Table 1: Findings of Chinese herbal medicine intervention.

| Types of intervention | Outcomes of intervention |
|-----------------------|--------------------------|
| **Chinese herbal medicines combined with other pharmaceuticals versus other pharmaceuticals** | **Effectiveness:** Forty-two trials with 4462 patients compared Chinese herbal medicines combined with pharmaceuticals versus other pharmaceuticals reported better outcomes in the treatment group (Chinese herbal medicines combined with pharmaceuticals) than in the control group (hypoglycemic Western medicines) with all or some of the following outcomes: glycated haemoglobin, glycemic level, blood lipid profiles, BMI, insulin resistance level and TCM clinical symptoms score. |
| **Chinese herbal medicines** | **Effectiveness:** Ten trials with 1201 patients compared Chinese herbal medicines with pharmaceuticals that were mainly | **Adverse effects:** Only two studies reported adverse effects with detailed information of |
|                        |                           |                          |
| Chinese herbal medicines or combined with other interventions or other | Effectiveness: Four trials with 794 patients compared Chinese herbal medicines or combined with other interventions to placebo. Other interventions were diet control and programmed daily exercise alone or in | Adverse effects: All four trials reported adverse effects with detailed information of what kinds of examinations performed for identifying |
| Pharmaceuticals versus placebo combination with hypoglycemic agents and lipid treatment. All four studies reported significant outcomes in treatment group (Chinese herbal medicines) than that in control group (placebo) with glycated haemoglobin and glycemic level control. TCM [1] symptoms score improved significantly in treatment groups in two studies. | Adverse effects, such as routine blood test, liver and kidney function test or ECG [14] as well as clinical symptoms. |
|---|---|
| Combined Chinese herbal medicines with other pharmaceuticals versus Chinese herbal medicines versus other pharmaceuticals. | Effectiveness: One study with 90 patients performed three groups comparison of Chinese herbal medicines combined with other pharmaceuticals versus Chinese herbal medicine versus pharmaceuticals, reported that combining TCM [1] and western medicine was more effective at controlling glycated haemoglobin and glycemic level than other two groups. | Adverse effects: There was no information in terms of adverse effects. |
| Chinese herbal medicines versus other pharmaceuticals. | Effectiveness: One study with 90 patients performed three groups comparison of Chinese herbal medicines versus pharmaceuticals versus other interventions (including diabetes education, diet control and exercise therapy), reported that Chinese herbal medicine group | Adverse effects: There was no information was reported in terms to adverse effect. |
| and western medicine group were more effective at controlling glycated haemoglobin and glycemic level than other intervention group |
**Table 2** Characteristics of included studies *ordered by study ID*

Zhu LQ 2009  
Clinical research on improving insulin resistance in type 2 diabetes mellitus with Chinese medicine Tangmaikang

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
Randomisation ratio: 1:1 |
|----------|---------------------------------------------------------------|
| Participants | Ethnic: Chinese n=138  
Inclusion criteria: T2DM WHO 1999; insulin resistance (HOMA-IR); TCM differentiation China 1993: Qi and Yin deficiency, Qi and blood deficiency; informed consent  
Exclusion criteria: have diabetes ketosis, ketoacidosis and infections, pregnancy diabetes, hyperthyroidism or hepatitis and other diseases which can lead to hyperglycemia within one month; psychotic and senile dementia cannot cooperate; severe heart, brain, liver, kidney complications or severe primary complications; pregnancy or breastfeeding; long-term or current use insulin treatment |
| Interventions | Number of study centres: 1  
Location: China  
Setting: outpatients and inpatients in TCM hospital  
Intervention:  
Basic treatment: diet control, exercise therapy and oral intake of hypoglycemic medicine: metformin sustained-release tablet, sulfonylurea and acarbose.  
Treatment group: basic treatment plus TCM medicine: Tangmaikang (TMK) including Huangqi, Shengdihuang, Shudihuang, Danshen, Nixui, Chishao, Huanglian, Huangjing, Gegen, Yinyanghuo  
Control group: use basic treatment to control FBG 4.5-6.5mmol/L and 2hPBG 4.5-8.0mmol/L |
| Outcomes | FBG, 2hBG, Fins, HbAlc, HOMA-IR, blood fat and blood coagulation had obvious improvement in varied level after treatment and treated group had better improvement than control group. |
Measured safety index by general physique examination (BMI, BP, and Pulse etc.), blood routine examination, urine routine examination, liver function and kidney function examination etc. 
Outcomes were assessed at baseline and trial completion

| Study details | Duration of intervention: 3 months  
|              | Duration of Follow-up: not reported  
|              | Run-in period: none  

| Stated aim of study | “A Research on the effect of Chinese medicine TMK on improving IR in T2DM”  

| Bias | Authors judgement | Support for judgement |
|------|-------------------|-----------------------|
| Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into 2 groups”, no described information in sufficient detail to allow a definite judgement |
| Allocation concealment (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into 2 groups”, no described information in sufficient detail to allow a definite judgement |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | Two cases lost follow up in treated group and eight cases lost in control group before the interventions. No exclusion or losses were reported after the interventions, and the number of participants remained the same at the endpoint of study |
Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors

Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear

Wu JJ 2015

Curative effect of therapy with Chinese medicine on type 2 diabetes of damp-heat type and life quality

Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
Randomisation ratio: 1:1

Participants | Ethnic: Chinese n=120
Inclusion criteria: T2DM WHO 1999; TCM differentiation: damp-heat type
Exclusion criteria: patients used insulin before were selected in study, psychotic, dementia, anemia, severe infection, myocardial infarction, heart failure, severe renal dysfunction, active hepatitis, tumour, pregnancy, breastfeeding, diabetes ketosis acidosis, hypertonicity coma

Interventions | Number of study centres: 1
Location: China
Setting: inpatients in TCM hospital
Intervention: diet control, diabetes health education and exercise instruction
Treatment group was treated with differential therapy with Chinese medicine jia wei gan lu xiao du dan (include: Hua Shi Fen, Yinchen, Huangqin, Shichangpu, Huoxiang, Chuanbeimu and Lianqiao) on the basis of treatment in control group
Control group use oral hypoglycemic western medicine alone: metformin, acarbose, glipizide, sulfonylurea, rosiglitazone and so on.

Outcomes | The life quality score (QLICD-DM, SF-36FBG) of the patients in both group after treatment were improved significantly, and the improvement in treatment group was
better than that in the control group. The improvement of blood sugar (FBG, 2hPG), blood fat and HbAlc were better in treatment group than that in the control group. No information was reported in terms to adverse effect in this study. Outcomes were assessed at baseline and trial completion.

| Study details | Duration of intervention: 12 weeks  
|              | Duration of Follow-up: not reported  
|              | Run-in period: none  

| Stated aim of study | “to observe the curative effect of differential therapy with Chinese medicine on type 2 diabetes of damp-heat type and life quality of the patients”  

| Risk of bias | Bias | Authors judgement | Support for judgement |
|--------------|------|-------------------|-----------------------|
|  | Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into 2 groups”  
|  | Allocation concealment (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into 2 groups”  
|  | Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study  
|  | Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study  
|  | Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study  
|  | Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors  
|  | Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear  

Jiangtangjing Granule Treatment of Type 2 Diabetes Clinical Observation and Mechanism Research

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
| | Randomisation ratio: 1:1 |
| Participants | Ethnic: Chinese n=40  
| | Inclusion criteria: T2DM WHO 1999: FPG≥7.0mmol/L, or 2hPG≥11.1mmol/L; TCM differentiation: qi and yin deficiency  
| | Exclusion criteria: ≤18 y or ≥65y; pre-diabetes; pregnancy or breastfeeding, patients combine with other severe primary diseases or psychotic, patients with diabetic ketoacidosis and other acute metabolism disorders as well as associated infections within one month |
| Interventions | Number of study centres: 1  
| | Location: China  
| | Setting: outpatients in TCM hospital  
| | Intervention:  
| | Basic treatment: exercise intervention and diet intervention  
| | Treatment group: basic treatment + Chinese medicine Jiangtangjing granule (mainly include: Huangqi, Huangjing, Yiyiren, Gegen, Shanyao, shanzha, Shuizhi, baijiezi etc.) on the basis of treatment in control group  
| | Control group use western medicine alone: Saxagliptin |
| Outcomes | Both groups show significant difference in fasting blood sugar (FBG), blood sugar (2hPG), 2h postprandial glycosylated haemoglobin (HbAlc) compared with before, but the TCM symptoms integral change of Jiangtangjing granule group patients significantly reduced compared with the control group.  
| | Measured liver and kidney metabolism related indexes after the treatment and no abnormal was observed.  
| | Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 8 weeks  
| | Duration of Follow-up: not reported  
| | Run-in period: none |
| Stated aim of study | “To observe the Jiangtangjing granule in effect of treatment for type 2 diabetes and its hypoglycemic mechanism of the initial study” |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Risk of bias                                  | Authors judgement                                                                 | Support for judgement                                                                 |
| Bias                                                                 |                                                                                                                                  |                                                                                     |
| Random sequence generation (selection bias) | Unclear risk                                                                                                                   | It only mentioned in the trial that “patients were randomly divided into Jiangtangjing group and control group” |
| Allocation concealment (selection bias)      | Unclear risk                                                                                                                   | It only mentioned in the trial that “patients were randomly divided into Jiangtangjing group and control group” |
| Blinding of participants and personnel (performance bias) | Unclear risk                                                                                                                   | The information was not reported in this study                                         |
| Blinding of outcome assessment (detection bias) | Unclear risk                                                                                                                   | The information was not reported in this study                                         |
| Incomplete outcome data (attrition bias)     | Low risk                                                                                                                       | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)         | Unclear risk                                                                                                                   | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                   | Unclear risk                                                                                                                   | The intervention groups were comparable, as it mentioned in the trial ‘no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear |

Zhou JG 2012

Influence on insulin Resistance of Type 2 diabetes mellitus with Lijian Decoction
| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
Randomisation ratio: 1:1 |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
| Participants | Ethnic: Chinese n=96  
Inclusion criteria: T2DM WHO 1999; HOMA-IR (FPGxFINS/22.5) ≥28;  
Exclusion criteria: liver and renal dysfunction, type 1 diabetes, tumour, hematopoiesis system disease as well as psychotic, acute myocardial infarction, severe heart rhythm abnormal, acute heart failure or chronic heart dysfunction over level 3 |
| Interventions | Number of study centres: 1  
Location: China  
Setting: patients in TCM college hospital  
Intervention: two groups used sulphonylureas, metformin, and alpha glucosidase inhibitor conventional therapy for 4 weeks. When fasting glucose<7.0mmol/L, the treatment group combined with Lijian Decoction (Lizhihe, Huoxiang, Peilan, Cangzhu, Jixuecao, Guijianyu)  
Control group maintained the original conventional treatment |
| Outcomes | Compare to control group, blood cholesterol (TC), triglyceride (TG), low-density lipoprotein (LDL-C), high-density lipoprotein (HDL-C), fasting plasma glucose (FBG), fasting insulin (FINS) and insulin sensitivity index (ISI) were significantly decreased in treatment group after treatment.  
Blood, urine, stool routine examination and liver, kidney function examination, measured adverse effect. No adverse effect observed during the intervention.  
Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 8 weeks  
Duration of Follow-up: not reported  
Run-in period: 4 weeks |
| Stated aim of study | “To observe the effect of treatment of eliminating dampness with aromatics for type 2 diabetes mellitus” |
| Risk of bias |  |  |  |
| **Random sequence generation (selection bias)** | Unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| **Allocation concealment (selection bias)** | Unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| **Blinding of participants and personnel (performance bias)** | Unclear risk | The information was not reported in this study |
| **Blinding of outcome assessment (detection bias)** | Unclear risk | The information was not reported in this study |
| **Incomplete outcome data (attrition bias)** | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| **Selection reporting (reporting bias)** | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| **Other bias** | Unclear risk | The intervention groups were comparable, as it mentioned in the trial that “no significant difference was found between groups on sex, age, medical condition and disease course Other aspects of bias were unclear. |

**Nie JT 2010**

**Effects of combing traditional Chinese medicine with Western medicine on life quality and carbohydrate metabolism in patients with type 2 diabetes**

| **Methods** | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
| Randomisation ratio: 1:1 |

| **Participants** | Ethnic: Chinese n=118 |
| Inclusion criteria: T2DM TCM differentiation: qi and yin deficiency with blood stasis |
| Interventions | Number of study centres: 1  
Location: China  
Setting: inpatients in TCM hospital  
Intervention:  
Basic treatment: controlling blood pressure, adjusting blood lipid and having diabetic diet  
Combining TCM and western medicine group: added TCM herbs according to syndrome differentiation (Huangqi, Huaiyangao, Fuling plus Gegen, Tianhuafen or Shengshigao, Huanglian, Zhihu, Shendihuang, Maidong and Gegen or Fuzi, Rougui, Lurong and Fupengzi or Taoren, Honghua or Shenqu, Maiya and Yiyiren or Yanhuoshuo, Jiangchan, Quangxie and Yujin) on the basis of western medicine group  
Western medicine (WM) group: insulin or oral blood sugar control medicine only in addition to basic treatment (no details information about the medicine) |
| Outcomes | After treatment, physiological and psychological/spiritual functions of QOL in both groups were improved markedly, variation of physiological and treatment functions in combining TCM with WM group in pre and post treatment had significant difference comparing with those in WM group. FPG, 2hPG, HbA1c obviously decreased and variation of observation indexes in combining TCM with WM in pre and post treatment had a significant decrease comparing with those in WM group.  
No information was reported in terms to adverse effect in this study  
Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 3 months  
Duration of Follow-up: not reported  
Run-in period: none |
| Stated aim of study | “To study the effects of combining traditional Chinese medicine with Western medicine on life quality (QOL) and carbohydrate metabolism in patients with type 2 diabetes” |
| Risk of bias | Bias | Authors judgement | Support for judgement |
| Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into combing TCM with WM group and WM group” |
|---------------------------------------------|--------------|--------------------------------------------------------------------------------------------------|
| Allocation concealment (selection bias)     | Unclear risk | It only mentioned in the trial that “patients were randomly divided into combing TCM with WM group and WM group” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear |

Hu YT 2014

Effect observation of integrated Chinese and western medicine in the treatment of obesity and type 2 diabetes mellitus

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 1:1                                                                                                          |
| Participants | Ethnic: Chinese n=150                                                                                                            |
Inclusion criteria: T2DM ADA 2003, TCM diagnostic criteria, obesity diagnostic criteria China 2003; age: 40-75 years old; stable condition and complications under ideal control; clear consciousness; informed consent;
Exclusion criteria: type 1 diabetes; tumour, combine with ketoacidosis or hypertonicity coma or severe infections, combine with severe disturbance of consciousness, severe heart, liver and renal failure; cannot take medicine according prescription; take other TCM; outcome is not clear; cannot cooperate

| Inclusions | Number of study centres: 1 |
| Location: China |
| Setting: inpatients in TCM hospital |
| Intervention: |
| Treated group added TCM treatment (Dangshen, Shashen, Taizishen, Huangbai, Shengdi, Huangqi, Chuangxiong, Dilong, Maidong, Zhimu, Tianhuafen) based on treatment in control group |
| Control group: conventional western medicine treatment: diabetic diet, rational exercise, emotional and psychological therapy, oral taking metformin |

| Outcomes | The curative effect (FPG, 2hPG) and the total effective rate of the decrease of body weight (waistline, BMI) in treatment group were better than that in control group, and the difference was statistically significant. |
| No information was reported in terms to adverse effect in this study |
| Outcomes were assessed at baseline and trial completion |

| Study details | Duration of intervention: 12 weeks |
| Duration of Follow-up: not reported |
| Run-in period: none |

| Stated aim of study | “To observe the clinical curative effect of integrated traditional Chinese and western medicine in the treatment of obese type 2 diabetes” |

| Risk of bias | Authors judgement | Support for judgement |
| Bias | Random sequence generation (selection bias) | Unclear risk |
| It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
Fu NY 2012

Insulin Resistance of Type 2 Diabetes Mellitus Diagnosis and Treatment of Traditional Chinese Medicine Clinical Observation

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
| Randomisation ratio: 1:6 |
| Participants | Ethnic: Chinese n=140 (20 in control group, 120 in treatment group)  
Inclusion criteria: T2DM WHO 1999, IR, TCM differentiation: yin deficiency with dryness-heat, damp-heat restrain spleen, qi and yin deficiency, blood stasis resistance of meridians |
| Exclusion criteria: type 2 diabetes with severe damage of heart, brain, kidney and other vital organs; life signs unstable, cannot cooperate with examination |
|---|
| Interventions | Number of study centres: 1 |
|              | Location: China |
|              | Setting: inpatients in TCM hospital |
|              | Intervention: |
|              | Treatment group added TCM formula according to TCM differential patterns on the basis of treatment in control group (Yin deficiency with dry heat: Shengdi, Shashen, Shihu, Tianhuafen, Gegen, Tiandong, Maidong, Zhimu, Huangqin, Huanglian; Damp-heat restrict spleen: Chenpi, Banxia, Fuling, Juemingzi, Zhexie, Ganchao, Zhuru, Dangnanxing; Qi and yin deficiency: Shenghuangqi, Shanyao, Dangshen, Shengdi, Xuanshen, Maidong, Digupi, Shanzhuyu, Changzhu, Wuweizi, Wumei; Phlegm stagnation: Dangshen, Shengdi, Xuanshen, Danggui, Baishao, Chuanxiong, Jixueteng, Danshen, Tianhuafen, Gegen, Rendongteng, Honghua) |
|              | Control group: metformin |
| Outcomes | Significant change with index (FPG, IAI, FINS, TG, HDL-C, TNF-α) was observed after treatment and treatment group has larger indexes variations than the control group. |
|           | No information was reported in terms to adverse effect in this study |
|           | Outcomes were assessed at baseline and trial completion |
| In Study details | Duration of intervention: 8 weeks |
|               | Duration of Follow-up: not reported |
|               | Run-in period: none |
| Stated aim of study | “To explore the pathogenesis of insulin resistance of traditional Chinese medicine and TCM treatment effect characteristics of insulin resistance type 2 diabetes cases by differentiation of TCM clinical observation” |
| Risk of bias | |
| Bias | Authors judgement | Support for judgement |
| Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
### Allocation concealment (selection bias)

**Unclear risk**

It only mentioned in the trial that “patients were randomly divided into treatment group and control group”

### Blinding of participants and personnel (performance bias)

**Unclear risk**

The information was not reported in this study

### Blinding of outcome assessment (detection bias)

**Unclear risk**

The information was not reported in this study

### Incomplete outcome data (attrition bias)

**Low risk**

No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study

### Selection reporting (reporting bias)

**Unclear risk**

The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors

### Other bias

**Unclear risk**

The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear

### Methods

Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone

Randomisation ratio: 1:1

### Participants

Ethnic: Chinese n=80

Inclusion criteria: T2DM WHO 1999, TCM diagnostic criteria: Xiaoke yin deficiency with heat, FPG≥5.8mmol/L ≤13.8mmol/L, BMI:21-35kg/m², HOMA-IR≥2.8; age: 35-85; T2DM over 6 months since diagnose, no insulin and other medicine affecting glycolipid metabolism; TCM pattern: yin deficiency with excess heat

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Zhang Y 2010

Influence on insulin resistance of Type 2 Diabetes Mellitus by the Treatment of Yangyin Qingre method
| Exclusion criteria: type 1 diabetes; severe cardio diseases, myocardial infarction, unstable stenocardia, chronic heart dysfunction; severe diabetic complications and liver, kidney disease, other endocrine disease; recent acute infectious disease and acute diabetic complications; systolic pressure≥160mmHg and /or diastolic pressure≥100mmHg; current with insulin treatment |
|-----------------|
| Interventions   | Number of study centres: 1 |
|                 | Location: China |
|                 | Setting: outpatients and inpatients in TCM hospital |
|                 | Intervention: two groups’ patients were by diet control, lipid-lowering drugs, hypoglycemic drug sulfonylurea and metformin for two weeks as observation platform period. Treatment group were added nourishing Yin and clear heat Chinese herbal decoction (Shengdi, Shanzhuyu, Huai-shanyao, Mudanpi, Fuling, Zelan, Zimu, Huangbai, Huanglian, Huangqin, Zhizi, Banxia, Chenpi, Yiyiren, Danshen, Taoren, Dangshen, Baizhu, Yujin, Chaihu) Control group remain the original treatment. |
| Outcomes        | Treatment group observed better results in efficiency and FPG, 2hPG, HbA1C, TC, TG, Fins, HOM-IR and the difference was significant. ECG, urine routine examination, liver and kidney function examination, ALT, SCR, BUN and UA, measured safety. No adverse effect observed during the intervention. Outcomes were assessed at baseline and trial completion |
| Study details   | Duration of intervention: 8 weeks |
|                 | Duration of Follow-up: not reported |
|                 | Run-in period: 2 weeks |
| Stated aim of study | “To observe the law YangyinQingre Chinese medicine for the effects of insulin resistance type 2 diabetes mellitus” |
| Risk of bias    | |
| Bias            | |
| Authors judgement | |
| Support for judgement | |
| Random sequence generation (selection bias) | Unclear risk |
| It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
|-----------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------|
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study |
| All outcomes | | |
| Blinding of outcome assessment (detection bias) | Unclear risk | The information was not reported in this study |
| All outcomes | | |
| Incomplete outcome data (attrition bias) | Low risk | Exclusion or losses were reported before the study and the number of participants remained the same at the endpoint of study |
| All outcomes | | |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear |

Xu Q 2007

A Clinical observation on Treatment of Integrated Chinese and Western Medicine for 35 cases of type 2 Diabetes

