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The efficacy of Guolin-Qigong on the body-mind health of Chinese women with breast cancer: a randomized controlled trial

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Abstract

Purpose This study was to evaluate the efficacy of a complementary Chinese treatment modality Guolin-Qigong (GLQG) for patients with breast cancer on the body-mind health.

Methods A randomized controlled clinical trial was conducted among 158 women with breast cancer. Subjects were randomized to receive GLQG (test group) versus a physical stretching program (control group) following conventional treatment for breast cancer. GLQG and stretching interventions were performed twice a week over 24 weeks. The primary outcome was the change in quality of life (QoL). Secondary outcome measures included anxiety, depression, and clinical indicators. All participants were assessed at four time-points, at the beginning of the study (T1), after 12 weeks of the intervention (T2), immediately after 24-week intervention (T3), and at 48-week follow-up visit (T4).

Results Improvements in QoL were evident in both groups but the test group fared better than the control group at the 12th week ($P < 0.01$) and particularly in emotional well-being ($P < 0.01$) and breast cancer-specific well-being ($P < 0.001$). The test group showed an improvement in anxiety levels ($P < 0.01$), whereas the control group showed improvements in depression ($P < 0.05$) but there was no significant difference between groups ($P > 0.05$). Both groups showed improvements in immunological function and the test group fared better than the control in TNF-α levels ($P < 0.05$). The results in subjects who practiced more than 4 times and 6 h per week were similar to that of all subjects; however, the improvement in anxiety in the GLQG group was more obvious. There are positive correlations between QoL and anxiety and depression.

Conclusions Both GLQG and physical stretching are beneficial during recovery following breast cancer. GLQC was more effective in terms of Qol improvements than physical stretching. Both programs brought improvements in anxiety or depression but had were comparable. GLQC group had a greater effect on immunological function than physical exercise.

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Introduction

Breast cancer is the most prevalent malignancy among women worldwide. Among women in Hong Kong, breast cancer has the highest incidence of all cancers and the mortality rate from breast cancer is ranked the third highest among all cancers [1]. Although the mortality of breast cancer patients has been declined due to early diagnosis, improved surgery, comprehensive chemotherapy, radiotherapy, and hormone therapy in recent years, the side

effects of these treatments are obvious and most breast cancer patients often experience poorer quality of life (QoL), psychological condition, and vitality status [2, 3].

A recent local study showed that about 75.5% of breast cancer patients adopted a sedentary lifestyle and more than 65.6% had high or moderate levels of stress [4]. Moreover, psychological factors were found to alter the immune function of cancer patients and in turn have affected the development and prognosis of breast cancer [5]. There are few studies in Western medicine relieving those unpleasant complications. Although simple psychological interventions showed some beneficial effects on QoL and psychological well-being of breast cancer patients, the findings of their efficacy are still mixed and inconclusive, with some studies indicating improvement while others demonstrating no change or even deterioration [6–8]. Therefore, the development of more effective and side-effect-free alternatives and complementary treatment in rehabilitation of breast cancer patients is important.

As a well-recognized complementary treatment modality for cancer patients, Guolin-Qigong (GLQG), which is a unique form of Qigong specifically designed for cancer patients, has been increasingly adopted with accumulating evidence of improving longevity, body, and mental health of cancer patients in China [9, 10]. The most distinct advantage of GLQG, compared with other types and forms of Qigong programs, is that it facilitates the inhaling of much oxygen into the body, which contributes to inhibiting the growth of tumor cells and is favorable to the rehabilitation of cancer patients [11]. Additionally, it is very good at regulating patients' emotion and boosting their spirit [12]. A recent study in China indicated that GLQG could improve the QoL and mental health of breast cancer patients significantly [13]. Other investigations also found that the effects of GLQG in cancer patients to be associated with the increase of the oxygen content in arterial blood, potentially further improving microcirculation and enhancing the immune function [11, 14, 15].

Although some sporadic reports claim that GLQG has the effect of improving QoL and extending survival in cancer patients, there is no scientific evidence yet. Previous studies mainly included the use of less rigorous randomized controlled research methods and unstandardized patient-based assessment, and smaller sample sizes. Therefore, this study assessed the hypothesis that GLQG could significantly improve participant's QoL, as well as their emotional condition, immune function, and tumor marker.

Methods

Study design

This was a randomized, controlled trial comprising two parallel groups: The GLQG group (who received 24 weeks' intervention with GLQG) compared with a control physical stretching group (who received 24 weeks' intervention of stretching). The measures of clinical outcomes mainly included the QoL, anxiety and depression levels, and several biomarkers in blood related to immune function and cancer progression and prognosis. The study was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB, UW 12-046).

Participants

A total of 158 Chinese breast cancer patients aged between 21 and 80 with histological diagnosis of primary breast cancer stage 0-IIIb were recruited by advertisements in Hong Kong from 2012 to 2013. They had completed surgical therapy, or/and radiotherapy, chemotherapy or a combination within the past one year and had not engaged in any forms of Qigong within the past 6 months. Exclusion criteria included breast cancer patients with any severe mental disorders, a history of psychiatric illness or taking of psychotropic drugs, those with any medical conditions that limit body movement and those with serious concomitant disease or other cancers. Figure 1 provided a CONSORT diagram of recruitment, randomization, and participants.

