dropout: Total:66.25%; a:65.00%; b:67.50%

Data are means and standard deviation unless otherwise indicated.
### 6 Risk of bias of the individual study level assessment

#### Table 3 Risk of bias

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1; High, 2; Unclear, 3; Low; Random sequence, was the method used to generate the allocation sequence sufficient to produce comparable groups?; Allocation concealment, was the method used sufficient to prevent intervention allocations from being foreseen in advance of allocation?; Blinding of participants, were sufficient measures used to blind participants to knowledge of which intervention they received?; Blinding of personnel, were sufficient measures used to blind intervention providers to knowledge of which intervention participants received?; Blinding of assessors, were sufficient measures used to blind outcome assessors to knowledge of which intervention participants received?; Incomplete outcome, reasons for attrition/exclusions from analyses/intention-to-treat analyses; Selective reporting, potential for bias due to selective outcome reporting; Other bias, any other concerns about bias not addressed by the other tool domains.
## Individual study level equity results

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1: Yes, 2: No, 3: Not reported, 4: Unclear; Social context, was the study conducted in a particular setting that might target/exclude specific populations?; Representative sample, are participants likely to be representative of the target population?; Sociodemographic, are there sociodemographic differences between withdrawals and exclusions?; PROGRESS, were place of residence, occupation, gender, religion, education and literacy, socioeconomic status and social capital categories reported at baseline?; Disadvantage, did the intervention include strategies to address diversity/disadvantage?; Fidelity check, was a fidelity check conducted?; Process measures, were process measures taken?; Providers, who provided the intervention, numbers, education/training, ethnicity, etc, if potentially relevant to acceptance and uptake by participants?; Sustainability, Was sustainability discussed or considered during study development?; Organisational context, was the political or organisational context described?; Partnerships referred, were any partnerships referred?; Data collectors, was there evidence for potential conflict of interest among authors or data collectors?; Unintended effects, were harms/unintended effects of the intervention described?
## BCT tables

### Table 5  BCT coding summary for all RCTs of VLCD and dietary intervention versus dietary intervention

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WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined.
Table 6  BCT coding summary for all RCTs of bariatric surgery

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| 8.7 | Graded tasks | Y | Y | Y | Y | Y | Y | Y | Y | 22.2 | 0 
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| 10.1 | Material incentive (behaviour) | Y | Y | Y | 11.1 | Y | Y | Y | 8.3 |
| 10.2 | Material reward (behaviour) | Y | Y | 11.1 | Y | 8.3 |
| 10.11 | Future punishment | Y | Y | 11.1 |
| 11.1 | Pharmacological support | Y | Y | 22.2 | Y | 8.3 |
| 12.5 | Adding objects to the environment | Y | Y | 22.2 | Y | 8.3 |

WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined.
Table 7  BCT coding summary low CHO (≤40 g CHO/d) versus other diet RCTs

| BCT Reference | BCT Description                          | Low CHO diet | Bazzano 20146 | Davis 2009a | Foster 2010b | Iqbal 2010c | Stern 2004d | BCT Total % | Other | Bazzano 2014 LF9 | Davis 2009 LF | Foster 2010 LFc | Iqbal 2010 LF | Stern 2004 LF convent. | BCT Total % |
|---------------|-----------------------------------------|--------------|---------------|-------------|-------------|-------------|-------------|-------------|-------|-----------------|--------------|----------------|-------------|----------------------|-------------|------------------|
|               | Quality of reported BCT description     |              | WD            | PD          | AD          | PD          | WD          | PD          | AD    | PD              |              | AD              | PD          | PD                    |              |
|               | Physical activity component             |              |               | PA          | PA          | PA          | PA          | PD          | PA    | PD              |              |                 |             | PD                    |              |
| 1.1           | Goal setting (behaviour)                | Y            | Y             | Y           | Y           | Y           | 100         | Y           | Y     | Y               | Y            |               |             | 100                   |              |
| 1.2           | Problem solving                         | Y            | Y             |              | Y           |              |              |              |       |                  |              |                 |             | 40                    |              |
| 1.5           | Review behaviour goals                  | Y            |               |              |              |              |              |              |       | Y               |              | Y               |             | 20                    |              |
| 2.2           | Feedback on behaviour                   | Y            | Y             | Y           |              |              |              |              |       | Y               |              | Y               |             | 20                    |              |
| 2.3           | Self-monitoring of behaviour            | Y            | Y             | Y           |              |              |              |              |       | Y               |              | Y               |             | 60                    |              |
| 3.1           | Social support (unspecified)            | Y            |               |              |              |              |              |              |       |                  |              |                 |             |                       |              |
| 4.1           | Instruction on how to perform a behaviour| Y            | Y             | Y           | Y           | Y           | 100         | Y           | Y     | Y               | Y            | Y               | 100         | 100                   |              |
| 4.2           | Information about antecedents           | Y            |               |              |              |              |              |              |       |                  |              |                 |             | 20                    |              |
| 5.1           | Information about health consequences   | Y            |               | Y           |              |              |              |              |       |                  |              |                 |             | 20                    |              |
| 8.7           | Graded tasks                            | Y            |               |              |              |              |              |              |       |                  |              |                 |             | 20                    |              |
| 9.1           | Credible source                         | Y            | Y             | Y           | Y           | Y           | 100         | Y           | Y     | Y               | Y            | Y               | 100         | 100                   |              |
| 10.3          | Nonspecific reward                      | Y            |               |              |              |              |              |              |       |                  |              |                 |             | 20                    |              |
| 12.5          | Adding objects to the environment       | Y            | Y             | Y           |              |              |              |              |       |                  |              | Y               |             | 60                    |              |
| 13.2          | Framing/reframing                       | Y            |               |              |              |              |              |              |       |                  |              |                 |             | 0                     |              |
| 14.4          | Reward approximation                    | Y            |               |              |              |              |              |              |       |                  |              |                 |             | 0                     |              |

WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity) BCTs that are unique to either control or intervention treatment arms in each study are underlined
Table 8  BCT coding summary for higher protein versus lower protein diets RCTs

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WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined
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WM = weight maintenance, WL = weight loss, MR = meal replacement, WD = Well described, AD = Adequately described in parts, PD = Poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined
## Table 10 BCT coding summary for orlistat RCTs

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| 9.1 |   | Credible source                           | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | 83.3 |
| 11.1 |   | Pharmacological support                    | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | 100 | Y | Y | Y | Y | Y | Y | Y | Y | 8.3 |

WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined.
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WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity).

BCTs that are unique to either control or intervention treatment arms in each study are underlined.
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WD = Well described, AD = Adequately described in parts, PD = Poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined
Table 13  BCT coding summary in-person delivery versus phone-internet only delivery RCTs

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WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined
### Table 14  BCT coding summary for IN SHAPE programme with trainer vs same programme without trainer (for people with serious mental illness) RCTs

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<tr>
<th>BCT Reference</th>
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<th>Barrels 2018°</th>
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<td>PF</td>
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<td>PA</td>
<td>PA</td>
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WD = Well described, AD = Adequately described in parts, PD = Poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity).

BCTs that are unique to either control or intervention treatment arms in each study are underlined.
## Table 15  BCT coding summary of inpatient session versus outpatient sessions RCTs

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<th>Outpatient/other</th>
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WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined
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WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity)

BCTs that are unique to either control or intervention treatment arms in each study are underlined.
Table 17  BCT coding summary of weight loss versus weight neutral RCTs

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**WD** = Well described, **AD** = adequately described in parts, **PD** = poorly described, **PA** = Physical activity advice only, **PF** = Physical facility (supervised activity)

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BCTs that are unique to either control or intervention treatment arms in each study are underlined
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WD = Well described, AD = adequately described in parts, PD = poorly described; PA = Physical activity advice only, PF = Physical facility (supervised activity).

BCTs that are unique to either control or intervention treatment arms in each study are underlined.
9 List of included studies for the review of UK studies


Counterweight Project Team The implementation of the Counterweight Programme in Scotland, UK. *Family Practice* 2012;29:139-44.


List of excluded studies for the review of UK studies

Not UK studies N=15


**BMI < 35 or unclear N=21**


Not Lifestyle Intervention or unclear N=18


**Less than 12 month assessment N=6**


**No data N=2**


**Not obtained N=4**


### Quality assessment non-RCTs

#### Table 20 Individual study level quality assessment of the UK non-randomised studies

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228
1, yes; 2, no; 3, unclear; Representative sample, were participants a representative sample selected from a relevant patient population?; Exclusion criteria, were the inclusion/exclusion criteria clearly described?; Disease progression, were participants entering the study at a similar point in their disease progression?; Patients consecutive, was selection of participants consecutive?; Prospective data, was data collection undertaken prospectively?; Groups comparable, were groups comparable on demographic characteristics and clinical features (comparative studies only)?; Comparison defined, was the intervention (and comparison) clearly defined?; Someone experience, was the intervention undertaken by someone experienced at performing the procedure?; Appropriate setting, was the intervention delivered in an appropriate setting?; Outcomes considered, were any of the important outcomes considered?; Outcome measures, were objective (valid and reliable) outcome measures used?; Outcomes blind, was the assessment of main outcomes blind (comparative studies only)?; Important effects, was follow-up long enough to detect important effects on outcomes of interest?; Dropouts reported, was information provided on non-respondents and dropouts?; Dropouts similar, did withdrawals/dropouts have similar characteristics to those who completed the study?; Follow-up similar, was length of follow-up similar between comparison groups (comparative studies only)?; Prognostic factors, were important prognostic factors identified?; Analyses adjusted, were the analyses adjusted for confounding factors (comparative studies only)?
## Equity results

### Table 21  Individual study level assessment of equity for UK studies

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<th>Study ID</th>
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<th>Representative Sample</th>
<th>Sociodemographic</th>
<th>PROGRESS</th>
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<td>Wallace 2015</td>
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</tbody>
</table>
List of included qualitative studies


Amy Janke E, Kozak AT. "The more pain I have, the more I want to eat": obesity in the context of chronic pain. *Obesity* 2012;20:2027-34.


Groven KS, Engelsrud G. Dilemmas in the process of weight reduction: Exploring how women experience training as a means of losing weight. *International Journal of Qualitative Studies on Health and Well being* 2010;5.

Gudzune KA, Clark JM, Appel LJ, Bennett WL. Primary care providers' communication with patients during weight counseling: a focus group study. *Patient Education and Counseling* 2012;89:152-7.


Owen-Smith A, Donovan J, Coast J. "Vicious circles": the development of morbid obesity. *Qualitative Health Research* 2014;24:1212-20.


List of excluded qualitative studies

BMI <35 or unclear N=34


Lozano-Sufrategui L, Pringle A, Carless D, McKenna J. 'it brings the lads together': a critical exploration of older men's experiences of a weight management programme delivered through a Healthy Stadia project. (Special Issue: Healthy stadia: an insight from policy to practice.). Sport in Society: Cultures, Commerce, Media, Politics 2017;20:303-15.


**Not UK study and not linked to intervention N=42**


Gonzalez-Cort A. Examining the impact of drastic weight loss in previously obese adults: Personal narratives and relationships in flux. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 2014;74.


Owen-Smith A, Coast J, Donovan J. "I can see where they're coming from, but when you're on the end of it ... you just want to get the money and the drug.": explaining reactions to explicit healthcare rationing. *Social Science & Medicine* 2009;68:1935-42.


