Effect of Warm-Supplementing Kidney Yang (WSKY) added to risperidone on quality of life in patients with schizophrenia: a randomized controlled trial

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Objective: To evaluate the quality of life, efficacy and safety of Warm-Supplementing Kidney Yang (WSKY) added to risperidone in patients with schizophrenia.

Design: A randomized controlled trial.

Setting: The outpatient and inpatient departments of three hospitals.

Subjects: One hundred and twenty patients with clinically diagnosed schizophrenia with predominantly negative symptoms were included in the study.

Intervention: All 120 patients were randomly assigned to double-blind treatment with WSKY group (n = 60) or placebo group (n = 60) added to risperidone for eight weeks.

Main measure: The efficacy measures included the World Health Organization Quality of Life Scale (WHOQOL-100), the Positive and Negative Syndrome Scale (PANSS), the Social Disability Screening Schedule and the Hamilton Rating Scale for Depression. Safety and tolerability were assessed throughout the trial.

Results: The scores of quality of life in the WSKY group showed statistically significant improvement at the end-point of treatment compared with those in the placebo group (WSKY, increasing 40.5 (29.4); placebo, increasing 14.4 (27.1); $F = 24.900, P < 0.001$), while the scores of social function and depression symptoms also showed statistically significant improvement. The response rates for the WHOQOL-100 total scores were 50.0% for the WSKY group versus 31.7% for placebo group ($\chi^2 = 4.172, P = 0.041$). There were no significant differences in the safety/tolerability measures between the WSKY group and the placebo group during treatment.

Conclusions: The results suggest that WSKY added to risperidone significantly improved the quality of life, social function, depression symptom compared with placebo added to risperidone.

Introduction

Optimal treatment of primary negative symptoms in schizophrenia is important because their presence is associated with poor outcome. Considerable progress has been made in delineating different...
domains of this illness, ranging from positive and negative symptoms to cognitive dysfunction and psychosocial vulnerabilities. Conventional antipsychotic agents have many side-effects, including extrapyramidal syndromes, akathisia, dystonia and parkinsonism, which may result in non-compliance. They are also generally poorly effective or ineffective against the negative symptoms of schizophrenia and are also associated with extensive side-effects that can themselves cause or exacerbate secondary negative symptomatology.

In comparison with conventional antipsychotic agents, atypical antipsychotic agents have advantages in certain important outcome areas: efficacy against both positive and negative symptoms and a reduction in the incidence of extrapyramidal symptoms and tardive dyskinesia. Negative symptoms are the most chronic symptoms of schizophrenia and even with recent advances in antipsychotic agents they remain mostly refractory to treatment. Selective serotonin reuptake inhibitors (SSRIs) and glycine transporter I inhibitors show early promise but require further study. Novel agents such as selegiline, naltrexone, dehydroepiandrosterone, galantamine, ginkgo, nitric oxide, L-deprenyl and pergolide show positive effects on general negative symptoms but remain untested against primary negative symptoms.

According to traditional Chinese medicine, schizophrenia is a syndrome caused by a yin–yang imbalance and herbal preparations such as Warm-Supplementing Kidney Yang (WSKY) or strong kidney yin are believed to improve the condition. A WSKY capsule contains 13 traditional Chinese herbs: Radix Aconiti Lateralis Preparata, Morinda officinalis How, Herba epimedii, Curculigo orchioides Gaertn, Cinnamomum cassia Presl, Rhizoma zingiberis, Codonopsis pilosula, Radix astragali, Radix Rehmanniae Praeparata, Plastrum Testudinis, Pericarpium Citri Reticulatae, Amomum villosum Lour, and Glycyrrhiza uralsensis Fisch. The main component or active ingredient of WSKY is believed to have the ability to excite or release acetylcholine in brain tissue, increase hypothalamic monoamine neurotransmitter concentrations, improve learning and memory in ageing rats and mice, improve the body’s regulation of neuroimmunologic effects and delay senility, and possess antidepressant effects. This may provide some benefit for negative and depression symptoms in schizophrenic patients.

