

# Needle Sensation and Personality Factors Influence Therapeutic Effect of Acupuncture for Treating Bell's Palsy: A Secondary Analysis of a Multicenter Randomized Controlled Trial

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## Abstract

**Background:** It has not been solved what kind of needle sensation might influence outcomes of acupuncture treatment. Effects of personality factors on the therapeutic effect of acupuncture have not been investigated. This study aimed to find the effects of the traits of personality on the objective outcome when different acupuncture techniques were used in treating patients with Bell's palsy.

**Methods:** We performed a secondary analysis of a prospective multicenter randomized controlled trial of acupuncture for Bell's palsy. Patients were randomly assigned to the de qi and control groups, respectively. The primary outcome was facial nerve function at month 6. The intensity of each needle sensation was rated by a visual analog scale. Psychosocial factors were assessed by the pretreatment mediator questionnaire; 16 Personality Factor Questionnaire (16PF) was used for assessing personality factors and digit cancellation test for assessing attention.

**Results:** After 6 months, patients in the de qi group had better facial function (adjusted odds ratio [OR]: 4.16, 95% confidence interval [CI]: 2.23–7.78). Path analysis showed that intensity of needle sensation of fullness had direct effect on House-Brackmann (HB) score at month 6. In de qi group, the low HB score on day 1 (OR: 0.13, 95% CI: 0.03–0.45) and the low Social Boldness score (OR: 0.63, 95% CI: 0.41–0.97) in 16PF were associated with better facial function. In control group, low HB score on day 1 (OR: 0.25, 95% CI: 0.13–0.50), low Vigilance score (OR: 0.66, 95% CI: 0.50–0.88), and high Tension score (OR: 1.41, 95% CI: 1.12–1.77) in 16PF were related to better facial function.

**Conclusions:** The needle sensation of fullness could predict better facial function and personality traits might influence outcomes of acupuncture treatment. Both of them should be considered seriously in acupuncture treatment and research.

**Key words:** 16 Personality Factor Questionnaire; Bell's Palsy; De Qi; Needle Sensation

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## INTRODUCTION

There is growing evidence from randomized controlled trials (RCTs) and meta-analyses that acupuncture had clinically significant effects (efficacy over placebo

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controls).<sup>[1-5]</sup> Recently, we have completed an RCT using acupuncture to treat Bell's palsy. The results have proved that acupuncture may also have clinically significant effects on objective functional outcome.<sup>[6]</sup> According to RCTs with subjective outcomes, compared with waiting list controls or "treatment as usual", both placebo acupuncture and real acupuncture might play important roles.<sup>[7]</sup> The difference between acupuncture and no acupuncture in effectiveness is often much greater than the difference between acupuncture and so-called "placebo acupuncture". Thus, psychosocial factors other than needle placement might be relevant to subjective outcomes of acupuncture. In particular, patients' beliefs about acupuncture could predict treatment outcomes in acupuncture for pain to a significant extent.<sup>[8]</sup>

According to the traditional Chinese acupuncture theory, two critical principles that are of the same importance in ensuring the effectiveness of acupuncture are "zhi shen" and "de qi". The one principle called "zhi shen" is gaining full control over the spirits of the patients and the acupuncturists.<sup>[9-11]</sup> The other one is named "de qi", a composite of unique sensations induced by needle insertion into the acupoint which has been widely investigated in recent years.<sup>[12]</sup> To ensure the effectiveness of acupuncture, during the whole acupuncture process including before needling, performing needling, and after needling, the acupuncturists were required to attend closely to the spiritual state of both acupuncturists and patients. The acupuncturists administrated the insertion until de qi was achieved by their patients. However, this important concept "zhi shen" in traditional Chinese acupuncture theory is hardly mentioned in western literature and emphasized in clinical practice in Western countries. What's more, among various kinds of needle sensations, what kind of needle sensation can predict outcomes of acupuncture treatment also remains undetermined. Thus, we analyzed the data on psychosocial factors from the above mentioned RCT to examine whether some quantifiable psychosocial measurements could improve the therapeutic effects of acupuncture treatment. Through rating different kinds of needle sensations by a visual analog scale, this study attempted to explore the relationship between each needle sensation and therapeutic effect of acupuncture.