**Not Qualitative Study N=10**


Hunt K, McCann C, Gray CM, Mutrie N, Wyke S. "You've got to walk before you run": Positive evaluations of a walking program as part of a gender-sensitized, weight-management program delivered to men through professional football clubs. *Health Psychology* 2013;32:57-65


Patients ineligible N=3


Intervention ineligible N=1


Not Obtained N=7


Volino MA. Factors influencing nurses' intentions to provide weight management education to hospitalized obese adults. Dissertation Abstracts International: Section B: The Sciences and Engineering 2015;75
DATA EXTRACTION FORM

1. Data entry, checks and additions to this form (add rows if necessary):

<table>
<thead>
<tr>
<th>Initials</th>
<th>Date</th>
<th>Action(s)</th>
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2. Bibliographical information

<table>
<thead>
<tr>
<th>Paper’s first author and year (e.g. Smith, 2010):</th>
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<tbody>
<tr>
<td>Journal</td>
<td></td>
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</table>

3. Summary of the key contribution(s) of the paper to our review (i.e. summary of relevant key findings/our observations and interpretations)
4. Characteristics of the study / paper

<table>
<thead>
<tr>
<th>Main aim of study</th>
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<tbody>
<tr>
<td>Aim/focus of paper (if narrower)</td>
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<td>Country/ies in which data was collected</td>
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<tr>
<td>Health care setting(s)</td>
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<tr>
<td>Participants (patients/providers)</td>
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<td>Design and methods</td>
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<td>Sample size</td>
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<td>Characteristics of the intervention (if not extracted as part of quantitative review)</td>
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</tr>
</tbody>
</table>

5. Main findings / themes as authors report and discuss them
(Summary of relevant points.)

<table>
<thead>
<tr>
<th>Descriptive summary of what the authors report relating to our review questions (Use authors’ language as far as possible. Can also add relevant illustrative quotes from study participants)</th>
<th>Rebalance team comments (Use space or more formal rows to ‘link’ comments to points in the left hand column as appropriate)</th>
</tr>
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</table>
6. Quality/Reviewers’ notes and reflections

<table>
<thead>
<tr>
<th>Notes about setting, sample etc? (implications for interpretation)</th>
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</thead>
<tbody>
<tr>
<td>Notes about design/methods? (implications for interpretation)</td>
</tr>
<tr>
<td>Conceptual clarity (i.e. are the data explained, not just described?)</td>
</tr>
<tr>
<td>Interpretive rigour (i.e. Are the findings adequately supported by the data presented?; Have the authors challenged their interpretations?)</td>
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<tr>
<td>Any other quality issues not covered above?</td>
</tr>
</tbody>
</table>

7. Any additional points from team discussions?

<table>
<thead>
<tr>
<th>Other publications from same study to retrieve? (Either NO or add refs /action)</th>
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<tbody>
<tr>
<td>Potentially relevant cited studies to check/get?</td>
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</table>

8. Follow-up actions

<table>
<thead>
<tr>
<th>Other publications from same study to retrieve? (Either NO or add refs /action)</th>
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</thead>
<tbody>
<tr>
<td>Potentially relevant cited studies to check/get?</td>
</tr>
</tbody>
</table>
### Characteristics of the included qualitative studies

#### Table 22 Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Aim (as described within the papers)</th>
<th>Condition of Focus</th>
<th>Participants Characteristics</th>
<th>Details of intervention</th>
<th>Qualitative data collection methods</th>
</tr>
</thead>
</table>
| **First Author:** Bennett<sup>149</sup>  
Year: 2014  
Category: A  
Country: USA | To understand primary care providers’ (PCPs) perspectives about their role in the intervention and in their patients’ weight loss, thereby providing insights to inform best practices in developing practice-based weight management programmes. | Patients with obesity in their usual care practices. | **Role:** Provider  
**Number providers interviewed:** 26 PCPs  
**Providers’ characteristics:** 15 female, 11 male, 24 physicians, 2 nurse practitioners, and 20 had internal medicine training. The mean time in practice was 16 years (SD ± 11.7), and mean number of patients in the trial was 11.1 (SD ± 6.8)  
**Socioeconomic and demographic characteristics:** 15 White, 6 Asian/Pacific Islander, 3 Black, 2 Other | The Practice-based Opportunities for Weight Reduction (POWER) was a 24 month trial that had two intervention groups (by phone and face-to-face) in which weight-loss health coaches (not PCPs) provided education and positive reinforcement. Participants in both intervention arms had access to the same online educational modules, self-monitoring tools and received both automated and individualized e-mails. Participants in the control arm met with a weight loss health coach at the time of randomization and, if desired, after the final data collection visit. They also received brochures along with a list of recommended weight loss websites. | Focus groups |
| **First Author:** Bradbury<sup>150</sup>  
Year: 2015  
Category: A  
Country: UK | To explore helpful (and unhelpful) aspects of coaching; the experiences of POWeR and the accompanying coaching, including what aspects people found most helpful. | Participants with obesity. | **Role:** Participant  
**Number of participants:** 58.  
**Planning and development stages:** 16 participants;  
**Feasibility stage:** 23 participants;  
**Community trial:** 19 participants. | Positive Online Weight Reduction (POWeR) is an e-health intervention designed to produce sustainable weight management. POWeR consisted of 12 sessions which taught users self- | Interviews |

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16 Characteristics of the included qualitative studies
unhelpful, appealing or unappealing, and what factors seemed to influence whether participants continued to follow POWeR.

Participants’ characteristics: From the community trial: age range 34-68, Participants were sampled from both the coaching arm (10 female, four male) and Web only arm (four female, one male) and varied in their usage of POWeR. 
Socioeconomic and demographic characteristics: NR 
Comorbidities: NR

<table>
<thead>
<tr>
<th>First Author: Gudzune</th>
<th>Year: 2012</th>
<th>Country: USA</th>
<th>To explore PCPs’ usual practices as part of weight counselling to identify how PCPs communicate with their patients about weight loss.</th>
<th>Patients with obesity in their usual care practices</th>
<th>See Bennett 2014</th>
<th>See Bennett 2014</th>
<th>Focus groups</th>
</tr>
</thead>
</table>

| First Author: Hunt | Year: 2014 | Country: UK | To report the characteristics of men participating in a randomised controlled trial of a weight management programme designed specifically to attract men, and, secondly, their accounts of why they decided to participate in the programme. | Men with obesity (BMI > 28 kg/m²), age 35-65 at high risk of ill-health due to obesity | Role: Participant
Number of participants: 63 men (who had attended at least six FFIT sessions of the programme). Participants characteristics: No specific data for qualitative analysed participants
Socioeconomic and demographic characteristics: NR
Comorbidities reported: NR | Football Fans in Training (FFIT) is a men-only, evidence-based, 12-session, weight management and physical activity group programme with subsequent minimal-contact weight loss maintenance support delivered free of charge at Scotland’s top professional football clubs by community coaches trained in diet, nutrition, physical activity and behaviour change techniques to a standard programme delivery protocol. | Focus groups |

<p>| First Author: Little | Year: 2015 | Country: UK | To explore patients’ expectations of POWeR+. | Participants with obesity (BMI ≥30) | Role: Participant and Provider | This is a 24-session web-based weight management interview | Interviews |</p>
<table>
<thead>
<tr>
<th>Year: 2017</th>
<th>Category: A</th>
<th>Country: UK</th>
<th>experiences of the POWeR+ programme, experiences of using the POWeR+ website and experiences of nurse support.</th>
<th>kg/m², or ≥28 with comorbidities) from general practice</th>
<th>Number of providers: 13 nurses (HCPs who supported POWeR+ were included in qualitative evaluation)</th>
<th>Number of participants: 31 POWeR+ programme users. 14 remote support (3 low users/11 high users) and 17 face-to-face support patients (2 low users/15 high users).</th>
<th>Participants’ characteristics: 15 female, 16 male, mean age 61 years (range 45-88 years).</th>
<th>intervention consisting of a series of 24 brief maintenance-oriented sessions for up to 6 months and links to encourage patients to continue to use the website to track their weight at least fortnightly until they have formed healthy eating habits that sustain weight management.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year: 2016</td>
<td>Category: A</td>
<td>Country: UK</td>
<td>To explore the many components of the WAP. By providing a summary of participant feedback on the overall helpfulness of the programme.</td>
<td>Adults (aged ≥ 18 years) with obesity (BMI of ≥ 30 kg/m² or a BMI of ≥ 28 kg/m² plus comorbidities) who wanted to lose weight</td>
<td>Role: Participant</td>
<td>Number of participants: 177. Participants who reported helpfulness of the programme at 12-months follow-up; 48 in the nurse arm and 129 in the WAP arm. People who dropped out of treatment were called; only 19 provided a reason for dropping out.</td>
<td>Participants’ characteristics: Not reported.</td>
<td>The WAP is a multicomponent programme that includes a range of concrete and verifiable tasks agreed individually with each participant and also includes monthly ‘maintenance’ sessions that targeted to improve participant motivation, allowing participants to discuss the challenges they have faced since the last session, and to anticipate challenges of the month ahead.</td>
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<tr>
<td>Year: 2016</td>
<td>Category: A</td>
<td>Country: UK</td>
<td>To assess lifestyle change barriers and facilitators across the first 18 months of study participation and to</td>
<td>Adults (aged ≥ 18 years) with obesity (BMI ≥ 27 kg/m²) taking</td>
<td>Role: Participant</td>
<td>Number of participants: 84. Participants in the control arm were interviewed once; 17 intervention</td>
<td></td>
<td>This was a 24-month study of the STRIDE comprehensive weight loss and lifestyle-change intervention that</td>
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</table>
| First Author: Abildso 15 | To examine physical and psychosocial differences at baseline between completers of and dropouts from a 12 week weight management program; to assess the physical, behavioural, and psychosocial impact on program completers; to compare the psychosocial changes of high and moderate weight losers; and to qualitatively explore factors associated with program adherence and weight loss. | Adults with obesity (BMI ≥ 30 kg/m² alone or a BMI of 25 to 29.9 kg/m² with comorbidities) | Role: Participant  
Number of participants: 11  
Participants characteristics: Mean age 46.2 (SD ± 8.5), 8 female, 3 male. Seven were successful program completers (three high weight losers, four moderate weight losers), and four were program dropouts or completers with low weight loss.  
Socioeconomic and demographic characteristics: 7 married, number of children 1.5 (SD ± 1.1)  
Comorbidities: Not reported | Weight loss is encouraged in the weight management program (WMP) through increasing physical activity and decreasing caloric intake. For a $45 monthly co-payment, the WMP benefit during Phase 1 (12 weeks) included assessment and follow-up meetings with an exercise physiologist and registered dietitian, monthly personal training sessions, and periodic phone calls from the insurance agency to track progress. | Interviews |
| --- | --- | --- | --- | --- | --- |
| First Author: Aschbrenner 134 | To explore participants’ perceptions and experiences with peer interactions | Obese (BMI ≥ 30 kg/m²) adults (aged 21 or older) with serious | Role: Participant  
Number of participants: 17 | A 24 week group-based lifestyle intervention that consisted of once weekly 1-hr | Focus groups |
<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>Category</th>
<th>Country</th>
<th>Objective</th>
<th>Role</th>
<th>Number of providers interviewed</th>
<th>Providers’ characteristics</th>
<th>Socioeconomic and demographic characteristics</th>
<th>Intervention components</th>
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</thead>
<tbody>
<tr>
<td>Asselin</td>
<td>2015</td>
<td>B</td>
<td>USA</td>
<td>To explore how primary care providers incorporate weight management in their practice.</td>
<td>Provider</td>
<td>29</td>
<td>7 mental healthcare workers, 7 registered dietitians, 15 registered nurses or nurse practitioners.</td>
<td>NR</td>
<td>Group weight management sessions facilitated by a psychologist and a public health professional; twice weekly (optional) 1-hr group exercise sessions led by a certified fitness trainer; and mobile technology and use of social media to increase motivation and facilitate self-monitoring and peer-to-peer support outside of in person group treatment or exercise sessions.</td>
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<tr>
<td>Asselin</td>
<td>2016</td>
<td>B</td>
<td>Canada</td>
<td>To describe the intervention, provide continual intervention monitoring and to identify contextual factors that could influence the primary outcome measure.</td>
<td>Participant</td>
<td>See Asselin 2015</td>
<td>See Asselin 2015</td>
<td>See Asselin 2015</td>
<td>Interviews and field notes of intervention sessions</td>
</tr>
<tr>
<td>Barham</td>
<td>2015</td>
<td>B</td>
<td>Canada</td>
<td>To improve nutrition and physical activity of county adults at highest risk for the development of mental illness (diagnosis of schizophrenia, schizoaffective disorder, major depressive disorder, or bipolar disorder) on stable pharmacological treatment.</td>
<td>Participant</td>
<td>See Asselin 2015</td>
<td>See Asselin 2015</td>
<td>See Asselin 2015</td>
<td>Written responses to</td>
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<tr>
<td>First Author: Borkoles, Year: 2011</td>
<td>To examine the effects of a non-dieting lifestyle intervention approach for women with morbid obesity designed in the framework of the self-determination theory and Health at Every Size on weight maintenance and psychological functioning.</td>
<td>Pre-menopausal females with morbid obesity (BMI ≥30 kg/m²) older than 18 years of age free of obesity-related diseases and fit for exercise</td>
<td>Role: Participant  Number of participants: Unclear  Number of programme participants provided written responses on the end of study programme evaluations. Participants characteristics: No specific data for those who provided written responses  Socioeconomic and demographic characteristics: Most were from the lower SES background, 21% had a degree and 57% left school at 16, 66.1% worked full time and 11% worked part-time, in mainly manual (29%) and administrative jobs (46.8%)  Comorbidities: 50% met the International Diabetes Federation</td>
<td>The WHEEL (Weight, Healthy Eating and Exercise in Leeds) study was a delayed-start, 12 weeks of intensive intervention and 40 week maintenance phase RCT comprising of community-based supervised exercise, lifestyle physical activity and psycho-educational classes on healthy eating and weight management.</td>
<td>Interviews</td>
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<td>First Author: Dahl</td>
<td>To describe how personnel argued for and perceived a residential weight-loss program, to investigate how the participants experienced the program, and to contrast these perspectives.</td>
<td>Adults (between 18 and 60 years old) with obesity (BMI &gt;40 kg/m² or &gt;35 kg/m² including comorbidities)</td>
<td>Role: Participant and Provider Number of participants: 10 Participants' characteristics: 10 Norwegian participants took part in interviews (8 in focus groups and 2 individually). The age and weight range for these 10 persons were the same as for the total sample (n=30). Age between 22 and 56 years old, their BMI was between 40 and 63, and the group’s mean body weight was 144 kg Socioeconomic and demographic characteristics: NR Comorbidities: NR Number of providers interviewed: 6 Providers’ characteristics: 2 males and 4 females, considered to be key personnel; the director, the administrative executive, and the leaders of the main areas diet, exercise and personal development.</td>
<td>This 18 week on-site program intervention took place at the Danish residential weight-loss centre. The program consisted of group-based intensive structured group exercise and educational sessions exercise, diet (individual calorie intake was based on energy calculations for a normal weight person with a sedentary activity level), and an educational program. The educational program comprised lessons about nutrition, monitoring of food intake and instruction in behavioural techniques from cognitive therapy. The personal development component included a minimum of two individual conversations with one of the psychotherapists, motivational meetings for all participants.</td>
<td>Focus groups and interviews</td>
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<tr>
<td>First Author: Danielsen</td>
<td>To explore the experiences of physical activity from a participant perspective prior to, during, and after an</td>
<td>Both genders, with a variety in age, degree of obesity (BMI ≥ 40 kg/m² or 35.0–39.9)</td>
<td>Role: Participant Number of participants: 8 Participants’ characteristics: 5 female, 3 male, aged 35 to 63 years;</td>
<td>The study was supplementary to a clinical controlled trial with a 1-year prospective follow-up study examining</td>
<td>Interviews</td>
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<tr>
<td>Country: Norway</td>
<td>Intensive inpatient lifestyle modification program, including a high volume of adapted physical activity for the treatment of severe obesity.</td>
<td>Kg/m² with comorbidities, and weight loss during the inpatient stay, as well as variation in weight-loss maintenance and lack of maintenance.</td>
<td>6 married/cohabitants and 2 single; BMI ranged from 37 to 60 kg/m² and body weight from 96 to 185 kg. Socioeconomic and demographic characteristics: NR. Co-morbidities: NR. The effects of a 10- to 14 week inpatient lifestyle modification program for participants with severe obesity. Two to three group-exercise sessions 5 days a week during the inpatient period, each lasting for a minimum of 45 minutes. Aiming to increase compliance, the activity was supervised by exercise scientists and physiotherapists, and the participants were introduced to adapted physical activity and equipment, and exercised together with other individuals with severe obesity.</td>
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| **First Author:** Groven¹⁶¹ | To show how the training is experienced from a first-person perspective, namely the patients themselves. | Female participants with obesity (BMI >35 kg/m²) from the weight-loss program in Norway. | Role: Participants. **Number of participants:** 5. **Participants’ characteristics:** Aged 35-63 years and had been overweight for more than 10 years. Socioeconomic and demographic characteristics: 3 married, 1 divorced and 1 widowed, 1 had a university degree, 2 had a college degree, and 2 had no formal education after high school. The women were at present or previously working in professions providing a service, or care, doing office work, or an academic job on various levels. **Comorbidities:** Not reported. | Group-based weight-loss program in Norway, a program organized by physiotherapists in the primary health system. Offered to eight women struggling with obesity problems in a particular district of Norway for one year. Total of 12 exercises were performed throughout the one-hr exercise program. The treatment also included group discussion for 1 hr per month. |

