The effectiveness of weight-loss lifestyle interventions for improving fertility in women and men with overweight or obesity and infertility: a systematic review update of evidence from randomized controlled trials. [Dataset]

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The effectiveness of weight-loss lifestyle interventions for improving fertility in women and men with overweight or obesity and infertility: a systematic review update of evidence from randomized controlled trials

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Supplementary Data

Supplementary data S1: Intervention Characteristics

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
Diet & Exercise										
Duval et al.,2015[55]	Canada	24 weeks	**Intervention group:** 24-week interdisciplinary lifestyle intervention involving individual meetings with dietician and kinesiologist plus 12 weekly group meetings. Nutritional counselling provided following 'Healthy Plate'. Participants were encouraged to increase physical activity levels. **Control group:** Standard fertility treatment. Participants followed up for 18 months or until the end of pregnancy	105 F	24	**Primary outcomes:** Pregnancy rate **Secondary outcome:** Live birth rates, Change in weight	30.5 (±4.8)	Details unavailable	Details unavailable	Details unavailable

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
Espinos et al., 2017[44]	Spain Fertility Unit, Hospital de la Santa Creu i Sant Pau	12 weeks	**Intervention group:** 12-week, tailored diet, provided by dietician, reducing kcal intake by 500-800kcal per day. Encouraged 3 main meals and 2 snacks Self-reported food intake every 15 days. Diet readjusted if no weight loss achieved at follow up. 60 minutes of physical activity on stationary bike or treadmill, three times per week, monitored by trained staff. **Control group:** Straight to IVF. Participants followed up for 12 months	41 F	21	**Primary outcome:** Pregnancy rates **Secondary outcomes**: Change in weight, oocytes retrieved, miscarriage rate, live birth rate	32.0 (±3.2)	91.7 (±11.8) *34.6 (±3.0)*	-6.4 (±7.72)	0.0 (±5.195)
Guzick et al., 1994[53]	USA Magee Women's Hospital, University of Pittsburgh Medical Centre	12 weeks	**Intervention group:** 8 weeks VLCD, lean meat, fish or fowl and liquid meal replacements providing 400 kcal/day. Followed by gradual food reintroduction for 4 weeks until participants consumed around 1200 kcal/day. Training in behaviour modification to aid long-term changes to eating habits. Advised to gradually increase physical activity levels; walking was encouraged. Advised to gradually increase	12 F	6	**Primary outcome:** Hormonal and insulin level changes **Secondary outcome:** change in weight, ovulation	32.2 (±4.9)*	108.0 (±13.0)*	-16.2kg (±10.5)	0.0 (±5.195)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
			distance walked to achieve around 3km, 5 days a week. **Control group:** Waitlist control. 8-week screening period involving regular blood tests before and after the 12-week intervention for both groups.							
Hoeger et al., 2004[49]	USA Reproductive Endocrinology Clinic, University of Rochester	48 weeks	**Intervention group: Comprised of 2 groups** Group 1, Lifestyle plus metformin: 24-week intensive phase followed by 24-week maintenance phase. Individualised meal plan provided for each participant. 500-1000 kcal/day deficit. Encouraged participants to eat low GI foods. Weekly group meetings in the intensive phase, to educate and monitor progress. Fortnightly group meetings in the maintenance stage for support and to monitor progress. Participants were encouraged to participate in 150 minutes of exercise each week. Group 2, Lifestyle (as above) plus placebo	38 F	11	**Primary outcome:** Return of ovulation **Secondary outcomes**: Success of weight-reduction regimen, preliminary differences on outcome measurements	28.6 (±5.0)	Details unavailable	-7.75** (±3.4)	-2.59** (±4.2)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
Legro et al., 2015[56]	USA Department of Obstetrics and Gynecology, University of Pennsylvania Penn State College of Medicine Multi-centre trial	16 weeks	**Control group: Comprised of 2 groups** Group 1, Metformin only Group 2, Placebo only **Intervention group:** Lifestyle plus Oral Contraceptive Pill (OCP): Reducing diet incorporating liquid meal replacements, prepared meals, snacks. Caloric deficiency calculated from each individual's body weight. Encouraged to gradually increase walking or similar aerobic exercise building to 30-35 mins on 5 days of the week Behavioural modification lessons were delivered by trained study coordinators. **Control group:** OCP only Recruited from October 2008 until December 2012, follow up until March 2014.	149 F	50	**Primary outcome:** Live birth rate **Secondary outcomes:** Ovulation rates, change in weight	28.6 (±3.4)	96.0 (±15.8) *35.1 (±4.6)*	-6.1 (±3.2)	-1.1 (±3.1)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
Moran et al., 2011[57]	Australia Repromed Infertility Clinic		**Intervention group:** Reducing diet to around 1,200 kcal/day. 1 meal a day replaced with a liquid meal replacement. 5-9 week intervention depending on when oocyte pick up and embryo transfer occurred. Prescribed a home-based conditioning and walking exercise programme. Diet and exercise advice provided by a qualified dietician. **Control group:** Standard dietary and lifestyle advice, provided face to face, focusing on factors influencing fertility. No follow up	46 F	18	**Primary outcome:** Pregnancy and live birth rates **Secondary outcomes:** Change in weight, change in waist circumference	33.8 (± 3.5)	93.0 (± 16.0) *34.0 (±4.5)*	-3.8 (±3.0)	-0.5 (±1.2)
Mutsaerts et al., 2016[41]	The Netherlands 6 University Medical Centres & 17 General Hospitals Multi-centre trial	24 weeks	**Intervention group:** 24 week reducing diet by 600kcal/day but not lower than 1,200kcal/day. Advised to increase physical activity to achieve 30 minutes of moderate exercise 2-3 times a week. Provided with pedometer, encouraged to take 10,000 steps daily. Motivational counselling was provided to promote awareness of a healthy lifestyle and to formulate individualised goals. Led by trained coaches, nurses and dieticians.	577 F	236	**Primary outcome:** Live birth rate **Secondary outcomes:** Change in weight, ongoing pregnancy rates, clinical pregnancy rates, miscarriage, fertility treatments, complications from treatments, gestational diabetes	29.7 (±4.5)	Details unavailable	-4.4 (±5.8)	-1.1 (±4.3)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
			Control group: Straight to standard fertility treatments Recruitment from June 2009 until June 2012, follow up for 24 months or until end of pregnancy.							
Palomba et al., 2010[58]	Italy Hospital Fertility Unit	6 weeks	**Intervention group**: Lifestyle plus Clomiphene Citrate (CC) Hypocaloric diet to achieve approximately 800kcal deficit per day (based on baseline caloric intake of individual) Interactive, educational group meetings held with the aim of improving adherence 3 structured exercise sessions per week involving 30 mins on stationary bike, intensity gradually increased until working at 60-70% VO2 max. **Control group:** CC (150mg daily) only . Recruitment from February 2008 until August 2009, follow up for 6 weeks.	96 F	32	**Primary outcome:** Ovulation rate **Secondary outcomes:** other reproductive outcomes, changes in anthropometric and hormonal measures and compliance	28.43 (± 8.31)	86.21 (± 6.98) *31.05* *(±2.98)*	-4.42 (±9.22)	-0.69 (±9.47)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
Rothberg et al., 2016[52]	USA Centre for Reproductive medicine, University of Michigan (UM) UM Weight Management Programme	16 weeks	**Intervention group:** 12-week VLCD, liquid meal replacements providing 800 kcal/day. Followed by 2 weeks partial meal replacement then 2-week transition to fully food-based plan. Met with dietician twice a month. Encouraged to increase exercise to 40 minutes per day. **Control group**: usual care in the centre. Conventional food-based diet recommended for 12 weeks;1200kcal/ daily, aiming for 0.45-1.8kg weight loss per week. One meeting with dietician at end, 3 optional follow up visits if the participant desired. Recruitment from October 2013 until March 2015. 12-month follow up for all but last participant who received 6-month follow up.	14 F	6	**Primary outcomes:** Feasibility of recruitment, randomisation, intervention implementation, retention **Secondary outcomes:** Change in weight, pregnancy rates, live birth rates, miscarriages, ovulation rates, BMI	33.0 (±5.0)	108.0 (±10.0) *41 (±4)*	-14 (±6.0)	-5 (±5.0)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
Sim et al., 2014[59]	Australia Fertility Unit, Royal Prince Alfred Hospital	12 weeks	**Intervention group:** 6-week VLCD incorporating liquid meal replacements providing around 600 kcal/day, followed by refeeding protocol involving mildly hypocaloric diet (600kcal daily deficit), individualised plan prescribed by a dietician Weekly group meetings involved dietary, exercise and psychological/behavioural advice relating to weight loss and infertility Encouraged to increase step count to 10,000 steps/ day over first 6 weeks and maintain that level for the remainder of the study. **Control group:** Standard care; advised to see GP for weight loss advice or referred to weight loss service if BMI >35kg/m^2**.** Received same printed material as intervention group. Recruitment from February 2007 to February 2011, follow up for 12 months.	49 F	26	**Primary Outcome:** Clinical pregnancy rate **Secondary outcomes**: Changes in anthropometric measures, reproductive parameters, fertility treatment measures, miscarriage rates and compliance	32.9 (± 3.3)	95.8 (± 12.7) *35.1* *(±3.8)*	-6.6 (±4.6)	-1.6 (±3.6)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
Diet Alone										
Becker et al., 2015[54]	Brazil Obstetrics & Gynaecology Service, Hospital de Clinicas de Porto Alegre	12 weeks	**Intervention group:** 12-week intervention Low GI, hypocaloric diet Individualised diet for each participant with calorie content equivalent to 20kcals/kg of their current body weight. 3-day food diary completed at baseline, 6 and 12 weeks. **Control group:** 3-day food diary at baseline, 6 and 12 weeks. Recruitment and follow up from January 2012-December 2013.	36 F	16	**Primary outcomes:** Anthropometric (change in weight, BMI) and metabolic changes. **Secondary outcomes:** Clinical pregnancy rate, live birth rate, oocyte retrieval, compliance to diet.	31.36 (± 0.89)* *28.67 (±0.06)*	77.03 (± 2.06)*	-4.51 (±3.11)	0.72 (±2.6)
Einarsson et al., 2017[48]	Sweden, Denmark & Iceland 9 Infertility Clinics Multi-centre trial	16 weeks	**Intervention group**: 12-week VLCD, liquid meal replacements providing 880kcal/ day. Followed by meetings with dietician for 2-5 weeks for reintroduction of solid food and weight stabilisation. Participants unable to complete VLCD were offered individualised weight loss counselling until start of IVF. **Control group**: Straight to IVF. Recruitment from October 2010 until January 2016,	317 F	152	**Primary outcome**: Live birth. **Secondary outcomes**: Pregnancy rate, miscarriage rate, live birth after spontaneous pregnancy, oocyte retrieval, change in weight.	31.5 (±4.3)	92.4 (±8.0)	-9.1 (±6.83)	1.19 (±1.95)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
			followed up until February 2017.							
Exercise Alone										
Kiel et al, 2018[50]	Norway University of Science & Technology & Department of Fertility, St Olavs Hospital Multi-center trial	10 weeks	**Intervention group:** High intensity interval training (HIIT) performed 3 times a week. 2 sessions involved working at 85-95% max HR for 4 minutes repeated four times. 1 session involved working at 100% max HR for 1 minute repeated 10 times. All sessions were supervised until the participant was familiar with the protocol. Exercise regime continued until ovulation induction. Encouraged to adhere to Norwegian diet recommendations but no other nutritional advice was provided. **Control group:** Usual care; advice from hospital staff about physical activity. Not discouraged	18 F	8	**Primary outcome:** Pregnancy rates **Secondary outcomes:** Insulin sensitivity, body composition	33.1 (±5.9)	85.7 (±3.5) *28.9 (±2.4)*	-0.6 (±6.08)	-0.7 (±6.11)