Estimation of sample size

The primary outcome in this study was patients' QoL. According to a prior randomized controlled study of Qigong intervention on breast cancer patients, the standard deviation of the primary outcome measure of FACT-B score was around 16 [16]. Assuming the QoL score distribution of each group was normal and the variance was equal, to detect a moderate difference (effect size = 0.5, Cohen's d = 0.5 SD) (difference of QoL score 8) between the two groups using a 2 independent samples t test at a two-sided 5% significance level with 80% power, a sample size of 64 participants per group was needed. Assuming the attrition rate was approximately 20%, a total of 158 subjects were recruited for the proposed study.
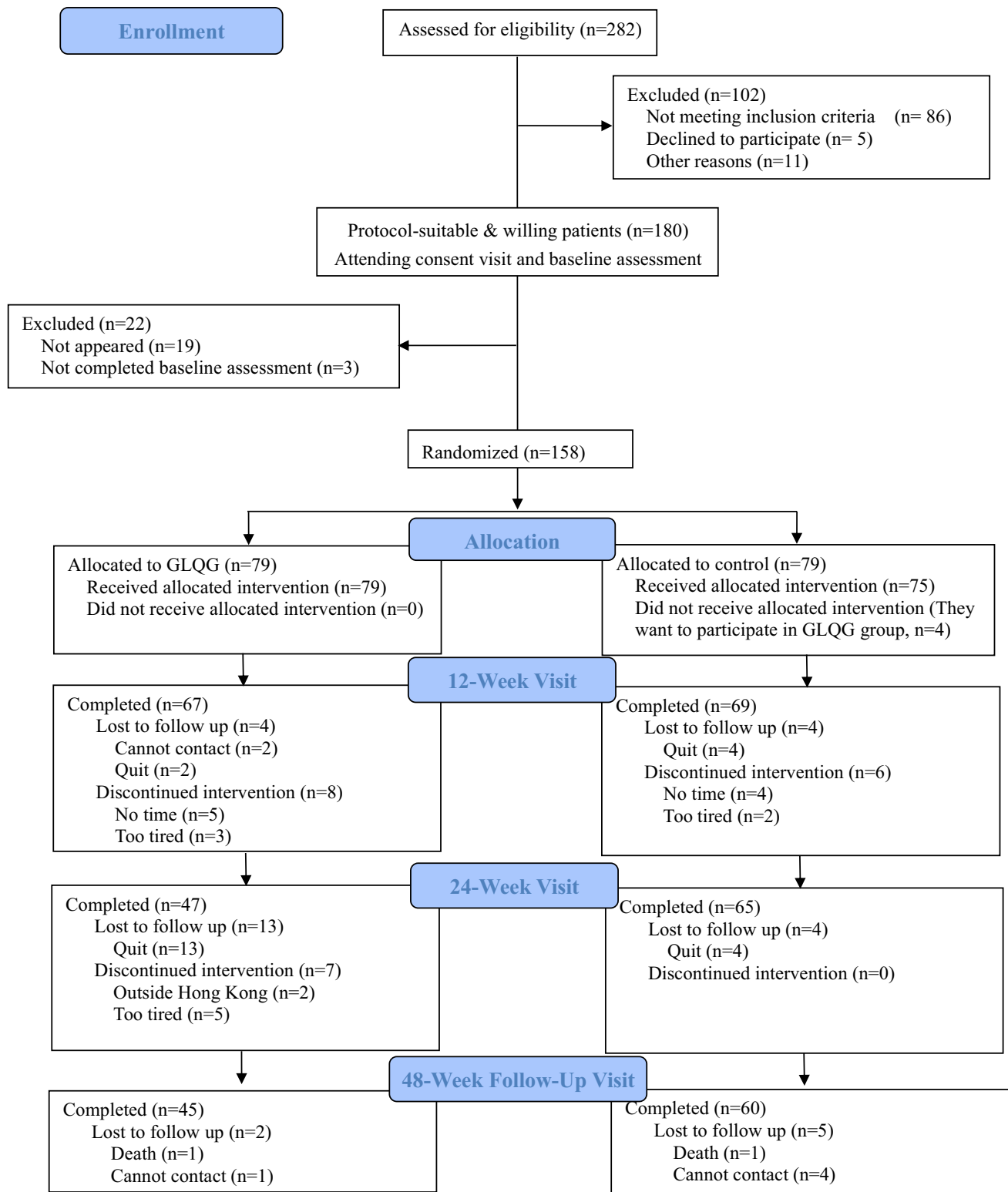
Fig. 1 CONSORT diagram of recruitment, randomization, and participants

Randomization and blinding

Registered patients were invited to attend an information session about the study. After screening, eligible subjects were invited to participate in the study and assigned to study. Subjects were block randomized to test and control group. Codes representing 2 groups were printed on one piece of A4 opaque paper and put into sealed envelopes by a research assistant. Then the envelope was opened by the patients themselves after the baseline assessments. Because this trial explored the effects of GLQG, it was not possible to 'blind' the patients. However, the randomization sequence and different groups were kept hidden from data collectors and analysts to 'blind' them.

Interventions

Eligible subjects were invited to participate in this project after obtaining their consent. There were two groups in this trial: GLQG group and physical stretching group. All subjects in the GLQG and physical stretching group were advised to report any illness or discomfort during the training program to the instructor concerned. To ensure compliance of the intervention program, all subjects were required to write a daily self-report diary recording the time and the intensity of their practice each day. In addition, all of them were closely monitored in the study and were given open clinical treatment as an additional safeguard, and advised not to join any other traditional Qigong classes or physical exercise such as Taichi and Yoga, etc.

