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

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# <u>Outline</u>

 Background -CF/CFS– Qigong and TCM Methods - Study design - Subjects Data collection and data analysis Results Conclusion

# 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

(Lee, et al, 2000; van't Leven, et al, 2009; Yiu, et al, 2005)

# Diagnosis criteria (CDC) for CFS

1. Unexplained, persistent fatigue

2. <u>Four or more</u> 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 sideeffects 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

#### 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 musculoskelectal 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)





# Traditional Chinese Medicine (TCM)

 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





(MDT) enipibel ecenido lanoitibar

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

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



# **Study design**



# Final sample in data analysis

<ul> <li>At TO:</li> <li>77 in Intervention group</li> <li>77 in control group</li> </ul>	TO	Qigong N=77	Control N=77
<ul> <li>Qigong class:</li> <li>– 5 dropped in Qigong group</li> <li>– 12 dropped in control</li> </ul>	Qigong Class	N=72	N= 65
<ul> <li>group</li> <li>At T1:</li> <li>15 dropped out</li> <li>3 dropped out</li> </ul>	T1	N=57	N=62

## Intervention

 10 sessions of Qigong exercise (wu xing ping heng gong, 五行平衡功) 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

By

- 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
  - $\geq$  3 days / week
    - vs < 3 days / week
  - $\geq$  30 minutes/time
    - vs < 30 minutes/time
- Chi-squared test for categorical data
- T-test for continuous data
- Data analysis was conducted by SPSS18



Demographic _	Interventi	Intervention $(n = 72)$		Control $(n = 65)$	
	Mean (SD)	N (%)	Mean (SD)	N (%)	
Age (years)	42.4 (6.7)	-	42.5 (6.4)	and the second second	<b>.97</b> 9
Gender					
Female		52 (72.2%)		53 (81.5%)	.198
Employment					
Full-time		55 (76.4%)		52 (80.0%)	
Part-time		3 (4.2%)		1 (1.5%)	.629
Housewife		9 (12.5%)		10 (15.4%)	.029
Unemployed		4 (5.6%)		1 (1.5%)	
Other		1 (1.4%)		1 (1.5%)	
Education		21(42,10/)		22 (50, 90/)	
Secondary school		31 (43.1%) 41 (56.9%)		33 (50.8%) 32 (49.2%)	.366
Tertiary or above		41 (30.9%)		32 (49.2%)	
Vlarital status					
Single		21 (29.2%)		23 (35.4%)	
Married/cohabiting		46 (63.9%)		38 (58.5%)	.738
Divorced/separated /widowed		5 (6.9%)		4 (6.2%)	
Have religion Yes		21 (29.2%)		24 (36.9%)	.334
Lifestyles					
Do exercise regularly		10 (26 40/)		17 (06 00)	.975
Smoking		19 (26.4%)		17 (26.2%)	.190
Alcohol drinking	5.0 (1.8)	6 (8.3%)	4.7 (2.2)	2 (3.1%)	.269
Sleep time (hours)		31 (43.1%)		22 (33.8%)	.434

\* 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 BMSIWB-spirituality between two groups at T0 and T1 (n = 137)

	Intervention $(n = 72)$	Control $(n = 65)$	$P^*$
	Mean (SD)	Mean (SD)	
CF' total score			-
Baseline (T0)	39.7 (6.6)	39.8 (6.3)	.916
Post intervention (T1)	[15] 24.4 (12.0)	[3] 34.1 (8.8)	.000
T'1 – T'0	[15] -14.7 (10.3)	[3] -5.8 (7.3)	.000.
CF physical score			
Baseline (T0)	24.7 (4.0)	24.6 (3.7)	.887
Post intervention (T1)	[15] 14.8 (7.4)	[3] 21.0 (5.2)	.000
T1 – TO	[15] -9.7 (6.5)	[3] -3.6 (4.2)	.000.
CF mental score			
Baseline (T0)	15.0 (3.8)	15.2 (3.9)	.750
Post intervention (T1)	[15] 9.6 (5.5)	[3] 13.1 (4.6)	.000
T1 - T0	[15] -5.0 (4.7)	[3] -2.2 (3.7)	.000
SF-12-PCS score	<u></u>		
Baseline (T0)	36.4 (6.6)	35.8 (7.2)	.632
Post intervention (T1)	[15] 41.3 (7.0)	[3] 38.3 (7.6)	.026
T1 – T0	[15] 4.8 (7.0)	[3] 2.6 (5.9)	.072
SF-12-MCS score			
Baseline (T0)	32.4 (10.2)	33.5 (8.7)	.514
Post intervention (T1)	[15] 42.6 (8.5)	[3] 34.0 (9.1)	.000
T1 - T0	[15] 9.8 (11.9)	[3] 0.5 (8.1)	.000
BMS-Spirituality score			
Baseline (T0)	65.2 (25.8)	71.1 (23.7)	.167
Post intervention (T1)	[15] 80.2 (22.7)	[3] 71.9 (24.3)	.057
T1 - T0	[15] 14.4 (21.9)	[3] 0.4 (19.0)	.000