Study	**Country/ Setting**	**Intervention Length**	**Intervention details**	**Sample Size/ Sex**	**n** (intervention)	**Outcomes**	**Age** (intervention group) Mean yrs (SD)	**Weight** (kg) *BMI* at start (intervention group) Mean (SD)	**Weight change (kg): intervention group** Mean (SD)	**Weight change (kg): control group** Mean (SD)
			from being active. Encouraged to adhere to Norwegian diet recommendations but no other nutritional advice was provided. Participants were followed up until they received results from their first round of IVF.							
Nasrekani et al., 2016[45]	Iran Fertility Clinic, Bojnurd	12 weeks	**Intervention group:** 12-week aerobic exercise programme. Intensity gradually increased over 12 weeks, starting off with 10-minute warm up and 10 minutes of non-stop aerobic exercises, increasing this by 1 minute each session building up to three 60-minute sessions per week. **Control group:** no intervention; could maintain sedentary lifestyle.	20 F	10	**Primary outcome:** Hormone levels; LH **Secondary outcome:** Weight in kg	30.9 (±7.14)	71.11 (±15.05) *28.43 (±6.78)*	-0.95 (±6.18)	0.05 (±5.93)
Pedometer plus diet & exercise counselling										
Nagelberg et al., 2016[51]	USA Reproductive Endocrinology Clinic, Los Angeles County	4 weeks	**Intervention group:** Referred to Wellness Clinic for dietary and exercise counselling Provided with a pedometer.	21 F	10	**Primary outcome:** Change in weight **Secondary outcomes:** Ovulation improvement, pregnancy rates	Details unavailable	Details unavailable	Details unavailable	Details unavailable

Study	Country/ Setting	Intervention Length	Intervention details	Sample Size/ Sex	n (intervention)	Outcomes	Age (intervention group) Mean yrs (SD)	Weight (kg) *BMI* at start (intervention group) Mean (SD)	Weight change (kg): intervention group Mean (SD)	Weight change (kg): control group Mean (SD)
+ University of Southern California Medical Center			Received weekly phone calls to discuss exercise and nutrition goals, reviewed weekly step count and given specific goals to increase step count by 50% to achieve 10,000 steps per day. **Control group:** Referred to Wellness Clinic for dietary and exercise counselling Weekly phone call to discuss exercise and nutrition goals. No pedometer.							

Abbreviations: BMI: body mass index; FSH: follicle-stimulating hormone; GI: Glycaemic index; HR: heart rate; IVF: in vitro fertilisation; LH: luteinizing hormone; VLCD: very low-calorie diet; OCP: oral contraceptive pill; Clomiphene citrate: CC

* Mean ± SE

** % weight change not actual weight reductio

Supplementary data S2: Search Strategy MEDLINE (Ovid)

1. exp infertility/
2. exp fertility/
3. exp Reproductive Techniques Assisted/
4. Polycystic Ovary Syndrome/
5. infertil$.tw.
6. fertil$.tw.
7. subfertil$.tw.
8. fecund$.tw.
9. infecund$.tw.
10. subfecund$.tw.
11. (concept$ adj3 delay$).tw.
12. (time adj3 pregnan$).tw.
13. (pregnan$ adj3 difficult$).tw.
14. PCOS.tw.
15. (polycyst$ adj3 ovar$).tw.
16. ivf.tw.
17. (assist$ adj3 concep$).tw.
18. (assist$ adj3 reproduc$).tw.
19. (ovulat$ adj3 induc$).tw.
20. clomifene.tw.
21. clomiphene.tw.
22. icsi.tw.
23. (intracytoplas$ adj3 sperm).tw.
24. or/1-23
25. weight loss/
26. Body Mass Index/
27. exp overweight/
28. Waist-Hip Ratio/
29. Waist-Height Ratio/
30. exp body fat distribution/
31. Waist Circumference/

32. (weight adj1 (los$ or reduc$ or maint$ or control)).tw.

33. (obese or obesity).tw.

34. slim$.tw.

35. overweight.tw.

36. bmi.tw.

37. body mas index.tw.

38. whr.tw.

39. (waist adj3 (hip or circumference)).tw.

40. or/25-39

41. randomized controlled trial.pt.

42. controlled clinical trial.pt.

43. randomi?ed.ab.

44. placebo.ab.

45. drug therapy.fs.

46. randomly.ab.

47. trial.ab.

48. groups.ab.

49. or/41-48

50. exp animals/ not humans/

51. 24 and 40 and 49

52. 51 not 50

53. exp "patient acceptance of health care"/

54. Health, Knowledge, Attitudes, Practice/

55. Patient Dropouts/

56. Physician-Patient Relations/

57. Nurse-Patient Relations/

58. exp motivation/

59. exp "attitude to health"/

60. barrier$.tw.