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 1:1 |

| Participants | Ethnic: Chinese n=69 |
|--------------|----------------------|
|              | Inclusion criteria: T2DM WHO 1999; have typical diabetes symptoms with once FPG≥7.0mmol/L or 2hPG≥11.1mmol/L or blood sugar≥11.1mmol/L; have no typical diabetes symptoms with twice FPG≥7.0mmol/L; or twice blood sugar ≥11.1mmol/L after OGTT, or once FPG≥7.0mmol/L and blood sugar≥11.1mmol/L after OGTT; |
TCM diagnostic criteria (China 1993): TCM differentiation: qi and yin deficiency; blood sugar<20mmol/L, age:40-75, voluntary to study and can take medicine according to prescription
Exclusion criteria: FPG≤7mmol/L or 2hPG≤11.1mmol after diet control and exercise therapy; combine with severe heart, liver, kidney complications or other severe primary diseases, or psychotic; have diabetic ketoacidosis and other acute metabolism disorders as well as with associated infections within one month; pregnancy, breastfeeding and drug allergy; type 2 diabetes with insulin treatment

| Interventions | Number of study centres: 1
Location: China
Setting: outpatients in TCM hospital
Intervention:
Treatment group added TCM decoction of lower blood sugar and nourishing yin decoction (Sheng Huangqi, Xuanshen, Shanyao, Dangshen, Maidong, Sheng Dihuang, Shu Dihuang, Wuweizi, Tianhuafen, Gegen, Danshen, Chishao, Chuanxiong) on the basis of treatment in control group
Control group: oral intake of hypoglycemic drug sulfonylurea (metformin)

| Outcomes | FPG, 2hPG and GHbA1c decreases significantly in both groups especially in treatment group; blood lipid (TC, TG, LDL-C, and HDL-C) and score of Chinese medical pattern and therapeutic effect improved significantly in treatment group.
No information was reported in terms to adverse effect in this study
Outcomes were assessed at baseline and trial completion

| Study details | Duration of intervention: 8 weeks
Duration of Follow-up: not reported
Run-in period: none

| Stated aim of study | “To observe the therapeutic effect of integrated therapy of Chinese and western medicine for type 2 diabetes”

| Risk of bias | Bias | Authors judgement | Support for judgement |
|-------------|-----|-------------------|----------------------|
| Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
|----------------------------------------|--------------|--------------------------------------------------------------------------------------------------|
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear |

Wang YG 2013

Clinical Observation on Si-huang Hypoglycemic Granule (SHHG) improving Patients Symptoms of TCM with T2DM

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals and placebo |
|---------|--------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 2:1                                                                         |
| Participants | Ethnic: Chinese n=126 (82 in treatment group, 44 in control group) |
|           | Inclusion criteria: T2DM WHO 1999; TCM diagnostic criteria; T2DM patients with long-term hyperglycosemia with HbA1c≥7.5%; patients not include in exclusion cases |
**Exclusion criteria:** pregnancy or breastfeeding; severe heart, liver, kidney and brain complications, or combine other severe primary diseases; have diabetes ketosis or hypertonicity coma or infections within 1 month; not satisfy with TCM diagnostic criteria

**Interventions**
- **Number of study centres:** 1
- **Location:** China
- **Setting:** inpatients and outpatients in TCM university hospital
- **Intervention:**
  - Treated group added Sihuang hypoglycemic granule (SHHG) (Huangqi, Sheng Dihuang, Dahuang, Huanglian, Guijijnyu) on the basis of conventional western medicine hypoglycemic therapy
  - Control group: conventional western medicine hypoglycemic therapy (glipizide and metformin oral intake) with placebo

**Outcomes**
- Two groups had good curative effect in reducing blood glucose and glycosylated haemoglobin (FPG, 1hPG, 2hPG, HbA1C), the treatment group is better than the control group in improving the TCM clinical symptoms (TCM symptom score).
- No information was reported in terms to adverse effect in this study
- Outcomes were assessed at baseline and trial completion

**Study details**
- **Duration of intervention:** 6 months
- **Duration of follow-up:** not reported
- **Run-in period:** none

**Stated aim of study**
- “To observe the effect of Danguard prescription on type 2 diabetes patients with long-term hyperglycosemia”

**Risk of bias**

| Bias                                | Authors judgement | Support for judgement                                                                 |
|-------------------------------------|-------------------|----------------------------------------------------------------------------------------|
| Random sequence generation          | Unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment              | Unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
Blinding of participants and personnel (performance bias)
All outcomes
Unclear risk
It only motioned when allocating patients in two groups, no report in intervention.

Blinding of outcome assessment (detection bias)
All outcomes
Unclear risk
The information was not reported in this study

Incomplete outcome data (attrition bias)
All outcomes
Low risk
No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study

Selection reporting (reporting bias)
Unclear risk
The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors

Other bias
Unclear risk
The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear

Luo YY 2010

Clinical Effect of Prescription for Invigorating spleen to reduce Sugar on the Insulin Resistance of Type 2 Diabetes Patients

Methods
Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
Randomisation ratio: 1:1

Participants
Ethnic: Chinese n=80
Inclusion criteria: T2DM WHO 1999; T2DM patients with insulin resistance, FPG>7mmol/L, FINS>15IU/L after basic treatment
Exclusion criteria: type 1 diabetes; pregnancy or breastfeeding or plan pregnancy; over sensitive to the treatment drug or the ingredients; have surgery or other emergency circumstance; have diabetic ketoacidosis or
hypertonicity coma; severe liver, kidney diseases, severe coronary heart disease; over 70 years old

| Interventions | Number of study centres: 1 |
|---------------|---------------------------|
|               | Location: China           |
|               | Setting: inpatients and outpatients in TCM hospital |
|               | Intervention: conventional diet and exercise therapy |
|               | Treatment group added TCM prescription for invigorating spleen to reduce blood sugar (Huangqi, Guijiantu, Shouwu, Huashanyao, Chaihu, Yujin, Zexie, Huangjing, Gegen; and Dangshen, Baizhu for Qi deficiency; Sheng Dihuang, Tianhuafeng for Yin deficiency; Huanglian for heat; Danggui for blood deficiency; Tusizi for Yang deficiency; Changzhu, Fuling and Yiyiren for Phlegm dampness) on the basis of control group |
|               | Control group: oral intake of metformin hydrochloride |

| Outcomes | More significant difference was observed in indicators (FPG, 2hBG, FINS, HbA1C, TC, TG, HDL-C, LDL-C and HOMA-IR) before and after treatment in treatment group |
|----------|----------------------------------------------------------------------------------------------------------------------------------|
|          | No adverse effect observed through liver, kidney, heart function examination and blood, urine and stool routine examination. |
|          | Outcomes were assessed at baseline and trial completion |

| Study details | Duration of intervention: 3 months |
|---------------|-----------------------------------|
|               | Duration of Follow-up: not reported |
|               | Run-in period: none |

| Stated aim of study | “To observe the clinical effect of prescription for invigorating spleen to reduce sugar on the insulin resistance of type 2 diabetes patients” |

| Risk of bias | Bias | Authors judgement | Support for judgement |
|--------------|------|-------------------|-----------------------|
|              | Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
|              | Allocation concealment (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Bias                                                                 | Risk      | Description                                                                 |
|---------------------------------------------------------------------|-----------|-----------------------------------------------------------------------------|
| Blinding of participants and personnel (performance bias)           | Unclear risk | The information was not reported in this study                             |
| All outcomes                                                        |           |                                                                             |
| Blinding of outcome assessment (detection bias)                     | Unclear risk | The information was not reported in this study                             |
| All outcomes                                                        |           |                                                                             |
| Incomplete outcome data (attrition bias)                            | Low risk  | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| All outcomes                                                        |           |                                                                             |
| Selection reporting (reporting bias)                                | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                                          | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, and disease course BMI, laboratory test indexes, insulin resistant index etc. Other aspects of bias were unclear |

Xu CX 2006

Clinical observation of Qi-Enriching and Yin-Nourishing, Heat-clearing and Blood-activating Therapy for 30 Cases of Type 2 Diabetes Insulin Resistance

| Methods                                                                 | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone Randomisation ratio: 1:1 |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Participants                                                          | Ethnic: Chinese n=60 Inclusion criteria: T2DM WHO 1999; FPG≥7mmol/L; blood sugar ≥ 11.1mmol/L; random blood sugar ≥11.1mmol/L ; OGTT 2hPG ≥ 11.1mmol/L; blood sugar cannot be controlled to ideal level after diet control, exercise therapy and western medicine treatment for over two weeks |
**Exclusion criteria:**
- type 1 diabetes; pregnancy diabetes; other type diabetes and diabetes with acute or severe complications within one month; over 75 years old

**Interventions**
- Number of study centres: 1
- Location: China
- Setting: inpatients and outpatients in hospital
- Intervention:
  - Treated group added TCM prescription for qi-enriching, yin-nourishing, heat-clearing and blood-activating (Taizishen, Huangqi, Guijianyu, Cangzhu, Xuanshen, Dihuang, Gegen, Shanyao, Tianhuafen, Zhimu, Shanzhuyu, Huanglian; add Maidong for severe Yin deficiency; add Yinyanghuo for cold aversion) on the basis of control group
  - Control group: diet control and exercise therapy with oral intake berberine tablet

**Outcomes**
- The total clinical effect and insulin resistance improving were significant higher in treatment group than in control group. 2hPG, FINS, HbA1C, TG, and ISI improved more obviously in treatment group than in control group.
- No information was reported in terms to adverse effect in this study
- Outcomes were assessed at baseline and trial completion

**Study details**
- Duration of intervention: 2 months
- Duration of Follow-up: not reported
- Run-in period: none

**Stated aim of study**
- “To observe the clinical efficacy of qi-enriching, yin-nourishing, heat-clearing and blood-activating therapy in treating type 2 diabetes insulin resistance”

**Risk of bias**

| Bias                                      | Authors judgement | Support for judgement |
|------------------------------------------|------------------|-----------------------|
| Random sequence generation (selection bias) | Unclear risk     | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias)  | Unclear risk     | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Bias                                                                 | Risk   | Description                                                                                   |
|----------------------------------------------------------------------|--------|---------------------------------------------------------------------------------------------|
| Blinding of participants and personnel (performance bias) All outcomes| Unclear risk | The information was not reported in this study                                               |
| Blinding of outcome assessment (detection bias) All outcomes         | Unclear risk | The information was not reported in this study                                               |
| Incomplete outcome data (attrition bias) All outcomes                | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)                                | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                                          | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general background. Other aspects of bias were unclear |

Li HM 2011

Effect of a prescription for tonifying kidney and spleen combination with conventional western medicine on blood sugar and hemorheology of patients with type 2 diabetes

| Methods                                                                 |                                                                 |
|------------------------------------------------------------------------|------------------------------------------------------------------|
| Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone | Randomisation ratio: 3:4 |

| Participants                                                          |                                                                                       |
|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| Ethnic: Chinese n=160 (60 in control group, 80 in treatment group)     |                                                                                       |
| Inclusion criteria: T2DM WHO 1999; TCM differentiation: spleen and kidney deficiency type |                                                                                       |
| Exclusion criteria: ≤18 y or ≥75y; critical medical history within 6 months: myocardial infarction, cerebrovascular accident, diabetes ketoacidosis; pregnancy or breastfeeding; diabetic ketoacidosis. |
| Interventions          | Number of study centres: 1  
|                       | Location: China             
|                       | Setting: inpatients and outpatients in TCM hospital 
| Intervention:         | Treated group added TCM decoction for tonifying kidney and spleen (Bajitian, Yinyanghuo, Duzhong, Taizishen, Biandou, Shanyao, Heshouwu, Mohanlian, Danshen, Baizhu, Fuling, Danshen, Shen Dahuang) on the basis of control group 
|                       | Control group: diabetes conventional treatment (diet control, exercise therapy, diabetes education and mental adjustment plus no more than two kinds of hypoglycemic western medicine: insulin inhibitor, alpha glucosidase inhibitor, metformin and glimepiride etc. 

| Outcomes              | The total effective rate in treatment group was higher than that in control group. The levels of FPG and 2hPG decreased after treatment in comparison with those before treatment in two groups but was superior in treatment group. Whole blood viscosity, plasma viscosity, haematocrit and fibrinogen in treatment group significantly decreased in comparison with those in control group after treatment. 
|                       | Blood, urine and stool routine examination have been measured before and after treatment and no adverse effect has been observed. 7 cases in control group used to have hypoglycemic symptom and it was relieved by having food. 
|                       | Outcomes were assessed at baseline and trial completion 

| Study details         | Duration of intervention: 2 months 
|                       | Duration of Follow-up: not reported 
|                       | Run-in period: none 

| Stated aim of study   | “To observe the effect of a prescription for tonifying kidney and spleen combination with conventional western medicine on blood sugar and hemorheology of type 2 diabetes patients with spleen and kidney deficiency type” 

| Risk of bias          | Authors judgement | Support for judgement |
| Source of Bias | Bias Type | Risk | Notes |
|---------------|-----------|------|-------|
| Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general background. Other aspects of bias were unclear |

Lin JJ 2014

Effect of Compound Hypoglycemic Yuye Oral Liquor combined with Metformin and glimepiride on Type 2 diabetes Mellitus

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 1:1 |

| Participants | Ethnic: Chinese n=80 |
|--------------|----------------------|
|              | Inclusion criteria: T2DM WHO 1999; T2DM blood sugar≥11.1mmol/L or FPG≥7.0mmol/L or 2hPG≥11.1mmol/L; TCM diagnostic criteria, China 2002. TCM |
differentiation: qi and yin deficiency; have never used blood sugar controlled medicine before, age:20-65 years old, informed consent, voluntary to examination and treatment
Exclusion criteria: not cooperated and psychotic; pregnancy or breastfeeding; combine other severe primary diseases; have diabetes ketoacidosis and other acute metabolism disorder as well as combine with infections within one month; need insulin treatment; sensitive to treatment drug

| Interventions | Number of study centres: 1 |
|---------------|---------------------------|
|               | Location: China           |
|               | Setting: outpatients in TCM hospital |
|               | Intervention: both groups have diet control, exercise therapy, diabetes education and other lifestyle adjustment. |
|               | Treatment group added TCM compound hypoglycemic Yuye oral liquor (Huangqi, Sheng Dihuang, Zhi Heshouwu, Huangjing, Taizishen, Zhimu, Yuzhu) on the basis of control group |
|               | Control group: metformin hydrochloride tablets and glimepiride tablets |

| Outcomes | FPG, 2hPG, and HbA1C were decreased after treatment and the decrease was more notable in treatment group than that in control group with statistically significant; TCM syndrome score was lower and clinical efficiency was higher in treatment group compared to control group with statistically significant. |
|          | One case had mild hypoglycemic symptom and two cases had mild nausea symptom in control group, one case had mild nausea in treatment group. The symptoms were disappeared after heteropathy. No difference observed between two groups about the adverse effect. Liver and kidney function examination were all normal. No severe adverse effect observed. |
|          | Outcomes were assessed at baseline and trial completion |

| Study details | Duration of intervention: 12 weeks |
|---------------|-----------------------------------|
|               | Duration of Follow-up: not reported |
|               | Run-in period: none |

| Stated aim of study | “To observe the clinical efficacy and safety of compound hypoglycemic Yuye oral liquor combined with metformin hydrochloride and glimepiride in the treatment of type 2 diabetes mellitus (deficiency of both Qi and Yin).” |

| Risk of bias | |
| Bias                                      | Authors judgement | Support for judgement                                                                 |
|------------------------------------------|-------------------|----------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | Unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias)  | Unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk      | The information was not reported in this study                                          |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk      | The information was not reported in this study                                          |
| Incomplete outcome data (attrition bias) All outcomes | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)     | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                               | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

**Zhu LY 2015**

Clinical Curative Effect of Self-made herbal Medicine Combined with Western Medicine on Diabetes

| Methods                                      |                                                                                  |
|----------------------------------------------|                                                                                  |
| Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone Randomisation ratio: 1:1 |                                                                                  |
| Participants                                 | Ethnic: Chinese n=70                                                            |
| **Inclusion criteria:** T2DM internal medicine 7th edition 2007, FPG≥7.0mmol/L or 2hPG≥11.1mmol/L; voluntary to study and informed consent; take medicine according to prescription; TCM diagnostic criteria 2002, TCM differentiation: yin deficiency with excess heat; can stick to take drug according to the prescription  
**Exclusion criteria:** liver and kidney dysfunction; pregnancy and breastfeeding; psychotic; severe diabetes complications; cannot cooperate; drop off due to no effect with the study drug |
| **Interventions** | Number of study centres: 1  
Location: China  
Setting: outpatients in TCM hospital  
Intervention: both groups have lifestyle improvement, health education, proper exercise, quit smoking, limit alcohol and other non-drug therapy  
Integrated group: self-made TCM prescription (Shanyao, Sheng Shigao, Huangqi, Tianhuafen, Sheng Dihuang, Zhimu, Xuanshen, Maidong, Huainiuxi, Fuling, Zexie, Tusizi, Taizishen, Biazhu, Cangzhu, Tiandong, Chishao, Danshen, Shanzhizi) on the basis of western group  
Western medicine group: oral intake metformin hydrochloride enteric coated tablets and gliclazide tablets |
| **Outcomes** | The combination group was significantly better than the control group in TCM syndromes score. FPG, 2hPG, FINS, 2hINS levels in integrated group were significantly lower than those in the western medicine group  
The adverse reactions occurred lower in integrated group than that in the western group.  
Outcomes were assessed at baseline and trial completion |
| **Study details** | Duration of intervention: 12 weeks  
Duration of Follow-up: not reported  
Run-in period: none |
| **Stated aim of study** | “To investigate the clinical efficacy of self-made prescription of traditional Chinese medicine combined with western medicine in the treatment of patients with diabetes mellitus” |
| **Risk of bias** |  |  |  |
| **Bias** | Authors judgement | Support for judgement |
|Random sequence generation (selection bias) | low risk | It mentioned in the trial that “patients were randomly divided into combination group and western medicine group by using random number table” |
|Allocation concealment (selection bias) | low risk | It mentioned in the trial that “patients were randomly divided into combination group and western medicine group by using random number table” |
|Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
|Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
|Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
|Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
|Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age distribution, medical condition and other general backgrounds. Other aspects of bias were unclear |

Kong M 2009
Qi-invigorating, Yin-nourishing and Blood circulation activating prescription Improving Insulin Resistance in patients with Type 2 Diabetes Mellitus

|Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|Randomisation ratio: 1:1 |
### Participants

**Ethnic:** Chinese n=70  
**Inclusion criteria:** T2DM WHO 1999; Homa-IR≥2.8 with insulin resistance; TCM diagnostic criteria 1993: qi and yin deficiency, qi and blood stagnation; informed consent; run-in period with lifestyle therapy and stop other medicine for one month with stable blood sugar but above normal  
**Exclusion criteria:** have diabetes ketosis, ketoacidosis and infections, pregnancy diabetes, hyperthyroidism or hepatitis and other diseases which can lead to hyperglycemia within 1 month; psychotic and senile dementia cannot cooperate; severe heart, brain, liver, kidney complications or severe primary complications; pregnancy or breastfeeding; long-term or current use insulin

### Interventions

**Number of study centres:** 1  
**Location:** China  
**Setting:** outpatients and inpatients in TCM hospital  
**Intervention:**  
- **Treatment group:** TCM prescription of qi-invigorating, yin-nourishing and blood circulation-activating (Huangqin, Sangbaipi, Sangye, Sangzhi, Sheng Dihuang, Shanyao, Danggui, Chishao) on the basis of control group  
- **Control group:** basic treatment: diet control, exercise therapy, health education and oral intake one of hypoglycemic drug: metformin, glipizide or diamicron

### Outcomes

**FPG, 2hPG, FINS, HbA1c, Homa-IR, blood fat and blood coagulation (PT, Fib, APTT, TC, TG) were all significantly improved and the improvement degree of treatment group was better than that of control group. The hypoglycemic and therapeutic effects on TCM syndrome in treatment group were superior to those in control group.**  
No information was reported in terms to adverse effect in this study  
Outcomes were assessed at baseline and trial completion

### Study details

**Duration of intervention:** 3 months  
**Duration of Follow-up:** not reported  
**Run-in period:** one month

### Stated aim of study

“To explore the mechanism of recipe of qi-invigorating, yin-nourishing and blood circulation-activating in the improvement of insulin resistance in patients with type 2 diabetes mellitus”
| Bias                                      | Authors judgement | Support for judgement                                      |
|------------------------------------------|-------------------|-----------------------------------------------------------|
| Random sequence generation (selection bias) | Unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias)  | Unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Blinding of participants and personnel (performance bias) (All outcomes) | Unclear risk      | The information was not reported in this study             |
| Blinding of outcome assessment (detection bias) (All outcomes) | Unclear risk      | The information was not reported in this study             |
| Incomplete outcome data (attrition bias) (All outcomes) | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)     | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                               | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, medical condition and disease course. Other aspects of bias were unclear |

Yu ZM 2015

Therapeutic Effect of Xiaoke Jiangtang Fang Combined with Pioglitazone Hydrochloride and Metformin Hydrochloride tablets on Patients with type 2 Diabetes

| Methods                                      | |
|----------------------------------------------|-----------------------------------------------------------|
| Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
| Randomisation ratio: 1:1                      |
| Participants | Ethnic: Chinese n=96  
Inclusion criteria: T2DM WHO 1999; TCM diagnostic criteria: yin and yang deficiency, blood stasis with fluid stagnation; HbA1c 7%-11%; have never used other medicine before the study  
Exclusion criteria: type 1 diabetes; comply with cardiovascular, cerebrovascular and nervous system disease; severe heart dysfunction, liver and kidney primary disease; have medical history of surgery and severe trauma; psychotic |
|---|---|
| Interventions | Number of study centres: 1  
Location: China  
Setting: inpatients and outpatients in hospital  
Intervention: both groups have diet control and oral intake of pioglitazone hydrochloride and metformin hydrochloride tablets  
Observation group: TCM prescription Xiaoke Jiangtang Fang (Tianhuafen, Zhimu, Huanglian, Shichangpu, Shihu, Chuanxiong, Guijianyu; add Ouzhi, Maidong, Tiandong, Dihuang, Gegen for Lung heat; add Huangqin, Zhizi, Xuanshen, Maidong, Sheng Dihuang, Huainuxi for stomach heat; add Huangqi, Fuling, Baizhu, Huaishanyao, Danshen, Ganchao for Qi and Yin deficiency; add Shanyurou, Gouqizi, Shu Dihuang, Huaishanyao for liver kidney Yin deficiency) plus pioglitazone hydrochloride and metformin hydrochloride tablets |
| Outcomes | The effective rate of observation group was significantly higher than control group. BMI, FBG, 2hPG, HbA1c, TG, high/midst/low shear rate of blood viscosity, plasma viscosity, fibrinogen in two groups were significant decreased after treatment, and the decrease in observation group were significant lower than those of control group were. The score of TCM symptom in observation group was also significant lower than that of control group after treatment. No information was reported in terms to adverse effect in this study  
Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 3 months  
Duration of Follow-up: not reported  
Run-in period: none |
| Stated aim of study | “To evaluate the therapeutic effect of Xiaoke Jiangtang Fang combined with pioglitazone hydrochloride and metformin hydrochloride tablets on patients with type 2 diabetes” |
Zheng HX 2014

An observation of the clinical effect of Taohong Siwu decoction in the treatment of T2DM

