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A Feasibility Study on the Implementation of Qigong Exercises in the Elderly Population Suffering From Chronic Back Pain

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Abstract

Background: Chronic Back Pain (CBP) is a common symptom bothering the elderly population seeking medical care. The most common strategy suggested for the relief of this condition is pharmacological and causes harmful side effects. Yi Ren Medical Qigong (YRMQ) has demonstrated that just one single application of this gentle exercise could reduce chronic pain in elderly people. The objective of this clinical trial was to evaluate the effectiveness of qi therapy in decreasing pain or discomfort.

Methods: This pilot study evaluated the use of YRMQ in a group of seven participants with CBP. Participants aged 66.7+/-3.4 years with CBP took part in weekly one-h group qigong sessions in addition to practicing a shorter version of the exercises at home twice a week. Pain intensity was evaluated using a Visual Analog Scale (VAS), showing reduction of symptoms. Other assessment tools such as the Roland Morris Disability Questionnaire (RMDQ) and the Brief Pain Inventory (BPI) scales were used to measure the pain reduction over the course of the 5-week trial.

Results: A total of 7 subjects (4 women and 3 men) were enrolled successfully in the trial. Out of the seven participants, 28.6% (two) of the subjects came every week, 42.8% (three) missed one week, while 28.6% (two) missed two or more weeks. The mean adjusted low back intensity using the VAS started at 4.43+/-2.76 and ended at 3.16+/-2.4 (P=0.144). The quality of life was measured with the RMDQ and showed a reduction from the beginning of the trial at 6.43+/-5.65 to the end at 4+/-4.24 (P=0.042). Finally the two-part BPI also decreased from the baseline to week-5 respectively (Part I and II) from 4.61+/-2.82 to 2.65+/-0.91 (P=0.043) and from 4.25+/-2.74 to the end at 2.23+/-1.29 (P=0.043). No serious or life-threatening adverse effects were found.

Conclusion: Qigong has proven to provide at least in the short term some reduction of pain and pain medication use. Our preliminary efficacy results were consistent with previous qigong studies showing improvement of back pain via assessment score changes, but not enough significant statistical evidence relevant to prove replicable efficacy of the proposed exercises. There were still multiple limitations to our trial such as the study group not having a control group to compare the results. The small sample size associated with our pilot design limited our statistical power. Conducting a 5 week pilot trial of qigong exercises for an elderly population sample with CBP was moderately feasible.

Keywords: Chronic back pain; qi therapy; pain medication

Introduction

In the light of scientific advancement related to today's modern medicine, chronic pain conditions are still a common problem. According to recent findings, some sort of chronic pain affects the American population seeking medical care; there has nonetheless yet to be an effective cure or treatment that has completely eradicated the pain condition [1]. Bullington et al. claim, "The complexity of pain is rooted in a multidimensional phenomenon that constantly travels between biology and culture" [2]. Taking into account the existential aspects of this condition (emotional, socio-political and psychological) can test the physician to use sustainable treatment plans not only instantly benefiting the patient's symptoms, but also providing meaning to their everyday life.

In the 21st century, a holistic model for mind-body well-being is increasingly employed by the health and medical professions. In 2001, The World Health Organization (WHO) defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".

There are many traditional complementary interventions that have been employed for the prevention and cure of disease; however medical qigong is being closely monitored due to the fact that it can also strengthen health. It has been researched to improve our activity level through auto-modulation of the mind-body connection [3]. In the Chinese tradition, qi is a term that refers to a kind of vital energy [4]. Kerr [5], "the term qigong is usually used to describe what the Chinese call qi practices, which cultivate the qi by using slow movements, matched to breathing exercises and meditative visualizations". Due to its well-known health benefits, a community of around 70 million Chinese engages in qigong exercises daily [6] and there are many qigong clinics available for group and individual practice. After reviewing medical texts detailing treatment plans offered by some Chinese hospitals, qigong was often integrated with traditional Chinese medicine and with conventional western biomedicine as a treatment modality prescribed to the patient by their physician.

When deepening the understanding of traditional Chinese medical belief, most of the patterns converge in the idea that chronic pain can be considered to primarily result from an imbalance of qi circulation or perhaps a disharmony and depletion in the reserve of vital energy. Change in the pattern or flow of qi can result in diseases; this

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presentation can involve some form of blocked transmissions, stasis impairments or simple imbalances that are very difficult to eradicate. This kind of pathology can give rise to a list of symptoms such as inflammation, limitation of motion, abnormal hot or cold sensations, lack of smoothness, or more apparently change in the color of the skin. The practice of qigong therapy in response to these symptoms can offer a healing method based on "a restoring, enhancing, renewing, rejuvenating, revitalizing, or replenishing process by the self as well as by others to attain harmony and balance" [3].