Participants assigned to the GLQG intervention group were divided into 3 classes according to the enrollment sequence (about 26–27 patients in each class, with the same content and instructor in each training round) to successively receive 24-week intervention with GLQG (two 60-min sessions per week). Each 60-min GLQG training was conducted by a certified GLQG master with more than 10 years of practicing and tutor experience. Printed materials about basic theory and techniques of GLQG were provided to these subjects prior to the exercise. In each session, techniques of GLQG (consisting of meditation, breathing, walking with hand swing, phonation, and massage) were introduced to the participants [17, 18]. In addition to the collective practice sessions, all participants were asked to maintain routine self-practice (at least 40 min each day) using an instructional DVD in other days during this period. A trained research assistant with social work training background and experienced GLQG practitioners under the supervision of the Principal Investigator helped monitor each session of the training program.

Participants in the stretching group practiced stretching for 24 weeks (two 60-min sessions per week). The stretching mainly aimed at relieving the dysfunction of affected upper limbs and improving physical fitness. This sentense means that the exercise intensity of stretching is similar to GLQG, but stretching cannotcontrol thought and breathing which is totally different from GLQG. The practice of stretching was conducted by a fitness trainer. Similar to the GLQG group, participants in this group were demanded to do self-practice daily too.

Both treatment group and stretching group received exercise training following the ACSM guidelines (same dosage exercise at IPAQ-C).

Assessment measures

The primary outcome of this study was the change of QoL score from baseline to the end of the 24-week intervention, which was measured by the Chinese version of the Functional Assessment of Cancer Therapy-Breast Cancer (FACT-B). It consists of 37 items scored on a 5-point Likert scale, ranging from 0 to 4 with higher scores indicating better quality of life [19, 20]. There were some secondary outcomes including anxiety and depression measures and clinical objective examination (immune function and specific marker of breast cancer) during the 24-week intervention. Anxiety and depression were measured by the Hospital Anxiety and Depression Scale (HADS), consisting of 14 items with two subscales providing separate measures of anxiety and depression [21]. The lower scores indicate more improved emotion. Prior researchers pointed out that breast cancer was accompanied by immune dysregulation, characterized by reduced interleukin-2 (IL-2), interferon-γ (IFN-γ), and tumor necrosis factor-α (TNF-α). Accordingly, IL-2, IFN-γ, and TNF-α in serum were measured by an ELISA method to reflect the immune function [22]. Carcinoma Antigen 15-3 (CA 15-3), a circulation antigen, is the most important specific marker for breast cancer and mainly applied for predicting the prognosis of breast cancer [23]. In addition, the level of CA 15-3 in serum was assessed by radioimmunoassay and the socio-demographic (e.g., age, marital status, education, and occupation) and disease-related variables (e.g., cancer stage and type of treatment strategy) were also obtained.

All participants were assessed on four time-points. At the beginning of the study (T1), after 12 weeks of the intervention (T2), immediately after 24-week of intervention (T3), and at the 48-week follow-up visit (T4). In this study, all participants were encouraged to adhere to regular self-practice. They were asked to complete the questionnaires conducted by a trained research assistant and blood samples were collected between 8:00 and 10:00 am on the four time-points mentioned above. Quality and compliance to intervention were achieved by checking attendance records and the diary of self-practice was kept by each participant. All outcome assessors were blinded to the intervention types of participants.

Statistical analysis

Statistical analysis was performed using SPSS 19.0 for Windows version. The intent-to-treat analysis was utilized to deal with the missing data, that is to say, the data collected at the last time-point were adopted for the next time-point statistical analysis. Baseline demographic and medical characteristics were assessed by independent t tests and χ^2 tests. Data from the QoL, anxiety and depression, and objective indicators were analyzed with a mixed-effect model. For each outcome variable, time-points T2, T3, and T4 were regarded as the within-patients factor and the T1 was used as a covariate, and treatment group was the between-patients factor. In this model, the between-patients factor reflected the treatment effect and the interaction between time-point and treatment group showed whether the treatment effect differed between T2, T3, and T4. Treatment effects at T2, T3, and T4 were presented as adjusted mean differences with 95% CIs. Pearson correlation analyses were performed to explore the relationship between the primary outcome and secondary outcomes.

Results

Demographic and clinical characteristics at baseline

A total of 282 breast cancer patients were screened and 158 eligible subjects were randomly assigned to the GLQG group and the physical stretching group after screening. During the course of the study, 136 subjects completed the mid-term assessment (86.1%) after receiving the allocated 12-week intervention. Having received 24-week intervention (T3), 112 subjects completed the immediate post-intervention assessment (70.9%). The T4 data were obtained on 105 patients (66.5%). According to patients' logbooks, 20 patients in the GLQG group and 19 patients in the physical stretching group practiced more than 4 times and 6 h per week (Fig. 1).

Baseline demographic and clinical characteristics were summarized in Table 1. No significant differences were observed between the two groups in these characteristics.

Intervention effect on QoL and secondary outcomes in all subjects

Figures 2 and 3 illustrated the unadjusted group means for all outcome variables at each of the time-points and the corresponding difference between the two groups for all patients after adjusting for the baseline levels.

Primary outcome (QoL) Both groups showed significant improvement in QoL over time and GLQG group showed significantly higher scores at the 12th week (T2) after

adjusting for baseline levels and the mean difference was 8.05 (95% CI, 3.74–14.36; $P = 0.002$) (Fig. 2a).