| Year: 2010 | Category: B | Interviews |

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¹⁶¹ Groven, A. (2010). To show how the training is experienced from a first-person perspective, namely the patients themselves. *Journal of Clinical Medicine*, 9(5), 543-552.
| First Author: Jackson | Year: 2007 | To evaluate the effectiveness and acceptability of a specialist health visitor-led weight management clinic in primary care. | Patients with a BMI $\geq 30 \text{ kg/m}^2$ | Role: Participants  
Number of participants: Unclear  
how many of 25 questionnaires returned provided written responses  
Participants’ characteristics: Not reported  
Socioeconomic and demographic characteristics: Not reported | Specialist health visitor-led intervention based on the Jan Felgens ‘12E2’ model. The specialist health visitor sought to inspire participants through a combination of shared goal setting, reflection, problem-solving, positive affirmation and reinforcement. Consultations took place at the health centre and a relaxed, unhurried atmosphere was created. The average consultation time was 20 minutes (range 10–30 minutes), although the first appointment took approximately 1 hr and gave participants time to reflect on their lifestyles and to plan realistic goals for healthy eating and physical activity with the specialist health visitor. | Open ended response options to questionnaire |
|---|---|---|---|---|---|---|
| First Author: Janke | Year: 2012 | To explore experiences of chronic pain and obesity and behavioural connections between pain, health behaviours, and obesity treatment outcomes. | Primary care clinics, Midwestern Veteran’s Affairs hospital, >18 years, BMI $\geq 25 \text{ kg/m}^2$; weekly pain at intensity $\geq 4$ in prior 3 months; and medical condition with persistent pain | Role: Participant  
Number of participants: 30  
Participants characteristics: 24 male, 6 female  
26 $\geq 50$y, mean BMI 36.8 kg/m² (SD ± 8.9)  
Socioeconomic and demographic characteristics: 22 were white, 20 post high school education, and 14 unemployed/disabled,13 retired  
Comorbidities: average pain intensity was 5.6 (SD ± 1.9) and average pain interference was 3.6 (SD ± 2.1), scale 0-10. | Examine experiences and factors that help or hinder engagement in healthy behaviours; barriers and facilitators for treatments for weight and/or pain control. | Focus groups and interviews |
<table>
<thead>
<tr>
<th>First Author: Jennings</th>
<th>Year: 2014</th>
<th>Country: UK</th>
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</table>
| To facilitate weight loss by implementing progressive and sustainable lifestyle changes, based on individually agreed goals over a 1-year programme. Focus groups were conducted to explore participants’ experiences. | Adults (over 18 years) with obesity (BMI ≥40 kg/m², or BMI ≥30 kg/m² with obesity-related comorbidities and/or waist circumference ≥102 cm in men or ≥88 cm in women) | Role: Participant  
Number of participants: 12  
Participants’ characteristics: No specific data for qualitative analysed participants  
Socioeconomic and demographic characteristics: No specific data for qualitative analysed participants  
Comorbidities: No specific data for qualitative analysed participants.  
The Fakenham weight management service (FWMS) provides Tier 3 services. This paper was service evaluation and had a cohort design recruited patients to a 1-year programme.  
Focus groups |

<table>
<thead>
<tr>
<th>First Author: Jimenez Lopez</th>
<th>Year: 2012</th>
<th>Country: Mexico</th>
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</thead>
</table>
| To explore the motivations of patients involved in a with reduction programme, by analysing their experiences. | Patients with obesity included in a waiting list for bariatric surgery at a public hospital | Role: Participant  
Number of participants: 10  
Participants’ characteristics: 2  
Male, 8 women, mean age 45.2, mean BMI 41.3 kg/m²  
Socioeconomic and demographic characteristics: NR  
Comorbidities: NR  
The dynamic of the intervention included the modification of dietary habits by a psychologic intervention, as recommended by the federal law of obesity management  
The focus group included ten patients with one investigator as an active observer, and 12 weekly sessions.  
Focus groups |

<table>
<thead>
<tr>
<th>First Author: Kidd</th>
<th>Year: 2013</th>
<th>Country: USA</th>
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</table>
| To describe the effect of an 8 week mindful eating intervention on mindful eating, weight loss self-efficacy, depression, and biomarkers of weight in urban, underserved, women with obesity; and to identify themes of the lived experience of mindful eating. | Females (aged 30 years and older) with obesity (BMI ≥30 kg/m²) | Role: Participant  
Number of participants:12  
Participants’ characteristics: Mean weight was 119.7 kg (SD ± 16.87), BMI 44.7 kg/m² (SD ±6.9) . Age ranged from 31–61 and averaged 51.8 years (SD ± 9.1)  
Socioeconomic and demographic characteristics: 7 African American, 5 unemployed, and 4 married; 11 graduated from high school, 6 had college degrees  
Comorbidities: Not reported  
The study used a mixed methods design. A one group pre-test/ post-test design examined the effect of an 8 week mindful eating intervention on the psychosocial variables and biomarkers. Weekly group sessions lasted 60 to 90 minutes and consisted of education and application of mindful eating principles.  
Focus groups |
<table>
<thead>
<tr>
<th><strong>First Author:</strong> Pera</th>
<th><strong>Year:</strong> 2016</th>
<th><strong>Country:</strong> Spain</th>
</tr>
</thead>
</table>
| To explore the meaning of obesity in elderly persons with knee osteoarthritis and to determine the factors that encourage or discourage weight loss. | Participants with obesity, knee osteoarthritis, and polypathology | **Role:** Participant  
**Number of participants:** 10  
**Participants characteristics:** 2 male, 8 female, mean age 67.23 (SD ± 7.87), BMI 40.47 kg/m² (SD ± 4.22), mean weight 92.35 kg (SD ± 8.93)  
**Socioeconomic characteristics:** 1 No education, 5 Primary (<5 years), 3 Secondary (<10 years), 1 Higher (>10 years), 2 Housewife, 8 Retired  
**Comorbidities:** Mean number of co-morbidities 7.02 (SD ± 3.08) | The therapeutic education and functional preadaptation program was a 4-month program consisted of two 40-minute individual visits and three 90-minute group sessions for participants with obesity, knee osteoarthritis and polypathology. The program was designed following the methodology established for this type of program and was based on social learning theories. |

<table>
<thead>
<tr>
<th><strong>First Author:</strong> Counterweight</th>
<th><strong>Year:</strong> 2008</th>
<th><strong>Country:</strong> UK</th>
</tr>
</thead>
</table>
| To explore key barriers and facilitators of practice and patient engagement in the Counterweight Programme and to describe key strategies used to address barriers in the wider implementation of this weight management programme in UK primary care. | Patients with obesity in routine primary care | **Role:** Participant and Provider  
**Number of participants:** 37 patients  
**Number of providers:** weight management advisers (n = 7) in a focus group. In depth interviews were conducted with 15 PNs and 7 GPs across 11 practices.  
**Participants’ and/or providers characteristics:** Not reported  
**Socioeconomic and demographic characteristics:** Not reported  
**Comorbidities reported:** Not reported | The Counterweight Project was set up to establish and improve obesity management in primary care by implementing an evidence-based weight management intervention that is practice focused. It was developed using theoretical models of behavioural change and, the best available methods from the published evidence. |

<table>
<thead>
<tr>
<th><strong>First Author:</strong> Shaw</th>
<th><strong>Year:</strong> 2013</th>
<th><strong>Country:</strong> USA</th>
</tr>
</thead>
</table>
| To evaluate the acceptability, feasibility, and efficacy of daily text messages using regulatory focus theory to help individuals sustain weight loss. | Individuals had to own a mobile phone, be able to receive text messages, and have lost 5% of their body weight since entering the Duke Diet and Fitness Centre | **Role:** Participant  
**Number of participants:** 60  
**Participants’ characteristics:** No specific data for qualitative analysed participants  
**Socioeconomic and demographic characteristics:** No specific data for qualitative analysed participants  
**Comorbidities:** Not reported | Clients who received treatment at a residential weight loss management program that provides education, practical behavioural strategies, and ongoing support to make long term changes at the Duke Diet and Fitness Centre (DFC), participated in this |
To describe the collaborative process used to develop an obesity management programme based on current Australian guidelines for GPs and their patients to be used in primary care.

