**Appendix F. Study Characteristics Table**

Table F-1. Study characteristics table for SMI comparative effectiveness reviewa

| **Study****Country****Randomized Patients (N)** | **Patient Characteristics** | **Intervention** | **Comparator** | **Outcomes****Timing** | **Effectiveness Rating****Funding** | **Study Quality:****Hard Outcomes****Soft Outcomes** |
| --- | --- | --- | --- | --- | --- | --- |
| Alvarez-Jimenez, 2006[1](#_ENREF_1) Europe61 | Mean age: 26.8Female N: 15Male N: 46Nonwhite: NRSchizophrenia N: 61Bipolar N: NROther N: NR | Early behavioral intervention:10–14 weekly or twice weekly individual therapy sessions following a flexible but manualized program, provided by a master's-level psychologist, focused on education, motivation, and skills training to enhance control over factors associated with antipsychotic weight gain. | Enhanced usual care "designed to provide patients with the same physical care that is offered in a comprehensive early psychosis program." | BMIWeight (kg)3 months, 4 months, 6 months, 12 months, 24 months | Mixed (4)Marques de Valddecilla Public Foundation– government | GoodNA |
| Assuncao, 2006[2](#_ENREF_2)South America54 | Mean age: 35.2Female N: 22Male N: 32Nonwhite: 18Schizophrenia N: 54Bipolar N: 0Other N: 0 | Nizatidine 600 mg/dayAll participants were continued on their pretrial dose of olanzapine (5-20 mg/day). | PlaceboAll participants were continued on their pretrial dose of olanzapine (5-20 mg/day). | Weight (kg)Total Cholesterol (mg/dl)LDL (mg/dl)Discontinuation due to adverse event"Treatment emergent adverse event"Psychiatric Symptom Severity: BPRS4 weeks, 8 weeks, 12 weeks | Efficacy (2)Industry | GoodGood |
| Atmaca, 2003[3](#_ENREF_3)Europe35 | Mean age: 27.9Female N: 14Male N: 21Nonwhite: NRSchizophrenia N: 35Bipolar N: N:NROther N: NR | Nizatidine 300 mg/dayAll participants were continued on their pretrial dose of olanzapine. | PlaceboAll participants were continued on their pretrial dose of olanzapine. | BMIWeight (kg)Psychiatric Symptom Severity: PANSSAny adverse event8 weeks | Efficacy (0)Not reported or unclear | FairFair |
| Atmaca, 2004[4](#_ENREF_4)Europe28 | Mean age: 30.2Female N: 12Male N: 13The sex of the 3 participants who did not complete the study was not reported.Nonwhite: NRSchizophrenia N: 28Bipolar N: NROther N: NR | Quetiapine 300 - 750 mg/day (mean dose 479 mg/day) + nizatidine 300 mg/day | Quetiapine 300 - 750 mg/day (mean dose 493 mg/day) + placebo | BMIWeight (kg)Psychiatric Symptom Severity: PANSSLeptin levels2 months | Efficacy (0)Not reported or unclear | FairFair |
| Ball, 2011[5](#_ENREF_5)US36 | Mean age: 47.0Female N: 11Male N: 25Nonwhite: 11Schizophrenia N: 36Bipolar N: NROther N: NR | Atomoxetine 120 mg/dayAll participants attended weekly group counseling, exercise sessions 3 times per week, and 10 weeks of Weight Watchers.All participants were continued on their pretrial dose of clozapine or olanzapine. | PlaceboAll participants attended weekly group counseling, exercise sessions 3 times per week, and 10 weeks of Weight Watchers.All participants were continued on their pretrial dose of clozapine or olanzapine. | Weight (kg)LDL (mg/dl)9 weeks, 24 weeks, 6 months | Mixed (4) Government, Industry | FairFair |
| Borba, 2011[6](#_ENREF_6)US20  | Mean age: 51.1Female N: 7Male N: 13Nonwhite: 2Schizophrenia N: 20Bipolar N: NROther N: NR | Ramelteon 8 mg/dayAll participants were continued on their pretrial medications. | PlaceboAll participants were continued on their pretrial medications. | BMIWeight (kg) HbA1c (%)Total cholesterol (mg/dl)LDL (mg/dl)2 months | Efficacy (0)Government, Industry | FairNA |
