BMJ Open

Effect of Baduanjin exercise on patients with chronic heart failure: protocol for a systematic review and meta-analysis

Jieying Li,[1] Feng Yu,[2] Na Huang,[1] Jianhui Lu,[1] Weixian Xu,[1] Nan Liu[2]

To cite: Li J, Yu F, Huang N, *et al*. Effect of Baduanjin exercise on patients with chronic heart failure: protocol for a systematic review and meta-analysis. *BMJ Open* 2019;**9**:e028771. doi:10.1136/bmjopen-2018-028771

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2018-028771).

Received 2 January 2019
Revised 17 May 2019
Accepted 21 June 2019

[1]First Clinical College, Guangzhou University of Chinese Medicine, Guangzhou, China
[2]Emergency Department, The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, China

Correspondence to
Professor Nan Liu;
liunan0954@126.com

ABSTRACT

Introduction Chronic heart failure (CHF) is defined when the heart is unable to pump sufficiently to maintain blood flow to meet the body's needs, and it is caused by various cardiopulmonary diseases. CHF is a common, lifelong and costly condition. Baduanjin exercise (BDJE), a form of traditional Chinese regimen, has been integrated into China's clinical practice in recent years and has shown promise in cardiac rehabilitation of CHF patients. However, the efficacy of BDJE on CHF patients has not been fully statistically evaluated. In this study, we aim to systematically examine the efficacy and safety of BDJE for CHF patients.

Methods and analysis A systematic literature search for articles up to October 2018 will be conducted in the following databases: Web of Science, Pubmed, Embase, Cochrane Library, Chinese Science and Technology Periodicals Database, Chinese National Knowledge Infrastructure and Wanfang Database. We will also search other resources. Randomised controlled trials that examined treatment of CHF patients with BDJE will be selected. Results will be analysed by assessing the quality of life of patients using the Minnesota living with heart failure questionnaire, and measurement of distance walked over a span of 6 min in the 6 min walk test. RevMan 5.3 will be used for data synthesis, sensitivity analysis, meta-regression analysis, subgroup analysis and risk of bias assessment. A funnel plot will be developed to evaluate reporting bias, and Begg and Egger tests will be used to assess funnel plot symmetries. Grading of recommendations assessment, development and evaluation system will be utilised to assess the quality of evidence.

Ethics and dissemination This systematic review will be submitted to a peer-reviewed journal.

PROSPEROregistration number CRD42018114672.

Strengths and limitations of this study

- This study will be the first to assess the safety of Baduanjin exercise and its effect on chronic heart failure patients.
- The grading of recommendations assessment, development and evaluation system will be used to further evaluate study findings.
- Language bias should be considered due to the inclusion of both English and Chinese studies.
- Clinical heterogeneity can also exist, because of variations in treatment frequency and duration and the use of additional therapies (eg, herbal medicine).

INTRODUCTION

Chronic heart failure (CHF) is a progressive and debilitating disease that underlies the ongoing inability of the heart to perform its circulatory function with the desired efficiency due to structural and/or functional (systolic ordiastolic) alterations.[1] CHF is a long-term condition with symptoms that gradually worsens over time while the acute heart failure has a sudden onset and symptoms. Shortness of breath, fatigue, swelling of the legs and ankles, chest pain and coughing are the most common symptoms in CHF patients. A limited ability to exercise which associated with the life expectancy, frequency of hospitalisation and quality of life (QoL), is a primary symptom among CHF patients.[2]

Despite advancements in the treatment of CHF, the condition still has a high morbidity and mortality. It is a rapidly growing public health issue with an estimated prevalence of more than 37.7 million individuals globally, and the total medical costs for patients with heart failure (HF) are expected to double from US $20.9 billion in 2012 to $53.1 billion by 2030 in the USA.[3] It is therefore crucial to study potential treatments of CHF aimed to retard and stagnate the progression of the condition and explore methods to improve the QoL of CHF patients. Progress on new drugs has been minimal, and the current effective treatment for clinically CHF patients is ivobradine after the advent of Angiotensin Receptor Blocker in the 1990s.[4] Furthermore, indiscriminate or prolonged uses of the referred drugs may lead to severe side effects, such as hypotension, electrolyte and fluid depletion.[5] Traditional Chinese medicine (TCM) emphasises on syndrome differentiation and focuses treatment based on the overall concept of the patient, while