61. obstacle$.tw.

62. facilitat$.tw.

63. discourag$.tw.

64. encourag$.tw.

65. motivat$.tw.

66. (inhibit$ or prohibit$).tw.

67. burden$.tw.

68. dropout?.tw.

69. (drop$ adj1 out$).tw.

70. (internal adj1 conflict$).tw.

71. willpower$.tw.

72. (self adj1 (efficac$ or sabotag$ or percep$)).tw.

73. or/53-72

74. 24 and 40 and 73

75. Qualitative Research/

76. questionnaires/

77. exp interviews as topic/

78. (qualitative or interview$ or focus group? or questionnaire$ or survey$).tw.

79. (ethnos$ or grounded or thematic or interpretive or narrative).tw.

80. or/75-79

81. 24 and 40 and 80

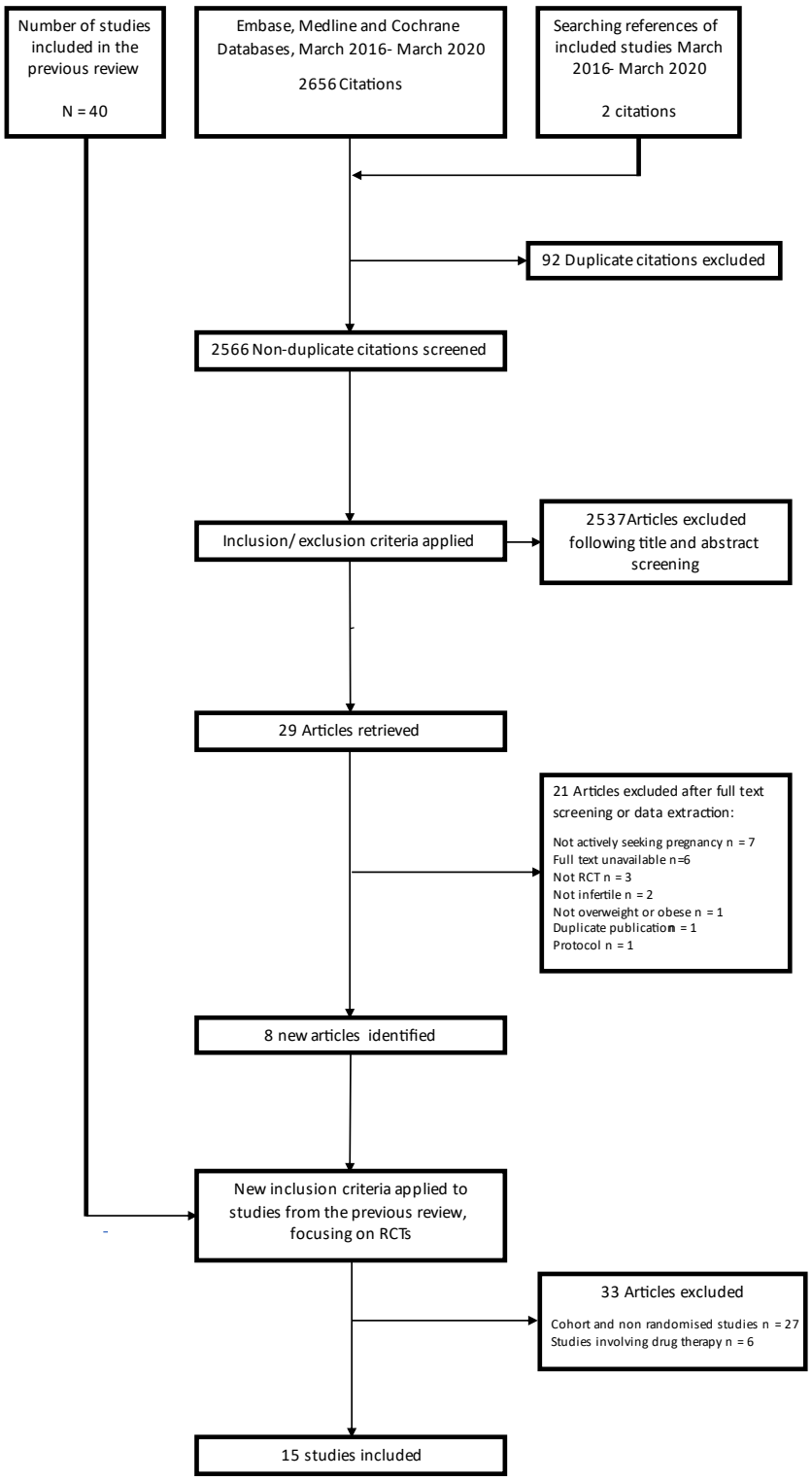
82. 74 or 81

83. 52 or 82

84. 83 not abstract.pt.

85. limit 84 to ed=20160319-20200331

Supplementary data S3: Flow diagram process of study selection



Supplementary data S4: Quality Assessment of all RCTs

Study	Random sequence generation	Allocation concealment	Blinding; participants and personnel	Blinding; outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Becker et al (2015)[54]	Unclear	Unclear	High	Unclear	High	Unclear	Low
Duval et al (2015)[55]	Low	Low	High	Unclear	High	Low	Low
Einarsson et al (2017)[48]	Low	Unclear	High	Low	Low	Unclear	High
Espinos et al (2017)[44]	Low	Unclear	High	Unclear	Unclear	Low	Low
Guzick et al (1994)[53]	Unclear	Unclear	High	Unclear	Unclear	Low	Low
Hoeger et al (2004)[49]	Low	Low	High	Unclear	Low	Low	Low
Kiel et al (2018)[50]	Low	Low	High	Unclear	Low	Low	Low
Legro et al (2015)[56]	Low	Low	High	Unclear	Low	Unclear	High
Moran et al (2011)[57]	Low	Unclear	High	Unclear	High	Unclear	Low
Mutsaerts (2106)[41]	Low	Low	High	Unclear	Low	Low	Low

Nagelberg et al (2016)[51]	Low	Unclear	High	Unclear	Low	High	Unclear
Nasrekani et al (2016)[45]	Unclear	Unclear	High	Unclear	Unclear	Unclear	Unclear
Palomba et al (2010)[58]	Low	Low	High	Low	Low	Unclear	Low
Rothberg et al (2016)[52]	Low	Low	High	Unclear	Low	Unclear	High
Sim et al (2014)[59]	Unclear	Low	High	Low	High	Unclear	Low