Methods
Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
Randomisation ratio: 1:1
| Participants | Ethnic: Chinese n=54  
Inclusion criteria: T2DM ADA; age>18 years old; first diagnosis of diabetes; no other vital organs damage; no recent acute diabetes complications; patients are agree with treatment and can stick with long-term treatment, also with informed consent  
Exclusion criteria: type 1 diabetes; have diabetes ketoacidosis or hyperglycemia hypertonicity syndrome and other acute complications; combine with acute cardiovascular and cerebrovascular disease; combine tumour, infection, active infection, immune system disease, hemopoietic system disease; T2DM with severe heart, liver and kidney dysfunction; pregnancy or breastfeeding; allegory or intolerant to all drugs; combine clinical proteinuria, dominance proteinuria or persistent proteinuria; psychotic cannot cooperate; age<18 years; medical history not completed |
| Interventions | Number of study centres: 1  
Location: China  
Setting: outpatients in hospital  
Intervention: both two groups have diabetes dietary therapy and oral intake metformin hydrochloride sustained-release tablets  
Observation group: TCM prescription Taohong Siwu decoction modified (Zhimu, Huangqi, Shanyao, Shu Dihuang, Rougui, Duzhong for Ying and Yang Deficiency; Xiyangshen, Huangqi, Gegen, Shu Dihuang, Maidong for Qi and Yin deficiency; Shanyao, Niuxi, Sheng Dihuang, Gouqi, Fuling for Liver and Kidney Yin deficiency; Sheng Dihuang, Huangbai, Baizhu, Zhihu, Huanglian, Danggui, Maidong for Yin deficiency with heat; Yiyiren, Xingren, Baikouren, Huanglian, Banxia, Tongcao for Damp-heat) plus metformin hydrochloride sustained-release tablets |
| Outcomes | FBG, 2hPG and HbA1c significantly decreased after treatment in both two groups. The decrease of 2hPG in observation group was significantly lower than the control group. The occurrence of clinical symptoms in observation group was significantly lower than the control group  
No information was reported in terms to adverse effect in this study  
Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 3 months  
Duration of Follow-up: not reported  
Run-in period: none |
**Stated aim of study**

"To explore and observe the clinical curative of Taohong Siwu decoction using TCM in the treatment of type 2 diabetes mellitus on the basis of taking metformin hydrochloride sustained-release tablets."

| Risk of bias          | Authors judgement | Support for judgement                                                                 |
|-----------------------|-------------------|----------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that "patients were randomly divided into observation group and control group" |
| Allocation concealment (selection bias) | Unclear risk | It only mentioned in the trial that "patients were randomly divided into observation group and control group" |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial "no significant difference was found between groups on age, FBG, 2hPBG, HbA1C. Other aspects of bias were unclear |

Liu YH 2008

Clinical research on effect of YiqiYangyinHuoxue (supplementing Qi, nourishing Yin and activating Blood circulation decoction) in improving insulin resistance in patients with type 2 diabetes
| **Methods** | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
Randomisation ratio: 1:1 |
| **Participants** | Ethnic: Chinese n=110  
Inclusion criteria: T2DM WHO 1999; insulin resistance HOMA-IR criteria; TCM diagnosis criteria China 2006, TCM differentiation: qi and yin deficiency, qi and blood stagnation  
Exclusion criteria: have diabetes ketosis, ketoacidosis and infections, pregnancy diabetes, hyperthyroidism or hepatitis and other diseases which can lead to hyperglycemia within 1 month; psychotic and senile dementia cannot cooperate; severe heart, brain, liver, kidney complications or severe primary complications; pregnancy or breastfeeding; long-term or current use insulin |
| **Interventions** | Number of study centres: 1  
Location: China  
Setting: outpatients and inpatients in TCM hospital  
Intervention: basic treatment: diet control and exercise therapy and oral intake of hypoglycemic western medicine: metformin, sulfonylurea, acarbose or glipizide  
Observation group: TCM prescription of supplement qi, nourish yin and active blood circulation (Huangqi, Danggui, Shanyao, Sangbaipi, Snagye, Sangzhi, Chishao, Dilong) on the base of basic treatment  
Control group: basic treatment |
| **Outcomes** | FBG, 2hBG, FINS, HOMA-IR, blood fat and blood coagulation (PT, APTT, Fib, TC, TG) of treatment group was distinctly improved compared with that of control group  
No information was reported in terms to adverse effect in this study  
Outcomes were assessed at baseline and trial completion |
| **Study details** | Duration of intervention: 3 months  
Duration of Follow-up: not reported  
Run-in period: stop other TCM medicine over 2 weeks |
| **Stated aim of study** | “To study the therapeutic effect of integrated use of Chinese and Western medicine on the improvement of insulin resistance in patients with both deficiency of vital energy and yin and blood stasis in patients of type 2 diabetes” |
| **Risk of bias** | |
| Bias                                      | Authors judgement | Support for judgement                                                                 |
|-------------------------------------------|-------------------|---------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | Unclear risk      | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias)   | Unclear risk      | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study                                         |
| Blinding of outcome assessment (detection bias) | Unclear risk | The information was not reported in this study                                         |
| Incomplete outcome data (attrition bias)  | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)      | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, disease course, medical condition. Other aspects of bias were unclear |

Deng HL 2012

Clinical observation of Tangwei capsule combined with Metformin in treatment of patients with Type 2 Diabetes Mellitus

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 5:6                                                                                                       |

| Participants | Ethnic: Chinese n=110 (50 in control group, 60 in treatment group) |
|--------------|--------------------------------------------------------------------|
|              | Inclusion criteria: T2DM WHO 1999; TCM diagnosis criteria China 1993 |
Exclusion criteria: severe kidney dysfunction, diabetes combine with ketoacidosis, insulin resistance patients and pregnancy or breastfeeding

| Interventions | Number of study centres: 1  
|               | Location: China  
|               | Setting: outpatients in TCM hospital  
|               | Intervention: both two groups have diet control and diabetes education and other secondary treatment  
|               | Control group: metformin hydrochloride tablets orally intake  
|               | Observation group: TCM prescription Tangwei capsule (Huangqi, Xiyangshen, Huangjing, Tianhuafen, Gegen, Huanglian, Danshen) on the basis of control group  

| Outcomes | The total effective rate in treatment group was higher than that in control group.  
|          | FPG, 2hPG, HbA1c, TG, BMI, hemorheology index: whole blood viscosity, plasma viscosity, platelet adhesion rate and LDL-C were all more significantly decreased after treatment and the treatment group has better clinical effect compared to control group  
|          | 3 cases have nausea in treatment group, 4 cases have stomach discomfort and all relieve without intervention. No kidney function damage after the treatment have been observed in both groups  
|          | Outcomes were assessed at baseline and trial completion  

| Study details | Duration of intervention: 3 months  
|              | Duration of Follow-up: not reported  
|              | Run-in period: not described  

| Stated aim of study | “To observe the clinical effect of Tangwei capsule combined with metformin in treatment of patients with type 2 diabetes mellitus”  

| Risk of bias | Authors judgement | Support for judgement  
| Bias Random sequence generation (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups”  
| Allocation concealment (selection bias) | Unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups”  
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study  

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| All outcomes | Blinding of outcome assessment (detection bias) | Unclear risk | The information was not reported in this study |
| --- | --- | --- | --- |
| All outcomes | Incomplete outcome data (attrition bias) | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| All outcomes | Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

Zhang YL 2012
Pei Ruixia’s Modified Er Dong Tang Combined with Western Medicine Therapy to treat Type 2 Diabetes of Lung and Kidney Qi Yin Deficiency Randomized Controlled Study

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
| --- | --- |
| Randomisation ratio: 1:1 |

| Participants | Ethnic: Chinese n=80 |
| --- | --- |
| Inclusion criteria: T2DM WHO 1999; DM clinical symptoms + random blood sugar≥11.1mmol/L or FPG≥7.0mmol/L or OGTT 2hPG≥11.1mmol/L; age:30-70 years old; informed and signed consent |
| Exclusion criteria: age<30 years or > 70 years old; cannot take medicine according to prescription and hard to judge treatment effect; allergic constitution or allergy to ingredients of study drugs; no enough data to support the therapeutic effects and safety; use others drug which influence the treatment |

| Interventions | Number of study centres: 1 |
| --- | --- |
| Location: China |
| Setting: inpatients in TCM hospital |
| Intervention: both groups have conventional therapy: diabetic diet, exercise and lifestyle, blood pressure, blood glucose, expansion of the crown etc. Control group: pioglitazone capsule, metformin enteric coated tablets Observation group: TCM prescription modified Er Dong Tang (Tiandong, Maidong, Tianhuafen, Huangqin, Zhimu, Gancao, Beishashen, Heye) on the basis of control group |
|---|
| Outcomes | Treatment group is more effective than the control group in clinical effects. FPG, 2hPG and HbA1c were significantly lower but no significant difference between two groups. No information was reported in terms to adverse effect in this study. Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 3 months Duration of Follow-up: not reported Run-in period: not described |
| Stated aim of study | “Observe the efficacy of Pei Ruixia’s Modified Er Dong Tang combined with western medicine therapy to treat lung and kidney qi yin deficiency pattern type 2 diabetes” |
| Risk of bias | |
| Bias | Authors judgement | Support for judgement |
| Random sequence generation (selection bias) | low risk | It mentioned in the trial that “randomized parallel controlled is used and patients were randomly divided into two groups by random number table” |
| Allocation concealment (selection bias) | low risk | It mentioned in the trial that “randomized parallel controlled is used and patients were randomly divided into two groups by random number table” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
Incomplete outcome data (attrition bias) | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study
---|---|---
All outcomes | | |
Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors
---|---|---
Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on demography data and clinical features (sex, age, and disease course). Other aspects of bias were unclear
---|---|---

Lu PY 2013

Clinical Research of combined Traditional Chinese and Western Medicine in the Treatment of Type 2 Diabetes

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|---|---|
| Randomisation ratio: | 1:1 |

| Participants | Ethnic: Chinese n=128 |
|---|---|
| Inclusion criteria: T2DM, age:31-77 years old; others not described |
| Exclusion criteria: not described |

| Interventions | Number of study centres: 1 |
|---|---|
| Location: China |
| Setting: inpatients in hospital |
| Intervention: |
| control group: oral intake metformin and glipizide |
| Observation group: TCM hypoglycemic 1 (no mention of detailed herbs) based on control group |

| Outcomes | FPG, 2hPG, and HbA1c all significantly decreased after treatment and much lower in treatment group. hospitalization days and cost are also lower in treatment group |
4 cases in control group and 3 cases in experimental group had hypoglycemic symptom in the early stage of treatment and it had disappeared after had some food. No information reported about liver and kidney function. Outcomes were assessed at baseline and trial completion.

| Study details | Duration of intervention: 12 weeks |
|--------------|----------------------------------|
|              | Duration of Follow-up: not reported |
|              | Run-in period: not described |

| Slated aim of study | “To explore the clinical curative effect of combined traditional Chinese and western medicine in the treatment of type 2 diabetes” |

| Risk of bias | Bias                                                                 | Authors judgement | Support for judgement |
|--------------|----------------------------------------------------------------------|-------------------|-----------------------|
|              | Random sequence generation (selection bias)                         | low risk          | It mentioned in the trial that “patients were randomly divided into control group and experimental group by using random number table method” |
|              | Allocation concealment (selection bias)                             | low risk          | It mentioned in the trial that “patients were randomly divided into control group and experimental group by using random number table method” |
|              | Blinding of participants and personnel (performance bias) All outcomes | Unclear risk      | The information was not reported in this study |
|              | Blinding of outcome assessment (detection bias) All outcomes        | Unclear risk      | The information was not reported in this study |
|              | Incomplete outcome data (attrition bias) All outcomes               | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
|              | Selection reporting (reporting bias)                                | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
|              | Other bias                                                         | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was |
Xie PF 2009

The clinical research on treatment of type 2 diabetes mellitus by western medicine combining with traditional Chinese medicine

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
Randomisation ratio: 1:1 |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
| Participants | Ethnic: Chinese n=60
Inclusion criteria: T2DM WHO 1999; therapeutic effects are not ideal with western medicine of sulfonylurea, metformin or alpha glucosidase inhibitor; TCM differentiation: qi and yin deficiency with abundance heat
Exclusion criteria: combined with severe acute diabetes complication |
| Interventions | Number of study centres: 1
Location: China
Setting: outpatients or inpatients in TCM hospital
Intervention:
Treatment group: TCM prescription Jinqijiangtangpian (Huangqi, Huanglian, Jinyinhua) on the basis of control group
Control group: dietary and exercise therapy + western medicine: sulfonylurea, metformin or alpha glucosidase inhibitor |
| Outcomes | FBG, 2hPBG, HbA1C, TC and TG in treatment group were significantly lower than that in the control group. No difference found in fasting insulin, C peptide. 2h postprandial insulin and C peptide rose. HOM A-β rose, HOMA-R declined.
Liver, kidney function, blood and urine routine examination were measured for adverse effect. No abnormal was observed from above test
Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 12 weeks
Duration of Follow-up: not reported
Run-in period: not described |
| Stated aim of study | “To investigate the effect of western medicine combining with traditional Chinese medicine on patients with T2DM and function of islet β cell” |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------|

### Risk of bias

| Bias                                           | Authors judgement | Support for judgement                                                                 |
|------------------------------------------------|--------------------|---------------------------------------------------------------------------------------|
| Random sequence generation (selection bias)    | unclear risk       | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias)        | unclear risk       | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study                                        |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study                                        |
| Incomplete outcome data (attrition bias) All outcomes | Low risk           | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)            | Unclear risk       | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                      | Unclear risk       | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on disease course, age, sex, blood sugar, HbA1C and insulin. Other aspects of bias were unclear |

Gao ZT 2015

Clinical Efficacy of Yupujiangtang Decoction in treatment of 50 Patients with T2DM

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 2:3                                                                                                        |
**Participants**

- Ethnic: Chinese n=50 (20 in control group, 30 in treatment group)
- Inclusion criteria: T2DM WHO 1999: DM clinical symptoms plus random blood sugar ≥11.1mmol/L or FPG≥7.0mmol/L or OGTT2hPG≥11.1mmol/L; TCM differentiation China 2002 : qi and yin deficiency; 31-72 years old; informed and signed consent
- Exclusion criteria: type 1 diabetes; diabetes with severe heart, brain, kidney and retinal diseases; tumour and cancer patients; pregnant and breastfeeding diabetes; allergy to the study drugs.

**Interventions**

- Number of study centres: 1
- Location: China
- Setting: outpatients or inpatients in TCM hospital
- Intervention: diet control and rational exercise
- Treatment group: TCM prescription Yupujiangtang decoction (Renshen, Huangqi, Huanglian, Qumai, Gualougen, Shanyao, Fangji, Fuling, Gouqizi, Zexie, Cijili, Yuzhu, Wubeizi, Nvzhenzi, Yvmixv) on the basis of control group
- Control group: Novolin 50 R Penfill injection and take metformin tablets

**Outcomes**

- Blood glucose level (FPG, OGTT2h, GHbA1c) had significant difference and the total effective rate of TCM syndrome was 95%
- No detail information was reported in terms to adverse effect in this study
- Outcomes were assessed at baseline and trial completion

**Study details**

- Duration of intervention: 8 weeks
- Duration of Follow-up: not reported
- Run-in period: not described

**Stated aim of study**

- "To observe the clinical efficacy and safety of Yupujiangtang decoction in treatment of patients with type 2 diabetes mellitus"

**Risk of bias**

| Bias                              | Authors judgement | Support for judgement                                                                 |
|-----------------------------------|-------------------|---------------------------------------------------------------------------------------|
| Random sequence generation        | low risk          | It mentioned in the trial that "patients were divided into treatment group and control group by random number method" |
| (selection bias)                  |                   |                                                                                       |
| Allocation concealment            | low risk          | It mentioned in the trial that "patients were divided into two treatment group and control group by random number method" |
| (selection bias)                  |                   |                                                                                       |
| Bias                                                                 | Risk    | Description                                                                                                                                 |
|----------------------------------------------------------------------|---------|-------------------------------------------------------------------------------------------------------------------------------------------|
| Blinding of participants and personnel (performance bias)            | Unclear| The information was not reported in this study                                                                                         |
| All outcomes                                                         |         |                                                                                                                                            |
| Blinding of outcome assessment (detection bias)                      | Unclear| The information was not reported in this study                                                                                         |
| All outcomes                                                         |         |                                                                                                                                            |
| Incomplete outcome data (attrition bias)                             | Low     | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study                            |
| All outcomes                                                         |         |                                                                                                                                            |
| Selection reporting (reporting bias)                                 | Unclear| The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                                           | Unclear| The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

Shu Q 2013

Dan Melon Decoction in Treating phlegm and Blood Stasis Type of Type 2 Diabetes: clinical Analysis of 50 Cases

| Methods                                                                 |
|------------------------------------------------------------------------|
| Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
| Randomisation ratio: 1:1                                               |

| Participants                                                          |
|-----------------------------------------------------------------------|
| Ethnic: Chinese n=100                                                  |
| Inclusion criteria: T2DM , TCM differentiation: phlegm stagnation; age:43-75 y, disease course 1-17 year |
| Exclusion criteria: not described                                      |

| Interventions                                                        |
|---------------------------------------------------------------------|
| Number of study centres: 1                                           |
| Location: China                                                     |
| Setting: patients in hospital                                       |
| Intervention:                                                       |
Observation group: TCM prescription Dan melon decoction (Danshen, Gualou, Xiebai, Chuanxiong, Danggui, Chishao, Banxia) on the basis of control group
Control group: conventional treatment of western medicine: metformin sustained-release tablets and/or rosiglitazone with insulin

| Outcomes | FBG, 2hPG, HbA1C, TC, TG, LDL-C and HDL-C decreased in observation group compared with the control group with significant difference. No information was reported in terms to adverse effect in this study Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 90 days Duration of Follow-up: not reported Run-in period: not described |
| Stated aim of study | “Effect of Chinese medicine in the treatment of type 2 diabetes and application value” |

| Risk of bias | Authors judgement | Support for judgement |
|-------------|-------------------|----------------------|
| Random sequence generation (selection bias) | low risk | It mentioned in the trial that “patients were divided into observation group and control group by random number method” |
| Allocation concealment (selection bias) | low risk | It mentioned in the trial that “patients were divided into two observation group and control group by random number method” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
|-------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------|
| Other bias                          | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

Sun H 2013

Modified Lianmei Granule Treatment for Type 2 Diabetes with Obesity in Early Satage

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 1:1 |

| Participants | Ethnic: Chinese n=60 |
|--------------|----------------------|
|              | Inclusion criteria: T2DM China 1994 and combine with obesity:BMI≥25kg/m²; TCM differentiation: qi and yin deficiency , phlegm and turbid stagnation; cases which are not in exclusion criteria |
|              | Exclusion criteria: not meet above diagnostic criteria ; age:<18y, >65y; pregnancy or breastfeeding; TCM herb and metformin, ARB allergy; have severe heart, liver, kidney complications or combine other severe primary diseases, psychosis; have diabetes ketoacidosis, hypertonicity coma and combine with infections within one month; type 1 diabetes |

| Interventions | Number of study centres: 1 |
|---------------|---------------------------|
|               | Location: China |
|               | Setting: outpatients and inpatients in TCM hospital |
|               | Intervention: |
|               | treatment group: TCM prescription modified Lianmei granule (Huanglian, Renshen, Wumei, Dahuang, Maidong, Sheng Dihuang, Shanzhuyu, Danshen, Cangzhu) on the basis of control group |
|               | control group: diet control and exercise therapy + oral intake western medicine: raigor column nai |
The improvement of the clinical symptoms and weight loss in treatment groups for obese patients with type 2 diabetes with high blood sugar, high cholesterol are better than that in control group. No detail information was reported in terms to adverse effect in this study. Outcomes were assessed at baseline and trial completion.