## METHODS

### Data source

The study was approved by the Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology, and was conducted in accordance with the provisions of the *Declaration of Helsinki* (1975, amended 1983) and *Good Clinical Practice guidelines*. Written informed consent was obtained from each participant.

We analyzed data from a RCT designed to compare efficacy of acupuncture with either strong or weak stimulation among patients with Bell's palsy.<sup>[6]</sup> The patients were included as the following criteria: (1) must be unilateral facial nerve weakness without an identifiable cause

within 168 h after the onset of symptoms; (2) aged from 18 to 65 years; and (3) have not received any treatment before randomization. We excluded the patients who were illiterate, had facial paralysis caused by herpes zoster, had recurrent facial paralysis, had noticeable asymmetry of the face before the onset of illness (which may affect evaluation), or had a history of peptic ulcer disease, severe hypertension, uncontrolled diabetes, liver and kidney dysfunction, mental illness, or serious systemic diseases that might affect the treatment. The pregnant women were also excluded.

Our trial was guided by the CONSORT statement. The flowchart of this study is shown in Figure 1 and other study information is shown in Supplementary Material 1. Details of this study have been previously published.<sup>[6]</sup>

### Outcome assessment

The primary outcome was facial nerve function measured by the criteria of the House-Brackmann (HB) score.<sup>[13]</sup> The endpoint was Grade 1 on the HB score (complete recovery) at month 6. The HB scale is based on a six-grade score: Grade 1 indicates normal function and Grade 6 indicates complete paralysis. Patients were asked to show four standard facial expressions: at rest, raised eyebrows, eyes tightly closed, and showing teeth, which were recorded by a digital camcorder. All digital data were assessed and graded independently by three neurologists of Tongji Hospital; the neurologists were unaware of the study-group assignments and the stage of assessment.

### Baseline psychosocial factors

We considered that several baseline psychological factors might be potentially correlated with the HB score at the end of treatment, including participants' gender, age, education status, occupation, personality traits, attention, and the

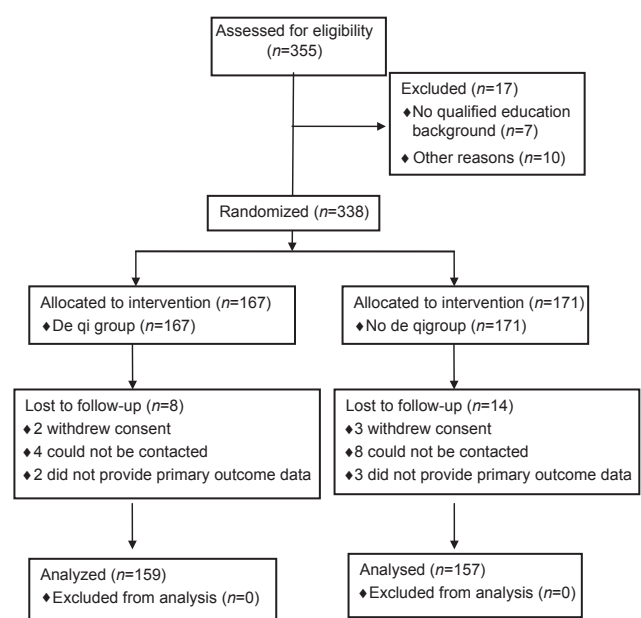


Figure 1: The flowchart of this study.

score of the pretreatment mediator questionnaire (PMQ). On the right day of randomization, all patients were asked to fill in PMQ designed for assessing pretreatment mediators including prior belief in acupuncture, experience of acupuncture treatment, and influence of people around the patients before acupuncture treatment, which consists of five related questions [Supplementary Material 2]. Patients' personality traits were assessed by the Cattell's 16 Personality Factor Questionnaire (16PF).<sup>[14]</sup> The digit cancellation test was conducted to measure the patients' attention at baseline.<sup>[15]</sup>