The purpose of this study was to perform a feasibility test on the implementation of qigong exercises in the elderly population with CBP. Although there are many benefits to the practice of qigong, one of the main reasons this exercise could be of support to the elderly population suffering from CBP is due to its positive effects on the sympathetic nervous system. When activity in this system is reduced, tremendous pain relief can occur [7]. According to the WHO (2002), "population aging is a triumph of humanity but also a challenge to society. Worldwide, the number of persons over 60 years is growing faster than any other age groups". The United Nations claims that "the number of this age group was estimated to be 688 million in 2006, projected to grow to almost 2 billion by 2050" (2004). It is also worth mentioning that the growing numbers of falls in the older adults has an impact on the well-being of that population; therefore, preventative and healthy attitudes should be encouraged to counteract this negative trend [8].

Methods

Study design

This feasibility study determined the potential of the proposed qigong protocol to be accepted and implemented in a population aiming 10 elderly participants suffering from CBP. Based on the guidelines set in the Doctorate of Acupuncture and Oriental Medicine capstone project manual, a recruitment of 5-15 subjects is successful enough to demonstrate that a pilot study is significant to promote further research studies on the topic. Therefore, our study proposed to aim for a population size of a similar range evaluating the recruitment success, retention rates, home practice compliance and adherence to the proposed exercises by monitoring adverse effects. These exercises were geared to energize their qi and promote blood flow in the pain-causing areas of stagnation. The sessions were held once a week for a total of 5 weeks with assessments taken at baseline, weeks 3 and 5. Any changes in pain, and back-related function were detected using VAS, the RMDQ and the BPI.

Subjects

Recruitment took place at the Bastyr University, Bastyr Center for Natural Health, nearby grocery stores, senior centers and other community locations via print advertising (flyers). The student investigator personally informed the clinical supervisors at the Bastyr Center for Natural Health of the research via email and presentations. Interested eligible potential participants called the number on the flyers to register for the study.

Inclusion criteria

- Must be 60 years of age and up
- Must have been suffering from back pain for more than 3 months
- Must agree to log in the times of home practices
- Must read and speak English

Exclusion criteria

The following variables were chosen to minimize confounding factors and better assess the benefit of qigong with CBP:

- Serious acute or chronic organic illness such as cancer and advanced stage immune or blood disorders
- Diagnosed mental disorder that requires medication and counseling
- Known abuse of alcohol and drugs reported in medical history
- Documented participation in other intervention studies or receiving additional therapy that has not been reported as part of their usual regimen for the duration of the clinical trial.

Consent

A consent form was given to the participants to sign prior to beginning the study. This form acknowledged the risks of participating in the clinical trial such as possible changes in complexion, warm sensations in the hands and feet, increased salivation and emotional changes. Participants were allowed to discontinue with the protocol at any time they felt concerned with these effects.

Research setting

The study took place in a group setting at the Bastyr Center for Natural Health (BCNH). The specific qigong exercises were developed by Yi Ren Qigong Center founder Guan-Cheng Sun, PhD who was employed as a research scientist and qigong instructor by Bastyr University at the time of the study. Dr. Guan-Cheng Sun, Lauri Amidon-Dinces, a certified Yi Ren Qigong instructor and Nathalie Guillaume, the student investigator led a 2 h training session on the first week of the study. The following 5 weeks were allocated to the specific 60 min Qigong session that has been geared toward reducing CBP symptoms. The training was an important part of the trial and consisted of a thorough demonstration of each movement with built-in down time for the assimilation of the exercises.

Procedure

The research team developed a reproducible standardized qigong protocol for CBP intended for individuals with little or no exercises experience. The intervention consisted of a training session and 5 weekly 60 min YRMQ sessions led by the experienced qigong instructor Lauri Amidon-Dinces and the student investigator Nathalie Guillaume, followed by questionnaires at baseline, weeks 3 and 5. The movements were geared to treat the qi imbalance related to CBP. Participants committed to doing the exercises at home at least twice a week with the help of a pre-handed DVD and manual. This information also provided insight on their adherence to the study, commitment level and interest in implementing qigong as a potential tool to alleviate their CBP symptoms.

The qigong program was the same at each session and consisted of 3 parts. Each section was integrated directly from the YRMQ methods and has a cumulative effect when practiced together. Easing the stress of pain by encouraging a restful state and promoting self-manual stimulation also become integral parts of Qigong's therapeutic effect.

Below is a summary of the 3 parts:

Part I: Warm up movements

Part II: Basic movements to affect body awareness, balance, coordination and muscle tension

Part III: Relaxation and mindfulness meditation with self-performed body massage at the end

Detailed procedures of the intervention

Participants were trained at a 2 h seminar to initiate the YRMQ activation. After the initial training, participants were asked to follow a regular practice of 30 min per practice session, at least twice a week at home for 5 weeks. In addition, Lauri Amidon-Dinces and Nathalie Guillaume held weekly one-h qigong group sessions during the intervention. The weekly administered MOSES provided insight on any adverse effects that the exercises may have caused on the participants' current health condition.