Some reliable articles have reported that certain herbal medicines are effective for psychiatric conditions, and that a combination treatment of modern drugs with herbs is useful in enhancing efficacy and reducing both recovery time and side-effects. Traditional Chinese medicine was found to be superior to antipsychotic drugs in its effects on anti-anxiety/depression and antipsychomotor inhibition. Many of the articles, however, were lacking methodological rigour and there are limited published studies on the effects of WSKY on normal or schizophrenic patients. In order to investigate whether WSKY had favourable effects on negative symptoms we conducted a randomized, double-blind, clinical trial to evaluate the quality of life, efficacy and safety of WSKY added to risperidone in patients with negative symptoms in schizophrenia.

Materials and methods

Patients

Study participants were selected from male and female patients aged 18–45 years, who met the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) diagnostic criteria for schizophrenia, Clinical Global Impression Severity scale score 4, predominance of negative symptoms (the Positive and Negative Symptom Scale negative subscale 21, and at least 1 point higher than positive subscale) were eligible for inclusion. Other inclusion criteria were Hamilton Rating Scale for Depression <7 and Rating Scale for Extrapyramidal Side Effects <5. Exclusion criteria included: substance abuse, dependence or intoxication, suicidal tendencies, significant medical history (head trauma, epilepsy, thyroid disease, meningoencephalitis), electro-cardiography abnormalities, laboratory testing (blood and urine) >20% different from reference ranges, pregnancy or lactation and treatment with clozapine within four weeks of enrolment.

Study design and procedure

This was an eight-week, multicentre, randomized, double-blind, placebo-controlled clinical trial.
The study was conducted from January 2004 to December 2006 and involved three centres (a university hospital and two psychiatric hospitals) in China including both inpatient and outpatient clinics.

All raters underwent regular inter-rater reliability training using training modules; the intraclass correlation coefficients were greater than 0.85 for all the objective scales.

The study was approved by the hospitals’ institutional review boards, and all patients gave written informed consent. If the patients were not able to give consent, family members provided consent. The study protocols conformed to the principles of the Declaration of Helsinki. All examinations and assessments were free of charge, and compensation for transportation and telephone fees/charges during the study period was provided.

The WSKY and placebo capsules were distributed by the Pharmacy Department of the three hospitals. The study drug was a 0.3 g 13-herb combination capsule. The placebo capsule contained 0.3 g starch and was identical in appearance to the study drug.

The randomization scheme was maintained in the same location. The drug investigator designed treatment codes that were marked with randomized numbers from 1 to 140 using a random numbers table (SAS version 8.2; SAS Institute Inc., Cary, NC, USA) and contained treatment information. For 70 randomly selected numbers a WSKY capsule was added to risperidone therapy; for the remaining 70 randomly selected numbers a placebo capsule was added to risperidone therapy. The drug investigator did not have access to the treatment codes for the duration of the study and they were disclosed only in case of a medical emergency (e.g. when appropriate management of the patient required drug treatment disclosure).

During the screening period, the patients underwent physical examination, electrocardiogram, haematology and urine testing, blood chemistry screening, and all scale assessments. After screening, the patients meeting inclusion criteria received a number according to the time they entered the trial (i.e. patient 1 received drug 1; patient 2 received drug 2). Patients were assigned to a clinical investigator and scheduled to see the same clinical investigator after weeks 2, 4 and 8 for consultation and a scale was routinely used to evaluate symptoms and quality of life during clinical trials.

At each clinical visit, patients were questioned as to whether they had experienced any health-related issues since the previous visit. A Treatment Emergent Symptoms Scale assessment was administered. The patients were instructed to report adverse events at any time during the study. At the final visit, physical examination, electrocardiogram, haematology and urine testing, and blood chemistry screening were repeated. At each clinical visit, the investigator performed a drug count to determine compliance. If the ratio was less than 75%, the patients were considered non-compliant.