Health professionals involved in obesity management programme based on current Australian guidelines for GPs and their patients to be used in primary care

Role: Provider
Number of providers: 38
Providers' characteristics: 15 GPs, 14 GPs registrar, 5 healthcare consumer representative, 2 representative bodies for chronic illness, 1 dietician, 1 psychologist
Socioeconomic and demographic characteristics: Not reported

The Change Programme is a GP-delivered weight management programme that was developed based on Australian guidelines for the management of obesity in primary healthcare. It is based on one of the pillars of general practice—"patient centeredness". No directive patient goals were stated and the work was individualized. The programme consists of a GP handbook, patient workbook and computer template. This programme. The patients initially attended appointments every 2 weeks, with less frequent appointments as the programme continued.

To assess the acceptability and feasibility of a GP-delivered weight management programme.

Providers: Fully qualified GPs from the Australian Capital Territory and New South Wales.

Role: Participant and Provider
Number of providers: 12
Providers' characteristics: The recruited GPs had an average 12 years of experience (range 4–30 years). The GPs worked in four urban practices and one rural practice.
Number of patient participants: 15 interviewed

See Sturgiss 2016a

Interviews and focus groups
| First Author: Sturgiss<sup>169</sup>  
Year: 2017  
Category: B  
Country: Australia | To assess the self-efficacy and confidence of GPs before and after implementing a weight management programme in their practice.  
Participants’ characteristics: No specific data for qualitative analysed participants.  
Socioeconomic and demographic characteristics: NR  
Comorbidities: Not reported | GPs working in 5 different general practices  
Role: Provider  
Number of providers: 12  
Providers’ characteristics: 12 GPs practised in 5 different general practices, 1 rural and 4 urban, and had between 4 and 30 years clinical experience  
Socioeconomic and demographic characteristics: Not reported | See Sturgiss 2016a | Interviews |
|---|---|---|---|---|
| First Author: Turner<sup>170</sup>  
Year: 2015  
Category: B  
Country: UK | To determine both physiological benefits and qualitative information, namely patient satisfaction, associated with the service.  
Participants with obesity attending Multidisciplinary Weight Management Clinic (MDWMC) at Aneurin Bevan Hospital, Wales | Patients with obesity attending Multidisciplinary Weight Management Clinic (MDWMC) at Aneurin Bevan Hospital, Wales  
Role: Participant  
Number of participants: 180  
Participants characteristics: 131 female, 49 male, ages ranged between 19 and 74  
Socioeconomic and demographic characteristics: Not reported  
Comorbidities: Not reported | Obesity management in Wales includes the provision of a 1:1 MDWMC. Strategic management of obesity in Wales is guided by The All Wales Obesity Pathway and recommends MDWMCs for people with obesity who have one or more co morbidities and who have tried several interventions without success, or who have complex emotional relationships with food. | Interviews |
| First Author: VanWormer<sup>171</sup>  
Year: 2010  
Category: B  
Country: USA | To examine the association between participant and program experiences and satisfaction with a weight loss intervention.  
Adults (18 years or older) with obesity (BMI ≥ 32 kg/m²) employees of a managed care organization | Adults (18 years or older) with obesity (BMI ≥ 32 kg/m²) employees of a managed care organization  
Role: Participant  
Number of participants: 78 (not clear if all of these provided qualitative information)  
Participants’ characteristics: Mean age 46.9 (SD ± 8.3), 70 female, 8 | Participants were randomly assigned to either an immediate or delayed start group. The intervention lasted 6 months. During treatment, participants received a written responses to open ended response options within a questionnaire | Written responses to open ended response options within a questionnaire |
male, 55 married or living with a partner, 23 not married; body weight (kg) 106.2 (SD ± 16.32), BMI 38.3 kg/m² (SD ± 5.2) 
Socioeconomic and demographic characteristics: 36 college or graduate degree, 42 had less than college degree 
Comorbidities: Not reported 

**First Author:** Young
**Year:** 2017
**Country:** USA
To determine whether computerized provision of weight management with peer coaching is feasible to deliver, is acceptable to patients, and is more effective than in-person delivery or usual care.

| Adults (18 years or older) with obesity (BMI >30 or 28–30 kg/m² with self-reported weight gain of at least 10 pounds in the last 3 months), with diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, major depressive disorder with psychosis, or posttraumatic stress disorder; with prescribed an antipsychotic medication  | Role: Participant
**Number of participants:** 48 (24 randomized to WebMOVE and 24 randomized to MOVE SMI)
**Participants’ characteristics:** No specific data for qualitative analysed participants
**Socioeconomic and demographic characteristics:** No specific data for qualitative analysed participants
**Comorbidities:** Not reported |
| Patients were randomized to a computerized weight management program led by a master’s level mental health clinician. The program was delivered by phone and emphasized a strengths-based approach with motivational interviewing. MOVE SMI is an in-person weight management program led by a master’s level mental health clinician. | Interviews |
To explain how these services are perceived and received by participants in a community-based intervention so that specific recommendations can be made to health professionals working with similar populations and in similar settings.

**West Virginia public employees’ insurance agency weight management program (WMP), which is open to insured members that have a BMI >25 kg/m²**

**Role:** Participant
**Number of participants:** 567 (not clear how many provided qualitative data within the questionnaire)

**Participants’ characteristics:** 437 female, 130 male

**Socioeconomic and demographic characteristics:** Not reported

**Comorbidities:** Self-reported medication usage for 36% heart disease or high blood pressure, 31% anxiety or depression 21% high cholesterol, 12.7% diabetes, 9% sleep apnea

The WMP was a 2-year long benefit, and a $20 monthly co-payment that allowed participants to meet with a registered dietitian, exercise physiologist, and certified personal trainer at various point throughout their time in the program. The majority of individuals in the program also spoke with a health behaviour counsellor via telephone every 6 to 8 weeks. The WMP was offered at approximately 60 approved exercise facilities in West Virginia, such as YMCAs, wellness centres, fitness centres, and physical therapy clinics.

**Written responses to open ended response options within a questionnaire**

---

To present a synthesis of data from two qualitative studies in which both the development and the experience of living with morbid obesity in men and women were explored in depth.

**Individuals who met the United Kingdom NICE criteria for a morbid obesity (BMI ≥ 40 kg/m², or 35 kg/m² with comorbidity), and sought access to treatment for their condition**

**Role:** Participant
**Number of participants:** 31 (Study 1 n = 13; Study 2 n = 18)

**Participants characteristics:** 9 males, 3 age group 20–29, 11 age group 30–39, 7 age group 40–49, 9 age group 50–59, 1 60+ age group

**Socioeconomic and demographic characteristics:** 15 non manual employment, 5 manual

The qualitative approach to both studies, to investigate individual experiences of developing and living with morbid obesity. The first study (Study 1) as part of a broader investigation into patients’ experiences of implicit and explicit rationing. The core results the

**Interviews**
**First Author:** Owen Smith  
**Year:** 2016  
**Category:** C  
**Country:** UK

To focus on experiences of accessing treatment for morbid obesity in primary care.

<table>
<thead>
<tr>
<th>Role: Participant and providers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients and providers at a weight management clinic at a general hospital in the South West of England</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of participants: 22 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of providers: 11 clinicians</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants’ characteristics:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 male, 15 female, 9 age group 20-39, 12 age group 40-59, 1 age 60+</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Socioeconomic and demographic characteristics:</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 white British, 4 professional, 8 other non-manual, 3 manual, 6 unemployed, 1 retired</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 joint pain/mobility issues, 11 depression/other depressive disorder, 10 breathlessness/respiratory difficulties, 9 diabetes, 8 hypertension, 4 sleep apnoea, 4 cardiac problems, 3 fertility issues</td>
</tr>
</tbody>
</table>

Data collection was undertaken using in-depth interviews with patients and clinicians working in a specialist secondary care facility, and analysis took a constant comparative approach. Patients were followed from before their first consultation in secondary care up to 36 months after referral.

| Interviews |

---

Categories:  
A= Qualitative and mixed-methods studies linked to eligible RCTs, including any qualitative data reported as part of papers reporting quantitative outcomes.  
B= Qualitative and mixed-methods studies linked to ineligible RCTs and identified non-randomised intervention studies including any reported qualitative data.  
C= UK-based qualitative studies not linked to any specific interventions that draw on the experiences and perceptions of adults with BMI ≥35 (and/or providers involved in their care). ¥=Studies included in review 2 (long term randomised and non-randomised studies conducted in UK). BMI= Body Mass Index, calculated weight (kg) / height (m²)
List of included studies for the review of economic evaluations


List of excluded studies for the review of economic evaluation

Not a full economic evaluation (N=112)


Bell-Higgs AE, Brosnahan NT, Clarke AM, Dow MS, Haynes SM, Lyons GF, et al. The implementation of the Counterweight programme in Scotland, UK. *Family Practice* 2012;29:i139-i44.


Blazeby JM, Byrne J, Welbourn R. What is the most effective operation for adults with severe and complex obesity? *BMJ* 2014;348.


Colborne M. Britain's "sugar tax" tackles obesity. *CMAJ* 2016;188.


Leahey TM, Wing RR. A randomized controlled pilot study testing three types of health coaches for obesity treatment: Professional, peer, and mentor. *Obesity* 2013;21:928-34.


Sheipe M. Breaking through obesity with gastric bypass surgery. *Nurse Practitioner* 2006;31:12-4, 7, 8, 21; quiz 2-3.


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Wise J. Audit shows that bariatric surgery is cost effective. *BMJ* 2014;**349**:g6735.


**Other study design (N=19)**


Anonymous. Obese patients committed to weight loss can be given orlistat, says the NICE. *Pharmaceutical Journal* 7139;**266**.


Oliver A. Is nudge an effective public health strategy to tackle obesity? Yes. *BMJ* 7803;342.


Conference abstract only (N=6)


BMI less than 35 kg/m or not stated (N=39)


Bradley DW, Murphy G, Snetselaar LG, Myers EF, Qualls LG. The incremental value of medical nutrition therapy in weight management. *Managed Care* 2013;22:40-5.

Brethaue SA. Bariatric surgery in class i obesity (body mass index 30-35 kg/m²). *Surgery for Obesity and Related Diseases* 2013;9:e1-e10.


Dallat MA, Soerjomataram I, Hunter RF, Tully MA, Cairns KJ, Kee F. Urban greenways have the potential to increase physical activity levels cost-effectively. *European Journal of Public Health* 2014;24:190-5.