Supplementary data S5: Funnel Plots

Figure S5a. Funnel Plot: Change in weight

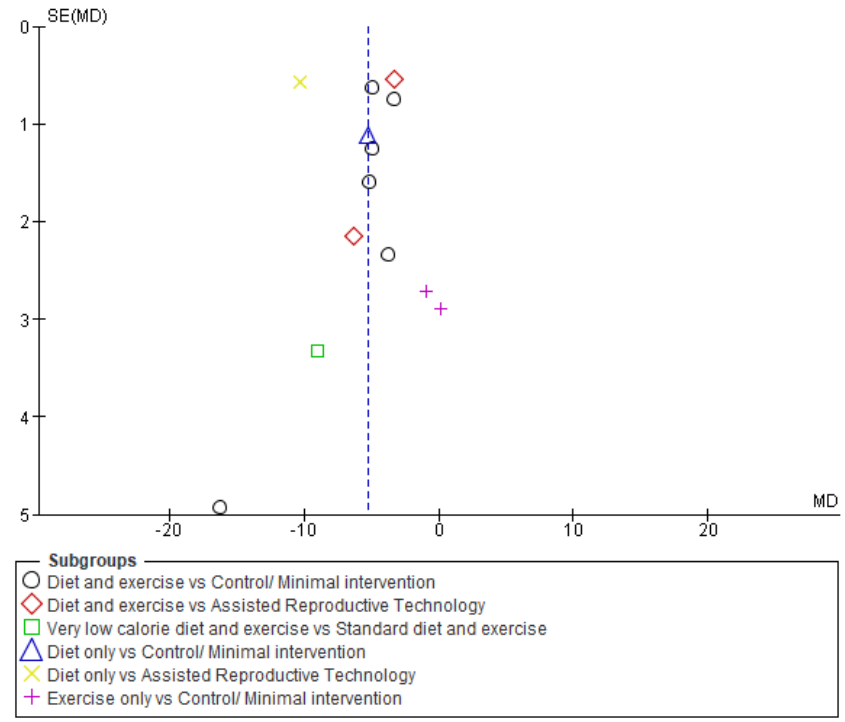


Figure S5b. Funnel Plot: Live Birth Rate

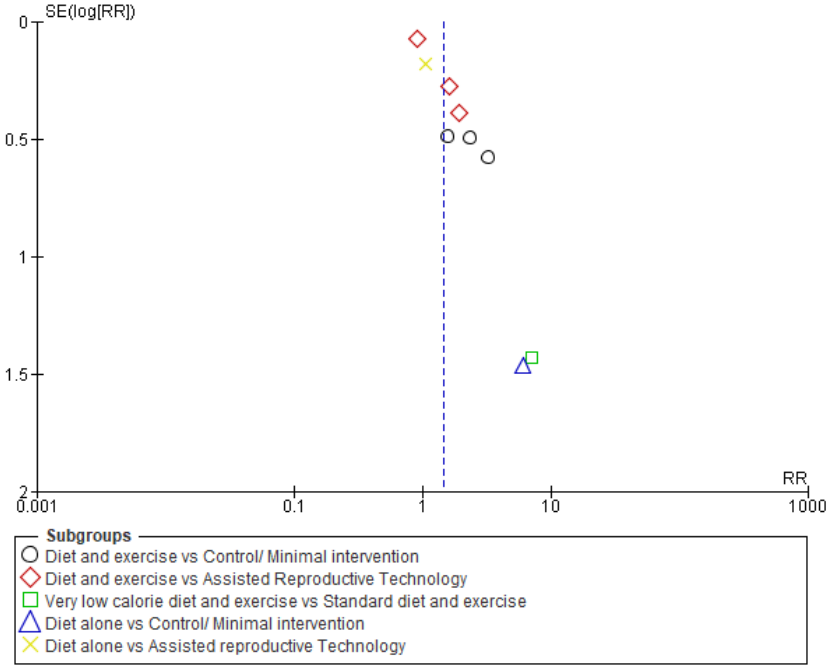
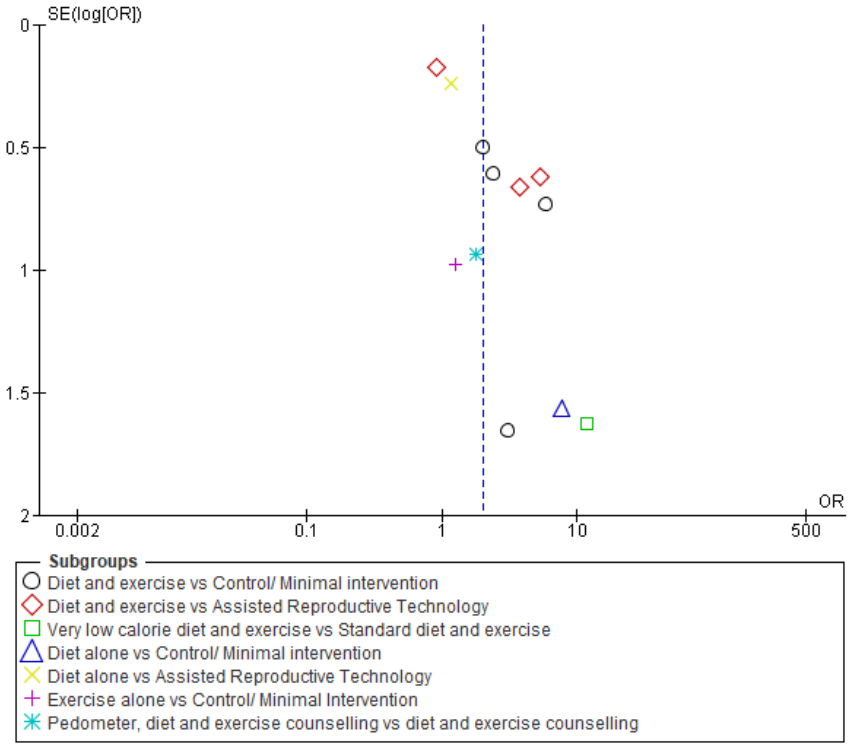
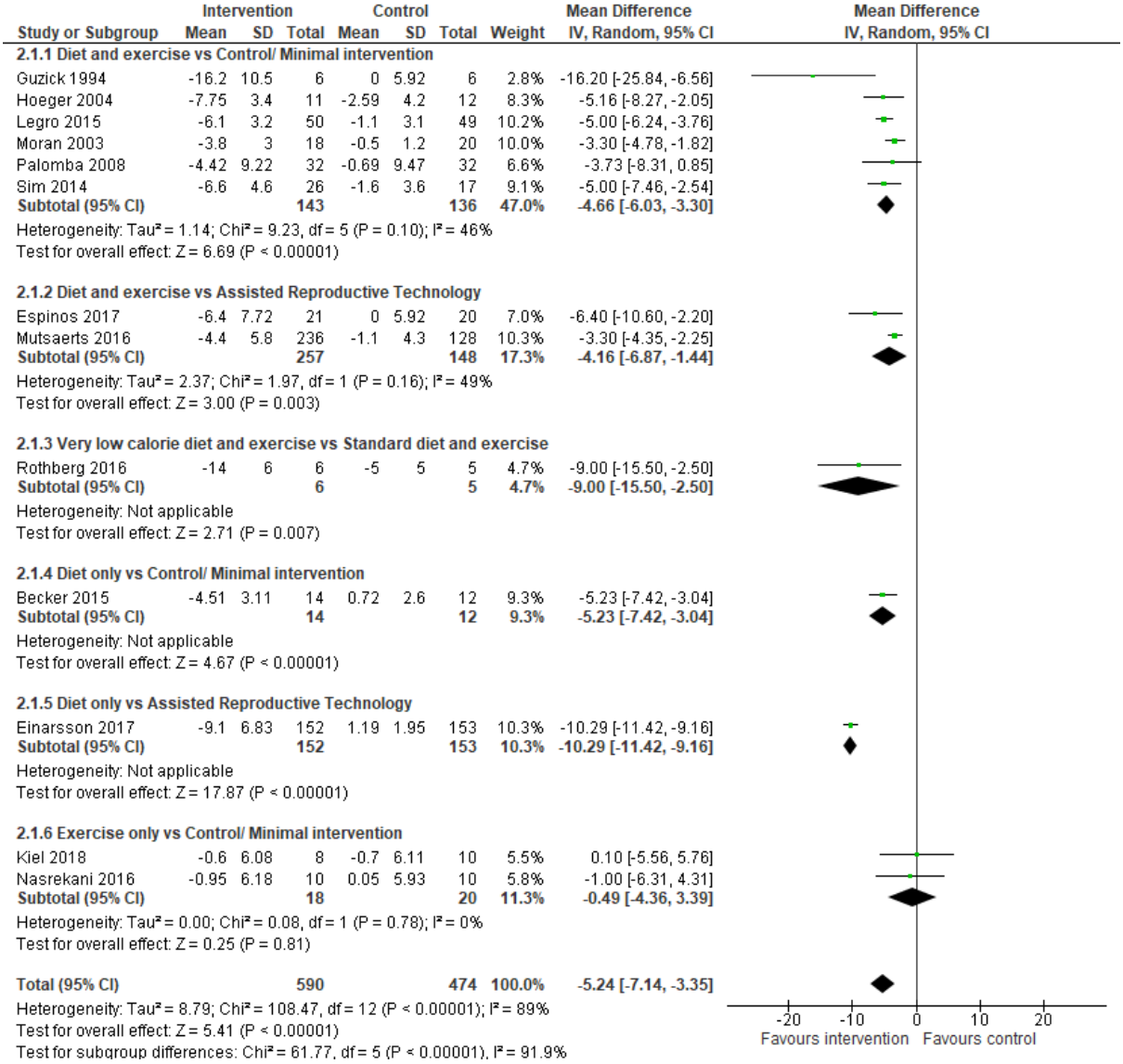