One hundred and twenty subjects who met the entry criteria were assigned to treatment with WSKY capsule (n = 60) or placebo (n = 60) added to risperidone for eight weeks (Figure 1).

**Intervention**

Patients receiving previous, non-depot antipsychotic treatment underwent a 2–7 day washout period before randomization. The doses of WSKY or placebo with 2.7 g/day (0.9 g three times daily) were defined. Risperidone was administered as follows: 1 mg every night from day 1 to day 4; 1 mg twice daily (noon and evening) from day 5 to day 9; and from day 10 to the end-point, the risperidone dosage (within 8 mg/day) for each patient was adjusted according to the clinical judgement of the research psychiatrist. Anticholinergic medication (biperiden hydrochloride ≤8 mg/day) was administered if extrapyramidal syndromes were present at inclusion to the study or in the case of a new incidence during the treatment phase. Concomitant lorazepam (<4 mg) and zopiclone (<15 mg) were allowed to counteract agitation and sleep problems. But antidepressants, mood stabilizers, psychostimulants and antipsychotics other than the study drugs were not allowed.

**Main measure**

The primary efficacy measures were the Chinese version of the World Health Organization Quality of Life Scale (WHOQOL-100) and the Positive
Assessed for eligibility ($n = 267$)
- Excluded ($n = 127$)
  - Not meeting inclusion criteria ($n = 99$)
  - Refused to participate ($n = 21$)
- Enrolled ($n = 267$)
  - Screening ($n = 140$)
    - Excluded ($n = 20$)
      - Not meeting inclusion criteria ($n = 13$)
      - Refused to participate ($n = 7$)
  - Randomized ($n = 120$)
    - Randomized to WSKY added to riseridone therapy ($n = 60$)
      - Completed 8 weeks trial ($n = 58$)
        - Dropped out ($n = 2$)
      - Analysis ($n = 60$, for clinical tests)
    - Randomized to placebo added to riseridone therapy ($n = 60$)
      - Completed 8 weeks trial ($n = 58$)
        - Dropped out ($n = 2$)
      - Analysis
- Allocation

Figure 1 The study flowchart.

and Negative Syndrome Scale. The WHOQOL-100 was assessed by patients’ self-report at baseline and weeks 4, and 8. The Positive and Negative Syndrome Scale was assessed by physician report at baseline and at weeks 2, 4, and 8.

The secondary efficacy measures included the Social Disability Screening Schedule, the Hamilton Rating Scale for Depression, the WHOQOL-100 six domains (physical domain, psychological domain, independence domain, social relationships domain, environment domain, spirit) as well as overall well-being, and the Positive and Negative Syndrome Scale three subscales (positive symptoms, negative symptoms and general psychopathology).

The safety measures included vital signs, body weight, electrocardiogram, laboratory assessments, Treatment Emergent Symptoms Scale, the Abnormal Involuntary Movement Scale and Rating Scale for Extrapyramidal Side Effects.

Analyses

The main analyses were performed on an intent-to-treat (ITT) basis, including all patients who were randomly assigned to treatment and received study medication. All end-point analyses used a last observation carried forward approach; that is, the last available visit was used as the end-point. Within-group changes from baseline to end-point (last observation carried forward) were analysed by Wilcoxon signed-rank test. Between-group comparisons of change from baseline were analysed by analyses of covariance (ANCOVA), using investigation site, baseline value and age, which differed between the groups, as covariates.
in the model. Analyses for the primary efficacy variables were performed using visit-wise (observed cases) and last observation carried forward data. A chi-square test was used to compare the proportion of positive treatment response rates on the WHOQOL-100, defined as the WHOQOL-100 >20% increase from baseline to end-point in the scores in the two groups. Because there were multiple comparison, Bonferroni correction was performed. Fisher’s exact test or the chi-square test was used to compare adverse events as appropriate. All statistical tests were two-tailed, with a significance level of \( P = 0.05 \). The Statistical Package for Social Science (SPSS) version 12.0 for Windows (SPSS Inc., Chicago, IL, USA) was used for the statistical analyses.

