

1 **Appendix 1: Available published examples of good reporting of Chinese herbal**
2 **medicine formulas**

3

4 **Title, abstract and keywords**

5 *Item 1a. Statement of whether the trial targets on a TCM Pattern, a Western*
6 *medicine-defined disease or a Western medicine-defined disease with a specific TCM*
7 *Pattern, if applicable*

8 **Example** (Stating the trial of a CHM formula targeting on a Western
9 disease with a specific TCM Pattern)

10 “Efficacy of Zhenjingdingzhi decoction in treating insomnia with Qi-deficiency of
11 heart and gallbladder: a randomized, double-blind, controlled trial” (1).

12

13 *Item 1b. Illustration of the name and form of the formula used, and the TCM Pattern*
14 *applied, if applicable*

15 **Example** (A structured summary illustrating the name and form of a CHM formula
16 used and the TCM Pattern applied)

17 “Objective: To evaluate the clinical efficacy of Zhenjingdingzhi decoction in treating
18 insomnia with Qi-deficiency of heart and gallbladder.” (1).

19

20 *Item 1c. Determination of appropriate keywords, including “Chinese herbal*
21 *medicine formula” and “randomized control trial”*

22 **Example** (There are no available literatures with keywords “Chinese herbal medicine
23 formula” and “randomized controlled trial”).

24

25 **Background and Objectives**

26 *Item 2a. Statement with biomedical science approaches and/or TCM approaches*

27 **Example** (Including explanation with both biomedical science approach and TCM
28 approach)

29 “In Chinese medicine, the primary syndrome type of acute exacerbation of chronic
30 obstructive pulmonary disease (AECOPD) is phlegm-heat obstructing the lungs. The
31 actions of Xuan Bai Cheng Qi formula are to clear lung heat and dissipate phlegm, so
32 for this reason it is commonly prescribed for AECOPD. Xuan Bai Cheng Qi is a
33 classical prescription dating to the Qing Dynasty (late 1700s) text Systematic
34 Differentiation of Warm Pathogen Diseases by Wu Jutong. Our previous studies found
35 that Xuan Bai Cheng Qi improves oxidant/antioxidant imbalance, pulmonary
36 inflammation in the rat model of COPD. Clinical studies have postulated that Xuan
37 Bai Cheng Qi is effective as a supplementary remedy for treating AECOPD or
38 respiratory failure.” (2)

39

40 *Item 2b. Statement of whether the formula targets a Western medicine-defined disease,*
41 *a TCM Pattern or a Western medicine-defined disease with a specific TCM Pattern*

42 **Example** (Illustrating the objectives of a trial targeting on a Western
43 medicine-defined disease with a specific TCM Pattern)

44 “We performed a multicenter, randomized, double-blind, placebo-controlled clinical
45 trial to evaluate the efficacy and safety of Xuan Bai Cheng Qi in the treatment of
46 acute exacerbation of chronic obstructive pulmonary disease (AECOPD) of the
47 syndrome type phlegm-heat obstructing the lungs.” (2)

48

49 **Participants**

50 *Item 4a. Statement of whether participants with a specific TCM Pattern were*
51 *recruited, in terms of i) diagnostic criteria, and ii) inclusion and exclusion criteria.*
52 *All criteria used should be universally recognized, or reference given to where*
53 *detailed explanation can be found.*

54 **Example** (Illustrating the diagnostic criteria and inclusion criteria of a TCM Pattern
55 with recognized reference)

56 “Patient selection and diagnostic criteria ... The TCM standard for diagnosing
57 syndromes was worked out with reference to the standard for diagnosing the type of
58 Liver stagnation and Spleen deficiency in the guidelines of diagnosing and treating
59 functional dyspepsia. Major symptoms are stomach pain or discomfort and anorexia
60 and loose stools. Minor symptoms include: (1) abdominal distention and pain; (2)
61 impatience; (3) insomnia and dreamful sleep; (4) belching and acid reflux; (5)
62 physical and mental fatigue; and (6) abdominal distention after eating. Patients with
63 all the major symptoms and two or more minor symptoms were diagnosed as
64 suffering from the syndrome of liver depression and spleen deficiency ... Inclusion
65 and exclusion criteria ... To be included in the study, patients had to meet the
66 following inclusion criteria ... (2).” (3)