Western medicine (WM) studies for the specific causes of the diseases and bases treatments on medical tests. Due to the fundamental differences in approaches between the two medicines, it could be speculated that TCM can complement and improve the range of treatment of WM. A number of clinical literatures indicated that a combination of treatment of TCM and WM in the treatment of CHF patients was superior to that of the group who received only WM. There were reduced recurrence rate, improved overall prognosis and relieved symptoms in TCM and WM group thereby improving patients' QoL.[6]

There has been an increased focus on cardiac rehabilitation (CR), a medically supervised programme aimed at improving cardiovascular health. CR includes medical evaluation and baseline patient assessment, education concerning medication adherence, risk factor reduction including dietary recommendations, psychosocial support (which may include peer support), as well as supervised exercise training and counselling.[7] The benefits of exercise training have been recognised among patients with CHF and is widely recommended by physicians, and therefore exercise-based cardiac rehabilitation (EBCR) is an invaluable tool in the management of CHF.[8] EBCR was considered to be a contraindication for CHF patients before 1970s, for it was believed that exercise might place the heart muscle under more stress. However in modern times, EBCR is the Class I recommendation of the international guidelines for the treatment and management of chronic stable heart failure.[9] Many researches show that EBCR can potentially improve exercise load of CHF patients, as well as QoL in recent years. A large number of evidence-based studies support the safety of EBCR for CHF patients. Additionally, numerous domestic studies reported no adverse effects on CHF patients when undergoing cardiopulmonary exercise test and aerobic cardiac exercise rehabilitation (such as walking, swimming and cycling).[10] HF-ACTION study established a link between exercise therapy and alleviation of depressive symptoms of CHF patients. The study concluded that improvements in exercise ability are directly proportional to the alleviation of depressive symptoms.[9 11]

TCM theory holds that the asthenia of vital qi and the sthenia of evil qi leads to CHF, and heart-qi deficiency is the root of the disease which leads to blood stasis.[12] Huangdi Neijingis is an ancient medical text and has been the fundamentals of Chinese Medicine for more than two millennia. It states that 'movement to nourish form, stillness to nourish spirit', indicating the ancient Chinese's understanding and acknowledgement of the importance of proper exercise to strengthen one's physique. It is understood that movements can exhilarate Yang Qi, adjust Qi and blood to alleviate the symptoms of heart failure and improve the QoL of patients. Traditional Chinese exercise such as Taijiquan, Qigong and Baduanjin has been undertaken by many as a form of proper exercise passed down from the Chinese ancestors thus have found a surge in popularity around the world in recent years.[13] Tai Chi, Wuqinxi, Qigong and Baduanjin were found to have positive effects on balance control, cardiovascular fitness, fatigue and QoL in CHF patients.[14–16] However, Tai Chi and Wuqinxi are complicated and difficult to master and might therefore limit patient's adherence to the exercise regimen. On the other hand, Baduanjin exercise (BDJE) also known as the 'eight section brocades', is an aerobic exercise with simple, slow and relaxing movements, which is composed of eight set of actions including support heaven with both hands, dragon sprays water with force, big bird spreads its wings, lift window to look at the moon on the left, descend to earth with force, beautiful maiden twists her waist to the right, extend shoulders to bring hands together and dragon claws to the left.[17] In accordance to TCM theory, BDJE can regulate the vital energy of collateral channels and organs in the body as well as relieve the cardiac load and improve the body's ability to transport and utilise oxygen in blood circulation, so that it can reduce oxygen consumption of myocardial.[18] BDJE can also improve the elasticity of blood vessels effectively, inhibit the formation of free radicals and reduce the blood viscosity to ensure the normal flow of blood.[13 17 19]

However, no systematic review about the effect of BDJE on CHF patients has been carried out or published so far. An examination of this therapy's effect on CHF patients is therefore urgently needed. Consequently, we plan to conduct a systematic review and meta-analysis to evaluate current evidence of BDJE on CHF patients.