| Brar, 2005[7](#_ENREF_7)US71 | Mean age: 40.3Female N: 42Male N: 29Nonwhite: 36Schizophrenia N: 71Bipolar N: 0Other N: 0 | 20 manualized behavioral therapy sessions, twice weekly for 6 weeks followed by weekly for 8 weeks, covering diet, nutrition, exercise, and self-monitoring of behavioral changes. | Usual care | BMIWeight (kg)Systolic blood pressure (mmHg)Diastolic blood pressure (mmHg)14 weeks | Efficacy (1)Industry | FairFair |
| Brown, 2011[8](#_ENREF_8)US89 | Mean age: 44.6Female N: 54Male N: 35Nonwhite: 35Schizophrenia N: NRBipolar N: NROther N: NR | Recovering Energy Through Nutrition and Exercise for Weight Loss (RENEW): weekly individual visits for 12 weeks followed by monthly individual visits and weekly phone calls for the following 3 months. Sessions focused on weight loss strategies including social support, goal setting, skills training, and compensatory strategies for cognitive impairments. | Usual care | Weight (lb)3 months, 6 months | Efficacy (1)Government, Industry | FairFair |
| Bustillo, 2003[9](#_ENREF_9)US30 | Mean age: 34.5Female N: 6Male N: 24Nonwhite: 15Schizophrenia N: 30Bipolar N: NROther N: NR | Olanzapine 10 mg/day plus fluoxetine 20-60 mg/day (mean dose 56 mg/day) | Olanzapine 10 mg/day plusplacebo | Weight (kg)Psychiatric Symptom Severity: PANSS-Positive SymptomsPsychiatric Symptom Severity: HAM-DAdverse Event: Extrapyramidal symptoms4 months | Efficacy (2)Government, Industry | FairFair |
| Carrizo, 2009[10](#_ENREF_10)South America61 | Mean age: 38.9Female N: NRMale N: NRNonwhite: 50Schizophrenia N: 52Bipolar N: 2The numbers for diagnoses are based on the number of individuals who completed the trial, which was 54. 61 were randomizedOther N: NR | Metformin 500-1000 mg/dayAll participants continued taking their pretrial clozapine, although it was unclear if dosing was changed during the trial. Mean starting dose of clozapine for intervention arm was 180 mg/day. | PlaceboAll participants continued taking their pretrial clozapine, although it was unclear if dosing was changed during the trial. Mean starting dose of clozapine for placebo arm was 207 mg/day. | BMIWeight (kg) HbA1c (%)Systolic blood pressure (mmHg)Diastolic blood pressure (mmHg)Psychiatric Symptom Severity: BPRS7 weeks, 14 weeks | Efficacy (1)Government, Industry | FairFair |
| Cavazzoni, 2003[11](#_ENREF_11)US175 | Mean age: NRFemale N: NRMale N: NRNonwhite: NRSchizophrenia N: 169Bipolar N:NROther N: NR175 randomized, 169 completed and analyzed. | This was a 3-arm trial with 2 active arms.Arm 1: Pretrial dose of olanzapine plus nizatidine 300 mg/day Arm 2: Pretrial dose of olanzapine plus nizatidine 600 mg/day | Pretrial dose of olanzapine + placebo | Weight (lb)Psychiatric Symptom Severity: BPRS1, 2, 3, 4, 5, 6, 8, 12, and 16 weeks | Efficacy (1)Industry | FairPoor |
| Deberdt, 2008[12](#_ENREF_12)US133 | Mean age: 44.0Female N: NRMale N: NRNonwhite: NRSchizophrenia N: 133Bipolar N: 0Other N: 0 | Antipsychotic switching:FROM olanzapine 10-20 mg/day TO quetiapine 300-800 mg/day | CONTINUE olanzapine 10-20 mg/dayComparators were continued on olanzapine although the dose of olanzapine could be changed during the trial. | BMIWeight (kg) HbA1c (%)Total cholesterol (mmol/L)LDL (mmol/L)1, 2, 3, 5, 7, 10, 12, 16, 18, 22, and 24 weeks | Mixed (5)Industry | FairFair |