**Results**

**Clinical characteristics of patients**

Of 140 patients who were screened, 120 patients were included in the study, and 116 (96.7%) completed the eight-week programme. A total of 4 patients did not complete the entire study: 2 patients in the WSKY group (1 because of abnormal bleeding time and 1 withdrew informed consent) and 2 patients in the placebo group (1 because of abnormal hepatic function and 1 withdrew informed consent). All patients were adequately compliant.

No significant differences were observed in the two groups in terms of age, sex, education level, age of onset and duration of illness, or baseline scores on the WHOQOL-100, Positive and Negative Syndrome Scale, Social Disability Screening Schedule, Hamilton Rating Scale for Depression, Abnormal Involuntary Movement Scale and Rating Scale for Extrapyramidal Side Effects (Table 1). The participants in our study viewed their quality of life as low in the two groups at baseline.

The mean dose of risperidone in the WSKY group at the last observation was significantly lower than that in the placebo group (3.45 vs. 3.80 mg/day; \( P = 0.022 \)).

**Efficacy analyses**

For the primary efficacy measured, differences between the treatment groups were not significant at baseline in either the WHOQOL-100 total scores or the Positive and Negative Syndrome Scale total scores. There were significant differences in WHOQOL-100 total score improvements between the two groups at week 8 in the observed cases and at the end-point (last observation carried forward) \( (F = 25.793, P = 0.000 \) and \( F = 24.900, P = 0.000 \), respectively), but the differences in the Positive and Negative Syndrome Scale total score improvements were not significant between the two groups \( (F = 3.328, P = 0.071 \) and \( F = 0.444, P = 0.516 \), respectively) (Table 2). The response rates for the WHOQOL-100 total scores in the WSKY group were significantly higher than those in the placebo group in both the last observation carried forward and completers analyses. For last observation carried forward analysis, the response rates for the WHOQOL-100 total scores were 50.0% for the WSKY group versus 31.7% for the placebo group \( (\chi^2 = 4.172, P = 0.041) \). For study completers, the response rates of the WSKY and placebo groups for the WHOQOL-100 total scores were 51.7% and 32.8%, respectively \( (\chi^2 = 4.275, P = 0.039) \).

For secondary efficacy measures, differences between the treatment groups were not significant at baseline in the Social Disability Screening Schedule, Hamilton Rating Scale for Depression, WHOQOL-100 six domains as well as overall well-being, and Positive and Negative Syndrome Scale three subscales. The reductions in the scores for the Social Disability Screening Schedule and the Hamilton Rating Scale for Depression from baseline to end-point (last observation carried forward) were significantly greater in the WSKY group than those in the placebo group (Table 2). The improvements in the scores for physical domain, psychological domain, independence domain, social relationships domain, environment domain, overall well-being from baseline to end-point (last observation carried forward) were not significant between the two groups (Table 2).
Safety/tolerability analyses

WSKY or placebo added to risperidone were both well tolerated. Treatment-emergent adverse events were reported in 32 (53.3%) of the WSKY group and in 34 (56.7%) of the placebo group. Patients in the WSKY group reported the following adverse events (>5%): tremor, 14 (23.3%); insomnia, 10 (16.7%); akathisia, 8 (13.3%); somnolence, 8 (13.3%); headache, 8 (13.3%); weight gain, 8 (13.3%); constipation, 7 (11.7%); dizziness, 4 (6.7%); lassitude, 3 (5.0%). Patients in the placebo group reported the following adverse events (>5%): tremor, 12 (20.0%); akathisia, 12 (20.0%); somnolence, 10 (16.7%); headache, 7 (11.7%); weight gain, 7 (11.7%); insomnia, 6 (10.0%); constipation, 5 (8.3%); nausea, 5 (8.3%); lassitude, 5 (8.3%). No significant difference was found between the groups. No serious or intolerable adverse events were reported.