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**Interventions out with scope (N=40)**


Allender S, Rayner M. The burden of overweight and obesity-related ill health in the UK. *Obesity Reviews* 2007;8:467-73.


Wilding JPH. Treatment strategies for obesity. Obesity Reviews 2007;8:137-44.


Zomer E, Owen A, Magliano DJ, Liew D, Reid CM. The effectiveness and cost effectiveness of dark chocolate consumption as prevention therapy in people at high risk of cardiovascular disease: Best case scenario analysis using a Markov model. BMJ ;344.

Not adult population (N=2)


No relevant outcomes (N=3)


Follow-up less than 1 year (N=1)

<table>
<thead>
<tr>
<th>Quality Criterion</th>
<th>Dimension of quality</th>
<th>Question</th>
<th>Response (✓, ×, unclear or NA)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S1</strong></td>
<td>Statement of decision problem / objective</td>
<td>Is there a clear statement of the decision problem?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Is the objective of the evaluation and model specified and consistent with the stated decision problem?</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Is the primary decision maker specified?</td>
<td></td>
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</tr>
<tr>
<td><strong>S2</strong></td>
<td>Statement of scope / perspective</td>
<td>Is the perspective of the model clearly stated?</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Are the model inputs consistent with the stated perspective?</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Has the scope of the model been stated and justified?</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Are the outcomes of the model consistent with the perspective, scope and overall objective of the model?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>S3</strong></td>
<td>Rationale for structure</td>
<td>Is the structure of the model consistent with a coherent theory of the health condition under evaluation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Are the sources of data used to develop the structure of the model specified?</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Are the causal relationships described by the model structure justified appropriately?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>S4</strong></td>
<td>Structural assumptions</td>
<td>Are the structural assumptions transparent and justified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Are the structural assumptions reasonable given the overall objective, perspective and scope of the model?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>S5</strong></td>
<td>Strategies / Comparators</td>
<td>Is there a clear definition of the options under evaluation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Have all feasible and practical options been evaluated?</td>
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<tr>
<td></td>
<td>Is there justification for the exclusion of feasible options?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>S6</td>
<td>Model type</td>
<td>Is the chosen model type appropriate given the decision problem and specified causal relationships within the model?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S7</td>
<td>Time horizon</td>
<td>Is the time horizon of the model sufficient to reflect all important differences between options?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S8</td>
<td>Disease states / pathways</td>
<td>Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S9</td>
<td>Cycle length</td>
<td>Is the cycle length defined and justified in terms of the natural history of disease?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Data:**

<p>| D1 | Data identification | Are the data identification methods transparent and appropriate given the objectives of the model? |
|    |   | Where choices have been made between data sources, are these justified appropriately? |
|    |   | Has particular attention been paid to identifying data for the important parameters in the model? |
|    |   | Has the quality of the data been assessed appropriately? |
|    |   | Where expert opinion has been used, are the methods described and justified? |
| D2 | Data modelling | Is the data modelling methodology based on justifiable statistical and epidemiological techniques? |
| D2a | Baseline data | Is the choice of baseline data described and justified? |
|    |   | Are transition probabilities calculated appropriately? |
|    |   | Has a half cycle correction been applied to both cost and outcomes? |
|    |   | If not, has this omission been justified? |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>D2b</strong></td>
<td>Treatment effects</td>
<td>If relative treatment effects have been derived from the trial data, have they been synthesised using appropriate techniques?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Have the methods and assumptions used to extrapolate short term results to final outcomes been documented and justified?</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Have alternative extrapolation assumptions been explored through sensitivity analysis?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Have assumptions regarding the continuing effect of treatment once treatment is complete been documented and justified?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Have alternative assumptions regarding the continuing effect of treatment been explored through sensitivity analysis?</td>
<td></td>
</tr>
<tr>
<td><strong>D2c</strong></td>
<td>Costs</td>
<td>Are the costs incorporated into the model justified?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Has the source for all costs been described?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Have discount rates been described and justified given the target decision-maker?</td>
<td></td>
</tr>
<tr>
<td><strong>D2d</strong></td>
<td>Quality of life weights (utilities)</td>
<td>Are the utilities incorporated into the model appropriate?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Is the source for the utility weights referenced?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Are the methods of derivation for the utility weights justified?</td>
<td></td>
</tr>
<tr>
<td><strong>D3</strong></td>
<td>Data incorporation</td>
<td>Have all data incorporated into the model been described and referenced in sufficient detail?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Has the use of mutually inconsistent data been justified (i.e. are assumptions and choices appropriate)?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Is the process of data incorporation transparent?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If data have been incorporated as distributions, has the choice of distribution for each parameter been described and justified?</td>
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<tr>
<td></td>
<td></td>
<td>If data have been incorporated as distributions, is it clear that second order uncertainty is reflected?</td>
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<td>-----------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>D4</strong></td>
<td><strong>Assessment of uncertainty</strong></td>
<td>Have the four principal types of uncertainty been addressed?</td>
<td>If not, has the omission of particular forms of uncertainty been justified?</td>
</tr>
<tr>
<td><strong>D4a</strong></td>
<td><strong>Methodological</strong></td>
<td>Have methodological uncertainties been addressed by running alternative versions of the model with different methodological assumptions?</td>
<td></td>
</tr>
<tr>
<td><strong>D4b</strong></td>
<td><strong>Structural</strong></td>
<td>Is there evidence that structural uncertainties have been addressed via sensitivity analysis?</td>
<td></td>
</tr>
<tr>
<td><strong>D4c</strong></td>
<td><strong>Heterogeneity</strong></td>
<td>Has heterogeneity been dealt with by running the model separately for different subgroups?</td>
<td></td>
</tr>
<tr>
<td><strong>D4d</strong></td>
<td><strong>Parameter</strong></td>
<td>Are the methods of assessment of parameter uncertainty appropriate?</td>
<td>If data are incorporated as point estimates, are the ranges used for sensitivity analysis stated clearly and justified?</td>
</tr>
</tbody>
</table>

**Consistency:**

| **C1** | **Internal consistency** | Is there evidence that the mathematical logic of the model has been tested thoroughly before use? | |
| **C2** | **External consistency** | Are any counterintuitive results from the model explained and justified? | If the model has been calibrated against independent data, have any differences been explained and justified? |
|         |                             | Have the results of the model been compared with those of previous models and any differences in results explained? | |
Table 24 Quality assessment in economic evaluations alongside clinical trials

<table>
<thead>
<tr>
<th>Quality Criterion</th>
<th>Question</th>
<th>Response (✓, ✗, questionable, unclear or NA)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Was a well-defined question posed in answerable form?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom, where, and how often)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Was the effectiveness of the programme or services established?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Were costs and consequences measured accurately in appropriate physical units (e.g. hrs of nursing time, number of physician visits, lost work-days, gained life years)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Were the cost and consequences valued credibly?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Were costs and consequences adjusted for differential timing?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Are the outcomes of the model consistent with the perspective, scope and overall objective of the model?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Was an incremental analysis of costs and consequences of alternatives performed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Was allowance made for uncertainty in the estimates of costs and consequences?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Did the presentation and discussion of study results include all issues of concern to users?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Detailed discussion of the quality assessment

**Quality assessment of trial-based economic evaluations**

Table 25 Quality assessment of studies according to the Drummond checklist (N=11 studies)

<table>
<thead>
<tr>
<th>Study identifier</th>
<th>Quality assessment scores</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes N/10 (%)</td>
<td>No N/10 (%)</td>
</tr>
<tr>
<td>Finkelstein 2014</td>
<td>9/10 (90%)</td>
<td>0/10 (0%)</td>
</tr>
<tr>
<td>Hollenbeak 2016</td>
<td>6/10 (60%)</td>
<td>4/10 (40%)</td>
</tr>
<tr>
<td>Keating 2009</td>
<td>1/10 (10%)</td>
<td>6/10 (60%)</td>
</tr>
<tr>
<td>Little 2017</td>
<td>6/10 (60%)</td>
<td>3/10 (30%)</td>
</tr>
<tr>
<td>McRobbie 2016</td>
<td>8/10 (80%)</td>
<td>1/10 (10%)</td>
</tr>
<tr>
<td>Meenan 2016</td>
<td>8/10 (80%)</td>
<td>2/10 (20%)</td>
</tr>
<tr>
<td>Perri 2014</td>
<td>8/10 (80%)</td>
<td>1/10 (10%)</td>
</tr>
<tr>
<td>Ritzwoller 2013</td>
<td>8/10 (80%)</td>
<td>1/10 (10%)</td>
</tr>
<tr>
<td>Tsai 2005</td>
<td>5/10 (50%)</td>
<td>2/10 (20%)</td>
</tr>
<tr>
<td>Tsai 2013</td>
<td>7/10 (70%)</td>
<td>3/10 (30%)</td>
</tr>
<tr>
<td>van Gemert 1999</td>
<td>8/10 (80%)</td>
<td>0/10 (0%)</td>
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</table>
Quality assessment of decision models

Table 26 reports quality assessment findings from decision modelling studies included in the review. Summary scores across each of the categories in the Philips criteria are provided. Full records are available from the authors on request. A dummy quality assessment form can be found in section 23.
Table 26  Quality assessment of decision modelling studies (N=35 studies)

<table>
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<tr>
<td></td>
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<td>Unclear N/20 (%)</td>
</tr>
<tr>
<td>Ackroyd, 2006[186]</td>
<td>8/20 (40%)</td>
<td>7/20 (35%)</td>
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<tr>
<td>Anselmino 2009[187]</td>
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<td>2/20 (10%)</td>
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<td>Borisenko, 2015[188]</td>
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<td>2/20 (10%)</td>
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<tr>
<td>Campbell 2010[189]</td>
<td>16/20 (80%)</td>
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<td>4/20 (20%)</td>
</tr>
<tr>
<td>Castilla 2014[190]</td>
<td>14/20 (70%)</td>
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</tr>
<tr>
<td>Chang 2011[191]</td>
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<td>6/20 (30%)</td>
<td>6/20 (30%)</td>
</tr>
<tr>
<td>Clegg 2002[192]</td>
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<td>4/20 (20%)</td>
<td>4/20 (20%)</td>
</tr>
<tr>
<td>Craig 2002[193]</td>
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<td>4/20 (20%)</td>
</tr>
<tr>
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<td>Hertzman 2005[195]</td>
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<tr>
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</tr>
<tr>
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<td>Ikramuddin 2009&lt;sup&gt;197&lt;/sup&gt;</td>
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<tr>
<td>James 2017&lt;sup&gt;198&lt;/sup&gt;</td>
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<tr>
<td>Jensen 2005&lt;sup&gt;199&lt;/sup&gt;</td>
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<tr>
<td>Keating 2009&lt;sup&gt;b&lt;/sup&gt;&lt;sup&gt;180&lt;/sup&gt;</td>
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<tr>
<td>Klebanoff 2017&lt;sup&gt;200&lt;/sup&gt;</td>
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<td>5/20 (25%)</td>
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<tr>
<td>Lee 2013&lt;sup&gt;203&lt;/sup&gt;</td>
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<td>5/20 (25%)</td>
<td>2/20 (10%)</td>
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<td>1/20 (5%)</td>
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<tr>
<td>McEwen 2010&lt;sup&gt;206&lt;/sup&gt;</td>
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<td>McLawhorn 2016&lt;sup&gt;207&lt;/sup&gt;</td>
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<td>Meads 2014&lt;sup&gt;208&lt;/sup&gt;</td>
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<td>Michaud 2012&lt;sup&gt;209&lt;/sup&gt;</td>
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<tr>
<td>Miners 2012&lt;sup&gt;210&lt;/sup&gt;</td>
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<tr>
<td>Picot 2009&lt;sup&gt;211&lt;/sup&gt;</td>
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<td>1/20 (5%)</td>
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<tr>
<td>Pollock 2013&lt;sup&gt;213&lt;/sup&gt;</td>
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<td>0/20 (0%)</td>
</tr>
<tr>
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<td>Structure</td>
<td>Data</td>
<td>Consistency</td>
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<tr>
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<td>Unclear N/20 (%)</td>
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<tr>
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<tr>
<td>Trueman 2010&lt;sup&gt;215&lt;/sup&gt;</td>
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<tr>
<td>Veerman 2011&lt;sup&gt;216&lt;/sup&gt;</td>
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<td>0/20 (0%)</td>
</tr>
<tr>
<td>Wang 2014&lt;sup&gt;217&lt;/sup&gt;</td>
<td>10/20 (50%)</td>
<td>7/20 (35%)</td>
<td>3/20 (15%)</td>
</tr>
<tr>
<td>Wilson 2015&lt;sup&gt;218&lt;/sup&gt;</td>
<td>13/20 (65%)</td>
<td>2/20 (10%)</td>
<td>4/20 (20%)</td>
</tr>
</tbody>
</table>
**Disease health states**