The proposed YRMQ intervention consisted of a set of 10 gentle and simple exercises:

Part I: Warm Up Movements (15 min)

- Gentle body shaking exercise (2 min)
- Subtle energy field construction exercise (3 min)
- Internal power station activating exercise (5 min)
- Internal energy centers activating exercise (5 min)

Part II: Basic Movements to Affect Body Awareness, Balance, Coordination and Muscle Tension (30 min)

- Autonomic nervous system activation exercise (10 min)
- Autonomic nervous system balancing exercise (10 min)
- Kidney energy recharging exercise (10 min)

Part III: Relaxation and Mindfulness Meditation with Self Performed Body Massage at the End (15 min)

- Brain-adrenal glands relaxation exercise (10 min)
- Cool down exercise (3 min)
- Gentle tapping (2 min)

A DVD with the shorter version of these exercises was developed. The DVD of YRMQ for CBP takes a total of approximately 30 min. A YRMQ training manual was also developed to outline the details of each exercise to guide the participants step by step and assist their practice at home and during weekly group sessions. It was important that participants practiced the above exercises with a constant awareness of qi-energy between their hands, as well as between the hands and the body, with natural breathing and movements, hence the importance of the training session. For this reason, participants received a DVD and manual of YRMQ to assist with their home practice at the end of the qigong training session.

There were three steps of treatments in this intervention summarized in Table 1.

Pain and quality of life assessment

Past experiments reviewed by Lee et al. [9] have used a variety of assessment tools to measure the potential of qigong in reducing pain symptoms in the study population. For the purpose of this feasibility study, the VAS, RMDQ and BPI were instruments of choice used at baseline, weeks 3 and 5.

Home exercise compliance and adverse effects

In addition to the pain and quality of life assessment, there were weekly reports that monitored home exercise compliance and adverse effects that may have been caused by the proposed protocol.

- The exercise logs served as an important tool to validate the implementation of the study. It determined the participants' compliance and understanding of how the qigong exercises could potentially alleviate their CBP symptoms if performed regularly.
- The MOSES was used to assess adverse events in the study. The information collected from this assessment tool also potentially answered questions regarding participants who might have dropped out of the study due to physiological changes.

Statistical analyses

The data was analyzed using a free calculator available on the website http://www.graphpad.com. The data is presented in mean +/- SD and was pulled at baseline, weeks 3 and 5 utilizing the Wilcoxon signed ranked test which is a statistical hypothesis test used when comparing two related samples, matched samples or repeated measurements on a single sample to assess whether their population mean ranks differ. This test determined whether one of the two samples of independent observations tended to have larger values than the other. A significance level of 0.05 was used with the test meaning that 0.025 is in each tail of the distribution of the feasibility study's test statistic. By using a two-tailed test, regardless of the direction of the relationship of our hypothesis, we are testing for the possibility of the relationship in both directions. Due to the limited-nature of this feasibility study, emphasis was placed on the recruitment success as preliminary data for future studies dedicated to the efficacy of the qigong exercises. Formal sample size calculations have only a limited role in this feasibility study and therefore power was omitted. Even with a small feasibility study of this scale, the answers obtained were precise enough to be useful.

Results

The study participants were recruited from February 28th to March 10th 2012. Flyers were placed at the Bastyr Center for Natural Health, Bastyr University, nearby grocery stores, community and senior centers.

The subjects were assigned a number starting with 0.0.1 according to the respective order they called to enroll in the study. There were nine inquiries of which one did not qualify due to unavailability on the meeting days and one could not commit to the study after enrolling due

Steps	1. Initial Training	2. Weekly Group Practice (once a week) and Home Practice (twice a week)	Phone Follow up with Potential Study Drop outs
Timeline in study	Baseline	Weeks 1-5	The week following when the participant no longer came to weekly group practice
Goals to achieve	Successful training in YRMQ	1) Compliance to proposed qigong protocol 2) Relieved pain levels and improved back related function	To inquire on why they dropped out of the study

The three steps followed during the study are explained here as: 1) Initial Training 2) Weekly group practice and home practice and 3) Phone follow-up with potential study drop-outs

Table 1: Steps of treatment.

to schedule related conflicts. The mean age of the seven subjects was 66.7 +/- 3.4 years.

The subjects suffered from back pain for various length of time ranging from 2 to 20 years with baseline pain scores ranging from 1/10 to 8/10. Although the expected pain score for a typical CBP study participant would be higher than a 1/10, due to the fluctuating nature of this condition, the continued intake of prescribed medication and other healing modalities (which was encouraged throughout the trial), participants who scored over a 0/10 (the absence of pain) were still considered eligible for the study. The inclusion criteria were kept broad because of the specific aims of the study focusing on feasibility rather than efficacy. Other modalities used during the qigong exercise protocol included anti-inflammatory drugs, massage, physical medicine (hydrotherapy and soft tissue manipulations), naturopathic and chiropractic care as well as other mind-body exercises such as tai ji, yoga, pilates and meditation. Although this combination can be considered a great deal of supplemental modalities, due to the excruciating symptoms associated to CBP most patients suffering from this disorder are using a multidisciplinary treatment plan approach.

Study feasibility assessment

Recruitment success: Given the short window of 10 days to recruit 10 study participants meeting the required inclusion and exclusion criteria, enrolling 7 subjects (4 women and 3 men) who successfully participated in the trial met our expectations at 70%, which is very encouraging for future studies. The gender and age distribution of the subjects in this pilot study are reported in Table 2.