### Statistical analysis

All tests were two-tailed and the differences were considered to be statistically significant when  $P < 0.05$ . Data extraction and statistical analyses were conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC, USA) and the R Statistical Environment, package "grplasso". For each group, we used the least absolute shrinkage and selection operator (LASSO) algorithm for variable selection and refit the model using a standard logistic regression. Candidate variables of the model included center, gender, age (divided by 10 years), education status, occupation, side of palsy, time between onset of palsy and start of treatment (divided by 72 h), the HB score on day 1, attention (1: correctness ratio  $\leq 97\%$ , 2:  $>97\%$  correctness ratio  $\leq 99\%$ , 3: correctness ratio  $>99\%$ ), and the scores of PMQ and 16PF.

To examine the association of feeling factors with HB score at month 6, we used multivariable logistic regression analysis after controlling for all confounding variables, including gender, age, treatment, interval between the onset of palsy and the start of treatment, and HB score on day 1. HB scores of patients at month 6 were grouped into two categories in our logistic regression: 1 for normal function and 0 for others. To prevent the model from multicollinearity and overfitting, 10-fold cross-validation with minimax concave penalty (MCP)-penalized method was used for variable selection (R: package "ncvreg").

After variable selection, path analysis was used to test the causal relations among the variables specialized in the model. It allowed for the simultaneous conduction of multiple linear regression analyses and could determine and illustrate whether the data were consistent with the researcher's casual hypothesis. In our previous research, variables such as treatment, HB score on day 1, and Vigilance and Tension scores in 16PF may influence the value of HB score at month 6. All these variables were selected as the path analytic model's exogenous variables. Besides, all the feelings which selected by the cross-validation process and HB score at month 6 were selected as the path analytic model's endogenous variables. Path coefficients were computed via two multiple regression analyses based on the hypothesized model. Note the dependent (endogenous) variable HB score at month 6 was a binary variable for logistic regression but a continuous variable for path analysis (raw data: score 1–6).

## RESULTS

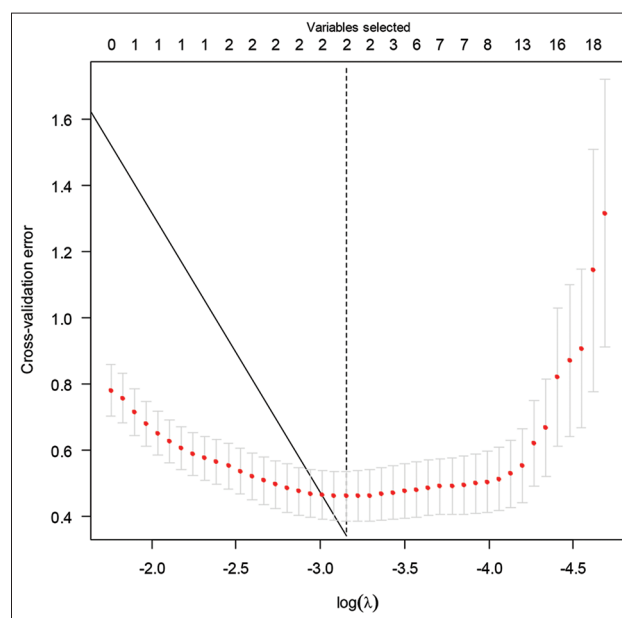
Totally, 316 subjects with complete variable records were analyzed and the patients were divided into two groups: de qi group ( $n = 159$ ) and control group ( $n = 157$ ). After 6 months, more patients had complete recovery in de qi group (89.8%) than control group (70.8%) (adjusted for age, gender, treatment center, interval between onset of palsy and start of treatment, HB score on day 1; adjusted odds ratio [OR]: 4.16, 95% confidence interval [CI]: 2.23–7.78).