Figure S5c. Funnel Plot: Pregnancy Rate



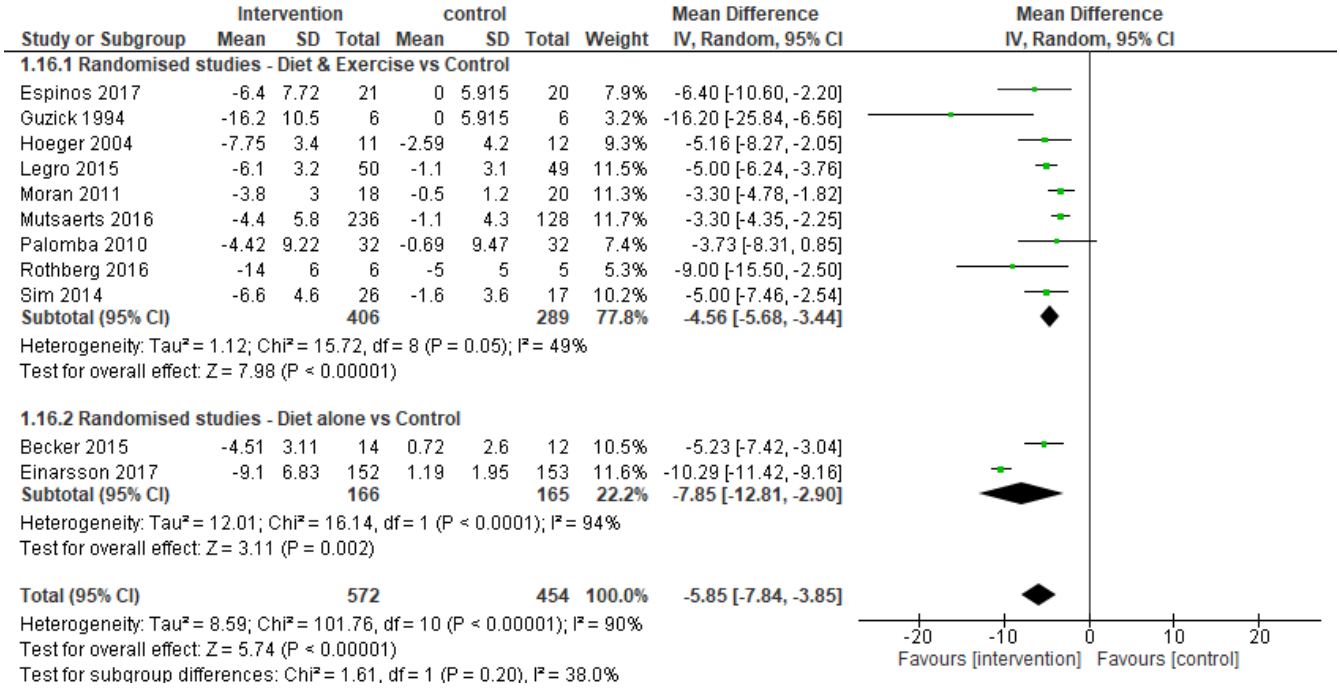
Supplementary data: Forest Plots

Supplementary data S6. Change in weight: effect of interventions versus control on weight change in kg



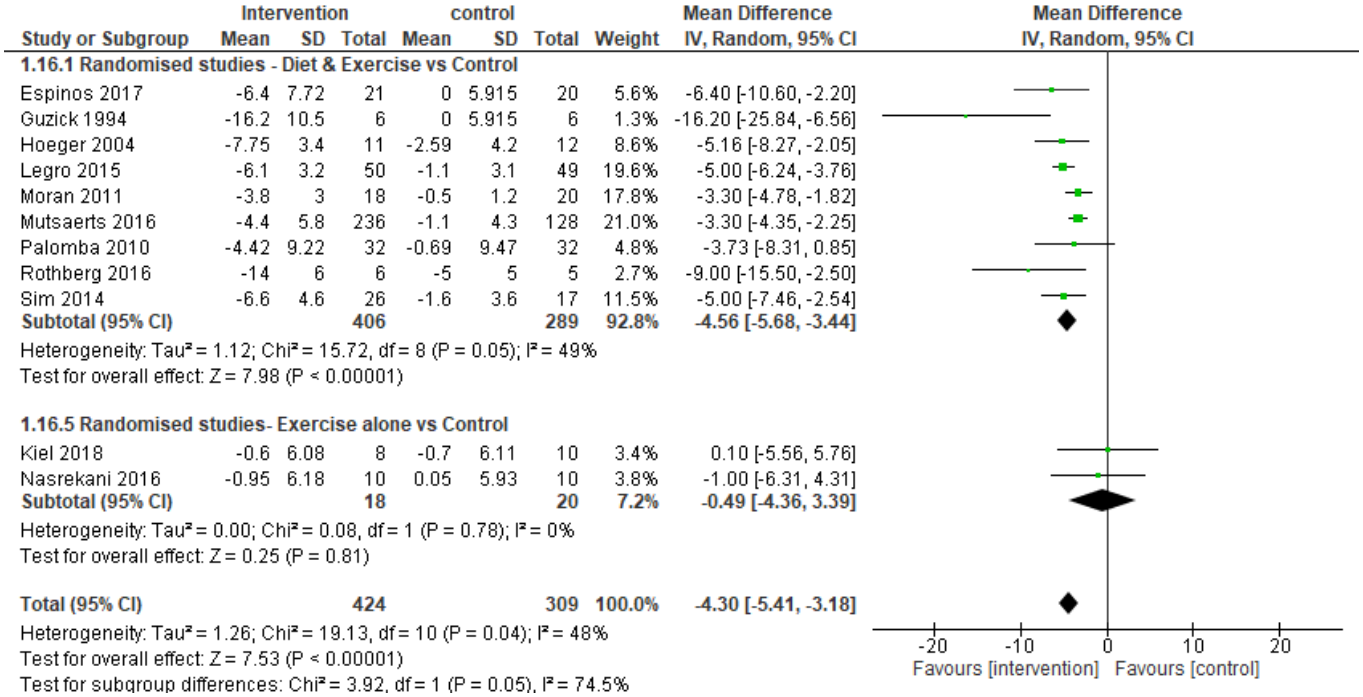
Supplementary data S7a. Forrest plots exploring differences in Change in Weight (subgroups).

Change in weight, diet and exercise versus diet only: effect of interventions versus control on weight change in kg



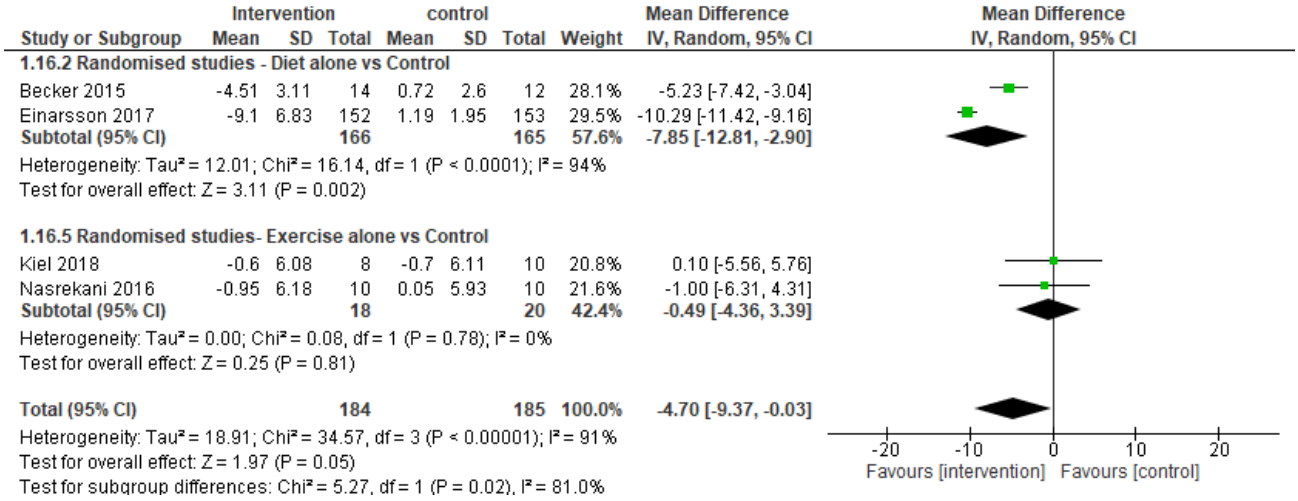
Supplementary data S7b. Forrest plots exploring differences in Change in Weight (subgroups).