CF: Chalder's fatigue, PCS: physical component summary, MCS: mental component summary, BMS-spirituality: Body-Mind-Sprit-Spirituality \* T-test, [Number of missing data]

#### 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

	Intervention group $(n = 72)$
Days of Qigong practice	
/week	
No practice	4 (5.6%)
1 – 2 days	14 (19.4%)
3 — 4 days	20 (27.8%)
5 – 6 days	12 (16.7%)
Every day	6 (8.3%)
Missing	16 (22.2%)
<b>Duration per time (minutes)</b>	
No practice	3 (4.3%)
< 15	6 (8.3%)
15 – 30	19 (26.4%)
30 – 45	23 (31.9%)
45 – 60	4 (5.6%)
> 60	1 (1.4%)
Missing	16 (22.2%)

# Table 4 Comparison between groups by Qigong practice frequency per weekand duration of Qigong practice per time

≥ 3 days/week	2 <b>1 1</b>		Duration of Qigong practice		
	< 3 days/week		≥ 30 minutes/time	< 30 minutes/time	
(n = 38)	(n = 18)	P*	(n = 28)	(n = 28)	P*
Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
39.2 (6.0)	38.4 (7.4)	.702	38.8 (5.3)	39.0 (7.5)	.902
21.8 (11.2)	29.1 (12.3)	.032	20.9 (8.9)	27.4 (13.8)	.004
-17.3 (8.9)	-9.3 (11.4)	.006	-17.9 (8.4)	-11.6 (11.3)	.021
24.4 (4.1)	24.3 (4.3)	.922	24.0 (3.8)	24.7 (4.4)	561
13.1 (7.0)	17.9 (7.3)	.021	12.3 (5.5)	16.9 (8.4)	.020
-11.3 (5.9)	-6.4 (6.7)	.007	-11.7 (5.5)	-7.8 (7.0)	.023
14.8 (3.7)	14.2 (4.0)	.585	14.8 (3.0)	14.4 (4.5)	.675
8.8 (5.2)	11.2 (5.7)	.117	8.6 (4.8)	10.5 (6.0)	.181
-6.0 (4.1)	-2.9 (5.4)	.023	-6.2 (4.3)	-3.8 (5.0)	.059
36.3 (7.2)	36.8 (6.7)	.800	36.2 (7.5)	36.8 (6.6)	.744
42.1 (7.3)	39.2 (6.2)	.149	42.2 (6.6)	40.1 (7.4)	.269
5.8 (6.9)	2.4 (7.1)	.089	6.0 (6.6)	3.3 (7.4)	.151
33.9 (10.5)	31.2 (10.1)	.362	35.9 (10.5)	30.1 (9.5)	.032
44.3 (8.1)	39.8 (8.2)	.058	44.6 (8.3)	41.1 (8.2)	.112
10.4 (11.0)	8.6 (14.1)	.602	8.7 (11.4)	11.0 (12.6)	.475
65.7 (27.5)	66.4 (22.2)	.922	66.2 (27.0)	65.7 (24.9)	.939
82.8 (23.3)	75.7 (21.5)	.275	83.5 (22.3)	77.5 (23.3)	.329
17.1 (18.9)	9.2 (27.4)	.214	17.3 (19.8)	11.9 (24.2)	.359
	Mean (SD)           39.2 (6.0)           21.8 (11.2)           -17.3 (8.9)           24.4 (4.1)           13.1 (7.0)           -11.3 (5.9)           14.8 (3.7)           8.8 (5.2)           -6.0 (4.1)           36.3 (7.2)           42.1 (7.3)           5.8 (6.9)           33.9 (10.5)           44.3 (8.1)           10.4 (11.0)           65.7 (27.5)           82.8 (23.3)	Mean (SD)Mean (SD) $39.2 (6.0)$ $38.4 (7.4)$ $21.8 (11.2)$ $29.1 (12.3)$ $-17.3 (8.9)$ $-9.3 (11.4)$ $24.4 (4.1)$ $24.3 (4.3)$ $13.1 (7.0)$ $17.9 (7.3)$ $-11.3 (5.9)$ $-6.4 (6.7)$ $14.8 (3.7)$ $14.2 (4.0)$ $8.8 (5.2)$ $11.2 (5.7)$ $-6.0 (4.1)$ $-2.9 (5.4)$ $36.3 (7.2)$ $36.8 (6.7)$ $42.1 (7.3)$ $39.2 (6.2)$ $5.8 (6.9)$ $2.4 (7.1)$ $33.9 (10.5)$ $31.2 (10.1)$ $44.3 (8.1)$ $39.8 (8.2)$ $10.4 (11.0)$ $8.6 (14.1)$ $65.7 (27.5)$ $66.4 (22.2)$ $82.8 (23.3)$ $75.7 (21.5)$	Mean (SD)Mean (SD) $39.2 (6.0)$ $38.4 (7.4)$ .702 $21.8 (11.2)$ $29.1 (12.3)$ .032 $-17.3 (8.9)$ $-9.3 (11.4)$ .006 $24.4 (4.1)$ $24.3 (4.3)$ $922$ $13.1 (7.0)$ $17.9 (7.3)$ .021 $-11.3 (5.9)$ $-6.4 (6.7)$ .007 $14.8 (3.7)$ $14.2 (4.0)$ .585 $8.8 (5.2)$ $11.2 (5.7)$ .117 $-6.0 (4.1)$ $-2.9 (5.4)$ .023 $36.3 (7.2)$ $36.8 (6.7)$ .800 $42.1 (7.3)$ $39.2 (6.2)$ .149 $5.8 (6.9)$ $2.4 (7.1)$ .089 $33.9 (10.5)$ $31.2 (10.1)$ .362 $44.3 (8.1)$ $39.8 (8.2)$ .058 $10.4 (11.0)$ $8.6 (14.1)$ .602 $65.7 (27.5)$ $66.4 (22.2)$ .922 $82.8 (23.3)$ $75.7 (21.5)$ .275	Mean (SD)Mean (SD)Mean (SD)Mean (SD) $39.2 (6.0)$ $38.4 (7.4)$ $702$ $38.8 (5.3)$ $21.8 (11.2)$ $29.1 (12.3)$ $032$ $20.9 (8.9)$ $-17.3 (8.9)$ $-9.3 (11.4)$ $006$ $-17.9 (8.4)$ $24.4 (4.1)$ $24.3 (4.3)$ $922$ $24.0 (3.8)$ $13.1 (7.0)$ $17.9 (7.3)$ $001$ $12.3 (5.5)$ $-11.3 (5.9)$ $-6.4 (6.7)$ $007$ $-11.7 (5.5)$ $14.8 (3.7)$ $14.2 (4.0)$ $585$ $14.8 (3.0)$ $8.8 (5.2)$ $11.2 (5.7)$ $.117$ $8.6 (4.8)$ $-6.0 (4.1)$ $-2.9 (5.4)$ $023$ $-6.2 (4.3)$ $36.3 (7.2)$ $36.8 (6.7)$ $.800$ $36.2 (7.5)$ $42.1 (7.3)$ $39.2 (6.2)$ $.149$ $42.2 (6.6)$ $5.8 (6.9)$ $2.4 (7.1)$ $.089$ $6.0 (6.6)$ $33.9 (10.5)$ $31.2 (10.1)$ $.362$ $35.9 (10.5)$ $44.3 (8.1)$ $39.8 (8.2)$ $.058$ $44.6 (8.3)$ $10.4 (11.0)$ $8.6 (14.1)$ $.602$ $8.7 (11.4)$	Mean (SD)Mean (SD)Mean (SD)Mean (SD)Mean (SD) $39.2 (6.0)$ $38.4 (7.4)$ .702 $38.8 (5.3)$ $39.0 (7.5)$ $21.8 (11.2)$ $29.1 (12.3)$ $0.32$ $20.9 (8.9)$ $27.4 (13.8)$ $-17.3 (8.9)$ $-9.3 (11.4)$ $0.06$ $-17.9 (8.4)$ $-11.6 (11.3)$ $24.4 (4.1)$ $24.3 (4.3)$ $922$ $24.0 (3.8)$ $24.7 (4.4)$ $13.1 (7.0)$ $17.9 (7.3)$ $0.021$ $12.3 (5.5)$ $16.9 (8.4)$ $-11.3 (5.9)$ $-6.4 (6.7)$ $0.07$ $-11.7 (5.5)$ $-7.8 (7.0)$ $14.8 (3.7)$ $14.2 (4.0)$ $5.85$ $14.8 (3.0)$ $14.4 (4.5)$ $8.8 (5.2)$ $11.2 (5.7)$ $.117$ $8.6 (4.8)$ $10.5 (6.0)$ $-6.0 (4.1)$ $-2.9 (5.4)$ $.023$ $-6.2 (4.3)$ $-3.8 (5.0)$ $36.3 (7.2)$ $36.8 (6.7)$ $.800$ $36.2 (7.5)$ $36.8 (6.6)$ $42.1 (7.3)$ $39.2 (6.2)$ $.149$ $42.2 (6.6)$ $40.1 (7.4)$ $5.8 (6.9)$ $2.4 (7.1)$ $.089$ $6.0 (6.6)$ $3.3 (7.4)$ $33.9 (10.5)$ $31.2 (10.1)$ $.362$ $35.9 (10.5)$ $30.1 (9.5)$ $44.3 (8.1)$ $39.8 (8.2)$ $.058$ $44.6 (8.3)$ $41.1 (8.2)$ $10.4 (11.0)$ $8.6 (14.1)$ $.602$ $8.7 (11.4)$ $11.0 (12.6)$ $65.7 (27.5)$ $66.4 (22.2)$ $.922$ $66.2 (27.0)$ $65.7 (24.9)$ $82.8 (23.3)$ $75.7 (21.5)$ $.275$ $83.5 (22.3)$ $77.5 (23.3)$

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 cocial interaction offect

- 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.

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