Retention rate: For a clinical trial of this type, occasional missed classes are to be expected which can potentially deviate the data collection process. The key component of this section is that none of the participants dropped out due to a study related issue making this trial's retention rate 100%. Out of the seven participants, 28.6% (two) of the subjects came every week, 42.8% (three) missed one week, while 28.6% (two) missed two or more weeks as reported on Table 3.

Home exercise compliance: Participants were given weekly reports that monitored home exercise compliance. These exercise logs served as an important tool to validate the implementation of the study. It determined the participants' compliance and understanding of how the cumulative effect of the qigong exercises could potentially alleviate their CBP symptoms if performed regularly. No direct correlation could be made between the proposed protocol's dose response and its accumulation effect due to the lack of a larger sample size and irregularity of attendance; however the 100% compliance rate on fully committed weeks can be attributed to the positive trends seen in the pain score decrease and quality of life improvement. As shown in Table 4 below, all of the participants practiced at least twice a week (a total of 10 times throughout the study duration) unless they were ill or out of town for a short period of the week and didn't have access to a DVD player such as in participant 0.0.3's case or in the case of participant 0.0.7, suffering from some type of non-study related ailment that prevented them from exercising. Both participants 0.0.1 and 0.0.4 had to go out of town towards the end of the study for family emergencies, justifying their lack of compliance to the exercise routine. One of the participants (0.0.6) reported doing the exercises with his wife and really enjoyed that. All the participants reported that the DVD was very easy to follow and would have actually preferred a full 60-min version instead of the short 30 min. One participant (0.0.4) reported doing an improvised shorter version before bedtime and another (0.0.3) reported doing them by memory when traveling. The Table 4 shows the exercise compliance report.

Subject	Age	Gender
0.0.1	72	F
0.0.3	66	M
0.0.4	65	F
0.0.6	69	M
0.0.7	67	F
0.0.8	67	F
0.0.9	61	M
Mean Age	66.7+/-3.4	

The study had a total of seven participants of which four females and three males with a mean age of 66.7+/-3.4 years

Table 2: Subject gender and age.

Subject	Training	Week 1	Week 2	Week 3	Week 4	Week 5
0.0.1	X	X	X	X	X	0
0.0.3	X	X	X	X	0	X
0.0.4	X	X	X	X	0	0
0.0.6	X	X	X	X	X	X
0.0.7	X	X	0	0	0	X
0.0.8	X	0	X	X	X	X
0.0.9	X	X	X	X	X	X

X=Present and O=Absent. Attendance of the study participants during the weekly group practices. 28.6% (two) of the subjects came every week, 42.8% (three) missed one week, while 28.6% (two) missed two or more weeks

Table 3: Attendance chart.

Subject	Week 1	Week 2	Week 3	Week 4	Week 5	Total Practice Time
0.0.1	2	2	2	2	n/a	8/10
0.0.3	3	3	3	1	2	12/10
0.0.4	2	3	5	n/a	n/a	10/10
0.0.6	5	5	5	4	4	23/10
0.0.7	2	n/a	n/a	n/a	2	4/10
0.0.8	2	3	3	2	3	13/10
0.0.9	2	2	2	2	2	10/10

This table reports the participants' compliance to the bi-weekly home practice totaling 10 times in the 5 weeks study period. 28.6% practiced less than 10 times (0.0.1=8/10 and 0.0.7=4/10), 28.6% practiced the required 10 times (0.0.4 and 0.0.9) and the remaining 42.8% practiced more than 10 times (0.0.3=12/10, 0.0.6=23/10 and 0.0.8=13/10)

Table 4: Exercise compliance chart.

Adverse events monitoring: The MOSES was used to assess adverse events in the study. The information collected from this assessment tool also potentially answered questions regarding participants who might have not complied with the study due to physiological changes. There were minor to no side effects associated with only 3 out of 7 of the participants reporting changes of which two of them were related to other health issues pertaining to traveling and food poisoning. Only one participant (0.0.8) however, had some side effects that were exclusively related to the study. On a scale from 1 to 4, she reported the following sensations on week 2 (Table 5).

Her medication regimen included Vicodin 7.5 mg 1-2 times per day (a total of 7-14 tablets per week) at bedtime and Gabapentin 3 times per day (a total of 21 tablets per week). However on week 5, she changed her prescription from Vicodin 7.5 mg to Tramadol 50 mg, only took Vicodin 7.5 mg once (a total of 1 tablet per week) and 2 Tramadol 50 mg twice that week (a total of 4 tablets per week) without taking any Gabapentin. These changes are indicators that medication dosage

should be closely monitored for future studies in order to analyze the effectiveness of the exercises (Figure 1).

Pain and quality of life assessment

The following table is the summary of Z values and statistical significance (Tables 6 and 7).

Changes in pain level with the VAS: Pain levels were assessed with the VAS and data was pulled at baseline, weeks 3 and 5. With this assessment tool, patients' subjective pain score can be reported during the treatment and whether or not the pain is reduced can be monitored. From baseline to week 3, the Z value was -0.962 and from week 3 to week 5, it changed to 0.272. However, the overall Z value from the beginning of the trial to the end was 1.46. When analyzing participant 0.0.6, 0.0.7 and 0.0.8 who were assessed from baseline to week 5, we noticed a trend toward pain reduction from the beginning of the trial to the end. The VAS can be a very tricky tool to use when assessing CBP due to the fluctuating nature of the condition; it can reflect a biased subjective summary of the participant's condition. This can represent a limitation in the accuracy of the data and future studies should use a wider variety of objective assessments in order to justify the trials' outcome (Figure 2).