There were also significant differences between the two groups on both subscales of emotional well-being (Fig. 2d) and breast cancer-specific well-being (Fig. 2f) over time. The GLQG group showed significantly higher scores on both subscales at T2 (emotional well-being: adjusted mean difference was 2.14 with 95% CI of 1.40–4.88, $P = 0.004$; breast cancer-specific well-being: adjusted mean difference was 2.23 with 95% CI of 1.82–6.63, $P < 0.001$). The group's main effect for functional well-being was also significant and the score of the GLQG group was significantly higher than stretching group at T4 (Fig. 2e, adjusted mean difference was 1.78 with 95% CI of 0.43–3.14, $P = 0.014$).

Subjects in the GLQG group showed significant improvement in their scores for overall QoL and physical well-being, emotional well-being, functional well-being, and breast cancer-specific well-being except for social/family well-being from baseline to T4 ($P < 0.001$). In the stretching group, scores in overall QoL, physical well-being, emotional well-being, and breast cancer-specific well-being also increased significantly from baseline to T4 ($P < 0.001$), while there were no significant differences in social/family and functional well-being.

Secondary outcomes

Anxiety and depression Anxiety levels improved significantly in the GLQG group ($P < 0.01$) and depression levels improved among the physical stretching group ($P < 0.05$) from baseline to T4. However, there were no significant differences in anxiety and depression levels between the two groups over time when accounting for the adjusting factors (Fig. 3a, b).

Immunologic function Both groups showed significant increase in IL-2, IFN-γ, and TNF-α from baseline to T4 ($P < 0.001$). The GLQG group showed significantly higher scores in TNF-α at T4 compared with physical stretching group after adjusting for baseline levels (Fig. 3e, adjusted mean difference was 1.95 with 95% CI of 0.48–3.41, $P = 0.03$).

Tumor marker Figure 3f showed a significant decrease in CA 15-3 in both groups over time ($P < 0.001$).

Intervention effect on QoL and secondary outcomes in subjects who practiced >4 times and 6 h per week

Figures 4 and 5 showed the results of mixed effect model among subjects who practiced >4 times and >6 h per week between the two groups.

Primary outcome (QoL) There were significant improvement in total QoL and four subscales in both

Table 1 Demographic and clinical characteristics

Characteristic	GLQG group (n = 79)			Control group (n = 79)			P
	No.	%	Mean ± SD	No.	%	Mean ± SD	
Age, years			50.9 ± 7.0			51.3 ± 7.3	0.764
Education level							0.464
Primary school or less	8	10.1		9	11.4		
High school	47	59.5		52	65.8		
College graduate	13	16.5		13	16.5		
Postgraduate	11	13.9		5	6.3		
Marital status							0.513
Single	17	21.5		13	16.5		
Married/cohabitation	57	72.2		63	79.7		
Separated/divorced/widowed	5	6.3		3	3.8		
Employment status							0.927
Employed full time	21	26.6		22	27.8		
Employed part time	5	6.3		6	7.6		
Not employed	53	67.1		51	64.6		
Breast cancer stage							0.176
0	7	8.9		8	10.1		
I	22	27.8		34	43.1		
II	32	40.5		26	32.9		
III	18	22.8		11	13.9		
Surgery							0.698
No	6	7.6		4	5.1		
Mastectomy	46	58.2		44	55.7		
Lumpectomy	27	34.2		31	39.2		
Chemotherapy							
No	17	21.5		29	36.7	0.109	
Ongoing	13	16.5		10	12.7		
Completed	49	62.0		40	50.6		
Radiotherapy							0.421
No	35	44.3		34	43.0		
Ongoing	3	3.8		7	8.9		
Completed	41	51.9		38	48.1		
Chinese Medicine treatment							0.272
No	23	29.1		32	40.5		
Yes (before)	21	26.6		15	19.0		
Ongoing	35	44.3		32	40.5		

P values were calculated by independent t test and χ^2 tests

groups from baseline to T4 except for social/family well-being. There was significant improvement in QoL in the GLQG group compared with the controls at T2 (Fig. 4a) and the adjusted mean difference was 8.39 with 95% CI of 0.74–15.04 ($P = 0.018$). The GLQG group showed significant higher scores of emotional well-being with adjusted mean difference of 3.30 compared with the physical stretching group at T2 (Fig. 4d, 95% CI, 1.70–8.89, $P = 0.002$), and also higher scores of breast cancer specific well-being at T2, T3 and T4 with adjusted mean difference of 2.29, 2.62 and 2.87 respectively (Fig. 4f, $P < 0.001$,

95% CI, 0.10–5.48 at T2; 95% CI, 0.15–5.09; 95% CI, 0.02–5.72).

