Effects of Qigong exercise and its dose-response relationship in reducing fatigue for patients with Chronic Fatigue Syndrome: A randomized waitlist-controlled trial

Jessie S. M. CHAN
MPH, PhD candidate
Centre on Behavioral Health
Department of Social Work and Social Administration
The University of Hong Kong
Background
**CF/CFS**

- Fatigue is a common problem
- Chronic Fatigue (CF): fatigue or exhaustion for 6 months or longer
- Chronic Fatigue Syndrome (CFS)
  - Unexplained persistent fatigue at least 6 months
  - No definite effective treatment yet

- The prevalence of CF/CFS in general population is much higher than in clinical population

Diagnosis criteria (CDC) for CFS

1. Unexplained, persistent fatigue

2. **Four or more** of the following symptoms for 6 months or more:

   - Impaired memory or concentration
   - Postexertional malaise
   - Unrefreshing sleep
   - Muscle pain
   - Sore throat
   - Multi-joint pain
   - Tender lymph nodes
   - Headaches

(According to: US Centers for Disease Control and Prevention (CDC))
Exclusion criteria

• Any active medical condition that may explain CF (eg. Sleep apnoea or side-effects of medication)
• Any previously-diagnosed medical conditions (eg. Hepatitis B or C)
• Major depressive disorder, any bipolar affective disorder, schizophrenia
• Alcoholism or other substance abuse
• Severe obesity
CFS-like illness

- Only based on self-reported fatigue characteristics, symptoms and medical history
- Approximate criteria for CFS
- No confirm clinical examination
  (Steel, 1998)
- May contain people with **CF or CFS**
- A large part of the patients with CF/CFS in the community remains unrecognized by the general practitioners
  (van’t Leven, et al., 2009)
Current treatments for CFS

• Western treatments and medications are often associated with limited clinical benefits
  (Huibers et al., 2004)

• Some may even experience undesirable side-effects
  (Chen et al, 2010)

• Complementary and alternative therapies are often used by individuals with CF/CFS to manage their symptoms
  (Afari et al., 2000; Porter et al, 2010)

• Only cognitive behavior therapy and grated exercise therapy can be effective in treating fatigue and associated symptoms
  (Afari & Buchwald, 2003)
Grated exercise therapy (GET)

• Too-vigorous exercise may
  – damage the immune system and increase oxidative stress
  – lead to an increase in fatigue and musculoskeletal pain
  (Jammes, et al., 2005; Niji, et al., 2008a; Sorensen et al., 2003)

• Exercise limit can prevent post-exertional malaise for people with CFS
  (Niji, et al., 2008b)

• Diaphragmatic breathing in meditation can reduce exercise-induced oxidative stress
  (Martarelli, et al., 2009)
Qigong

- Qigong is an ancient art of self-healing exercise
  - mind regulation
  - body regulation
  - breath regulation

- Qigong includes
  - Gentle mind-body exercise
  - Meditation

(Manek & Lin, 2012)
Qigong focuses on the balance between yin and yang, as well as smoothing the circulation of qi (vital energy) in meridian system (Qi vital energy channel) of the human body.
Traditional Chinese Medicine (TCM)

From the perspective of TCM:

- CF/CFS is caused by blood stasis due to Qi (vital energy) deficiency

- Stimulation of the blood and Qi circulation (行氣活血) is the core treatment strategy for CF/CFS

(Adam, et al., 2009; Chen, et al., 2010)
Few studies on Qigong and CF/CFS

• Qigong exercise has been applied in two pilot studies for the treatment of CF/CFS

  – Desirable effects were found
  – The effects of Qigong should be further tested in large-scale RCTs

(Craske, et al, 2009; Dybwad, 2007)

  – To the best of our knowledge, no study on dose-response relationship of Qigong and CF/CFS
Our previous study

- Our Previous Randomized Controlled Trails (RCT) (n=114) has demonstrated that Qigong exercise had short-term effect in reducing fatigue, improving quality of life, and improving the spiritual wellbeing.

(Chan JSM, et al. (Abstract) Annals of Behavioral Medicine, s224, 2011)
Objectives

• To assess the effects of Qigong exercise on fatigue, quality of life and spiritual wellbeing of people with CF/CFS to confirm our previous results.