| Elmslie, 2006[13](#_ENREF_13)Australia/New Zealand60 | Mean age: 42.0Female N: 49Male N: 11Nonwhite: NRSchizophrenia N: NRBipolar N:60Other N: NR | Carnitine L-tartrate 15 mg/kg/day | Placebo control | BMIWeight (kg)Waist circumference change (cm)26 weeks | Mixed (3)Private foundation | GoodGood |
| Evans, 2005[14](#_ENREF_14)Australia/New Zealand51 | Mean age: 34.2Female N: 29Male N: 22Nonwhite: NRSchizophrenia N: 38Bipolar N: 8Other N: 5 | Nutrition education: 6 planned, 1 hour contacts including education on diet, nutrition, physical activity, and exercise and assistance in goal setting, provided every 2 weeks by an accredited practicing dietitian. | Usual care | BMIWeight (kg)3 months, 6 months | Efficacy (1)Industry | PoorPoor |
| Fleischhacker, 2010[15](#_ENREF_15)Europe, Africa207 | Mean age: 39.0Female N: 73Male N: 134Nonwhite: 10Schizophrenia N: 207Bipolar N: 0Other N: 0 | Aripiprazole 5–15 mg/day; mean dose = 11.1 mg/dayAll participants were continued on their prestudy dose of clozapine throughout the trial. | PlaceboAll participants were continued on their prestudy dose of clozapine throughout the trial. | BMIWeight (kg)Total Cholesterol (mg/dl)LDL (mg/dl)Discontinuation due to adverse eventAll-cause mortalityHRQOL/Physical function: Subjective Well Being Under Neuroleptics Scale score2, 4, 6, 8, 10, 12, 14, and 16 weeks | Mixed (3)Industry | GoodGood |
| Forsberg, 2008[16](#_ENREF_16)Europe41 | Mean age: 41.0Female N: 16Male N: 25Nonwhite: NRSchizophrenia N: NRBipolar N: NROther N: NR | Multimodal lifestyle intervention of 70 group visits over 12 months, with activities including fitness exercises, practice buying and preparing food, learning to monitor heart rate, and activity scheduling. Participants received 50% subsidy on entrance and rental fees at sports centers. | Once weekly art class for 12 months. | BMIWeight (kg) HbA1c (%)Systolic blood pressure (mm Hg)Diastolic blood pressure (mm Hg)Smoking cessationNumber of participants meeting criteria for Metabolic syndrome13.5 months | Mixed (4)Government, Private foundation | FairNA |
| Gillhoff, 2010[17](#_ENREF_17)Europe50 | Mean age: 48.0Female N: 23Male N: 27Nonwhite: NRSchizophrenia N: NRBipolar N: 50Other N: NR | Multimodal lifestyle intervention including weekly fitness training, 7 psychotherapeutic/educational sessions, and 4 cooking and nutrition classes over the course of 5 months. | Wait list / Usual Care | BMIWeight (kg) HbA1c (%)Total cholesterol (mmol/L)LDL (mmol/L)Systolic blood pressure (mm Hg)Diastolic blood pressure (mm Hg)5 months, 11 months | Efficacy (2)Industry | FairNA |
| Graham, 2005[18](#_ENREF_18)US21 | Mean age: NRFemale N: 9Male N: 12Nonwhite: 5Schizophrenia N: 18Bipolar N: 3Other N: 0 | Amantadine up to 300 mg/day (no further dosing details given) + 12 weekly sessions of healthy lifestyle education program and 3 month membership to gym or commercial weight loss program | Placebo + 12 sessions of healthy lifestyle education program and 3 month membership to gym or commercial weight loss program | BMIWeight (lb)1 month, 2 months, 3 months | Mixed (3)Government, Industry | PoorNA |
| Hoffmann, 2012[19](#_ENREF_19)US, Europe, Asia, Middle East, Mexico199 | Mean age: 38.5Female N: 79Male N: 120Nonwhite: 112Schizophrenia N: 199Bipolar N: NROther N: NR | This was a 3-arm trial with 2 active arms.Arm 1: Pretrial dose of olanzapine plus metformin 1000-1500 mg/day, followed by amantadine 200 mg/day if metformin was ineffectiveArm 2: Pretrial dose of olanzapine plus amantadine 200 mg/day, followed by metformin 1000-1500 mg/day if amantadine was ineffective | Pretrial dose of olanzapine only | BMIWeight (kg) HgA1c (%)Total cholesterol (mmol/L)LDL (mmol/L) Discontinuation due to adverse eventPsychiatric Symptom Severity: BPRSPsychiatric Symptom Severity: CGIPsychiatric Symptom Severity: MADRS22 weeks | Mixed (3)Industry | PoorPoor |