No significant difference was seen regarding changes in vital signs or laboratory parameters, including electrocardiograms, between the groups. The change in scores from baseline to end-point on the Abnormal Involuntary Movement Scale and Rating Scale for Extrapyramidal Side Effects was not significantly different between the groups ($F = 1.021, P = 0.314$ and $F = 2.524, P = 0.115$, respectively) (Table 2). No treatment difference was detected in the adjunctive use of anticholinergic agents (WSKY, 63.3% (38/60); placebo, 80.0% (48/60); $\chi^2 = 3.386, P = 0.066$).

Discussion

This was an eight-week, multicentre, randomized, double-blind, placebo-controlled clinical trial. It was found that the quality of life of schizophrenic patients with predominantly negative symptoms in the WSKY group showed significant improvements

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Baseline demographic and clinical characteristics of the participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics</td>
<td>Placebo ($n = 60$)</td>
</tr>
<tr>
<td>Gender, male/female</td>
<td>30/30</td>
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<tr>
<td>Age, mean (SD), years</td>
<td>33.0 (9.6)</td>
</tr>
<tr>
<td>Education, mean (SD), years</td>
<td>11.0 (3.2)</td>
</tr>
<tr>
<td>Duration of illness, mean (SD), years</td>
<td>10.6 (9.0)</td>
</tr>
<tr>
<td>Age of onset, mean (SD), years</td>
<td>21.0 (6.2)</td>
</tr>
<tr>
<td>WHOQOL-100 scores at baseline, mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Total scores</td>
<td>318.4 (34.1)</td>
</tr>
<tr>
<td>Physical domain</td>
<td>68.1 (12.9)</td>
</tr>
<tr>
<td>Psychological domain</td>
<td>55.1 (8.9)</td>
</tr>
<tr>
<td>Independence domain</td>
<td>65.8 (12.4)</td>
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<tr>
<td>Social relations domain</td>
<td>50.3 (8.5)</td>
</tr>
<tr>
<td>Environment domain</td>
<td>48.1 (10.5)</td>
</tr>
<tr>
<td>Spirit</td>
<td>27.1 (19.2)</td>
</tr>
<tr>
<td>Overall well-being</td>
<td>59.3 (36.4)</td>
</tr>
<tr>
<td>PANSS scores at baseline, mean (SD)</td>
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</tr>
<tr>
<td>Total scores</td>
<td>88.4 (13.1)</td>
</tr>
<tr>
<td>Negative subscale</td>
<td>27.5 (5.3)</td>
</tr>
<tr>
<td>Positive subscale</td>
<td>17.6 (5.1)</td>
</tr>
<tr>
<td>General psychopathology</td>
<td>43.2 (8.2)</td>
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<tr>
<td>SDSS scores at baseline, mean (SD)</td>
<td>13.6 (4.4)</td>
</tr>
<tr>
<td>HRSD scores at baseline, mean (SD)</td>
<td>5.3 (4.6)</td>
</tr>
<tr>
<td>AIMS scores at baseline, mean (SD)</td>
<td>3.2 (2.8)</td>
</tr>
<tr>
<td>RSESE scores at baseline, mean (SD)</td>
<td>0.2 (0.9)</td>
</tr>
</tbody>
</table>