**Study details**
- Duration of intervention: 12 weeks
- Duration of Follow-up: not reported
- Run-in period: not described

**Stated aim of study**
“To observe modified Lianmei granule the clinical curative effect of early treatment of obesity with type 2 diabetes”

| Bias                                      | Authors judgement | Support for judgement                                           |
|-------------------------------------------|-------------------|----------------------------------------------------------------|
| Random sequence generation (selection bias)| unclear risk      | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias)   | unclear risk      | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)      | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |
Clinical Application Study of Yiqi yangyi huoxue Method in Type 2 Diabetes

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
| Randomisation ratio: 1:1 |

| Participants | Ethnic: Chinese n=100  
| Inclusion criteria: T2DM WHO, FBG\(\geq 7\)mmol/L, 2hPG\(\geq 11.1\)mmol/L, diagnosis as type 2 diabetes by laboratory test. TCM diagnostic criteria China 1992, TCM differentiation: qi and yin deficiency, blood stasis  
| Exclusion criteria: diabetes ketoacidosis and severe infection, hyper thyroidism or hepatitis or other diseases which can cause hyperglycemia; have severe complications with heart, brain, liver, kidney and so on; pregnancy and breastfeeding |

| Interventions | Number of study centres: 1  
| Location: China  
| Setting: inpatients in TCM hospital  
| Intervention:  
| experimental group: yiqi yangyi huoxue herbal treatment programs (Huangqi, Taizishen, Danshen, Mudanpi, Suoyanghua, Shanyao, Sheng Dihuang, Wuweizi, Hesouwu, Huangjing, Dahuang) on the basis of control group  
| control group: extension of diabetic knowledge, dietary and exercise therapy auxiliary metformin |

| Outcomes | Both groups have FBG, 2hPG and GHbA1c under control. The experimental group had significant statistical difference in the changed improve the efficacy of TCM symptoms compare to control group  
| No information was reported in terms to adverse effect in this study  
| Outcomes were assessed at baseline and trial completion |

| Study details | Duration of intervention: 4 months  
| Duration of Follow-up: not reported  
| Run-in period: not described |

| Stated aim of study | “To explore the effects of Yiqi yangyi huoxue method of type 2 diabetes, summarize new clinical thinking” |
Risk of bias

| Bias                                           | Authors judgement | Support for judgement |
|------------------------------------------------|-------------------|-----------------------|
| Random sequence generation (selection bias)   | unclear risk      | It only mentioned in the trial that “patients were randomly divided into experimental group and control group” |
| Allocation concealment (selection bias)       | unclear risk      | It only mentioned in the trial that “patients were randomly divided into experimental group and control group” |
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias)       | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)           | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                     | Unclear risk      | No clear information mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

Jia QL 2014

Clinical observation of 45 cases of Qingreyiqi decoction compatibility in the treatment of type 2 diabetes

Methods

Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
Randomisation ratio: 1:1
| Participants | Ethnic: Chinese n=90  
Inclusion criteria: T2DM WHO, voluntary to the study and signed consent form, first diagnosed with type 2 diabetes, Age: 53-67 years  
Exclusion criteria: not described |
| Interventions | Number of study centres: 1  
Location: China  
Setting: inpatients in TCM hospital  
Intervention:  
Observation group: oral Qingreyiqi decoction Sheng Dahuang, Sheng Huangqi, Shanyao, Gegen, Danshen, Sheng Dihuang, Sheng Huangqi, Gouqizi, Chishao, Danggui, Zhimu, Chuanxiong, Tianma) on the basis of control group  
Control group: conventional treatment: health education, dietary and exercise therapy and conventional oral hypoglycemic agents like metformin etc. |
| Outcomes | Total effective rate of observation group was apparently higher than the control group. The fasting blood glucose (FBG), 2 hours postprandial blood glucose (2hPG), glycosylated haemoglobin (GHbA1c), and blood lipid index (TG, TC, LDL-C0 of two group were obviously decreased, but the observation group decreased more significantly.  
Blood routine examination, liver and kidney function were supervised to measure adverse effect of drug. No abnormal observed in blood routine examination, liver and kidney function. One case had nausea and vomiting.  
Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 12 weeks  
Duration of Follow-up: not reported  
Run-in period: not described |
| Stated aim of study | “To discuss the efficacy and safety of the Qingreyiqi decoction compatibility in the treatment of type 2 diabetes” |
| Risk of bias |  
| Bias | Authors judgement | Support for judgement |
| Random sequence generation (selection bias) | low risk | It mentioned in the trial that “patients were divided into observation group and control group by random file number method” |
| **Allocation concealment (selection bias)** | Low risk | It mentioned in the trial that “patients were divided into observation group and control group by random file number method” |
|------------------------------------------|----------|----------------------------------------------------------------------------------------------------------------------------------|
| **Blinding of participants and personnel (performance bias)** All outcomes | Unclear risk | The information was not reported in this study |
| **Blinding of outcome assessment (detection bias)** All outcomes | Unclear risk | The information was not reported in this study |
| **Incomplete outcome data (attrition bias)** All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| **Selection reporting (reporting bias)** | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| **Other bias** | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on sex, age, disease course, FBG and blood lipid. Other aspects of bias were unclear |

**Zhang XL 2013**

Clinical Observation of traditional Chinese Medicine Combing with Insulin on Treating 38 Cases of Asymptomatic Type 2 Diabetes

| **Methods** | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|-------------|-----------------------------------------------------------------------------------------------------------------------------|
|             | Randomisation ratio: 1:1                                                                                                       |
| **Participants** | Ethnic: Chinese n=74 Inclusion criteria: T2DM China 2012, asymptomatic type 2 diabetes, agree with insulin treatment; age: 28-76y, average age 54.3 y; average FBG=13.4mmol/L (treatment group), 13.1mmol/L (control group), average blood sugar after three meals=18.4mmol/L (treatment group), 17.9mmol/L (control group) |
| Exclusion criteria: not described |
|--------------------------------|
| **Interventions** |
| Number of study centres: 1 |
| Location: China |
| Setting: inpatients in TCM hospital |
| Intervention: |
| treatment group: TCM prescription Erzhi Siwu decoction (Nvzhenzi, Hanliancao, Sheng Dihuang, Chishao, Chuangxiong, Danggui, Huanglian, Gegen, Huangqi, Tianhuafen and add Shigao, Xuanshen, Dahuang, Zhimu, Shanzhuyu, Sangpiaoxiao, Xianlingpi, Fuling, Baizhu, Dangshen, Cangzhu based on syndrome differentiation) on the basis of control group |
| control group: conventional diabetes health education, diabetes diet and insulin therapy |
| **Outcomes** |
| Fasting blood glucose was controlled within 3.9-7mmol/L and postprandial blood glucose 2 hours was less 10mmol/L, observing the difference of the amount of insulin and incidence of hypoglycemia between two groups. The incidence of hypoglycemia of the treatment group was lower than the controlled group. |
| No detail information was reported in terms to adverse effect in this study |
| Outcomes were assessed at baseline and trial completion |
| **Study details** |
| Duration of intervention: 3 months |
| Duration of Follow-up: not reported |
| Run-in period: not described |
| **Stated aim of study** |
| “To observe the curative effect of combining traditional Chinese medicine and insulin to treat asymptomatic type 2 diabetes” |
| **Risk of bias** |
| **Bias** | Authors judgement | Support for judgement |
| Random sequence generation (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study |
| Bias Type                                      | Risk Assessment | Description                                                                                                                                 |
|-----------------------------------------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Blinding of outcome assessment (detection bias) | Unclear risk    | The information was not reported in this study                                                                                               |
| Incomplete outcome data (attrition bias)      | Low risk        | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study                                |
| Selection reporting (reporting bias)          | Unclear risk    | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors     |
| Other bias                                    | Unclear risk    | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

**Jiang YC 2004**

Clinical observation on Combination of Chinese Medicine and Western Medicine for the Treatment of 51 Cases of Type 2 Diabetes Mellitus

**Methods**
- Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
- Randomisation ratio: 37 in control group, 51 in treatment group

**Participants**
- Ethnic: Chinese n=88
- Inclusion criteria: T2DM WHO 1999; diagnosed with type 2 diabetes after blood sugar, urine sugar and insulin function test; can follow up according to doctor’s advice, informed and signed consent
- Exclusion criteria: combine with nephrosis, ketoacidosis and other severe complications

**Interventions**
- Number of study centres: 1
- Location: China
- Setting: outpatients or inpatients in hospital
- Intervention: treatment group: TCM prescription compound hypoglycemia decoction (Huangqi, Shanzhuyu, Renshen, Jiegeng, Gegeng, Yuzhu, Nvzhenzi, Sheng Dihuang,
**Stated aim of study**

“To discuss the curative effect of combining traditional Chinese medicine and western medicine to treat type 2 diabetes”

| Risk of bias | Bias | Authors judgement | Support for judgement |
|--------------|------|-------------------|-----------------------|
| **Random sequence generation** (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| **Allocation concealment** (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| **Blinding of participants and personnel** (performance bias) | Unclear risk | The information was not reported in this study |
| **Blinding of outcome assessment** (detection bias) | Unclear risk | The information was not reported in this study |
| **Incomplete outcome data** (attrition bias) | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| **Selection reporting** (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |

**Outcomes**

Treatment group had better improvement in clinical effects and glucose metabolism (FBG, PBG, 24h urine blood sugar)

No adverse effect was observed in both groups during the treatment

Outcomes were assessed at baseline and trial completion

**Study details**

Duration of intervention: 2 months

Duration of Follow-up: not reported

Run-in period: not described

**Shanqifen, Gancao, and add Zhimu for thirsty, Digupi for wasting, Sangpiaoxiao for diuresis) on the basis of control group**

**control group:** oral intake gliclazide plus strict diet control
Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial "no significant difference was found between groups on general backgrounds like age, sex and disease course etc. Other aspects of bias were unclear.

Li Z 2013

Clinical observation on 30 Cases of Type 2 Diabetes Mellitus Treated with the Method of Relieving Liver and Reinforcing Spleen

Methods
- Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
- Randomisation ratio: 1:1

Participants
- Ethnic: Chinese n=60
- Inclusion criteria: T2DM ADA 1999, TCM diagnostic criteria China 2002, TCM differentiation: liver stagnation and spleen deficiency; age: 18-70 years with both sex; no distinct diabetic acute and chronic complications; no insulin treatment before, no herb treatment and medicine which affect blood lipid before 2 weeks of study
- Exclusion criteria: type 1 diabetes and diabetes with special causation, pregnant diabetes; pregnancy, breastfeeding and allergy to the study drugs and not suitable to the study; combine with cardiovascular, renal, hemopoietic system and other severe primary diseases, psychosis; have diabetes acute complications within recent one month

Interventions
- Number of study centres: 1
- Location: China
- Setting: outpatients and inpatients in TCM hospital
- Intervention:
  - Basic treatment: life style regulation and diet therapy; control general calorie intake; insist rational aerobic exercise, prevent or reduce obese, maintain healthy weight
  - Treatment group: TCM prescription: smoothing the liver and strengthening the spleen decoction (Sheng Huangqi, Shanyao, Fuling, Yiyiren, Chaihu, Baishao, Shanyurou, Suanzaoren, Gegen, Sangye) on the basis of control group
Control group: basic treatment + conventional treatment: oral intake metformin enteric coatel tablets or acarbose

| Outcomes | There is significant difference between treatment group and control group in glucose and lipid acid level (FBG, 2hPPG, HbA1c), insulin resistance index (IRI) and traditional Chinese clinical symptoms. Blood, urine, and stool routine examination, liver and kidney function test were measure for adverse effect, and no abnormal and adverse effects were observed during the treatment. Outcomes were assessed at baseline and trial completion. |
| --- | --- |

| Study details | Duration of intervention: 8 weeks |
| --- | --- |
| Duration of Follow-up: not reported |
| Run-in period: not described |

Stated aim of study: “To observe the effect of treatment of smoothing the liver and strengthening the spleen with type 2 diabetes in clinic”

| Risk of bias | Authors judgement | Support for judgement |
| --- | --- | --- |
| Random sequence generation (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
Other bias | Unclear risk
---|---
The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds like age, sex and disease course etc. Other aspects of bias were unclear

Wang XN 2015
Clinical Observation of Traditional Chinese Medicine Coptis Chinensis Treatment of Type 2 Diabetes Mellitus

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
Randomisation ratio: 1:1 |
|---|---|

| Participants | Ethnic: Chinese n=75
Inclusion criteria: T2DM WHO 1999; have never used other hypoglycemia medicine within half month before the study; informed and signed written consent before the study
Exclusion criteria: FBG ≥14mmol/L and/or 2hPBG ≥18mmol/L; liver and kidney function distinct abnormal; younger than 30 years; BMI ≥30kg/m² |
|---|---|

| Interventions | Number of study centres: 1
Location: China
Setting: patients in TCM hospital
Intervention:
observation group: TCM prescription: coptis granules on the basis of control group
control group: oral intake metformin tablet |
|---|---|

| Outcomes | FBG and 2hPBG were statistically significant lower in observation group than control group after 30 days treatment. The improving of insulin resistance and abnormal metabolism of lipid in control group were ineffective; observation group has better clinical effect in improving insulin resistance and recovery of islet function, and significantly improved in patients with dyslipidemia.
No information was reported in terms to adverse effect in this study
Outcomes were assessed at baseline and trial completion |
|---|---|

| Study details | Duration of intervention: 60 days
Duration of Follow-up: not reported |
**Stated aim of study**

“To investigate the clinical effect of *Coptis chinensis* in treating type 2 diabetes mellitus”

**Risk of bias**

| Bias                                      | Authors judgement | Support for judgement                                                                 |
|-------------------------------------------|-------------------|---------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | low risk          | It mentioned in the trial that “patients were randomly divided into observation group and control group by using random number table method” |
| Allocation concealment (selection bias)   | low risk          | It mentioned in the trial that “patients were randomly divided into observation group and control group by using random number table method” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk      | The information was not reported in this study                                         |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk      | The information was not reported in this study                                         |
| Incomplete outcome data (attrition bias) All outcomes | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)       | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of sex, age and disease course. Other aspects of bias were unclear |

Ye LF 2013
Effect of Sanhuang Tang on Insulin Resistance Index and Inflammatory Factors of Obese Type 2 Diabetes

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
Randomisation ratio: 1:1 |
|----------|-------------------------------------------------------------------------------------------------|
| Participants | Ethnic: Chinese n=69  
Inclusion criteria: T2DM WHO 1999 diabetes diagnostic criteria: clinical symptoms + anytime blood sugar≥7.0mmol/L; OGTT2h≥11.1mmol/L; TCM differentiation: phlegm hot junction; BMI≥25kg∙m⁻²; age: 18-75 year; informed consent  
Exclusion criteria: not accord with inclusion criteria; type 1 diabetes, pregnant diabetes and other types of diabetes; have diabetes ketoacidosis, diabetes hyperglycemia hypertonicity status and other acute complications; combine with heart, brain, liver, kidney and other severe diseases; have used insulin and other similar treatment; pregnancy or breastfeeding; not good at comply with treatment or psychosis |
| Interventions | Number of study centres: 1  
Location: China  
Setting: outpatients and inpatients in TCM hospital  
Intervention:  
Sanhuang tang group: plus Sanhuang tang (Huanglian, Huangqin, Dahuang) on the basis of control group  
Western medicine group: lifestyle intervention plus metformin |
| Outcomes | Sanhuang tang group is statistically significant in improving clinical symptoms, glucose and lipid metabolism and insulin resistance and reduce the level of inflammatory factors (FBG, 2hPBG, HbA1C, TC, TG, TNF-α, IL-6, HOMA-IR) compare to western medicine group  
Blood, urine, stool routine examination and liver, kidney function test had taken, but no other details were mentioned about adverse effect.  
Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 3 months  
Duration of Follow-up: not reported  
Run-in period: not described |
**Stated aim of study**

“To observe the efficacy of Chinese herbal formula Sanhuang tang in treating obese type 2 diabetes”

| Risk of bias | 
|---|---|---|---|
| **Bias** | Authors judgement | Support for judgement |
| Random sequence generation (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly distributed into Sanhuang tang group and western medicine group” |
| Allocation concealment (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly distributed into Sanhuang tang group and western medicine group” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on age, sex and disease course etc. Other aspects of bias were unclear |

Cai Z 2015

**Effects of Fructus Schisandrae Decoction on the Changes of Serum IL-2 and IL-6 of Patients with type 2 Diabetes**
### Methods
Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone

Randomisation ratio: 1:1

### Participants
Ethnic: Chinese n=88

Inclusion criteria: up-to-date diabetes diagnostic criteria: polydipsia, polyuria, polyphagia and no other reasons weight loss plus one of following: random blood sugar≥11.1mmol/L; FBG≥7.0mmol/L; OGTT2h≥11.1mmol/L. on the basis of above plus one of followings can be diagnosed as T2DM: low insulin level, insulin resistance. Age≤70y; involuntary to the study and signed consent and meet with ethical criteria

Exclusion criteria: not meet with T2DM diagnostic criteria; severe liver and gallbladder disease; malignant tumour; age ≤40y, ≥70y; have mental disease

### Interventions
Number of study centres: 1

Location: China

Setting: outpatients and inpatients in TCM hospital

Intervention:

Experimental group: TCM herb Schisandra chinensis (Wuweizi) on the basis of control group

Control group: conventional treatment: oral intake of Metformin Hydrochloride Capsules

### Outcomes
The cytokines (IL-2 and IL-6 levels) improved in both groups after treatment and more statistically significantly improved in experimental group. The level of glycated haemoglobin (HbA1c) reduced in both groups after treatment and the decrease were more statistically significant in experimental group than control group. Level of blood lipid (TC, TG and LDL) were improved and the improvement was more statistically significant in experimental group

No information was reported in terms to adverse effect in this study

Outcomes were assessed at baseline and trial completion

### Study details
Duration of intervention: 3 months

Duration of Follow-up: not reported

Run-in period: not described

### Stated aim of study
“To investigate the clinical curative effect of Fructus Schisandra Decoction on type 2 diabetes mellitus disease and the change of serum IL-2, IL-6 levels”
### Risk of bias

| Bias                                      | Authors judgement | Support for judgement                                                                 |
|-------------------------------------------|--------------------|---------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | unclear risk       | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias)   | unclear risk       | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study                                         |
| Blinding of outcome assessment (detection bias) | Unclear risk | The information was not reported in this study                                         |
| Incomplete outcome data (attrition bias)  | Low risk           | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)      | Unclear risk       | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                | Unclear risk       | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

### Guan X 2006

**Influence of Liuweidihuang Pill and Ginkgoibca Leave to the Lipotoxicity and Insulin Resistance in Early Time of Type 2 Diabetes Mellitus**

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|---------|------------------------------------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 1:1                                                                                                           |
| Participants | Ethnic: Chinese n=104                                                                                                           |
| Inclusion criteria: T2DM WHO 1999, polydipsia, polyuria, weight loss and repetitive infection, random blood sugar $\geq 11.1\text{mmol/L}$; FBG $\geq 7.0\text{mmol/L}$; OGTT $2h \geq 11.1\text{mmol/L}$; TCM differentiation: internal heat from yin deficiency and blood stasis in meridians; age: 30-70 years; have no distinct diabetes complication, diagnosis with diabetes over three months; BP $\leq 180/110\text{mmHg}$; BMI $\leq 30$; have used no more than two kinds of hypoglycemic medicine and blood sugar is under control when enrolled with the study; informed consent and voluntary to the study Exclusion criteria: not meet with inclusion criteria; type 1 diabetes and diabetes due to special reason and pregnant diabetes; diabetes severe acute complication like ketoacidosis, diabetes hypertonicity; vascular complications: myocardial infarction, cerebrovascular accident, lower limb angionosis; severe heart, liver, lung, kidney, blood or other life-threatening disease like tumor or AIDS; pregnancy, breastfeeding; easy lost follow-up; current use medicine affect blood sugar, BP and blood lipid; in other study currently |

| Interventions | Number of study centres: 1  
Location: China  
Setting: outpatients in TCM hospital  
Intervention:  
Basic treatment: dietary and exercise therapy + no more than two kinds of hypoglycemia medicine: insulin inhibitor, alpha glucosidase inhibitor, metformin, insulin, glimepiride  
experimental group: basic treatment plus TCM herb Liuweidihuang capsule and Yinxingye tablet  
control group: basic treatment plus TCM herb placebo |

| Outcomes | TC, TG, LDL-C, FFA and TNF-α had better control in experimental group than control group with FFA and TNF-α has statistical difference. No difference for FBG, 2hPBG, and HbA1c in both groups before and after treatment. Clinical symptoms, FINS and IR changes also have no statistically significance. No information was reported in terms to adverse effect in this study Outcomes were assessed at baseline and trial completion |

| Study details | Duration of intervention: 6 months  
Duration of Follow-up: not reported  
Run-in period: not described |
### Stated aim of study

“evaluate the influence and clinical application of Jinqi hypoglycemic tablet on vascular endothelial cells active factor of patients with diabetes mellitus by observing the change of correlation factor about vascular endothelial cells damage before and after therapy”

### Risk of bias

| Bias                                           | Authors judgement | Support for judgement                                                                                                                                 |
|------------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Random sequence generation (selection bias)    | unclear risk      | It only mentioned in the trial that “patients were randomly divided into experimental group and control group”                                        |
| Allocation concealment (selection bias)        | unclear risk      | It only mentioned in the trial that “patients were randomly divided into experimental group and control group”                                        |
| Blinding of participants and personnel (performance bias) All outcomes | low risk          | Double-blinded and placebo controlled for both researcher and patients                                                                              |
| Blinding of outcome assessment (detection bias) All outcomes       | low risk          | Double-blinded and placebo controlled for both researcher and patients                                                                              |
| Incomplete outcome data (attrition bias) All outcomes               | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study                                   |
| Selection reporting (reporting bias)           | low risk          | The protocol of the trial was strictly double-blinded for both researcher and patients                                                               |
| Other bias                                     | low risk          | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of sex, age and disease course. SBP, DBP, FBG, HbA, TC, TG, ALT, Cr, FFA, TNA, IR and TCM symptom score are also have no statistically significant difference in both groups before study. |

Shen LX 2007
Study on improvement of islet $\beta$ cell function in patients with type 2 diabetes by integrative Chinese and Western medicine

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
Randomisation ratio: 1:1:1 |
|---|---|
| Participants | Ethnic: Chinese $n=65$ (group A:23, group B:25, group C:24)  
Inclusion criteria: T2DM WHO 1999, age $\leq 65y$, have no pharmacotherapy within 3 months; FBG, PG2h and HbA1c are all increase (FBG$\leq 7.0$mmol/L, PG2h$\leq 11.1$mmol/L, HbA1c$\geq 6.5\%$)  
Exclusion criteria: stress status, severe liver and kidney dysfunction, have disease which affect glucose metabolism |
| Interventions | Number of study centres: 1  
Location: China  
Setting: patients in medical college hospital  
Intervention: diabetes health education, diet control and proper exercise therapy for all three groups  
Group A: sulfonylurea oral intake  
Group B: insulin  
Group C: insulin + TCM prescription Dachaihu decoction (Chaihu, Huangqin, Zhishi, Huanglian, Dahuang, Banxia) |
| Outcomes | After treatment, the damaged islet $\beta$ cell function was not improved and the secretive peak value of C2 peptide was still low and delayed in group A. But it shifted earlier and indicated a certain degree of improvement and recovery of islet $\beta$ cell function in group B and C with statistically significant in Group C. FBG, P2BG and HbA1c decreased after treatment in three groups with more decreased in Group B and C and Group C was more significant.  
No information was reported in terms to adverse effect in this study  
Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 1 year  
Duration of Follow-up: not reported  
Run-in period: not described |
| Stated aim of study | “evaluate the influence of eliminating heat by nourishing Yin and activating blood and removing stasis TCM on inflammatory factor of type 2 diabetes in earlier period ” |
# Risk of bias

| Bias                                                        | Authors judgement | Support for judgement                                                                                                                                 |
|-------------------------------------------------------------|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Random sequence generation (selection bias)                 | unclear risk      | It only mentioned in the trial that “patients were randomly divided into 3 groups”                                                                  |
| Allocation concealment (selection bias)                     | unclear risk      | It only mentioned in the trial that “patients were randomly divided into 3 groups”                                                                  |
| Blinding of participants and personnel (performance bias)   | unclear risk      | The information was not reported in this study                                                                                                       |
| Blinding of outcome assessment (detection bias)             | unclear risk      | The information was not reported in this study                                                                                                       |
| Incomplete outcome data (attrition bias)                    | Low risk          | 7 cases lost follow up in three groups (2 in Group A, 3 in Group B and 2 in Group C) with same reasons as lost contact with across three groups.     |
| Selection reporting (reporting bias)                        | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors             |
| Other bias                                                  | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

**Liu HZ 2007**

**Effects of Danzhi Jiangtang Capsule on β-cell Function of pancreatic Islet in Type 2 Diabetes**

| Methods                                                        | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone |
|                                                               | Randomisation ratio: 1:1                                                                                                     |
| Participants                                                  | Ethnic: Chinese n=62                                                                                                          |
### Inclusion criteria:
T2DM WHO 1999; TCM differentiation China Zhengzhou conference 1986: qi deficiency, yin deficiency, and China Beijing conference 1988: blood stasis. Age: 56-87 year.
Exclusion criteria: not described

### Interventions

| Number of study centres | 1 |
|-------------------------|---|
| Location                | China |
| Setting                 | outpatients and inpatients in TCM university hospital |
| Intervention:           | Conventional hypoglycemia treatment: sulfonylurea, glucosidase inhibitor or insulin treatment; hypertension and coronary disease treatment |
| Treatment group         | conventional treatment + TCM Danzhi Jiangtang Capsules oral intake (Taizishen, Sheng Dihuang, Tusizi, Mudanpi, Zexie, Shuizhi) |
| Control group           | conventional treatment + rosiglitazone |

### Outcomes

Comparing with those of control group, the score of TCM syndrome, indices of FBG, 2hPG, blood insulin (empty, 30min, 2h and 3h), ISI, Homa-IR, Homa-B were significantly improved (P<0.05, P<0.01).