METHODS AND ANALYSIS

Inclusion and exclusion criteria for study selection.

Type of studies

All randomised controlled trials (RCTs) that evaluated the safety and effect of BDJE on CHF patients will be included regardless of the duration of the treatment.

Participants

The inclusion criteria for participants will be as follows: (a) ≥18 years; (b) diagnosed with CHF based on WHO's definition of CHF including HF with reduced ejection fraction or preserved ejection; (c) diagnosed with stable heart failure by a physician according to New York Heart Association (NYHA) class I–III. Patients will be excluded if they had (a) impaired mobility, defined as a limitation in independent physical movement of the body; (b) history of unstable structural valvular diseases, open-heart surgery, or chronic obstructive pulmonary disease (COPD); (c) diagnosis of major depression and cognitive disorders; or (d) unstable vital signs, defined as blood pressure >180/110 mm Hg or <90/60 mm Hg and resting heart rate >100 beats/min.

Interventions

Control group patients will receive standard treatment according to HF guidelines and be advised to maintain their daily routine. The intervention group will receive

Table 1 Search terms

Search block	Search items
Participants	Cardiac Failure OR Heart Decompensation OR Heart Failure OR Right-Sided Heart Failure OR Myocardial Failure OR Congestive Heart Failure OR Left Sided Heart Failure
Intervention	Qigong OR Baduanjin OR Baduanjin exercise OR eight section brocades OR regimen OR Chinese regimen OR Chinese ancient regimen OR rehabilitation exercise
Study design	Randomized controlled trial OR controlled clinical trial OR randomized OR placebo OR drug therapy OR randomly OR trial OR groups

BDJE of various duration and frequency based on routine regimens except conventional therapy.

Outcome measures

The primary outcome measures will be QoL assessed by the Minnesota living with heart failure questionnaire and walking distance in the 6 min walk test. The secondary outcome measures will be peak VO2, ejection fraction, NYHA class, Hypersensitive C-reactive protein (hsCRP) and N-Terminal Pro–B-Type Natriuretic Peptide (NT-proBNP).

Search strategy

Electronic searches

The following electronic databases will be searched from inception to October 2018: Web of Science, Pubmed, Embase, Cochrane Library, Chinese Science and Technology Periodicals Database, Chinese National Knowledge Infrastructure and Wanfang Database. Search terms are grouped into three blocks (table 1).

Other resources

The following sources will also be searched to identify clinical trials, which are in progress or completed: Google scholar (http://scholar.google.com) and Baidu scholar (http://xueshu.baidu.com/);

Clinical Trials.gov (http://www.clinicaltrails.gov) and Chinese Clinical Trial Registry (http://www.chictr.org/cn/); the reference lists of the retrieved articles.

Study selection and data extraction

NoteExpress 3.2 will be used to manage literatures and remove duplications. First, two reviewers (NH and JL) will screen the titles and abstracts of all the retrieved studies to find potentially eligible studies independently. The potentially eligible studies for which no relevant outcomes is presented, where relevant information is unavailable or results are duplicated will be excluded. Then two reviewers (NH and JL) will independently review the full texts for the potentially eligible studies. After filtering the final eligible articles, the data from the included articles will be extracted independently from two authors (NH and JL). Disagreements will be resolved through discussion and if indispensable, discrepancies will be discussed with the third author (FY). We will use a spreadsheet to record information from eligible articles about study design, year of publication, study location, study period and authors. We also record participant, interventions and outcomes. Lastly, all the included studies will be taken into systematic reviews and the studies which are selected according to the quality of included literatures will be made a meta-analysis. A Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow chart will be produced to show the number of articles identified, screened, included and excluded, reasons for exclusion and to ascertain eligible studies. The study selection process will be described in a PRISMA flow chart (http://www.prisma-statement.org), which is presented in online supplementary appendix 1.