The decision models in two NIHR HTA reports undertaken for NICE modelled T2DM, and in an extended model form Clegg 2002\textsuperscript{192} by Picot 2009\textsuperscript{211} included coronary heart disease and stroke. However, for the cohort with morbid obesity, this extension of the model was not applied. Some studies focused on the type 2 diabetic population only (with a BMI$\geq$35 kg/m$^2$), and therefore included disease risks associated with T2DM (MI, angina, CHF, stroke, peripheral vascular disease, end-stage renal disease, and other complications such as foot ulcers and hypoglycaemic events). Borisenko 2015\textsuperscript{188} included various obesity-related disease health states within the Markov model – T2DM, angina pectoris, myocardial infarction, stroke, transient ischaemic attack, heart failure, and peripheral arterial disease. Chang 2011\textsuperscript{191} used a mixed proportional hazards model dividing the cohort into those with obesity-related diseases and without. Both groups were assigned either surgery or no surgery. Their projections were then dependent on their weight and obesity-related disease status change (from a meta-analysis of surgical outcomes). Veerman 2011\textsuperscript{216} and Lee 2013\textsuperscript{203} developed a multi-state multiple cohort Markov model including multi-state life tables that considered numerous obesity-related diseases which depended on the weight loss experienced by the cohort. Michaud 2012\textsuperscript{209} developed a micro-simulation model that predicted future health outcomes (obesity-related diseases) based on BMI using non-linear transition equations. Wilson 2015\textsuperscript{218} used a modelling programme that predicted disease outcomes based on cohort characteristics and weight loss, but failed to extrapolate related costs.

Hoerger 2010,\textsuperscript{196} Ikramuddin 2009\textsuperscript{197} and Pollock 2013\textsuperscript{213} also accounted for diabetes-related complications such as coronary heart disease and stroke. Craig 2002\textsuperscript{193} and Salem 2008\textsuperscript{214} did not specify the type of decision model used. The model developed by Craig 2002\textsuperscript{193} only included drug costs associated with obesity-related diseases. However, it was not clear whether obesity related disease events were incorporated in the final cost-effectiveness estimate.
Weight regain assumptions

WMPs

Wilson 2015\textsuperscript{218} project weight loss over three years, splitting data into two different subgroups, depending on the degree of achievement of weight loss targets by nine months. Trueman 2010\textsuperscript{217} included a more optimistic assumption regarding weight regain, but used observational data from a cohort where less than 5\% had BMI over 35 kg/m\textsuperscript{2} raising doubts about the reliability of the modelled BMI trajectories in a population with severe obesity. However, sensitivity analysis explored varying the rate of weight regain between 0.3-1 kg/year and this did not change cost-effectiveness conclusions.

Miners 2012,\textsuperscript{210} a UK study, assumed that all patients would regain weight at the rate of 1 kg per year. They did not explore the weight regain assumption in the sensitivity analyses, for the subgroup with a BMI of 35 kg/m\textsuperscript{2}, meaning it was not possible to determine the sensitivity of the model to this assumption. Meads 2014,\textsuperscript{208} another UK study, based the weight regain assumption on a systematic review of weight loss drugs and assumed that an individual’s annual weight gain was 0.429 kg/year post intervention. It is unclear whether regain following drug therapy is an appropriate proxy for regain following a lifestyle intervention.

Bariatric surgery

For bariatric surgery, some studies utilised the long term data from the SOS study.\textsuperscript{219} Keating\textsuperscript{180} and Hoerger\textsuperscript{196} instead included an annual probability of T2DM remission into the model using the SOS study with 10 years of follow-up.

Effectiveness, treatment outcomes and linking of evidence

The effectiveness data were usually incorporated into a model that predicted the risk of cardiovascular events. The model predictions would depend on factors including BMI, systolic blood pressure, HbA1c, and lipids to finally determine the changes in relative risks of disease events (T2DM, stroke, CHD, cancer, hypertension and other obesity-related disease events). Some studies were not clear in their methods of linking the clinical evidence to obesity-related diseases.
A range of modelling approaches were used to link risk factor data (e.g. BMI) to disease events. Castilla 2014 and Miners 2012 simulated patients’ characteristics (age, sex, BMI) leading to changes in the relative risks of obesity-related disease events which impacted the time to experiencing an event. Chang 2011 used a mixed proportional hazards model, to predict outcomes based on patients’ characteristics, weight and obesity-related disease status. Five studies applied a T2DM incidence/remission rate (which benefitted the surgery group) based on the SOS study. In Lee 2013 and Veerman 2011, the disease incidence was adjusted based on weight change. Picot 2009 included predictions of CHD and stroke for those with obesity (however, not morbid obesity). This prediction (using Framingham risk equations) was based on change in systolic blood pressure, lipids (reported from trials included in their clinical effectiveness review), sex and smoking status. The same Framingham risk equation was applied in Borisenko 2015 to estimate 10-year cardiovascular risks. Risk equations, implemented within the Core Diabetes model are used in two studies use the future elderly model to predict health outcomes using non-linear transition equations that depend on individuals’ characteristics such as sex, race, and health factors. Ackroyd 2006 and Anselmino 2009 estimated the size of the BMI drop (in the 5-year trial time horizon) and the duration of this BMI change. They also estimated the number of patients in T2DM remission and the duration of this remission. Lewis 2014 developed a model that linked changes in BMI (and age) to the annual mortality rate. Trueman 2010 used a micro-simulation model simulating a UK representative population over a lifetime. The risk of developing obesity-related diseases (T2DM, coronary heart disease and colon cancer) changed over time depending on people’s BMI. Wilson 2015 also used a simulation model (matching the study cohort) that predicted costs and outcomes (including disease outcomes) based on peoples’ BMI. Hertzman 2005 and Lacey 2005 used similar methods to estimate costs and health effects. They used a treatment algorithm where people who lost ≥5% weight continued to receive orlistat. Those who failed this target had the same 12 month weight loss as the placebo group. The risk of T2DM depended on BMI.
Sensitivity analyses

Structural uncertainty

Only 9 studies\(^{180, 181, 189, 190, 198, 199, 205, 206, 213}\) varied the weight regain assumption in a sensitivity analysis, 8 of which were applied in evaluations of surgery. Campbell 2010\(^{189}\) used a more conservative assumption. They assumed people would regain half the weight lost after five years. Surgery was still the cost-effective option. The result that changed was the comparison between GB and RYGB where GB ended up dominating RYGB instead of RYGB being the cost-effective option as in the base-case. Lee 2013\(^{203}\) assumed an annual reduction in weight loss after 15 years (instead of stable weight loss), and cost-effectiveness results did not change the conclusion, surgery remained cost-effective. Michaud 2012\(^{209}\) assumed that patients regain 50% of the weight loss after 10 years (opposed to permanent weight loss in the base-case). Surgery remains the cost-effective option. Ikramuddin 2009\(^{199}\) found that when assuming a weight regain of 3.322 kg/m\(^2\) over the next 10 years after surgery, the ICER increased slightly but the conclusions did not change. James 2017\(^{198}\) found that when assuming a full weight regain at 5, 10 or 20 years’ time, the ICER increased substantially ranging from US$53492 to US$487691. Jensen 2005\(^{199}\) explored the weight regain assumption, where instead of assuming people regain weight according to a natural trajectory, they explored two scenarios where 1) all weight would be regained within 3 years then followed a natural BMI trajectory or 2) BMI remained stable. This did not change the cost-effectiveness results, surgery remained cost-effective. Varying the weight regain rate was reported to not change the results, surgery remained cost-effective in Maklin 2011\(^{204}\) (although incremental costs and effects were not reported for the sensitivity analyses).

Parameter uncertainty

Varying the underlying effectiveness of an intervention, i.e. an intervention’s weight loss delivered, is an important area of uncertainty to explore. Borisenko 2015\(^{188}\) varied the weight change at one year from 20 to 4 kg/m\(^2\), and surgery remained cost-effective (though not dominant). McLawhorn 2016\(^{207}\) varied the probability of excess weight loss, however, this did not alter the conclusion from the cost-effectiveness results. Michaud 2012\(^{209}\) varied the weight loss (by 10%) and found that this only changed the ICERs slightly. Salem 2008\(^{214}\) also varied the percentage of excess body
weight loss which increased the ICER but was still well below any commonly used threshold. The weight loss accrued was also tested in sensitivity analyses in Ackroyd 2006 and Anselmino 2009 by reducing the BMI and T2DM remission by 20% for surgery and compared to watchful waiting. This changed the end result for the UK, where GB and GBP were no longer cost-saving but remained cost-effective (Ackroyd 2006) and in a Spanish study surgery also was no longer cost-saving but remained cost-effective (Anselmino 2009). Picot assumed that less experienced surgeons may generate less weight loss for patients. This did not change the conclusion from the cost-effectiveness results. Craig 2002 reduced the excess weight loss by more than one third and this resulted in the ICER increasing beyond the threshold of US$50,000 (to US$57200) for a man with BMI 40 kg/m² aged 45y. For women the ICER only slightly increased. Maklin 2011 found that varying the excess weight loss did not change the results, surgery remained dominant.
Table 27 Study characteristics on decision modelling studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Economic evaluation type</th>
<th>Study Type</th>
<th>Costing perspective</th>
<th>Cost year</th>
<th>Currency</th>
<th>Discount rate - costs</th>
<th>Discount rate - benefits</th>
<th>Primary economic outcome measurement</th>
<th>Model description (details)</th>
<th>Health states model</th>
<th>Base-case time horizon</th>
<th>PSA?</th>
<th>Value of information analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ackroyd, 2006(^{186})</td>
<td>CUA</td>
<td>Decision model</td>
<td>Third payer perspective in Germany, France and the UK</td>
<td>2005</td>
<td>GBP and Euro</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY</td>
<td>A deterministic linear algorithm was programmed in Microsoft Excel(^{TM})</td>
<td>T2DM</td>
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<td>CUA/CEA</td>
<td>Decision model</td>
<td>Payer perspective</td>
<td>2009</td>
<td>Euro</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY</td>
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<td>Assume as per Ackroyd 2006(^{189})</td>
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<td>Borisenko 2015(^{188})</td>
<td>CUA</td>
<td>Decision model</td>
<td>Swedish health care payer</td>
<td>2012</td>
<td>Euro</td>
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<td>3%</td>
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<td>Markov model</td>
<td>T2DM, angina pectoris, myocardial infarction, stroke, transient ischaemic attack, heart failure, and peripheral arterial disease</td>
<td>Lifetime</td>
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<td>No</td>
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<td>Campbell 2010(^{189})</td>
<td>CUA</td>
<td>Decision model</td>
<td>Third payer perspective</td>
<td>2006</td>
<td>US$</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>Markov model</td>
<td>Not obese, obese, morbidly obese I, morbidly obese II, super obese and death</td>
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<td>No</td>
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</table>