67

68 **Interventions**

69 *Item 5. Description[s] for different types of formulas should include the following:*

70 **5A. For fixed CHM formulas**

71 *1. Name, source and dosage form (e.g. decoction, granules, power)*

72 **Example** (Illustrating the name, source and form of a CHM formula)

73 “Our group developed a Chinese herbal formula Yishen Huazhuo decoction (YHD) to
74 treat mild Alzheimer’s disease (AD)” (4)

75

76 *2. Name, source, processing method and dosage of each medical substance. Names of*

77 *substances should be presented in at least two languages: Chinese (PinYin), Latin or*
78 *English. Names of the parts of the substances used should be specified*

79 **Example** (Illustrating the names of all substances, dosage and processing method)

80 “The treatment group received ShengJinRunZaoYangXue granulesMaidong 10
81 g (Dwarf Lilyturf Tuber, Radix Ophiopogonis), Shihu 10g (Dendrobium, Herba
82 Dendrobii) and Zhigancao 6 g (Prepared Liaurice Root, Radix Glycyrrhizae
83 preparata).” (5)

84

85 *3. Authentication method of each ingredient, and how, when, where, by whom it was*
86 *conducted; statement of whether any voucher specimen were retained, and if yes,*
87 *where they were kept and whether they are accessible*

88 **Example** (Illustrating the authentication method of each ingredient and where
89 voucher specimen was kept)

90 “All crude herbal materials were obtained from a local company of herbal supply. The
91 identity of each herbal material, including habitat, harvest seasons, and the
92 preparation of crude material, were authenticated by a senior Chinese herbalist. A
93 sample specimen was kept in Department of Psychiatry, the First Hospital of Xian
94 Jiaotong University.” (6)

95

96 *4. Principles, rationale and interpretation of forming the formula*

97 **Example** (Illustrating the principles and rationale of forming the CHM formula)

98 “Zhenjingdingzhi decoction was extracted by the late Professor Jianhua Hu, Shanghai
99 famous specialist of TCM, originating from the therapy theory of tranquilizing mind
100 by nourishing the heart. It was based on the famous prescription Ganmaidazao
101 decoction from Prescriptions of the *Jin Kui Yao Lue • Fu Ren Za Bing* of Zhang
102 Zhongjing, adding Danshen (*Radix Salviae Miltiorrhizae*)..... Danshen (*Radix*
103 *Salviae Miltiorrhizae*) has the property of nourishing blood and tranquilizing
104 mind..... Compatibility of all the medicine makes therapeutic effect on nourishing
105 heart, tranquilizing, mind, resuscitation and relieve stasis.” (1)

106

107 *5. Reference(s) as to the efficacy of the formula, if any*

108 **Example** (Illustrating the efficacy of the CHM formula from previous study)

109 “Our own and prior studies suggest the potential efficacy of Chinese herbal medicine
110 (CHM) for IBS. By their complex pharmacologic nature CHM formulations offer a
111 novel approach by addressing the multifactorial nature of IBS.” (7)

112

113 *6. Pharmacological study results of the formula, if any*

114 **Example** (Illustrating the pharmacological activities of CHM formula studies)

115 “Modern pharmacologic research shows that saikoside has anti-inflammatory,
116 immunoregulatory and liver protective functions, but can also inhibit cholinesterase,
117 act as a quasi-choline sample and adjust the digestive and nervous systems
118 *White atractylodes rhizome* can activate the muscarinic receptors of the
119 gastrointestinal tract and acetylcholine receptors, and accelerate gastrointestinal
120 motility and evacuation. *Poria cocos* can increase 5-HT levels, indicating that the
121 Xiaoyao pill can alter central monoamine neurotransmitter and hormone levels”
122 (3)

124 *7. Production method of the formula, if any*

125 **Example** (Illustrating the production method of the formula)