Change in weight, diet and exercise versus exercise only: effect of interventions versus control on weight change in kg

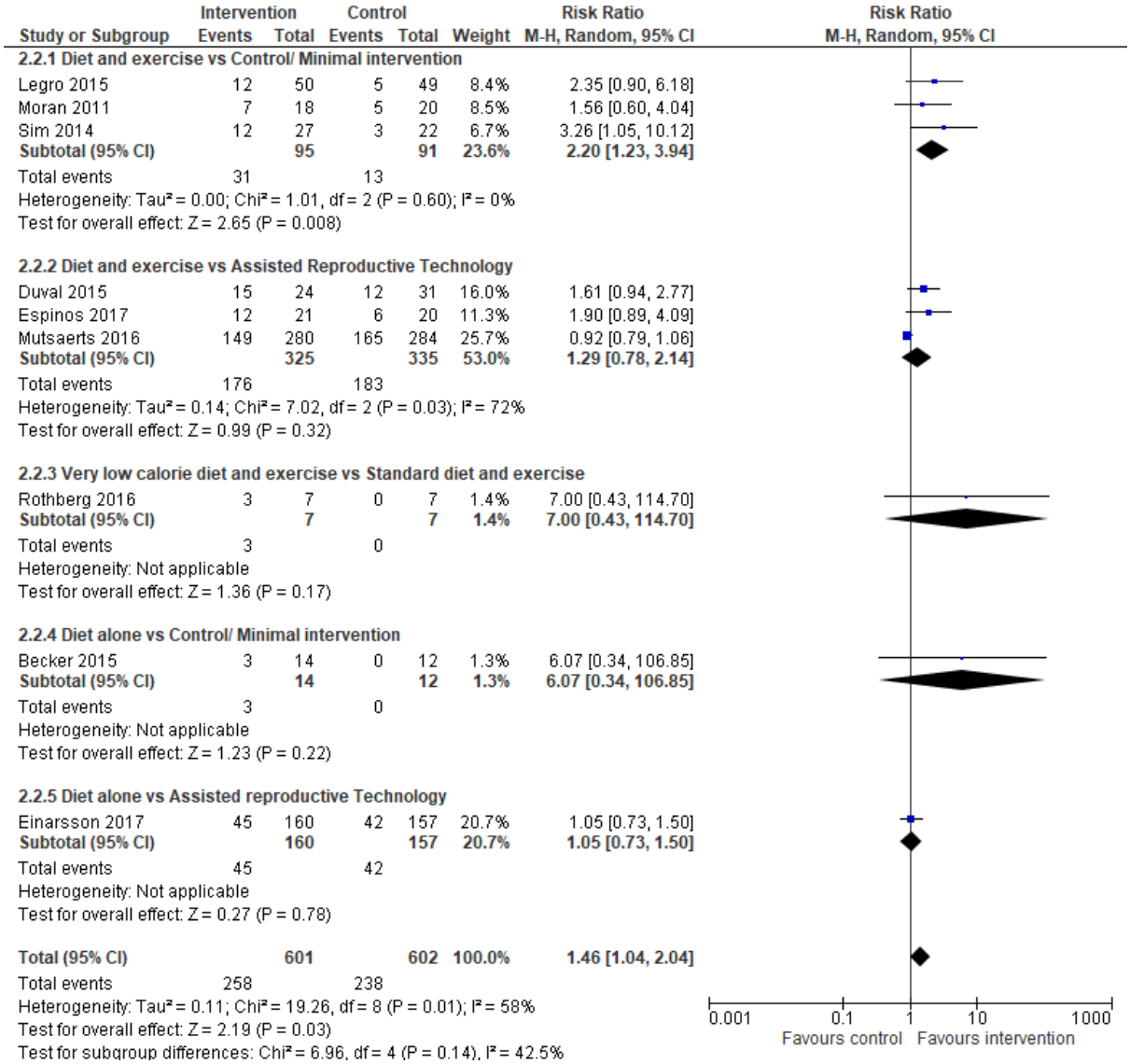


Supplementary data S7c. Forrest plots exploring differences in Change in Weight (subgroups).

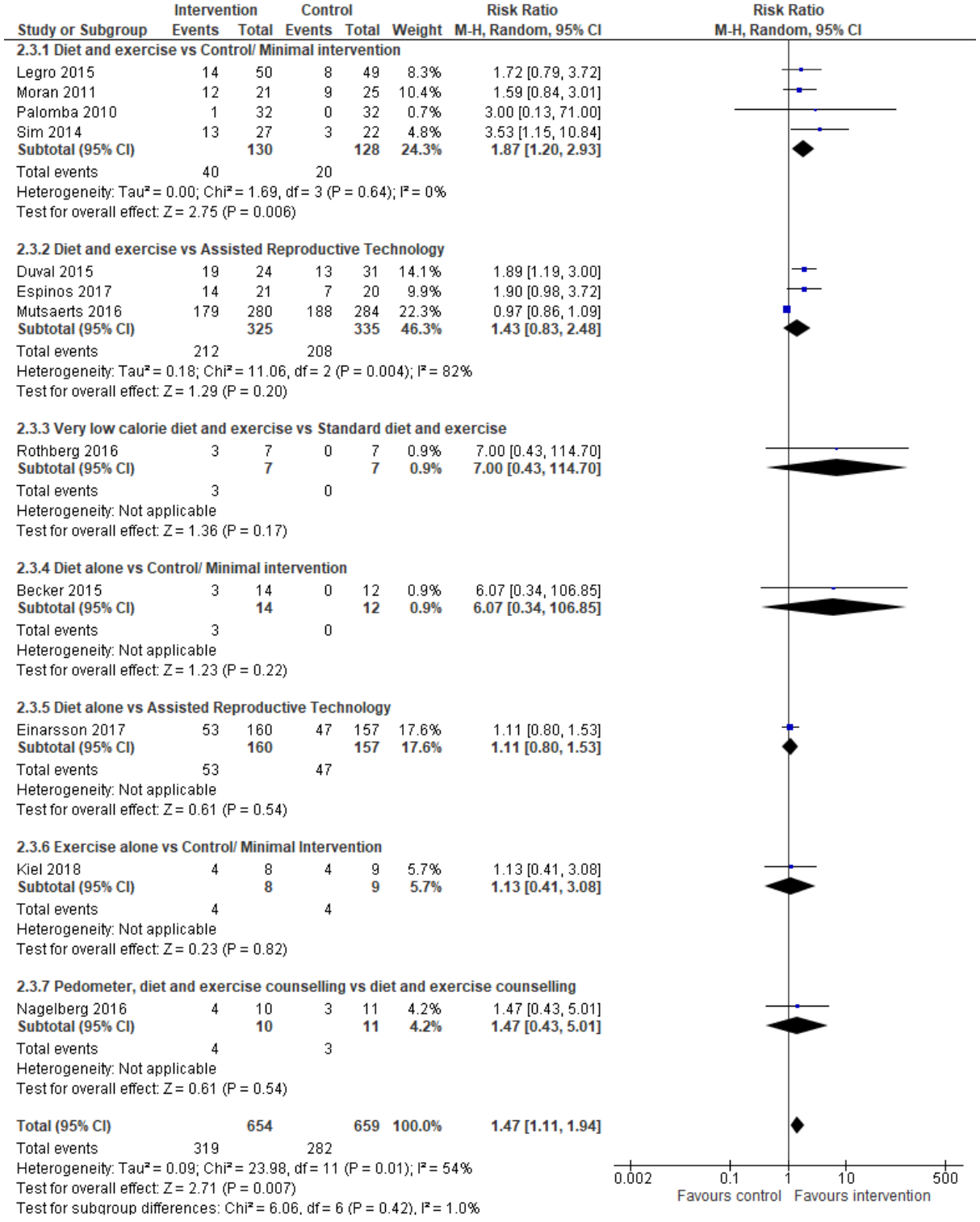
Change in weight, diet only versus and exercise only: effect of interventions versus control on weight change in kg