No information was reported in terms to adverse effect in this study.

Outcomes were assessed at baseline and trial completion.

### Study details

Duration of intervention: 2 months
Duration of Follow-up: not reported
Run-in period: not described

### Stated aim of study

"To observe the effects of Danzhi Jiangtang Capsules on B-cell function of pancreatic islet in patients with type 2 diabetes and explore its contribution to treating and delaying the development of type 2 diabetes."

### Risk of bias

| Bias                     | Authors judgement | Support for judgement |
|--------------------------|-------------------|-----------------------|
| Random sequence generation (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
### Blinding of participants and personnel (performance bias)
- **Unclear risk**
- The information was not reported in this study

### Blinding of outcome assessment (detection bias)
- **Unclear risk**
- The information was not reported in this study

### Incomplete outcome data (attrition bias)
- **Low risk**
- No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study

### Selection reporting (reporting bias)
- **Unclear risk**
- The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors

### Other bias
- **Unclear risk**
- The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general baseline and clinical backgrounds of sex, age, disease course, score of TCM syndrome, BMI, FPC and HbA1c. Other aspects of bias were unclear

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**Shi XD 2015**

The curative effect observation of Xiaoke pill and glibenclamide treatment of type 2 diabetes mellitus

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
| Randomisation ratio: 1:1 |
| Participants | Ethnic: Chinese n=100
Inclusion criteria: T2DM WHO 1999; age: 46-62, all cases≤65 years, 24 cases combined with hypertension. FPG mean= 8.4-8.5mmol/L, 2hPG mean=12.5-12.8mmol/L, HbA1c mean=7.4-7.6%; both groups have DM clinical symptoms; no insulin treatment before, liver and kidney function normal, whole blood test normal
Exclusion criteria: diabetes complication; combined coronary heart disease and brain infarction; weak constitution; hypocortisonism; hypoanteriorpituitarism |
### Interventions
- **Number of study centres**: 1
- **Location**: China
- **Setting**: inpatients in hospital
- **Intervention**: both groups have general treatment: quit smoking and alcohol, lifestyle intervention and dietary plan, regular exercise and exercise therapy
- **Treatment group**: glibenclamide and aspirin therapy oral intake
- **Control group**: Xiaoke pill (Huangqi, Dihuang, Shanyao, Wuweizi, Tianhuafen, Gegen, Yumixu) and aspirin therapy oral intake

### Outcomes
The symptoms of diabetes significantly improved with 56% in treatment group and 82% in control group respectively.
- Peripheral blood sugar, urine sugar, urine ketone bodies, urine protein and blood picture observed for measurement of efficacy.
- BP, liver and kidney function, fundus examination was measures and no abnormal observed. 4 cases in treatment group had hypoglycemic reaction and 2 cases out of 4 had mild nausea and vomiting. No any adverse effects observed in control group.
- Outcomes were assessed at baseline and trial completion

### Study details
- **Duration of intervention**: 90 days
- **Duration of Follow-up**: not reported
- **Run-in period**: not described

### Stated aim of study
"To discuss the effect of Xiaoke pill and glibenclamide treatment of type 2 diabetes mellitus"

### Risk of bias

| Bias                                      | Authors judgement | Support for judgement                                                                 |
|-------------------------------------------|-------------------|---------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias)   | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study |

- All outcomes
| Category                                           | Risk       | Description                                                                                                                                 |
|----------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Blinding of outcome assessment (detection bias)    | Unclear    | The information was not reported in this study                                                                                               |
| All outcomes                                       |            |                                                                                                                                              |
| Incomplete outcome data (attrition bias)           | Low        | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study                                |
| All outcomes                                       |            |                                                                                                                                              |
| Selection reporting (reporting bias)               | Unclear    | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                         | Unclear    | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear |

Lan KJ 2011

23 Cases of the Traditional Chinese Medicine Combined Insulin Treatment for Type 2 Diabetes of the Clinical Effect of analysis

| Methods                                           | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  |
|----------------------------------------------------|---------------------------------------------------------------------------------------------|
|                                                    | Randomisation ratio: 1:1                                                                      |
| Participants                                       | Ethnic: Chinese n=43                                                                         |
|                                                    | Inclusion criteria: T2DM WHO 1999; need insulin treatment; average age: 58.7±6.4 year, average disease course: 5.4±2.6, BMI: 23.1±3.3 kg/m |
|                                                    | Exclusion criteria: not described                                                             |
| Interventions                                      | Number of study centres: 1                                                                   |
|                                                    | Location: China                                                                             |
|                                                    | Setting: inpatients in army hospital                                                         |
|                                                    | Intervention: dietary control and exercise therapy                                           |
|                                                    | Combined group: insulin treatment + TCM herb decoction (Huangqi, Dannanxing, Chuanxiong, Gualou, Fuling, Zexie, Xiangfu, Shu Dihuang, Huanglian, Gegen, Danshen) |
Control group: insulin treatment

Outcomes were assessed at baseline and trial completion at 2 weeks for FPG, 2hPBG, and at 3 months for HbA1c. Mean 2h PBG and FBG decreased significantly at endpoint in the combination group compared with control group (P<0.05). The HbA1C excursion were significant lower after 3 months (P<0.05). No information was reported in terms to adverse effect in this study.

Study details
- Duration of intervention: 3 months
- Duration of Follow-up: not reported
- Run-in period: not described

Stated aim of study
- “To compare the level of HbA1c in insulin-requiring patients with diabetes (T2DM) treated twice daily with Chinese herbal remedies combined with insulin.”

Risk of bias

| Bias                                      | Authors judgement | Support for judgement                                                                 |
|-------------------------------------------|-------------------|---------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias)   | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk      | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk      | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)      | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
The intervention groups were comparable, as it mentioned in the trial "no significant difference was found between groups on general backgrounds of age, sex, disease course, BMI and so on. Other aspects of bias were unclear.

Yang LQ 2010

Clinical observation of Dangua Prescription on Type 2 Diabetes Patients with long-term hyperglycosemia

Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone
Randomisation ratio: 2:1

Participants

Ethnic: Chinese n=126
Inclusion criteria: T2DM WHO 1999; blood sugar control is not ideal for long time, HbA1C>7.5% last for one year; not included in exclusion criteria. TCM differentiation China 2002: phlegm dampness symptoms and blood stasis symptoms
Exclusion criteria: pregnant or breast-feeding; severe heart, liver, kidney and brain complications, or combine other severe primary diseases; have diabetes ketosis, ketoacidosis, hypertonic coma and infections; not accord with TCM differentiation

Interventions

Number of study centres: 1
Location: China
Setting: outpatients and inpatients in TCM university hospital
Intervention: both groups have diabetes education, diet control and exercise therapy
Treatment group: Dangua prescription (Danshen, Gualou, Chuanxiong, Chishao, Banxia, Xiebai) on the basis of control group
Control group: insulin, hypoglycemia medicine: gliclazide, metformin and rosiglitazone, single or combined.

Outcomes

Compared with control group, 2hPG, HbA1C, c peptide, 2h postprandial C peptide, high shear viscosity of whole blood, low shear viscosity of whole blood, fibrinogen and cumulative score of symptoms were decreased (P<0.05). The average dosage of insulin in treatment group was less than that in control group (P<0.05). The total
The effective rate was 92.68% in the treatment group and 77.27% in control group with \( P<0.05 \). Liver and kidney function, ECG were measured before and after the treatment and no adverse effect or complication were observed in both intervention group. Outcomes were assessed at baseline and trial completion.

| Study details | Duration of intervention: 90 days  
Duration of Follow-up: not reported  
Run-in period: none |
|---------------|----------------------------------|
| Stated aim of study | “To observe the effect of Dangua prescription on type 2 diabetes patients with long-term hyperglycosemia.” |

### Risk of bias

| Bias | Authors judgement | Support for judgement |
|------|-------------------|-----------------------|
| Random sequence generation (selection bias) | unclear risk | It only mentioned that the “patients were randomly divided into control group and treatment group” |
| Allocation concealment (selection bias) | unclear risk | It only mentioned that the “patients were randomly divided into control group and treatment group” |
| Blinding of participants and personnel (performance bias) All outcomes | unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general background of |
Zhang YH 2008

Effect of Didang Tang on type 2 diabetes with insulin resistance

| Methods      | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone  
|             | Randomisation ratio: 1:1 |
| Participants | Ethnic: Chinese n=73  
|             | Inclusion criteria: T2DM WHO 1999, no sensitive to insulin treatment with high blood insulin level. age: 35-77 years  
|             | Exclusion criteria: liver and kidney dysfunction, type 1 diabetes, tumor, hemopoietic system disease, psychotic, acute myocardial infarction, severe arythmia, acute heart failure or chronic heart dysfunction over grade three. |
| Interventions| Number of study centres: 1  
|             | Location: China  
|             | Setting: patients in TCM hospital  
|             | Intervention: treatment group: sulfonylurea, metformin and alpha glucosidase inhibitor routine treatment for 4 weeks and plus TCM formula Didang Tang (Dahuang, Taoren, Shuizhi, Mengchong) for 8 weeks  
|             | control group: sulfonylurea, metformin and alpha glucosidase inhibitor routine treatment |
| Outcomes     | After treatment, TC, TG, LDL-C, FBG, FINS and ISI in treatment group have decreased compared to control group and with statistical significant. Outcomes were assessed at baseline and trial completion  
|             | Measured Ccest x-ray, blood and urine routine examination, liver and kidney function test for safety and no abnormal had been observed in terms to adverse effect related to study drugs. No complication and other severe adverse effects observed during the intervention. |
| Study details| Duration of intervention: 8 weeks  
|             | Duration of Follow-up: 12 weeks |
Run-in period: 4 weeks

| Stated aim of study | “to observe the effect of Didang Tang on type 2 diabetes with insulin resistance and discuss the prevention and treatment of type 2 diabetes with TCM principle of moving blood and clearing stagnation” |
|---------------------|------------------------------------------------------------------------------------------------------------------|

### Risk of bias

| Bias                                                                 | Authors judgement | Support for judgement                                                                                                                                                                                                 |
|---------------------------------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Random sequence generation (selection bias)                         | low risk          | It mentioned in the trial that “patients were randomly divided into experimental group and control group by computer random table method”                                                                               |
| Allocation concealment (selection bias)                             | low risk          | It mentioned in the trial that “patients were randomly divided into experimental group and control group by computer random table method”                                                                               |
| Blinding of participants and personnel (performance bias)           | unclear risk      | The information was not reported in this study                                                                                                                                                                         |
| All outcomes                                                       |                   |                                                                                                                                                                                                                      |
| Blinding of outcome assessment (detection bias)                     | unclear risk      | The information was not reported in this study                                                                                                                                                                         |
| All outcomes                                                       |                   |                                                                                                                                                                                                                      |
| Incomplete outcome data (attrition bias)                            | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study                                                                                                       |
| All outcomes                                                       |                   |                                                                                                                                                                                                                      |
| Selection reporting (reporting bias)                                | unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors                                                                           |
| Other bias                                                         | unclear risk      | The intervention groups were comparable, as it mentioned in the trial that “no significant difference was found between groups on general backgrounds of sex, age and distribution of complications between both groups. Other aspects of bias were unclear |

Ji LN 2013
### Methods

Parallel randomised controlled, double blinded, multicentre non-inferiority clinical trial of Chinese herbal medicine with or without other pharmaceuticals compared with other pharmaceuticals alone

| Randomisation ratio: 1:1 |

### Participants

| Ethnic: Chinese n=800 |

Inclusion criteria, drug naïve patients with BMI within 18kg/m²-28kg/m²; patients who received treatment with metformin at a stable dose ≥750mg/day for at least 3 months before screening with BMI within 18kg/m²-35kg/m²; stable body weight within at least 3 months before screening; poor glycemic control with FPG between 126-234mg/dl (7.0-13mmol/L) and HbA1c≥7.0% at screening.

Exclusion criteria, FPG≥13mmol/L or HbA1c≥11%, more than 3 episodes of severe hypoglycemia within 6 months before screening, allergic to sulfonylureas or their ingredients, treatment with glucose-lowering agents other than metformin or insulin within 3 months before screening or with exogenous insulin for more than 1 week within 3 months before screening, a history of heart disease within 1 year before screening, a history of abnormal kidney function or serum creatinine levels reaching the upper limit of normal, ALT or AST≥2.5 times the upper limit of normal, suffering from acute or chronic hepatitis, haemoglobin disease or chronic anemia, or underlying conditions that could lead to poor complication.

### Interventions

| Number of study centres: 20 |

Location: 19 participant centres in China and 1 participant centre in Queensland, Australia

Setting: patients in hospitals

Intervention: control diet and do exercise

Drug naïve group: Xiaoke Pill (Radix Puerariae, Radix Rehmanniae, Radix Astragali, Radix, Trichosanthis, Stylus Zeae Maydis, Fructus Schisandrae Sphenantherar and Rhizoma Dioscoreae) in Xiaoke Pill arm, Glibenclamide in Glibenclamide arm

Metformin group: Xiaoke Pill + Metformin in Xiaoke Pill arm, Glibenclamide + Metformin in Glibenclamide arm
### Outcomes

Clinical and Biochemical measurements: HbA1c, FPG, C-peptide, hsCRP, adiponectin and lipids, LDL-C, HDL-C, triglyceride, liver function test, complete blood count, urine routine assay, kidney function test, twelve-lead ECG, physical examination;

Outcome in drug naïve group: patients in the Xiaoke Pill arm were 38% less likely to have any hypoglycemia compared to those in the Glibenclamide arm. The average annual rate of hypoglycemia was 24% lower in patients treated with Xiaoke Pill. Patients in Xiaoke Pill arm were also 41% less likely to have a mild hypoglycemic episode compared to those in the Glibenclamide arm. All with statistically significant with above outcome.

Outcome in Metformin Group: patients in Xiaoke Pill arm were 24% less likely to have any hypoglycemia compared to those in the Glibenclamide arm. The average annual rate of hypoglycemia was 62% lower in patients treated with Xiaoke Pill. All with statistically significant with above outcome.

Safety and Efficacy outcomes measured by incidence of hypoglycaemia, change in HbA1c level, change in fasting glucose level, β-cell function, insulin resistance levels; fasting lipid profiles and TCM symptoms score.

No serious adverse event reported during the study.

Outcomes were assessed at baseline and trial completion.

| Study details | Duration of intervention: 48 weeks |
|---------------|-----------------------------------|
|               | Duration of Follow-up: not reported |
|               | Run-in period: 4 weeks |

| Stated aim of study | "To establish the safety and efficacy of traditional Chinese medicine combined with glibenclamide to treat type 2 diabetes mellitus." |

| Notes | Randomised controlled trial with 2 arms |

| Risk of bias | Authors judgement | Support for judgement |
|--------------|-------------------|-----------------------|
| Bias Random sequence generation (selection bias) | low risk | It mentioned in the trial that "randomization was performed centrally and was concealed and stratified in blocks of four" |
| Bias Type                                      | Risk Level | Description                                                                                                                                 |
|-----------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Allocation concealment (selection bias)       | low risk   | It mentioned in the trial that “randomization was performed centrally and was concealed and stratified in blocks of four”                |
| Blinding of participants and personnel (performance bias) | low risk   | Double-blinded and placebo-controlled                                                                                                    |
| Blinding of outcome assessment (detection bias) | low risk   | Double-blinded and placebo-controlled                                                                                                    |
| Incomplete outcome data (attrition bias)      | Low risk   | Only 2 patients in TCM group early stopped.                                                                                               |
| Selection reporting (reporting bias)          | low risk   | The protocol of the trial was clear, so the review authors could examine the possibility of selection outcome reporting.                   |
| Other bias                                    | unclear risk | The intervention groups were comparable, as it listed characteristics of the patients at baseline in the trial and no significant difference found between groups on demographics and anthropometric characteristics as well as blood pressure, metabolic characteristics and lipids. Other aspects of bias were unclear |

Chen ZH 2014

Treatment of Type 2 Diabetes Mellitus Patients of Qi-Yin Deficiency Phlegm-Stasis Inter-obstruction Syndrome by Jiangtang Xiaozhi Capsule and Pioglitazone Tablet: a Non-inferiority Randomized Controlled Trial

| Methods | Randomised parallel controlled prospective clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone |
|---------|--------------------------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 1:1                                                                                            |
| Participants | Ethnic: Chinese n=73  
Inclusion criteria: T2DM WHO 1999, have diabetes history, FBG 7.0-11.1mmol/L or 2hPBG 11.1-16.6 mmol/L and blood sugar keep the same level after 2 weeks run-in-period; age 30-70 years old, both sex; have no insulin treatment before and good for comply with therapy; informed and signed consent; TCM diagnostic criteria China 2002, TCM differentiation: qi-yin deficiency phlegm-stasis inter-obstruction syndrome  
Exclusion criteria: liver and kidney dysfunction; combine severe cardiovascular and hemopoietic system disease or other severe primary disease as well as psychosis; have diabetes ketoacidosis and other acute metabolism disorder within one month; pregnancy and breastfeeding; combine with severe infections in recent one month; allergic constitution; not comply in run-in period; have history of excessive drinking and drug taking; use Pioglitazone or patent herb which can affect the evaluation of the therapeutic effect |
| Interventions | Number of study centres: 1  
Location: China  
Setting: outpatients in TCM hospital  
Intervention:  
Run-in period: dietary and exercise therapy under the supervisor of physician and nutritionist  
JTXZC group: TCM prescription: Jiangtang Xiaozhi capsule (Huangqi, Nuzhenzi, Lizhihe, Kunbu, Jianghuang, Huanglian)  
Pioglitazone group: Pioglitazone tablet |
| Outcomes | BW, BMI (waist circumference, hip circumference, waist-to-hip ratio), HbA1c, FBG or 2h PBG, TNF-α and PAI-1 were lower after treatment in both groups. The level of NF-κB was apparently lowered after treatment in Pioglitazone group, but also decreased in JTXZC group with statistical difference. The scoring of TCM symptoms improved after treatment in both groups with statistically significant in experimental group.  
Measured blood, urine and stool routine examination, liver and kidney function examination as well as ECG before and after the study. No abnormal were observed in above test. |
I case in JTXZC group had nausea symptom after initial take the herb and better later change to taking herb after meal; 3 cases in Pioglitazone group had some mild adverse effects. No severe adverse reactions observed in both intervention groups. Outcomes were assessed at baseline and trial completion.

| Study details       | Duration of intervention: 8 weeks |
|---------------------|-----------------------------------|
|                     | Duration of Follow-up: every 2 weeks |
|                     | Run-in period: 2 weeks             |

| Stated aim of study | “To evaluate the efficacy and safety of Jiangtang Xiaozhi capsule in treating type 2 diabetes mellitus of qi- yin deficiency phlegm-stasis inter-obstruction syndrome and to observe its effect on inflammatory factors and fibrinolytic factors” |

| Risk of bias | Authors judgement | Support for judgement |
|--------------|--------------------|------------------------|
| Bias         |                    |                        |
| Random sequence generation (selection bias) | low risk | It mentioned in the trial that “patients were randomly divided into two groups by statistical software random digit table method ” |
| Allocation concealment (selection bias) | low risk | It mentioned in the trial that “patients were randomly divided into two groups by statistical software random digit table method ” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors, except only mentioned full analysis set was adopted for the outcome |
The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of sex, age, and disease course, distribution of complication in both groups and disease condition. Other aspects of bias were unclear.