126 “Xuan Bai Cheng Qi granules produced and packaged by Jiang Yin Tian Jiang
127 Pharmaceutical Co. Ltd. (Jiangsu, China) under good manufacturing practice
128 regulations of China (Approval Number: 0905301–4). Xuan Bai Cheng Qi granules
129 were prepared by decocting the four herbs together, resulting in a concentrated liquid
130 and extraction and capture of the volatile oils. The concentrated liquid was
131 spray-dried on a starch base powder to obtain the final product. Each package of
132 granules was 4.5 g.” (2)

134 *8. Quality control of each ingredient and of the product of the formula, if any. This
135 would include any quantitative and/or qualitative testing method(s); when, where,
136 how and by whom these tests were conducted; whether the original data and samples
137 were kept, and, if so, whether they are accessible*

138 **Example 1** (Illustrating the quality control of the CHM formula)

139 “Formulation stability and shelf-life testing was conducted across 36 months,
140 ensuring the formulation did not deteriorate” (7)

141 **Example 2** (Illustrating the quantitative and qualitative testing methods conducted)

142 “The XJXGF formula (Xin-Ju-Xiao-Gao-Fang formula) mainly consists of rhubarb,
143 coptis, semen cassia and citrus aurantium. Abundant compounds within XJXGF have
144 been separated and identified by HPLC chromatography (Fig. 1). The detected
145 compounds include gallic acid, geniposidic acid, verbascoside, naringin, berberine,
146 aurantio-obtusin, aloemodin, rhein, emodin, chrysophanol, and physcion.” (8)

148 *9. Safety assessment of the formula, including tests for heavy metals and toxic
149 elements, pesticide residues, microbial limit, and acute/chronic toxicity, if any. If yes,
150 it should be stated when, where, how and by whom these tests were conducted, if the
151 original data and samples were kept, and, if so, whether they are accessible*

152 **Example** (Illustrating the safety assessment of the formula)

153 “The finished product was certified to comply with pesticide residue levels,
154 microbiological contaminants, and heavy metals to TGA (Australian Therapeutic
155 Goods Administration standards).” (7)

156

157 *10. Dosage of the formula, and how the dosage was determined*

158 **Example** (Illustrating how the dosage of CHM formula was determined)

159 “The dose of 7.5g b.i.d. showed better therapeutic effect than that of 2.5 and 5.0 b.i.d.
160 among 96 subjects (32 per arm) in trial I and was therefore selected for comparison
161 with placebo in trial II.” (9)

162

163 *11. Administration route (e.g. oral, external)*

164 **Example** (Illustrating how the CHM formula was taken)

165 “The decoction was used (group A) to soak affected hands and feet, and hot water was
166 added to keep the decoction hotter than 39°C during soaking, once a day, for 30 min
167 each time, with 7 days as one course” (10)

168

169 **5B. For individualized CHM formulas**

170 *1. Same recommendations 5A 1-11*

171 **Example** (Please refer to Examples 5A1-11)

172

173 *2. Additional information: how, when and by whom the formula was modified.*

174 **Example** (Illustrating the details how the CHM formula was modified)

175 “The study intervention was planned by the investigator in cooperation with
176 experienced TCM herbalists (Yun Xiao Chen, Kassel, Germany and Andreas Holl,
177 Vienna, Austria). Four expected “clinical patterns” and matching herbal formulae
178 were defined (Table 1). the basic formulae were constituted (7–10 herbs)
179 The exact combination and dosage of herbs in the formulae reflected the clinical
180 opinion and experience of the investigator and the supervising doctors During
181 follow-up visits, the basic formulae could be substituted for one another or be adapted
182 according to symptoms by adding predefined herbs to the basic formulae (Table 1).”
183 (11)

184

185 **5C. For patent proprietary CHM formulas**

186 *1. Reference to publicly available materials, such as Pharmacopeia, for the details
187 about the composition, dosage, efficacy, safety, and quality control of the formula*

188 **Example** (Illustrating the reference for the detailed information)

189 “The Jinlida consists of 17 Chinese medicinal herbs, including ginseng, polygonati,
190 atractylodis lanceae, sophorae flavescens, ophiopogon japonicus, rehmanniae,