• To investigate the dose-response relationship and give some guidelines on frequency and duration of Qigong exercise in treatment of CF/CFS.
Significance of study

- The prognosis for untreated CFS is poor
- Better outcome is predicted by less-severe fatigue at baseline (Cairns & Hotopf, 2005)
- Early detection and treatment in the community
  - prevent the deterioration
  - also reduce the future healthcare and socioeconomic burdens
Methods
A community based study

- Press conference to promote the study and recruit subjects
Study design

- Randomized waitlist-controlled trial
- On-line screening questionnaire

Subjects:
- Adults aged 18-55 years old
- Had CFS symptoms based on self-reported symptoms and medical history by online screening questionnaire based on CDC CFS criteria
- Without medical examination by physicians
Sample size calculation

Assuming treatment effect = 3 and SD = 5 according to previous local CFS study (Yiu, et al, 2007)

- To achieve 80% power at significant level of 0.05
  - 53 subjects required in each group

- Assuming 30% dropout rate
  - At least 76 required in each group
1441 participants filled in online screening questionnaire

1023 ineligible participants were excluded

418 participants met the inclusion criterion

264 participants who were unselected, randomly or uncontacted or unavailable for qigong class were excluded

154 participants were included in study

Randomly assigned to intervention group (n = 77)

Final sample at T0 (n = 72)

5 dropped out before QG

15 dropped out

Randomly assigned to control group (n = 77)

Final sample at T0 (n = 65)

12 dropped out before QG

3 dropped out

Post intervention (T1) (n = 57)

Post intervention (T1) (n = 62)
Study design

Eligible CFS-like illness patients
n=154

T0

Randomization

N=77

Qigong group
10 sessions Qigong class for 5 weeks 2 hours/session

Control group
No Qigong during this period

T1
Final sample in data analysis

- **At T0:**
  - 77 in Intervention group
  - 77 in control group

- **Qigong class:**
  - 5 dropped in Qigong group
  - 12 dropped in control group

- **At T1:**
  - 15 dropped out
  - 3 dropped out
**Intervention**

- 10 sessions of Qigong exercise (wu xing ping heng gong, 五行平衡功能) class
- 2 hours per session, and twice a week for 5 weeks
- Self practice (15 – 30 minutes per day) at home
- Two parts
  - Movement exercise (10 forms)
  - Meditation
Outcome measurements

• Primary outcome: Chalder’s Fatigue (CF) scale (14 items)  
   (Chalder, et al, 1993; Wong, 2010)
   - Total fatigue score: sum of all items
     • Physical fatigue: sum of items 1 - 8
     • Mental fatigue: sum of items of 9 - 14

• Quality of life: SF-12 Health Survey Questionnaire (12 items)  
   (Ware, 1996; Lam, 2005)
   • Physical Component Summary (PCS)
   • Mental Component Summary (MCS)

• Body-Mind-Spirit integrative well-being (BMSIWB)-Spirituality  
  (13 items)
  • Tranquility
  • Disorientation
  • Resilience  
  (Ng, S.M, et al., 2005)
Data collection and analysis

- Data including
  - Demographic data
  - Lifestyle
  - Chalder’s fatigue
  - SF-12
  - BMSIWB-Spirituality
  by the online questionnaire

- Two time points
  - Baseline (T0)
  - Post-training (T1)

- After Qigong class
  - Frequency and duration of self-Qigong practice

- Comparison
  - Intervention and control groups
  - In Qigong group
    - ≥ 3 days / week
    - vs < 3 days / week
    - ≥ 30 minutes/time
    - vs < 30 minutes/time

By

- Chi-squared test for categorical data
- T-test for continuous data
- Data analysis was conducted by SPSS18
Results
<table>
<thead>
<tr>
<th>Demographic</th>
<th>Intervention (n = 72)</th>
<th>Control (n = 65)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>N (%)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>42.4 (6.7)</td>
<td>52 (72.2%)</td>
<td>42.5 (6.4)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>52 (72.2%)</td>
<td>53 (81.5%)</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>55 (76.4%)</td>
<td>52 (80.0%)</td>
<td></td>
</tr>
<tr>
<td>Part-time</td>
<td>3 (4.2%)</td>
<td>1 (1.5%)</td>
<td></td>
</tr>
<tr>
<td>Housewife</td>
<td>9 (12.5%)</td>
<td>10 (15.4%)</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>4 (5.6%)</td>
<td>1 (1.5%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (1.4%)</td>
<td>1 (1.5%)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary school</td>
<td>31 (43.1%)</td>
<td>33 (50.8%)</td>
<td></td>
</tr>
<tr>
<td>Tertiary or above</td>
<td>41 (56.9%)</td>
<td>32 (49.2%)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>21 (29.2%)</td>
<td>23 (35.4%)</td>
<td></td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>46 (63.9%)</td>
<td>38 (58.5%)</td>
<td></td>
</tr>
<tr>
<td>Divorced/separated/widowed</td>
<td>5 (6.9%)</td>
<td>4 (6.2%)</td>
<td></td>
</tr>
<tr>
<td>Have religion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>21 (29.2%)</td>
<td>24 (36.9%)</td>
<td></td>
</tr>
<tr>
<td>Lifestyles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do exercise regularly</td>
<td>19 (26.4%)</td>
<td>17 (26.2%)</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>6 (8.3%)</td>
<td>2 (3.1%)</td>
<td></td>
</tr>
<tr>
<td>Alcohol drinking</td>
<td>5.0 (1.8)</td>
<td>4.7 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Sleep time (hours)</td>
<td>31 (43.1%)</td>
<td>22 (33.8%)</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-squared test for categorical variable and T-test for continuous variable
Table 2 Comparison of Chalder’s fatigue (CF) scale, Quality of life (SF-12) and BMS-Spirituality between two groups at T0 and T1 (n = 137)