301
<table>
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<th>Study Type</th>
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<th>Cost year</th>
<th>Currency</th>
<th>Discount rate - costs</th>
<th>Discount rate - benefits</th>
<th>Primary economic outcome measurement</th>
<th>Model description (details)</th>
<th>Health states model</th>
<th>Base-case time horizon</th>
<th>PSA?</th>
<th>Value of information analysis</th>
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<td>Castilla 2014</td>
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<td>2012</td>
<td>Euro</td>
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<td>3%</td>
<td>Cost per QALY</td>
<td>Discrete-event simulation model</td>
<td>Comorbidity, death</td>
<td>Lifetime</td>
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<td>Chang 2011</td>
<td>CUA</td>
<td>Decision model</td>
<td>Payer perspective (US sources)</td>
<td>2010</td>
<td>US$</td>
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<td>3%</td>
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<td>Mixed proportional hazard model</td>
<td>No obese related disease (ORD), diseased (develop ORD, ORD worsened, ORD improved) and death</td>
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<td>CUA</td>
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<td>Payer perspective</td>
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<td>GBP</td>
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<td>1.5%</td>
<td>Cost per QALY</td>
<td>NR</td>
<td>NR</td>
<td>20 years</td>
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<td>Payer perspective</td>
<td>2001</td>
<td>US$</td>
<td>3%</td>
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<td>Cost per QALY</td>
<td>Deterministic decision model</td>
<td>Initial BMI, reoperation, reduced BMI, death</td>
<td>Lifetime</td>
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<td>CUA</td>
<td>Decision model</td>
<td>Societal perspective stated (looks more like payer perspective)</td>
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<td>Euro</td>
<td>3%</td>
<td>3%</td>
<td>Cost savings and QALYs gained per patient</td>
<td>Markov model (assumed microsimulation)</td>
<td>Morbid obesity, Normal BMI, Surgical complication, Diabetes, CV Disease, Sleep Apnea, Joint pain/ostheoarthrosis , Cancer, ESRD, Death.</td>
<td>Lifetime (though not explicitly stated for QALYs)</td>
<td>Yes</td>
<td>No</td>
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<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
<td>Discount rate - benefits</td>
<td>Primary economic outcome measurement</td>
<td>Model description (details)</td>
<td>Health states model</td>
<td>Base-case time horizon</td>
<td>PSA?</td>
<td>Value of information analysis</td>
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<td>CUA</td>
<td>Decision model</td>
<td>Swedish healthcare system</td>
<td>2003</td>
<td>Euro</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>Decision tree</td>
<td>Responders (continue Orlistat), non-responders (discontinue Orlistat), T2DM, no T2DM</td>
<td>10 years</td>
<td>Yes</td>
<td>No</td>
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<td>Hoerger 2010&lt;sup&gt;1&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Payer perspective</td>
<td>2007</td>
<td>US$</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>Markov model (Centres for Disease Control and Prevention (CDC)-RTI Diabetes Cost-Effectiveness Model)</td>
<td>Diabetes-related complications on three microvascular disease paths (nephropathy, neuropathy, and retinopathy) and two macrovascular disease paths (coronary heart disease [CHD] and stroke)</td>
<td>NR (however, follow-up costs reported for year 6 and over)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Ikramuddin 2009&lt;sup&gt;1&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Third-party payer</td>
<td>2007</td>
<td>US$</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>Markov type model (Core Diabetes Model)</td>
<td>T2DM</td>
<td>35 years</td>
<td>Yes (non-parametric bootstrapping)</td>
<td>No</td>
</tr>
<tr>
<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
<td>Discount rate - benefits</td>
<td>Primary economic outcome measurement</td>
<td>Model description (details)</td>
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<td>Base-case time horizon</td>
<td>PSA?</td>
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<tr>
<td>James 2017&lt;sup&gt;198&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Payer perspective</td>
<td>2015</td>
<td>AUD</td>
<td>5%</td>
<td>5%</td>
<td>Cost per QALY.</td>
<td>Markov model</td>
<td>Morbid obesity, normal BMI, surgical complication, T2DM, cardiovascular disease, sleep apnoea, joint pain/osteoarthrosis, cancer, end-stage renal disease (ESRD), death</td>
<td>Lifetime</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Jensen 2005&lt;sup&gt;199&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Payer perspective</td>
<td>2004</td>
<td>US$</td>
<td>NR</td>
<td>NR</td>
<td>Cost per QALY.</td>
<td>Decision tree</td>
<td>Immediate complications, no immediate complications, BMI reduced, BMI not reduced, alive(time), dead</td>
<td>NR</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Keating 2009b&lt;sup&gt;180&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Health care system</td>
<td>2006</td>
<td>AUD</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY.</td>
<td>Markov (micro-simulation) model</td>
<td>T2DM remission, T2DM relapse, and death</td>
<td>Lifetime</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
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<tr>
<td>Klebanoff 2017&lt;sup&gt;200&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Societal perspective stated, but appears more like payer perspective.</td>
<td>2014</td>
<td>US$</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>State transition model - appears to be estimated through simulation</td>
<td>NASH F0-F3 (the four stages of NASH disease), compensated cirrhosis without HCC, compensated cirrhosis with HCC, decompensated cirrhosis without HCC, decompensated cirrhosis with HCC, treatment-induced NASH remission and death</td>
<td>Lifetime</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Lacey 2005&lt;sup&gt;202&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Irish health-care perspective</td>
<td>2003</td>
<td>Euro</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>NR</td>
<td>NR</td>
<td>3 years</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
<td>Discount rate - benefits</td>
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<tr>
<td>Lee 2013&lt;sup&gt;203&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Third-party payers and societal perspective (examined in additional costing scenarios)</td>
<td>2003</td>
<td>AUS</td>
<td>3%</td>
<td>3%</td>
<td>Cost per DALYs averted</td>
<td>Multi-state, multiple cohort Markov model</td>
<td>Obesity-related diseases such as hypertensive heart disease; stroke; ischemic heart disease; diabetes mellitus; osteoarthritis; post-menopausal breast cancer; colon cancer; endometrial cancer; and kidney cancer</td>
<td>Lifetime (until reached 100 years of age)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Lewis 2014&lt;sup&gt;204&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>NHS England</td>
<td>2012</td>
<td>GBP</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY</td>
<td>de novo economic model</td>
<td>NR</td>
<td>10 years</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Maklin 2011&lt;sup&gt;205&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Finnish healthcare system</td>
<td>2010</td>
<td>Euro</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>Combination of decision tree and Markov model. Alive (no abdominoplasty or reoperation), abdominoplasty, reoperation, and dead.</td>
<td>10 years</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>McEwen 2010&lt;sup&gt;206&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Third payer perspective.</td>
<td>NR</td>
<td>US$</td>
<td>3%</td>
<td>3.5%</td>
<td>Cost per QALY</td>
<td>NR</td>
<td>NR</td>
<td>2 years/lifetime</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
<td>Discount rate - benefits</td>
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<tr>
<td>McLawhorn 2016&lt;sup&gt;297&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Societal perspective.</td>
<td>2012</td>
<td>US$</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>Markov model</td>
<td>Bariatric surgery, knee osteoarthritis, primary total knee arthroplasty, revision total knee arthroplasty, repeat revision total knee arthroplasty, chronically failed revision total knee arthroplasty, and dead</td>
<td>40 years</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Meads 2014&lt;sup&gt;208&lt;/sup&gt;</td>
<td>CUA</td>
<td>Decision model</td>
<td>Personal health and social services</td>
<td>NR</td>
<td>GBP</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY</td>
<td>Markov model</td>
<td>T2DM, primary stroke, primary MI, T2DM + stroke, T2DM + MI, secondary stroke, secondary MI, and dead</td>
<td>Lifetime</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
<td>Discount rate - benefits</td>
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<td>Base-case time horizon</td>
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<tr>
<td>Michaud 2012</td>
<td>CEA</td>
<td>Decision model</td>
<td>Third payer perspective, as well as implications for markets and institutions.</td>
<td>2010</td>
<td>US$</td>
<td>3%</td>
<td>3%</td>
<td>Cost per gain in life years.</td>
<td>Microsimulation model (Future Elderly Model)</td>
<td>NR</td>
<td>Lifetime</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Miners 2012</td>
<td>CUA</td>
<td>Decision model</td>
<td>UK health services perspective.</td>
<td>2009</td>
<td>GBP</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY.</td>
<td>Discrete event simulation model.</td>
<td>Disease state (CVD fatal event, CVD, non-fatal event, survivor of CVD, T2D), death</td>
<td>Lifetime</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Picot 2009</td>
<td>CUA</td>
<td>Decision model</td>
<td>NHS and Personal Social Services</td>
<td>2008</td>
<td>GBP</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY</td>
<td>The presentation of a state transition diagram indicates the use of a Markov model.</td>
<td>No comorbidity, remission of comorbidity, T2DM, CHD, stroke, and death</td>
<td>20 years</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
<td>Discount rate - benefits</td>
<td>Primary economic outcome measurement</td>
<td>Model description (details)</td>
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<tr>
<td>Picot 2012^222</td>
<td>CUA</td>
<td>Decision model</td>
<td>UK National Health Service (NHS) and personal and social services</td>
<td>2010</td>
<td>GBP</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY.</td>
<td>Markov model</td>
<td>No comorbidity, remission of comorbidity, T2DM, CHD, stroke, dead</td>
<td>20 years</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Pollock 2013^233</td>
<td>CUA</td>
<td>Decision model</td>
<td>NHS</td>
<td>2010</td>
<td>GBP</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY.</td>
<td>Version 8.0 of the core Diabetes Model (CDM), a published computer simulation model of type 2 diabetes, comprising several inter-dependent semi-Markov sub-models.</td>
<td>Diabetes-related complications (angina, myocardial infarction, congestive heart failure, stroke, peripheral vascular disease, retinopathy, macular oedema, cataract, hypoglycaemia, ketoacidosis, lactic acidosis, nephropathy, neuropathy, foot ulcer and amputation)</td>
<td>40 years</td>
<td>Yes (non-parametric bootstrapping)</td>
<td>No</td>
</tr>
<tr>
<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
<td>Discount rate - benefits</td>
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<td>Model description (details)</td>
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<tr>
<td>Salem 2008²¹⁴</td>
<td>CUA</td>
<td>Decision model</td>
<td>Payer perspective.</td>
<td>2004</td>
<td>US$</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>Refer to Craig 2002.³¹³</td>
<td>Refer to Craig 2002³¹³</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Trueman 2010²¹⁶</td>
<td>CUA</td>
<td>Decision model</td>
<td>Health care payer.</td>
<td>2005</td>
<td>GBP</td>
<td>3.5%</td>
<td>3.5%</td>
<td>Cost per QALY</td>
<td>Individual-level simulation model.</td>
<td>Gain weight, lose weight, weight unchanged, no weight related comorbidities, develops diabetes, develops colon cancer, develops CHD and death</td>
<td>Lifetime</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Veerman 2011²¹⁶</td>
<td>CUA</td>
<td>Decision model</td>
<td>Both health sector perspective and patient perspective.</td>
<td>2003</td>
<td>AUS</td>
<td>3%</td>
<td>3%</td>
<td>Cost per DALY</td>
<td>Proportional multi-state life table Markov model.</td>
<td>Stroke, ischemic heart disease, hypertensive heart disease, T2DM, osteoarthritis, post-menopausal breast cancer, colon cancer, endometrial cancer and kidney cancer</td>
<td>Lifetime</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Study</td>
<td>Economic evaluation type</td>
<td>Study Type</td>
<td>Costing perspective</td>
<td>Cost year</td>
<td>Currency</td>
<td>Discount rate - costs</td>
<td>Discount rate - benefits</td>
<td>Primary economic outcome measurement</td>
<td>Model description (details)</td>
<td>Health states model</td>
<td>Base-case time horizon</td>
<td>PSA?</td>
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<tr>
<td>Wang 2014</td>
<td>CUA</td>
<td>Decision model</td>
<td>Health care system perspective.</td>
<td>2010</td>
<td>US$</td>
<td>3%</td>
<td>3%</td>
<td>Cost per QALY</td>
<td>Decision-tree model followed by a lifetime natural history model.</td>
<td>Dead, alive, no rehospitalisation within the first 30 days after the procedure</td>
<td>Lifetime</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Wilson 2015</td>
<td>CUA</td>
<td>Decision model</td>
<td>Participant perspective.</td>
<td>NR</td>
<td>US$</td>
<td>3%</td>
<td>NR</td>
<td>Cost per QALY</td>
<td>Estimated outcomes using the Archimedes Outcomes Analyzer.</td>
<td>NR</td>
<td>5, 10 and 20 year time horizons (base-case not specified)</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Modelled projections of the future prevalence of males and females with a healthy-weight (BMI <25 kg/m², in light grey), overweight (BMI 25-29.9 kg/m², in dark green), and with class I & II obesity (BMI 30-39.99 kg/m² in dark grey) and class III obesity (BMI ≥40 kg/m² in light green) aged between 18 to 100 years old are reported in this section, by gender and age.