Addressing missing data or unclear measurement scales

If necessary, we will contact authors of articles through email or telephone to request missing data or additional information about evaluation scales. If sufficient information cannot be obtained in this way, we will analyse the available data and take into account the potential impact of insufficient data on the review results in the discussion section.

Risk of bias in included studies

Risk of bias for the studies included in meta-analyses will be evaluated according to the cocharne handbook. This recommends the assessment of several sources of bias, including random sequence generation, allocation concealment, blinding of outcome assessments, incomplete outcome data and selective outcome reporting. Since double-blinding is impossible to achieve in clinical trials, the bias among participants and investigators will not be considered. The risks will be judged as low, high or unclear (unclear or unknown risk of bias).

Data synthesis and analysis

The statistical analysis will be performed according to the recommendations of the cochrane handbook and using the software of cochrane collaboration, RevMan 5.3, available from the cochrane website (http://tech.cochrane.org/revman). All outcomes will be continuous variables. The standardised mean difference and its 95% CIs will be calculated. Initially, a fixed-effect model will be used to compare the outcomes expressed in the same scale. The heterogeneity of the effects of trials will be evaluated by the Q^2 test and the I^2 test. Heterogeneity will be considered as substantial if the I^2 statistic ≥50% and p<0.10. If heterogeneity is considered as substantial, reasons for this heterogeneity will be searched for and a random-effect model could be used for comparison.

Additional analyses

Sensitivity analysis, meta-regression analysis and subgroup-stratified analysis based on various study characteristics will be performed, such as type, location and

quality of study, sample size, adjustment (or not) for confounders, Baduanjin regimens and other relevant parameters (eg, diet and lifestyle) to explore potential sources of heterogeneity. We will create a qualitative synthesis if data extraction is insufficient.

Assessment of reporting biases

A funnel plot will be conducted to evaluate reporting bias of the included studies. Begg and Egger tests will be used to assess funnel plot symmetry and we will interpret values of $p<0.1$ as showing statistical significance (ie, publication bias).

Quality of evidence

We will evaluate the quality of evidence of the included studies through the Grading of Recommendations Assessment, Development and Evaluation approach. The limitations of the study, inconsistencies, indirect evidence, inaccuracies and publication bias will also be considered. Four levels of quality of evidence will be used: high, moderate, low or very low.

Ethics and dissemination

We aim to publish this systematic review in a peer-reviewed journal. Our findings will provide information about the safety and effect of BDJE for patients with CHF. The study will not involve individual privacy, thus ethical approval is not required.

Patient and public involvement

Patients and the public were not involved in the design of the study.

DISCUSSION

BDJE can boost qi and blood circulation, stimulate metabolism and coordinate the internal organs by nourishing qi, relaxing muscles and enhancing strength. It regulates heart, breathing and dredge channels and vessels to relieve heart pressure, keeps individuals calm and modify spirits.[20] Previous studies have certified the positive effects of aerobic exercise (such as walking,[21–24] CR training[25] or Tai Chi[26] on the fatigue and QoL on CHF patients. In addition to Chinese ancient regimens like BDJE being beneficial to CHF, the effects of Chinese Herbal Medicine (CHM) and acupuncture have also been highlighted in numerous studies as being beneficial to CHF patients. Several prescribed formulae have been clinically proven more effective for the treatment of CHF when compared with standardised WM. The prescribed formulae used in the comparison includes DanshenYin, Qishenyiqi Dripping pill, Fufangdanshen Dripping pill and so on.[5] The coexistence of WM and TCM is known as integrative medicine (IM). The introduction of WM into China in the 16th century created a healthcare model unique to China, where TCM and WM are both effectively implemented into the healthcare system of the people. China's system is therefore essential for comparisons between both medicines to be conducted with the least possible bias, as well as a global platform to introduce TCM to the world. An example of effective IM is cardiovascular disease (CVD), restenosis after percutaneous coronary intervention and myocardial ischemia reperfusion injury.[27]There is evidence for several promising integrative therapies for the treatment and prevention of CVD, including meditation, yoga, acupuncture and herbal therapies.[28] Current evidence from RCTs indicates that IM might be effective in control of cardiovascular risk factors, and exert beneficial effects on CVD and CHF.[29] CHM in the treatment of CVD by activating the signalling pathway of NO, inhibiting inflammation, attenuating oxidative stress and inhibiting apoptosis.[30] The long-loop pathway as the physiologic mechanism of acupuncture which can specifically improve cardiac function and QoL measures in the management of CVD and CHF.[31] IM used among patients with CVD is common, with dietary supplements (eg, CoQ10, garlic, vitamin D and so on) and mind-body therapies being the most commonly used treatment modalities.[32]