Side-Effect	Intensity (1-4)
1. Imbalance	2/4
2. Restlessness	3/4
3. Tremor	3/4
4. Tingling	3/4
5. Itchiness	3/4
6. Chills	3/4
7. Crying	3/4
8. Irritability	3/4
9. Withdrawn	2/4
10. Flatulence	3/4
11. Constipation	2/4
12. Weight decrease	3/4
13. Urination increase	n/a
14. Poor concentration	n/a
15. Insomnia 3-4 nights	n/a

This table displays the physiological changes that occurred for participant 0.0.8 while on the second week of the trial. Although they did not interfere with her daily life per her oral reports, she was conscious of the noticeable changes that were happening in her body as it was healing itself and becoming pain-free

Table 5: Participant 0.0.8 MOSES chart for week 2.

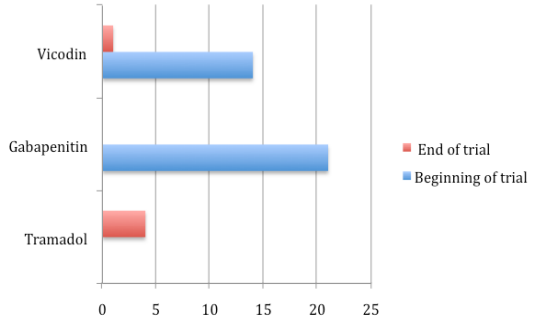

Figure 1: Medication changes for participant 0.0.8.

In this figure, the amount of pain medication participant 0.0.8 was taking from the beginning of the trial had gone through a dramatic change in dosage toward the end of the trial showing that the proposed YRMQ protocol could potentially reduce the need for anti-inflammatory drugs

Instrument	Time period	Z	P-value
VAS	Baseline – Week 3	-0.962	0.336
	Week 3 – Week 5	0.272	0.785
	Baseline – Week 5	1.461	0.144
RMDQ	Baseline – Week 3	-1.473	0.141
	Week 3 – Week 5	0.447	0.655
	Baseline – Week 5	2.032	0.042**
BPI-1	Baseline – Week 3	-1.472	0.141
	Week 3 – Week 5	0.365	0.715
	Baseline – Week 5	2.023	0.043**
BPI-2	Baseline – Week 3	-2.201	0.028**
	Week 3 – Week 5	1.461	0.144
	Baseline – Week 5	2.023	0.043**

** Indicates statistical significance at alpha <0.05 (Wilcoxon signed rank test)

Table 6: Z-values and statistical significance.

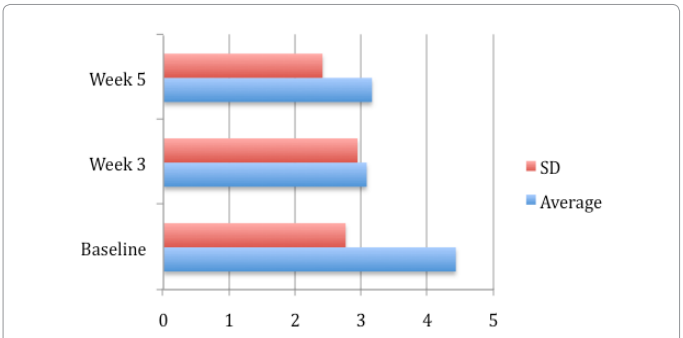

Figure 2: Visual analog scale (VAS).

This chart shows the average group VAS scores taken at baseline, week 3 and week 5, reporting a clear reduction in pain intensity form the beginning of the trial at 4.43+/-2.76 to the end at 3.16+/-2.41 (P=0.144)

Changes in back-related function:

Assessing with the RMDQ: Back related function was assessed with the RMDQ and data was pulled at baseline, weeks 3 and 5. This assessment tool allowed us to determine if the YRMQ protocol changed the quality of life in the participants suffering from CBP symptoms. From baseline to week 3, the z-value was -1.473, from week 3 to week 5 it was 0.447 and from the beginning of the trial to the end, the z-value was 2.032 with a p-value of 0.042. This indicates that 5-week practice of YRMQ following the protocol could potentially enhance back-related function and increase quality of life in subjects suffering from CBP. A total of 5 out of 7 participants (0.03, 0.0.6, 0.0.7, 0.0.8 and 0.0.9) showed decrease in scores (Figure 3).

Assessing with the BPI: To further assess the changes in back-related function and quality of life, the BPI was used. This tool is particularly important in the measure that it allows the participants to shade in the area of pain and report any additional modalities used for treating the condition. The participants unanimously identified the source of their CBP to be located in the lower lumbar region and did not include any modalities in their wellness regimen that were unreported at enrollment.

A) The first part of this test measured the pain severity with four questions (BPI-1). From baseline to week 3, the z-value was -1.472, from week 3 to week 5 it was 0.365 and from the beginning of the trial to the end the z-value was 2.023 with a p-value of 0.043.