When the LASSO algorithm was applied to determine whether the patient had a complete recovery, we found several factors [Table 1]. In de qi group, low HB score on day 1 (OR: 0.13, 95% CI: 0.03–0.45) and low Social Boldness score (OR: 0.63, 95% CI: 0.41–0.97) in 16PF were associated with the better facial function. In control group, low HB score on day 1 (OR: 0.25, 95% CI: 0.13–0.50) and low Vigilance score (OR: 0.66, 95% CI: 0.50–0.88) and high Tension score (OR: 1.41, 95% CI: 1.12–1.77) in 16PF were associated with better facial function.

Of the 316 patients who completed the 6-month follow-up visit, 262 (82.9%) rated de qi on the visual analog scale and the other 54 (17.1%) stated that they could not understand or differentiate between the 8 elements of needle sensations and, thus, did not complete the scale. Of these 54 patients, 24 were in the de qi group and 30 were in the control group.

It was found that in both groups, the score of experience and belief in acupuncture questionnaire, gender, age, education status, occupation, and attention had no prominent effects on objective outcome after 6 months.

For logistic regression, the binomial deviance was chosen as cross-validation error. To minimize the cross-validation error, only two variables were entered in the model [Figure 2].



**Figure 2:** 10-fold cross-validation with minimax concave penalty-penalized method for variable selection. Two variables were entered in the model.

**Table 1: Analyses of factors associated with complete recovery for Bell's palsy**

Groups	Factors	Coefficient	OR	95% CI	P
De qi	HB score on day 1	-2.08	0.13	0.03-0.45	<0.01
	Social Boldness score in 16PF	-0.46	0.63	0.41-0.97	0.04
Control	HB score on day 1	-1.38	0.25	0.13-0.50	<0.01
	Vigilance score in 16PF	-0.41	0.66	0.50-0.88	<0.01
	Tension score in 16PF	0.34	1.41	1.12-1.77	<0.01

CI: Confidence interval; OR: Odds ratio; 16PF: 16 Personality Factor Questionnaire; HB: House-Brackmann.

They were needle sensation of fullness and HB score on day 1. However, it has revealed that only the needle sensation of fullness was associated with HB score at month 6. Then, they both selected as the path analytic model's endogenous variables. Path coefficients were calculated via two multiple regression analyses based on the hypothesized model. The results are presented in Table 2.

According to the model [Figure 3], the path coefficients showed that HB score on day 1, needle sensation of fullness, Vigilance score in 16PF, and Tension score in 16PF had direct effects on HB score at month 6. If HB score on day 1 raised 1 unit, the HB score at month 6 would increase 0.27 unit. Inversely, if the score of needle sensation of fullness raised 1 unit, the HB score at month 6 would decrease 0.55 unit. Meanwhile, if the Vigilance score in 16PF raised 1 unit, the HB score at month 6 would increase 0.19 unit, and if the Tension score in 16PF raised 1 unit, the HB score at month 6 would decrease 0.12 unit. Furthermore, the treatment has a direct effect on needle sensation of fullness and an indirect effect on HB score at month 6 via the needle sensation of fullness. The de qi (treatment) group's score of needle sensation of fullness was 0.58, more than the control group, and the de qi group's HB score at month 6 was 0.32, less than the control group.