In summary, IM will play a potent role in primary and secondary prevention of chronic disease, in particular CVD in the future.[33] The safety and efficacy of BDJE on CHF patients will be examined in the review. A systematic review of other IM treatment methods for CVD and CHF should be carried out in order to provide more evidence to further guide treatment for CHF and CVD patients.

PRISMA Protocols 2015 checklist[34] of this protocol is presented in online supplementary appendix 2.

Contributors JYL, FY and NL conceived and designed the study. The manuscript of this protocol was drafted by JYL, FY and NH and revised by JHL and WXX. NH and JHL designed the search strategies and will perform the search, screening and assessment of the risk of bias independently. JYL and WXX will analyze and interpret the data. FY will arbitrate any disagreements during the review. All authors approved the final version of this protocol.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1. Mishra S, Mohan JC, Nair T, *et al*. Management protocols for chronic heart failure in India. *Indian Heart J* 2018;70:105–27.
2. Fleg JL, Cooper LS, Borlaug BA, *et al*. Exercise training as therapy for heart failure: current status and future directions. *Circ Heart Fail* 2015;8:209–20.
3. Ziaeian B, Fonarow GC, Gc. F. Epidemiology and aetiology of heart failure. *Nat Rev Cardiol* 2016;13:368–78.
4. Huang J. The current status and the prospect of TCM in the treatment of chronic heart failure. *Journal of Cardiovascular and Cerebrovascular Diseases combined with traditional Chinese and Western Medicine* 2015;13:1–2.
5. Wang Y, Wang Q, Li C, *et al*. A review of Chinese herbal medicine for the treatment of chronic heart failure. *Curr Pharm Des* 2017;23:5115–24.