Secondary outcomes

Anxiety and depression The group main effect of anxiety was significant and anxiety was significantly relieved in the GLQG group compared with the physical stretching group ($P = 0.033$). The depression had been relieved significantly in both groups from baseline to T4 (Fig. 5a, b, GLQG group, $P = 0.036$; Stretching group, $P = 0.011$).
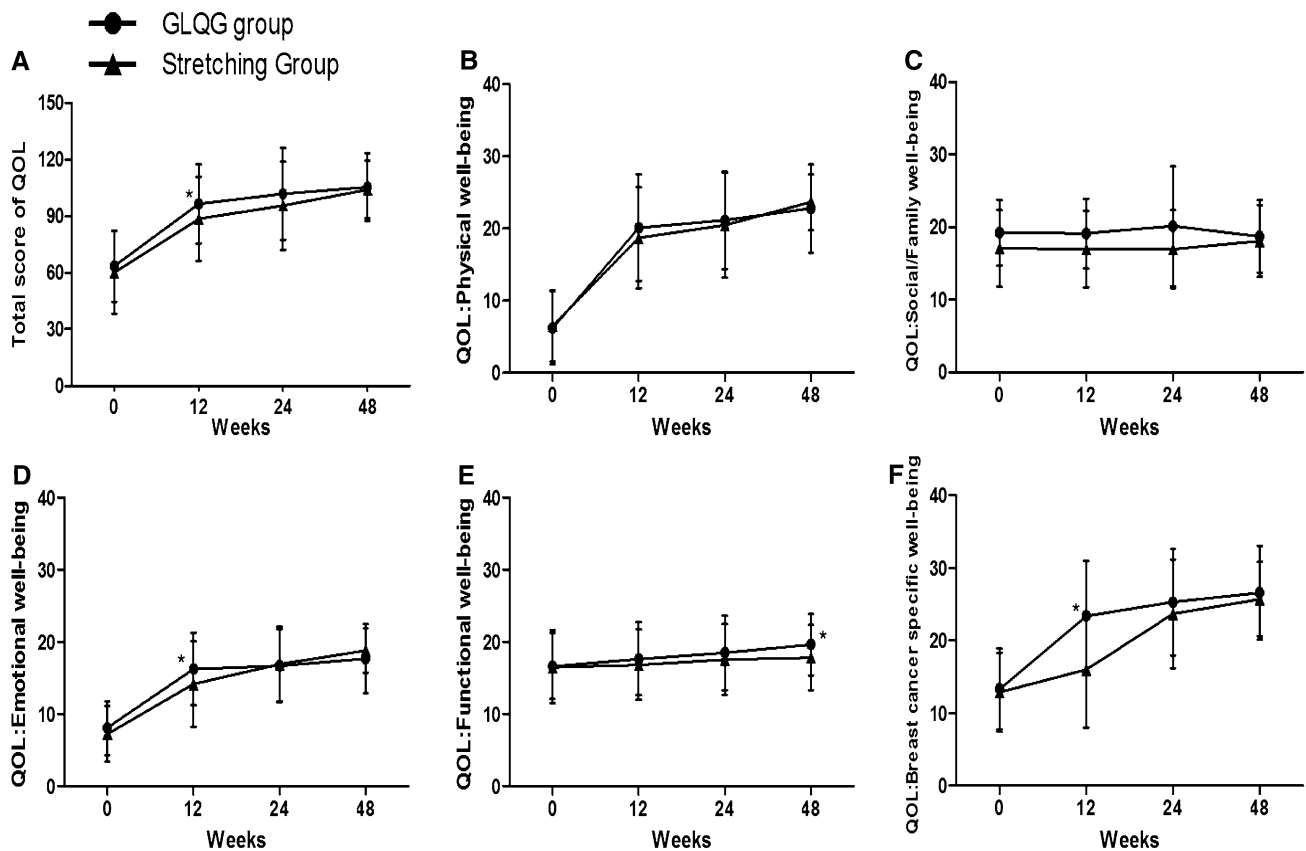
Fig. 2 Changes in primary outcome QoL assessed by FACT-B for all patients. *Note*: Changes of primary outcome in QoL **a** Total score of QoL, **b** QoL: Physical well-being, **c** QoL: Social/Family well-being, **d** QoL: Emotional well-being, **e** QoL: Functional well-being, and **f** QoL: Breast cancer-specific well-being at T2, T3, and T4 in the GLQG and stretching groups. Results shown were mean ± SD from mixed models adjusting for baseline levels. *P < 0.05 means statistically significant differences between two groups comparison

Immunologic function Both groups showed a significant increase in IL-2, IFN-γ, and TNF-α from baseline to T4 (Fig. 5c, d, e, P < 0.001). The group's main effects of IFN-γ were significant (P = 0.03) and the index was significantly increased in the GLQG group compared with the physical stretching group at T2 with an adjusted mean difference of 3.40 (95% CI, 1.26–5.54).

Tumor marker Both groups showed a significant decrease in CA 15-3 over time (P < 0.001). The differences were not significant between the two groups over time (Fig. 5f).

Correlations between primary outcome and secondary outcomes

Pearson correlation analyses were used to assess whether there is correlationship between the primary outcome QoL and secondary outcomes anxiety, depression, IL-2, IFN-γ, TNF-α, and CA 15-3. The results indicated a positive but weak correlations between QoL and anxiety (r = 0.385, P < 0.001) and between QoL and depression (r = 0.237, P = 0.003) (Fig. 6). No significant correlations were found

between Qol with IL-2, Qol with IFN-γ, QoL TNF-α, and Qol with CA 15-3.

Adverse events

Four events may potentially have been attributed to the GLQG intervention: two subjects reported the recurrence of knee pain and two others reported shoulder problems. These adverse events were relieved after further action guidance and correction by the certified GLQG master.