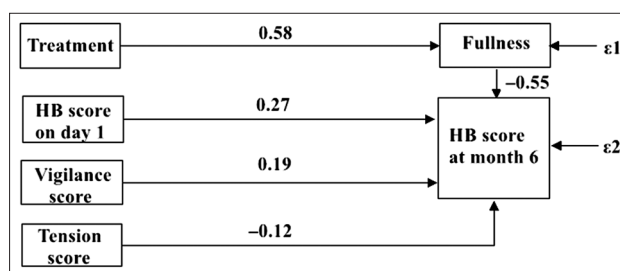
## DISCUSSION

The findings to date suggested that a number of psychosocial factors, in particular, patients' beliefs about acupuncture, predict treatment outcomes in acupuncture for pain to a significant extent.<sup>[8]</sup> As for objective outcomes in acupuncture treatment, there is almost no report in literature exploring in this regard. Our findings suggested that different personality traits played the different roles on the objective outcome when using acupuncture treating patients with Bell's palsy. The score of experience and belief in acupuncture questionnaire, gender, age, education status, occupation, and attention had no prominent effects on objective outcome after 6 months. After 6 months, patients in the de qi group had a better facial function (adjusted OR: 4.16, 95% CI: 2.23-7.78). In control group, recovery of facial nerve function was generally attributed to spontaneous recovery and prednisone. Moreover, in de qi group, it is attributed to acupuncture, in addition to spontaneous recovery and prednisone. We found that low Social Boldness score in 16PF was associated with better facial nerve function in de qi group, which was distinguished from the control group. According to Cattell's 16PF, the

**Table 2: Path coefficients via two multiple regression analyses based on the hypothesized model**

Outcome variables	R <sup>2</sup>	Predictor variables	β	P
HB score at month 6	0.40	HB score on day 1	0.27	<0.01
		Fullness	-0.55	<0.01
		Vigilance score in 16PF	0.19	<0.01
		Tension score in 16PF	-0.12	0.02
Needle sensation of fullness	0.33	Treatment	0.58	<0.01

Predictor variables with a significant level <0.05 were retained in the final model. The path coefficients were Standardized coefficients. OR: Odds ratio; 16PF: 16 Personality Factor Questionnaire; HB: House-Brackmann.



**Figure 3:** Path analysis for HB score at month 6. HB score on day 1, needle sensation of fullness, Vigilance score in 16PF, and Tension score in 16PF had direct effects on HB score at 6 months. Meanwhile, treatment had a direct effect on needle sensation of fullness and an indirect effect on HB score at month 6 via the needle sensation of fullness. HB: House-Brackmann; 16PF: 16 Personality Factor Questionnaire.

patients with low Social Boldness score in 16PF tend to be shy and hesitant, showed more obedience to their acupuncturists. Therefore, low Social Boldness score in 16PF might strengthen therapeutic effects of acupuncture with de qi-related techniques. That was contrary to common belief that introversion usually led to more physical health problems. "De qi", an internal compound sensation of soreness, tingling, fullness, aching, cool, warmth, heaviness, and a radiating sensation at and around acupoints, is elicited by manipulation of the needles (rotated as well as being moved upward and downward). The explanation is most likely that the patients with low Social Boldness score would be more easily to believe the words of the acupuncturists and pay more attention to their body and their sensations elicited by needles, thereby gaining more benefit from de qi acupuncture treatment. This interesting phenomenon calls for further investigations, which ought to shed light on the underlying mechanism of acupuncture.

As expected, low HB score on day 1 was associated with better recovery in both groups, such that those with worse facial nerve function at baseline would have worse facial nerve function at month 6. However, it was found that low Vigilance score in 16PF was associated with better outcome in the control group. In contrast to the patients with high Vigilance score who were tense and frustrated, those with low Vigilance score were more relaxed and tranquil, they could concentrate their attention to the whole acupuncture process and response to their acupuncturists' instructions optimistically. It is implied that people who were trusting, unsuspecting, and accepting might have better therapeutic effects mainly from spontaneous recovery and medication. What's more, people with low Apprehension score got better therapeutic effects. It might be that they were more inclined to worry about their states as to ask for assistance and be more confident in acupuncturists and their therapeutic schedules.

It has been corroborated by systematic reviews that acupuncture is an effective treatment in a wide variety of diseases. Nevertheless, few studies have investigated the relationship between different kinds of needle sensations and outcomes of acupuncture. We found that the intensity of needle sensation fullness might predict outcomes in Bell's palsy, which suggested that the intensity of different needle sensations should be paid more attention in the future practice and research.