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 72)</th>
<th>Control (n = 65)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td><strong>CF total score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>39.7 (6.6)</td>
<td>39.8 (6.3)</td>
<td>.916</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>[15] 24.4 (12.0)</td>
<td>[3] 34.1 (8.8)</td>
<td>.000</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>[15] -14.7 (10.3)</td>
<td>[3] -5.8 (7.3)</td>
<td>.000</td>
</tr>
<tr>
<td><strong>CF physical score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>24.7 (4.0)</td>
<td>24.6 (3.7)</td>
<td>.887</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>[15] 14.8 (7.4)</td>
<td>[3] 21.0 (5.2)</td>
<td>.000</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>[15] -9.7 (6.5)</td>
<td>[3] -3.6 (4.2)</td>
<td>.000</td>
</tr>
<tr>
<td><strong>CF mental score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>15.0 (3.8)</td>
<td>15.2 (3.9)</td>
<td>.750</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>[15] 9.6 (5.5)</td>
<td>[3] 13.1 (4.6)</td>
<td>.000</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>[15] -5.0 (4.7)</td>
<td>[3] -2.2 (3.7)</td>
<td>.000</td>
</tr>
<tr>
<td><strong>SF-12-PCS score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>36.4 (6.6)</td>
<td>35.8 (7.2)</td>
<td>.632</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>[15] 41.3 (7.0)</td>
<td>[3] 38.3 (7.6)</td>
<td>.026</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>[15] 4.8 (7.0)</td>
<td>[3] 2.6 (5.9)</td>
<td>.072</td>
</tr>
<tr>
<td><strong>SF-12-MCS score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>32.4 (10.2)</td>
<td>33.5 (8.7)</td>
<td>.514</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>[15] 42.6 (8.5)</td>
<td>[3] 34.0 (9.1)</td>
<td>.000</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>[15] 9.8 (11.9)</td>
<td>[3] 0.5 (8.1)</td>
<td>.000</td>
</tr>
<tr>
<td><strong>BMS-Spirituality score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>65.2 (25.8)</td>
<td>71.1 (23.7)</td>
<td>.167</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>[15] 80.2 (22.7)</td>
<td>[3] 71.9 (24.3)</td>
<td>.087</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>[15] 14.4 (21.9)</td>
<td>[3] 0.4 (19.0)</td>
<td>.000</td>
</tr>
</tbody>
</table>

Comparison between Qigong and control groups at T0 and T1

Figure 2 Comparison of outcomes between two groups at T0 and T1, with p-values for interaction effect of group*time
Table 3 Weekly self-practice Qigong at home during Qigong training in intervention group

<table>
<thead>
<tr>
<th>Days of Qigong practice /week</th>
<th>Intervention group (n = 72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No practice</td>
<td>4 (5.6%)</td>
</tr>
<tr>
<td>1 – 2 days</td>
<td>14 (19.4%)</td>
</tr>
<tr>
<td>3 – 4 days</td>
<td><strong>20 (27.8%)</strong></td>
</tr>
<tr>
<td>5 – 6 days</td>
<td>12 (16.7%)</td>
</tr>
<tr>
<td>Every day</td>
<td>6 (8.3%)</td>
</tr>
<tr>
<td>Missing</td>
<td>16 (22.2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration per time (minutes)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No practice</td>
<td>3 (4.3%)</td>
</tr>
<tr>
<td>&lt; 15</td>
<td>6 (8.3%)</td>
</tr>
<tr>
<td>15 – 30</td>
<td>19 (26.4%)</td>
</tr>
<tr>
<td><strong>30 – 45</strong></td>
<td><strong>23 (31.9%)</strong></td>
</tr>
<tr>
<td>45 – 60</td>
<td>4 (5.6%)</td>
</tr>
<tr>
<td>&gt; 60</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Missing</td>
<td>16 (22.2%)</td>
</tr>
</tbody>
</table>
Table 4 Comparison between groups by Qigong practice frequency per week and duration of Qigong practice per time