	VAS_O	vAS_3	vAS_5	RAIDOJI	RMD0_3	R/400_5	DPI_O	13P1_3	87I_5	8P1_0	13P2_3	872_5
VAS_0 PearsOn Correlation	1	516	113	0.777	0.584	0.256	0.931"	586	631	895	971"	0.545
Sig (2-lailed)		295	856	0.04	244	0.678	2	221	221	6	0.001	0.342
6	7	6	5	7	6	5	7	6	5	7	6	5
V9S_3 Pearson Correlation	516		909	182	893	807	398	987"	688	447	653	0.813
Sig (2.1a9e10	195		31	730	16	193	435	0	312	374	159	187
ri	6	6	4	6	6	4	6	6	1	6	6	4
vAS_5 Pearson Correlation	113	909	I	0.185 9	939	869	• 175	879	401	0.103	350	661
Srg (2.tarie4)	856	91		765	61	56	779	121	934	870	650	224
1	5	4	5	5	4	5	5	**4**	5	5	4	5
R141)0_0 Pearson Cortelabon	777'	182	-186	I	189	311	633	/05	829	815'	775	452
Sr9 (2-1444)	40	730	765		325	611	127	697	256	25	70	445
11	7	6	5	7	6	5	7	**6**	5	7	6	5
RMD0_3 Pearson Conelatton	564	893'	939	489	1	969	358	876'	767	561	720	671
SI (2.tatte3)	244	16	61	325		31	496	22	233	247	106	129
N	6	6	4	6	6	4	6	6	4	6	6	4
RIAD0_5 Pearson Correlation	256	807	869	311	0.969	1	-960	722	646	73	488	0.848
Sig (2.1a9ec0	678	193	56	611	31		797	278	239	907	512	0.069
N	5	4	5	5	4	5	5	4	5	5	4	5
6F1_0 Pearson Correlation	931"	398	-175	633	358	..160	1	491	415	913"	894'	0.115
Sig (2-)a9ed)	2	435	779	0.127	186	797		319	487	4	16	0.853
al	r	6	5	7	6	5	r	6	5	7	6	5
8P1_3 Pearson Correlation	586	987-	879	205	876'	722	494	1	615	513	709	0.749
Sig (2 -laded)	221	0	II I	697	22	278	319		385	298	115	251
Pi	6	6	1	6	6	4	6	6	4	6	6	4
8F1_5 Pearson Correlabon	639	688	401	629	767	646	415	615	I	**749**	832	509
04 12444e16	253	312	504	256	233	239	487	365		145	168	381
N	5	4	5	5	4	5	5	**4**	5	5	**4**	5
8P2_0 Pearscm C44414661	895-	**447**	-903	815'	561	73	913"	513	719	1	956"	191
SI (2.1a4e0)	6	374	870	25	247	907	1	298	145		3	758
N	7	6	5	7	6	5	7	6	5	7	6	5
13P2_3 Pearson Correlation	971"	653	350	775	720	**M I**	894'	709	832	956"	1	826
SI (2-tatiee)	1	159	650	70	106	512	16	115	168	3		**174**
N	6	6	**4**	6	6	**4**	6	6	**4**	6	6	**4**
872_5 Pearson Correlation	545	813	661	452	871	848	115	749	509	191	826	1
Sig (2 -laded)	342	187	224	445	129	69	853	251	381	758	174	
N	5	4	5	5	1	5	5	4	5	5	4	5

• Correlatron IS 9197199171311110 00614701(2.13104)
•• Correlation IS $1951603111 al the 0 01 8711 (2-131144)
The above bivariate correlation matrix indicates the relationship between each instrument. For example at the baseline, VAS and BPI-1 were statistically significantly correlated at Pearson's r=0.931 (p=0.002). VAS and BPI-1 were also correlated at week 3 measurements (r=0.987) but not at week 5 (r=0.401). This indicates that instruments used in this study were not redundant

Table 7: The bivariate correlations.

All 7 participants displayed a lower score at the end of the trial (Figure 4).

B) The second part of this test measured the pain interference with seven questions (BPI-2). This section is mostly focused on the participant's mood and overall wellness; therefore it can give some great insight on how the proposed YRMQ protocol can potentially help in coping with the debilitating symptoms of CBP. From baseline to week 3, the z-value was -2.201, from week 3 to week 5 it was 1.461 and from the beginning of the trial to the end it was 2.023 with a p-value of 0.043 correlating with all 7 participants displaying a lower score towards the end of the trial just like the BPI-1 (Figure 5).

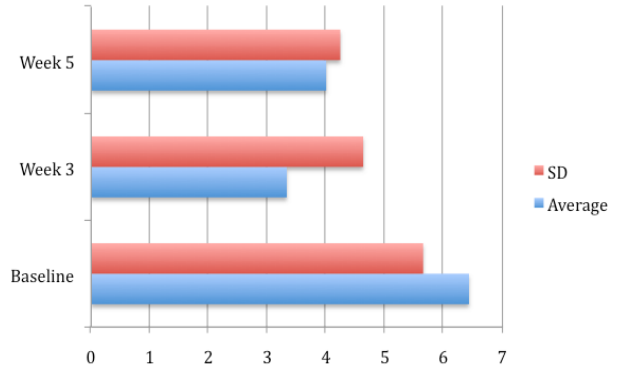

Figure 3: Roland Morris disability questionnaire (RMDQ).