$^a$Based on the $\chi^2$ test, independent $t$-test or ANCOVA. WSKY, Warm-Supplementing Kidney Yang; WHOQOL-100, World Health Organization Quality of Life scale; PANSS, Positive and Negative Syndrome Scale; SDSS, Social Disability Screening Schedule; HRSD, Hamilton Rating Scale for Depression; AIMS, Abnormal Involuntary Movement Scale; RSESE, Rating Scale for Extrapyramidal Side Effects; ANCOVA, analyses of covariance.
### Table 2  Changes in the quality of life, efficacy, and safety measures from baseline to endpoint of the study participants treated with placebo or WSKY group (last observation carried forward analysis)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Placebo group (n = 60)</th>
<th>WSKY group (n = 60)</th>
<th>ANCOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline, mean (SD)</td>
<td>4-week, mean (SD)</td>
<td>End-point, mean (SD)</td>
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<tr>
<td>WHOQOL-100 scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total scores</td>
<td>318.4 (34.1)</td>
<td>328.0 (37.6)</td>
<td>333.5 (40.9)</td>
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<tr>
<td>Physical domain</td>
<td>68.1 (12.9)</td>
<td>70.6 (13.4)</td>
<td>74.7 (12.8)</td>
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<tr>
<td>Psychological domain</td>
<td>55.1 (8.9)</td>
<td>59.5 (10.0)</td>
<td>61.5 (11.9)</td>
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<tr>
<td>Independence domain</td>
<td>65.8 (12.4)</td>
<td>65.5 (10.7)</td>
<td>69.1 (12.9)</td>
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<tr>
<td>Social relations domain</td>
<td>50.3 (8.5)</td>
<td>51.9 (10.2)</td>
<td>51.9 (10.6)</td>
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<tr>
<td>Environment domain</td>
<td>48.1 (10.5)</td>
<td>51.4 (10.2)</td>
<td>51.3 (12.6)</td>
</tr>
<tr>
<td>Spirit</td>
<td>27.1 (19.2)</td>
<td>28.4 (19.2)</td>
<td>29.6 (19.3)</td>
</tr>
<tr>
<td>Overall well-being</td>
<td>59.3 (36.4)</td>
<td>54.5 (14.9)</td>
<td>55.3 (17.0)</td>
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<tr>
<td>PANSS scores</td>
<td></td>
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<td>88.4 (13.1)</td>
<td>70.2 (11.3)</td>
<td>62.0 (10.4)</td>
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<td>Negative subscale</td>
<td>27.5 (5.3)</td>
<td>21.6 (5.3)</td>
<td>19.6 (4.5)</td>
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<tr>
<td>Positive subscale</td>
<td>17.6 (5.1)</td>
<td>15.0 (4.1)</td>
<td>13.1 (3.4)</td>
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<tr>
<td>General</td>
<td>43.2 (8.2)</td>
<td>33.7 (6.1)</td>
<td>29.3 (6.7)</td>
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<tr>
<td>psychopathology</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>SDSS scores</td>
<td>13.6 (4.4)</td>
<td>11.3 (3.7)</td>
<td>9.3 (4.1)</td>
</tr>
<tr>
<td>HRSD scores</td>
<td>5.3 (4.6)</td>
<td>4.5 (5.1)</td>
<td>3.6 (4.3)</td>
</tr>
<tr>
<td>AIMS scores</td>
<td>3.2 (2.9)</td>
<td>4.0 (2.9)</td>
<td>4.1 (2.9)</td>
</tr>
<tr>
<td>RSESE scores</td>
<td>0.2 (0.9)</td>
<td>1.1 (1.9)</td>
<td>1.2 (2.0)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Adjusted for age, investigation site, and baseline value.

<sup>b</sup>P<sub>c</sub> = P<sub>LOCF</sub> observed indexes number.