<table>
<thead>
<tr>
<th></th>
<th>Frequency of Qigong practice</th>
<th>Duration of Qigong practice</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≥ 3 days/week</td>
<td>≤ 3 days/week</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n = 38)</td>
<td>(n = 18)</td>
<td></td>
</tr>
<tr>
<td><strong>CF total score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>39.2 (6.0)</td>
<td>38.4 (7.4)</td>
<td>.702</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>21.8 (11.2)</td>
<td>29.1 (12.3)</td>
<td><strong>.032</strong></td>
</tr>
<tr>
<td>T1 – T0</td>
<td>-17.3 (8.9)</td>
<td>-9.3 (11.4)</td>
<td><strong>.006</strong></td>
</tr>
<tr>
<td><strong>CF physical score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>24.4 (4.1)</td>
<td>24.3 (4.3)</td>
<td>.922</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>13.1 (7.0)</td>
<td>17.9 (7.3)</td>
<td><strong>.021</strong></td>
</tr>
<tr>
<td>T1 – T0</td>
<td>-11.3 (5.9)</td>
<td>-6.4 (6.7)</td>
<td><strong>.007</strong></td>
</tr>
<tr>
<td><strong>CF mental score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>14.8 (3.7)</td>
<td>14.2 (4.0)</td>
<td>.585</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>8.8 (5.2)</td>
<td>11.2 (5.7)</td>
<td>.117</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>-6.0 (4.1)</td>
<td>-2.9 (5.4)</td>
<td><strong>.023</strong></td>
</tr>
<tr>
<td><strong>SF-12-PCS score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>36.3 (7.2)</td>
<td>36.8 (6.7)</td>
<td>.800</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>42.1 (7.3)</td>
<td>39.2 (6.2)</td>
<td>.149</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>5.8 (6.9)</td>
<td>2.4 (7.1)</td>
<td>.039</td>
</tr>
<tr>
<td><strong>SF-12-MCS score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>33.9 (10.5)</td>
<td>31.2 (10.1)</td>
<td>.362</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>44.3 (8.1)</td>
<td>39.8 (8.2)</td>
<td>.058</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>10.4 (11.0)</td>
<td>8.6 (14.1)</td>
<td>.602</td>
</tr>
<tr>
<td><strong>BMSWBI-Spirituality</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (T0)</td>
<td>65.7 (27.5)</td>
<td>66.4 (22.2)</td>
<td>.922</td>
</tr>
<tr>
<td>Post intervention (T1)</td>
<td>82.8 (23.3)</td>
<td>75.7 (21.5)</td>
<td>.275</td>
</tr>
<tr>
<td>T1 – T0</td>
<td>17.1 (18.9)</td>
<td>9.2 (27.4)</td>
<td>.214</td>
</tr>
</tbody>
</table>

CF: Chalder’s Fatigue,
Comparison of outcomes between two groups by weekly frequency of Qigong practice at T0 and T1

Figure 3 Comparison of outcomes between two groups by weekly frequency of Qigong practice at T0 and T1, with p-values for interaction effect of group*time
Comparison of outcomes between two groups by duration of Qigong practice per time at T0 and T1

Figure 4 Comparison of outcomes between two groups by duration of Qigong practice per time at T0 and T1, with p-values for interaction effect of group*time
**Strengths**

- To the best of our knowledge, first study on dose-response relationship of Qigong and CF/CFS
- Large scale RCT
- Promising results
- May give the useful prescription guideline for clinicians and patients
Future direction

• Recruit the subjects fully meet the CDC criteria for CFS with medical examination

• Other exercise or health education in control group
  – To reduce social interaction effect

• Diary of self Qigong practice at home

• Record not only Qigong practice, but also other exercise practice in the daily life
Conclusions

• Qigong exercise can help patients with CF/CFS reduce the level of fatigue.

• Qigong exercise can help improve mental health and spiritual wellbeing.

• A practice regimen of at least 3 days per week and at least 30 minutes each time may produce better results.
Acknowledgments

• My supervisors
  – Prof. Cecilia L.W. Chan, PhD
  – Dr. Rainbow T.H. Ho, PhD
• Dr. Yuen L.P. Chinese clinician, MD. (Qigong Master)
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• Prof. So K.F., PhD
• Dr. Benson Liu, PhD
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• All staffs in International Association for Health and Yangsheng
• All participants in our Qigong study
Thank You!

Jessie S. M. CHAN
Email: chansm5@hku.hk, http://cbh.hku.hk
Centre on Behavioral Health
Department of Social Work and Social Administration
The University of Hong Kong