191 polygoni multiflori, dogwood, poria, perrin, coptis chinensis, anemarrhena,
192 epimedium, salvia, puerariae, semen litchi, and cortex lycii radices. The quality of
193 these herbs and decoction preparation was in accordance with the Chinese
194 Pharmacopoeia (2005).” (12)

195

196 *2. Illustration the details of the formula, namely i) the proprietary product name (i.e.*
197 *brand name), ii) name of manufacturer, iii) lot number, iv) production date and expiry*
198 *date, v) name and percentage of added materials; and vi) any additional quality*
199 *control measures were conducted*

200 **Example** (Illustrating the details of patent proprietary CHM formula)

201 “5-Ling Granule (5-LGr) were prepared by Tasly Pharmaceuticals Inc. (Tianjin,
202 China) (batch no.: 2007B01/2008101 for 5-LGr; The detailed manufacturing
203 procedure of 5-LGr has been posted in the website of the China Patent Inquiry System
204 and carried out in strict compliance with the standards of Good Manufacturing
205 Practice (GMP). Raw weight and ratio of herbal materials of 5-LGr are listed in Table
206 1.” (13)

207

208 *3. Statement of whether the patent proprietary formula is used in the trial for the*
209 *condition which is identical to the publicly available reference*

210 **Example** (Determining the patent proprietary formula is used in the trial for the
211 condition which is identical to the reference)

212 “Qili qiangxin capsules were approved by China Food and Drug Administration for
213 the treatment of heart failure in 2004. The current study evaluated the effects of qili
214 qiangxin capsules in patients with chronic heart failure.” (14)

215

216 **5D. Control groups**

217 *-Placebo control*

218 *1. Name and amount of each ingredient*

219 **Example** (Illustrating the ingredients in placebo)

220 “An inert placebo was designed matching CHM capsules in size, weight, color, taste,
221 and smell, consisting of cornstarch (80.48%), caramel (11.39%), citric acid (7.10%),
222 coloring (lemon yellow powder [H1794] 0.60% and brown powder [H9885].” (7)

223

224 *2. Description of the similarity of placebo with the intervention (e.g. color, smell,*
225 *taste, appearance, packaging)*

226 **Example** (Indicating the similarity of placebo with CHM formula)

227 “Both the placebo and herbal tablets were identical in shape, size, color and taste.
228 Furthermore, to minimize the effect of the distinctive smell of herbal preparations on

229 double blinding, the herbal tablets and placebo were all contained in blister packs
230 made from plastic film and aluminium foil, with six tablets in each blister pack.” (15)

231

232 *3 Quality control and safety assessment, if any*

233 **Example** (Illustrating the quality control and safety assessment of the placebo)

234 “Herbs of the control group were routinely examined to be free of contaminants by a
235 professional company (Mag. Ph.R. Kottas-Heldenberg und Söhne, Dragenhandel
236 GesmbH, Vienna, Austria).” (11)

237

238 *4. Administration route, regimen and dosage*

239 **Example** (Illustrating the administration route, regimen and dosage of placebo)

240 “Three bags (15g in granule) and 4.5 bags (22.5g in granule) of 5-LGr or matching
241 placebo granules per day were given to patients aged 5-12 and 13-18 years,
242 respectively. The assigned amount of granules (1 or 1.5 bag) was dissolved into
243 120-150ml of hot water and taken three times daily.” (13)

244

245 *5. Production information: where, when, how by whom the placebo was produced*

246 **Example** (Illustrating the producer information)

247 “5-Ling Granule and placebo granules used in this study were prepared by Tasly
248 Pharmaceuticals Inc. (Tianjin, China) (batch no.: 2007B01/2008101 for 5-LGr;
249 2007C01/2007L01 for placebo granules).” (13)

250

251 *-Active control*

252 *1. If a CHM formula was used, see the recommendations 5A to 5C*

253 **Example** (Please refer to Examples 5A1-5C3)

254

255 *2. If a chemical drug was used, see Item 5 of CONSORT statement (16)*

256 **Example** (Please refer to examples in CONSORT 2010 Explanation and Elaboration
257 [17])