| Karagianis, 2009[20](#_ENREF_20)US, Canada, Europe, Mexico149 | Mean age: 39.0Female N: 68Male N: 81Nonwhite: 71Schizophrenia N: 106Bipolar N: 41Other N: 2 | Antipsychotic-switching:FROM standard tablets of olanzapine 5-20 mg/dayTO orally disintegrating olanzapine 5-20 mg/day (mean dose 14.3 mg/day) | CONTINUE standard tablets of olanzapine 5-20 mg/day (mean dose 14.9 mg/day) | BMIWeight (kg) HbA1c (%)Total cholesterol (mg/dl)LDL (mg/dl)Systolic blood pressure (mm Hg)Diastolic blood pressure (mm Hg)Discontinuation due to adverse eventHRQOL/Physical Function: Subjective Well Being Under Neuroleptics Scale score2, 4, 6, 8, 10, 12, 14, and 16 weeks | Mixed (4)Industry | GoodGood |
| Khazaal, 2007[21](#_ENREF_21)Europe61 | Mean age: 40.7Female N: 33Male N: 28Nonwhite: NRSchizophrenia N: 49Bipolar N: 5Other N: 7  | 12 weekly CBT-based manualized groups, provided by a master's-level psychologist, covering nutrition, diet, activity, exercise, and psychoeducation | One 2-hour nutrition education group | BMIWeight (kg)3 months, 6 months | Efficacy (1)Not reported or unclear | FairNA |
| Kwon, 2006[22](#_ENREF_22)Asia48 | Mean age: 31.3Female N: 33Male N: 15Nonwhite: NRSchizophrenia N: 48Bipolar N: 0Other N: 0 | 8 session CBT weight management program focused on diet and exercise management, with a dietician and an exercise coordinator.All participants continued their pretrial dose of olanzapine (5-20 mg/day). | Usual careAll participants continued their pretrial dose of olanzapine (5-20 mg/day). | BMIWeight (kg) Systolic blood pressure (mm Hg)Diastolic blood pressure (mm Hg)HRQOL/Physical Function: WHO-QOL-BREF, physical health subscore4 weeks, 8 weeks, 12 weeks | Efficacy (1)Industry | FairPoor |
| Littrell, 2003[23](#_ENREF_23)US70 | Mean age: 34.1Female N: 27Male N: 43Nonwhite: 18Schizophrenia N: 70Bipolar N: 0Other N: 0 | Olanzapine plus16-session manualized education intervention administered by a master's-level clinician, focused on diet, nutrition, exercise, goal and activity setting, and self-monitoring. | Olanzapine only | BMIWeight (lb)4 months, 6 months | Mixed (3)Industry | GoodNA |
| Mauri, 2008[24](#_ENREF_24)Europe49 | Mean age: 38.9Female N: 28Male N: 21Nonwhite: NRSchizophrenia N: 5Bipolar N: 43Other N: 1 | 5–7 psychoeducational groups on diet, exercise, nutrition, self-monitoring, and goal-setting.All participants were continued on their pretrial dose of olanzapine. | Usual careAll participants were continued on their pretrial dose of olanzapine. | BMIWeight (kg)Total Cholesterol (mg/dl)LDL (mg/dl)Psychiatric Symptom Severity: GAFAdverse Event: drug-related3 months | Efficacy (1)Industry | PoorPoor |
| McDonnell, 2011[25](#_ENREF_25)"26 countries worldwide" - no further details provided1065 | Mean age: 38.9Female N: 459Male N: 856The sex of the participants starting the trial was reported; the total participants starting n=1315, but this lead-in period was not randomized. By the point of the randomized part of the trial, there were 1065 individuals, but the breakdown for sex was not reported.Nonwhite: 299Schizophrenia N: 921Bipolar N: NROther N: NR | Antipsychotic switching:FROM oral tablets of olanzapineTO long-acting injectable olanzapine 45 mg every 4 weeks | Continue oral tablets of olanzapine 10-20 mg/day (mean dose 14.3 mg/day) | BMIWeight (kg)Total Cholesterol (mg/dl)LDL (mg/dl)Discontinuation due to adverse eventAdverse event: "Treatment-emergent adverse event"24 weeks | Efficacy (2)Industry | FairFair |