Niu XX 2014

Clinical Observation of Panax Quinquefolium Hypoglycemic Pills on Treatment of Type 2 Diabetes

| Methods | Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone  
| Randomisation ratio: 1:1 |
| Participants | Ethnic: Chinese n=180  
| Inclusion criteria: T2DM WHO 1999, average age: 53.80±9.75, average disease course: 4.31 year  
| Exclusion criteria: not described |
| Interventions | Number of study centres: 1  
| Location: China  
| Setting: outpatients in TCM hospital  
| Intervention: both groups have exercise therapy and diet control  
| Experimental group: Panax quinquefolium hypoglycemic pills (Xiyangshen, Shu Dihuang, Sheng Dihuang, Maidong, Tiandong, Huangqi, Shihu, Zhiqiao, Zexie, Pipaye) oral intake  
| Control group: Metformin Hydrochloride tablet oral intake |
| Outcomes | The improvement of clinical test result in experimental group was better that that in control group with statistically significant. HbA1c rate of experimental group was significantly increased, 2hPBG and FBG both decreased significantly. The total effects including clinical symptoms in experimental group are statistically higher than that in control group.  
| No information was reported in terms to adverse effect in this study  
| Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 4 months  
|              | Duration of Follow-up: not reported  
|              | Run-in period: not described |
| Stated aim of study | “To observe the clinical effect of type 2 diabetes mellitus with the treatment of Panax quinqueflium Hypoglycemic pill” |

| Bias | Authors judgement | Support for judgement |
|------|-------------------|-----------------------|
| Random sequence generation (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Allocation concealment (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into two groups” |
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study |
| All outcomes | | |
| Blinding of outcome assessment (detection bias) | Unclear risk | The information was not reported in this study |
| All outcomes | | |
| Incomplete outcome data (attrition bias) | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| All outcomes | | |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of disease course, age and sex. Other aspects of bias were unclear. |

Song W 2014

Clinical Research of Chinese Medicine in Treating Patients with type 2 Diabetes
| **Methods** | Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone  
Randomisation ratio: 1:1 |
| **Participants** | Ethnic: Chinese n=128  
Inclusion criteria: T2DM WHO 1999, disease course within 5 years, have never taken any hypoglycemia drug and lipid decrease drug before 2 month of study; age: 25-80y; informed and signed consent  
Exclusion criteria: FBG>10mmol/L, 2hPGB or random blood sugar>15mmol/L; HbA1c>10.0%; have recent distinct liver kidney dysfunction and infection, trauma, cardiovascular accident etc. stress status; combine with diabetic acute complications and pregnant diabetes or breastfeeding as well as potential pregnancy, hyperthyroid or other disease which lead to hyperglycemia and type 1 diabetes; possible allergy to study drug or have severe intestine absorption dysfunction |
| **Interventions** | Number of study centres: 1  
Location: China  
Setting: outpatients and inpatients in TCM hospital  
Intervention:  
Basic therapy: diet, exercise and diabetic education  
Treatment group: basic therapy + TCM prescription based on syndrome differentiation (Kidney tonify:Gouji, Chuanxuduan, Nuzhenzi, Hanliancao; Nourish Qi and Yin: Bei Huangqi, Dihuang, Digupi; Soothe liver and regulate Qi: Chaihu, Baishao, Bohe, Yujin; clear heat and generate fluid: Shigao, Zhimu, Gegen, Liaoqiao; clear fu and reduce heat: Dahuang, Zhishi, Huomaren; nourish heart calm spirit: Yejiaoteng, Yuanzhi, Shuanzhaoren; clear ying cool blood: Mudanpi, Maidong, Xuanshen, Chishao; clear damp-heat: Cangzhu, Huangbai, Yiyiren, Cheqiancao, Mianyinchen, add Fuling, Chaobaizhu, Fabanxia, Shenqu for damp restrict spleen; add Laifuzi, Zhiqiao, Chuanxiaopu for stomach bloat; add Gualoupi, Xiebai for depressed chest; move blood to clear stasis: Danshen, Sanling, Ezhu, Zelan)  
Control group: basic therapy + acarbose |
| **Outcomes** | The total effective rate improved after treatment in both group without significant difference. The total effective rate in TCM symptoms improved and showing significant difference of better in treatment group. FBG, 2hPBG and HbA1c |
significantly improved in both group. The BMI, AUCi, blood lipid (TC, TG, LDL-C, HDL-C) level in treatment group significantly improved compared to control group. Measured blood routine examination, liver and kidney function before and after treatment and no abnormal was observed. 16 case in control group had bloating and diarrhoea and was under control without any impact on study. No adverse effects observed in treatment group. Outcomes were assessed at baseline and trial completion.

| Study details | Duration of intervention: 6 months |
|---------------|-----------------------------------|
|               | Duration of Follow-up: 3 month     |
|               | Run-in period: not described       |

Stated aim of study

“To observe the clinical efficacy on type 2 diabetes treated with professor FAN Guanjie’s experienced prescription of Chinese medicine.”

| Risk of bias                                             | Authors judgement | Support for judgement                                                                 |
|---------------------------------------------------------|--------------------|---------------------------------------------------------------------------------------|
| Bias                                                    |                    |                                                                                       |
| Random sequence generation (selection bias)             | low risk           | It mentioned in the trial that “patients were randomly divided into control group and treatment group by random number table” |
| Allocation concealment (selection bias)                 | low risk           | It mentioned in the trial that “patients were randomly divided into control group and treatment group by random number table” |
| Blinding of participants and personnel (performance bias)| Unclear risk       | The information was not reported in this study                                       |
| Blinding of outcome assessment (detection bias)         | Unclear risk       | The information was not reported in this study                                       |
| Incomplete outcome data (attrition bias)                | Low risk           | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)                    | Unclear risk       | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of sex, age and disease course. Other aspects of bias were unclear. |

Ye RQ 2014

Effect of Jianpi Zengmin Decoction on Insulin Resistance in Type 2 Diabetes Mellitus

| Methods | Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone  
Randomisation ratio: 1:1 |
| Participants | Ethnic: Chinese n=100  
Inclusion criteria: T2DM WHO 1999, HOMA-IR ≥ 2.8; TCM diagnostic criteria China 2002, obesity diagnostic criteria China 1997; age: 20-70 year, informed consent with the study and can complete the treatment, observation and examinations.  
Exclusion criteria: type 1 diabetes or other kinds of diabetes and pregnant diabetes; combine with acute diabetes complication; have severe heart, kidney and liver etc. complications, severe hypertension or combine other severe primary disease; pregnancy or breastfeeding, psychosis and potential allergy to the study drug; cannot comply with prescription, diet and exercise therapy and affect the treatment |
| Interventions | Number of study centres: 1  
Location: China  
Setting: outpatients in TCM hospital  
Intervention:  
Basic treatment: diet therapy, exercise therapy and same type of hypoglycemic drug (apart from metformin etc. which may have relative allergy ingredients as the study herb)  
Treatment group: basic therapy + TCM prescription Jianpi Zengmin decoction (Dangshen, Fuling, Baizhu, Fabanxia, Chenpi, Huangqi, Danshen, Shanyao, Gegen, Shanzha, Chishao, Zhigancao)  
Control group: basic therapy + metformin hydrochloride |
Outcomes

The total effective rate was 90% in treatment group with significant difference compare to 70% in control group. HOMA-IR, BMI, TG, CHOL, FBG and 2hPG reduced significantly in both group. The difference of HOMA-IR and TG levels in treatment group compare to control group was statistically significant.

No information was reported in terms to adverse effect in this study

Outcomes were assessed at baseline and trial completion

Study details

Duration of intervention: 8 weeks
Duration of Follow-up: not reported
Run-in period: not described

Stated aim of study

“To observe the effect of Jianpi Zengmin decoction on insulin resistance in type 2 diabetes.”

Risk of bias

| Bias                              | Authors' judgement | Support for judgement                                                                 |
|-----------------------------------|--------------------|---------------------------------------------------------------------------------------|
| Random sequence generation        | unclear risk       | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment            | unclear risk       | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Blinding of participants and      | Unclear risk       | The information was not reported in this study                                         |
| personnel (performance bias)      |                    |                                                                                       |
| All outcomes                      |                    |                                                                                       |
| Blinding of outcome assessment    | Unclear risk       | The information was not reported in this study                                         |
| (detection bias)                  |                    |                                                                                       |
| All outcomes                      |                    |                                                                                       |
| Incomplete outcome data           | Low risk           | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| (attrition bias)                  |                    |                                                                                       |
| All outcomes                      |                    |                                                                                       |
| Selection reporting (reporting    | Unclear risk       | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| bias)                             |                    |                                                                                       |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear. |

Ma CL 2015

Therapeutic Effect of Middle-warming and Spleen-strengthening and Kidney-tonifying therapy for Type 2 Diabetes Mellitus

| Methods | Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone |
|---------|---------------------------------------------------------------------------------------------------------|
|         | Randomisation ratio: 2:1                                                                                |

| Participants | Ethnic: Chinese n=99 (Chinese medicine group 66, control group 33) |
|--------------|------------------------------------------------------------------|
|              | Inclusion criteria: T2DM WHO 1999; 7.8mmol/L≤FBG≤13.9mmol/L and/or 11.1mmol/L≤2hPBG≤25mmol/L; FINS≥15mU/mL; have done dietary and exercise therapy for 2 weeks; age: 30-70 y |
|              | Exclusion criteria: acute stress status like severe infection; severe liver and kidney dysfunction |

| Interventions | Number of study centres: 1 |
|---------------|----------------------------|
|               | Location: China |
|               | Setting: outpatients and inpatients in TCM hospital |
|               | Intervention: diet and weight control plan |
|               | Chinese medicine group: TCM prescription: middle-warming, spleen-strengthening and kidney-tonifying (Shu Fuzi, Sheng Huangqi, Ganjiang, Zhigancao, Hongshen, Rougui, Baizhu, Yunling, Shu Dihuang, Shanyurou, Huai shanyao, Wuzhuyu, Danggui, Zhuyizang) |
|               | Control group: metformin tablet oral intake |

| Outcomes | After treatment, insulin sensitivity index and HDL-C were improved and FBG, 2hPG, HbA1c, TG, FINS, BMI decreased in the Chinese medicine group. The effect on lowering TG, FINS, BMI and improving efficacy of ISI, HDL-C was better in Chinese medicine group than that in control group with statistically significant. |
No examination reported in terms to adverse effect in this study. It only mentioned in the discussion that no complication or adverse effects were observed in Chinese medicine group. Outcomes were assessed at baseline and trial completion.

### Study details
- **Duration of intervention:** 8 weeks
- **Duration of Follow-up:** not reported
- **Run-in period:** 2 weeks

### Stated aim of study
"To observe the effect of middle-warming, spleen-strengthening and kidney-tonifying therapy on lowering glucose, regulating blood lipid, increasing insulin sensitivity and decreasing body mass index in type 2 diabetes mellitus patients."

### Risk of bias

| Bias                              | Authors judgement | Support for judgement |
|-----------------------------------|-------------------|-----------------------|
| Random sequence generation (selection bias) | low risk          | It mentioned in the trial that “patients were divided into Chinese medicine group and control group by random number table method” |
| Allocation concealment (selection bias) | low risk          | It mentioned in the trial that “patients were divided into Chinese medicine group and control group by random number table method” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk      | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk      | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk          | Exclusion or losses were reported before the intervention, and the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                        | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was
found between groups on clinical backgrounds. Other aspects of bias were unclear.

Zhu HY 2012

The Chinese Medicine Syndrome Differentiation Treatment of Type 2 Diabetes with Insulin Resistance

| Methods       | Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone  
|               | Randomisation ratio: 1:1 |
| Participants  | Ethnic: Chinese n=80  
|               | Inclusion criteria: T2DM WHO 1999 with insulin resistance, TCM differentiation China 2004: yin deficiency with excess heat, qi and yin deficiency, yin and yang deficiency  
|               | Exclusion criteria: combine with ketoacidosis, hyperosmolar coma, severe infection and other acute complications, or severe heart failure and other severe primary disease; heart rate increase no more than 30% after daily continuous exercise for half hour; secondary diabetes, psychosis; use insulin treatment |
| Interventions | Number of study centres: 1  
|               | Location: China  
|               | Setting: patients in TCM hospital  
|               | Intervention:  
|               | Observation group: TCM syndrome differentiation treatment (Sheng Dihuang, Maidong, Niuxi, Zhimu and Shigao for yin deficiency with excess heat; Taizishen, Huangqi, Huaiyishanyao, Xuanshen, Maidong, Shanzhuyu for Qi and Yin deficiency; Gan Dihuang, Shanyao, Shanzhuyu, Zexie, Fuling, Mudanpi, Paofuzi for Yin Yang deficiency)  
|               | Control group: topiramate glibenclamide ketone |
| Outcomes      | Compared with the control group, the fasting insulin (Fins) and pancreatic β cell function index (Homa-IS) increased and the total efficacy was improved in observation group with statistically significant.  
|               | No information was reported in terms to adverse effect in this study  
|               | Outcomes were assessed at baseline and trial completion |
| Study details | Duration of intervention: 8 weeks |
### Risk of bias

| Bias                                      | Authors judgement | Support for judgement |
|-------------------------------------------|-------------------|-----------------------|
| Random sequence generation (selection bias) | low risk          | It mentioned in the trial that “patients were divided into control group and observation group by random number table method” |
| Allocation concealment (selection bias)   | low risk          | It mentioned in the trial that “patients were divided into control group and observation group by random number table method” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk      | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk      | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk          | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)      | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear. |

Zheng J 2013

Clinical Study of Qingre Zaoshi Jianpi Traditional Chinese Medicine in the Treatment of Shire Kunpi Syndrome Primary Type Diabetes
Methods
Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone
Randomisation ratio: 1:1

Participants
Ethnic: Chinese n=82
Inclusion criteria: T2DM WHO 1999, TCM differentiation China 2002: heat and dampness syndrome primary type 2 diabetes
Exclusion criteria: heart, brain and other severe physical and psychological disorders; other types diabetes; combine with ketoacidosis, hypertonic status and other diabetes acute complications within one month

Interventions
Number of study centres: 1
Location: China
Setting: outpatients and inpatients in TCM hospital
Intervention:
Treatment group: clearing heat and dispelling dampness tonifying spleen TCM herb formula (Banxia, Cangzhu, Chenpi, Fuling, Huangqin, Huanglian, Xuanshen, Ganjiang, Danshen)
Control group: metformin hydrochloride tablet

Outcomes
The difference of total effective power in two groups was statistically significant with 65% in control group and 85.7% in treatment group. FPG, PFG and HbA1c were all decreased after treatment and more decrease in treatment group with statistical significance
No information was reported in terms to adverse effect in this study
Outcomes were assessed at baseline and trial completion

Study details
Duration of intervention: 8 weeks
Duration of Follow-up: not reported
Run-in period: not described

Stated aim of study
“To observe the clinical curative effect of clearing heat and dispelling dampness tonifying spleen traditional Chinese medicine in the treatment of heat and dampness syndrome primary type 2 diabetes.”

Risk of bias

| Bias | Authors judgement | Support for judgement |
|------|-------------------|-----------------------|

98
| Random sequence generation (selection bias) | low risk | It mentioned in the trial that “patients were divided into treatment group and control group according to random number table method” |
| --- | --- | --- |
| Allocation concealment (selection bias) | low risk | It mentioned in the trial that “patients were divided into treatment group and control group according to random number table method” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of sex, age and disease course. Other aspects of bias were unclear. |

Zhou C 2013

Clinical Curative Effect Observation on TCM Treatment in Different Time of 317 Incident Cases of Type 2 Diabetes

| Methods | Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone |
| --- | --- |
| Randomisation ratio: 1:1 |

| Participants | Ethnic: Chinese n=317 |
Inclusion criteria: T2DM WHO 1999, new-onset of type 2 diabetes and have never used medicine before; have diabetes education, reasonable exercise and diet, active coordination with the treatment and adhere to treatment for 2 months. Exclusion criteria: severe complication such as ketoacidosis, hepatitis, TB, severe infection and so on.

### Interventions
- **Number of study centres:** 1
- **Location:** China
- **Setting:** outpatients and inpatients in TCM hospital
- **Intervention:** diabetes education, reasonable exercise and diet
- **Treatment group:** TCM formula of hypoglycemic by regulate qi benefit spleen and reinforce kidney (Yipijiangtangwan: Shanyao, Baizhu, Jineijin, Sharen, Yunling, Wumei, Zexie, Peilan, Heye; Tiaoqijiangtangwan: Chaihu, Yujin, Jiangchan, Nuzhenzi, Wuweizi, Huangqi, Maidong, Xiyangshen, Huangqin, Banxia; Tangshenkangwan: Fuzi, Shanzhuyu, Sheng Dihuang, Xinyangshen, Bajitian, Taoren, Honghua, Yinyanghuo, Mugua)
- **Control group:** metformin

### Outcomes
- **The curative effect and clinical symptoms, blood fat and islet function improvement (FPG, 2hPG, TC, TG, HDL-C, INS, C peptide, GLU) in treatment group were statistically significant compared with control group.**
- **No information was reported in terms to adverse effect in this study.**
- **Outcomes were assessed at baseline and trial completion.**

### Study details
- **Duration of intervention:** 3 months
- **Duration of Follow-up:** not reported
- **Run-in period:** not described

### Stated aim of study
- **"To observe the curative effect of traditional Chinese medicine on treating new-onset type 2 diabetes."**

### Risk of bias

| Bias                          | Authors judgement | Support for judgement                                                                 |
|-------------------------------|-------------------|---------------------------------------------------------------------------------------|
| Random sequence generation    | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
### Allocation concealment (selection bias)

- **Risk:** Unclear risk
- **Unclear risk:** It only mentioned in the trial that “patients were randomly divided into treatment group and control group”

### Blinding of participants and personnel (performance bias)

- **All outcomes:** Unclear risk
- **Unclear risk:** The information was not reported in this study

### Blinding of outcome assessment (detection bias)

- **All outcomes:** Unclear risk
- **Unclear risk:** The information was not reported in this study

### Incomplete outcome data (attrition bias)

- **All outcomes:** Low risk
- **Low risk:** No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study

### Selection reporting (reporting bias)

- **Unclear risk:** The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors

### Other bias

- **Unclear risk:** The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds. Other aspects of bias were unclear.

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**Du LK 2014**

**Mechanism of improving insulin resistance in type 2 diabetes with the method of supplementing qi and nourishing Yin, removing phlegm to resolve blood stasis**

| Methods | Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone  
Randomisation ratio: 1:1 |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Participants | Ethnic: Chinese n=80  
Inclusion criteria: T2DM WHO 1999, IR China Li XJ 2001. TCM differentiation, China 2002: spleen qi deficiency with phlegm obstructing  
Exclusion criteria: not described |
| Interventions | Number of study centres: 1  
Location: China |
Setting: inpatients and outpatients in TCM hospital

Intervention:
Basic treatment: dietary and exercise therapy, hypertension and regulating lipid treatment
Treatment group: basic treatment + TCM formula of supplementing qi and nourishing Yin, removing phlegm to resolve blood stasis (Huangqi, Renshen, Danshen, Huangjin, Chishao, Cangzhu, Xuanshen)
Control group: basic treatment + Avandia

Outcomes
The treatment group improved TNF-α, leptin, ADP level and better than control group with statistically significance; two groups had equal effect in improving insulin resistance; the treatment group significantly improved blood lipid level (TC, TG, LDL-C) and the indexes were superior to those in control group with statistically significance.
No information was reported in terms to adverse effect in this study
Outcomes were assessed at baseline and trial completion

Study details
Duration of intervention: 8 weeks
Duration of Follow-up: not reported
Run-in period: not described

Stated aim of study
“To discuss the possible mechanism of improving insulin resistance in Type 2 diabetes mellitus with the method of supplementing qi and nourishing Yin, removing phlegm to resolve blood stasis.”

Risk of bias

| Bias                                      | Authors judgement | Support for judgement                                      |
|-------------------------------------------|-------------------|------------------------------------------------------------|
| Random sequence generation (selection bias) | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias)   | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Blinding of participants and personnel (performance bias) | Unclear risk | The information was not reported in this study |
Blinding of outcome assessment (detection bias)

All outcomes

Unclear risk

The information was not reported in this study

Incomplete outcome data (attrition bias)

All outcomes

Low risk

No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study

Selection reporting (reporting bias)

Unclear risk

The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors

Other bias

Unclear risk

The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of sex, age and disease course. Other aspects of bias were unclear.

Guan Y 2015

Clinical efficacy of spleen-strengthening, heat-clearing and turbidity-eliminating therapy in treatment of insulin resistance type 2 diabetes

Methods

Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone

Randomisation ratio: 1:1

Participants

Ethnic: Chinese n=62

Inclusion criteria: T2DM WHO 2007; Obesity international obesity organisation 2000, BMI ≥25kg/m²; insulin resistance China 2007; TCM differentiation China 2002: spleen deficiency with dampness excess and phlegm-heat with internal depression; age: 40-70 year.

Exclusion criteria: not described

Interventions

Number of study centres: 1

Location: China

Setting: outpatients or inpatients in TCM university hospital

Intervention:
Basic treatment: diabetes prevention and treatment education, diet and exercise control
Treatment group: basic treatment + TCM formula of spleen-strengthening, heat-clearing and turbidity-eliminating therapy (Fuling, Shanyao, ChaoYiyiren, ChaoBaizhu, Cangzhu, Sharen, Chaozhizi, Juhong, DanJuye, Guijianyu, Heye, Sangye)
Control group: basic treatment + metformin enteric-coated tablet

| Outcomes                                                                 | There was a significant difference in overall response rate between the treatment group and the control group (87.5% vs 53.33%, *P*<0.01). After treatment, both groups showed significant improvement in FBG, 2hPG, FINS, IRI, TC, and TG (*P*<0.01 or *P*<0.05), and the treatment group showed significant improvements in 2hPG, TC and APN than the control group (*P*<0.01 or *P*<0.05).
|                                                                          | No information was reported in terms to adverse effect in this study.
|                                                                          | Outcomes were assessed at baseline and trial completion.

| Study details | Duration of intervention: 8 weeks  
|              | Duration of Follow-up: not reported  
|              | Run-in period: not described  

| Stated aim of study | “To observe the clinical efficacy of spleen-strengthening, heat-clearing and turbidity-eliminating therapy in treating obese patients with type 2 diabetes and insulin resistance.”  

| Risk of bias |  
| Bias | Authors judgement | Support for judgement |
| Random sequence generation (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Blinding of participants and personnel (performance bias) | Unclear risk | No detail information reported in this study, and only mentioned it was single-blinded trial. |
Yu DQ 2004

Effect and security of traditional Chinese medicine prescription on urine albumin excreting rate type 2 diabetes

| Blinding of outcome assessment (detection bias) | Unclear risk | No detail information reported in this study, and only mentioned it was single-blinded trial. |
| Incomplete outcome data (attrition bias) | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of sex, age and disease course. Other aspects of bias were unclear. |

Methods
Randomised controlled clinical trial of Chinese herbal medicine compared with placebo
Randomisation ratio: 1:1

Participants
Ethnic: Chinese n=71
Inclusion criteria: T2DM WHO 1999; age: 45-75year; course of diabetes over 3 months and blood sugar is stable in recent 2 month
Exclusion criteria: type 1 diabetes or special type of diabetes or combine acute diabetic complication and acute or chronic infection; pregnancy or breastfeeding; ALT≥113U/L; Cr≥170µmol/L, have history of other chronic renal disease before; had malignant tumour before; combine other severe disease, cannot follow up on time; have used ACEI or ARB medicine within 1 month

Interventions
Number of study centres: 1
Location: China
Setting: outpatients in university hospital
Intervention: both groups have diet control, hypoglycemia, hypo tension and hypo lipid treatment
Treatment group: TCM prescription of clearing heat and detoxicating, promoting blood circulation and removing blood stasis (Huangqi, Baihuasheshecao, Banzhilian, Baizhu etc.)
control group: placebo

Outcomes
Albumin excreting rate (UAER), microcirculation nail bed flow, HbA1c, FBG, 2hPG, TC, TG, HDL-c, LDL-c, Apo-a, Apo-b and BMI were measured. At the end of trial, the treatment group showed decrease of UAER level with P=0.000.
Measured Liver, kidney function and routine blood test before and after the treatment, no abnormal observed.
Adverse effects observed. Two cases in treatment group and four cases in control group had adverse effects of stomach and they are tolerable.
Outcomes were assessed at baseline and trial completion

Study details
Duration of intervention: 24 weeks
Duration of Follow-up: 4, 8, 12, 16, 20, and 24 weeks after treatment
Run-in period: not described

Stated aim of study
"To evaluate the effect and safety of traditional Chinese medicine prescription on urine albumin excreting rate of type 2 diabetes."