258

259 **Outcomes**

260 **Item 6a.** *Illustration of outcome measures with Pattern in detail*

261 **Example** (Illustrating the assessment of outcomes with TCM symptoms, signs and
262 Pattern)

263 “We assessed each patient’s symptoms before and after treatment by means of a rating
264 scale (See Additional File 1), which was completed by the treating physicians when
265 they interviewed their patients before and after treatment (at baseline and week 4).
266 The rating scale consisted of 11 items (2 for the main symptoms, 7 for the

267 accompanying symptoms and 2 for tongue and pulse) with 2 (yes or no or 4 options
268 (absent, mild, moderate or severe) for each item. Each option was represented by a
269 fixed score, the higher the score, the more severe the symptom, and vice versa. The
270 total score of the rating scale was called syndrome integral.” (18)

271

272 **Harms**

273 **Item 19** (*There is no extension for this item*)

274 **Example** (Illustrating all important harms and unintended effects in each group)

275 “Two patients in the maxingshigan–yinqiaosan group had nausea and vomiting. No
276 side effects were observed in the control, oseltamivir, or combination therapy group.
277 No difference in complications after treatment was observed among the 4 groups: 1
278 case of pulmonary tuberculosis in the control group, 2 cases of pneumonia in the
279 oseltamivir group, 1 case of bronchitis in the maxingshigan–yinqiaosan group, and no
280 complications in the combination therapy group.” (19)

281

282 **Generalizability**

283 **Item 21** *Discussion of how the formula works on different TCM Patterns or diseases*

284 **Example** (Illustrating the potential application of study result for other Western
285 medicine-defined diseases in the same TCM Pattern)

286 “In TCM, syndromes are the foundations for therapeutic principles, and the same
287 method of treatment can be applied to patients with the same syndrome, no matter
288 what disease, as defined in Western terms, they have. In the present study, the
289 significance of the syndrome was maintained by recruiting only subjects with not only
290 functional constipation (a disease diagnosed by conventional medicine) but also the
291 “excessive” syndrome (a syndrome pattern diagnosed by TCM). Therefore, the results
292 of this study are useful for making clinical recommendations.” (9)

293

294 **Interpretation**

295 **Item 22** *Interpretation with TCM theory*

296 **Example** (Interpreting the results with TCM theory)

297 “Henoch-Schonlein purpura nephritis (HSPN) in children is mainly caused by
298 damp-heat and will further impair spleen and kidney. According to the pathogenesis
299 of HSPN, removing heat, promoting diuresis, nourishing kidney, and consolidating
300 essence can treat HSPN. Considering the physiological and pathological
301 characteristics of child patients, medicinal materials were selected to be slightly
302 purging and nourishing to strengthen body resistance and eliminate pathogenic factors.
303 Chinese herbs were used in this study to treat damp-heat syndrome. After treatment
304 for 4 and 12 weeks, the obvious decline in the total score of damp-heat confirms that

305 Chinese herbs have a good curative effect on alleviating syndromes and signs of
306 damp-heat in the acute stage (within 4 weeks) of the disease. From TCM theory, the
307 accumulation of dampness can affect spleen function and deficiency of spleen Qi
308 causes failure of the body to absorb nutrients ... Hematuria is mainly caused by
309 obstruction of collaterals by stasis and heat. The therapy puts more stress on clearing
310 damp-heat and attaches less importance to removing heat from blood, promoting
311 blood circulation, or removing blood stasis. However, this may clarify that internal
312 accumulation of damp-heat is the main syndrome of early-stage child HSPN. With a
313 long course of treatment, the improvement in total score for syndromes and the total
314 effective rate of urinary protein and urinary red cells were higher in the Chinese herb
315 group. This indicates that the internal accumulation of damp-heat is the main cause
316 for lingering illness and the therapy of clearing away heat, promoting diuresis, and
317 removing heat from blood should be adopted throughout the treatment.” (20)

318

319 **References**

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321 treating insomnia with Qi-deficiency of heart and gallbladder: a randomized,
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394

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