Discussion

This was the first RCT study to explore the efficacy of GLQG on the body-mind health of Hong Kong Chinese women with breast cancer by comparing with stretching. There were statistically significant intervention effects for QoL, TNF-α, and IFN-γ between the GLQG group and the physical stretching group over time. The differences were the most significant at the 12-week intervention visit. The results of subjects who practiced >4 times and >6 h per
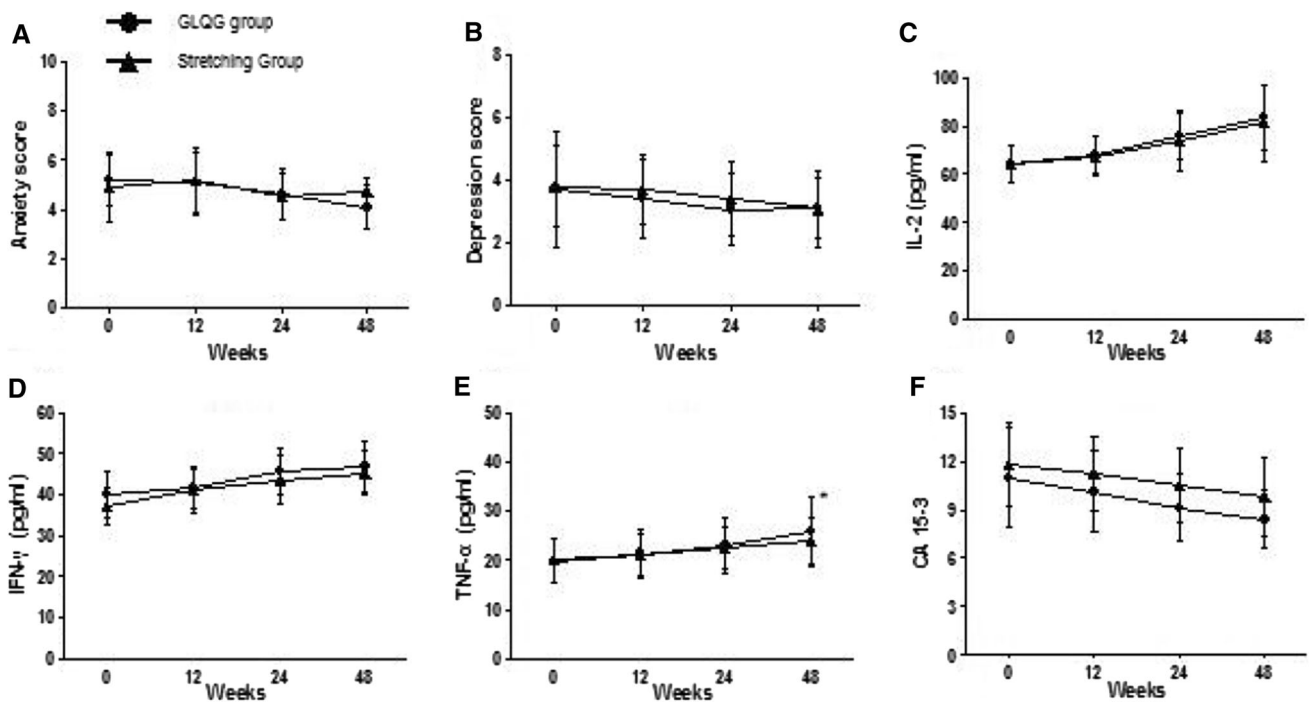
Fig. 3 Changes in secondary outcomes anxiety, depression, immunologic function, and tumor marker for all patients. *Note*: Changes of secondary outcomes in **a**, **b** anxiety and depression assessed by HADS, **c**, **d**, **e** immunologic function IL-2, IFN-γ and TNF-α and **f** tumor marker CA 15-3 at T2, T3, and T4 in the GLQG and stretching groups. Results shown were mean ± SD from mixed models adjusting for baseline levels. *$P < 0.05$ means statistically significant differences between two groups comparison
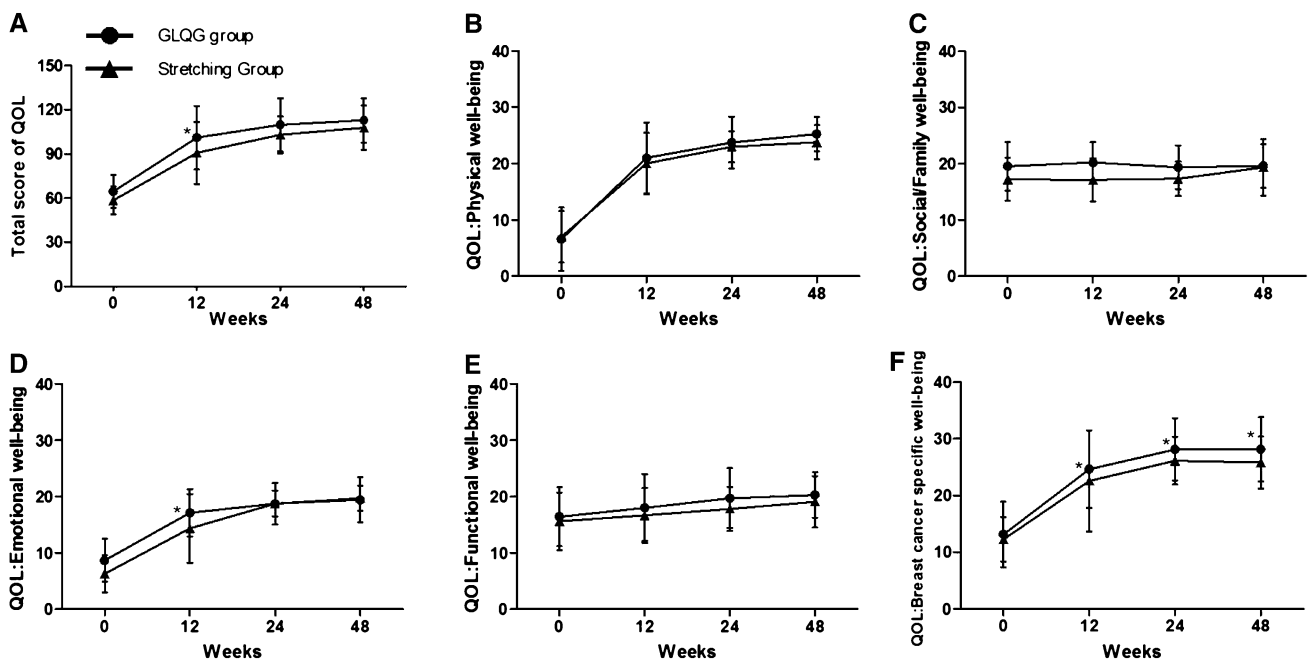