| McElroy, 2012[26](#_ENREF_26)US42 | Mean age: 33.7Female N: 13Male N: 29Nonwhite: 9Schizophrenia N: 1Bipolar N: 42Other N: NR | Zonisamide 100-600 mg/day (mean dose 380 mg/day) All participants were registered to receive Personal Wellness Solution Counseling. All participants continued their pretrial dose of olanzapine. | PlaceboAll participants were registered to receive Personal Wellness Solution Counseling. All participants continued their pretrial dose of olanzapine. | BMIWeight (kg)Total cholesterol (mg/dl)LDL (mg/dl)Systolic blood pressure (mm Hg)Diastolic blood pressure (mm Hg)Psychiatric Symptom Severity: CGI-S, bipolar version1, 2, 3, 4, 6, 8, 10, 12, 14, and 16 weeks | Efficacy (2)Industry | GoodGood |
| McKibbin, 2006[27](#_ENREF_27)US64 | Mean age: 54.0Female N: 20Male N: 37Nonwhite: 22Schizophrenia N: 57Bipolar N: NROther N: NR64 randomized, 52 completed and analyzed | Diabetes Awareness and Rehabilitation Training (DART): 90 minute, weekly, manualized sessions (up to 24 sessions, mean number of sessions 16.2), based on Social Cognitive Theory, addressing diabetes, nutrition, lifestyle, exercise, self-empowerment, self-monitoring, and incentives | Usual care plus 3 brochures from the American Diabetes Association on diabetes management | BMIHbA1c (%)LDL (mg/dl)Systolic blood pressure (mm Hg)Diastolic blood pressure (mm Hg)6 months, 12 months | Efficacy (2)Government | FairFair |
| Narula, 2010[28](#_ENREF_28)Asia72 | Mean age: 31.1Female N: 23Male N: 44Nonwhite: NRSchizophrenia N: 67Bipolar N: NROther N: NR72 randomized, 67 completed and analyzed. | Olanzapine 5-20 mg/day +topiramate 100 mg/day | Olanzapine 5-20 mg/day +placebo | BMIWeight (kg)Total cholesterol (mg/dl)LDL (mg/dl)Systolic blood pressure (mm Hg)Diastolic blood pressure (mm Hg)Psychiatric Symptom Severity: PANSS3 months | Efficacy (1)Not reported or unclear | FairFair |
| Newcomer, 2008[29](#_ENREF_29)"Multinational" 173 | Mean age: 39.2Female N: 62Male N: 111Nonwhite: 55Schizophrenia N: 173Bipolar N: NROther N: NR | Antipsychotic switching:FROM olanzapine at 10-20 mg/day (mean 15.9 mg/day)TO aripiprazole 15 mg/day (mean 16.0 mg/day) | CONTINUE olanzapine at 10-20 mg/day (mean 15.9 mg/day) | Weight (kg)Total Cholesterol (mg/dl)LDL (mg/dl)Any Adverse EventPsychiatric Symptom Severity: CGI-I6 weeks, 8 weeks, 12 weeks, 14 weeks | Mixed (4)Industry | FairFair |
| Nickel, 2005[30](#_ENREF_30)Europe49 | Mean age: 34.9Female N: 49Male N: 0Nonwhite: NRSchizophrenia N: 20Bipolar N: NROther N: NR | Topiramate 250 mg/day | Placebo | Weight (kg)HRQOL/Physical Function: SF36-Physical FunctioningHRQOL/Physical Function: SF36-Role10 weeks | Efficacy (1)Not reported or unclear | FairFair |
| Skrinar, 2005[31](#_ENREF_31)US30 | Mean age: 37.8Female N: 20Male N: 10Nonwhite: NRSchizophrenia N: NRBipolar N: NROther N: NR | 48 exercise sessions (4 per week) plus 12 health education sessions (1 per week), including healthy eating, weight management, adequate amounts of exercise, stress relief, spirituality and wellness, and individual planning to incorporate wellness activities.Participants attended an average of 31 exercise sessions. | Usual care | BMIWeight (kg)Total cholesterol (mg/dl)Psychiatric Symptom Severity: SCL-90, SF-36, QOL3 months | Efficacy (2)Industry | FairFair |