This chart shows the average group RMDQ scores taken at baseline, week 3 and week 5, reporting a clear enhancement of back related function and quality of life form the beginning of the trial at 6.43+/-5.65 to the end at 4+/-4.24 (P=0.042)

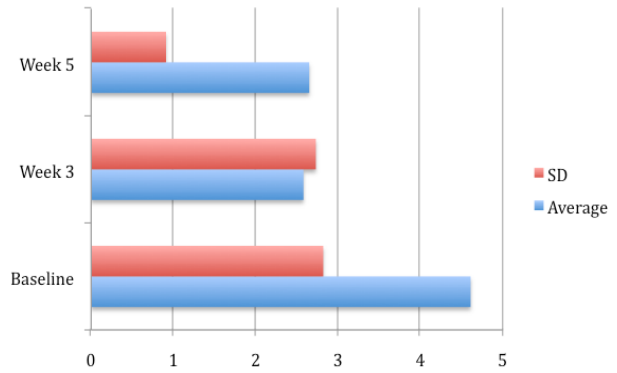

Figure 4: Brief pain inventory- Part 1 (BPI-1).

This figure shows the average Brief Pain Inventory-Part 1 (BPI-1) scores taken at baseline, week 3 and week 5 reporting a clear enhancement of back related function and quality of life form the beginning of the trial at 4.61+/-2.82 to the end at 2.65+/-0.91 (P=0.043)

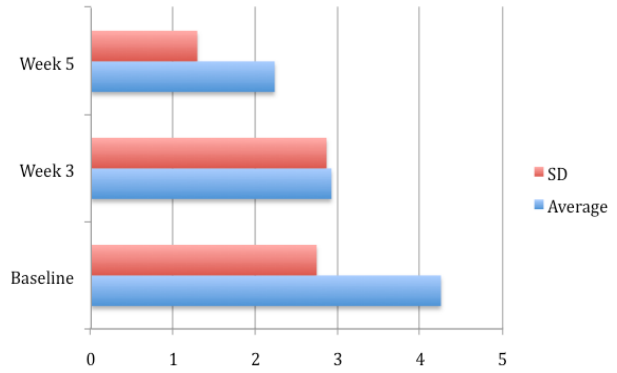

Figure 5: Brief pain inventory- Part 2 (BPI-2).

This chart shows the average BPI-2 scores taken at baseline, week 3 and week 5 reporting a clear enhancement of back related function and quality of life form the beginning of the trial at 4.25+/-2.74 to the end at 2.23+/-1.29 (P=0.043)

Discussion

This qigong study in the elderly population set out to determine the feasibility of a specific qigong protocol on easing the signs and symptoms associated with CBP. The design of the protocol was easy to replicate in order to see if it could efficiently be implemented in the study population. Based on the YRMQ perspective, the exercises were chosen for their actions in the Kidney energy depletion; this was presented in the reviewed literature as a leading cause of CBP. This study was a pilot trial; therefore the number of participants recruited was not enough to provide the power needed to allow for any generalizations to be made regarding efficacy. The results of the study demonstrated favorable outcomes when employing statistical analysis. This research project's objective did not specifically set out to determine efficacy, rather the study set out to test the feasibility of implementing the proposed protocol in the study population.

We found it was feasible to recruit and retain a small sample of elderly adults for a 5-week pilot study of a standardized qigong intervention for CBP. Adherence to treatment assignment during the 5-week intervention period was good, with no serious adverse events. Qigong participants showed a positive trend in pain intensity reduction and enhancement of quality of life over the 5 weeks compared to when they enrolled in the study as seen in the Results section.

Although the Wilcoxon ranked test didn't show statistical significance for the VAS ranges among the study participants from baseline to week 5 of the trial, the RMDQ, BPI-1 and BPI-2 all showed significant differences (P=0.042, 0.043, 0.043, respectively). Excluding those who were not able to take the assessments all 3 times despite trending towards pain reduction in scores, there was nonetheless a good proportion of study participants experiencing a trend towards decrease in pain and improved quality of life at 5 weeks via the assessment tools used. Our results would have changed significantly if outcomes should have been measured without imputing missing data due to the irregularity of attendance and participant absence.

These assessments tools indicated a positive trending towards pain reduction and enhancement of quality of life. The compliance to perform the home exercises and minimal reports of side effects were also very reassuring to further investigate the therapeutic benefits of this qigong protocol in a larger sample size. Due to the small population used, some of these findings, while compelling, may have been by chance. Based on these findings, the results of the study cannot be generalized to the elderly population suffering from CBP. Nonetheless, the preliminary data gathered from this study sets the stage for larger future studies.

Another major limitation of this uncontrolled trial may have been the choice to opt not to employ a randomly selected comparison group, making it unsuitable for fully evaluating the limited- efficacy of qigong in the treatment of CBP. Due to the short time allocated for the study and small sample size, very little was known about the potential of qigong to relieve CBP symptoms.