6. Gong QH, Shi LP, Qi P, *et al*. Research status of TCM in the treatment of chronic heart failure. *Journal of practical traditional Chinese Medicine* 2018;34:868–70.
7. Ades PA, Keteyian SJ, Balady GJ, *et al*. Cardiac rehabilitation exercise and self-care for chronic heart failure. *JACC Heart Fail* 2013;1:540–7.
8. McMahon SR, Ades PA, Thompson PD. The role of cardiac rehabilitation in patients with heart disease. *Trends Cardiovasc Med* 2017;27:420–5.
9. Yancy CW, Jessup M, Bozkurt B, *et al*. ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013;2013:e147–239.
10. Jiang FR, Liu DJ, Kong YM. Progress in the study of the role of cardiac rehabilitation exercise in CHF patients. *Journal of Cardiovascular Rehabilitation Medicine* 2018;27:716–20.
11. Henkin Y. [Participation in cardiac rehabilitation after coronary bypass surgery: good news, bad news]. *Harefuah* 2012;151:522–56.
12. Zhu M, SN li. The research progress of traditional chinese medicine on chronic heart failure. *Chinese Traditional Patent Medicine* 2018;40:1804–7.
13. Wang XQ, Pi YL, Chen PJ, *et al*. Traditional Chinese exercise for cardiovascular diseases: systematic review and meta-analysis of randomized controlled trials. *J Am Heart Assoc* 2016;5:e002562.
14. Yao CD, Li F, Yb. M. Effect of Tai chi on cardiac rehabilitation of patients with chronic heart failure. *Journal of Cardiovascular Rehabilitation Medicine* 2010:364–7.
15. Yeh GY, Wood MJ, Wayne PM, *et al*. Tai chi in patients with heart failure with preserved ejection fraction. *Congest Heart Fail* 2013;19:77–84.
16. Yu J. Modern distance education of traditional Chinese Medicine in China. *Study on the effect of TCM Aerobics on exercise endurance in CHF patients* 2015;13:12–14.
17. Xiong X, Wang P, Li S, *et al*. Effect of Baduanjin exercise for hypertension: a systematic review and meta-analysis of randomized controlled trials. *Maturitas* 2015;80:370–8.
18. Shi XM, Jiang GL, Liu WH, *et al*. The influence of baduanjin on cardiopulmonary function during cardiac rehabilitation for CHD patients. *Med & Pharm J Chin PLA* 2017;29:24–7.
19. Chen BL, Guo JB, Liu MS, *et al*. Effect of traditional Chinese exercise on gait and balance for stroke: a systematic review and meta-analysis. *PLoS One* 2015;10:e0135932.
20. Xy W, Li L, Ding PR, *et al*. The impact of baduanjin exercise on 62 coronary heart disease patients with depression. *World Chinese Medicine* 2014;9:39–43.
21. Oka RK, De Marco T, Haskell WL, *et al*. Impact of a home-based walking and resistance training program on quality of life in patients with heart failure. *Am J Cardiol* 2000;85:365–9.
22. Corvera-Tindel T, Doering LV, Woo MA, *et al*. Effects of a home walking exercise program on functional status and symptoms in heart failure. *Am Heart J* 2004;147:339–46.
23. Gary RA, Sueta CA, Dougherty M, *et al*. Home-based exercise improves functional performance and quality of life in women with diastolic heart failure. *Heart Lung* 2004;33:210–8.
24. Hassanpour Dehkordi A, Khaledi Far A. Effect of exercise training on the quality of life and echocardiography parameter of systolic function in patients with chronic heart failure: a randomized trial. *Asian J Sports Med* 2015;6:e22643.
25. Pozehl B, Duncan K, Hertzog M. The effects of exercise training on fatigue and dyspnea in heart failure. *Eur J Cardiovasc Nurs* 2008;7:127–32.
26. Yeh GY, McCarthy EP, Wayne PM, *et al*. Tai chi exercise in patients with chronic heart failure: a randomized clinical trial. *Arch Intern Med* 2011;171:750–7.
27. Wang J, Xiong X. Current situation and perspectives of clinical study in integrative medicine in china. *Evid Based Complement Alternat Med* 2012;2012:1–11.
28. Aggarwal M, Aggarwal B, Rao J. Integrative medicine for cardiovascular disease and prevention. *Med Clin North Am* 2017;101:895–923.
29. Hao P, Jiang F, Cheng J, *et al*. Traditional Chinese medicine for cardiovascular disease: evidence and potential mechanisms. *J Am Coll Cardiol* 2017;69:2952–66.
30. Liu C, Huang Y. Chinese herbal medicine on cardiovascular diseases and the mechanisms of action. *Front Pharmacol* 2016;7:469.
31. Ni YM, Frishman WH. Acupuncture and cardiovascular disease: focus on heart failure. *Cardiol Rev* 2018;26:93–8.
32. Mehta D. Integrative medicine and cardiovascular disorders. *Prim Care* 2017;44:351–67.
33. Shi DZ. Integrative medicine intervention for chronic disease management-cardiovascular disease. *Chin J Integr Med* 2018;24:883–5.
34. Shamseer L, Moher D, Clarke M, *et al*. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ* 2015;350:g7647.