**Males**

Figure 1 shows the prevalence of obesity for males aged 18 and over for the next 30 years. Future obesity trend projections for males, by 5-year age group are reported in Figures 2 to 14. The prevalence of males with class III obesity is projected to increase across all age groups by 2050. This is accompanied by a relatively stable prevalence of healthy-weight males across all age groups. The prevalence of males with obesity (class I & II) is projected to rise most markedly in males aged 45-49 years old. The overweight group is projected to become the prevalent BMI group by 2050 for males 65-74 years old, although the likelihood with which this will occur for the 80+ year old age group is less certain owing to its smaller sample population size. The 45-49 year old age group is projected to comprise the highest proportion of males (50%) with obesity (class I & II) by 2050. Males aged 55-59 and 75 years and above is projected to comprise the highest proportion of males with obesity (48% and 58% respectively) by 2050.
Figure 1  BMI projections 18-100 year old Males (2016-2046)
Figure 2  Projected BMI prevalence in 15-19 males (2016-2046)

Figure 3  Projected BMI prevalence in 20-24 year old males (2016-2046)
Figure 4  Projected BMI prevalence in 25-29-year old males (2016-2046)

Figure 5  Projected BMI prevalence in 30-34 year old males (2016-2046)
Figure 6  Projected BMI prevalence in 35-39 year old males (2016-2046)

Figure 7  Projected BMI prevalence in 40-44 year old males (2016-2046)
Figure 8  Projected BMI prevalence in 45-49 year old males (2016-2046)

Figure 9  Projected BMI prevalence in 50-54 year old males (2016-2046)
Figure 10  Projected BMI prevalence in 55-59 year old males (2016-2046)

Figure 11  Projected BMI prevalence in 60-64 year old males (2016-2046)
Figure 12  Projected BMI prevalence in 65-69 year old males (2016-2046)

Figure 13  Projected BMI prevalence in 70-74 year old males (2016-2046)
Figure 14  Projected BMI prevalence in 75 years and over males (2016-2046)
**Females**

Figure 15 presents the breakdown of the BMI projections by year for females aged over 18 years and Figures 16 to 27 report projections by 5-year age group. The prevalence of females with class III obesity is projected to increase across all age groups. This is accompanied by a slight decrease in the prevalence of healthy-weight females across all groups with the exception of 60-64 and 75+ year olds which is projected to remain stable at approximately 30% through to 2050, and of 30-34 year olds which is projected to rise over this time period. The prevalence of females with obesity (class I & II) is projected to rise most markedly in 45-49 year olds, while females aged 65-69 years old is projected to increase most for obesity class III. In addition, 25-29 year olds are projected to comprise the highest proportion (40%) of females with obesity (class I & II) by 2050 while 65-69 years olds are projected to have the highest proportion of females with obesity class III (approximately 50%) by 2050.
Figure 15  BMI projections 18-100 year old Females (2016-2046)
Figure 16  Projected BMI prevalence in 15-19 year old females (2016-2046)
Figure 17  Projected BMI prevalence in 25-29 year old females (2016-2046)

Figure 18  Projected BMI prevalence in 30-34 year old females (2016-2046)
Figure 19  Projected BMI prevalence in 35-39 year old females (2016-2046)

Figure 20  Projected BMI prevalence in 40-44 year old females (2016-2046)
Figure 21  Projected BMI prevalence in 45-49 year old females (2016-2046)

Figure 22  Projected BMI prevalence in 50-54 year old females (2016-2046)
Figure 23  Projected BMI prevalence in 55-59 year old females (2016-2046)

Figure 24  Projected BMI prevalence in 60-64 year old females (2016-2046)
Figure 25  Projected BMI prevalence in 65-69 year old females (2016-2046)

Figure 26  Projected BMI prevalence in 70-74 year old females (2016-2046)
Figure 27  Projected BMI prevalence in 75 years and over females (2016-2046)
## Intervention costings

### Table 28  Bariatric surgery costs

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
<th>Year 7</th>
<th>Year 8</th>
<th>Year 9</th>
<th>Year 10</th>
<th>Annual costs from year 11 to 30</th>
<th>Total costs year 1 to 10 (undiscounted)</th>
<th>Total costs over a lifetime (undiscounted)</th>
</tr>
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<td>Surgery cost</td>
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<td>£0</td>
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<td>Direct staff time</td>
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### Table 29  Bariatric surgery control (WMP2)

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<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Total costs</th>
</tr>
</thead>
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<tr>
<td>Direct staff time</td>
<td>£416</td>
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<td>£150</td>
<td>£204</td>
<td>£111</td>
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<td>£199</td>
<td>£36</td>
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<td>£0</td>
<td>£271</td>
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<td>Materials</td>
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<td>£0</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td>£5</td>
</tr>
<tr>
<td>Meal replacement costs</td>
<td>£134</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td>£134</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>£754</strong></td>
<td><strong>£152</strong></td>
<td><strong>£186</strong></td>
<td><strong>£204</strong></td>
<td><strong>£111</strong></td>
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### Table 30  VLCDs

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<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct staff time</td>
<td>£458</td>
<td>£193</td>
<td>£53</td>
<td>£9</td>
<td>£713</td>
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<td>£267</td>
<td>£75</td>
<td>£8</td>
<td>£0</td>
<td>£349</td>
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<td>Materials</td>
<td>£5</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td>£5</td>
</tr>
<tr>
<td>Meal replacement costs</td>
<td>£1,163</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td>£1,163</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>£1,893</strong></td>
<td><strong>£268</strong></td>
<td><strong>£60</strong></td>
<td><strong>£9</strong></td>
<td><strong>£2,230</strong></td>
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### Table 31  VLCD control (WMP1)

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<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct staff time</td>
<td>£406</td>
<td>£193</td>
<td>£53</td>
<td>£9</td>
<td>£661</td>
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<td>Meal replacement costs</td>
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<td>£0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>£619</strong></td>
<td><strong>£268</strong></td>
<td><strong>£60</strong></td>
<td><strong>£9</strong></td>
<td><strong>£956</strong></td>
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### Table 32 Costs and utilities of surgery complications

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<th>Procedure</th>
<th>Utility value</th>
<th>Source</th>
<th>Utility weight</th>
<th>Rates of complications</th>
<th>Source</th>
<th>Rate of complications, rescaled</th>
<th>Utility weight * rate of complication</th>
<th>Total costs of complications</th>
<th>Total cost * rate of complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal hernia</td>
<td>0.6800</td>
<td>Canavan 2015²²⁰</td>
<td>0.7907</td>
<td>1%</td>
<td>Puzziferri et al. 2014²²¹</td>
<td>6%</td>
<td>0.0488</td>
<td>£2,951.81</td>
<td>£59.04</td>
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<tr>
<td>Incisional hernia</td>
<td>0.6800</td>
<td>Canavan 2015²²⁰</td>
<td>0.7907</td>
<td>1%</td>
<td>Puzziferri et al. 2014²²¹</td>
<td>6%</td>
<td>0.0488</td>
<td>£2,951.81</td>
<td>£59.04</td>
</tr>
<tr>
<td>Marginal ulcer</td>
<td>0.6800</td>
<td>Canavan 2015²²⁰</td>
<td>0.7907</td>
<td>1%</td>
<td>Puzziferri et al. 2014²²¹</td>
<td>6%</td>
<td>0.0488</td>
<td>£882.99</td>
<td>£8.83</td>
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<tr>
<td>Anaemia</td>
<td>0.7640</td>
<td>NICE 2015²²²</td>
<td>0.8884</td>
<td>2%</td>
<td>Puzziferri et al. 2014²²¹</td>
<td>12%</td>
<td>0.1097</td>
<td>£172.40</td>
<td>£3.45</td>
</tr>
<tr>
<td>Iron deficiency requiring transfusion</td>
<td>0.7640</td>
<td>NICE 2015²²²</td>
<td>0.8884</td>
<td>2%</td>
<td>Puzziferri et al. 2014²²¹</td>
<td>12%</td>
<td>0.1097</td>
<td>£172.40</td>
<td>£3.45</td>
</tr>
<tr>
<td>Operational revision rates for abdominal pain</td>
<td>0.6800</td>
<td>Canavan 2015²²⁰</td>
<td>0.7907</td>
<td>0.10%</td>
<td>Puzziferri et al. 2014²²¹</td>
<td>0.62%</td>
<td>0.0049</td>
<td>£1,691.87</td>
<td>£1.69</td>
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<tr>
<td>Operational revision rates for non-healing ulcer</td>
<td>0.6800</td>
<td>Canavan 2015²²⁰</td>
<td>0.7907</td>
<td>0.10%</td>
<td>Puzziferri et al. 2014²²¹</td>
<td>0.62%</td>
<td>0.0049</td>
<td>£2,076.60</td>
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<tr>
<td>Gastrointestinal bleeding rate</td>
<td>0.7350</td>
<td>Campbell 2015²²⁰</td>
<td>0.8547</td>
<td>1%</td>
<td>Puzziferri et al. 2014²²¹</td>
<td>6%</td>
<td>0.0528</td>
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<td>Cholecystectomy year 1</td>
<td>0.6400</td>
<td>Brazzelli 2014²²³</td>
<td>0.7442</td>
<td>8%</td>
<td>Picot 2009²¹¹</td>
<td>49%</td>
<td>0.3675</td>
<td>£2,442.12</td>
<td>£195.37</td>
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<tr>
<td>Procedure</td>
<td>Utility value</td>
<td>Source</td>
<td>Utility weight</td>
<td>Rates of complications</td>
<td>Source</td>
<td>Rate of complications, rescaled</td>
<td>Utility weight * rate of complication</td>
<td>Total costs of complications</td>
<td>Total cost * rate of complication</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>--------------</td>
<td>------------</td>
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<td>------------------------</td>
<td>---------------------------</td>
<td>-------------------------------</td>
<td>--------------------------------------</td>
<td>-------------------------------</td>
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</tr>
<tr>
<td>Cholecystectomy year 2</td>
<td>0.6400</td>
<td>Brazzelli 2014$^{23}$</td>
<td>0.7442</td>
<td>12%</td>
<td>Picot 2009$^{24}$</td>
<td>100%</td>
<td>0.7442</td>
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<td>293.0544647</td>
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<td>Average utility weighted value across all health states</td>
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Average utility weighted value across all health states: 16% * 0.7958 = 0.7442
### Table 33 Cost-effectiveness analysis excluding surgery as a comparator

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<tr>
<th>Intervention</th>
<th>Int £</th>
<th>Disease £</th>
<th>Total £</th>
<th>QALY</th>
<th>Analysis vs. Baseline</th>
<th>ICER (versus, Baseline)</th>
<th>Incremental analysis</th>
<th>ICER (versus, next best alternative)</th>
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<tr>
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<td>£2,909</td>
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<tr>
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<td>16,202</td>
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### 6% Discounting of costs and QALYs

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<th>WMP1</th>
<th>VLCD added to WMP1</th>
<th>WMP2</th>
<th>Look Ahead</th>
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<td>£761,679</td>
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<tr>
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<td>£1,729</td>
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<tr>
<td><strong>Look Ahead</strong></td>
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<td>£643</td>
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### 5 year time horizon

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