Fig. 4 Changes in primary outcome QoL assessed by FACT-B for patients who practiced >4 times and 6 h per week. *Note*: Changes of primary outcome in QoL **a** Total score of QoL, **b** QoL: Physical well-being, **c** QoL: Social/Family well-being, **d** QoL: Emotional well-being; **e** QoL: Functional well-being, and **f** QoL: Breast cancer-specific well-being at T2, T3, and T4 in the GLQG and stretching groups for patients who practiced >4 times and 6 h per week. Results shown were mean ± SD from mixed models adjusting for baseline levels. *$P < 0.05$ means statistically significant differences between two groups comparison
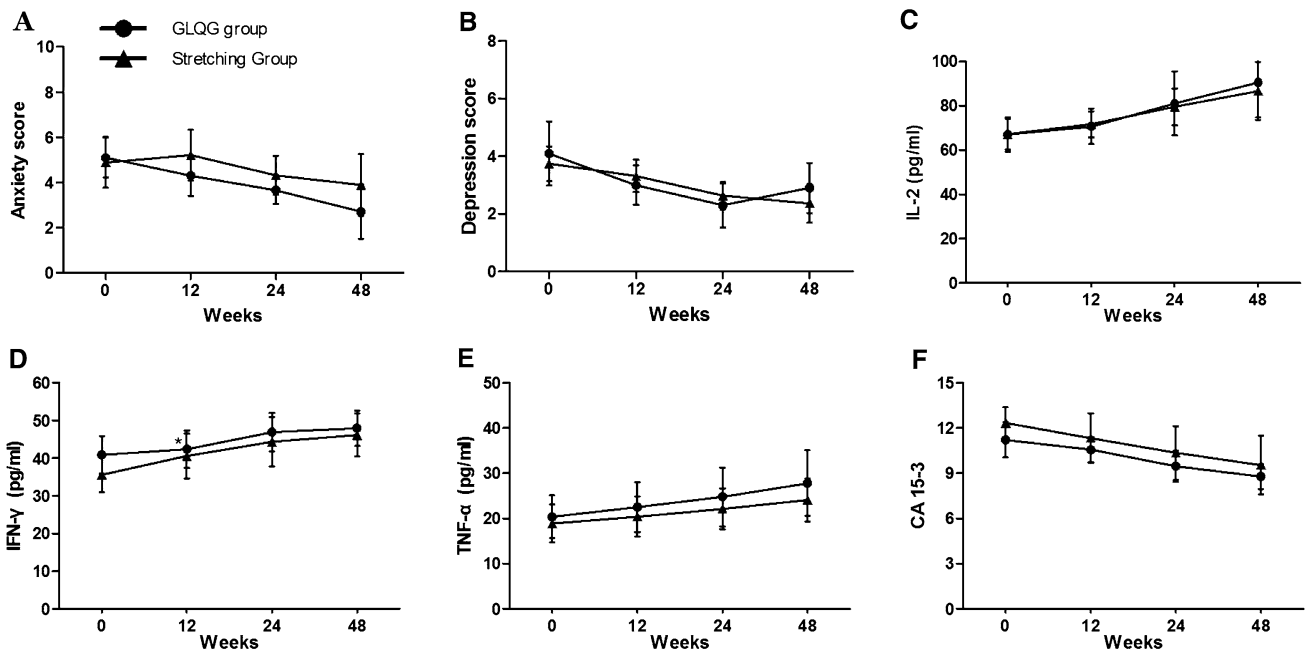
Fig. 5 Changes in secondary outcomes anxiety, depression, immunologic function, and tumor marker for patients who practiced >4 times and 6 h per week. *Note*: Changes of secondary outcomes in **a**, **b** anxiety and depression assessed by HADS, **c**, **d**, **e** immunologic function IL-2, IFN-γ, and TNF-α and **f** tumor marker CA 15-3 at T2, T3, and T4 in the GLQG and stretching groups for patients who practiced >4 times and 6 h per week. Results shown were mean ± SD from mixed models adjusting for baseline levels. *$P < 0.05$ means statistically significant differences between two groups comparison
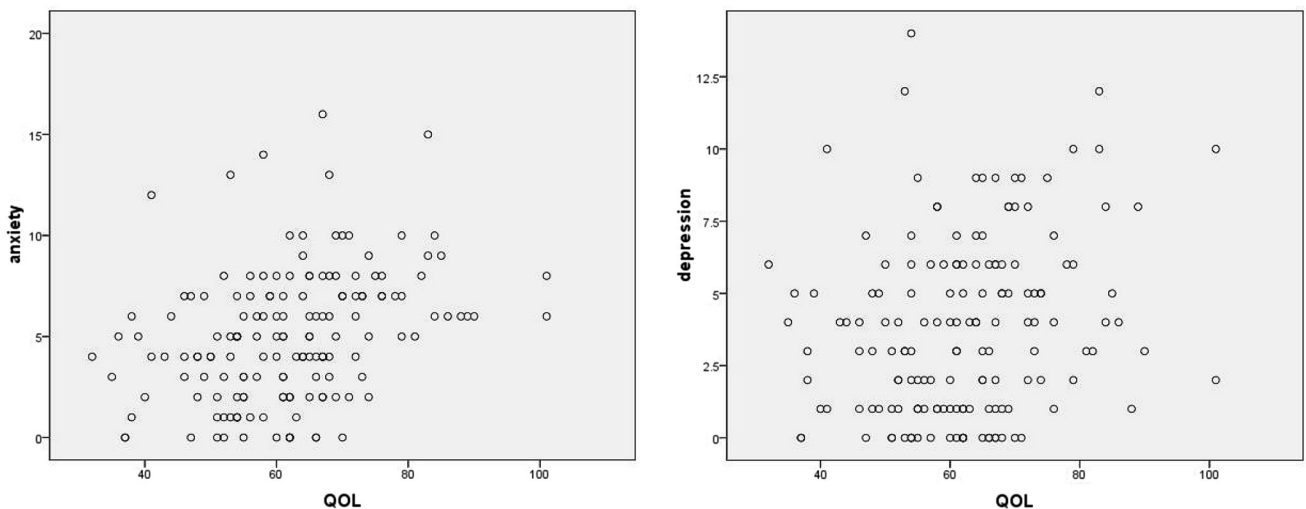