Risk of bias
| Bias                                               | Authors judgement | Support for judgement                                                                 |
|----------------------------------------------------|-------------------|---------------------------------------------------------------------------------------|
| Random sequence generation                         | unclear risk      | It only mentioned in the trial that "patients were randomly divided into treatment group and control group" |
| Allocation concealment                              | unclear risk      | It only mentioned in the trial that "patients were randomly divided into treatment group and control group" |
| Blinding of participants and personnel              | Unclear risk      | No detail information reported in this study, and only mentioned it was single-blinded trial. |
| Blinding of outcome assessment                      | Unclear risk      | No detail information reported in this study, and only mentioned it was single-blinded trial. |
| All outcomes | Low risk | 11 losses were reported (5 in treatment group 6 in control group) with similar reasons for missing data across groups  |
| Incomplete outcome data (attrition bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors  |
| All outcomes | Unclear risk | No information reported in the trial about general backgrounds of study groups. Other aspects of bias were unclear.  |

Wang SH 2014

A randomized, double-blinded, multicentre clinical trial for Tangke Soft Capsules in the treatment of Type 2 diabetes

| Methods | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with placebo alone  |
| Partipation | Randomisation ratio: 1:1  |
| Equipment | Ethnic: Chinese n=200  |
| Inclusion criteria: T2DM China 2007, FPG≥7.0mmol/L, or 2hPG≥11.1mmol/L; or random blood sugar≥11.1mmol/L; TCM differentiation China 2002: Qi and Yin deficiency; diabetes for over 3 months; have done diet control and/or exercise therapy, or oral intake hypoglycemic western medicine besides diet control and exercise therapy, and condition is stable for over 2 months but blood sugar is still under the normal: 7.0mmol/L ≤FPG≤13.3mmol/L, or 11.1mmol/L≤2hPG≤22.9mmol/L; age: 18-70 years old; informed and signed consent Exclusion criteria: pregnant or breast-feeding woman, patients with severe complications on heart, brain, liver and kidney or combine with other severe primary diseases, psychotic; sensitivity patients; patients with ketosis and associated infections within one month; ALT 1.5 time over than normal; Cr over than normal; can’t take medicine based on prescription; current attending other clinical trial  |
| Interventions | Number of study centres: multicentre (5)  |
| Location: China  |
| Study details | Duration of intervention: 12 weeks |
|--------------|----------------------------------|
|              | Duration of Follow-up: not reported |
|              | Run-in period: none |

**Stated aim of study**

“To evaluate the efficacy and safety of Tangke Soft Capsules (extract of Schisandrae chinensis Fructus) for the treatment of Type 2 diabetes.”

**Risk of bias**

| Bias                                      | Authors judgement | Support for judgement                                      |
|-------------------------------------------|-------------------|------------------------------------------------------------|
| Random sequence generation (selection bias) | unclear risk      | It only mentioned that the trial was randomised in two treatment groups |
| Allocation concealment (selection bias)    | unclear risk      | It only mentioned that the trial was randomised in two treatment groups |
| Blinding of participants and personnel (performance bias) | low risk          | It mentioned double-blinded, placebo-controlled clinical trial |

**Outcomes**

Observed FBG, 2hBG, TCM pattern changes, ECG and adverse events monitor of function of liver and kidney, blood and urine, safety problems. Compared with the baseline, the level of HbA1C, FPG and 2h PG after treatment in the Tangke group decreased significantly (P<0.01), but no markedly compared with placebo group. So was for FPG. There was a significant difference in the drop of 2hPG between Tangke and placebo group (P=0.044).

No serious adverse events and hypoglycemic episodes observed in both intervention groups.

Outcomes were assessed at baseline and trial completion.

**Setting:** outpatients and inpatients in five TCM university hospital

**Intervention:** basic treatment: hypoglycemia agents, exercise and dietary therapy

**Treated group:** basic treatment plus TCM medicine: Tangke soft Capsules (Wuweizi)

**Control group:** use basic treatment plus placebo soft capsules
| Incomplete outcome data (attrition bias) | Low risk | 19 losses were reported with 9.5% general lost rate at the endpoint of study with balanced missing outcome data in numbers across intervention groups |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on baseline data of age, body lengths, BMI, disease course and medical conditions. Other aspects of bias were unclear |

Chao ML 2009

Improving insulin resistance with traditional Chinese medicine in type 2 diabetes patients

| Methods | Parallel randomised double-blinded, placebo-controlled, clinical trial of Chinese herbal medicine compared with placebo |
|         | Randomisation ratio: 1:1 |

| Participants | Ethnic: Chinese n=43 |
|             | Inclusion criteria: newly diagnosed T2DM WHO 1999, FPG≥7mmol/L and/or OGTT 2h≥11.1mmol/L; age range: 18-70 years; overweight with BMI 23-35 kg/m² and with poor glucose level after a 1-month diet control, two FPG concentrations between 7-10 mmol/L within a month |
|             | Exclusion criteria: had used any antidiabetic drugs; with health problems of cardiac, hepatic, renal, other chronic diseases, or acute diabetic complications including diabetic ketoacidosis or hyperosmolar hyperglycemic non-ketotic coma, as determined by history, examination and routine blood chemistry; women of childbearing age were pregnant or planning for pregnancy |

| Interventions | Number of study centres: 2 |
|               | Location: China |
|               | Setting: patients in university affiliated hospital |
|               | Intervention: diet and exercise advise |
| Bias                                      | Authors judgement | Support for judgement                                                                 |
|------------------------------------------|-------------------|-----------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | low risk          | It mentioned in the trial that “randomization was performed centrally and was concealed and stratified in blocks of four” |
| Allocation concealment (selection bias)   | low risk          | It mentioned in the trial that “randomization was performed centrally and was concealed and stratified in blocks of four” |
| Blinding of participants and personnel (performance bias) | low risk          | Double-blinded and placebo-controlled                                                   |
| Blinding of outcome assessment (detection bias) | low risk          | Double-blinded and placebo-controlled                                                   |

TCM group: TCM prescription: compound powder form with 50 mg of Coptis chinensis, 30 mg of Astragalus membranaceus and 120 mg of Lonicera japonica
Placebo group: placebo in indistinguishable tablets

Outcomes
BMI, waist-hip, SBP, DBP, FPG, PPG, HbA1c, TG, TC, HDL, LDL, INS0, INS120, GDR, CRP, IL-6, RBP4, adiponectin, ALT were assessed at baseline and trial completion
Glucose disposal rate in the TCM group was significantly improved as compared to that in the placebo group (P<0.05)
Assessed Renal and hepatic function, blood counts at baseline and the end of the study for safety purpose. Only mild adverse symptoms observed for 5 cases and the frequency of side effects was not significantly different between the two groups. No severe side effect occurred during the study; no episode of hypoglycemia reported.

Study details
Duration of intervention: 3 months
Duration of Follow-up: not reported
Run-in period: 2 weeks

Stated aim of study
“To evaluate the efficacy of TCM on insulin sensitivity and other related metabolic factors in type 2 diabetes patients.”

Risk of bias

Study details
Duration of intervention: 3 months
Duration of Follow-up: not reported
Run-in period: 2 weeks

Stated aim of study
“To evaluate the efficacy of TCM on insulin sensitivity and other related metabolic factors in type 2 diabetes patients.”

Risk of bias

Bias                                      | Authors judgement | Support for judgement                                                                 |
|------------------------------------------|-------------------|-----------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | low risk          | It mentioned in the trial that “randomization was performed centrally and was concealed and stratified in blocks of four” |
| Allocation concealment (selection bias)   | low risk          | It mentioned in the trial that “randomization was performed centrally and was concealed and stratified in blocks of four” |
| Blinding of participants and personnel (performance bias) | low risk          | Double-blinded and placebo-controlled                                                   |
| Blinding of outcome assessment (detection bias) | low risk          | Double-blinded and placebo-controlled                                                   |
Incomplete outcome data (attrition bias)
All outcomes

Low risk
Only 2 patients in TCM group early stopped.

Selection reporting (reporting bias)

low risk
The protocol of the trial was clear, so the possibility of selection outcome reporting could be examined by the review authors

Other bias

Unclear risk
The intervention groups were comparable, as it listed comparison of clinical characteristics between two groups and no significant difference found. Other aspects of bias were unclear

Tong XL 2013

The safety and effectiveness of TM81, a Chinese herbal medicine, in the treatment of type 2 diabetes: a randomised double-blind placebo-controlled trial

**Methods**

Parallel randomised large-scale, placebo-controlled, clinical trial of Chinese herbal medicine compared with placebo

Randomisation ratio: 3:1

**Participants**

Ethnic: Chinese n=480 (TM81 group 360, placebo group 120)

Inclusion criteria: T2DM early-stage WHO 1999, 30-65 years old, BMI ≥ 24kg/m². After the initial screening, subjects entered a 2-week run-in period with diet control and programmed daily exercise. Then subjects still with HbA1C ≥7.0% and FPG level between 7.0 and 13.9mM or 2hPG>11.1mM were enrolled. A consent form was signed by all subjects prior to enrolment

Exclusion criteria: have been treated for diabetes for > 1 month by conventional medications, physical therapy, psychological therapy, herbal medicine or dietary supplements; have been treated with antidiabetic drugs 3 weeks prior to screening; have had diabetic ketoacidosis or serious infections within 1 month; have uncontrolled hypertension; pregnant females, or those planning to be pregnant; breast feeding; have hepatic and renal dysfunctions, pulmonary function insufficiency, cardiac failure, acute myocardial infarction and other serious diseases; have severe chronic diabetic complications; chronic gastrointestinal diseases, or that are generally not healthy; allergic to Chinese herbal medicines; have mental...
disorders; on-going allergic symptoms; participating in other clinical trials or prior participation in TM81 trials; alcoholism, taking antipsychotic agents or substance abuse or dependence; have factors that may affect trial execution based on investigator’s judgement, such as changeable working and living environments that may lead to withdrawal from the trial; have unstable antihypertension effects during drug administration; or taking weight-loss medicines

| Interventions | Number of study centres: 10  
| Setting: patients in university affiliated hospital  
| Intervention: both groups have diet control and programmed daily exercise  
| TM81 group: TM81 (Tang-Min-Ling-Wan) formula: quantitative control limits raw herbs of Rhizoma Coptidis, Radix Paeoniae Alba, radix Scutellariae, Pericarpium Citri Reticulatae, Rhizoma Rhei and other Chinese herbs  
| Placebo group: placebo capsulated in similar packing, appearance, shape, size and colour with TM81 capsule |

| Outcomes | After treatment, the decrease of HbA1C, FPG and PG is statistically significant in TM81 group compared to placebo group. The TM81 was more effective for patients with higher baseline HbA1C levels. The TM81 group also showed improved β-cell function and increased homeostatic model assessment. Body weight, BMI and waist circumstance of subjects in TM81 group reduced and the symptoms related to diabetes were improved.  
| During the trial, there were no medium or serious adverse events reported. 24 mild adverse events reported in the TM81 group versus 7 mild adverse events reported in the placebo group. There was one case with abdominal cramping and diarrhoea that disappeared shortly without treatment. No abnormal ECG, hepatic functions or rental functions observed at week 12. There were no significant differences in the types and frequency of adverse reactions between two groups.  
| Outcomes were assessed at baseline and trial completion |

| Study details | Duration of intervention: 12 weeks  
| Duration of Follow-up: week 0, Week 4, week 8 and week 12  
| Run-in period: 2 weeks |

| Stated aim of study | “To evaluate the safety and effectiveness of TM81 in the treatment of type 2 diabetes patients.” |
| Risk of bias                      | Authors judgement | Support for judgement |
|----------------------------------|-------------------|-----------------------|
| **Random sequence generation**   | low risk          | It mentioned in the trial "randomization and blinding were conducted by personnel who did not participate in data acquisition and evaluation. A computer program used to generate the subject assignment. Each subject was given a unique number and this number was used throughout the trial." |
| **Allocation concealment**       | low risk          | It mentioned in the trial "randomization and blinding were conducted by personnel who did not participate in data acquisition and evaluation. A computer program used to generate the subject assignment. Each subject was given a unique number and this number was used throughout the trial." |
| **Blinding of participants and personnel** | low risk | All investigators blinded from the study drug assignment, in which only a randomization code disclosed. Unblinding was conducted only after all study data were collected |
| **Blinding of outcome assessment** | low risk          | All investigators blinded from the study drug assignment, in which only a randomization code disclosed. Unblinding was conducted only after all study data were collected |
| **Incomplete outcome data**      | Low risk          | 68 subjects in the TM81 group and 13 subjects in the placebo group dropped out. The proportion of missing outcomes is 16.88% which is not enough to have a clinically relevant impact on the intervention effect estimate compared with observed event risk |
| **Selection reporting**          | low risk          | The protocol of the trial was clear, so the possibility of selection outcome reporting could be examined by the review authors |
| **Other bias**                   | Unclear risk      | The intervention groups were comparable, as it listed comparison of baseline data between two groups and |
no significant difference found for most of baseline items apart from HbA1C and 2hPG. Other aspects of bias were unclear

Deng DQ 2015

Study on Treatment of Reinforcing Spleen and dissipating Dampness and Promoting Blood Circulation (TRDP) on the Function of Pancreatic βCells in Patients with Type 2 Diabetes Mellitus

| Methods       | Randomised controlled clinical trial of combined medicine (Chinese herbal medicine + other pharmaceuticals) compared with other pharmaceuticals alone and Chinese herbal medicine alone
|               | Randomisation ratio: 1:1:1 |
| Participants  | Ethnic: Chinese n=90 (30 in each of TCM, western medicine and TCM combined with western medicine)
|               | Inclusion criteria: T2DM WHO 1999; TCM differentiations: spleen deficiency with dampness stagnation and blood stasis, blood sugar is still abnormal after dietary and exercise therapy, initially occurred T2DM
|               | Exclusion criteria: type 1 diabetes ketoacidosis or diabetes hypertonic coma, or combine with moderate or over hypertension, coronary disease myocardial infarction, severe arrhythmia, liver kidney hemopoietic system and other severe complications, allergy to the study drugs or have acute hyperglycemia due to other diseases |
| Interventions | Number of study centres: 1
|               | Location: China
|               | Setting: patients in TCM university hospital
|               | Intervention: dietary control and exercise therapy
|               | TCM group: strengthen spleen eliminate dampness and move the blood
|               | Western medicine group: Pioglitazone
|               | TCM combined with western medicine group: TCM (Cangzhu, Baizhu, Fuling, Chenpi, Houpo, Cheqianzi, Zexie, Honghua, Sangshen, huzhang, Guijianyu) + Pioglitazone |
| Outcomes      | After treatment, FBG, PBG, HbA1c, FINS, IAI, HOMA-IR, HOMA-β, IL-6, TNF-α of three groups decreased significantly than those before treatment (P>0.05). TCM |
The combined Western medicine group was more effective than the two other groups (P<0.05).

No information was reported in terms of adverse effects in this study.

Outcomes were assessed at baseline and trial completion:

| Study details | Duration of intervention: 2 months |
|---------------|-----------------------------------|
|               | Duration of follow-up: not reported |
|               | Run-in period: not described       |

**Stated aim of study**

“To explore the effects of TRDP on β cell function in the treatment of type 2 diabetes mellitus.”

**Risk of bias**

| Bias                                      | Authors judgement | Support for judgement                                                                 |
|-------------------------------------------|-------------------|---------------------------------------------------------------------------------------|
| Random sequence generation (selection bias) | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Allocation concealment (selection bias)   | unclear risk      | It only mentioned in the trial that “patients were randomly divided into treatment group and control group” |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | The information was not reported in this study |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | The information was not reported in this study |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias)      | Unclear risk      | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias                                | Unclear risk      | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of |
age, sex and medical conditions. Other aspects of bias were unclear

Ge SM 2012

Clinical effect of the “Eight method of Fan’s in the treatment of early type 2 diabetes in 30 patients

| Methods | Randomised controlled clinical trial of Chinese herbal medicine compared with other pharmaceuticals alone as well as diet control and exercise therapy  
|         | Randomisation ratio: 1:1:1 |
|         |                          |
| Participants | Ethnic: Chinese n=90 (30 in each of TCM treatment group, WM treatment group and control group)  
|              | Inclusion criteria, T2DM WHO 1999; early diagnosed T2DM within half year; age≥30 y; have or not used hypoglycemia treatment with western medicine or insulin; stop using western medicine, insulin, TCM or patent TCM for over 2 weeks; cooperate with diet and exercise therapy; have no significant life event before and after treatment; stable emotion, regular life, diet and exercise are stable.  
|              | Exclusion criteria: not described |
| Interventions | Number of study centres: 1  
|              | Location: China  
|              | Setting: outpatients in medical university hospital  
|              | Intervention:  
|              | Chinese medicine treatment group: pure TCM treatment with The Eight method of Fan’s method based on syndrome differentiation (Kidney deficiency: Gouji, Chuanduan, Nuzhenzi, Hanliancao; Qi and Yin deficiency: Beiqi, Shengdi, Digupi; Liver qi stagnation: Chaihu, Baishao, Bohe, Danpi; Lung Stomach heat: Shigao, Zhimu, Gegen, Lianqiao; Fuexcess with constipation: Dahuang, Zhishi, Huomaren; Heart spirit lose nourishment: Yejiateng, Yuanzhi, Suanzhaoren; Heat into blood fen: Danpi, Chishao, Maidong, Yimi, Mianyinchen; Excess dampness restrict spleen: Fuling, Chaobaizhu, Fabanxia, Shenqu; add Laifuzi, Zhiqiao, Chuanpu for stomach bloat; add Gualoupi, Xiebai for chest depression; Blood stasis: Danshen, Sanleng, Ezhu, Zelan)  
|              | Acarbose treatment group: acarbose  
|              | Control group: dietary and exercise therapy |

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Outcomes | FBG, PBG, HbA1c, TG, CH, Cr, clinical symptoms were measured. The effective rates were 83.3% in Chinese medicine treatment group and 80% in acarbose treatment group with no significant difference. The effective rates of two groups were higher than that of the control group with statistically significant difference. No information was reported in terms to adverse effect in this study. Outcomes were assessed at baseline and trial completion.

Study details | Duration of intervention: 6 months
| Duration of Follow-up: not reported
| Run-in period: not described

Stated aim of study | “To observe clinical effect of 'The Eight method of Fan’s’ to treat type 2 diabetes.”

Risk of bias

| Bias | Authors judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into Chinese medicine group, the acarbose treatment group and the control group” |
| Allocation concealment (selection bias) | unclear risk | It only mentioned in the trial that “patients were randomly divided into Chinese medicine group, the acarbose treatment group and the control group” |
| Blinding of participants and personnel (performance bias) | Unclear risk | No detail information reported in this study, and only mentioned it was single-blinded trial. |
| Blinding of outcome assessment (detection bias) | Unclear risk | No detail information reported in this study, and only mentioned it was single-blinded trial. |
| Incomplete outcome data (attrition bias) | Low risk | No exclusion or losses were reported, but the number of participants remained the same at the endpoint of study |
| Selection reporting (reporting bias) | Unclear risk | The protocol of the trial was not available, so the possibility of selection outcome reporting could not be examined by the review authors |
| Other bias | Unclear risk | The intervention groups were comparable, as it mentioned in the trial “no significant difference was found between groups on general backgrounds of sex, age and so on. Other aspects of bias were unclear. |
Table 3. Characteristics of excluded studies [ordered by study ID]

| Study           | Reason for exclusion |
|-----------------|----------------------|
| Cao YX 2015     | Duration of study 30 days |
| Deng LN 2007    | Duration of study 2 weeks |
| Zeng YP 2006    | Duration of study 2 weeks |
| Fan GJ 2006     | Duration of study 4 weeks |
| Shi YH 2014     | Duration of study 4 weeks |
| Tong BL 2007    | Duration of study 6 weeks |
| Chen ZQ 2006    | Duration of study 4 weeks |
| Lv WZ 2008      | Duration of study 1 month |
| Yu H 2009       | Duration of study 2 weeks |
| Chen XJ 2010    | Duration of study 4 weeks |
| Wang GL 2012    | Duration of study 20 days |
| Han F 2014      | Duration of study 4 weeks |
| Liu YH 2015     | Duration of study 30 days |
| Tian YH 2010    | Duration of study 30 days |
| Wu WY 2004      | Duration of study 4 weeks |
| Hu MF 2008      | Duration of study 45 days |
| Xu MY 2013      | Duration of study 30 days |
| Hu JG 2013      | Duration of study 30 days |
| Shi J 2011      | Duration of study 4 weeks |
| Tang XY 2012    | Duration of study 4 weeks |
| Wang JS 2008    | Duration of study 4 weeks |
| Guo YQ 2015     | Duration of study 30 days |
| Zhong YZ 2012   | Not mention the duration of study |
| Author     | Year | Study Type                      | Duration/Method                                                                 |
|------------|------|---------------------------------|--------------------------------------------------------------------------------|
| Chen Q     | 2006 | Not mention the duration of study, non-randomised study |                                                                       |
| Zhu YL     | 2015 | Duration of study 4 weeks, non-randomised study |                                                                       |
| Liu Y      | 2014 | Duration of study 2 weeks, testing TCM herb extract |                                                                       |
| Xie XN     | 2012 | Duration of study 4 weeks, combined acupoint injection with TCM herb extract therapy |                                                                       |
| Huang TS   | 2015 | Duration of study 1 month, combined acupoint injection with TCM herb extract therapy |                                                                       |
| Yan YJ     | 2007 | Duration of study 1 month, combined with ear acupuncture treatment |                                                                       |
| Chen DS    | 2007 | Multiple study centre randomized single-blinded controlled trial, duration of study 4 weeks |                                                                       |
| Ning HJ    | 2015 | Non-randomized study, combined with acupuncture and Tui Na treatment |                                                                       |
| Liu HY     | 2008 | RCT testing TCM herb extract berberine |                                                                       |
| Gan JR     | 2012 | RCT testing TCM herb extract berberine in treatment of adverse effect caused by T2DM drug |                                                                       |
| Zhao MY    | 2013 | Non-randomized controlled study |                                                                       |
| Zhang LB   | 2014 | Non-randomized controlled study (pseudo RCT) |                                                                       |
| Li MH      | 2011 | Non-randomized controlled study (pseudo RCT) |                                                                       |
| Zhou XL    | 2013 | Non-randomized control study (pseudo RCT) |                                                                       |
| Ren C      | 2012 | Non-randomized controlled study (pseudo RCT) |                                                                       |
| Lin ZR     | 2010 | Non-randomized controlled study |                                                                       |
| Mo JF      | 2013 | Non-randomized concurrent controlled trial |                                                                       |
| Yu ZF      | 2011 | Non-randomized controlled study |                                                                       |
| Jin YH     | 2015 | Retrospective randomized controlled study |                                                                       |
| Chen GH    | 2006 | Case series |                                                                       |
| Zheng M    | 2006 | RCT compared different herbal medicines |                                                                       |
| Wang WH    | 2010 | Randomized double blinded controlled trial compared different herbal medicines |                                                                       |
| Su XY      | 2015 | RCT compared different herbal medicines |                                                                       |
| He CL      | 2013 | Case series study of carotid artery intima-media thickness and lipid of type 2 diabetes artery atherosclerosis |                                                                       |
| Ma RW      | 2010 | RCT study of treating T2DM complication – diabetic macro-vascular disease |                                                                       |
| Fang ZH    | 2009 | RCT study of impaired blood vessel endothelium in prothrombotic state of T2DM |                                                                       |
| Sun XZ     | 2011 | RCT study of treating T2DM carotid atherosclerotic plaque |                                                                       |
| Jiang T    | 2014 | RCT study of treating T2DM with carotid plaques |                                                                       |