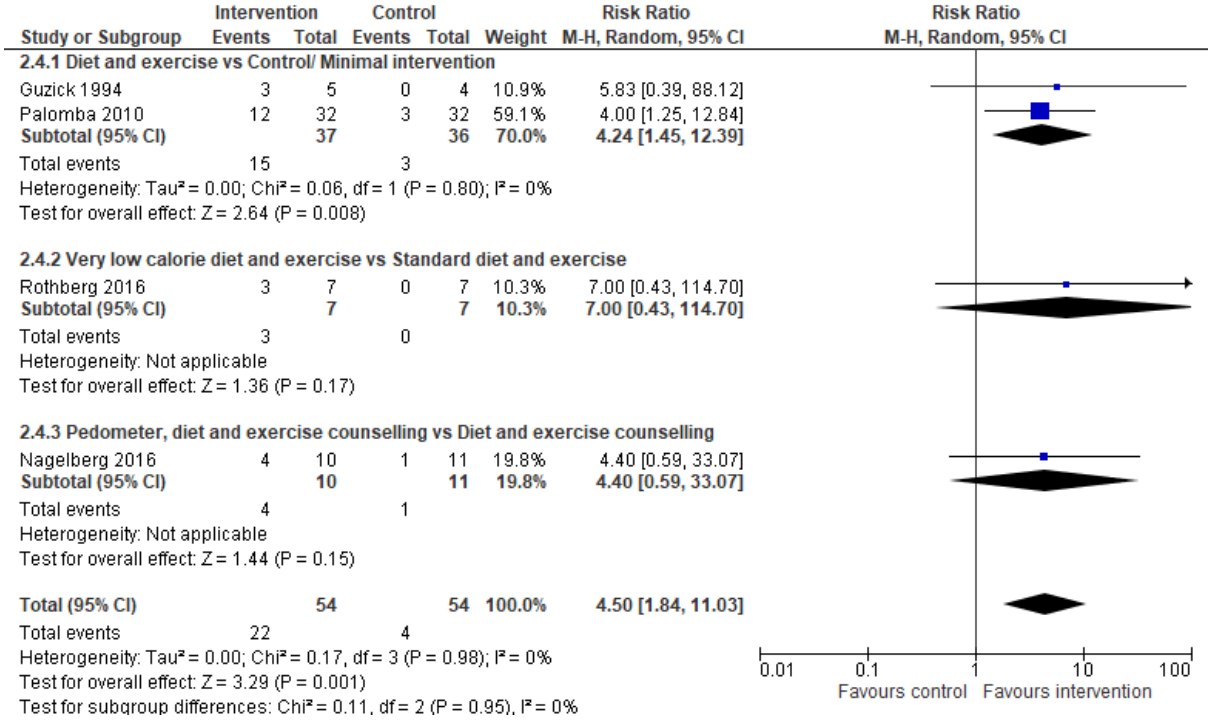
Supplementary data S8. Live birth rates: effect of interventions versus control



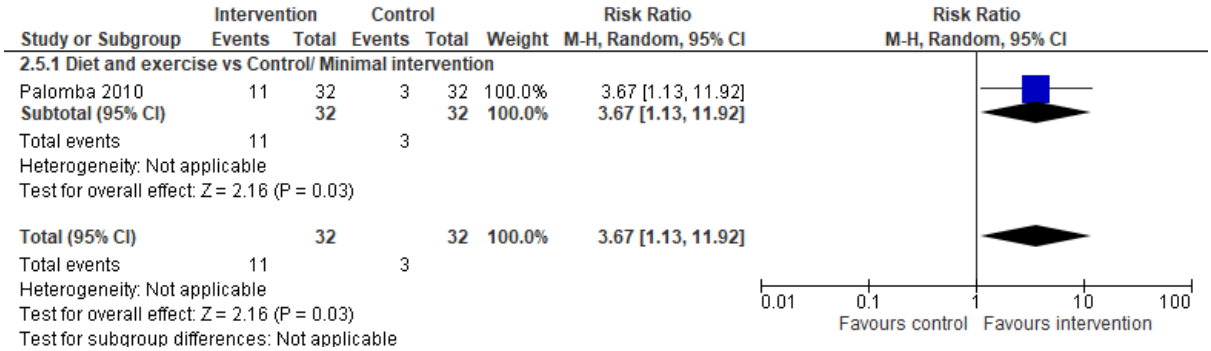
Supplementary data S9. Clinical pregnancy rates: effect of interventions versus control



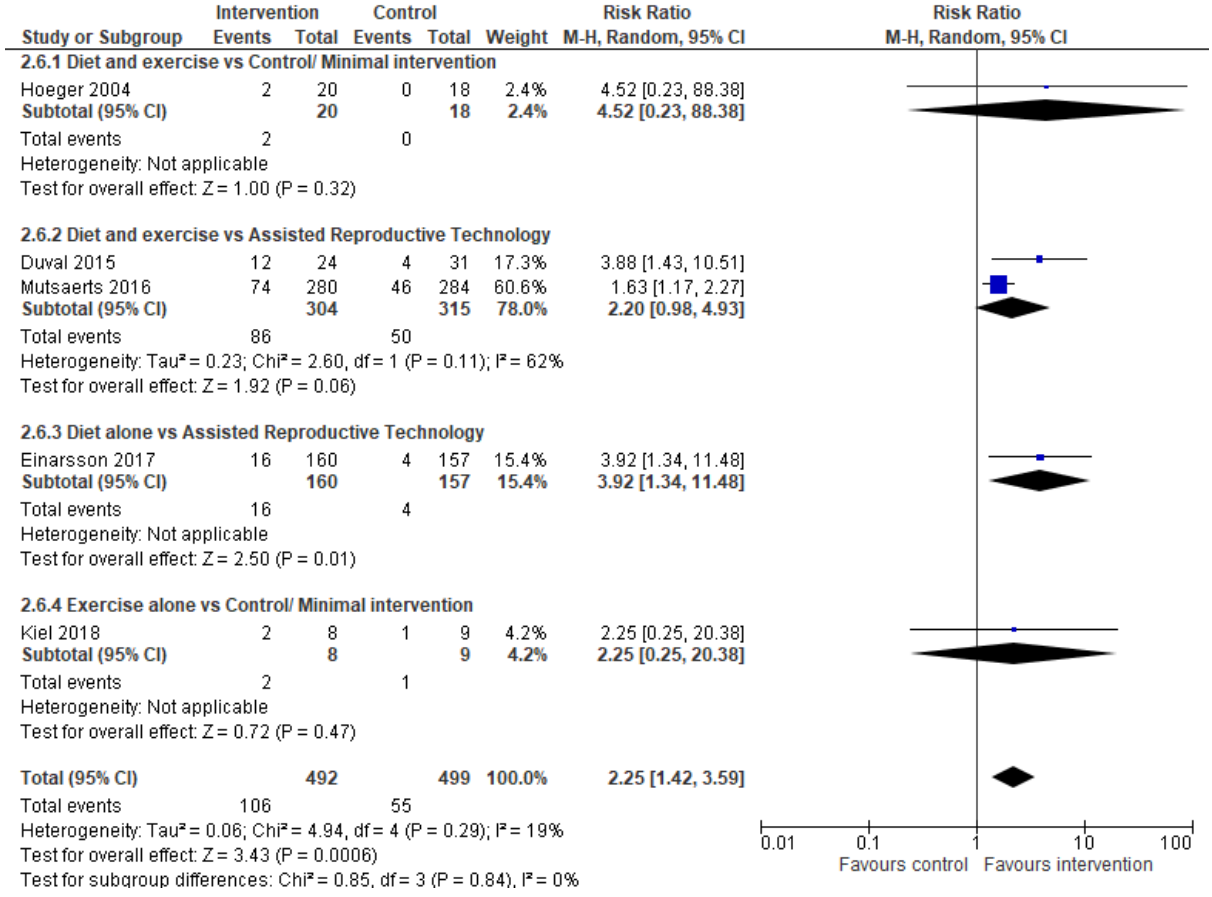
Supplementary data S10. Improvement in ovulation: effect of interventions versus control