Fig. 6 Correlations between QoL and anxiety, depression

week were similar to that of all subjects, except that improvement in anxiety was more obvious.

The QoL was regarded as a primary outcome in this study as our pilot study found that the QoL of patients had significant differences after practicing GLQG compared to baseline. Moreover, several studies have also shown the significant differences in breast cancer patients' QoL before and after treatments such as surgery, chemotherapy, and radiotherapy [24, 25]. In our clinical study, significant differences in the overall score of QoL between the GLQG group and the physical stretching group were observed, which reinforced and extended results found in other studies that Qigong exercise could improve QoL in cancer patients [26, 27]. Regarding the five subscales, subjects in the GLQG group had a greater increase in emotional well-being and breast cancer-specific well-being than subjects in the physical stretching group. One explanation is that Qigong belongs to mind–body exercise while stretching or

Western physical exercise only includes body exercise. This is supported by studies on yoga and Taichi showed significantly improved mood, whereas the results of aerobic or resistance exercise on mood were less significant than yoga, Qigong, and Taichi [28–31]. The mean treatment effect of QoL was 8, which can represent a clinically important difference in QoL in cancer patients [32].

This study also evaluated the changes of anxiety, depression, and immunologic factors. Anxiety was significantly relieved in the GLQG group compared with the physical stretching group in subjects who practiced >4 times and >6 h per week, which is consistent with other studies demonstrating that increased frequency of physical exercise could improve emotion in cancer patients [33]. Studies have shown that cancer progression is closely associated with immune responses which are modulated by cytokines produced by T lymphocytes and type 1 T cells such as IL-2, IFN-γ, and TNF-α which are reduced significantly in cancer patients [21]. However, the relationship between immune function and physical exercise has currently not been established yet. In our study, there were significant differences in the presence of immune factors IFN-γ and TNF-α between the two groups.

In fact, there were also significant differences in almost all outcomes within each group from baseline to 48-week follow-up, potentially further demonstrating that all physical exercise can improve QoL, emotion, and immune function [34–36]. However, there exists a limitation in our study, which consists of not comparing the GLQG group to a usual care control group. The control group performed stretching together which in part may in itself have social support effects/consequences.

Additionally, there are other potential limitations in this study. Firstly, the rate of drop out was high at the 24-week follow-up (29.1%, 40.5% in the GLQG group vs 17.7% in the physical stretching group). The main reason was that many subjects felt that some technical exercises in GLQG were difficult to master, in addition, there was not a fixed time to "entry static" and practice. There were also some patients who reported that their physical strength was insufficient so they were not able to achieve a complete set of GLQG achievement. This may explain why the differences between the two groups were more significant at 12 weeks than at 24 weeks. Secondly, those who really practiced GLQG everyday reported that they felt the flow of *qi* in the body, and they were uneasy if they did not practice GLQG. However, the feeling of *qi* was not easy to describe and had not been recorded. Therefore, the subjects who captured the essence of GLQG, practiced well, and felt the flow of *qi* was a valuable factor. This would be worth further exploration. Thirdly, the mechanism behind the efficacy of GLQG on improving emotions in breast

cancer patients was not explained and needs to be explored through animal experiments.

Conclusions

Both GLQG and physical stretching are beneficial during recovery following breast cancer. GLQC was more effective in terms of QoL improvements than physical stretching. Both programs brought improvements in anxiety or depression but were comparable. GLQC group had a greater effect on immunological function than physical exercise. In conclusion, to answer whether or not GLQG can be used as an adjunctive therapy for the rehabilitation of breast cancer and introduced into clinical settings requires more long-term and convincing evidence.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The study was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB, UW 12-046). All procedures performed in the study were in accordance with the ethical standards of HKU and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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