The previous studies found that high expectation for acupuncture might be positive to outcome of pain,<sup>[16-18]</sup> and it was more significant in patients receiving verum acupuncture than in patients receiving minimal acupuncture or validated sham acupuncture.<sup>[17,18]</sup> However, our study did not find similar results when outcome was objective. That was, positive pretreatment mediators might not have effects on objective outcome during acupuncture treatment. To the best of our knowledge, no RCTs have been conducted to investigate the effects of personality traits and attention on the objective functional outcome of acupuncture treatment. We found that some certain personality traits could strengthen the therapeutic effect of acupuncture and attention might not be a significant predictor of outcome after acupuncture treatment.

Our study also had several limitations. First, personality traits are so complex that we were unable to fully assess one's personality traits with only one questionnaire. In fact, there are many assessments can help. However, we finally chose the 16PF because it was easier to administrate and less expensive. Second, the insufficient sample size could have influenced our results.

In conclusion, among various kinds of needle sensations, only the needle sensation of fullness could predict better facial function. The needle sensation of fullness claims more of our attention in acupuncture practice and research. Personality traits may have different effects on the objective outcome when different acupuncture techniques are used to treat patients with Bell's palsy. Among patients treated with the strong stimulation (de qi) acupuncture, low Social

Boldness score in 16PF may strengthen the therapeutic effect of acupuncture. In acupuncture treatment and research, personality traits should be considered seriously. Fostering such positive patient attitudes (e.g., realistic and ethical) might be one way in which clinicians could further improve their effectiveness. Acupuncture treatment is not simply needle placement.

*Supplementary information is linked to the online version of the paper on the Chinese Medical Journal website.*

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## Conflicts of interest

There are no conflicts of interest.

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## **SUPPLEMENTARY MATERIAL 1**

### **Pretreatment mediator questionnaire**

1. “Did you receive any acupuncture treatment before? If you did, how many times did you receive?” Answer options were “never, one to three times, four to six times, seven to nine times, and more than ten times” (score 1, 2, 3, 4, or 5, respectively).
2. “How do you think of the effect of the acupuncture treatment you received?” Answer options were “not effective, slightly effective, effective, very effective, and cure” (score 1, 2, 3, 4, or 5, respectively).
3. “Did people around you, such as relatives, friends or acquaintances, receive acupuncture? If they did, how many times did they receive?” Answer options were “never, one to three times, four to six times, seven to nine times, and more than ten times” (score 1, 2, 3, 4, or 5, respectively).
4. “How do you think of the effect of the acupuncture treatment they (people around you) received?” Answer options were “not effective, slightly effective, effective, very effective, and cure” (score 1, 2, 3, 4, or 5, respectively).
5. “How well do you believe the acupuncture works in general?” Answer options were “not effective, slightly effective, effective, very effective, and cure” (score 1, 2, 3, 4, or 5, respectively).

## Supplementary Material 2:



## CONSORT 2010 checklist of information to include when reporting a randomized trial

Section/topic	Item number	Checklist item	Reported on page number
Title and abstract	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Protocol
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Protocol
	6b	Any change to trial outcomes after the trial commenced, with reasons	Protocol
Sample size	7a	How sample size was determined	Protocol
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Protocol
Randomization			
Sequence generation	8a	Method used to generate the random allocation sequence	Protocol
	8b	Type of randomization; details of any restriction (such as blocking and block size)	Protocol
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Protocol
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	13 and protocol
Blinding	11a	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how	protocol
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7–8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7–8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	6
	13b	For each group, losses and exclusions after randomization, together with reasons	6 and flowchart
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	Xu SB, <i>CMAJ</i> 2013
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Xu SB, <i>CMAJ</i> 2013
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Protocol
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Protocol
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	6–8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Protocol
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Xu SB, <i>CMAJ</i> 201
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits, and harms and considering other relevant evidence	11

Contd...



**Supplementary Material 2: Contd...**

<b>Section/topic</b>	<b>Item number</b>	<b>Checklist item</b>	<b>Reported on page number</b>
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	Support file
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13