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| Author          | Year | Study Description                                                                 |
|-----------------|------|-----------------------------------------------------------------------------------|
| Peng GH         | 2015 | RCT study of treating T2DM with peripheral neuropathy                             |
| Li C            | 2012 | Non-randomized controlled trial study of treating T2DM peripheral neuropathy       |
| Zhang XZ        | 2014 | RCT study of treating peripheral neuropathy in T2DM due to damp-heat flowing down |
| Shu JP          | 2014 | RCT study of treating nerve condition velocity in T2DM peripheral nerve            |
| Shen XR         | 2015 | RCT study of treating T2DM angiopathy                                             |
| Xiao RR         | 2013 | RCT study of treating T2DM with peripheral neuropathy                              |
| Chen Y          | 2014 | RCT study of treating T2DM peripheral neuropathy                                  |
| Sun YR          | 2012 | RCT study of treating T2DM peripheral neuropathy                                  |
| Wen ZM          | 2012 | Non-randomized controlled trial study of treating T2DM complication – diabetic nephropathy |
| Xu ZL           | 2014 | RCT study of treating early T2DM nephropathy                                      |
| Li JW           | 2013 | RCT study of preventing early T2DM nephropathy                                     |
| Kong LX         | 2014 | RCT study of treating T2DM with membranous nephropathy                             |
| Du YB           | 2011 | RCT study of treating early and metaphase T2DM nephropathy                         |
| Jiang XY        | 2005 | RCT study of treating late T2DM nephropathy                                       |
| Feng SH         | 2015 | RCT study of treating elderly T2DM nephropathy                                    |
| Wei QL          | 2006 | RCT study of early diabetic nephropathy                                           |
| Miao JY         | 2013 | RCT study of treating T2DM complicated with non-alcoholic steatohepatitis         |
| Xiao FY         | 2012 | RCT study of treating T2DM complicated with non-alcoholic fatty liver disease      |
| Wu LK           | 2012 | RCT study of treating T2DM combined with fatty liver disease                       |
| Zou H           | 2012 | RCT study of treating T2DM with fatty liver disease                                |
| Wu LK           | 2011 | RCT study of treating fatty liver in T2DM                                         |
| Meng LW         | 2015 | RCT study of treating T2DM and dyslipidemia                                       |
| Zhao FH         | 2012 | RCT study of treating T2DM with dyslipidemia and its effect to weight, BMI, FBG, P2HGB, HbA1c and blood fat |
| Zhao X          | 2012 | RCT study of treating T2DM complicated with depression                             |
| Jia SQ          | 2009 | RCT study of treating T2DM accompanied by depression                              |
| Sui JX          | 2015 | RCT study of prevention of diabetic retinopathy                                   |
| Zhang M         | 2010 | RCT study of treating obese diabetes eye ground hemorrhage                         |
| Huo JJ          | 2015 | RCT study of treating T2DM with hyperuricemia                                     |
| Lu XR           | 2013 | RCT study of treating T2DM and hypertension                                       |
| Jiang D         | 2009 | RCT study of treating T2DM complicated with hypertension                          |
| Author          | Year | Study Title                                                                 |
|-----------------|------|-------------------------------------------------------------------------------|
| Jiao YP         | 2013 | RCT study of treating hypertension with T2DM                                  |
| Dang ZL         | 2014 | RCT study of treating T2DM complicated with gastroesophageal reflux disease  |
| Su H            | 2008 | RCT study of treating T2DM gastroparesis                                     |
| Xu HJ           | 2014 | RCT study of treating T2DM secondary constipation                             |
| Zhang YD        | 2009 | RCT study of treating constipation in T2DM                                   |
| LJ              | 2015 | RCT study of T2DM cardiovascular disease autonomic neuropathy heart rate variability |
| Shi BD          | 2015 | RCT study of treating T2DM urinary tract infection                           |
| Guan JT         | 2014 | RCT study of treating T2DM with acute cerebral infarction                     |
| Shen HH         | 2013 | RCT study of treating T2DM and periodontal disease                           |
| Li SF           | 2011 | Prospective randomised controlled study of treating chronic diabetic foot ulcers |
| Liu Q           | 2013 | RCT study of treating T2DM by pharmaceuticals with total alkali from morus folium jiangtang capsule |
| Xu J            | 2008 | RCT study of changes in vascular endothelial cell active factors in T2DM and treating of diabetes complications |
| Wang X          | 2007 | RCT study of TCM on inflammatory factor of earlier period T2DM. and the protocol and drugs of the trial are very similar with one of included studies (Guan X 2006) |
| Ye X            | 2014 | RCT study of treating T2DM, but have no mention of treatment method and intervention medicine. |
| Li XH           | 2010 | RCT study of treating T2DM, but have no mention of intervention medicine for control group. |
| Cai HZ          | 2015 | RCT study of testing TCM herb extract                                         |
| Qiang G         | 2015 | RCT study of treating T2DM with vascular dementia                            |
| Shi G           | 2015 | RCT study of treating T2DM complicated with pulmonary tuberculosis           |
| Li ZQ           | 2013 | RCT study of T2DM treatment with TCM herb, but no details of treating herbs due to full text is not available |
| Leung P.C       | 2012 | RCT study of TCM herbal formula treatment for T2DM patients with chronic ulcers |
| Fang ZH         | 2013 | RCT study of treating T2DM vascular lesions                                  |
| Ni Q            | 2012 | RCT study of treating type 2 pre-diabetes                                    |
| Tian GQ         | 2008 | RCT study of treating T2DM complicated with hyperlipidemia, but no details of treating herbs due to full text is not available |
| Zuo GL 2009 | RCT study of treating T2DM with atherosclerosis |
|----------|-----------------------------------------------|
| Uno T 2005 | Non-RCT study with study duration 1 month |
| Zhang Y 2015 | RCT study of treating T2DM with multi-centres and big samples, but won’t be completed until early-2016 (only available for the letter to the editor) |

Table 4. List of Chinese herbal medicines used as treatment for type 2 diabetes

| No. | Pharmaceutical name       | Botanical name                                                                 | Chinese Pinyin name |
|-----|--------------------------|-------------------------------------------------------------------------------|---------------------|
| 1   | Astragali Radix          | Astragalus membranaceus (Fisch.) Bge.                                         | Huangqi             |
| 2   | Rehmanniae Radix         | Rehmannia glutinosa Libosch.                                                 | Shengdihuang        |
| 3   | Rehmanniae Radix Praeparata | Rehmannia glutinosa Libosch.                                                 | Shudihuang          |
| 4   | Salviae Miltiorrhizae Radix et Rhizoma | Salvia miltiorrhiza Bge.                                                      | Danshen             |
| 5   | Achyranthis Bidentatae Radix | Achyranthes bidentata Bl.                                                     | Niuxi               |
| 6   | Paeonieae Rubra Radix    | Paeonia lactiflora Pall.                                                      | Chishao             |
| 7   | Coptidis Rhizoma         | Coptis chinensis Franch.                                                      | Huanglian           |
| 8   | Polygonati Rhizoma       | Polygonatum sibiricum Red.                                                    | Huangjing           |
| 9   | Puerariae Radix          | Pueraria lobata (Willd.) Ohwi                                                  | Gegen               |
| 10  | Epimedii Folium          | Epimedium brevicomu Maxim.                                                    | Yinyanghuo          |
| 11  | Talcum                   | Magnesium Silicate                                                             | Hua Shi Fen         |
| 12  | Artemisiae Scopariae Herba | Artemisia capillaris Thunb.                                                   | Yinchen             |
| 13  | Scutellariae Radix       | Scutellaria baicalensis Georgi                                                | Huangqin            |
| 14  | Aconi Tatarinowii Rhizoma | Acorus tatarinowii Schott; Acorus gramineus Soland.                           | Shichangpu          |
| 15  | Agastaches Herba         | Agastache rugosa (Fisch & Mey.) O. Ktxe.                                     | Huoxiang            |
| 16  | Fritillariae Cirrhosae Bulbus | Fritillaria cirrhosa D. Don                                               | Chuanbeimu          |
| 17  | Forsythiae Fructus       | Forsythia suspensa (Thunb.) Vahl                                              | Lianqiao            |
| 18  | Coicis Semen             | Coix lacryma-jobi L. var. mayuen (Roman.) Stapf                              | Yiyiren             |
| No. | Common Name | Scientific Name | Traditional Name |
|-----|-------------|-----------------|------------------|
| 19  | Dioscoreae Rhizoma | Dioscorea opposita Thunb. | Shanyao |
| 20  | Crataegi Fructus | Crataegus pinnatifida Bge. | Shazha |
| 21  | Hirudo | Hirudo orientalis, Hirudo troctina, and Hirudo verbana | Shuizhi |
| 22  | Semen Sinapsis seu Brassicae | Sinapis alba (L.) Boiss; Brassica Juncea (L.) Czern. | Baijiezi |
| 23  | Litchi Semen | Litchi chinensis Sonn. | Lizhihe |
| 24  | Ecliptae Herba | Eclipta prostrata L. | Mohanlian |
| 25  | Eupatori Herba | Eupatorium fortunei Turcz. | Peilan |
| 26  | Atractylodis Rhizoma | Atractyloides chinensis (DC.) Koidz. | Cangzhu |
| 27  | Centelleae Herba | Centella asiatica (L.) Urb. | Jixuecao |
| 28  | Smilacis Glabrae Rhizoma | Smilax glabra Roxb. | Tufuling |
| 29  | Trichosanthis Radix | Trichosanthes kirilowii Maxim./ Trichosanthes rosthronii Harms | Tianhuafen |
| 30  | Gypsum Fibrosum | Gypsum fibrosum | Shigao |
| 31  | Anemarrhenae Rhizoma | Anemarrhena asphodeloides Bge. | Zhimu |
| 32  | Ophiopogonis Radix | Ophiopogon japonicus (L.f) KerGawl. | Maidong |
| 33  | Radix Aconitii Lateralis Praeparata | Aconitum carmichaelii Debx. | Fuzi |
| 34  | Cinnamomi Cortex | Cinnamomum cassia Presl | Rougui |
| 35  | Cornu cervi pantotrichum | Cervus elaphus, Cervus nippon | Lurong |
| 36  | Rubi Fructus | Rubus chinii Hu | Fupenzi |
| 37  | Granati Pericarpium | Punica granatum L. | Shiliupi |
| 38  | Persicae Semen | Prunus persica (L.) Batsch/ Prunus davidiana (Carr.) Franch. | Taoren |
| 39  | Carthami Flos | Carthamus tinctorius L. | Honghua |
| 40  | Massa Fermentata Medicinalis | Artemisiae Annuae, Fructus Xanthii, Semen Armeniaceae Amarum, Semen Phascoli Calcarati | Shenqu |
| 41  | Hordei Fructus Germinatus | Hordeum vulgare L. | Maiya |
| 42  | Corydalis Rhizoma | Corydalis yanhusuo W.T. Wang | Yanhusuo |
| No. | Name | Common Name | Scientific Name | Pinyin |
|-----|-------|-------------|-----------------|--------|
| 43  | Bombyx Batryticatus | Bombyx mori L. (Fam. Bombycidae) | Jiangcan |
| 44  | Curcumae Radix | Curcuma wenyujin Y.H.Chen et C.Ling | Yujin |
| 45  | Codonopsis Radix | Codonopsis pilosula (Franch.) Nannf. | Dangshen |
| 46  | Glehniae Radix | Glehnia littoralis Fr. Schmidt ex Miq. | Beishashen |
| 47  | Pseudostellariae Radix | Pseudostellaria heterophylla (Miq.) Pax ex Pax et Hoffm. | Taizishen |
| 48  | Phellodendri Chinensis Cortex | Phellodendron chinense Schneid. | Chuanhuangbai |
| 49  | Chuanxiong Rhizoma | Ligusticum chuangxiong Hort. | Chuanxiong |
| 50  | Pheretima Earthworm | Pheretima aspergillum | Dilong |
| 51  | Dendrobii Caulis | Dendrobium nobile Lindl. | Shihu |
| 52  | Asparagi Radix | Asparagus cochinchinensis (Lour.) Merr. | Tianmendong |
| 53  | Citri Reticulatae Pericarpium | Citrus reticulata Blanco | Chenpi |
| 54  | Pinelliae Rhizoma | Pinellia ternata (Thunb.) Breit. | Banxia |
| 55  | Cassiae Semen | Cassia obtusifolia L. | Juemingzi |
| 56  | Alismatis Rhizoma | Alisma orientalis (Sam.) Juzep. | Zexie |
| 57  | Bambusae Caulis in Taenia | Bambusa tuldoides Munro | Zhuru |
| 58  | Arisaema Cum Bile | Arisaema erubescens (Wall.) Schott | Dannanxing |
| 59  | Scrophulariae Radix | Scrophularia ningpoensis Hemsl. | Xuanshen |
| 60  | Lycii Cortex | Lycium chinense Mill. | Digupi |
| 61  | Corni Fructus | Comus officinalis Sieb. et Zucc. | Shanzhuyu |
| 62  | Schisandraceae Chinensis Fructus | Schisandra chinensis (Turcz.) Baill. | WuweiZi |
| 63  | Mume Fructus | Prunus mume (Sieb.) Sieb. et Zucc. | Wumei |
| 64  | Angelicae Sinensis Radix | Angelica sinensis (Oliv.) Diels | Danggui |
| 65  | Paeoniae Alba Radix | Paeonia lactiflora Pall. | Baishao |
| 66  | Spatholobi Caulis | Spatholobus suberectus Dunn | Jixueteng |
| 67  | Lonicerae Japonicae Caulis | Lonicera japonica Thunb. | Rendongteng |
| 68  | Moutan Cortex | Paeonia suffruticosa Andr. | Mudanpi |
| No. | Latin Name                        | Chinese Name                      | Function |
|-----|----------------------------------|----------------------------------|----------|
| 70  | Lycopii Herba                    | Lycopus lucidus Turcz. var. hirtus Regel | Zelan    |
| 71  | Gardeniae Fructus               | Gardenia jasminoides Ellis       | Zhizi    |
| 72  | Atractylodis Macrocephalae       | Atractylodes macrocephala Koidz. | Baizhu   |
| 73  | Bupleuri Radix                  | Bupleurum chinense DC.           | Chaihu   |
| 74  | Herba Buchneriae                | Winged Euonymus Twig, Ramulus Euonymi | Guijianyu |
| 75  | Polygoni Multiflori Radix       | Polygonum multiflorum Thunb.     | Heshouwu |
| 76  | Cuscutae Semen                  | Cuscuta chinensis Lam.           | Tusizi   |
| 77  | Morindae Officinalis Radix      | Morinda officinalis How          | Bazitian |
| 78  | Eucommia Cortex                 | Eucommia ulmoides Oliv.         | Duzhong  |
| 79  | Polygonati Odorati Rhizoma      | Polygonatum odoratum (Mill.) Druce | Yuzhu   |
| 80  | Mori Cortex                     | Morus alba L.                    | Sangbaipi |
| 81  | Mori Folium                     | Morus alba L.                    | Sangye   |
| 82  | Mori Ramulus                    | Morus alba L.                    | Sangzhi  |
| 83  | Nelumbinis Rhizomatis Nodus     | Nelumbo nucifera Gaertn.         | Oujie    |
| 84  | Glycyrhizae Radix               | Glycyrrhiza uralensis Fish.      | Gancao   |
| 85  | Lycii Fructus                   | Lycium barbarum L.              | Gouqizi  |
| 86  | Tetrapanacis Medulla            | Tetrapanax papyrifer (Hook.) K. Koch | BaiKouren |
| 87  | Lablab Album Semen              | Dolichos lablab L.               | Baibiandou |
| 88  | Lonicerae Flos                   | Lonicera macranthoides Hand. - Mazz.; Lonicera hypoglauca Miq. ; Lonicera confuse DC.; Lonicera fulvotomentosa Hsu et S.C. Cheng | Jinyinhua |
| 89  | Ginseng Radix                   | Panax ginseng C. A. Mey.         | Renshen, |
| 90  | Dianthi Herba                    | Dianthus superbus L.             | Qumai    |
| 91  | Stephaniae Tetrandrae Radix     | Stephania tetrandra S. Moore     | Fangji   |
| No. | Chinese Name                      | Latin Name                                                                 | English Name     |
|-----|----------------------------------|-----------------------------------------------------------------------------|------------------|
| 92  | Tribuli Fructus                  | Tribulus terrestris L.                                                      | Cijili           |
| 93  | Trichosanthis Fructus            | Trichosanthes kirilowii Maxim. ; Trichosanthes rosthronii Hamss              | Gualou           |
| 94  | Allii Macrosteononis Bulbus       | Allium macrostemon Bge. ; Allium chinense G. Don                            | Xiebai           |
| 95  | Cynomorii Herba                  | Cynomorium songaricum Rupr.                                                | Suoyang          |
| 96  | Gastrodiae Rhizoma               | Gastrodia elata Bl.                                                        | Tianma           |
| 97  | Ootheca Mantidis                 | Paratenodera Sinensis, P. augustipennis Saussure, Statilia maculata...      | Sangpiaoxiao     |
| 98  | Herba Epimedi                    | Epimedium grandiflorum Morr.                                               | Xianlingpi       |
| 99  | Platycondonis Radix              | Platycondon grandiflorum (Jacq.) A. DC.                                    | Jiegeng          |
| 100 | Ziziphi Spinosaes Semen          | Ziziphus jujuba Mill. var. spinosa (Bunge) Hu ex H. F. Chou                | Suanzaoren       |
| 101 | Aurantii Immaturus Fructus       | Citrus aurantium L.                                                        | Zhishi           |
| 102 | Cyperi Rhizoma                   | Cyperus rotundus L.                                                        | Xiangfu          |
| 103 | Stylus Zea Maydis                |                                                                            |                  |
| 104 | Ligustri Lucidi Fructus          | Ligustrum lucidum Ait.                                                     | Nuzhenzi         |
| 105 | Laminariae Thallus               | Laminaria japonica Aresch. ; Ecklonia kurome Okam.                          | Kunbu            |
| 106 | Aurantii Fructus                 | Citrus aurantium L.                                                        | Zhiqiao          |
| 107 | Eriobotryae Folium               | Eriobotrya japonica (Thunb.) Lindl.                                        | Pipaye           |
| 108 | Menthae Herba                    | Mentha haplocalyx Briq.                                                     | Bohe             |
| 109 | Cibotii Rhizoma                  | Cibotium barometz (L.) J. Sm.                                               | Gouji            |
| 110 | Dipsaci Radix                    | Dipsacus asper Wall. ex Henry                                              | Xuduan           |
| 111 | Menthae Herba                    | Mentha haplocalyx Briq.                                                     | Bohe             |
| 112 | Fructus Cannabis.                | Cannabis sativa L. Common Name: Cannabis seed, Hemp seed.                  | Huomaren         |
| 113 | Caulis Polygoni Multiflori.      | Polygonum multiflorum Thunb. (Polygonaceae).                               | Yejiatoeng       |
| 114 | Polygalae Radix                  | Polygala tenuifolia Wild. ; Polygala sibirica L.                            | Yuanzhi          |
| 115 | Plantaginis Herba                | Plantago asiatica L. ; Plantago depressa Wild.                             | Cheqiancao       |
| 116 | Raphani Semen                    | Raphanus sativus L.                                                         | Laifuzi          |
| No. | Common Name | Latin Name                                                                 | Location |
|-----|-------------|---------------------------------------------------------------------------|----------|
| 117 | Spargani Rhizoma | Sparganium stoloniferum Buch. - Ham.                                      | Xiapu    |
| 118 | Curcumae Rhizoma | Curcuma phaeocaulis Val.                                                  | Sanleng  |
| 119 | Ginseng Radix et Rhizoma Rubra | Panax ginseng C. A. Mey.                                                  | Ezhu     |
| 120 | Endothelium Corneum Gigeriae Galli. | Gallus gallus domesticus Brisson                                           | Ganjiang |
| 121 | Amomi Fructus | Amomum villosum Lour. ; Amomum villosum Lour. var. xanthioides T. L. Wu et Senjen ; Amomum longiligulare T. L. Wu | Sharen   |
| 122 | Chaenomelis Fructus | Chaenomeles speciosa (Sweet) Nakai                                          | Mugua    |
| 123 | Citri Exocarpium Rubrum | Citrus reticulata Blanco                                                  | Juhong   |
| 124 | Lophatheri Herba | Lophatherum gracile Brongn.                                               | Danzhuye |
| 125 | Mombusa Barbatae Herba | Scutellariae barbata D. Don                                                | Banzhilian|
| 126 | Magnoliae Officinalis Cortex | Magnolia officinalis Rehd. et Wils.                                       | Houpo    |
| 127 | Plantaginis Semen | Plantago asiatica L. ; Plantago depressa Wild.                            | Cheqianzi|
| 128 | Mori Fructus | Morus alba L.                                                             | Sangshen  |
| 129 | Polygoni Cuspidati Rhizoma | Polygonum cuspidatum Sieb. et Zucc.                                      | Huzhang  |
Table 5. Abbreviations

|   | Abbreviation | Description                           |
|---|--------------|---------------------------------------|
| 1 | TCM          | Traditional Chinese Medicine          |
| 2 | WHO          | World Health Organisation             |
| 3 | ADA          | American Diabetes Association         |
| 4 | HbA1C        | Glycated haemoglobin                  |
| 5 | FBG          | fasting blood glucose                 |
| 6 | 2hPBG        | 2 hour postprandial blood glucose     |
| 7 | TC           | Total cholesterol                     |
| 8 | TG           | Triglyceride                          |
| 9 | LDL-C        | Low-density lipoprotein-cholesterol   |
| 10| HDL-C        | High-density lipoprotein-cholesterol  |
| 11| BMI          | Body mass index                       |
| 12| HOMA-IR      | Homeostatic Model Assessment of Insulin Resistance. |
| 13| ISI / IAI    | insulin sensitivity index             |
| 14| ECG          | electrocardiogram                     |
| 15| RCT          | randomised controlled trial           |
| 16| T2DM         | type 2 diabetes mellitus              |