Although several studies have demonstrated racial and socioeconomic disparities in CBP treatments and outcomes, few intervention studies for this condition have targeted the elderly population. Our feasibility data illustrates some of the opportunities and challenges of such studies.

The large number of respondents during our short recruitment

time may reflect a significant interest in an unmet need for back pain treatment among elderly people living in the Seattle area. Basing the study in the Bastyr community that most participants were familiar with was convenient to them and also may have facilitated recruitment. Obtaining long-term retention rate of the entire study group was challenging since only 4 of the 7 participants committed to the weekly group practice regularly, however, it may reflect the reality of that population often dependent on a caregiver or responsible for taking care of their family obligations. Perhaps for future studies, we should design a longer trial of at least 12 weeks where only a set amount of classes (i.e.,: maximum 3 classes) should be permitted to be missed if the participants still want to remain in the trial.

Our preliminary efficacy results are consistent with previous qigong studies showing improvement of back pain via assessment score changes, but not enough significant statistical evidence relevant to prove replicable efficacy of the proposed exercises. An important difference between our trial and prior studies is that our study included a specific CBP protocol developed by Dr. Guan-Cheng Sun who has extensive research experience in the field. Furthermore, our participants verbally reported considerably greater pain and worse function before the trial.

Despite this revealing testimony, there were still multiple limitations to our trial such as the study group not having a control group to compare the results. These nonspecific aspects may have played a significant role in the Qigong's effect. Not having a blinded group and the use of self-measured assessment tools may have further contributed to bias. The small sample size associated with our pilot design limited our statistical power. Regarding generalization, it is unknown whether our findings can be replicated in other elderly groups, multiple locations, non-research qigong programs, and with different qigong teachers. In addition, our findings apply only to patients with nonspecific CBP as opposed to excluded conditions such as sciatica or spinal canal stenosis.

Strengths of our study, however, include the quick recruitment response of a diverse population with moderate-to-severe chronic back pain in a very a short period (70% of the expectation set), a successful retention rate (0% drop out due to a study related issue), home exercise compliance (most of the participants practiced at least twice a week unless they were ill or out of town), matching results from other standardized reproducible qigong interventions, standard enrollment criteria and outcome measures used in other CBP trials. Our future studies should focus on increasing the compliance to 100% as a requirement to remain in the study instead of allowing optional home exercises to count towards the data collection.

In summary, conducting a 5 week pilot trial of qigong exercises for an elderly population sample with CBP was moderately feasible. Qigong has proven to provide at least in the short term some reduction of pain and pain medication use. Although medication change was not a main objective of the study, after reviewing the MOSES, participants who were taking pain medication reported reduction and even cessation of their intake frequency. Opportunities for future qigong and CBP research in the elderly population include larger trials testing new strategies for improving recruitment, adherence, and outcomes; comparing effectiveness and cost of qigong to other common CBP treatments; and targeting the wider Seattle area.

Conclusion

The results of this study suggest several next steps for studying the potential for qigong exercises to help with CBP symptoms in the elderly population. The first step would be to complete a similar study with a larger number of subjects. The small number of this study did not allow for a power analysis and the required n for statistical significance was not determined. With a longer recruiting period and more advertisement, this could increase the number of participants in the future. The study demonstrated a number of feasible components, however it was lacking in the number of positive results for the intervention protocol. At this point, it is difficult to determine without the appropriate number of study participants if the actual YRMQ for CBP protocol is feasible.

A second step would be to design a controlled trial. There are a number of potential options for a controlled trial. Using other well-researched forms of gentle activities such as chair aerobic exercises could be a great comparison tool to show the difference in benefits of YRMQ. The creation of a control group would allow for a comparison of control and qigong arms of the study, allowing the research team to better assess whether or not subjects got better on their own or improved due to the qigong intervention. Another option could be to compare the YRMQ group to a non-exercise group in order to better understand the impact of the protocol on their health.

A third and last possibility is to design a study to assess the impact of qigong on an already active population engaging in some form of exercise. Due to the fact that the older adults could be less active in general, recruiting a group that engages in any other exercise protocol as supporting criteria could potentially show how the YRMQ protocol can specifically alleviate their pain by promoting more blood and qi circulation than regular exercises. This activity factor in the elderly population could be a valuable aim of future research.

The successes and challenges surrounding this YRMQ study demonstrate the need for future research. The lack of standardized care in biomedicine opens the door for complimentary modalities like qigong to fill the treatment gap. The study shows a number of ways that qigong could positively impact the quality of life for future CBP patients by laying the groundwork for larger studies in the future, giving interested researchers a workable direction in study design.

Summary

Combined, these four subgroups of questions and three assessment questionnaires totaled 35 questions. In this pilot study, the 7 subjects were asked to answer each question to the best of their ability. Based on their answers and the statistical analysis, a handful of positive trending patterns were discovered in the areas of pain relief and quality of life improvement but very little statistical significance was found though some of the p-values marked positive trending numerical changes from baseline to week 5. No power analysis was done due to the small sample size.

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