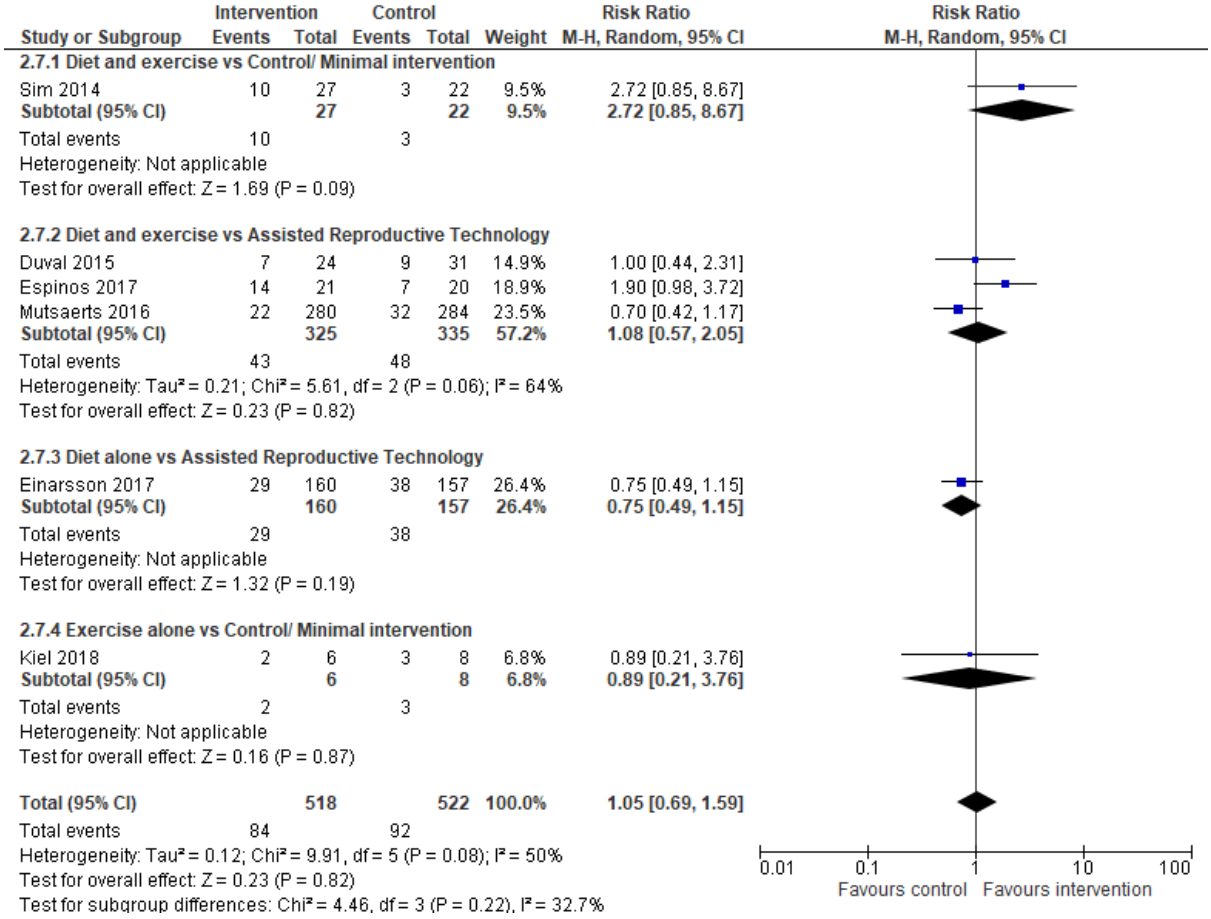
Supplementary data S11. Menstrual cycle irregularity: effect of interventions versus control



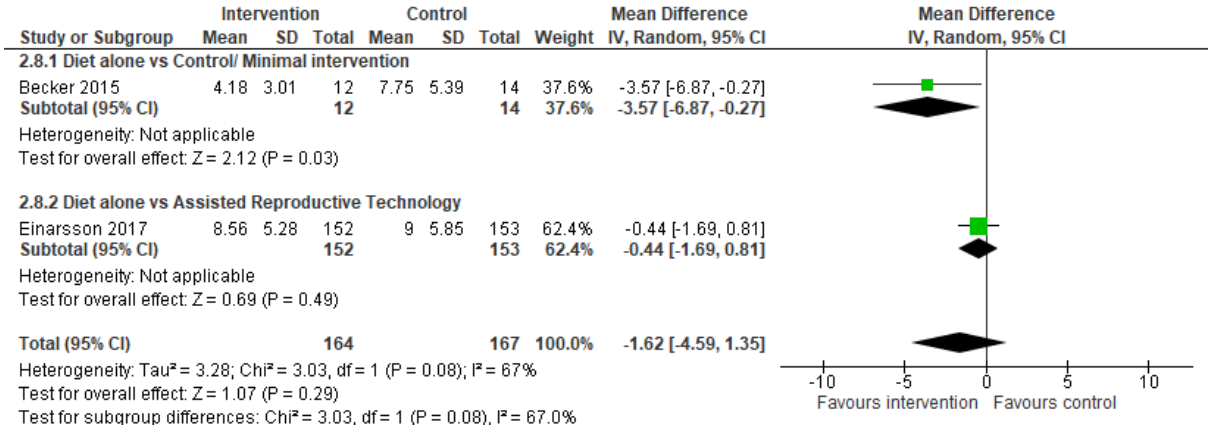
Supplementary data S12. Natural conceptions: effect of interventions versus control



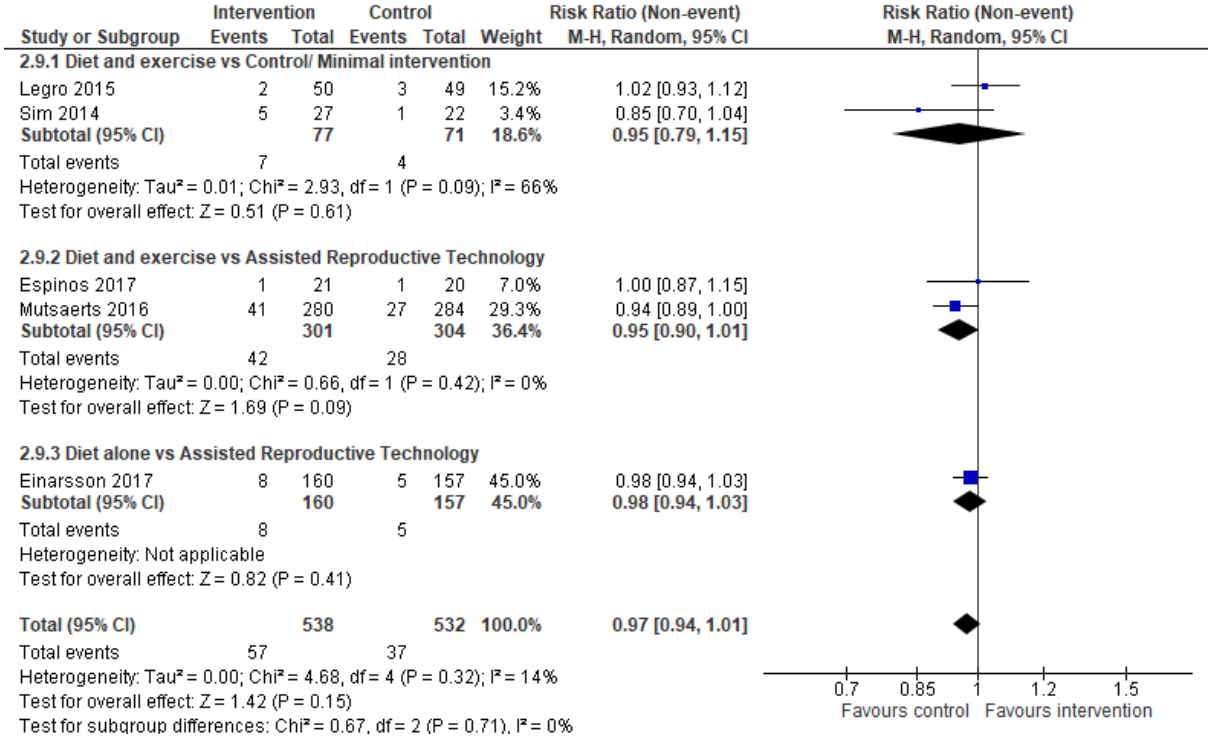
Supplementary data S13. Conceptions following Assisted Reproductive Technology: effect of interventions versus control



Supplementary data S14. Number of oocytes retrieved: effect of interventions versus control



Supplementary data S15. Miscarriage per participant: effect of interventions versus control



Supplementary data S16. Miscarriage per pregnancy: effect of interventions versus control