| Stroup, 2011[32](#_ENREF_32)US215 | Mean age: 41.0Female N: 78Male N: 137Nonwhite: 92Schizophrenia N: 215Bipolar N: NROther N: NR | Antipsychotic switching:FROM olanzapine at 5-20 mg/day (mean 18.5 mg/day) OR quetiapine at 200-1200 mg/day (mean 502 mg/day) OR risperidone 1-16 mg/day (mean 4.1 mg/day)TO aripiprazole 5-30 mg/day (mean 16.9 mg/day)PLUS a manualized behavioral intervention occurring weekly for 4 weeks and monthly thereafter, including diet, exercise, and education on reducing risk of cardiovascular disease. | CONTINUE: olanzapine 5-20 mg/day (mean 18.0 mg/day) ORquetiapine 200-1200 mg/day (mean 572 mg/day) OR risperidone 1-16 mg/day (mean 4.1 mg/day). Doses of medication could be adjusted during the trial, but medication could not be switched.PLUS a manualized behavioral intervention occurring weekly for 4 weeks and monthly thereafter, including diet, exercise, and education on reducing risk of cardiovascular disease. | BMIWeight (kg) HbA1c (%)Total cholesterol (mg/dl)LDL (mg/dl)Other CVD Summary Risk ScoreDiscontinuation due to adverse eventAdverse Event: DeathAdverse Event: HospitalizationAdverse Event: Any serious adverse eventPsychiatric Symptom Severity: CGI24 weeks | Mixed (5)Government,Industry | GoodGood |
| Wang, 2012[33](#_ENREF_33)Asia72 | Mean age: NRFemale N: 32Male N: 34Nonwhite: NRSchizophrenia N: 66Bipolar N: 0Other N: 0 | Metformin1000 mg/day (250 mg bid for first 3 days; 500 mg bid for remainder) | Placebo | Discontinuation due to adverse eventBMIWeight (kg)Fasting glucose4 weeks, 8 weeks, 12 weeks | Efficacy (2)Scientific Research Fund of Liaoning Science and Technology Agency, China | FairFair |
| Wu, 2008[34](#_ENREF_34)Asia128 | Mean age: 26.3Female N: 64Male N: 64Nonwhite: NRSchizophrenia N: 128Bipolar N: 0Other N: 0 | This was a 4-arm trial with 3 active arms.Arm 1: Metformin 750 mg/dayArm 2: Manualized lifestyle intervention including sessions on diet, exercise, medication adherence, goal setting, and activity scheduling. Some sessions included family; some sessions were provided by an exercise physiologist or a dietician.Arm 3: Metformin 750 mg/day and manualized lifestyle intervention | Usual care plus placebo | BMIWeight (kg)Discontinuation due to adverse eventInsulin level (µIU/mL)Psychiatric Symptom Severity: PANSS4 weeks, 8 weeks, 12 weeks | Mixed (5)Government | GoodGood |
| Wu, 2012[35](#_ENREF_35)Asia84  | Mean age: NR Female N: 84Male N: 0Nonwhite: 84Schizophrenia N: 84Bipolar N: 0Other N: 0 | Metformin1000 mg/day  | Placebo | BMIWeight (kg)Discontinuation due to adverse eventFasting blood glucose in mmol/L1,2,3,4,5,6 months | Mixed (3)Government | GoodGood |

aData for major outcomes are available from the authors upon request.

Abbreviations: BMI=body mass index; BPRS=Brief Psychiatric Rating Scale; CBT=cognitive behavioral training; CGI=clinical global impression; CVD=cardiovascular disease; GAF=global assessment of functioning; HAM-D=Hamilton Depression Rating Scale; HbA1c=glycosylated hemoglobin; HRQOL=health-related quality of life; LDL=low-density lipoprotein; MADRS=Montgomery-Asberg Depression Rating Scale; NA=not applicable; NR=not reported; PANSS=positive and negative syndrome scale; WHO-QOL-BREF=World Health Organization-Quality of Life (abbreviated)

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