WSKY, Warm-Supplementing Kidney Yang; WHOQOL-100, World Health Organization Quality of Life Scale; PANSS, Positive and Negative Syndrome Scale; SDSS, Social Disability Screening Schedule; HRSD, Hamilton Rating Scale for Depression; AIMS, Abnormal Involuntary Movement Scale; RSESE, Rating Scale for Extrapyramidal Side Effects; LOCF, last observation carried forward; ANCOVA, analyses of covariance.
compared with the placebo group. The response rates for the WHOQOL-100 total scores in the WSKY group were significantly higher than those in the placebo group. The improvements in the scores for physical domain, psychological domain, independence domain, social relationships domain, environment domain, overall well-being from baseline to end-point (last observation carried forward) were significantly higher in the WSKY group than those in the placebo group. This may have been due to the influence of treatment psychology in the schizophrenic patients because they believed in traditional Chinese medicine and a substantial proportion of psychiatric inpatients seek help from non-psychiatric facilities and/or folk healing methods in China. Another reason for this finding could be related to the lower drug (risperidone) doses and higher compliance. Ritsner reported that lower daily doses and longer antipsychotic treatment were associated with better quality of life.

Some reliable articles have reported that certain herbal medicines are effective for psychiatric conditions, and that a combination treatment of modern drugs with herbs is useful in enhancing efficacy and reducing both recovery time and side-effects. Traditional Chinese medicine was reported to be superior to antipsychotic drugs in its effects on anxiety/depression and antipsychomotor inhibition. The WSKY capsule is characterized by vigour and calmness. This may provide some benefit for negative symptoms and depression symptoms in schizophrenic patients. This study confirmed that the response rates for the Positive and Negative Syndrome Scale scores in the WSKY group were significantly higher than those in the placebo group. The WSKY capsule added to risperidone significantly improved social function and depression symptoms compared with placebo add to risperidone, but there were no significant differences in the improvements for positive symptoms, negative symptoms and general psychopathology from baseline to end-point (last observation carried forward) between the two groups.

For this study, WSKY or placebo added to risperidone were both well tolerated. No differences in treatment emergent adverse events were noted in >5% of the patients in the two groups, and no serious or intolerable adverse events were noted in either group. The changes in scores from baseline to end-point on the Abnormal Involuntary Movement Scale and Rating Scale for Extrapyramidal Side Effects were similar in the two groups. No significant difference was seen regarding changes in vital signs or laboratory parameters, including electrocardiograms, between the two groups. No treatment difference was found in the adjunctive use of anticholinergic agents.

Although the study results appeared to show an encouraging outcome in quality of life for people with schizophrenia with predominantly negative symptoms, there was weakness in the design. For example, there was a difference in the risperidone doses between the two groups, which could result in deviation of the outcome.

Schizophrenia is known to have a considerable impact on patients’ quality of life, such as previous work experience, education, clinical characteristics, including number and duration of hospitalizations, symptom severity, age of onset, negative symptoms, and impaired psychosocial functioning. These patients are deprived of social and psychological functions such as the provision of social support, structuring of time and self-esteem. Furthermore, the undesired effects of antipsychotic medication may be an additional burden on patients’ well-being and hence their quality of life. The undesired effects (e.g. dyskinesia) are likely to decrease compliance potentially protracting the course of illness and worsening the prognosis. Quality of life has become a key outcome measure in severe psychiatric disorders. The results appeared to show that the WSKY capsule added to risperidone provided some benefit for quality of life in patients with schizophrenia. It would be interesting to see whether the findings can be replicated in other populations where Chinese medicine is not routinely used.

Larger controlled studies for longer durations are needed to evaluate the true effectiveness of WSKY in the treatment of schizophrenia.

Conclusions

The results of this study suggest that WSKY added to risperidone significantly improved the quality of life, social function and depression
symptoms compared with placebo added to risperidone. The response rates in the WSKY group for the WHOQOL-100 and Positive and Negative Syndrome Scale scores were significantly higher than in the placebo group. All treatments were generally well tolerated.

Clinical messages

- Warm-Supplementing Kidney Yang (WSKY) capsule contains 13 traditional Chinese herbs.
- WSKY added to risperidone significantly improved the quality of life, social function and depression symptoms in patients with schizophrenia compared with placebo added to risperidone.

Acknowledgements

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References


